IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *Providence Health Care Society v. Canada (Attorney General),* 2014 BCSC 936

Date: 20140529
Docket: S-138411
Registry: Vancouver

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

And

Vancouver Coastal Health Authority

Intervenor

Before: The Honourable Chief Justice Hinkson

Reasons for Judgment

Counsel for the Plaintiffs, Providence Health Care Society, Bartosch, English, Lidstrom, Love and Murray:	J.J. Arvay, Q.C., A.M. Latimer, A. Juva
Counsel for Defendant:	L. Lachance, K. Reimer, S. Smiley
Counsel for Intervenor:	S. Tucker
Counsel for Interested party, British Columbia:	L. Greathead, K. Evans
Place and Date of Trial:	Vancouver, B.C. March 25, 26, and 27, 2014
Place and Date of Judgment:	Vancouver, B.C. May 29, 2014

[1] The plaintiff Providence Health Care Society ("Providence") is a non-profit organization incorporated in 2000 pursuant to the *Society Act*, R.S.B.C. 1996, c. 433. It operates a number of hospitals, residences and clinics in the City of Vancouver and provides care to vulnerable inner city residents, including those affected by addiction and infectious diseases.

[2] The plaintiffs Deborah Bartosch, Charles English, Douglas Lidstrom, Larry Love, and David Murray (who I will refer to as the "personal plaintiffs") have each deposed that they have a severe opioid addiction and have not responded to other available treatments for their addiction. They have also deposed that each of their physicians have submitted a Special Access Program ("SAP") request for diacetylmorphine (heroin) for their use.

[3] The personal plaintiffs apply on their own behalves, and on behalf of all persons with severe opioid addiction who have not responded to other available treatments, and whose physicians have submitted a SAP request for diacetylmorphine, for the following injunctive relief pending the trial of this action:

a) an interlocutory injunction exempting all plaintiff requests and future requests relating to the Study to Assess Longer-term Opioid Medication Effectiveness ("SALOME") from the application of ss. J.01.001 and C.08.010 of the *Food and Drug Regulations*, C.R.C., c. 870 [the *FDR*], insofar as they apply to access to diacetylmorphine and its salts;

b) a mandatory injunction directing the Attorney General of Canada and any agents, agencies, departments, directors, officers, offices and/or Ministers of the Federal Crown to provide all necessary regulatory approvals, permits and/or exemptions required to secure access to the diacetylmorphine granted under any plaintiff requests and/or future SALOME request on an expedited basis; and

c) a direction that the Court maintain jurisdiction to supervise all issues arising in respect of plaintiff requests and future SALOME requests.

[4] Providence seeks the same relief for the same persons.

[5] The application for injunctive relief is supported by the Attorney General of British Columbia, who appears pursuant to the *Constitutional Question Act*, R.S.B.C. 1996, c. 68, and by the intervenor, the Vancouver Coastal Health Authority.

The Legislative Scheme

[6] In his Application Response, the Attorney General of Canada set out the relevant parts of the legislative scheme that pertain to the plaintiffs' application:

> 2. Three United Nations Conventions, to which Canada is a signatory, form the basis for the current global drug control system: the United Nations *Single Convention on Narcotic Drugs, 1961* as amended by the 1972 Protocol; the United Nations *Convention on Psychotropic Substances, 1971*; and, the United Nations *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.*
>
> 3. The Conventions establish controls on specific narcotics, psychotropic substances and precursors that are listed in the Schedules to the Conventions. The Conventions control the production, manufacture, export, import, distribution and stocks of, trade in and use and possession of the scheduled narcotics, psychotropic substances and precursors.
>
> 4. The implementation of the United Nations international drug control conventions is monitored by the International Narcotics Control Board (the "INCB"). The INCB is an independent and quasi-judicial body that was established in 1968 in accordance with the *Single Convention on Narcotic Drugs, 1961.*
>
> 5. The legal status of heroin in Canada is governed by both the *Food and Drugs Act* (the "*FDA*") and the *Controlled Drugs and Substances Act* (the "*CDSA*") as well as the regulations made under those Acts. Together these Acts and their regulations form the principle legislative and regulatory scheme for access to and control of drugs in Canada.
>
> …
>
> 8. The *FDA* is rooted in the criminal law power and is concerned with the manufacture and sale of drugs in Canada. The *FDA* and its regulations create a comprehensive scheme for the regulation of the sale of drugs in Canada that is designed and intended to protect the health and safety of Canadians. The *FDA* and its regulations prohibit

the sale of drugs where their safety, efficacy and quality have not been demonstrated.

…

10. The *FDA* and the *Food and Drug Regulations* ("*FDR*") Part C restrict the sale of drugs in dosage form. Under the *FDR*, there are three ways in which an unauthorized drug in dosage form can be authorized for sale:

    (a) upon issuance of a Drug Identification Number ("DIN") for drugs in dosage form and upon issuance of a DIN and a Notice of Compliance ("NOC") for new drugs in dosage form;

    (b) in the context of a clinical trial, to which the Minister has not objected; or

    (c) pursuant to a letter of authorization under the Special Access Programme ("SAP").

…

20. The SAP is governed by sections C.08.010 and C.08.011 of the *FDR.* These provisions empower the Assistant Deputy Minister, Health Products and Food Branch, Health Canada (the "Director") with discretionary authority to issue SAP authorizations in response to requests from individual practitioners. The Director may authorize or deny access to a drug based on the data supplied by the practitioner and other information the Director may have in his or her possession.

21. The Director exercises his or her discretion to issue SAP authorizations by considering all information provided by the practitioner, the nature of the medical emergency, and the extent to which the data submitted in support of the request or is otherwise available is credible and relevant to the specified medical emergency.

22. A practitioner is responsible for initiating a request on behalf of a patient and ensuring that the decision to prescribe the drug for a specific indication is supported by credible evidence available in the medical literature or provided by the manufacturer.

…

24. During a SAP assessment, the Director determines, based on the information before him or her if: a) the condition is a medical emergency; b) all other marketed therapies have been tried and failed, considered and deemed unsuitable or otherwise unavailable; and c) there is credible data supporting the use, safety and efficacy of the drug for the medical emergency at issue.

…

30. The *FDR* do not permit the Director to issue an authorization for a restricted drug as defined in Part J of the *FDR* ("Part J (Restricted Drug Regulations)"), which is outlined below.

…

32. The *CDSA* applies to "controlled substances" and precursors listed in its schedules. Most of the controlled substances listed in the schedules to the *CDSA* are "drugs" as defined in the *FDA*. In simple terms, the *CDSA* prohibits all activities, including importation and distribution, involving the substances listed in the Schedules to the *CDSA* unless the activities are otherwise authorized under the *CDSA* or its regulations or an exemption is obtained under section 56 of the CDSA.

…

34. The Restricted Drug Regulations define the term "restricted drugs" and include a Schedule listing substances that are considered to be restricted drugs. The Restricted Drug Regulations also set out provisions authorizing the sale of restricted drugs for use in clinical and laboratory research, as well as provisions to sell, possess or otherwise deal in a test kit.

…

36. Section 56 of the CDSA permits the Minister to exempt any person or class of persons or any controlled substance or precursor from the application of all or any of the provisions of the CDSA or its regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

…

38. The CDSA and the Restricted Drug Regulations impose tight restrictions on the importation of restricted drugs. These measures aim to control and limit the importation of these drugs to control the abuse and diversion of these drugs.

39. Restricted drugs may only be imported into Canada by a licensed dealer, for example, a pharmaceutical manufacturer or distributor. A licensed dealer may import only substances that are listed on its license. To initiate an import, a licensed dealer must submit an import permit application to the Office of Controlled Substances. The application must specify, among other things, the quantity of the restricted drug to be imported and the purpose for which the drug is required. A licensed dealer must obtain an import permit every time they want to import a restricted drug.

…

41. The importation of certain drugs into Canada, such as heroin, is monitored by the INCB. Canada must provide an estimate to the INCB each year of how much heroin it will require for medical and scientific research purposes that year. Canada cannot authorize the importation of certain drugs, such as heroin, over the estimated amount unless it makes a request to the INCB and the INCB approves that request. This process may take weeks or months and approval is not guaranteed.

42. A permit is required by the licensed dealer to import a drug such as heroin into Canada and it is used by the Canada Border Services Agency to allow the entry of the shipment. Canada must provide Quarterly Statistics of Imports and Exports of Narcotic Drugs reports to the INCB, including the exact quantity of the drug that is imported.

43. Under the *FDA* and the *FDR*, heroin for the treatment of opioid addictions is a "drug" and would be considered a "new drug" for market authorization purposes. Because no manufacturer has a DIN and NOC for heroin for treatment of opioid addiction, its sale in dosage form is prohibited by the *FDR* C.08.002 and C.0.014. Currently, the sale of heroin through the SALOME clinical trial is ongoing, as the Minister did not object to its sale under Division 5 of the *FDR*. Further, because heroin is a restricted drug, the Director cannot authorize the sale of heroin under the SAP.

44. Under the CDSA, diacetylmorphine (heroin) and its salts ("heroin") is a controlled substance listed in Schedule I. As a result, all activities related to heroin are prohibited unless otherwise specifically authorized by the Restricted Drug Regulations or an exemption is obtained under section 56 of the CDSA. It is in part because of the significant harm such substances can cause that the penalties associated with illegal activities involving the controlled substances listed in Schedule I are the highest imposed by the CDSA.

45. Heroin can only be imported into Canada by a licensed dealer who is licensed to conduct activities with heroin.

46. As noted above, the importation of heroin into Canada is monitored by the INCB. Heroin cannot be imported into Canada above the pre-established estimates of annual medical and scientific requirements unless a request is made and approved by the INCB. For 2013, the importation estimate for heroin was 16.5 kg. For 2014, that estimate is 17.3 kg.

[7] Health Canada operates the SAP pursuant to ss. C.08.010 and C.08.011 of the *FDR.* Those sections provide:

> C.08.010. (1) The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the emergency treatment of a patient under the care of that practitioner, if
>
> (*a*) the practitioner has supplied to the Director information concerning
>
> (i) the medical emergency for which the drug is required,
>
> (ii) the data in the possession of the practitioner with respect to the use, safety and efficacy of that drug,
>
> (iii) the names of all institutions in which the drug is to be used, and
>
> (iv) such other data as the Director may require; and

> (*b*) the practitioner has agreed to
>
> (i) report to the manufacturer of the new drug and to the Director on the results of the use of the drug in the medical emergency, including information respecting any adverse reactions encountered, and
>
> (ii) account to the Director on request for all quantities of the drug received by him.
>
> (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.
>
> (2) The Director shall, in any letter of authorization issued pursuant to subsection (1), state
>
> (*a*) the name of the practitioner to whom the new drug may be sold;
>
> (*b*) the medical emergency in respect of which the new drug may be sold; and
>
> (*c*) the quantity of the new drug that may be sold to that practitioner for that emergency.
>
> C.08.011. (1) Notwithstanding section C.08.002, a manufacturer may sell to a practitioner named in a letter of authorization issued pursuant to section C.08.010, a quantity of the new drug named in that letter that does not exceed the quantity specified in the letter.
>
> (2) A sale of a new drug made in accordance with subsection (1) is exempt from the provisions of the Act and these Regulations.
>
> [Emphasis added.]

[8] Prior to the enactment of the *Regulations Amending Certain Regulations Relating to Access To Restricted Drugs*, S.O.R./2013-172 [the *Regulations*], s. J.01.001 of the *FDR* provided that "restricted drug" means "a drug set out in the schedule to this Part".

Background

[9] Diacetylmorphine is the active component of heroin, but it can be pharmaceutically produced without the impurities associated with street drugs. It is, however, now a restricted drug pursuant to the *FDR.*

[10] Severe Opioid Use Disorder is the term used in the latest edition of the Diagnostic and Statistical Manual of Mental Disorders consulted by the medical profession for the diagnosis of mental disorders. According to Dr. Evan Wood, a

specialist in internal medicine, epidemiology and addiction medicine, the term is used to refer to what is conventionally described as severe opioid addiction or opioid dependence. Dr. Wood describes the disorder as a serious and potentially life-threatening condition that will often require urgent medical attention.

[11] The treatment options presently available in Canada for opioid addiction include detoxification, treatment recovery, methadone maintenance therapy ("MMT") and buprenorphine. The evidence of experts in the treatment of opioid addiction relied upon by the plaintiffs is that for those who are refractory to presently available treatment for their addiction, the treatment of choice, and perhaps the only effective treatment, is to provide them with diacetylmorphine.

[12] Between March 2005 and July 2008, researchers at Providence conducted a randomized controlled trial to study the effectiveness of injectable diacetylmorphine, as compared to oral methadone, in retention in treatment and reducing illicit drug use and illegal activities among treatment-refractory opioid-dependant individuals. The study was named the North American Opiate Medication Initiative ("NAOMI").

[13] Participants in NAOMI were randomly selected to receive one of either oral methadone, injectable diacetylmorphine or injectable hydromorphone. The plaintiffs Ms. Bartosch and Mr. Murray participated in this trial.

[14] In 2011, researchers at the plaintiff Providence began the SALOME trial. SALOME is a single centre, double-blind, randomized controlled trial. Phase 1 of the trial compares whether injectable hydromorphone (a medication approved in Canada to treat pain) is as effective as injectable diacetylmorphine for patients with severe opioid addition who have previously not responded to MMT. The study is also testing whether oral diacetylmorphine and/or oral hydromorphone are as effective as injectable diacetylmorphine.

[15] The second phase of the SALOME trial is intended to test whether oral diacetylmorphine and/or oral hydromorphone are as effective as intravenous diacetylmorphine. Participants are randomly selected to receive one of either

injectable diacetylmorphine or hydromorphone for six months and then randomly selected to receive either oral or continued injectable treatment of the study drug the participant was provided in phase 1.

[16] 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.

[17] The SALOME trial will be unblinded in August 2014. The data results in respect of Phase 1 of SALOME will be available to Health Canada by the end of December 2014. These data results will be publically available in or around February or March 2015.

[18] Both SALOME and NAOMI were funded by the Canadian Institutes of Health Research, the major federal agency responsible for funding health research in Canada. I infer that the diacetylmorphine used in these trials thus far was provided by the Federal Government for research purposes, though I have not specifically been informed of the source of the drug by counsel. The SALOME trial will not be completed until 2016.

[19] The personal plaintiffs all participated in SALOME. Each entered the SALOME trial in 2012, and each has deposed that they experienced significant positive results in phase 1 of the trial. However, Ms. Bartosch, Mr. Lidstrom and Mr. Love did not feel that the treatment they received in Phase 2 of the trial was as effective for them.

[20] The SAP allows medical practitioners to request access to drugs that are unavailable for sale in Canada for patients with life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable. On September 20, 2013, Providence doctors received

SAP approvals from Health Canada for a 90 day supply of injectable diacetylmorphine for 16 of 36 applicants sponsored by Providence.

[21] 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.

[22] On September 27, 2013 Providence doctors received SAP approvals from Health Canada for a 90 day supply of injectable diacetylmorphine for another 5 applicants sponsored by Providence.

[23] Mr. Lidstrom and Mr. Murray each received approval from Health Canada to receive diacetylmorphine treatment at the Providence Crosstown Clinic for three months, but to date have not received any such treatment.

[24] 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 *Controlled Drugs and Substances Act*, S.C. 1996, c. 19 [the *CDSA*], and s. 30 of the *Food and Drugs Act,* R.S.C. 1985, c. F-27.

[25] Sections 1, 2 and 11 of the *Regulations* (collectively the "impugned provisions") are in issue here. Sections 1 and 2 of the *Regulations* replace the

definition of “restricted drug” in s. J.01.001 of the *FDR* to include, *inter alia,* “diacetylmorphine (heroin) and its salts.” Section 11 of the *Regulations* amends s. C.08.010 of the *FDR,* which deals 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.

[26] Since October 4, 2013 the Manager of the SAP has denied all SAP requests for diacetylmorphine on the basis that:

> 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.*

[27] Applications for diacetylmorphine treatment for Ms. Bartosch, Mr. English and Mr. Love pursuant to the SAP were submitted to Health Canada by their physicians, but were denied due to the new provisions of the *FDR.*

The Legal Principles

[28] The Supreme Court of Canada established a three part test for determining whether to grant an interlocutory injunction in *Manitoba (A.G.) v. Metropolitan Stores Ltd*., [1987] 1 S.C.R. 110, [1987] 3 W.W.R. 1. The three parts are: first, whether there is a serious question to be tried; second, whether the applicant will suffer irreparable harm if the injunction is not granted; and third, an assessment of the balance of convenience between the party or parties seeking the injunctive relief, and those opposing it.

[29] Justice Beetz, writing for the Court, discussed the test as follows at 127–129:

> The first test is a preliminary and tentative assessment of the merits of the case, but there is more than one way to describe this first test. The traditional way consists in asking whether the litigant who seeks the interlocutory injunction can make out a *prima facie* case. The injunction will be refused unless he or she can make out such a case: *Chesapeake and Ohio Railway Co. v. Ball*, [1953] O.R. 843, per McRuer C.J.H.C., at pp. 854–55. The House of Lords somewhat relaxed the first test in *American Cyanamid Co. v. Ethicon Ltd.*, [1975] 1 All E.R. 504, when it held that all that was necessary to meet this test was to satisfy the Court that there was a serious question to be tried as opposed to a frivolous or vexatious claim. Estey J. speaking for himself and five other members of the [Supreme Court of Canada] in a unanimous judgment referred to but did not comment upon this difference in *Aetna Financial Services Ltd. v. Feigelman*, [1985] 1 S.C.R. 2, at pp. 9–10.
>
> *American Cyanamid* has been followed on this point in many Canadian and English cases, but it has also been rejected in several other instances and it does not appear to be followed in Australia: see the commentaries and cases referred to in P. Carlson, "Granting an Interlocutory Injunction: What is the Test?" (1982), 12 *Man. L.J.* 109; B.M. Rogers and G.W. Hately, "Getting the Pre-Trial Injunction" (1982), 60 *Can. Bar Rev.* 1, at pp. 9-19; R.J. Sharpe, *Injunctions and Specific Performance* (Toronto 1983), at pp. 66-77.
>
> In the case at bar, it is neither necessary nor advisable to choose, for all purposes, between the traditional formulation and the *American Cyanamid* description of the first test: the British case law illustrates that the formulation of a rigid test for all types of cases, without considering their nature, is not to be favoured (see Hanbury and Maudsley, *Modern Equity* (12th ed. 1960), pp. 736-43). In my view, however, the *American Cyanamid* "serious question" formulation is sufficient in a constitutional case where, as indicated below in these reasons, the public interest is taken into consideration in the balance of convenience. But I refrain from expressing any view with respect to the sufficiency or adequacy of this formulation in any other type of case.
>
> The second test consists in deciding whether the litigant who seeks the interlocutory injunction would, unless the injunction is granted, suffer irreparable harm, that is harm not susceptible or difficult to be compensated in damages. Some judges consider at the same time the situation of the other party to the litigation and ask themselves whether the granting of the interlocutory injunction would cause irreparable harm to this other party if the main action fails. Other judges take the view that this last aspect rather forms part of the balance of convenience.
>
> The third test, called the balance of convenience and which ought perhaps to be called more appropriately the balance of inconvenience, is a determination of which of the two parties will suffer the greater harm from the granting or refusal of an interlocutory injunction, pending a decision on the merits.

[30] Here, the plaintiffs seek not only an injunction to maintain what they contend is the *status quo ante*, exempting them from the application of the impugned provisions, but also a mandatory injunction directing all necessary regulatory

approvals, permits and/or exemptions required to secure access to the diacetylmorphine be issued, and on an expedited basis.

[31] In *Canwest Pacific Television Inc. v. 147250 Canada Ltd.* (1987), 14 B.C.L.R. (2d) 104, [1987] B.C.J. No. 1262 (C.A.), a mandatory injunction for the transfer of certain shares was sought. The action in which the application was brought sought specific performance of an alleged sale of the shares, so the injunction, if granted, would provide to the plaintiffs the very remedy they sought in the action. Madam Justice McLachlin, as she then was, writing for the Court, held at 108–109:

> In *Aetna Fin. Services Ltd. v. Feigelman*, *supra*, the Supreme Court of Canada reviewed the principles governing the granting of orders prior to trial which are not confined to procedural matters, but which have the effect of altering the parties' rights over their property in the pre-trial period. At issue was a “Mareva” injunction depriving the defendant of the possession and use of his property pending trial.
>
> Canwest contends that the principles enunciated in *Aetna* must be confined to Mareva or similar injunctions and have no application in the case at bar. I cannot accept that submission. The language of the passages relied on by the chambers judge below clearly extends to any order which restricts the defendant's substantive rights without a trial.
>
> At p. 166, Estey J., for the court, distinguished between interlocutory applications of a procedural nature and those which affect the parties' substantive rights, stating:
>
> > As a general proposition, it can be fairly stated that in the scheme of litigation in this country, orders other than purely procedural ones are difficult to obtain from the court prior to trial.
>
> After referring to the need of the applicant to show irreparable harm if the order sought does not go, he went on to state:
>
> > A second and much higher hurdle facing the litigant seeking the exceptional order is the simple proposition that in our jurisprudence, execution cannot be obtained prior to judgment and judgment cannot be recovered before trial. Execution in this sense includes judicial orders impounding assets *or otherwise restricting the right of the defendant without a trial.*
>
> These passages make it plain that the essential distinction is not between Mareva orders and other types of interlocutory orders, but between interlocutory orders of a procedural nature and interlocutory orders which restrict a party's substantive rights before trial. The broad concept of execution as that word is used in *Aetna* extends to any order abrogating the defendant's rights prior to trial. Such orders, apart from certain exceptions, will not be granted.

> The exceptions set out by Estey J. and reviewed by the chambers judge below are the following:
>
> > 1. Orders for the preservation of assets, the very subject matter in dispute, where to allow the adversarial process to proceed unguided would see their destruction before the resolution of the dispute;
> >
> > 2. Where generally the processes of the court must be protected even by initiatives taken by the court itself;
> >
> > 3. To prevent fraud both on the court and on the adversary;
> >
> > 4. *Qua timet* injunctions under extreme circumstances to prevent a real or impending threat of removal of the assets from the jurisdiction.
>
> I conclude that the chambers judge did not err in applying the principles set out in *Aetna* on this application. Counsel for D.K.L. is correct when he says that the relief sought on this application should be granted only if the test for summary judgment is met, namely, that there is no arguable defence to the claim. Any other course would permit execution before judgment in circumstances where it is inappropriate.

[32] In *R.J.R. — MacDonald v. Canada (A.G.)*, [1994] 1 S.C.R. 311 at 333, 111 D.L.R. (4th) 385, Sopinka and Cory JJ. commented on the need for courts to be sensitive to and cautious of making rulings on applications for injunctive relief whose effect would deprive legislation enacted by elected officials of its effect. However, they recognized at the same time that:

> … the *Charter* charges the courts with the responsibility of safeguarding fundamental rights. For the courts to insist rigidly that all legislation be enforced to the letter until the moment that it is struck down as unconstitutional might in some instances be to condone the most blatant violation of *Charter* rights. Such a practice would undermine the spirit and purpose of the *Charter* and might encourage a government to prolong unduly final resolution of the dispute.

Discussion

a) Serious Question to be Tried

[33] The Attorney General of Canada has effectively conceded that the first part of the test for an injunction has been met, submitting that “[while] the respondent denies that there is merit to the applicants’ claims, it acknowledges that the issues raised by the applicants are neither frivolous nor vexatious.”

[34] For her part, the Attorney General of British Columbia takes the position from a division of powers perspective that the impugned provisions are *ultra vires* the federal government.

[35] I need not resolve the division of powers issue in order to deal with the application before me. However, it bears mentioning that in *Canada (Attorney General) v. PHS Community Services Society,* 2011 SCC 44 at paras. 66–70, [2011] 3 S.C.R. 134, the Supreme Court of Canada determined that the delivery of health care services is not a protected core of the provincial power over health care in ss. 92(7), (13) and (16) of the *Constitution Act*, *1867* (U.K.), 30 & 31 Victoria, c. 3, and is therefore not immune from federal interference.

[36] The Court explained that the federal role in the domain of health makes it impossible to precisely define what falls in or out of the provincial "core", concluding at para. 68 that "[overlapping] federal jurisdiction and the sheer size and diversity of provincial health power render daunting the task of drawing a bright line around a protected provincial core of health where federal legislation may not tread".

[37] As the application before me is for interlocutory relief, and the evidence relied upon by the opposing parties has not been tested, I propose to say little more about the merits of the plaintiffs' case or the Attorney General of Canada's response to that case. I accept that the plaintiffs have raised a serious question to be tried.

b) Irreparable Harm

[38] The second test consists in deciding whether the litigant who seeks the interlocutory injunction would, unless the injunction is granted, suffer irreparable harm; that is, harm which cannot be readily quantified in monetary terms or which cannot generally be cured by an award of damages. Some judges consider, at this stage, the situation of the other party to the litigation and ask themselves whether the granting of the interlocutory injunction would cause irreparable harm to this other party if the main action fails. Other judges take the view that this last aspect rather forms part of the balance of convenience.

[39] Prior to the introduction of the impugned provisions, the Assistant Deputy Minister, Health Products and Food Branch, Health Canada (the "Director") was given discretion to authorize special access to diacetylmorphine. The impugned provisions take away that discretion.

[40] The plaintiffs contend that the impugned provisions deprive them of their rights to life, liberty and security of the person pursuant to s. 7 of the *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 [the *Charter*] and their rights not to be discriminated against based upon the enumerated ground of disability contrary to s. 15 of the *Charter*. The plaintiffs contend that the alleged s. 7 deprivations are not in accordance with the principals of fundamental justice because they are arbitrary, overbroad, and grossly disproportionate to the alleged objective of the legislation.

[41] Other than accepting, as I do, that the impugned provisions are alleged to breach the plaintiffs *Charter* rights, I consider that it is inappropriate to address these contentions on this application.

i) Refractory Dependence

[42] The Attorney General of Canada contends that the injunctive relief sought for persons other than the plaintiffs with severe opioid addiction who have not previously responded to other available treatments for their addiction should be refused, as there is an absence of evidence upon which a conclusion could be reached as to whether such persons could properly be considered refractory.

[43] There is no agreed-upon definition of the term refractory. The experts relied upon by the plaintiffs contend that the term describes opioid addicted individuals who have proved unresponsive to MMT on previous attempts.

[44] The Attorney General of Canada relies on the evidence of Dr. Meldon Kahan, a witness who has extensively researched and gained substantial experience in the treatment of individuals suffering from opioid and other addictions. Dr. Kahan

contends that the term refractory should be used to describe: those who have undertaken MMT, but have continued to use heroin at least several times per week despite receiving a dose of at least 100 mg of methadone over a period of at least 2 months; those who have dropped out of such therapy because of intolerable side effects; or those who have received a trial at an optimal dose and duration of at least two of either buprenorphine, oral slow release morphine, or oral hydromorphone.

[45] In his affidavit of January 23, 2014, Dr. Kahan states that he is opposed to the use of diacetylmorphine to treat heroin addicts who have not responded to other available treatments for their addiction. The reasons for his opposition are set out in paragraph 16 of that affidavit:

> 16. My opposition to [Heroin Substitution Treatment ("HST")] is based on my review of the evidence on its safety and effectiveness, relative to methadone and other oral opioids. I reviewed the following types of evidence:
>
> - Evidence from controlled trials and observational studies on the impact of methadone at different doses on heroin use and treatment retention.
> - Evidence on the effectiveness of buprenorphine and morphine on treatment retention and heroin use.
> - Evidence from experimental studies on the potential risks of medically-administered intravenous opioids: suppression of breathing, low oxygen levels, and impaired cognitive function.
> - Evidence on the impact of program factors, such as take-home doses, on heroin use and treatment retention.

[46] Professor Martin Schechter, whose affidavit was filed by the plaintiffs, is the founding Director of the School of Population and Public Health in the Faculty of Medicine at U.B.C. In his affidavit of December 4, 2013, Professor Schechter commented at paras.6–9 and 11 that:

> 6. Heroin is a street drug sold in the black market that is a mixture of a number of substances. One of them is [diacetylmorphine ("DAM")], the ingredient that produces heroin's main effects, but street heroin contains many impurities in addition to DAM. Pure DAM, on the other hand, is a pharmaceutical medication, manufactured under pharmaceutical industry standards, with precise dosage, stability and sterility. The terms "heroin-assisted therapy" and "medically prescribed heroin" are actually misnomers because it is not street heroin that is being prescribed but rather the pure

pharmaceutical medication DAM. For this reason, I will refer to the treatment in question as diacetylmorphine-assisted therapy ("DAT").

7. Methadone is an oral medication that blocks the craving and withdrawal symptoms experienced by people with heroin addiction. MMT usually involves the once-daily provision of methadone. MMT is a convenient and effective treatment for many people with heroin addiction and should remain the treatment of first choice; however, there is an extremely vulnerable subgroup of people with heroin addiction for whom MMT and other existing treatments have not been successful despite repeated attempts. For convenience, I will refer to this subpopulation of people with chronic heroin addiction who are refractory to existing treatments as the "target population" because it is for this group that effective treatment is being sought. It has been estimated that the target population represents approximately 15% of people with heroin addiction. Attached hereto and marked as Exhibit C to this my affidavit is true copy of an article entitled "Prediction of relapse to frequent heroin use and the role of methadone prescription: an analysis of the Amsterdam Cohort Study among drug users" dated 2005.

8. Because Canadian medical professionals have no effective treatments to offer, members of the target population remain outside the health care system, deeply affected by the illness of addiction and its many consequences. Because street heroin is of unknown and variable dose, they are at significant risk of death due to overdose. Because street heroin is often injected in unsterile conditions, they are at significant risk of acquiring HIV, hepatitis C and other life-threatening infections. Because they are deeply entrenched in the black market, most of their time is spent in search of their next dose or "fix" of street heroin. This search often involves criminal activity and sex work.

9. A physician attempting to get an individual in the target population into treatment faces the following clinical question: Should one make yet another attempt at offering an existing treatment that is very likely not to engage and retain the patient in treatment, or should one try something different that may be more likely to retain the patient and stabilize them? Responding to this conundrum as early as 1972, the Le Dain commission wrote:

> *[O]ur recommendation is... that heroin maintenance be permitted on a controlled, experimental basis, as a treatment adjunct to be used in exceptional cases.... "On balance, however, we believe that the availability of heroin maintenance will increase the capacity of the overall treatment process to win patients from, the illicit market and for this reason, it is a justified experience. "*

…

11. It is understandable that one might, at first glance, ask whether DAT is simply providing an addict with the drug to which she or he is addicted. However, the premise of this is incorrect because DAT is not simply the administration of a drug. It is the application of a "bundle" of interventions that includes not only the provision of the pharmaceutical, but the opportunity for patients to benefit from up to thrice daily contact with doctors, nurses and counselors; the breaking of their cycle of criminality, sex work, jails and

> hospitalizations; and the stabilization of their previously chaotic lives which made improved health outcomes extremely unlikely. It is also worth noting that methadone is often co-prescribed as part of DAT, usually as an evening dose, to prevent overnight craving and withdrawal. For all of these reasons, DAT should not be viewed as the simple administration of DAM, but rather as an overall treatment strategy that is assisted by DAM but also by many other components.

[47] Dr. Kahan holds the view that NAOMI did not demonstrate that Heroin Substitution Treatment was superior to optimal methadone treatment. He stated that NAOMI demonstrated that patients who have previously failed methadone treatment programs often respond to a re-trial, and that many patients in the methadone group did well in the study. He concluded that these patients should be offered such a re-trial at a higher dosage.

[48] Dr. Kahan swore at paras. 26 and 87 of his affidavit that:

> 26. For patients who are refractory to methadone, three alternative oral medications are available: buprenorphine, oral morphine and oral hydromorphone. All three are far safer than intravenous heroin treatment. Buprenorphine is particularly useful for patients who experienced side effects with methadone, and patients who require take-home doses because of work or family commitments. Four randomized trials have demonstrated that slow morphine release morphine [*sic*] and methadone are of comparable efficacy.
>
> …
>
> 87. To determine why a patient has failed at or dropped out of methadone treatment, one needs the following information: i) the dose and duration of treatment, ii) whether the patient experienced ongoing withdrawal symptoms and cravings, iii) the patient's pattern of heroin use during treatment, iv) side effects with methadone, and v) the patient's reasons for dropping out of treatment. With this information, one can usually determine why the patient failed at methadone treatment. There are five main reasons for treatment failure: a) Early non-response, b) partial sustained response, c) intolerable side effects with methadone and d) program factors; and e) patient factors. Once these reasons are identified, an individualized treatment plan can be formulated.

[49] Dr. Kahan swore at para. 44 of his affidavit that there is no clinical need for the use of intravenous heroin. He expressed his opinion that patients who are truly refractory to an optimal trial of methadone, buprenorphine, and morphine or oral hydromorphone should be treated with intravenous hydromorphone.

[50] Dr. Eugenia Oviedo-Jokes, who is the principal investigator for the SALOME study, disagrees with many of Dr. Kahan's assertions and views about the treatment of opioid dependant patients and his use of the term refractory.

[51] The differences between these experts as to what constitutes refractory are, in many respects, more semantic than substantive insofar as they impact upon my decision on this application. When distilled down, the consensus seems to be that refractory means substantially resistant to conventional treatments such that further retrials of those treatments are unlikely to prove successful. On the materials before me, it appears the major difference is to where these individual physicians and researchers draw the line in finding an individual patient to be substantially resistant and therefore refractory. However, without the benefit of further evidence and cross examination, I cannot accept Dr. Kahan's more limited use of the term for the purposes of this application. As such, I use the term to mean the broader definition given above.

ii) Risks Associated with the Use of Heroin

[52] The plaintiffs submit that the irreparable harm faced by persons with severe opioid addiction who have not responded to other available treatments and whose physicians have submitted an SAP request for diacetylmorphine, if the relief that they seek is not granted, is set out in para. 7 of Dr. Wood's affidavit sworn December 3, 2013 in these proceedings:

> 7. Opioid Use Disorder is associated with a range of health and community concerns, including compulsive drug-seeking behaviour, infectious diseases and related risk behaviors (e.g., used syringe sharing, sex-trade involvement), fatal overdose and drug acquisition crime. Through their high consumption of illicit drugs, heroin-addicted individuals also contribute to the highly profitable and often violent illegal drug market which is believed to be largely controlled by organized crime groups.

[53] In his affidavit, Dr. Wood also deposed at paras. 6, 12, 14, 21 and 43 that:

> 6. … This fact has been recognized by various national and international public health bodies, including Health Canada. Attached hereto and marked as Exhibit C to this my Affidavit is a true copy of a letter from Ian MacKay, Manager, Health Canada's Special Access Programme ("SAP"), to Dr. Cheryl

McDermid, dated May 2, 2013, which states: “SAP considers CROD (Chronic Relapsing Opioid Dependence) to be a serious and/or life-threatening condition that will often require urgent medical attention.” This fact is also supported by a large body of literature and research. For instance, a study of mortality rates among intravenous-drug-using women in Vancouver’s Downtown Eastside reported age-adjusted rates of mortality almost 50 times higher than among British Columbia’s overall female population (Spittal et al., AIDS Care. 2006 Feb; 18(2): 101-8).

…

12. While medical detoxification (i.e., weaning individuals off of drugs of abuse), counselling, residential treatment and self-help (e.g., 12-step) programs have all been studied as addiction treatments, research has shown that these treatments fail in the vast majority of patients with severe Opioid Use Disorder. For instance, the recently completed study of prescription opioid addicted persons by the US National Institute on Drug Abuse known as the Prescription Opiate Abuse Treatment (POATS) study *(Archives of General Psychiatry.* 2011 Dec;68(12):1238-46) found that approximately 90% of prescription opioid addicted patients with opioid use disorder relapsed to opioid use when effective opioid agonist medication was tapered. As described below, this is just one of many studies demonstrating the value of maintaining patients on opioid agonist treatment. Attached hereto and marked as Exhibit E to this my Affidavit is a true copy of this study entitled “Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence” dated December 2011.

…

14. As is the case for many medical conditions where first line therapies sometimes fail to achieve a therapeutic benefit, available opioid agonist treatments (i.e., methadone and buprenorphine) are not successful for all patients and, in particular, for some of the most severely addicted individuals who may suffer from comorbid mental illnesses, such as the consequences of severe trauma. It is important to stress that accepted opioid agonists (e.g., methadone) were once highly controversial based on the view that it was simply maintaining a heroin-addicted individual on a substitute addictive agonist medication. To some extent this controversy exists to this day, but ultimately medical science has overcome this controversy, and buprenorphine and methadone are now on the World Health Organization’s list of essential medications.

…

21. From an evidence-based medicine perspective, and certainly in my opinion, the use of injectable diacetylmorphine is a much safer option than supervised use of oral or injectable hydromorphone for patients exiting the SALOME study, for several reasons. First, there is extensive experience with diacetylmorphine for this indication, and next to zero experience with hydromorphone, as I explain below. Specifically, experience with the prescription of diacetylmorphine to opioid-dependent patients began in the 1950s, and over the last several decades there has been a great deal of clinical experience regarding the safety and effectiveness of this approach in both observational clinical settings as well as the clinical trial setting. This has

> been well described in the literature. Attached hereto and marked as Exhibit I to this my Affidavit is a true copy of an article authored by Stimson and Ogborne entitled "Survey of addicts prescribed heroin at London clinics" published in the *Lancet* and dated May 30, 1970. Attached hereto and marked as Exhibit J to this my Affidavit is a true copy of an article authored by Rehm, Gschwend, Steffen, Gutzwiller, Dobler-Mikola and Uchtenhagen entitled "Feasibility, safety, and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study" published in the *Lancet* and dated October 27, 2001. Other studies are described below.
>
> …
>
> 43. As indicated above, past research suggests that when diacetylmorphine treatment is abruptly discontinued in patients who have been successfully treated with this therapy, greater than 80% will experience a severe health deterioration that places them at immediate risk of serious harm (e.g., HIV, hepatitis C, endocarditis, hypoxic brain injury) or death (for example, from a fatal heroin overdose) from resumption of unsupervised and unsterile street heroin use.

[54] In her affidavit of December 4, 2013, Professor Jane Buxton, who is associated with the U.B.C. School of Population and Public Health and is the harm reduction leader at the B.C. Centre for Disease Control, identified risks to users of illicit drugs, including the potential that a drug represented as heroin may in fact have a different and potentially dangerous active substance, may contain adulterants, or will be of an unknown potency.

[55] On the other hand, Dr. Kahan asserts at paras 65, 67 and 93–95 of his affidavit that even medically prescribed heroin is not without its own risks:

> 65. In contrast, safety data on medically prescribed heroin is scant compared to the wealth of information on morphine and hydromorphone. NAOMI and other controlled trials have shown that iv heroin has an extremely high rate of life-threatening events. Preliminary studies indicate that intravenous heroin commonly causes marked cerebral hypoxia post-injection, and another study found that patients on medically supervised heroin performed worse on cognitive tests than patients on methadone or buprenorphine. Further research is needed to confirm these findings. But until these studies have been conducted, the safety of long-term medically supervised heroin administration remains an open question. Switching a patient from a safe and potentially effective oral agent to an unsafe intravenous treatment is unethical and in violation of the First Do No Harm principle.
>
> …
>
> 67. Intravenous opioids should be only used as a treatment of last resort, in patients who are truly refractory to all other treatments. Intravenous opioids

reach the brain within seconds, whereas oral opioids are absorbed slowly and must first undergo metabolism through the liver before reaching the brain. Experimental studies have demonstrated that intravenous heroin causes a more rapid rise and higher peak blood levels of heroin and its metabolites than does oral ingestion of heroin (Girardin 2003). This makes intravenous use far more likely to cause intoxication, respiratory depression and hypoxia (lack of oxygen). In a meta-analysis of controlled trials, intravenous morphine and hydromorphone were associated with a measurable incidence of respiratory depression, but oral morphine and hydromorphone were not (Felden 2010). As described below, cerebral hypoxia is a common occurrence after injection of medically prescribed heroin.

…

93. Preliminary evidence suggests that heroin injection is commonly followed by clinically significant respiratory depression. In one placebo-controlled study, sixteen patients on HST were administered their usual dose. The arterial oxygen level dropped to below 80 in eight of the subjects, with a low pulse rate, low breathing rates, and abnormal EEG patterns were also observed. Another study found low levels of oxygen in the brain after HST patients received their usual heroin injection. (Stohler, Dursteler et al. 1999; Stoermer, Drewe et al. 2003). The authors state, “The criteria for the prescription and therapeutic use of IV HAT should be critically revised. ... additional studies of the safety of IOT are required. .. long-term complications such as brain lesions induced by frequent hypoxic states ... and consequent cognitive impairment... appear to be possible not only with illicit opioid use but with therapeutic use as well.” Until this study is replicated and more is known about the safety of heroin, it should be prescribed for research purposes only. Attached as Exhibit “Q” to this my affidavit is a copy of the Stohler study. Attached as Exhibit “R” to this my affidavit is a copy of the Stoermer study.

94. In the NAOMI trial, the heroin group experienced 16 life-threatening medication-related events (overdoses and seizures), for a rate of one event per six patients per year. This is an extremely high rate for an outpatient, long-term maintenance treatment. There were no life-threatening medication-related events in the methadone group. Other HST trials had similarly high rates. The Cochrane review of HST trials (Ferri 2012) reported that the risk of an adverse event related to the study medication was 13.5 times higher in the heroin group than in the methadone group. Post-injection hypoxia can also occur when patients leave the clinic, especially if the patient goes home and fall asleep, or takes benzodiazepines or drink alcohol. Studies have shown that benzodiazepine use is extremely common in heroin addicts (Bleich, Gelkopf et al. 2002)

95. The adverse events in the NAOMI trial resolved with treatment, and hospitalizations were not required. But non-fatal overdoses can have serious *sequelae*, including trauma, aspiration, and cognitive damage (Warner-Smith 2002). In a survey of patient complaints about HST, some patients reported cognitive deficits, muscle twitches and temporary paralysis of the limbs. The latter two symptoms can be caused by opioid toxicity and non-fatal overdose (Dursteler- MarcFarland 2006).

iii) The Personal Plaintiffs

[56] Each of the personal plaintiffs has returned to the use of illicit heroin after completing the second phase of the SALOME trial. They contend that this has occurred because they no longer receive treatment that is effective for them. They are supported in this view by Dr. MacDonald, a general practitioner in British Columbia with lengthy and broad experience in the treatment of opioid dependant patients.

[57] Ms. Bartosch deposed that she has been using heroin for approximately 16 years. It is her evidence that she has attempted to wean herself from the use of heroin several times, and that her single attempt at a methadone maintenance treatment was accompanied by uncomfortable side effects. She further deposed that she responded well to her treatment in the SALOME trial, but that since she no longer has access to effective treatment, she has returned to the use of illicit heroin.

[58] Mr. Love deposed that he has used illicit drugs since he was 13 years of age. His evidence is that he suffered injuries to his left knee while serving in the Canadian Armed Forces, and following his honourable discharge from the military in October of 1969, he moved to Vancouver and began using heroin to relieve the pain in his knee. He has been incarcerated for activities related to his drug use, but remains addicted to heroin. He further deposed that he has undergone alcohol and drug detoxification at least 50 times, and that he found that he was unable to function normally when on a methadone maintenance program.

[59] Mr. Love deposed that he was stabilized while in the SALOME trial until he was placed on oral hydromorphone, which he found ineffective. It is his evidence that he thus returned to the use of illicit heroin.

[60] Mr. Murray deposed that he has been injecting heroin and other opioids for approximately 42 years, despite at least ten attempts to treat his addiction to heroin by undergoing MMT. He further deposed that he participated in both the NAOMI and SALOME trials, but after each trial he relapsed into the use of illicit heroin. It is his

evidence that the oral hydromorphone treatment he received following his participation in the SALOME trial was ineffective in treating his heroin addiction.

[61] Mr. English deposed that he began injecting heroin and cocaine in or around 1985 when he was 21 years of age and considers that he was addicted to and dependant on heroin by the time he was 24 years of age. He deposed that he engaged in criminal activities to support his addiction. He also deposed that he entered a methadone maintenance program in 1993, but was unable to cope with the side effects of the treatment. A second treatment attempt in 1994 was similarly unsuccessful for him, but from 2010 until 2012 when he entered the SALOME trial he was able to stay on a methadone maintenance program. Since completing the SALOME trial, Mr. English has deposed that he has been prescribed hydromorphone which he uses once or twice per day, but that while he finds it better than methadone, it has proven ineffective in eliminating his need to use illicit heroin.

[62] Mr. Lidstrom has deposed that he began using heroin and other drugs some 40 years ago, when he was 16 or 17 years of age. He has enjoyed some periods of abstinence from the use of heroin, for as long as 10 years, but returned to its use in 1990. He has participated in 6 methadone maintenance programs, but found that they were ineffective in preventing his return to illicit street heroin or other opioids. He has experienced a number of health related difficulties which he associates with his drug use, and has a criminal record which he attributes to his need to finance his addiction.

[63] After 6 months in the SALOME trial Mr. Lidstrom was randomized onto oral treatment. He has deposed that he found this ineffective for him, and that he has since returned to the use of illicit heroin. Subsequently he was placed on oral hydromorphone, but this has not permitted him to refrain from the use of illicit heroin.

[64] Dr. Kahan disagrees that the personal plaintiffs necessarily face the risks described by Drs. Wood and Buxton. In his affidavit, Dr. Kahan challenges the assertion that the personal plaintiffs are refractory, asserting that they have not received optimal doses of methadone.

[65] Dr. Kahan swore in his affidavit at paras. 33–37 and 100 that:

> 33. Mr. Love was on a high dose of methadone. The clinical record does not indicate why he discontinued methadone treatment. He is taking immediate-release hydromorphone only twice per day, which is insufficient to relieve withdrawal symptoms. Therefore he cannot be classified as refractory to hydromorphone treatment.
>
> 34. In his two previous attempts. Mr. Murray's maintenance methadone doses were 80-100 mg, and 55 mg. These doses may have been insufficient to fully relieve withdrawal symptoms and suppress heroin use. He is only taking hydromorphone twice per day, therefore he is not necessarily refractory.
>
> 35. I do not believe Mr. English is refractory to methadone. In SALOME he did well on high doses of methadone (100-130 mg). He requested a rapid taper, not because of side effects but because he wanted to become abstinent.
>
> 36. Ms Bartosch is probably refractory to methadone treatment, because she experienced sweating and other side effects while on methadone. She is also probably refractory to buprenorphine, because she continued to use heroin while on it. She continues to experience withdrawal symptoms while on oral hydromorphone but it is only administered three times per day, which may be insufficient.
>
> 37. It is possible that Mr. Lidstrom is refractory to methadone treatment, since at one time his dose was 100 mg. I do not believe he is refractory to oral hydromorphone, because he responded well to a dose of 130 mg three times per day, with a small dose of methadone at night.
>
> …
>
> 100. The concerns I have expressed about HST are in stark contrast to the plaintiffs' descriptions of their lived experience with HST. The plaintiffs speak movingly of the marked improvements they have experienced in their health, mood and social life with HST. But it is important to note that the plaintiffs are comparing their lives on HST to their lives as out-of-treatment heroin addicts, or their lives while on methadone and still using heroin. If the plaintiffs had received optimal treatment with methadone or with other oral treatments, I believe there is a very good chance that they would have stopped illicit heroin use without HST, and the lives might have improved to an equal or greater degree. I have witnessed hundreds of patients who have made remarkable life transformations with methadone and other oral treatments. If they had been offered HST when they were actively addicted to heroin, they might well have accepted it, but I believe that they would have had a less productive and fulfilling work and family life.

[66] The Attorney General of Canada relies upon the evidence of Dr. Kahan and Dr. Conway, an expert in aspects of the treatment of intravenous drug users, to support its contention that for the individual plaintiffs, the available treatments for

their addiction have not been fully or effectively explored and that as a result, they cannot properly be considered refractory to such treatments. The evidence of the treatment experts relied upon by the Attorney General includes the view that oral morphine and oral hydromorphone are available treatments for opioid addiction, even though neither is listed by the Federal Government as indicated for the treatment of opioid addiction when issuing Drug Identification Numbers nor in the Notice of Compliance for morphine.

[67] The Attorney General of Canada contends that to satisfy the second part of the test for an injunction, the plaintiffs must establish that the harm they allege to be irreparable must be real and substantial, and that the harms alleged by the plaintiffs here are only speculative, raising but the mere possibility of harm.

[68] In *PHS Community Services Society*, the Supreme Court of Canada considered the applications of PHS, a non-profit organization that oversaw the operation of a safe injection facility that provided medical services to intravenous drug users in the Downtown Eastside of Vancouver, VANDU, a non-profit society that advocated on behalf of drug users, and two intravenous drug users, all of whom sought an extension of the facility's exemption from the operation of criminal laws in the *CDSA*.

[69] At paras. 7 and 10, the Supreme Court accepted that:

> [7] The residents of the DTES [Downtown Eastside of Vancouver] who are intravenous drug users have diverse origins and personal histories, yet familiar themes emerge. Many have histories of physical and sexual abuse as children, family histories of drug abuse, early exposure to serious drug use, and mental illness. Many injection drug users in the DTES have been addicted to heroin for decades, and have been in and out of treatment programmes for years. Many use multiple substances, and suffer from alcoholism. Some engage in street-level survival sex work in order to support their addictions. It should be clear from the above that these people are not engaged in recreational drug use: they are addicted. Injection drug use is both an effect and a cause of a life that is a struggle on a day to day basis.
>
> …
>
> [10] For injection drug users, the nature of addiction makes for a desperate and dangerous existence. Aside from the dangers of the drugs themselves, addicts are vulnerable to a host of other life-threatening

> practices. Although many users are educated about safe practices, the need for an immediate fix or the fear of police discovering and confiscating drugs can override even ingrained safety habits. Addicts share needles, inject hurriedly in alleyways and dissolve heroin in dirty puddle water before injecting it into their veins. In these back alleyways, users who overdose are often alone and far from medical help. Shared needles transmit HIV and hepatitis C. Unsanitary conditions result in infections. Missing a vein in the rush to inject can mean the development of abscesses. Not taking adequate time to prepare can result in mistakes in measuring proper amounts of the substance being injected. It is not uncommon for injection drug users to develop dangerous infections or endocarditis. These dangers are exacerbated by the fact that injection drug users are a historically marginalized population that has been difficult to bring within the reach of health care providers.

[70] The evidence proffered by the plaintiffs is similar to that accepted in *PHS Community Services Society*. That evidence is that drug addiction is a chronic disease and can be progressive, relapsing, and fatal, and that there are persons in British Columbia who have opioid addictions but who are refractory to presently available treatment for their addiction. The evidence is also that the risks of opioid dependence that is maintained by the use of illicit street drugs include fatal overdoses (which can be caused by the substitution of other substances for the drugs the user believes he or she has purchased, unknown strengths of such drugs, or the adulteration of such drugs), infections such as endocarditis, HIV/AIDS, and Hepatitis C, social disintegration, violence and criminal sanctions.

[71] In *PHS Community Services Society* the Supreme Court found that the Minister's failure to grant a s. 56 exemption to the safe injection facility engaged the claimants' s. 7 rights and contravened the principles of fundamental justice. The Court concluded that the effect of denying the services of the facility to the population it served and the correlative increase in the risk of death and disease to injection drug users was grossly disproportionate to any benefit that Canada might derive from presenting a uniform stance on the possession of narcotics and ordered the Minister to forthwith grant an exemption to the facility.

[72] The plaintiff submits that the process of withdrawal involves a combination of biochemical, psychological and social stresses that typically affect habitual drug users, putting them at a high risk of relapse when they attempt abstinence.

[73] I am not prepared, at this juncture, to accept the view of Dr. Kahan that, as the personal plaintiffs have not received what are in his view optimal doses of methadone, they are not refractory, or that they do not necessarily face the risks described by Drs. Wood and Buxton.

[74] I find that the risks identified by Dr. Woods and Buxton are risks faced by the personal plaintiffs, and by those on whose behalf they apply, which will be reduced if they receive injectable diacetylmorphine treatment from Providence physicians. These potential harms are clearly irreparable in nature.

c) The Balance of Convenience

[75] The plaintiffs contend that the injunctive relief sought is of little practical consequence to the Attorney General of Canada as the impugned provisions were made for purely political reasons or for reasons based on a misapprehension of the facts, the medical opinions and the evidence. I am not persuaded that this is the case.

[76] Ian MacKay is the Manager of the SAP. At paras. 50–51 of his affidavit of January 23, 2014, Mr. MacKay explained what transpires when a SAP request is received by his office:

> 50. During a SAP assessment, the Director determines, based on the information before her or him:
>
> (a) if the condition is a medical emergency;
>
> (b) whether all other marketed therapies have been tried and failed, considered and deemed unsuitable or otherwise unavailable; and
>
> (c) there is credible data supporting the use, safety and efficacy of the drug for the medical emergency at issue.
>
> 51. If a SAP authorization is issued, notice of the SAP authorization is transmitted to a specified manufacturer and a copy is provided to the applicant practitioner. SAP authorization permits the specified manufacturer to sell a specific quantity of the drug to a specific practitioner for a specific patient. An authorization does not compel a manufacturer to sell a drug; authorizations simply permit the sale of a drug provided the manufacturer is willing and able to supply the drug.

[77] Mr. MacKay cautioned, however, at para. 57 that:

> 57. The SAP is neither a mechanism to encourage the early use of drugs nor is it meant to circumvent clinical development of a drug or regulatory review of a submission for marketing. Access to any drug through the SAP should be limited in duration and quantity to meet emergency needs only. The SAP is intended for short term access to drugs. Long term access to any drug through SAP risks circumvention of the market authorization process.

[78] The Attorney General of British Columbia submitted that as the impugned provisions disturbed the *status quo ante*, and were enacted without time to consult with the Province of British Columbia, the public interest asserted by the Attorney General for Canada should carry less weight, particularly as the injunction sought is, at least in part, an exemption to allow the Director to exercise the discretion contemplated by the SAP, as opposed to the suspension of the legislation.

[79] I consider that there is public interest in both the control of illicit drugs through the criminal justice system, and in reducing the attendant social costs that will not be abated if the personal plaintiffs are refractory to the available treatments for their addiction other than diacetylmorphine, if diacetylmorphine would be effective to treat their addictions.

[80] I accept that the potential harms facing the personal plaintiffs, and those on whose behalf they apply, are grave and that an award of damages will be of little, if any, assistance to them. As such, those harms must weigh heavily in the balance, particularly given that the exemption requested by the applicants does not cause any material harm to the government pending the ultimate resolution of this matter at trial. While I must keep in mind Sopinka and Cory JJ.'s statements as to the caution required when considering whether to deprive duly enacted legislation of its effect on an interlocutory basis, I find that on the evidence before me an order to that effect is justified.

[81] SAP applications are considered and either approved or disapproved by those with expertise in both addictions and drug safety issues. In light of the seriousness of the potential harms facing the applicants, I am persuaded that the balance of convenience in this case favours those for whom such applications for injectable diacetylmorphine were approved on terms and conditions prior to the

enactment of the impugned provisions, or those whose applications may have been so approved had such applications been made prior to that enactment.

[82] I am not, however, persuaded that I can accede to the application for a mandatory injunction directing all necessary regulatory approvals, permits and/or exemptions required to secure access to the diacetylmorphine be granted. Such an order would, in my opinion, provide to the plaintiffs the very remedy they seek in this action.

[83] Further, the mandatory injunction sought would undercut the procedural safeguards in place regarding the importation and distribution of diacetylmorphine prior to the introduction of the impugned provisions. Those safeguards were described by Jacinthe David, the Acting Manager, Licences and Permits Division, Office of Controlled Substances, Controlled Substances and Tobacco Directorate in the Healthy Environments and Consumer Safety Branch of Health Canada, in her affidavit sworn January 23, 2014. At paras. 15 and 17–20 of that affidavit, Ms. David deposed that:

> 15. Under the Restricted Drug Regulations, restricted drugs may be imported into Canada only by a licensed dealer who is licensed to conduct activities with that particular restricted drug.
>
> …
>
> 17. A licensed dealer must obtain an import permit under the Restricted Drug Regulations every time that they want to import a restricted drug. The dealer may import a restricted drug only pursuant to the terms and conditions of the import permit.
>
> 18. To obtain an import permit, a licensed dealer must submit an import permit application to the Office of Controlled Substances. In the import permit application, the licensed dealer must specify:
>
> a) the quantity/item/strength of the restricted drug to be imported;
>
> b) the total restricted drug content of the items imported, for example, the weight of the imported item that is a restricted drug;
>
> c) the purpose for which it is required;
>
> d) the name of the exporter;
>
> e) the mode of transportation; and
>
> f) the customs point of import.

> 19. Health Canada may also request additional information with respect to the restricted drug to confirm that it will be sold only to parties authorized to possess that restricted drug under the CDSA and the Restricted Drug Regulations. Additional information may also be requested to assist Canada in meeting its international reporting obligations to the [International Narcotics Control Board (the "INCB")].
>
> 20. The importation of heroin into Canada is monitored by the INCB. Canada must provide an estimate to the INCB each year of how much heroin it will require for medical and scientific research purposes that year. Canada cannot authorize the importation of heroin over the estimated amount unless it makes a request for an increase to the INCB and the INCB approves the request. This process may take weeks or months and approval is not guaranteed. Canada's estimate for 2013 was 16.5kg and the estimate for 2014 is 17.3kg. These estimated amounts were increased in 2013 based on the need for heroin for the purposes of the SALOME clinical trial. Canada must also provide Quarterly Statistics of Imports and Exports of Narcotic Drugs reports to the INCB, including the exact quantity of heroin that has been imported.

[84] At para. 30, Ms. David deposed that:

> 30. The Office of Controlled Substances has not received any applications to date for import permits from ALMAT [the only non-governmental licensed dealer] or any other licensed dealer for the purpose of providing heroin to medical practitioners who have received SAP authorizations for heroin. Furthermore, pursuant to the Restricted Drug Regulations, a licensed dealer can provide heroin only to persons who are authorized to possess it. If those persons are not otherwise authorized to conduct activities with heroin under Part J *(Restricted Drug Regulations),* they would require an exemption under section 56 of the *CDSA*.

[85] Scott Harrison, the Director Urban Health & HIV/AIDS of Providence Health Care swore in part at paras. 3, 8, 9, 13, 15 and 16 of his affidavit dated January 30, 2014 that:

> 3. In summary, the reason that Health Canada has not received any applications for an importation permit is because Almat, the only non-governmental licensed dealer, after several discussions with Health Canada have resolved not to become involved until this legal case is settled.
>
> …
>
> 8. On November 20, 2013 I received an email from Mr. Boutaleb stating that Almat was waiting on a Health Canada response and would advise of any development as soon as possible. …
>
> 9. Mr. Boutaleb contacted me again, two hours later, on November 20, 2013, asking if Providence Health Care had the capacity to hold a full case of 90 x l0gm vials of DAM. …

> …
>
> 13. On November 29, 2013, Mr. Janmohammed and I called Mr. Boutaleb to discuss the purchase order further and find out if there was any progress. Mr. Boutaleb indicated that Almat was waiting for a response from Health Canada, that the delay was usual due to the reconciliation process that occurs at the end of the year and that by the second week of January, we would likely have some more clarity.
>
> …
>
> 15. On January 21, 2014, Mr. Janmohammed and I called Mr. Boutaleb and left a voicemail message.
>
> 16. On January 22, 2014, Mr. Janmohammed called Mr. Boutaleb and Mr. Boutaleb stated that Almat had had several discussions with the Office of Controlled Substances Canada with respect to the importation and permits for DAM related to the SAP approvals. I joined this teleconference and Mr. Boutaleb stated that "at this time, Almat are not able to assist you with this order." I asked for this to be emailed to me so I had it in writing. I did not receive the email I requested.

[86] While I am prepared to grant the interlocutory injunction sought by the plaintiffs on the ground that it amounts to a restoration of the *status quo ante*, I am not prepared to order that diacetylmorphine be delivered to individuals addicted to heroin for the purpose of treatment. This would put them in a position of advantage above where they would have stood had the impugned provisions never been introduced. Further, such an order would involve both interfering with the approval process of several expert regulatory bodies and potentially adversely affecting the allocation and distribution of the amounts of heroin that have been approved for importation by the International Narcotics Control Board. It would also likely involve provisions directly affecting individuals and entities, such as AMLAT, which are not parties to this litigation. As such, I refuse the mandatory injunction sought.

[87] As I have seized myself of the litigation between the parties, it would be redundant to provide a direction that I maintain jurisdiction to supervise all issues arising in respect of plaintiff requests and future SALOME requests.

Conclusion

[88] I grant an interlocutory injunction exempting all outstanding plaintiff requests and future SALOME requests for access to diacetylmorphine and its salts from the

application of ss. J.01.001 and C.08.010 of the *FDR*, insofar as they are for patients who are refractory to other treatments and whose physicians have made or make a SAP application.

[89] I dismiss the application for a mandatory injunction directing the Attorney General of Canada and any agents, agencies, departments, directors, officers, offices and/or Ministers of the Federal Crown to provide all necessary regulatory approvals, permits and/or exemptions required to secure access to the diacetylmorphine granted under any plaintiff requests and/or future SALOME requests on an expedited basis.

[90] I decline to make a direction that the Court maintain jurisdiction to supervise all issues arising in respect of plaintiff requests and future SALOME requests, on the basis that such a direction is unnecessary.

_____

The Honourable Chief Justice Hinkson