Serial No. 47/2014

CERTIFICATION OF DECLARATION

I the undersigned Pinhas Sivan, Notary at 11 Kiryat HaMadaa Street Jerusalem Israel hereby certify that on October 20th 2014 there appeared before me at my office Mr. Richard Daniel Bardenstein bearer of Israeli ID No. 304789332 And being satisfied that he knows the English language (the language of the declaration) and read in my presence the Declaration. And after I enquired and satisfied myself that the aboved named Mr. Richard Daniel Bardenstein understood the contents of the above-mentioned declaration, he duly confirmed by oath (declared) (declared by solemn affirmation) the truth of the above declaration.

This Certification is not a Certification to the Correctness of the Translation by the Notary, according to paragraph 7 (4) of the Notary Law, 5736 – 1976.

In witness whereof I have hereto set my signature and seal today. October 20th 2014.

Fees paid: 274 NIS including VAT.

חתימת

מספר סידורי 47/2014

אישור הצהרה

אני הח"מ פינחס סיון, נוטריון ברחוב קרית המדע 11 ירושלים מאשר כי ביום כ"ו תשרי תשע"ה- 20.10.2014 ניצב לפני במשרדי מר ריצ'רד דניאל ברנשטיין נושא ת.ז. מס' 304789332, ולאחר שנוכחתי שהוא יודע את השפה האנגלית (שפת ההצהרה) וקרא בנוכחותי את ההצהרה, ולאחר שבררתי ונוכחתי כי מר ריצ'רד דניאל ברנשטיין הנ"ל הבין את תוכן ההצהרה הנ"ל, נשבע כחוק (הצהיר בהן צדק) על אמיתות ההצהרה הנ"ל.

אישור זה אינו מהווה אישור נכונותו של התרגום על ידי הנוטריון על פי סעיף 7 (4) לחוק הנוטריונים, התשל"ו – 1976.

ולראיה באתי על החתום בחתימת ידי ובחותמי, היום כ"ו תשרי תשע"ה- 20.10.2014.

שכרי בסך 274 ש"ח כולל מע"מ שולם.

חותם הנוטריון

Notary's Seal

Court File No. T-2030-13

FEDERAL COURT

BETWEEN:

NEIL ALLARD
TANYA BEEMISH
DAVID HEBERT
SHAWN DAVEY

PLAINTIFFS

AND:

HER MAJESTY THE QUEEN IN RIGHT OF CANADA

DEFENDANT

AFFIDAVIT OF RICHARD BARDENSTEIN

I, Richard Bardenstein, Adv., of the city of Jerusalem in the State of Israel, MAKE OATH AND SAY:

1. I am a licensed attorney in Israel, and, as such, have knowledge of the matters contained in this affidavit. Unless I indicate to the contrary, these facts are within my personal knowledge and are true. Where I indicate that I have obtained the information from other sources, I verily believe those facts to be true.

2. **Issues Addressed in this Affidavit**

This affidavit addresses the following issues:

"The law, legal norms, regulations, guidelines and principles in Israel with respect to the sourcing, collection, storage, distribution and use of medical marijuana and, in particular, the following issues:

1. The process by which individuals become authorized to consume medical marijuana;
2. The amount of medical marijuana an individual user is permitted to possess and/or consume and how those amounts are determined;
3. How individual dosages are determined;
4. Restrictions, if any, on the forms of medical marijuana that may be consumed;
5. Restrictions, if any, on the medical conditions for which the consumption of medical marijuana may be authorized;
6. Whether the production of medical marijuana in residences is permitted and, if not, how medical marijuana is supplied to users;
7. Who is permitted to grow, produce or import medical marijuana or related products, to maintain inventories of medical marijuana, and to distribute medical marijuana to licensed users."

On June 10, 2014, BJ Wray, counsel for the Attorney General of Canada, provided me with an instruction letter for my expert report. Attached as **Exhibit "A"** is a copy of the instruction letter.

Background and Qualifications of Expert

3. The undersigned is a practicing attorney in Israel since 1991, JD Yale Law School 1988, formerly an advisor to several Ministers of Justice in Israel between 1995-1998, and an

advisor to Israeli Prime Minister Ehud Barak (1999-2001). A copy of my *curriculum vitae* is attached as **Exhibit "B"**.

4. In the course of the undersigned's private legal practice, I have handled and continue to handle commercial matters relating to the legal and regulatory regime governing the licensing of medical marijuana in Israel, including growing, import and export of the same. As such, the undersigned has become familiar with the law and practice relating to these matters, as well as the Israeli administrative framework that has executive and policy-forming responsibility in the field.

5. On June 10, 2014, BJ Wray, counsel for the Attorney General of Canada, provided me with a copy of the Code of Conduct for Expert Witnesses. Attached as **Exhibit "C"** is a signed copy of the Certificate Concerning Code of Conduct for Expert Witnesses.

The Legislative Framework for Medical Marijuana in Israel

6. As the Israeli Government stated in Government Decision no. 1050 of December 15, 2013 ("Government Decision 1050"), "in any arrangement having to do with the use of cannabis for medical purposes, the State is obligated to strict compliance with the provisions of the **Dangerous Drugs Ordinance [New Version], 5733-1973** ("the **Ordinance**", "Dangerous **Drugs Ordinance**")[i] and regulations thereunder, and the provisions of the **Single Convention on Narcotic Drugs, 1961**, including the amendments thereto from 1972."

The Dangerous Drugs Ordinance and Regulations

7. Under the Dangerous Drugs Ordinance, cannabis is included in the List of Dangerous Drugs (the full list comprises the First Schedule to the Ordinance). As a "Dangerous Drug", all growing, manufacture, production, preparation, or extraction" of cannabis is prohibited, except by permit from the "Director". [The "Director" is defined as the Director General of the Ministry of Health or the person(s) authorized by him, of which there are currently thirty-six, and these have a broad range of powers regarding the licensing of medical cannabis growth, production, distribution, possession and consumption (section 6 of the Ordinance)]. Furthermore, possession or use of cannabis is prohibited "except to the extent it is permitted by this Ordinance or regulations thereunder, or by license from the Director." (DDO Section 7(A)).

8. Because cannabis is listed in Part A of the First Schedule of the Ordinance, it is not a drug for which a doctor may write a prescription. Rather, all use is conditioned on receiving a permit through the procedure outlined below. Cannabis oil is specifically excepted from this part of the First Schedule – i.e., a doctor may write a prescription for it, but this assumes that the oil has been properly produced, distributed or imported by valid permit. *[Note: As of the submission of this affidavit, a Ministerial committee is considering amending this rule so that, for an unspecified time period, to address the rise in volume of licensed users, doctors may write prescriptions for medical cannabis for an approved list of illnesses, provided the patient has already properly received a license to use cannabis – R.B.]*

9. In addition, cannabis in its vegetable form (whether as buds or as oil extracts) has not been registered as a medication in Israel, as it has not in Western countries as a rule.

10. **Constitutional aspect – the freedom of vocation.** As a consequence of the classification of Cannabis and its products as a Dangerous Drug in Israel, the general constitutional right of individuals to engage in a vocation of their choice is largely inapplicable regarding the growing, processing sale or distribution of medical marijuana. That is, the freedom of vocation does not include the right to engage in criminal behavior. Thus, the right to choose a vocation, protected in Israel under Basic Law: Human Dignity and Liberty, 5752-1992, applies only within the circumscribed set of cases in which the person is operating under a valid license from the Director.

The Dangerous Drugs Regulations, 5739-1979

11. The Dangerous Drugs Regulations, 5739-1979 ("the Dangerous Drug Regulations", "DDR"), were enacted by the Minister of Health pursuant to his powers under the Dangerous Drugs Ordinance. They have been amended several times since their original enactment. These Regulations create arrangements covering the broad scope of actions relating to Cannabis among other dangerous drugs, including, among others, detailed procedures for licensing all phases of the growing, production, storage, supply, possession and use cycle, defining who can dispense the drug, procedures regarding prescriptions, packaging and labeling of approved medications, certain limitations on prescription quantities, maintenance of a required register of all medications handled by

growers, doctors and pharmacists, import and export licensing, transit of dangerous drugs through Israel, and more.

Specific regulations governing the licensing process for growing, storing, dispensing, possessing and using cannabis will be discussed in topical sequence below.

The Single Convention on Narcotic Drugs, 1961

12. Israel became a signatory to the Single Convention on 23 November 1962, thus becoming obligated to comply with the treaty's provisions, including the provisions relating to Cannabis, which is subject to both specific supervisory arrangements as well as the general powers applicable to all narcotics covered by the Convention.

13. Pursuant to Articles 23 and 28 of the Convention, Israel's Health Ministry serves as the government Agency that carries out the various functions in Article 23 regarding cannabis and cannabis oil (designating areas for cultivation, licensing growers and their growing areas, organizing the receipt of the cannabis crop from growers, and the exclusive authority regarding import, export, sale and possession of cannabis inventories.[ii] The Health Ministry's Medical Cannabis Agency, created by decision of the Government, handles all matters related to medical cannabis, with the involvement of other governmental authorities (the Agriculture Ministry, the Israel Police, and others) on an interministerial guidance committee and as required by the matter in question.[iii]

14. As will be set out in detail below, the legal and administrative arrangements in Israel regarding the supervision over all phases of medical cannabis sourcing, production, distribution and use are of a strictness and thoroughness characteristic of a narcotic drug. At the same time, the Government and regulatory authorities have made significant strides over the past several years in enabling medical use of cannabis by patients for whom it may bring significant relief, consistent with the strict oversight mentioned above.

Government Decision 1050 – Separating growers from users, centralizing operational responsibility, implementing treaty obligations

15. In December 2013, the Government of Israel approved, by Cabinet decision, changes in the regulatory regime governing medical marijuana. Among other things, the new arrangements included the creation of a thoroughgoing administrative structure supervising all phases of dealings regarding medical marijuana under the umbrella of the Ministry of Health and its authorized representatives or service providers. Another main goal of these reforms was to cut direct links between growers of medical marijuana from the licensed consumers, a separation that had not been maintained previously. This 2013 Government decision formalized the policy that had been followed for several years of not issuing any new residential growing licenses, and reducing to the extent possible the number of existing residential growing licenses, which is currently estimated at less than five.

Before reviewing the different facets of this recent, substantial regulatory reform – which is currently being challenged in Israel's Supreme Court – it will be useful to describe the previous regulatory arrangements, to clarify the context and nature of the reform.

Historical Background – Earlier Regulatory Schemes

16. Between 1993, when the first request for a license to use medical cannabis was submitted to the Israeli Health Ministry, and the end of 2005, when the total annual number of such requests was still less than one hundred ***[check precise number of requests]***, the Health Ministry adopted a more or less ad hoc approach to issuing licenses for medical cannabis. Initial attempts during this period to develop uniform criteria for licensing medical cannabis use, and government policy for sourcing the supply of medical cannabis to licensed users, did not bear fruit at this stage (among the sourcing options that were considered at the time, but not adopted: growing by a government entity, supply from police seizures of cannabis, licensing a kibbutz (cooperative settlement) or private business to grow the cannabis). As a practical matter, lacking a general policy regarding sourcing of cannabis, the Health Ministry's approval of a license for use of medical cannabis would be accompanied by permission to grow cannabis sufficient for the needs of that licensed user.

17. Between 2006-2011, while the number of licensed users in Israel grew from around 120 to roughly 9,300, the regulatory framework remained largely unchanged, although to accommodate the increased demand the Health Ministry licensed more private entities

to grow medical cannabis (at that point seven licenses were issued), and enabled distribution to licensed users through three accredited hospitals as well as through direct delivery.

18. **Government Decision 3609 (the "First Government Decision").** In 2011, the Israeli Government, building on the 2010 recommendations of a Public Committee, passed Government Decision 3609 regarding "Supervising and Arranging a Source of Supply of Cannabis for Medical and Research Purposes". Among other things, the Government formally charged the Ministry of Health (in consultation with the Internal Security and Agriculture Ministries) with responsibility for arranging a suitable regime for sourcing supervised supply of cannabis for medical purposes and research; and formally gave the Health Ministry the role as the "Government Agency" as defined in the Convention. A new interministerial Steering Committee was formed to formulate new arrangements for the growth, production and supply cycle in a manner consistent with Israel's obligations under the Convention, including preparation of public tenders as appropriate.

The First Government Decision also declared that Israel's policy preference moving forward would be to import the needed supply of medical cannabis, rather than relying on locally grown product. However, at the time no adequate foreign source was identified – which remains the case as of the submission of this affidavit – the First Government Decision stated that local growers' licenses would be expended for up to

two years, during which period the Interministerial Steering Committee was to address the challenge of securing a sufficient ongoing imported supply of cannabis.

One other section worth noting in the First Government Decision is the Government's decision to enable the Health Ministry to engage a single, private provider of logistical services – a company called Sar'el, which has long served as the purchaser and supplier of pharmaceutical drugs to Israeli hospitals – to act as its logistical arm regarding several facets of the cannabis production, collection, and distribution cycle, without a public tender.

Government Decision 1050 (the "Second Government Decision")

19. Several years of preparatory work by the interministerial Committee and other bodies culminated in the Government's approval of Decision 1050 on 15 December 2013, which altered several aspects of Israel's regulatory framework regarding medical cannabis, while preserving other aspects. The main components of this decision include the following:

    a. The Ministry of Health will continue to serve as the "Government Agency" pursuant to the Single Convention.

    b. The Government reconfirmed the preference for importing medical cannabis over sourcing it from local growers, as the best way to ensure a reliable supply for patients while protecting public security and preventing the use for non-medical purposes. However, as such a reliable imported source had not yet been identified

(and still has not as of the submission of this affidavit, to the best of my knowledge), the Health Ministry (together with the War on Drugs and Alcohol Authority) was charged with identifying and securing such an imported source of cannabis, while continuing to ensure the controlled supply of cannabis to licensed users. The practical effect of this policy is that the existing licensed growers have had their licenses extended periodically for six months or a year, and they have continued to be the source for medical cannabis to Israel's growing base of licensed users.

20. Principles of the new regulatory model under the Second Government Decision

Decision 1050 outlined the principles and main features of the new regulatory model for medical cannabis, which are as follows:

a. Cannabis is defined by Israeli law as a "Dangerous Drug", but the Health Ministry acknowledges that cannabis has medical uses that can ease the suffering of patients, even though cannabis is not a registered medication or preparation in Israel or anywhere else in the world.

b. In any arrangement relating to the use of cannabis for medical purposes, the State is bound to strict compliance with the provisions of the Dangerous Drugs Ordinance, the regulations thereunder and the Single Convention on Narcotic Drugs, 1961, as amended in 1972.

c. The Ministry of Health acts as the "Government Agency" pursuant to the Convention, as aforesaid. Within the Health Ministry, the Medical Cannabis Unit coordinates the handling of medical cannabis-related matters.

d. The Health Ministry believes that cannabis should be treated, to the extent possible, in the same manner as any other medical product, which requires supervision and regulatory arrangements to protect public health and welfare, taking into account the fact that cannabis is a plant, rather than a synthetic substance manufactured in a laboratory or factory.

e. Given the classification of cannabis as a Dangerous Drug, any arrangement regarding the medical use of cannabis in Israel must be as close as possible to arrangements relating to use of narcotic drugs.

f. Similarly, the duty of the Ministry of Health regarding supply of cannabis to patients is no different – no more and no less – than its duty regarding any other medical substance that is not deemed critical in emergencies or included in the official basket of approved medications that are subsidized by the State.

g. At the same time, the Ministry of Health seeks to remove obstacles to the supply of cannabis to patients who can benefit medically from it and are interested in purchasing it at their own expense.

h. The State is bound to protect public order and safety and public health, and is charged with preventing abuse or criminal activity related to dangerous drugs, including cannabis.

i. The State thus bears the overarching duty to supervise the cannabis market, through various governmental bodies (in the fields of health, police, customs, and agriculture), to issue licenses when necessary and to take all actions necessary to protect public order and health or to prevent abuse or criminal activity related to cannabis.

The Regulatory Model under The Second Government Decision

21. The operational provisions in the Second Government Decision continue and/or update several parts of the regulatory regime as it had developed until then, and introduce several reforms moving forward. The main operational features relevant for purposes of this affidavit are presented in the following paragraphs below.

22. **Medical criteria:** The Government recognized that in the case of cannabis, it is much harder to find private entities that will undertake the lengthy and expensive burden of proving its medical efficacy and safety, in part due to the inability to register a patent on a plant substance as a medication; and therefore the Government determined that the State will establish medical criteria for cannabis and cannabis products, so long as the use of cannabis for medical purposes is licensed and so long as cannabis is not registered in Israel as a medication or medical preparation.

Medical standards have been established for maximal and minimal concentrations of the main active components in the plant (THC, CBD and CBN), and the combinations between them. As of 2014, these permitted concentrations are as follows (in each table, the permissible variation of concentration is in parentheses):

Medical Cannabis Buds

Product	THC	CBD	CBN
"Cannabis Lite" Day Source/character of Sativa species	10% (6%-14%)	2% (0.2% - 3.8%)	0% (up to 1.5%)
"Cannabis Lite" Night Source/character of Indica species	10% (6% - 14%)	2% (0.2% - 3.8%)	0% (up to 1.5%)
"Cannabis" Day Source/character of Sativa species	15% (11% - 19%)	3% (0.5% - 5.5%)	0% (up to 1.5%)
"Cannabis" Night Source/character of Indica species	15% (11% - 19%)	3% (0.5% - 5.5%)	0% (up to 1.5%)
"Cannabis Forte" Day Source/character of Sativa species	20% (16% - 24%)	4% (1% - 7%)	0% (up to 1.5%)
"Cannabis Forte" Night Source/character of Indica species	20% (16% - 24%)	4% (1% - 7%)	0% (up to 1.5%)
"Cannabis CBD"	5% (2.5% - 7.5%)	9% (5% - 13%)	0% (up to 1.5 %)
"Cannabis CBD Forte"	3% (0.5% - 5.5%)	14% (10% - 18%)	0% (up to 1.5%)

Comments:

"Day": The intention is to products that characteristically provide an energetic feeling, stimulate appetite, etc. (originally based on Sativa species, but this is not obligatory, due to genetic interbreeding and improvement).

"Night": The intention is to products that characteristically provide a calming feeling, relaxation of muscle tone, promote sleep and so on (originally based on Indica species, but this is not obligatory, again, due to genetic interbreeding and improvement).

Medical Cannabis Oil

Product	THC	CBD	CBN
"Cannabis Oil Lite"	10% (6%-14%)	2% (0.2% - 3.8%)	0% (up to 1.5%)
"Cannabis Oil"	15% (11% - 15%)	3% (0.5% - 5.5%)	0% (up to 1.5%)
"Cannabis Oil Forte"	20% (16% - 24%)	4% (1% - 7%)	0% (up to 1.5%)
"Cannabis Oil CBD"	5% (2.5% - 7.5%)	9% (5% - 13%)	0% (up to 1.5 %)
"Cannabis CBD Oil Forte"	3% (0.5% - 5.5%)	14% (10% - 18%)	0% (up to 1.5%)

Medical Cannabis Cookies

(according to conditions in Health Ministry Dir. General's decision, see section __ below)

Product	THC	CBD	CBN
"Cannabis Lite Cookies"	10% (6%-14%)	2% (0.2% - 3.8%)	0% (up to 1.5%)
"Cannabis Cookies"	15% (11% - 15%)	3% (0.5% - 5.5%)	0% (up to 1.5%)
"Cannabis Forte Cookies"	20% (16% - 24%)	4% (1% - 7%)	0% (up to 1.5%)
"Cannabis CBD Cookies"	5% (2.5% - 7.5%)	9% (5% - 13%)	0% (up to 1.5 %)
"Cannabis CBD Forte Cookies"	3% (0.5% - 5.5%)	14% (10% - 18%)	0% (up to 1.5%)

23. Permitted forms of cannabis. Currently use of medical cannabis is allowed in Israel by the following means:

- cannabis buds intended for consumption by smoking, vaporization or swallowing;
- cannabis oil (extract)
- cookies (only for children who have permit to use cannabis, with recommendation of attending physician – *see* Decision of Director-

General of Ministry of Health, Prof. Ronnie Gamzo, 7 November 2013, www.health.gov.il/PublicationsFiles/Cannabis-cookies.pdf)

The Second Government Decision notes these permitted forms of use.

24. **Indications.** The Director-General of the Health Ministry has the authority to approve indications for medical cannabis, upon the advice and recommendation of the Medical Cannabis Indications Committee. As of the submission of this affidavit, the following indications are approved:

A. **Oncology:** (i) For patients undergoing chemotherapy, and six months following the end of chemotherapy, for relief of nausea, vomiting, or pain associated with treatment (without need of first exhausting other accepted treatments for relief of nausea, etc.); (ii) for relief of pain caused by metastasized cancer, after exhausting accepted treatment options.

B. **Gastroenterology:** For patients suffering from active, proven inflammatory intestinal disease (Crohn's disease or ulcerative colitis) and who meet both of the following conditions: (i) accepted pharmaceutical treatment of at least one immunomodulator (e.g., Imuran or Purinethol) has been exhausted without success for at least three months, as well as at least one TNF blocker (e.g., Humira or Remicade) at full saturation dosage (three treatments); and (ii) rejection of the option of surgical removal a short section of the diseased intestine.

C. **Pain:** For patients suffering from neuropathic pain from a clear organic source, who have been treated in a recognized plain clinic for at least one year prior to filing the

application for use permit, upon recommendation of the pain clinic after exhausting accepted treatment options.

D. **Infectious Diseases:** For patients diagnosed with AIDS, following exhaustion of accepted pharmaceutical treatment, who suffer from Cahexia (loss of at least 10% of body weight), to improve appetite, relieve vomiting digestive system symptoms.

E. **Neurology:** (i) For patients diagnosed with multiple sclerosis in spastic conditions which have not responded to accepted treatment; (ii) for patients diagnosed with Parkinson's Disease, who have been treated for at least one year with anti-Parkinson's treatment, who suffer from pain (whether chronic or resulting from rigidity) and who have not responded to accepted pain treatment. (Contraindication – active psychosis); (iii) For adult patients diagnosed with Tourette's Syndrome, who have significant problems in everyday functioning, which have not responded to accepted treatments. (Contraindications: active psychosis or genetic predisposition (immediate family) to psychotic diseases). Licenses for Tourette's syndrome are given for three month periods, and each renewal must be supported by an examination and recommendation by the patient's treating neurologist and his/her psychiatrist.

F. **Palliative care:** For patients deemed to have terminal conditions (six months' life expectancy or less).

G. **Psychiatry:** For patients diagnosed with PTSD who meet all of the following criteria: (i) medium severity or greater, with at least 30% disability for more than three years, with severe emotional distress; (ii) at least two accepted drug interventions for at

least two months each have been done, as well as two accepted psychological interventions; (iii) Absolute contraindication – a history of psychosis or drug abuse. During the first year of treatment with cannabis, the permit will be limited to six months each time, and during the second year, to one year for each permit period, and renewal is conditioned on the treating psychiatrist's report of the results of treatment and recommendation to continue.

H. **Exceptional Cases**: The permit procedure allows for the possibility of ad hoc permits for indications that have not yet been approved by the Health Ministry, at the discretion of one of the Directors, based among other things on detailed and accepted medical research and the recommendation of the Indications Committee, if desired. (*See* Procedure 106, Ministry of Health Pharmaceutical Division, "Licenses for Use of Cannabis", of March 2013, updated July 2014, p. 2-6.)

25. **Import and Local Growing of Cannabis.** The Second Government Decision reiterated the preference for an imported supply of medical cannabis over locally grown product, but acknowledged, yet again, that as of the date of the Decision (December 2013) no adequate foreign source had been identified. As a result the Government decided to continue sourcing medical cannabis locally for the time being, while ensuring strict compliance with the supervisory duties under the Convention and improving the 'processes' in the growing, production, collection, storage, and distribution cycle. It ordered the Health Ministry to proceed with a public tender for a closed list of growers, who would receive the license for up to five years. Under the terms of the Government

Decision, these growers need not have previous experience in growing cannabis. At the same time, the Government left open the possibility that it may import cannabis oil from abroad, and explicitly provided that a foreign producer of cannabis oil could compete in the tender for cannabis products.

One of the main consequences of this tender is that current growing licenses of all individuals and entities will be discontinued if they are not selected in the tender. This outcome is consistent with policy followed over several years, of not issuing new growing licenses, including residential growing licenses, and of narrowing the number of residential growing licenses to the extent possible,[iv] In the interim, until completion of the tender process, no new growing licenses will be issued to patients, and existing growing licenses will be extended for periods of up to one year. Individual persons were granted licenses more in previous years, before the number of user applications grew and the Health Ministry began developing more systemic answers to the patients' needs and the State's legal obligations. The total number of residential growing licenses never exceeded roughly 200, and currently is estimated at less than five. As such, while currently there are still individuals who are licensed to grow their supply of medical cannabis in residences, the Government's policy moving forward involves transferring local growing to a small number of licensed growers by tender, and eventually, to source most of the cannabis from abroad.

As discussed below, this tender, along with the other parts of the Second Government Decision is being challenged in a pending petition in the Israeli Supreme Court.

26. **Additional Responsibilities of Growers.** Entrenching established practice, the Government Decision clarified that licensed growers, both during the interim period until completion of the tender process and post-tender) will be responsible for separating the cannabis buds from the plant, drying the buds to the desired level of moistness, performing lab tests to verify compliance with medical criteria such as concentrations, and shall package and label the buds in wholesale packages.

27. **Collection, purchase, transport, storage.** Under the Second Government Decision, all phases of the supply and distribution cycle, from collecting the bulk-packaged cannabis buds and other parts of the cannabis plants, transport to a central logistics facility, processing and packaging the cannabis for distribution to the user, production of approved cannabis-based products, and distribution to users, shall be done under the supervision of the central Government Agency, with the assistance of the Sarel company mentioned above. In several of these areas, the actual service providers will be selected by public tender; in others, such as the production of cannabis-based products, Sarel itself may provide the services on behalf of the State, in which case there will not be a tender process. As of the submission of this affidavit, the number and scope of the tenders in these areas, and the division of labor between licensees and the Government Agency or its long arm (presumably Sarel) is being worked out at the ministerial level. The Second Government Decision states specifically, however, that in the event of a tender process for producers of cannabis products in Israel, growers of cannabis may also participate; and that during the interim period until such tender, a producer of cannabis-related products who is not also a

licensed cannabis grower (or uses raw cannabis grown by others), may produce such products only if the cooperation between the grower and producer is approved by the Health Ministry, and the cannabis plant materials are transferred by the Government Agency from the grower to the producer.

28. **Distribution to end user through pharmacies.** Currently medical cannabis and cannabis products are distributed to end users through a closed list of hospitals and a distribution center, as discussed above, in accordance with the provisions of the specific licenses involved. Under the Second Government Decision, the distribution to the licensed user is to be done solely through pharmacies, following a public tender process.

29. **Quantities of Cannabis Allowed for Use.** The doctor recommending use of cannabis for a patient has discretion to prescribe the amount of cannabis, up to 100 grams per month. Quantities for most patients average roughly 30g/month. Requests for dosages exceeding 100g/month may be submitted to the Health Ministry if the recommending doctor is an accredited specialist in the medical area from which the indication for prescribing cannabis arises at a "public medical institution" where the patient is being treated, with the approval of the hospital director or top medical director at the institution involved. (*See* Procedure 106, p. 6-7).

Petitions against the Second Government Decision and Current Status

30. The Second Government Decision has been challenged by a group of Israeli cannabis growers and users in a petition to the Israeli Supreme Court (H.C.J. 854/14, *Focus*

Medicinal Plants Ltd. et al. v. *State of Israel et al.*). The petition requests that the Court, sitting as High Court of Justice in a chancery-type proceeding, declare the entire Government Decision invalid. Many of the petitioners' arguments come from the realm of administrative law (e.g., lack of proper factual foundation for the decision, lack of consideration of existing stakeholders' rights and interests, breach of official promise, the Decision being *ultra vires* relative to the Dangerous Drugs Ordinance, transferring much of the activity and authority regarding medical cannabis to a non-governmental entity without a tender process, and without due justification). In addition, the petitioners raise one central constitutional claim, relating to the "freedom of vocation" and right to property of the existing licensed growers.

The petitioners do argue that the new regulatory regime will end up burdening and raising the cost of medical cannabis significantly for end users, but this claim is made in the context of an administrative law argument regarding the fundamental unreasonableness of the Decision and the process by which it was adopted, rather than an argument from the individual's constitutional rights.

Oral argument was heard before a three-judge panel of the Court on 1 October 2014. While the Court did not rule on the merits, and will not do so at least until after further clarifications from the State regarding the content and division of labor in the planned public tenders, and the issues to be reevaluated in December 2015 according to the Second Government Decision, the Court explicitly did not restrict the State from proceeding in planning and announcing the public tenders, nor did it issue any order *nisi*

or other interlocutory relief regarding the Decision, without prejudicing the Petitioners' rights to seek other administrative relief against specific tenders.

Until and to the extent of resolution of the High Court petition, the regulatory regime in Israel will be a composite of the arrangements in place on the eve of the Second Government Decision, and the policy changes introduced, but not yet implemented, in that Decision.

SWORN before me at the City of Jerusalem
Israel, this 20th day of October, 2014.

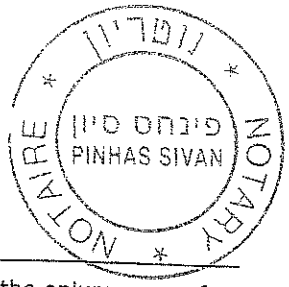
Richard Bardenstein

Notary Public for taking Affidavits in and for Israel

[i] Israeli legislation notes the year in which the legislation was enacted according to both the Hebrew Calendar (the number beginning with 57__) and then the Gregorian calendar year.

[ii] "Article 23 - *National Opium Agencies*

"1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.



"2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:

a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.

b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.

c) Each licence shall specify the extent of the land on which the cultivation is permitted.

d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.

e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

"3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

"Article 28 - ***CONTROL OF CANNABIS***

"1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.

"2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

"3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant."

(Single Convention on Narcotic Drugs, 1961)

[iii] Government (Cabinet) Decision no. 3609, **7 August 2011.**

[iv] *See*, e.g., the recommendations of the Interministerial Committee regarding use of Medical Cannabis in Israel of 27 October 2010, as published in a public announcement of 3 November 2010: "During the current interim period the situation will be "frozen" and no growing licenses, including [residential] licenses, will be approved beyond those currently existing (beyond increase in growing allotments according to need). In a gradual process a reduction, to the extent possible of currently existing residential growing licenses will be carried out."

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June 10, 2014

By Email to: richardb@netvision.net.il

Richard Bardenstein
12 Hartom St.
POB 45090
Jerusalem 91451

Dear Mr. Bardenstein:

Re: ***Allard et al. v. Her Majesty the Queen in Right of Canada***
Instruction Letter for Expert Report

Thank you for agreeing to provide the Attorney General of Canada ("AGC") with an expert report in the matter of *Allard et al. v. Her Majesty the Queen in Right of Canada*. As discussed, this Federal Court litigation involves a constitutional challenge to the *Marihuana for Medical Purposes Regulations* (the "MMPR").

Background Information

The plaintiffs in this litigation, all of whom are medical marijuana users, are challenging the constitutionality of the MMPR on the basis that they cause several unjustified violations of their rights to liberty and security of the person under the Canadian *Charter of Rights and Freedoms*.

The plaintiffs' constitutional challenge in *Allard* focuses on four aspects of the MMPR that differ from the old medical marijuana regime: (1) the elimination of personal cultivation of marijuana in favour of requiring approved individuals to purchase from licensed producers; (2) the restriction that licensed producers may not cultivate marijuana in dwelling places or outdoor areas; (3) the limit on possession of marijuana to either 150g or 30 times the amount prescribed for daily consumption by the individual's medical practitioner, whichever is less; and (4) the failure of the MMPR to permit the production and possession of non-dried marijuana such as cannabis oils, salves, tinctures and edibles.

The plaintiffs have obtained an injunction from the Court that permits them to continue personal production of medical marijuana until the constitutionality of the MMPR is decided by the Court.

The AGC is the defendant and it is the AGC's position that the current medical marijuana regime is constitutionally sound, a position that will be defended by legal counsel on behalf of the AGC.

Facts and Assumptions

The facts alleged by the plaintiffs are outlined in the Amended Notice of Civil Claim which is enclosed.

Questions for Your Expert Report

Please address the following matters in your expert report:

Discuss the law, legal norms, regulations, guidelines and principles in Israel with respect to the sourcing, collection, storage, distribution and use of medical marijuana and, in particular, address the following issues:

a) The process by which individuals become authorized to consume medical marijuana;
b) The amount of medical marijuana an individual user is permitted to possess and/or consume and how those amounts are determined;
c) How individual dosages are determined;
d) Restrictions, if any, on the forms of medical marijuana that may be consumed;
e) Restrictions, if any, on the medical conditions for which the consumption of medical marijuana may be authorized;
f) Whether the production of medical marijuana in residences is permitted and, if not, how medical marijuana is supplied to users;
g) Who is permitted to grow, produce or import medical marijuana or related products, to maintain inventories of medical marijuana, and to distribute medical marijuana to licensed users.

Format of Your Expert Report

Your report must be prepared in accordance with the Federal Courts Rules. As such, we ask that you do the following within the body of your report:

1. Set out the issues to be addressed in the report;
2. Describe your qualifications on the issues to be addressed;
3. Attach your current curriculum vitae as a schedule to the report;
4. Attach this letter of instruction as a schedule to the report;
5. Provide a summary of your opinions on the issues addressed in the report;
6. Set out the reasons for each opinion that is expressed in the report;
7. Attach any publications or other materials specifically relied on in support of the opinions;
8. If applicable, provide a summary of the methodology used in the report;
9. Set out any caveats or qualifications necessary to render the report complete and accurate, including those relating to any insufficiency of data or research and an indication of any matters that fall outside of your field of expertise; and,
10. Particulars of any aspect of your relationship with a party to the proceeding or the subject matter of your report that might affect your duty to the Court.

Please number each paragraph of your report as this will aid us in referring to your report in Court.

Please sign and date your report.

Duty to the Court

As an expert witness, you have a duty to the Court which is set out in the attached Code of Conduct for Expert Witnesses. Please carefully review this Code of Conduct and, after doing so, sign the attached Certificate and send it back to us.

Due Dates and Procedural Matters

We are required to file our expert reports on or before November 1, 2014. The trial has been set for three weeks commencing February 23, 2015. You may be required to attend the trial for cross-examination and, if so, we will attempt to accommodate your schedule to the extent possible.

Please keep all correspondence pertaining to this assignment in a separate "Expert Witness Report" folder.

We look forward to receiving a draft of your report the **first week of September, 2013**.

Please do not hesitate to contact me by telephone at 604-666-4304 if you require further information or have questions regarding the foregoing.

Yours truly,

BJ Wray
Counsel

Enclosures: Certificate for Expert Witnesses; Code of Conduct for Expert Witnesses; Amended Notice of Civil Claim

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richardb@netvision.net.il

EDUCATION

Yale Law School, New Haven, Connecticut, *J.D. 1988*
Editor, Yale Journal of International Law; Editor, Yale Journal of Law & Humanities; Director, Allard Lowenstein International Human Rights Project; Teaching Assistant in Torts

Yale University, Department of Political Science (1986-1988)
Graduate coursework, including in comparative politics and transition to democratic regimes.

University of Michigan, Ann Arbor, Michigan, *B.A. 1980, summa cum laude*
Honors Program in English Literature, sciences minor; Michigan Regents Alumni Scholar; Dean's List, all terms.

PROFESSIONAL EXPERIENCE

Richard Bardenstein & Co., Law Offices – Legal and Consulting Practice (1994-present)
International and domestic practice, devoted to commercial transactions, administrative law, commercial litigation, non-profits, estates and succession planning.

Our consulting practice helps non-Israeli clients build and execute Israel-related business development strategies, drawing on our broad range of relationships in the business, government and third sectors, identifying preferred partners or transactions, handling legal or regulatory issues, helping navigate differences in business culture, negotiating agreements, supervising local vendors, and acting as local representative when appropriate.

Clients include VC funds, investment banks, foreign and Israeli government agencies, tech companies, international consortia in public tenders, utilities and mining conglomerates, international religious institutions, hospitals, international media organizations, charitable foundations, high net worth individuals and NGOs.

Managing Director, Israel, *Access|Middle East* (2003 – 2005)
Successfully started up and directed Israeli operations for this international communications and media services organization that gave professional support to journalists worldwide who cover the Middle East, as well as to governmental entities and NGOs. Management tasks included strategic communications planning and implementation, government relations, fostering partnerships with NGOs, universities and other stakeholders; supervision of content and media production (video, audio, web); relations with consultants and experts in Israel, the Palestinian Authority, the U.S. and Europe; monitoring and analysis; managing journalist relations; and all internal operations.

Advisor to Prime Minister Ehud Barak (1999-2001)
Advisor to Prime Minister Ehud Barak in several areas, including speechwriting, diplomacy, media relations and communications.

PROFESSIONAL EXPERIENCE (cont.)

Advisor to the Minister of Justice (1995-1999)

External counsel to three successive Ministers of Justice regarding public international law matters.

- Formed interministerial steering committee responsible for preparing Israel's reports to UN treaty bodies in connection with five human rights conventions
- Author of State of Israel's first comprehensive report to the U.N. on implementation of the International Covenant of Civil and Political Rights
- Member of Israeli delegation to the U.N. Human Rights Committee in Geneva

Klimist & Sher Law Offices, Jerusalem -- Associate (1991-1994)

Associate in general civil practice firm headed by Gilead Sher, Adv., with emphasis on commercial transactions, intellectual property, administrative law and labor law.

Law Clerk to Adv. Dan Avi-Yitzhak, Jerusalem (1990) – Articled clerkship

Law Clerk to the Hon. Aharon Barak, Supreme Court of Israel (1989-1990) and to the **Hon. Eliahu Matza** (1988-1989) – Articled clerkship at Israel's highest court, including for the President of the Court.

Legal Commentator, CNN and other networks

Live commentary and backgrounding for the network during major international legal stories from Israel, including the John Demjanjuk appeal and the proceedings in its aftermath, commentary on the Yigal Amir trial for the murder of Yitzhak Rabin; commentary for Israeli and foreign media on legal and political affairs.

Account Executive and Staff Writer, *Hill & Knowlton, Inc.*, New York, New York (1982-83)

Conceived and carried out communications programs for foreign governments, Fortune 500 companies, public and private institutions, hi-tech companies and NGOs. Wrote policy papers, speeches, syndicated columns for major national media, television placements, annual reports, articles for trade media, promotional film scripts, PSAs, and others.

PROFESSIONAL ASSOCIATIONS, PUBLICATIONS, AWARDS, PUBLIC SPEAKING

Member, Board of Directors, Michigan-Israel Business Bridge

Member, Board of Directors and Business/Finance Committee, Jerusalem International YMCA

Past Deputy Chair, United States Subcommittee of the Israel Bar Association, Central Committee

Past Deputy Chair, International Relations Committee of the Israel Bar Association, Jerusalem District

Past Member, Supreme Court Subcommittee of the Israel Bar Association, Jerusalem District

Author, Initial and First Periodic Report of the State of Israel on the Implementation of the International Covenant on Civil and Political Rights, submitted in February 1998 to the United Nations Human Rights Committee.

PROFESSIONAL ASSOCIATIONS, PUBLICATIONS, AWARDS, PUBLIC SPEAKING (cont.)

Lecturer, Wexner Heritage Fellows Israel Program; Ministry of Justice training program; lectures to U.S. Federal judges on the Israel Supreme Court; public speaking engagements and published articles on a variety of business, legal and political topics.

United Nations Fellow, U.N. Centre for Human Rights, Geneva

Court File No. T-2030-13

FEDERAL COURT

BETWEEN:

NEIL ALLARD
TANYA BEEMISH
DAVID HEBERT
SHAWN DAVEY

PLAINTIFFS

and

HER MAJESTY THE QUEEN IN RIGHT OF CANADA

DEFENDANT

Certificate Concerning Code of Conduct for Expert Witnesses

I, Richard Bardenstein, having been named as an expert witness by the Defendant, Her Majesty the Queen in Right of Canada, certify that I have read the Code of Conduct for Expert Witnesses set out in the schedule to the *Federal Courts Rules* and agree to be bound by it.

Date: October 20, 2014

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