Court File Number: T-1176-21

FEDERAL COURT

BETWEEN:

NATHAN KRULJAC

Applicant

-and-

MINISTER OF HEALTH

Respondent

APPLICATION RECORD

Volume 2

Memorandum of Fact and Law

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APPLICANT'S MEMORANDUM OF FACT AND LAW

PART I – STATEMENT OF FACT

A. Overview

1. This is an application for *mandamus* to compel the Minister of Health **("Minister")** to render a decision on the Applicant's request for an exemption under s. 56(1) of the *Controlled Drugs and Substances Act*.[1] The Applicant has requested permission to undergo psilocybin-assisted psychotherapy to treat his debilitating depression and anxiety caused by end-of-life distress.

2. The Applicant's request for exemption engages s. 7 of the *Charter* because the *CDSA*'s prevention of access to medical treatment engages his security of person, and the potential of imprisonment for possession of controlled substances engages his liberty.

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[1] *Controlled Drugs and Substances Act*, SC 1996, c 19 [*CDSA*].

3. Concerns for arbitrariness, overbreadth, and gross disproportionality mean that the Minister must grant exemptions where the *CDSA*'s prohibition on possession of substances does not further the *CDSA'*s twin goals: the protection of health and public safety. Because the Minister cannot know whether a particular request is about such a situation without assessing and deciding the request, the Minister has a duty to assess and decide all exemption requests that are made for the purposes of medical treatment, and to do so in a timely manner.

4. Health Canada has granted exemptions to seven people in similar situations to the Applicant, all in less than 30 days. However, around the time that the Applicant submitted his request, Health Canada stopped deciding psilocybin exemption requests for non-terminal patients. Health Canada has stated that it will not decide non-terminal patients' requests until after Health Canada completes a policy analysis. This policy analysis may take more than a year; it has no definite or estimated end date; and there is no contingency plan to ensure the Applicant is not held in indefinite limbo. The policy analysis is not necessary to assess the Applicant's request, since Health Canada has stated that previous psilocybin exemption decisions had been made on a consistent and rational basis, and the goal of the policy analysis is not to change or influence the way psilocybin requests are assessed.

5. The Applicant submitted his request more than 230 days ago and has provided all the information the Minister needs to assess his request. While Health Canada has demonstrated its ability to assess psilocybin exemption requests in as little as one day when it chooses to, the Applicant is forced to suffer needlessly day after day.

6. The Applicant respectfully asks this Court to protect his s. 7 rights and grant *mandamus* compelling the Minister to render a decision, giving the Applicant the chance to access the medical treatment he desperately needs.

B. Applicant's End-Of-Life Distress

7. In 2006, at the age of 25, the Applicant was diagnosed with cancer, specifically Follicular B-Cell Non-Hodgkin's Lymphoma.[2] At that time, he was informed that the survival rate was exceptionally low.[3]

8. The Applicant endured extensive chemotherapy, and in 2013 his cancer went into remission. Since then, he has been under continual monitoring to assess his condition, including through blood work, oncology appointments, and CT scans.[4] Despite the cancer being in remission, the Applicant continues to suffer significant physical pain because of the chemotherapy and disease progression.[5]

9. The greatest pain, however, has been psychological. The Applicant suffers from debilitating end-of-life psychological distress from the idea that his cancer will return and kill him. He has severe anxiety, depression, and post-traumatic stress syndrome,[6] and feels as though he is "living with a time bomb […] waiting to go off."[7] He is terrified about how his death will affect his wife and young children.[8]

10. Over the years, the Applicant has attempted all conventional treatments available to him. He has tried psychiatry, counselling, group therapy, cognitive behavioural therapy, targeted group therapy, introspective writing, and private journaling, but nothing has brought him freedom from his suffering.[9] He has exhausted his finances, confidence, and energies to searching for relief.[10]

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[2] Affidavit of Nathan Kruljac, sworn August 3, 2021 **("Krujac Affidavit"),** para 2, **AR Vol 1, Tab 2, p 6**.
[3] Kruljac Affidavit, para 3, **AR Vol 1, Tab 2, p 6**.
[4] Kruljac Affidavit, para 4, **AR Vol 1, Tab 2, p 7**.
[5] Kruljac Affidavit, para 5, **AR Vol 1, Tab 2, p 7**.
[6] Kruljac Affidavit, para 6, **AR Vol 1, Tab 2, p 7**.
[7] Letter from Dr. Neil H Hanon to Minister Hajdu, March 5, 2021, Exhibit "C" to the Kruljac Affidavit **("Dr. Hanon Letter")**, para 1, **AR Vol 1, Tab 2(C), p 21**.
[8] Dr. Hanon Letter, para 1, **AR Vol 1, Tab 2(C), p 21**.
[9] Kruljac Affidavit, paras 7-8, **AR Vol 1, Tab 2, p 7**.
[10] Kruljac Affidavit, para 9, **AR Vol 1, Tab 2, p 7**.

C. Psilocybin Exemptions Granted

11. Psilocybin is a controlled substance listed in Schedule III of the *CDSA*. Its possession is illegal unless authorized, such by an exemption under s. 56(1) of the *CDSA*.[11]

12. On May 4, 2020, Health Canada received its first request for a s. 56(1) exemption for psilocybin-assisted psychotherapy from a patient with end-of-life distress. This request was followed shortly by three others. On August 4, 2020, the Minister granted these four exemptions.[12]

13. These exemptions allowed the four patients to possess up to 5 grams of psilocybin mushrooms for psilocybin-assisted psychotherapy under the supervision of a medical practitioner.[13]

14. The Minister continued to grant more of these exemption over the following months. As of October 1, 2021, the Minister had granted 52 such exemptions to patients suffering from end-of-life distress associated with a cancer or ALS diagnosis.[14]

15. Of these 52 exemptions, the Minister granted seven to non-terminal cancer patients.[15] In this context, "non-terminal" means that Health Canada has determined that the individual is not at or near the end of their life.[16] Health Canada has assessed the Applicant to be non-terminal.[17]

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[11] *CDSA*, *supra* note 1, s 4(1), Schedule III & s 56(1).
[12] Affidavit of Carol Anne Chenard, sworn September 16, 2021 **("Chenard Affidavit")**, para 30, **AR Vol 1, Tab 4, p 52**.
[13] *Ibid*.
[14] Table of Psilocybin Exemption Applications and Status as of October 1, 2021 **("October 1, 2021, Exemption Status Table")**, **AR Vol 1, Tab 10, pp 412-416**; Chenard Affidavit, para 33, **AR Vol 1, Tab 4, p 52**.
[15] Chenard Affidavit, para 33, **AR Vol 1, Tab 4, p 52**.
[16] Chenard Affidavit, para 47, **AR Vol 1, Tab 4, p 56**.
[17] *Ibid*.

16. Health Canada took between 14 and 29 days from receipt of request to provide each of these seven non-terminal patients a decision. The average time to render a decision in each non-terminal case was 21.6 days.[18]

17. These seven exemptions for non-terminal patients were assessed using consistent criteria set out in an assessment table.[19] The Minister claims, and the Applicant agrees, that the decisions were rational.[20] The Minister claims that these seven decisions were evaluated with a higher evidentiary standard than cases for terminal patients.[21] Even on this higher evidentiary standard, the Minister found there was sufficient scientific evidence on the safety and efficacy of using psilocybin to treat end-of-life distress to grant the exemptions.[22]

D. Applicant's Exemption Request

18. After having exhausted his finances and energies unsuccessfully on conventional treatments, the Applicant learned of the significant scientific research over the past decade that has shown psilocybin-assisted psychotherapy to be a very promising and low-risk treatment for anxiety and depression, including end-of-life distress.[23]

19. The Applicant consulted with his psychiatrist, Dr. Neil H. Hanon, and Dr. Hanon recommended the Applicant undergo psilocybin-assisted psychotherapy with an initial dose of three to five grams of psilocybin.[24]

20. On March 11, 2021, the Applicant submitted an application under s.56(1) of the *CDSA* requesting an exemption to allow him to undergo this medical treatment.[25]

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[18] These seven requests took 25, 23, 15, 14, 29, 21, and 24 days respectively: *see* October 1, 2021, Exemption Status Table, p 1, rows 15, 17, 19, 20, 23, 26 & p 2, row 4, **AR Vol 1, Tab 10, pp 412-413**.
[19] Transcript of Cross Examination of Carol Anne Chenard, October 4, 2021 **("Chenard Transcript")**, **AR Vol 1, Tab 7, p 365, lines 8-14**; Cross Examination Exhibit 1: Assessment Summary – Patient Psilocybin.pdf, **AR Vol 1, Tab 8**.
[20] Chenard Transcript, **AR Vol 1, Tab 7, p 367, lines 6-7**.
[21] Chenard Affidavit, para 35, **AR Vol 1, Tab 4, p 53**; Chenard Transcript, **AR Vol 1, Tab 7, p 377, lines 4-18**.
[22] Chenard Affidavit, para 33, **AR Vol 1, Tab 4, p 53**.
[23] Kruljac Affidavit, para 10, **AR Vol 1, Tab 2, p 7**.
[24] Dr. Hanon Letter, para 2, **AR Vol 1, Tab 2(C), p 21**.
[25] Kruljac Affidavit, para 12, **AR Vol 1, Tab 2, pp 7-8**; Chenard Affidavit, para 45, **AR Vol 1, Tab 4, p 55**.

Along with a description of his condition and his need for an exemption, the Applicant included a letter from his psychiatrist recommending the therapy.[26]

21. The Applicant was supported by TheraPsil, a non-profit coalition dedicated to helping Canadians in medical need access legal, psilocybin-assisted psychotherapy to treat end-of-life distress.[27] Because of this, the Applicant was aware of many of the questions asked to prior requestors, and he pre-emptively included the answers to thirteen questions that Health Canada had previously required of others, including details about safety and security measures.[28] The Applicant also informed Health Canada that there were no clinical trials available for him to take part in.[29]

22. On March 17, 2021, the Applicant received an email from Health Canada requesting the full address for the location in which the proposed psilocybin therapy sessions would take place.[30] He provided Health Canada with this information on April 21, 2021.[31]

23. Since then, the Applicant has emailed Health Canada and the Minister multiple times requesting a decision be rendered.[32]

24. At the time of writing, more than 230 days after the request was made, no decision has been rendered on the Applicant's request.[33]

E. Respondent's Freeze on Non-Terminal Requests

25. Unknown to the Applicant, around the time that he submitted his request, Health Canada initiated a *de facto* freeze on deciding s. 56(1) psilocybin requests for non-terminal patients.

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[26] Kruljac Affidavit, para 14, **AR Vol 1, Tab 2, p 8**; Dr. Hanon Letter, **AR Vol 1, Tab 2(C), p 21**.
[27] Kruljac Affidavit, para 15, **AR Vol 1, Tab 2, p 8**.
[28] Section 56 Application, Kruljac Affidavit, Exhibit "A", pp 2-3, **AR Vol 1, Tab 2(A), pp 13-14**.
[29] *Ibid*, p1, para 2, **AR Vol 1, Tab 2(A), p 12**.
[30] Kruljac Affidavit, para 17, **AR Vol 1, Tab 2, p 8**.
[31] Kruljac Affidavit, para 18, **AR Vol 1, Tab 2, p 8**; Email to Health Canada, April 21, 2021, Kruljac Affidavit, Exhibit "F", **AR Vol 1, Tab 2(F), p 27**.
[32] Kruljac Affidaivt, paras 18-24, **AR Vol 1, Tab 2, pp 8-9**.
[33] *See* Kruljac Affidavit, para 25, **AR Vol 1, Tab 2, p 9**.

26. Around March 2021, Health Canada began conducting a policy analysis related to psilocybin exemption requests.[34] Problematically, "it was decided that requests such as Mr. Kruljac's, for individuals not at or near end of life, would remain under review until the analysis is completed"[35] despite there being "no definite end date" for the policy analysis.[36]

27. Although the Respondent prefers not to refer to this as a "freeze",[37] the following facts, which demonstrate a *de facto* freeze, are not in dispute:

    a. From February 9, 2021, to October 1, 2021, 28 psilocybin exemption requests were submitted by non-terminal patients, and, as of October 1, 2021, the Minister had decided none of them.[38]

    b. In that same time period, 21 psilocybin exemption requests were submitted by terminal patients, and, as of October 1, 2021, the Minister had approved all of them except for one, which had been submitted four days prior, on September 27, 2021.[39]

    c. Health Canada has decided that requests submitted by non-terminal patients will remain "under review" until the policy analysis is complete.[40]

    d. This decision is not pursuant to any official policy or rule.[41]

    e. Health Canada has received all the information it needs from the Applicant to decide his request.[42]

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[34] Chenard Affidavit, para 39, **AR Vol 1, Tab 4, p 54**.
[35] Chenard Affidavit, para 47, **AR Vol 1, Tab 4, p 56**.
[36] Chenard Affidavit, para 57, **AR Vol 1, Tab 4, p 58**.
[37] *See* Chenard Transcript, **AR Vol 1, Tab 7, p 397, lines 16-25; p 398, lines 1-3**.
[38] Chenard Transcript, **AR Vol 1, Tab 7, p 393, lines 3-5**; October 1, 2021, Exemption Status Table, **AR Vol 1, Tab 10, pp 414-416**.
[39] October 1, 2021, Exemption Status Table, **AR Vol 1, Tab 10**, **p 413-414**.
[40] Chenard Affidavit, para 47, **AR Vol 1, Tab 4, p 56**.
[41] Chenard Transcript, **AR Vol 1, Tab 7, p 393, lines 6-12**.
[42] Chenard Transcript, **AR Vol 1, Tab 7, p 402, lines 1-2**.

f. The Applicant's decision package could presently be sent to the decision-maker to decide.[43]

g. Health Canada has decided not to provide the Applicant's decision package to the decision-maker until the policy analysis is complete.[44]

h. Health Canada does not have a definite end date by which the policy analysis will be complete,[45] nor do they have an estimated date.[46]

i. It is possible the policy analysis could take more than a year.[47]

j. Health Canada does not have a contingency plan to render a decision on the Applicant's request, or those of other non-terminal patients, if the policy analysis goes on for an extended period of time.[48]

k. Non-terminal patients may be blocked indefinitely from having their applications decided, but Health Canada "hopes" this is not the case.[49]

28. Although Health Canada is not entirely clear as to what the outcome of the policy analysis will be,[50] they have explicitly stated that the goal of the policy analysis is not to change, or in any way influence, the way that psilocybin requests are assessed.[51]

29. The Respondent has also not identified any resource constraints that would prohibit them from rendering a decision on the Applicant's request. In fact, the affiant for the Respondent has stated that if Health Canada analysts provided the Applicant's decision package to the decision-maker, they could render a decision in 30 days at

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[43] Chenard Transcript, **AR Vol 1, Tab 7, p 398, lines 23-25**.
[44] Chenard Transcript, **AR Vol 1, Tab 7, p 396, lines 1-3**.
[45] Chenard Affidavit, para 57, **AR Vol 1, Tab 4, p 58**.
[46] Chenard Transcript, **AR Vol 1, Tab 7, p 387, lines 6-7**.
[47] Chenard Transcript, **AR Vol 1, Tab 7, p 387, lines 13-15**.
[48] Chenard Transcript, **AR Vol 1, Tab 7, p 399, lines 5-9, 15-20**.
[49] Chenard Transcript, **AR Vol 1, Tab 7, p 399, lines 21-25; p 400, lines 1-2**.
[50] *See* Chenard Transcript, **AR Vol 1, Tab 7, p 386, lines 1-8**.
[51] Chenard Transcript, **AR Vol 1, Tab 7, p 386, lines 12-13**.

the absolute maximum, and likely faster than this.[52] Health Canada has previously rendered some psilocybin exemption decisions within 1 day of receipt of application.[53]

PART II – POINTS IN ISSUE

30. The Applicant submits that the following issues are to be determined:

ISSUE 1: Does the Minister owe the Applicant a duty to render a decision on the Applicant's s. 56(1) exemption request?

ISSUE 2: Should this Court grant *mandamus* compelling the Minister to render a decision?

PART III – SUBMISSIONS

Issue 1: The Minister Must Decide s. 56(1) Medical Exemptions

31. The Minister owes a duty to the Applicant to assess his exemption request and render a decision in a timely manner, pursuant to s. 7 of the *Charter*. The duty to decide is so uncontroversial that the Minister admitted it in *PHS*.[54]

32. Two key cases make this duty evident. The first is *R v Parker*.[55] In *Parker*, the accused required marijuana to control his epilepsy. He was charged with possession under s. 4 of the *CDSA*. The Ontario Court of Appeal struck down the marijuana prohibition in s. 4 because it violated Parker's s. 7 rights to liberty and security of person.[56] In doing so, the Court considered the impact of the possibility of access through the regulatory scheme or a s. 56 exemption, but it held that these

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[52] Chenard Transcript, **AR Vol 1, Tab 7, p 402, lines 3-6; p 403, lines 1-4**.
[53] October 1, 2021, Exemption Status Table, p 1, row 7 & p 2, row 12, **AR Vol 1, Tab 10, p 412 & 413**.
[54] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 124, [2011] 3 SCR 134.
[55] *R v Parker*, 49 OR (3d) 481, 188 DLR (4th) 385 (ONCA) [*Parker*].
[56] *Ibid* at para 210.

defenses did not save the provision because their availability was "illusory",[57] and the delays involved in s. 56 applications endangered applicants' health.[58]

33. The second is *Canada (Attorney General) v. PHS Community Services Society*.[59] In *PHS*, the Minister of Health denied the s. 56 exemption application of Insite, a safe injection site. The Supreme Court of Canada held that s. 4 of the *CDSA* engaged all three s. 7 rights, but it was not arbitrary, overbroad, and grossly disproportionate because s. 56 acted as a "safety valve", excluding cases that did not further the *CDSA*'s goals of health and public safety from s. 4's blanket prohibition.[60] However, the Court held that the Minister's denial of the exemption was arbitrary and grossly disproportionate and ordered *mandamus* compelling the Minister to grant the exemption.[61]

34. The Court based its order on the following general principle: where evidence indicates that an exemption will improve health, and there is little to no evidence that it will have a negative impact on public safety, the Minister must grant the exemption.[62]

35. Section 56(1) gives the Minister discretion to grant exemptions where the Minister is of the opinion that an exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.[63] However, the Minister's discretion is not absolute. It must conform to the *Charter*.[64] Because the decision engages s. 7 rights, "[t]he Minister cannot simply deny an application for a s. 56 exemption on the basis of policy *simpliciter*; insofar as it affects *Charter* rights, [her] decision must accord with the principles of fundamental justice."[65]

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[57] *Ibid* at paras 163 & 174.
[58] *Ibid* at para 189.
[59] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44, [2011] 3 SCR 134 [*PHS*].
[60] *Ibid* at paras 113 & 114.
[61] *Ibid* at para 150.
[62] *Ibid* at paras 140 & 152.
[63] *CDSA*, *supra* note 1, s 56(1).
[64] *PHS*, *supra* note 59 at para 117.
[65] *Ibid* at para 128.

36. Section 7 and the principles of fundamental justice impose a duty on the Minister when she receives s. 56(1) exemption requests. The duty is this: when a person requests an exemption to possess a controlled substance for medical reasons, the Minister has a duty to assess and decide the exemption in a timely manner, and to approve the request if the evidence indicates the treatment will improve the person's health, and there is little or no evidence that it will have a negative impact on public safety.

37. The basis for this duty is as follows, and is elaborated on in the corresponding sections below:

    a. Section 7 of the *Charter* is engaged when the Minister receives a s. 56(1) exemption request for medical treatment.

    b. If the exemption is not likely to negatively impact health or public safety, denying the exemption will violate the principles of fundamental justice.

    c. If the Minister does not render a decision, it will constitute an arbitrary denial because the denial is made without assessing the required factors.

    d. In the time between when exemption request is made and decision is rendered, the denial of medical treatment is arbitrary, so this time must not be more than negligible.

A. Request for Medical Exemption Engages Section 7

38. The Applicant's s. 7 *Charter* rights were engaged when he submitted the s. 56(1) exemption request for medical treatment because the *CDSA*'s prohibition on possession of psilocybin engages the Applicant's rights to liberty and security of person.

1) Liberty is Engaged

39. Section 4(1) of the *CDSA* prohibits possession of psilocybin:

> "Except as authorized under the regulations, no person shall possess a substance included in Schedule I, II or III."[66]

40. Psilocybin is listed in Schedule III of the *CDSA*,[67] so contravention of s. 4(1) may result in imprisonment for up to three years.[68]

41. Section 4(1) engages the Applicant's liberty interest because it exposes him to the threat of imprisonment if he possesses psilocybin for the purposes of medical treatment. It also engages the liberty interest of any psychotherapist the Applicant needs to assist and supervise him in psilocybin-assisted psychotherapy.[69]

42. Section 4(1) also engages the Applicant's liberty interest because it infringes on his right to make decisions that are of fundamental personal importance, including the choice of medication to alleviate the effects of a serious mental illness.[70]

2) Security of Person is Engaged

43. Section 4(1) engages the Applicant's security of person. If the Applicant is not granted an exemption, no psychotherapist will be able to offer medical supervision nor provide him with the necessary psychotherapy at the time of his consumption and possession of psilocybin.

44. In *PHS*, the Supreme Court concluded that engagement of health care providers' liberty interests results in limits to patients' security of person because it denies them access to health care.[71] The Court also found that patients' security of person was directly engaged because patient would be unable to use drugs in the safer environment of professional health supervision:

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[66] *CDSA*, *supra* note 1, s 4(1).
[67] *CDSA*, *supra* note 1, Schedule III.
[68] *CDSA*, *supra* note 1, s 4(6).
[69] *PHS*, *supra* note 59 at para 90.
[70] *Parker*, *supra* note 55 at para 102.
[71] *PHS*, *supra* note 59 at para 91.

> "Where a law creates a risk to health by preventing access to health care, a deprivation of the right to security of the person is made out"[72]

45. The Applicant's security of person is engaged in both ways. First, the treatment that his doctor recommended is psilocybin-assisted psychotherapy – not merely the consumption of psilocybin. The Applicant is unable to properly treat his condition without a psychotherapist guiding him through the process. Thus, the engagement of the healthcare providers' liberty interests deprives the Applicant of his medical care.

46. Second, Health Canada's information indicates that there may be health risks associated with the consumption of psilocybin in an unsupervised manner.[73] However, this risk appears to be mitigated by consumption under the supervision of a medical professional.[74] Thus, the risk of adverse health consequences may be greater if the Applicant is forced to consume psilocybin in secret without medical supervision.

B. Denial of Certain Exemptions Violates PFJs

47. Since s. 7 is engaged by medical exemption requests, the refusal to approve such an exemption will be unconstitutional if it does not accord with the principles of fundamental justice.

48. Three principles of fundamental justice are relevant to the Minister's exercise of discretion: arbitrariness, overbreadth, and gross disproportionality. Each of these principles ask about the relationship between the law or ministerial decision and its objectives. Decisions under s. 56(1) must target the purposes of the *CDSA*. There are two purposes to the *CDSA*: the protection of health and public safety.[75]

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[72] *Ibid* at para 93.
[73] Chenard Affidavit, para 27, **AR Vol 1, Tab 4, p 51**.
[74] Chenard Transcript, **AR Vol 1, Tab 7, p 369, lines 23-25; p 370, lines 1-15**.
[75] *PHS*, *supra* note 59 at para 129.

49. A refusal will thus be arbitrary, overbroad, and grossly disproportionate if the exemption is unlikely to negatively affect health or public safety.

1) Arbitrariness

50. Arbitrariness asks whether there is a direct connection between the purpose of the law and the effect on the individual. There must be a rational connection between the object of the measure that causes the s. 7 deprivation, and the limits it imposes on life, liberty, or security of the person.[76]

51. In *PHS*, the Court held that the Minister's failure to grant Insite an exemption was arbitrary because the exemption would have furthered the twin goals, not undermined them.[77] The exemption would have had a positive effect on health and no negative impact on public safety.[78]

52. Accordingly, the Supreme Court stated as a general rule that when evidence indicates that a requested s. 56(1) exemption would decrease negative health conditions, and there is little or no evidence that it will have a negative impact on public safety, the Minister must grant the exemption.[79]

2) Overbreadth

53. Overbreadth describes situations where a law is so broad in scope that it includes some conduct that bears no relation to its purpose. In this sense the law is arbitrary in its application to a specific situation.[80]

54. The s. 4(1) prohibition on possession will be overbroad if s. 56(1) exemption requests for medical treatment are not assessed, decided, and granted if they would improve a person's health and have no negative impact on public safety. Without

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[76] *Canada (Attorney General) v Bedford*, 2013 SCC 72 at para 111, [2013] 3 SCR 1101 [*Bedford*].
[77] *PHS*, *supra* note 59 at para 131.
[78] *Ibid* at para 140.
[79] *Ibid* at para 152.
[80] *Bedford*, *supra* note 76 at para 112.

assessment, decision, and approval in these situations, s. 4(1)'s prohibition will capture some conduct that bears no relation to the *CDSA*'s twin purposes.

3) Gross Disproportionality

55. A Minister's exercise of discretion is grossly disproportionate when the seriousness of the deprivation is totally out of sync with the objective of the measure.[81] A grossly disproportionate effect on one person is sufficient to violate the norm.[82]

56. In *PHS*, the Court found that the denial of an exemption was grossly disproportionate to any benefit that might be derived from having a uniform stance on the possession of narcotics.[83]

57. In the present case, the denial of an exemption may be grossly disproportionate if the denial results in the prolongation of the Applicant's severe mental distress, even if there are some countervailing health or public safety considerations.

C. Minister's Failure to Decide Violates PFJs

58. The principles of fundamental justice are violated, not only by a denial, but also if the Minister fails to assess and decide an exemption request for medical treatment.

59. As discussed above, the Minister has a duty to approve requests for medical exemptions when health and safety would not be negatively impacted. While not every medical exemption request will meet this criterion, the Minister has no way of knowing which requests do if the Minister does not assess and render a decision on these requests.

60. Refusing to decide a request has the same result as denying a request: the requestor cannot access the medical treatment. This deprivation is arbitrary because the Minister cannot claim any rational connection between the refusal and the purposes of the *CDSA* if the Minister has not assessed the application to

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[81] *Ibid* at para 120.
[82] *Ibid* at para 122.
[83] *PHS*, *supra* note 59 at para 133.

determine the health and public safety impacts of the exemption and then based the denial on one or both grounds.

61. Whenever the Minister refuses or fails to decide a medical exemption request, she blocks the s.56(1) safety valve – the very thing that saves s. 4(1) from being unconstitutional.[84] If s. 56(1) does not let the pressure escape, s. 4(1) will explode.

62. It is not good enough for s. 56(1) to be available in theory. It must be available in practice. Subsection 56(1) was present in the *CDSA* during both *Parker* and *PHS*, but the two cases had different results because of the difference in practical availability. In *Parker*, the Court struck down s. 4(1) as it applied to marijuana because it found that the availability of the exemption was illusory.[85] The exemption was deemed illusory because "it was unknown how the process would work, how long it would take to process an application and when [the] application would be dealt with."[86]

63. In *PHS*, the Court found that the realistic availability of s. 56(1) moved the *Charter* problem from the statute to the Minister's exercise of power.[87] The Court distinguished *Parker* on the very basis that exemptions were illusory in that case but had since become realistically available.[88]

64. The situation in which non-terminal patients requesting s. 56(1) psilocybin exemptions now find themselves is strikingly similar to the situation described in *Parker*. Neither the patients nor Health Canada know how long it will take to process their applications or when the applications will be dealt with.[89] If the Minister does not make the s. 56(1) safety valve realistically available, s. 4(1) becomes a blanket provision, and the provision itself will be put back in jeopardy.

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[84] *Ibid* at para 113.
[85] *Parker*, *supra* note 55 at para 174.
[86] *Ibid*.
[87] *PHS*, *supra* note 59 at para 114.
[88] *Ibid* at para 118.
[89] *See* Chenard Affidavit, para 57, **AR Vol 1, Tab 4, p 58**; Chenard Transcript, **AR Vol 1, Tab 7, p 387, lines 6-7, 13-15**; **p 399, lines 5-9, 15-25**.

65. As such, and as admitted by the Minister in *PHS*,[90] the Minister has the obligation to assess and decide all s. 56(1) exemption requests for medical reasons.

D. Untimely Decisions Violate PFJs

66. In the realm of health care, the question of whether a treatment is eventually administered is not all that matters. The timing is just as important. Whenever the approval of a s. 56(1) medical exemption takes time, there is always an arbitrary violation of the applicant's s. 7 rights during the waiting period. During this period, the patient is deprived of the treatment without reason, regardless of how the Minister's decision eventually turns out.

67. Additionally, Health Canada's decision to wait until the policy analysis is complete before deciding non-terminal cases is arbitrary and grossly disproportionate. Health Canada is able to send the Applicant's case to be decided right away;[91] previous non-terminal cases have been decided on a consistent and rational basis;[92] and the goal of the policy analysis is not to change or influence the way exemption requests are decided.[93] This choice by Health Canada support staff is not an official policy,[94] and is arbitrary in that it is not rationally connected to the goals of health and public safety. In the alternative, if it is rationally connected to the goals, the negative effect on the Applicant is so out of sync with the *CDSA*'s objectives that it is grossly disproportionate.

68. The provision of medical care is of a different nature than many other legal matters. When a medical substance is given, the true benefit is not possession of the substance. Rather, the benefits granted are the days, months, and years, ahead – days that would have been filled with pain, suffering, and unproductivity but can now be filled with peace, joy, and productivity. So an extraordinary difference stems from

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[90] *See PHS*, *supra* note 59 at para 124.
[91] Chenard Transcript, **AR Vol 1, Tab 7, p 398, lines 23-25**.
[92] Chenard Transcript, **AR Vol 1, Tab 7, p 365, lines 8-14; p 367, lines 4-7**; Cross Examination Exhibit 1: Assessment Summary – Patient Psilocybin.pdf, **AR Vol 1, Tab 8**.
[93] Chenard Transcript, **AR Vol 1, Tab 7, p 386, lines 12-13**.
[94] Chenard Transcript, **AR Vol 1, Tab 7, p 393, lines 6-12; p 396, lines 1-3**.

when medical care is given. The 20-year-old who asks for treatment and is given it when he is 70 has been deprived of 50 suffering-free years as compared to the 20-year-old who asks and is given treatment the very next day.

69. The Court in *Parker* saw delay as an important reason for finding the s. 56(1) process, at the time, did not conform to the principles of fundamental justice. The Court stated, “These kinds of delays, which may be due to the administrative procedure, would further endanger the health of a person like Parker.”[95] It held that “[a]n administrative structure made up of unnecessary rules that results in an additional risk to the health of the person is manifestly unfair and does not conform to the principles of fundamental justice.”[96]

70. In *PHS*, s. 56(1) was called a safety valve. For a safety valve to be of any use, it must open immediately and release the pressure. When a boiler gets too hot, and the pressure is building and threatening to blow, you cannot wait a year, a month, or even a day after you pull the lever for the pressure to be released. It needs to happen instantaneously. A delay of even a few seconds could spell disaster.

71. While medical treatment operates on a slightly different timeframe, the concept is the same. This Court may take judicial notice of the fact that when a person receives a prescription from a doctor, they can usually go to the pharmacy and receive their medication in a few hours or days – not weeks or months. A delay of a few seconds or minutes is likely fine, and whether hours or days are appropriate may depend on the circumstance, but once the delay is in the realm of weeks and months, it is no longer a safety valve. It is now a significant arbitrary deprivation of security of person.

72. Therefore, s. 56(1) decisions on requested medical treatment must be made in hours or days for the administrative process not to result in arbitrary infringement of s. 7 in more than a negligible way. If the Minister does not have the resource

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[95] *Parker*, *supra* note 55 at para 189.
[96] *Ibid*.

capacity to render decisions quickly (although the Minister has not presented any evidence to support this), the Minister must select a different tool at her disposal to ensure access is available in a timely manner.

73. There are two ways that the government can provide access to controlled substances when required under s. 7. One is to grant a s. 56(1) exemption, as was the result in *PHS*, and the other is to enact regulations under *CDSA* s. 55, as the government did in response to *Parker*.[97] A key difference between these two options is the delay for patients. A regulatory scheme can take the individual decisions out of the hands of the Minister and place them in the hands of medical practitioners, thus reducing the resource burden on the Minister.

74. The government chose the s. 56(1) scheme as its preferred method to ensure access to medical psilocybin instead of the alternate paths of regulation or decriminalization,[98] and the government decided how much resources to put into hiring analysts to assess s. 56(1) requests. The patient in need of a medical exemption should not have to endure additional days, weeks, and months of suffering because of the government's choices in this regard.

E. Conclusion: The Minister's Duty

75. Therefore, as outlined above, the Minister has a duty, when in receipt of a request for a s. 56(1) exemption for medical treatment, to assess and decided the request in a timely manner, and to approve the request if the evidence does not demonstrate that the exemption would be likely to have a negative impact to health or public safety.

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[97] The government enacted the *Marihuana Medical Access Regulations*, SOR/2001-227, which have since been repealed; s*ee R v Woolsey*, 2018 BCPC 4 at para 22, 405 CRR (2d) 292.
[98] The Governor in Council has the power to delete any substance from Schedules III without requiring legislative action pursuant to *CDSA*, s 60.

Issue 2: Mandamus Should be Granted

76. The Applicant submits that it is appropriate for *mandamus* to be granted compelling the Minister to render a decision within 5 days.

A. Test for Mandamus

77. The test for *mandamus* is as follows:

1) there must be a legal duty to act;
2) the duty must be owed to the applicant;
3) there must be a clear right to performance of that duty, in particular;
    a. The applicant has satisfied all conditions precedent giving rise to the duty; and
    b. There was
        i. a prior demand for performance of the duty;
        ii. a reasonable time to comply with the demand unless refused outright; and
        iii. a subsequent refusal which can be either expressed or implied, e.g. unreasonable delay.
4) where the duty sought to be enforced is discretionary, certain additional principles apply;
5) no adequate remedy is available to the applicant;
6) the order sought will have some practical value or effect;
7) the Court finds no equitable bar to the relief sought; and
8) on a balance of convenience an order of mandamus should be issued.[99]

B. Elements of Test are Met

78. All eight elements of the test for *mandamus* are met.

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[99] *Canada (Health) v The Winning Combination* Inc, 2017 FCA 101 at para 60; *Apotex Inc v Canada (Attorney General)*, [1994] 1 FC 742, 69 FTR 152 (FCA), aff'd *Apotex Inc v Canada (Attorney General)*, [1994] 3 SCR 1100, 176 NR 1.

1) Legal Duty to Act

79. First, as outlined in Issue 1, above, the Respondent has a legal duty, pursuant to s. 7 of the *Charter*, to render a decision on the Applicant's request.

2) Duty Owed to Applicant

80. Second, the duty is owed to the Applicant since he is the person who requested the exemption and whose security of person is violated by the Minister's refusal to render a decision.

3) Clear Right to Performance of the Duty

81. Third, the Applicant has a clear right to performance of the duty because the Applicant has satisfied all conditions precedent giving rise to the duty by submitting his application on March 11, 2021, and providing all requested information.[100]

82. The Applicant made a demand for performance of the duty when he submitted his request and subsequently in emails on, *inter alia*, April 21, 2021, and June 11, 2021.[101]

83. At the time this application was commenced, a refusal to comply could be implied by the unreasonable delay of more than 137 days because the average timeframe to render a decision had been 27 days.[102] It has now been more than 230 days.

84. During these proceedings, the refusal has become explicit. The Respondent's affiant, Director of the Office of Controlled Substances, Carol Anne Chenard, stated in her affidavit that "it was decided that requests such as Mr. Kruljac's, for individuals not at or near end of life, would remain under review until the analysis is

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[100] Chenard Transcript, **AR Vol 1, Tab 7, p 402, lines 1-2**.
[101] Kruljac Affidavit, paras 12, 18 & 23, **AR Vol 1, Tab 2, pp 7, 8 & 9**.
[102] Chenard Affidavit, para 38, **AR Vol 1, Tab 4, p 54**.

completed."[103] And on cross-examination she stated, "Health Canada has decided to not put together a decision package until the policy analysis is complete".[104]

85. The Respondent has instituted a *de facto* freeze on assessing all exemption requests for psilocybin from non-terminal patients. This freeze is indefinite, pending the completion of a policy analysis with no definite[105] or even estimated end date.[106] The Respondent has stated that the analysis could possibly take more than a year.[107] Although Health Canada "hopes" the Applicant will not be blocked indefinitely from having his request decided, it cannot offer any assurance.[108] The Respondent has no contingency plan to ensure that the Applicant's request is eventually decided should the policy analysis drag on for years.[109]

86. This indefinite delay amounts to a silent denial of the exemption. It is a denial without any assessment of the elements needed to conform with the *Charter*. It would be unconstitutional for the Minister to deny an exemption request for medical treatment where she had not considered the effects on health and public safety, and the Minister can not be permitted to do in silence what she would not be allowed to do by overt act.

4) Duty is Not Discretionary

87. Fourth, the duty sought to be enforced is not discretionary since it is required by s. 7 of the *Charter*. Even if the substantive result of the decision might be discretionary, the duty to render a decision is not discretionary.

88. On requests where the exemption would further the twin goals of the *CDSA*, rather than undermine them, the result itself is not discretionary; the Minister must approve

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[103] Chenard Affidavit, para 47, **AR Vol 1, Tab 4, p 56**.
[104] Chenard Transcript, **AR Vol 1, Tab 7, p 396, lines 1-3**.
[105] Chenard Affidavit, para 57, **AR Vol 1, Tab 4, p 58**.
[106] Chenard Transcript, **AR Vol 1, Tab 7, p 387, lines 6-7**.
[107] Chenard Transcript, **AR Vol 1, Tab 7, p 387, lines 13-15**.
[108] Chenard Transcript, **AR Vol 1, Tab 7, p 399, lines 21-25; p 400, lines 1-2**.
[109] Chenard Transcript, **AR Vol 1, Tab 7, p 399, lines 5-9, 15-20**.

the request or the decision will be arbitrary.[110] In order to know whether or not the Applicant's case is one such case (and it likely is), the Minister must, at a minimum, assess the case and render a decision in this respect.

5) No Other Adequate Remedy Available

89. Fifth, no other adequate remedy is available to the Applicant since he cannot access psilocybin-assisted psychotherapy, as recommended by his doctor, if he is not granted an exemption. There are currently no clinical trials involving psilocybin in which he can participate, and because of the severity of his condition, he cannot wait for one to be made available.[111]

6) Order Will Have Practical Value and Effect

90. Sixth, the order sought will have a practical value and effect. It will compel the Minister to render a decision on the Applicant's exemption request. Given the Applicant's similarity to the seven non-terminal patients for whom exemptions have already been granted, this will likely result in the grant of an exemption, and the Applicant will be able to access the medical treatment he needs to relieve his extreme suffering.

91. Even if the exemption is not granted, the practical value and effect will be that the Applicant is provided with reasons for the denial. He will then be able to seek judicial review if he believes the decision is unreasonable or unconstitutional, which he is currently unable to do because of the complete lack of a decision.

7) No Equitable Bar to Relief

92. Seventh, there is no equitable bar to the relief sought.

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[110] *PHS*, *supra* note 59 at paras 151-153.
[111] Kruljac Affidavit, para 11, **AR Vol 1, Tab 2, p 7**.

8) Balance of Convenience Favours Granting Mandamus

93. Eighth, the balance of convenience favours granting *mandamus* since the salutary effects on the Applicant's health far outweigh any speculative deleterious effects.

94. The only possible deleterious effect of ordering a decision be rendered is that the decision will be rendered in absence of the additional information provided by the ongoing policy analysis. This is not a deleterious effect. Health Canada has already made more than 67 decisions on psilocybin exemption requests without the benefit of this policy analysis, and Health Canada itself claims that those decisions were made on a consistent and rational basis.[112] Seven of the previously decided applications were from non-terminal patients, whose applications were subjected to a higher evidentiary threshold for safety and efficacy than terminal patients, and the exemptions were granted even with this higher threshold.[113] Health Canada continues to render decisions on terminal patients' requests while the policy analysis is underway.[114] Additionally, Health Canada has stated that the goal of the policy analysis is not to change, or in any way influence, the way that psilocybin requests are assessed.[115]

95. By contrast, the salutary effects of ordering a decision be rendered are enormous. The Applicant is currently living with unbearable mental suffering. It affects every area of his life, including his ability to take care of his children and to work. He suffers from anxiety, depression, and post-traumatic stress syndrome,[116] and feels as though he is "living with a time bomb […] waiting to go off."[117] He is terrified about how his death will affect his wife and young children.[118]

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[112] Chenard Transcript, **AR Vol 1, Tab 7, p 365, lines 8-14**; Cross Examination Exhibit 1: Assessment Summary – Patient Psilocybin.pdf, **AR Vol 1, Tab 8**; Chenard Transcript, **AR Vol 1, Tab 7, p 367, lines 6-7**.
[113] Chenard Affidavit, paras 33 & 35, **AR Vol 1, Tab 4, p 53**.
[114] *See* October 1, 2021, Exemption Status Table, **AR Vol 1, Tab 10, p 413**.
[115] Chenard Transcript, **AR Vol 1, Tab 7, p 386, lines 12-13**.
[116] Kruljac Affidavit, para 6, **AR Vol 1, Tab 2, p 7**.
[117] Dr. Hanon Letter, para 1, **AR Vol 1, Tab 2(C), p 21**.
[118] *Ibid*.

96. The Applicant has attempted all conventional treatments available to him, but nothing has brought him freedom from his suffering.[119] With these attempts he has exhausted his finances, confidence, and energies.[120]

97. The Applicant's psychiatrist has recommended the Applicant undergo psilocybin-assisted psychotherapy,[121] since significant scientific research over the past decade that has shown psilocybin-assisted psychotherapy to be a very promising and low-risk treatment for anxiety and depression, including end-of-life distress.[122] If this *mandamus* is granted, the Applicant will be given the opportunity to be fairly assessed so that he can obtain the medical treatment his doctor has recommended, and potentially be relieved of his unbearable suffering.

C. Appropriate Timeline is 5 days

98. The only question remaining is how long the Respondent should be given to render the decision. The Applicant submits that 5 days is reasonable, appropriate, and just.

99. Health Canada and the Minister have demonstrated that they are able to complete all stages of the assessment and decision process rapidly, if not immediately, when they decide to do so. In two terminal patients' cases, the Minister granted approval the day after the request was received.[123]

100. In the seven requests by non-terminal patients, the Minister granted approvals 14, 15, 21, 23, 24, 25, and 29 days after the requests were received.[124] This averages to 21.6 days.

101. The Applicant's file is not at the start of the process; rather it is very near the end. It is ready to be handed to the decision maker.[125] The application process consists

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[119] Kruljac Affidavit, paras 7-8, **AR Vol 1, Tab 2, p 7**.
[120] Kruljac Affidavit, para 9, **AR Vol 1, Tab 2, p 7**.
[121] Dr. Hanon Letter, para 2, **AR Vol 1, Tab 2(C), p 21**.
[122] Kruljac Affidavit, para 10, **AR Vol 1, Tab 2, p 7**.
[123] October 1, 2021, Exemption Status Table, p 1, row 7 & p 2, row 12, **AR Vol 1, Tab 10, p 412 & 413**.
[124] These seven requests took 25, 23, 15, 14, 29, 21, and 24 days respectively: *see* October 1, 2021, Exemption Status Table, p 1, rows 15, 17, 19, 20, 23, 26 & p 2, row 4, **AR Vol 1, Tab 10, p 412 & 413**.
[125] Chenard Transcript, **AR Vol 1, Tab 7, p 398, lines 23-25**.

of seven stages: 1) acknowledgement, 2) official response, 3) review, 4) request for information, 5) preparation of decision package, 6) approvals, and 7) decision.[126] The 3rd stage, review, is the part of the process that takes the most time.[127] The Applicant's file is currently being held at the end of the 5th stage, and the only reason the 5th stage is not considered complete is because Health Canada has decided to wait for the policy analysis before moving on.[128]

102. If Health Canada began moving forward with the application today, all that would need to be done is to seek approval from the Section Head, Manager, and Director, and then the decision maker would be able to make a decision.[129] The Respondent's affiant stated that the longest this would take is a month, if every one of these steps took the longest they could.[130]

103. The Respondent's affiant admitted, however, that she was being very conservative in her estimate – she was trying to "give a longer rather than a short time period".[131] In reality, the average time for approval of non-terminal patients, from start to finish, was 21.6 days, and some requests have made their way through all seven stages in just one day. Given that the Applicant's file is very near the end of the process, it would not be difficult for the Minister to render a decision within 5 days.

104. As a final consideration, the delay that the Applicant has already experienced must be noted. He submitted his application more than 230 days ago, at the time of writing, and he should not be forced to suffer any longer than absolutely necessary.

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[126] Chenard Transcript, **AR, Vol 1, Tab 7, p 380, line 22 to 382, line 15**.
[127] Chenard Transcript, **AR, Vol 1, Tab 7, p 382, lines 21-24**.
[128] Chenard Transcript, **AR, Vol 1, Tab 7, p 395, lines 13-16**.
[129] Chenard Transcript, **AR, Vol 1, Tab 7, p 382, lines 11-15**.
[130] Chenard Transcript, **AR, Vol 1, Tab 7, p 403, lines 1-4.**
[131] Chenard Transcript, **AR, Vol 1, Tab 7, p 402, lines 24-25**.

PART IV – ORDER SOUGHT

105. Based on the foregoing, the Applicant seeks the following relief:

a. An order of *mandamus* compelling the Respondent to render a decision on the Applicant's s. 56(1) request within 5 days;
b. The costs of this application; and
c. Such further and other relief as counsel may request and this Honourable Court may permit.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 26 October 2021

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PART V – LIST OF AUTHORITIES

Legislation

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

2. *Controlled Drugs and Substances Act*, SC 1996, c 19

Jurisprudence

3. *Apotex Inc v Canada (Attorney General)*, [1994] 1 FC 742, 69 FTR 152

4. *Apotex Inc v Canada (Attorney General)*, [1994] 3 SCR 1100, 176 NR 1

5. *Canada (Attorney General) v Bedford*, 2013 SCC 72, [2013] 3 SCR 1101

6. *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44, [2011] 3 SCR 134

7. *Canada (Health) v The Winning Combination Inc*, 2017 FCA 101

8. *R v Parker*, 49 OR (3d) 481, 188 DLR (4th) 385

9. *R v Woolsey*, 2018 BCPC 4, 405 CRR (2d) 292