

NOV 13 2013



IN THE SUPREME COURT OF BRITISH COLUMBIA

S-13841.1

No. _____
Vancouver Registry

BETWEEN:

PROVIDENCE HEALTH CARE SOCIETY and DEBORAH BARTOSCH,
CHARLES ENGLISH, DOUGLAS LIDSTROM, LARRY LOVE and DAVID
MURRAY on their own behalf and on behalf of all persons with severe opioid
addiction who have previously not responded to other available treatments and on
whose behalf a SAP request for diacetylmorphine is made by a medical
practitioner

PLAINTIFFS

AND:

ATTORNEY GENERAL OF CANADA

DEFENDANT

NOTICE OF CIVIL CLAIM

Name and address of each Plaintiff

Providence Health Care Society
c/o Arvay Finlay
1320 – 355 Burrard Street
Vancouver BC V6C 2G8

Deborah Bartosch, Charles English, Douglas Lidstrom, Larry Love and David Murray on
their own behalf and on behalf of all persons with severe opioid addiction who have
previously not responded to other available treatments and on whose behalf a SAP
request for diacetylmorphine is made by a medical practitioner
c/o Pivot Legal Society
121 Heatley Avenue
Vancouver BC V6A 3E9

Name and address of each Defendant

Attorney General of Canada
900 - 840 Howe Street
Vancouver BC V6Z 2S9

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 plaintiff.

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

Parties

1. The Plaintiff Providence Health Care Society ("Providence" or the "Society") is a non-profit organization incorporated in 2000 pursuant to British Columbia's *Society Act*, R.S.B.C. 1996, c. 433, with a registered office located at 900-900 Howe Street, Vancouver, British Columbia V6Z 2M4.

2. The Plaintiff Deborah Bartosch (“Bartosch”), age 56, suffers from opioid dependence that is refractory to currently available treatment. Bartosch was a research participant in the Study to Assess Longer-term Opioid Medication Effectiveness (“SALOME”) on whose behalf a medical practitioner made a Special Access Programme (“SAP”) request for diacetylmorphine, the chemical name for the drug commonly known as “heroin.” Bartosch lives in Vancouver, British Columbia.
3. The Plaintiff Charles English (“English”), age 49, suffers from opioid dependence that is refractory to currently available treatment. English was a research participant in SALOME on whose behalf a medical practitioner made a SAP request for diacetylmorphine. English lives in Vancouver, British Columbia.
4. The Plaintiff Douglas Lidstrom (“Lidstrom”), age 59, suffers from opioid dependence that is refractory to currently available treatment. Lidstrom was a research participant in SALOME on whose behalf a medical practitioner made a SAP request for diacetylmorphine. Lidstrom lives in Vancouver, British Columbia.
5. The Plaintiff Larry Love (“Love”), age 62, suffers from opioid dependence that is refractory to currently available treatment. Love was a research participant in SALOME on whose behalf a medical practitioner made a SAP request for diacetylmorphine. Love lives in Vancouver, British Columbia.
6. The Plaintiff David Murray (“Murray”), age 62, suffers from opioid dependence that is refractory to currently available treatment. Murray was a research participant in SALOME on whose behalf a medical practitioner made a SAP request for diacetylmorphine. Murray lives in Vancouver, British Columbia.
7. The Defendant Attorney General of Canada (“Canada”) has an address for service at 900 – 840 Howe Street, Vancouver, British Columbia, V6Z 2S9.

Providence Health Care Society

8. Providence facilities were founded by various congregations of religious nuns. With the approval of the Archbishop, five congregations of nuns agreed to an amalgamation of their facilities and formed the Society in 2000.
9. Providence is also a “public juridic person” under Canon Law and continues to do its work in the name of the Catholic Church. One of its fundamental pillars is the concept of preferential treatment of the poor and marginalized.
10. Providence is governed by an independent Board of Directors appointed by members of the Society.
11. Providence is funded by the provincial government for the services it provides the residents of British Columbia. Its hospitals are public hospitals and work under the legislative and policy oversight of the Province of British Columbia (the “Province”).

12. Providence operates under an agreement between the Province and the Denominational Health Association of which Providence is a member. This agreement recognizes the rights of owners of denominational care facilities to own, manage and operate their respective facilities and carry out their respective religious missions. It obligates the owners to meet provincial standards and national accreditation for health care, meet the conditions of any agreements with teaching facilities, and plan and deliver health care services in collaboration with other health bodies. Providence also has an affiliation agreement with the Vancouver Coastal Health Authority which sets out the terms under which Providence provides health care services and receives funding from the health authority.
13. Providence is committed to providing care to vulnerable inner city residents, many of whom have been negatively affected by addiction and infectious diseases such as human immunodeficiency virus ("HIV") / acquired immune deficiency syndrome ("AIDS"), hepatitis C and drug and alcohol-related illnesses.
14. Providence operates a number of hospitals, residences and clinics including the Providence Crosstown Clinic, an addictions clinic located at 84 West Hastings Street, Vancouver, British Columbia.

The Individual Plaintiffs

15. Each of the individual plaintiffs is an injection drug user who has a long term addiction to injectable heroin.
16. Each of the individual plaintiffs has suffered significant adverse physical, psychological and psychosocial health effects as a result of his or her addiction.
17. Each of the individual plaintiffs has made numerous attempts at sobriety including multiple attempts at methadone maintenance therapy. Many have also attempted suboxone treatment and detoxification programs. All of these therapies have proven ineffective.

Addiction

18. Drug addiction is a chronic disease and can be progressive, relapsing and fatal. One aspect of the disease is the continuing need or craving to consume the substance to which the addiction relates.
19. Individuals with opioid dependence that is refractory to treatment are at a high risk of relapse when they attempt abstinence. For people with addictions such as those in the Downtown Eastside, the route to long-term abstinence can be a long and difficult process characterized by many treatment attempts and a high life-long risk of relapse.
20. The risks of opioid dependence from illicit street drugs include fatal overdoses, infections (including endocarditis, HIV/ AIDS infection, and hepatitis C virus infection), social disintegration, violence and criminal sanction.

21. The associated burdens on communities include medical, public health, and criminal-justice costs as well as public disorder and crimes against property.
22. The Downtown Eastside of Vancouver is the epicentre of a public health emergency relating to long-standing addiction and injection drug use in that community that reached a peak of epidemic proportions in the 1990s. The public health epidemic has had tragic consequences for individuals, their families, and their communities, and has significantly burdened the local health care system creating a pressing public health concern.

Health Measures to Assist People with Addictions in Vancouver

23. In 2003, Insite opened. A provincially-regulated health care facility, Insite is a controlled environment where injection drug users from the Downtown Eastside inject themselves with illicit drugs using clean equipment, under the supervision of nurses and paramedical staff. Insite's clients also have access to health care and social services, including addictions counseling and on-demand detoxification.
24. In 2007, PHS Community Services Society and two individual plaintiffs sought constitutional protection for Insite, its clients and staff. In May 2011, the Supreme Court of Canada held that the s. 7 *Charter* rights of life, liberty and security of the person for clients and staff of Insite were engaged by s. 4 of the *Controlled Drugs and Substances Act*, S.C. 1996, c. 19 (the "*CDSA*"). However, because the Minister of Health has the power to grant exemptions under the *CDSA*, the s. 7 infringement is in accordance with the principles of fundamental justice. The Supreme Court of Canada ordered the Minister of Health to grant an exemption to Insite under s. 56 of the *CDSA*.
25. Providence has conducted or is in the process of conducting two randomized controlled trials studying the effectiveness of diacetylmorphine as compared to other substances in treating patients with opioid dependence that was refractory to treatments (the North American Opiate Medication Initiative ("NAOMI") and SALOME).
26. Between March 2005 and July 2008, in Vancouver and Montreal, Providence conducted an open-label, phase 3, randomized controlled trial in Canada comparing injectable diacetylmorphine with oral methadone maintenance therapy in patients with opioid dependence that was refractory to treatment. NAOMI confirmed the superiority of diacetylmorphine-assisted therapy over optimized methadone maintenance therapy for patients with severe opioid addiction who had previously not responded to methadone. Bartosch and Murray were each research participants in NAOMI.
27. In 2011, Providence researchers began enrolling participants for one year of study in the SALOME trial at the Providence Crosstown Clinic in Vancouver. SALOME is a single centre double blind randomized controlled trial comparing whether injectable hydromorphone (a medication approved in Canada to treat pain) is as effective as injectable diacetylmorphine for patients with severe opioid addiction who have previously not responded to methadone maintenance therapy. The study is also testing whether oral diacetylmorphine and/or oral hydromorphone are as effective as injectable diacetylmorphine. Participants are randomized to either injectable diacetylmorphine or

hydromorphone for six months and then randomized to either oral or continued injectable treatment of the study drug the participant was provided in phase 1. The initial study design required 322 participants in order to definitively answer the research questions. However, the SALOME Data Safety Monitoring Board (an independent data quality monitoring group) recently concluded that the study sample of 202 participants would be sufficient to answer the research questions. The recruitment of participants for the study is now complete and the treatment phase of the study will conclude at the end of 2014.

28. Some Providence staff members are employed at Providence Crosstown Clinic. Physicians who practice at Providence are not staff but are granted privileges to work at Providence facilities. Such physicians provide services to the SALOME research participants at the Providence Crosstown Clinic including care for such patients exiting the study.
29. Each of the individual plaintiffs entered SALOME in 2012. Each of the individual plaintiffs experienced significant positive physical, psychological and psychosocial health effects as a result of his or her participation in at least one phase of SALOME.
30. In Phase 2 of SALOME, Bartosch and Lidstrom were randomized to oral medication, however this treatment was not as effective for them.
31. Each of the individual plaintiffs exited SALOME in 2013.

The SAP Applications

32. Health Canada operates the SAP pursuant to ss. C.08.010 and C.08.011 of the *Food and Drug Regulations*, C.R.C., c. 870.
33. The SAP allows medical practitioners to request access to drugs that are unavailable for sale in Canada. This access is limited to patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable or are unavailable.
34. The medical practitioner is responsible for initiating a request on behalf of a patient and ensuring that the decision to prescribe the drug is supported by credible evidence available in the medical literature or provided by the manufacturer. It is also the medical practitioner's responsibility to ensure that patients are well informed of the possible risks and benefits of the drug being requested.
35. Between January 2013 and November 9, 2013, in consultation with each individual plaintiff and in the context of providing services to the SALOME research participants at the Providence Crosstown Clinic including care for such patients exiting the study, physicians who practice at Providence made SAP requests for diacetylmorphine for a number of individual patients, including the named individual plaintiffs herein, who had exited from SALOME and for whom traditional treatment was not working ("Plaintiff Requests"). Two physicians who are contracted by Providence supported these applications. If authorized under the SAP, the diacetylmorphine would have been provided at the Providence Crosstown Clinic.

36. Further SAP requests will be made for research participants who have yet to exit SALOME, who want the treatment and for whom this treatment is medically indicated (“Future SALOME Requests”).
37. In addition, SAP requests will likely be made by physicians with privileges at Providence facilities and supported by physician leaders and administrators at Providence on behalf of persons with severe opioid addiction who have previously made numerous attempts at recovery but had not responded to other available treatments, who wanted the treatment, and for whom this treatment is medically indicated but who did not participate in SALOME (“Other Requests”).
38. In respect of the Plaintiff Requests made on behalf of Lidstrom and Murray, each of these individual plaintiffs received approval from Health Canada to receive this treatment at the Providence Crosstown Clinic for three months. However, to date, no individual plaintiff has begun receiving the diacetylmorphine treatment that was approved by Health Canada and this apparently due to the legal uncertainty created by the *Regulations Amending Certain Regulations Relating to Access to Restricted Drugs* (the “Regulations”).
39. In respect of the Plaintiff Requests made on behalf of Bartosch, English and Love, each of these Plaintiff Requests were denied due to certain provisions of the *Regulations*. Each of these individual plaintiffs has exited SALOME and begun treatment with oral hydromorphone. This treatment is not effective for these individual plaintiffs.
40. All Future SALOME Requests and Other Requests will be rejected on the same basis and the negative impacts of such a denial of treatment will be similar.
41. These patients face serious health threats if ongoing treatment is limited to a medication that has previously failed (e.g. methadone) or a medication known to be inferior to methadone (e.g. suboxone) or an unproven and experimental medication (hydromorphone). If the individual plaintiffs and others are denied access to effective treatment for their addiction, they are each likely to suffer significant negative physical, psychological and psychosocial health effects including a relapse to using illicit street heroin.
42. The safest and most proven therapeutic approach, and the one most consistent with accepted medical practice and ethics, would be to provide diacetylmorphine when the patient exits the study, rather than continue failed, inferior or unproven and experimental medications, since this treatment has already been proven to be effective. It is a physician’s professional ethical responsibility, to protect the health and safety of seriously ill research participants after they have volunteered their time to be part of a Health Canada approved and Canadian Institutes of Health Research funded research study.
43. Health Canada made a number of requests for additional information, each of which was answered.
44. On September 20, 2013, Health Canada issued 16 Letters of Authorization for the sale of diacetylmorphine to Drs. Cheryl McDermid and Scott MacDonald, physicians with

privileges at Providence Crosstown Clinic. A further 5 approvals were issued within one week of the original 16. These authorizations limit authorization to procure diacetylmorphine for a treatment regimen of 90 days.

45. Providence is making every effort to procure diacetylmorphine for the 21 individuals for whom authorization has been granted but the providers have yet to dispense this treatment.
46. Even on the assumption that the providers do eventually dispense the treatment, once the 90 day treatment regimen is completed, the *Regulations* preclude any further access for these individuals through the SAP. As such, the *Regulations* give rise to the same risks of physical, psychological and psychosocial harms for these 21 individuals, albeit at a later date.

Health Minister's Response

47. Also on September 20, 2013, the Minister of Health issued a statement which provided in part:

Earlier today, officials at Health Canada made the decision to approve an application under the Special Access Program's current regulations to give heroin to heroin users - not to treat an underlying medical condition, but simply to allow them to continue to have access to heroin for their addiction even though other safe treatments for heroin addiction, such as methadone, are available.

This decision is in direct opposition to the government's anti-drug policy and violates the spirit and intent of the Special Access Program.

I am taking immediate action to protect the integrity of the Special Access Program and ensure this does not happen again.

The Special Access Program was designed to treat unusual cases and medical emergencies; it was not intended as a way to give illicit drugs to drug addicts.

Our policy is to take heroin out of the hands of addicts, not to put it into their arms.

48. On October 2, 2013, the Governor in Council, on the recommendation of the Minister of Health, made the *Regulations* pursuant to s. 55(1) of the *CDSA* and s. 30 of the *Food and Drugs Act*, R.S.C. 1985, c. F-27.
49. Sections 1, 2 and 11 of the *Regulations* are relevant here (collectively the "impugned provisions"). Sections 1 and 2 of the *Regulations* replace the definition of "restricted drug" in s.J.01.001 of the *Food and Drug Regulations* to include, *inter alia*, "diacetylmorphine (heroin) and its salts." Section 11 of the *Regulations* amend s. C.08.010 of the *Food and Drug Regulations*, which deal with the SAP, to provide that:

(1.1) The Director shall not issue a letter of authorization under subsection (1) for a new drug that is or that contains a restricted drug as defined in section J.01.001.

50. Since October 4, 2013 the Manager of the SAP has denied all SAP requests for diacetylmorphine on the basis that:

Diaphin (Diacetylmorphine)

Your request for emergency access to the above named product cannot be authorized. The drug requested is a "restricted drug" as defined in Part J of the *Food and Drug Regulations*, and is not eligible for authorization by the programme in accordance with subsection C.08.010 (1.1). For your reference, a copy of the relevant provision is inserted below and the content of the regulations is attached.

C.08.010 (1.1) The Director shall not issue a letter of authorization under subsection (1) for a new drug that is or that contains a restricted drug as defined in section J.01.001.

Part 2: RELIEF SOUGHT

The Plaintiffs seek the following relief:

1. a declaration that the impugned provisions are *ultra vires* and do not apply to the Plaintiff Requests, Future SALOME Requests and Other Requests on the basis of ss. 92(7), (13) and (16), or any combination thereof, of the *Constitution Act, 1867 (U.K.)*, 30 & 31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5 (the "*Constitution Act, 1867*"), and on the basis of the doctrine of interjurisdictional immunity;
2. a declaration that to the extent that the impugned provisions prohibit the Director from granting the Plaintiff Requests, Future SALOME Requests and Other Requests, they unjustifiably infringe s. 7 of the *Canadian Charter of Rights and Freedoms* (the "*Charter*"), Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982 (U.K.)*, 1982, c. 11 (the "*Constitution Act, 1982*") and are, to that extent, of no force and effect;
3. a declaration that to the extent that the impugned provisions prohibit the Director from granting the Plaintiff Requests, Future SALOME Requests and Other Requests, they unjustifiably infringe s. 15 of the *Charter* and are, to that extent, of no force and effect;
4. an order in the nature of a mandatory injunction directing the Manager of the SAP to grant the Plaintiff Requests and Future SALOME Requests;
5. in the alternative, an order directing the Manager of the SAP to reconsider or consider the Plaintiff Requests and Future SALOME Requests in light of his authority to grant them;

6. an interlocutory injunction exempting all Plaintiff Requests and Future SALOME Requests from the application of the impugned provisions;
7. costs, including special costs and applicable taxes on those costs; and
8. such further and other relief as this Honourable Court deems meet and just.

Part 3: LEGAL BASIS

1. The Plaintiffs rely on:
 - a. Sections 91 and 92 of the *Constitution Act, 1867*.
 - b. the *Charter* and, in particular, ss. 1, 7, 15 and 24; and
 - c. s. 52 of the *Constitution Act, 1982*.

The Federalism Arguments

2. The treatment and management of patients with severe opioid addiction who have previously not responded to other available treatments and, in particular, the determination of whether access to diacetylmorphine is an appropriate treatment for such persons, are matters relating to health care, the regulation and delivery of health services, the practice of medicine, and regulation of the patient-physician relationship. These are matters within the exclusive jurisdiction of the Province on the basis of ss. 92(7), (13) and (16), or any combination thereof, of the *Constitution Act, 1867*.
3. The doctrine of interjurisdictional immunity applies to confer the limited grant of immunity from the impugned provisions to allow treatment of such patients to fall within the jurisdiction of the Province as an exercise of its core powers relating to health care, the regulation and delivery of health services, the practice of medicine, and the regulation of the patient-physician relationship.

Charter, Section 7

4. Section 7 of the *Charter* states as follows:
 7. 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.
5. The rights to life, liberty and security of the person are engaged and infringed by state-imposed restrictions that deprive patients with severe opioid addiction who have previously not responded to other available treatments and on whose behalf a SAP request for diacetylmorphine is made by a medical practitioner of the right to access treatment.

Principles of Fundamental Justice

6. The application of the impugned provisions to patients with severe opioid addiction who have previously not responded to other available treatments and on whose behalf a request by a medical practitioner is made is arbitrary, overbroad and grossly disproportionate.

Charter, Section 15

7. Section 15(1) of the *Charter* reads as follows:

15. (1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

8. The impugned provisions operate to deprive patients with severe opioid addiction who have previously not responded to other available treatments and on whose behalf a SAP request for diacetylmorphine is made by a medical practitioner of the equal protection of the law and impose a disproportionate burden of the law by their discriminatory operation on and application to them by reason of their physical and mental disabilities.

Charter, Section 1

9. Section 1 of the *Charter* reads as follows:

1. The *Canadian Charter of Rights and Freedoms* guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

10. The said infringements of ss. 7 and s. 15 cannot be justified pursuant to the criteria of s. 1, the burden of proof of which lies on Canada.

Plaintiffs' address for service: Arvay Finlay
1320 – 355 Burrard Street
Vancouver BC V6C 2G8

Fax number address for service (if any): 1.888.575.3281

E-mail address for service (if any): jarvay@arvayfinlay.com

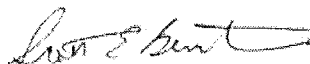
Place of trial: Vancouver, British Columbia

The address of registry is: 800 Smithe Street, Vancouver, BC, V6Z 2C5



Dated: 13 Nov 2013

Signature of lawyer for plaintiffs
Joseph J. Arvay, Q.C.



Scott E. Bernstein

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

- I. (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

[The following information is provided for data collection purposes only and is of no legal effect.]

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This is a constitutional challenge, based on ss. 7 and 15 of the *Charter*, to the *Regulations Amending Certain Regulations Relating to Access to Restricted Drugs* to the extent that they operate to deprive patients with severe opioid addiction who have previously not responded to methadone maintenance therapy from the ability to access treatment for their illness.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

[Check one box below for the case type that best describes this case.]

A personal injury arising out of:

- a motor vehicle accident
- medical malpractice
- another cause

A dispute concerning:

- contaminated sites
- construction defects

- real property (real estate)
- personal property
- the provision of goods or services or other general commercial matters
- investment losses
- the lending of money
- an employment relationship
- a will or other issues concerning the probate of an estate
- a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[Check all boxes below that apply to this case]

- a class action
- maritime law
- aboriginal law
- constitutional law
- conflict of laws
- none of the above
- do not know

Part 4: *[If an enactment is being relied on, specify. Do not list more than 3 enactments.]*

Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (U.K.), 1982, c. 11

Constitution Act, 1867 (U.K.). 30 & 31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5

Constitution Act, 1982, being Schedule B to the Canada Act 1982 (U.K.), 1982, c. 11