Court File No.: T-1560-22

FEDERAL COURT

SIMPLIFIED ACTION

B E T W E E N :

THOMAS HARTLE, JANIS HUGHES, JAMES DOSWELL, BRUCE TOBIN, SHANNON McKENNEY, KATHERINE MARYKUCA, JESSE MERKS, and JANE HARRISON

Plaintiffs

and

HER MAJESTY THE QUEEN

Defendant

STATEMENT OF DEFENCE

A. OVERVIEW

1. Except where expressly admitted herein, the Defendant, Her Majesty the Queen ("Canada"), denies the allegations contained in the Statement of Claim ("Claim") and puts the Plaintiffs to the strict proof thereof.

2. Canada admits the allegations of fact contained in paragraphs 17, 26, 28, and 34 of the Claim.

3. Canada denies the allegations of fact contained in paragraph 8, 18, 19, 20, 27, 29-50, 52-68, 73-92, and 176-183 of the Claim.

4. Canada has no knowledge of the allegations of fact contained in the balance of the Claim.

5. With respect to paragraphs 16 and 31 of the Claim, pursuant to *Order in Council 2022-0549*, dated May 26, 2022, as well as the *Food and Drugs Act*, R.S.C. 1985, c. F-27 ("*FDA*"), Canada states, and the fact is, the correct Ministers with responsibility over the matters at issue are the Minister of Mental Health and Addictions, Associate Minister of Health, as well as the Minister of Health (hereinafter collectively referred to as the "Minister").

6. Canada further states, and the fact is, none of the declaratory relief sought under the *Charter* in the Claim is permitted under Rule 292 of the *Federal Courts Rules*.

B. LEGISLATIVE BACKGROUND

1) International Conventions/Obligations

7. Canada is a party to three United Nations ("UN") international drug control conventions: the *Single Convention on Narcotic Drugs, 1961* (as amended by the 1972 Protocol), the *Convention on Psychotropic Substances, 1971*, and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988* (collectively, the "UN Conventions").

8. The UN Conventions establish a system for international drug control by which parties to the UN Conventions, including Canada, agree to give effect to the UN Conventions' terms within their territories and to cooperate with other states in executing the UN Conventions' provisions.

9. The UN Conventions establish controls on the manufacture, import, export, and distribution of specific narcotics, psychotropic substances, and precursors (i.e. chemicals that can be used in the production of controlled substances) listed in Schedules appended to each of the UN Conventions, with the intention of permitting their availability for

legitimate medical and scientific purposes while limiting their abuse and diversion to the illegal market.

10. Of particular relevance to this Claim is the *Convention on Psychotropic Substances, 1971* ("1971 Convention"). Psilocybin and psilocin, the substances at issue in the present matter, are listed as Schedule I drugs under this Convention. Parties to this convention must prohibit the use of Schedule I drugs except for scientific and very limited medical purposes by authorized persons, and are responsible for providing close supervision of these activities.

11. The *Controlled Drugs and Substances Act*, S.C. 1996, c. 19 ("*CDSA*") is the primary means by which Canada fulfills its obligations under the UN Conventions, including the *Convention on Psychotropic Substances, 1971*. The *FDA* as well as the *Cannabis Act,* S.C. 2018, c. 16, also provide additional important control measures for the regulation of substances that are subject to controls under the UN Conventions in Canada.

2) Historical Legal Framework

12. Prior to 1997, the legislative framework for controlled substances was made up of the *Narcotic Control Act* and two different parts of the *Food and Drugs Act*—Parts III (controlled drugs) and IV (restricted drugs). Enacted in 1961, the *Narcotic Control Act*, S.C. 1960-61, c. 35, included provisions allowing the Governor in Council to make regulations in respect of the legal availability and use of narcotics, including for medicinal purposes.

13. The *FDA* was first enacted in 1920. Many of the substances found in Schedule I of the 1971 Convention were later added to Part IV of the *FDA*. Psilocybin, in particular, was added to Part IV, Schedule H of the *FDA* in 1974.

14. The *Narcotic Control Act* was repealed, as were Parts III and IV and Schedule H of the *FDA*, and replaced with the *CDSA*, which consolidated Canada's controlled substances legislation. Since the *CDSA* came into force in 1997, Parts G and J of the *Food and Drug Regulations*, C.R.C., c. 870 ("*FDR*") are deemed to have been made under the *CDSA* and form part of the legislative framework for controlled substances.

15. As a result, psilocybin and psilocin were listed under Schedule III of the *CDSA* and scheduled as "restricted drugs" under Part J of the FDR, which allows the sale of restricted drugs for the purposes of clinical testing or laboratory research. Substances listed in the Schedule to Part J of the *FDR* do not currently have approved medical uses; however, some Part J substances, like psilocybin, are currently being evaluated in clinical trials.

16. It is also important to note that psilocybin and psilocin meet the definition of "drug" under the *FDA* and therefore cannot legally be sold in Canada unless their sale has been authorized by Health Canada pursuant to the *FDA* and its regulations [for example, through issuance of a Clinical Trial Authorization or via the Special Access Program ("SAP")].

3) Current Legal Framework

17. The *CDSA* and the *FDA*, as well as the regulations made under those *Acts*, form the present regulatory scheme for the control and authorization of drugs containing controlled substances in Canada.

18. The *CDSA* and the *FDA* are also distinct statutory regimes. As all controlled substances meet the definition of "drug" under the *FDA*, all controlled substances are regulated under both the *CDSA* and the *FDA*.

19. The *FDA* governs the manufacture, import, sale, packaging, labelling, and advertising of drugs in Canada. The purposes of the *FDA* include

the protection of public health and safety and the prevention of deception, recognizing the importance of bringing safe and effective quality-controlled medicines to market to advance the health of Canadians.

20. The *FDA* applies to all food, drugs, cosmetics, and medical devices sold in Canada, whether manufactured in Canada or imported. The *FDA* and its regulations (including the Parts of the *FDR* other than Parts G and J) promote the safety and prevention of deception in relation to food, drugs, cosmetics, and medical devices by governing their manufacture, import, sale, packaging, labelling, and advertising. All drugs sold in Canada are regulated under the *FDA*, including those containing controlled substances; however, drugs containing controlled substances are subject to further controls under the *CDSA.*

21. The *CDSA* is a legislative framework for the control of substances that can alter mental processes and that may produce harm to an individual or public health when diverted or misused. The purpose of the *CDSA* is to protect public health and maintain public safety by balancing the need for access to the substances scheduled under the *CDSA* and its regulations for legitimate medical, scientific, and industrial uses with the risks associated with their misuse and their diversion to illegal markets. Under the *CDSA*, various activities with controlled substances and precursors are prohibited unless specifically allowed through regulations or by an exemption granted by the Minister.

22. Health Canada is the federal government department with lead responsibility for the administration of the *CDSA* and its regulations. The Governor in Council makes regulations as required, including orders amending the Schedules to the *CDSA*.

23. The substances regulated under the *CDSA* are grouped into six Schedules to the *Act* based on their properties and effects. Schedules I

to V list controlled substances, while Schedule VI lists precursors, which are necessary in the production of certain controlled substances.

24. Part J of the *FDR* regulates activities with restricted drugs and (amongst other things) authorizes their use for clinical or laboratory research.

4) The Impugned Provisions

25. The impugned provisions pertain to possession (s. 4 of the *CDSA*), trafficking (s. 5), production (s. 7), and possession or sale for use in production or trafficking (s. 7.1) of controlled substances.

26. These provisions, Schedule III of the *CDSA*, Part C of the *FDR*, and the Schedule to Part J of the *FDR* are all the subject of the relief sought by the Plaintiffs and are referred collectively as the "Impugned Provisions."

27. As mentioned, psilocybin and psilocin are among the "controlled substances" listed in Schedule III of the *CDSA* and are also among the "restricted drugs" in the Schedule to Part J of the *FDR*.

5) Subsection 56(1) Exemptions

28. Subsection 56(1) of the *CDSA* allows the Minister to exempt persons or controlled substances or precursors from the application of any provisions of the *CDSA* or its regulations.

29. These exemptions can allow for the use of a controlled substance or precursor for necessary scientific or medical reasons, or if it is otherwise in the public interest. An exemption under s. 56(1) may be issued to permit activities involving controlled substances or precursors that would otherwise be prohibited, particularly where no other regulatory regime would permit the relevant activities. An exemption usually includes a specific period of validity and terms and conditions for the types of activities permitted.

30. However, exemptions issued under s. 56(1) of the *CDSA* cannot exempt the person or class of persons, or the controlled substance or precursor, from requirements relating to drugs under the *FDA*. This includes the prohibition on the sale of drugs that have not been approved under the *FDA* and that have not otherwise been authorized under the *FDA*.

31. Examples of activities where exemptions have been issued under s. 56(1) of the *CDSA* include:

    a. Research with a controlled substance, including administration to animals or in human clinical trials, by physicians, veterinarians and other researchers affiliated with universities and private industry;

    b. Travelling across international borders with prescribed controlled substances, such as narcotics; and

    c. Establishing overdose prevention sites, also known as urgent public health need sites.

32. Each request for an exemption under s. 56(1) is considered on a case-by-case basis, in a fair and unbiased manner, and consistent with the public health and safety objectives of the *CDSA* and all relevant information. If the decision is to refuse an exemption, the reasons for that decision are provided.

33. The majority of all s. 56(1) exemption requests received are considered routine. Those include requests for scientific research such as clinical trials and laboratory research. Non-routine requests would include requests for unique medical, scientific, or public interest purposes, such as for class or religious exemptions.

6) Special Access Program

34. The SAP receives, processes, and considers requests from practitioners seeking special access to unauthorized drugs for individual patients with serious or life-threatening conditions in instances where

conventional therapies have failed, are unsuitable, or are unavailable. The SAP's regulatory functions are carried out in accordance with the provisions of Part C of the *FDR*, made under the *FDA*.

35. The SAP is governed by ss. C.08.010 to C.08.011.3 of the *FDR*. These provisions provide the Minister of Health with discretion to issue SAP authorizations in response to requests from practitioners licensed to treat patients with prescription drugs.

36. The Minister exercises discretion to issue SAP authorizations by considering all the 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 a specified medical emergency. Based on this information, the Minister determines whether,

    a. the situation constitutes 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.

37. In addition to other requirements, the *FDR* stipulates that the Minister may only issue a letter of authorization if the practitioner agrees to report certain information about the drug to the manufacturer of the new drug and to the Minister.

38. The SAP is neither a mechanism to encourage the early use of drugs nor meant to circumvent clinical development of a drug or regulatory review of a submission for marketing. The SAP is intended for short-term access to drugs as long-term access to any drug through the SAP risks circumvention of the market authorization process.

39. At the present time, there are no approved therapeutic products

containing psilocybin or psilocin in Canada or elsewhere. This means that products containing psilocybin and/or psilocin have not undergone the rigorous scientific review process required to be authorized for sale in Canada or elsewhere.

7) Clinical Trials

40. A clinical trial is an investigation in respect of a drug for use in humans that involves human participants. Its intention is to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug; identify any adverse events in respect of the drug; study the absorption, distribution, metabolism and excretion of the drug; or ascertain the safety or efficacy of the drug. A trial can be sponsored by a drug company, a researcher from a hospital, university or research organization, or a physician and can involve a single patient or as many as tens of thousands.

41. Any clinical trial is subject to Part C, Division 5 of the *FDR*, which is designed to ensure the protection of clinical trial participants while supporting clinical research. No person can sell or import a drug for the purpose of a clinical trial unless they are authorized to do so under Part C, Division 5 of the *FDR*.

42. Under Part C, Division 5 of the *FDR*, sponsors must file a Clinical Trial Application to conduct a clinical trial if they are investigating a drug that has not received market authorization for the indicated use (such as psilocybin). Once a No Objection Letter has been issued in respect of a Clinical Trial Application, the qualified investigator can apply for an authorization under Part J of the *FDR*. An authorization under Part J of the *FDR* allows for the sale of a restricted drug by a licensed dealer to an institution for the purposes of clinical testing by qualified investigators [see s. J.01.059(1) of the *FDR*]. Approval from a Research Ethics Board must also be obtained before starting a clinical trial.

43. Sponsors must report any serious and unexpected adverse drug reactions that occur during a clinical trial to Health Canada.

C. RELIEF SOUGHT BY THE PLAINTIFFS

44. Canada specifically denies that any *Charter* right of the Plaintiffs has been breached and puts the Plaintiffs to the strict proof thereof.

45. Canada denies that the Plaintiffs are entitled to any of the relief set out in paragraphs 176-183 of the Claim.

46. Canada states the Plaintiffs do not properly challenge the legislative scheme but rather they impugn Canada's conduct as being without and/or inconsistent with legal authority. Canada states that the recourse for the Plaintiffs is to pursue appropriate administrative law remedies.

47. Canada further states the Plaintiffs make broad generalized allegations and seek to apply the *Charter* as the instrument for judicial review of government decision-making. Canada states that these generalizations set out in the Claim are not justiciable. There is no duty to legislate.

48. In the alternative, if any of the Plaintiffs' *Charter* rights were limited, as alleged, which Canada denies, Canada states that any infringement was demonstrably justified in a free a democratic society and hence saved by section 1 of the *Charter*.

49. In the further alternative, in the event that any part of *CDSA, FDA,* or the *FDR* are found inconsistent with the *Charter*, Canada states that a suspension of a declaration of constitutional invalidity or inapplicability should be granted for a period of at least 24 months in order to permit Parliament sufficient time and flexibility to amend the legislation as appropriate.

50. Canada relies on, among others to be determined before trial, the following:

a. *Canadian Charter of Rights and Freedoms*, Part 1 of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K), 1982, c. 11;

b. *Constitution Act, 1867*, 30 & 31 Vict, c.3;

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

d. *Controlled Drugs and Substances Act*, S.C. 1996, c. 19 and the regulations to that *Act*;

e. *Crown Liability and Proceedings Act*, R.S.C. 1985, c. C-50 and the regulations to that *Act*; and,

f. *Food and Drugs Act*, R.S.C. 1985, c. F-27 and the regulations to that *Act*.

51. Canada seeks an order dismissing this action, with costs to Canada.

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ATTORNEY GENERAL OF CANADA
Department of Justice Canada
Ontario Regional Office
National Litigation Sector
120 Adelaide Street West, Suite 400
Toronto, Ontario
M5H 1T1

Per: Victor Paolone/ Adrian Zita-Bennett
Tel: 647-256-7548/ 416-526-2299
Email: victor.paolone@justice.gc.ca
adrian.zita-bennett@justice.gc.ca
Our file: 500102714

Counsel to the Defendant

TO: THE ADMINISTRATOR
Federal Court of Canada
180 Queen Street West
Suite 200
Toronto, Ontario
M5V 3L6

AND TO: LEWIN & SAGARA LLP
Barristers & Solicitors
2175 Danforth Avenue
Toronto, Ontario
M4C 1K4

Per: Paul Lewin
Tel: 416-499-7945 ext. 100
Fax: 1-877-459-9747
Email: paullewin@bellnet.ca

HAMEED LAW
Barristers & Solicitors
43 Florence Street
Ottawa, Ontario
K2P 0W6

Per: Nicholas Pope
Tel: 613-656-6917
Fax: 613-232-2680
Email: npope@hameedlaw.ca

EMILY AMIRKHANI
Barrister & Solicitor
855 2nd Street Southwest
Suite 3500
Calgary, Alberta
T2P 4J8
Tel: 403-260-9716
Email: emily.amirkhani@blakes.com

R-GROUP LEGAL
Barristers & Solicitors
7777 10th Street Northeast
Suite 102
Calgary, Alberta
T2E 8X2

Per: David Wood
Tel: 403-463-5091
Email: david@rgrouplegal.com

JACK LLOYD
Barrister & Solicitor
43 Front Street East
Suite 400
Toronto, Ontario
M5E 1B3
Tel: 647-235-3972
Fax: 416-352-5524
Email: jacklloydman@gmail.com

Counsel to the Plaintiffs