

**FEDERAL COURT**

BETWEEN:

TRUEHOPE NUTRITIONAL SUPPORT LIMITED, and DAVID HARDY

Applicants

- and -

THE ATTORNEY GENERAL OF CANADA and  
THE MINISTER OF HEALTH OF CANADA

Respondents

**FORM 69 Rule 69**

**NOTICE OF CONSTITUTIONAL QUESTION**

The Applicants, Truehope Nutritional Support Limited and David Hardy, intend to question the constitutional validity of subparagraph 23(1)(d) and section 26 of the *Food and Drugs Act*, R.S. 1985, c. F-27 (the "Act"). The Applicants maintain that subparagraph 23(1)(d) and section 26 of the Act violate sections 7 and 8 of the *Canadian Charter of Rights and Freedoms* (the "Charter"). Further, the Applicants maintain that the violations are not saved by section 1 of the *Charter*.

The question is to be argued on Monday the 2nd day of November, 2009, at 9:30 in the forenoon for a duration of fifteen (15) days. The hearing will take place at 635 - 8th Avenue S.W., 3rd Floor, in the City of Calgary, Alberta.

**The following are the material facts giving rise to the constitutional question:**

1. Subparagraph 23(1)(d) of the Act permits an inspector to seize articles such as drugs if the inspector believes on reasonable grounds any provision of the Act or the Regulations has been contravened. This subparagraph also authorizes the detention of detained items "for such time as may be necessary".

2. Section 26 of the Act compels an inspector who has seized an article to release it only when he/she is satisfied that all the provisions of the Act and Regulations have been complied with.

3. The Applicant Truehope Nutritional Support Limited ("Truehope") is a non-profit organization incorporated in Alberta. Truehope is involved with a natural health product called Empowerplus and provides support for Empowerplus users.

4. On or about April 22, 2003, the Respondents seized and detained 72 bottles of Empowerplus. These bottles were part of a shipment from the United States dated April 17, 2003 (the "April 17, 2003 shipment"). This detention is still ongoing.

5. On or about May 21, 2003, the Respondents seized and temporarily detained 57 bottles of Empowerplus. These bottles were part of a shipment from the United States dated May 16, 2003 (the "May 16, 2003 shipment"). This shipment was released by the Respondents on or about May 26, 2003.

6. The Applicant David Hardy ("Hardy") resides in Raymond, Alberta. Hardy is the President of Truehope, a creator of Empowerplus, and a proponent of the benefits of Empowerplus. Hardy purchased an order of Empowerplus which was shipped as part of the April 17, 2003 shipment. The product was intended for use by his family members but was seized and detained by the Respondents.

7. Empowerplus is manufactured in the United States. Individuals who choose this product and live in Canada import it from the United States. Empowerplus has a NAFTA harmonization number for vitamins and minerals.

8. Empowerplus is a natural health product made up principally of vitamins and minerals. Research supports its use as a treatment for nutritional deficiencies including mental conditions and illnesses associated with nutritional deficiencies such as bipolar disorder.

9. In addition, Truehope provides free educational, psychological, and

individual support to users of Empowerplus through its "participant support program," which includes regular consultations with purchasers of Empowerplus (the "Truehope Program").

10. Empowerplus is only available for sale in Canada through the Truehope Program. Canadians who join the Truehope Program can order Empowerplus which is then shipped from the United States.

11. Empowerplus is shipped from the U.S. through UPS and is separately delivered to each purchaser. Each order of Empowerplus is placed into a separate box for each purchaser. Each box is individually addressed to the purchaser's residence or designated point of delivery. Each delivery is made separately to individual purchasers by UPS. Each consignee is given a specific UPS tracking number and an individual invoice recording the particular transaction.

12. In the shipping process, individual boxes are shrink wrapped onto pallets for ease of transport and to reduce brokerage fees at customs. In 2003 a master invoice was produced for each pallet and was sent to Kaylene Titcomb, an employee of United Parcel Services. Ms. Titcomb was named as the recipient of a box of documents summarizing the individual consignments and deliveries. She did not receive any quantity of the product Empowerplus.

13. The Respondent Minister of Health has the responsibility for compliance with and enforcement of the Act and Regulations enacted pursuant to the Act. This responsibility is discharged on a day-to-day basis by Health Canada, including the Health Products and Food Branch Inspectorate ("HPFB Inspectorate") which is an arm of the Health Products and Food Branch of Health Canada. The Respondent Minister of Health is responsible for decisions taken by Health Canada, its branches and the HPFB Inspectorate.

14. The April 17, 2003 shipment was initially seized on or about April 22, 2003 when purchasers and consignees of the product informed Truehope of the failure of delivery. Truehope inquired of UPS and was informally told that the goods had been seized and detained by Health Canada. Truehope received a letter from the

HPFB, dated April 28, 2003, announcing the seizure and detention.

15. While the HPFB Inspectorate continued to deal with various shipments of Empowerplus, on or about May 21, 2003, the HPFB Inspectorate directed the seizure of the May 16, 2003 shipment. This shipment was later released on or about May 26, 2003.

16. In the Notice of Seizure for the April 17, 2003 shipment, the HPFB Inspectorate purported to act pursuant to Section 9(1), 9(2) and 23 of the Act and sections A.01.040 and C.01014 of the *Food and Drug Regulations*. The HPFB Inspectorate continues to hold the goods from the April 17, 2003 shipment, purportedly under the authority of Section 26 of the Act.

17. Empowerplus is now classed as a Natural Health Product under the Regulations. The Natural Health Product class was created on January 1, 2004, when the *Natural Health Product Regulations*, SOR/2003-196 came into force. Empowerplus has received a licence from Health Canada pursuant to these Regulations.

18. The Natural Health Product Regulations were enacted because most Natural Health Products could not comply with the previous regulations. At the time of the seizures there were 40,000 to 50,000 different Natural Health Products being sold in Canada. Most of the Natural Health Products sold in Canada at the time of the seizures did not comply with the regulations.

19. The seizures were part of a wider enforcement initiative to stop all sales of Empowerplus in Canada (the "Enforcement Initiative"). The Enforcement Initiative included: issuing public warnings; conducting a search of Truehope's business premises; shutting down a clinical trial at the University of Calgary; seizing items from Truehope; advising Customs to deny entry into Canada of shipments of Empowerplus, and charging Truehope under the Act.

20. The Enforcement Initiative was not uniform. Shipments to members of the Canadian Mental Health Association (the "CMHA") that were seized as part of the Enforcement Initiative were allowed into Canada whenever the CMHA asked the

Minister of Health to permit those shipments.

21. In March 2004, the Minister of Health agreed to permit the importation of Empowerplus under certain conditions.

22. The charges under the Enforcement Initiative ended with most of the charges being stayed and Truehope being acquitted of the charge that proceeded. Truehope was acquitted because the Court found it was necessary for Truehope to continue selling Empowerplus to prevent deaths and hospitalizations. The Court also commented that Truehope may have been criminally negligent if it had stopped selling Empowerplus.

23. As a result of the seizures, other users of Empowerplus were deprived of access and secure access to Empowerplus, which product provides the nutritional balance for their health and alleviates the symptoms of their mental conditions. Their health and mental well-being were severely compromised by the seizures and they feared uncertainty in future supply.

24. As a result of the seizures, Hardy was deprived of access and secure access to Empowerplus, which provides the nutritional balance for his family members, some of whom suffer from mental illness.

25. As a result of the seizures, Hardy and other users of Empowerplus suffered serious psychological stress.

26. As a result of the seizures, the physical and/or mental health of Hardy and other users of Empowerplus was put in jeopardy.

27. As a result of the seizures and the Enforcement Initiative the seizures were a part of, many otherwise law-abiding Canadians began smuggling Empowerplus into Canada to protect their health or the health of family members.

28. Section 23 permits an inspector to enter any place where the inspector believes on reasonable grounds any article to which the Act or Regulations apply is manufactured, prepared, preserved, packaged or stored and then grants the

powers outlined in subsections (a) and (d). In this case the inspector made no entry and the product was seized and detained when it was at the United Parcel Service Facility, after it had been shipped.

29. The product was seized and detained without written notice to the owners/purchasers of the product.

30. The seizures were the result of unfair, arbitrary, biased and discriminatory enforcement decisions. Such decisions were also inconsistent with the stated policy of Health Canada on many matters including Ministerial statements and Health Canada directives in relation to natural health products, special measures for drug identification numbers, and personal use exceptions.

31. The prohibition in section A.01.040 of the Regulations only applies when the goods are imported into Canada for sale. The Empowerplus product seized and detained was ordered by individuals for their personal use.

32. The application of section 23 of the Act insofar as it is interpreted to apply to the import of Empowerplus, infringes the guarantee against unreasonable search and seizure in section 8 of the *Charter*, which cannot be saved under section 1 of the *Charter*.

33. Section 23 of the Act permits search and seizure without a warrant, is too broad and unrestrained and cannot be read in such a way as to limit its scope. The seizures under section 23 of the Act and the holding of products under section 26 of the Act infringe the guarantee against unreasonable search and seizure in section 8 of the *Charter*, which cannot be saved under section 1 of the *Charter*.

34. Section 23 of the Act permits inspectors to seize and detain any article in relation to which the inspector believes on reasonable grounds any provision of the Act or the Regulations has been contravened. Under section 23 drugs, Natural Health Products or medical devices that individuals rely upon for their health or very lives can be seized without any regard to the health consequences of making the seizure.

35. When making a seizure under section 23 of the Act, an inspector is not required to balance the potential health risk of the seizure against the severity or lack of severity of the alleged violation of the Act and/or Regulations which would permit the seizure under section 23.

36. Seizures under section 23 of the Act of drugs, Natural Health Products and medical devices that individuals rely upon for their health or very lives are made by inspectors who may not have medical training and therefore may not be qualified to assess the health risks of the seizures.

37. Seizures under section 23 of the Act have the effect of removing drugs, Natural Health Products or medical devices from individuals that rely upon them for their health or very lives. Such seizures deny individuals:

- (a) sovereignty over their own bodies;
- (b) the right to treatments of their choice;
- (c) access to effective treatments, and
- (d) the right not to have effective treatments removed without a consideration of the health risks of removing the treatments.

38. A person whose health or very life depends upon a drug, Natural Health Product or medical device that has been seized under section 23 of the Act has no recourse under the Act or Regulations to review or to contest the seizure.

39. The purpose and the effect of sections 23 and 26 is to allow inspectors who may not be qualified to make health decisions, to take away drugs, Natural Health Products or medical devices from individuals whose health or very life depends upon the drug, Natural Health Product or medical device.

40. There is no time limit for seizures under section 23 of the Act. The inspector can detain "for such time as may be necessary".

41. Section 26 mandates when an inspector has to release items seized under section 23. Under section 26, an Inspector is only obligated to release seized items when the inspector is satisfied that all the provisions of the Act and

Regulations have been complied with. Under section 26 of the Act inspectors are not obligated to release items seized under section 23 as long as the inspector believes that any provision of the Act or the Regulations is being contravened.

42. Under section 26 of the Act drugs, Natural Health Products or medical devices that individuals rely upon for their health or very lives can be detained without any regard to the health consequences of making the detention.

43. Under section 26 of the Act, an inspector is not required to balance the potential health risk of the detention against the severity or lack of severity of the alleged violation of the Act and/or Regulations which would permit the detention under sections 23 and 26.

44. Decisions to continue to detain under section 26 of the Act of drugs, Natural Health Products and medical devices that individuals rely upon for their health or very lives are made by inspectors who may not have medical training and who may not be qualified to assess the health risks of the detentions.

45. There is no requirement for seizures under section 23 of the Act or detentions under s. 26 of the Act to be reported to a Justice of the Peace or to any other person.

46. There is no mechanism in the Act or Regulations for any review of a seizure under section 23 of the Act.

47. There is no mechanism in the Act or Regulations for any review of a detention under sections 23 or 26 of the Act.

48. There is nothing in the Act or Regulations compelling the Minister of Health to release drugs, Natural Health Products or medical devices seized under section 23 of the Act that are essential for physical or mental health.

49. Sections 23 and 26 of the Act violate the right to life liberty and security of the person guaranteed in s. 7 of the Charter.

50. Seizures under section 23 of the Act, including the seizures forming the subject of this Application, are not in accordance with the principles of fundamental justice.

51. Section 26 of the Act which only requires release when an Inspector is satisfied that the Act and Regulations are fully complied with permits the continued detention of items seized under section 23 of the Act in a manner that is not consistent with the principles of fundamental justice.

52. Searches and seizures under section 23 are made without a warrant.

53. Searches and seizures under section 23 of the Act are without any prior authorization of any kind.

54. Under section 23 the decision to search and seize is made without any evidence under oath to establish that an offence has been committed or that evidence will be found at the place of the search.

55. Section 23 permits inspectors to seize without a warrant any property in relation to which the inspector believes on reasonable grounds an offence has occurred, without regard to:

- (i) the nature of the property;
- (ii) the nature of the alleged offence;
- (iii) the effect the seizure of the property will have on a person, a family or a business, or
- (ii) the reasonableness or unreasonableness of the seizure.

56. Sections 23 and 26 of the Act permit inspectors to seize and detain property without notice to the owner or other persons with rights to the property.

57. Subparagraph 23(1)(d) has been declared to be of no force or effect by the Federal Court of Canada for violating s. 8 of the *Charter*.

58. Sections 23 and 26 of the Act cannot be saved by section 1 of the *Charter*.

**The following is the legal basis for the constitutional questions.**

**I. The Section 7 Violation of both subparagraph 23(1)(d) and section 26.**

59. Section 7 of the *Charter* provides:

"Everyone has the right to life, liberty and security of the person, and the right not to be deprived thereof except in accordance with the principles of fundamental justice."

60. In determining the constitutionality of legislation, a Court must look at both the purpose and the effect of the legislation.

61. There is generally a three stage process for determining whether a section 7 violation has occurred.

**The first question** to be resolved is whether there exists a real or imminent deprivation of life, liberty, security of the person, or a combination of these interests.

**The second stage** involves identifying and defining the relevant principle or principles of fundamental justice.

**Finally**, it must be determined whether the deprivation has occurred in accordance with the relevant principle or principles.

Where a deprivation of life, liberty, or security of the person has occurred or will imminently occur in a manner which does not accord with the principles of fundamental justice, a s. 7 infringement is made out.

62. **The first question:** based on the material facts above, there been a real or imminent deprivation of life, liberty or the security of the person or a combination of these interests for both Hardy and others.

63. The physical and mental health of Hardy and others was put at risk by the seizures and detentions.

64. The liberty of Hardy and others was put at risk due to the possibility of jail for providing a product that Canadians depended on for their health.

65. The seizures took away the right of Hardy and others to make personal health decisions. This engaged the liberty interest of Hardy and others. The right to liberty protected by s. 7 includes the right to make health decisions without interference from the State. Health decisions are decisions of fundamental personal importance.

66. The section 7 protection of "security of the person" also includes the right to choice of treatment. The seizures had both the purpose and the effect of denying Hardy and others of the right to choice of treatment.

67. The section 7 right to security of the person includes the right to be free from state interference with both bodily integrity and serious state-imposed psychological stress. The seizures interfered with the right of Hardy and others to be free from state interference with bodily integrity. The seizures interfered with the right of Hardy and others to be free from serious state-imposed psychological stress.

68. The purpose of the seizures was to deny Hardy and others access to Empowerplus, a health product that they or family members relied upon for their physical and mental health.

69. **The second question:** identifying and defining the relevant principle or principles of fundamental justice.

70. There are three rules to identifying principles of fundamental justice. They are:

- (1) they must be legal principles;
- (2) they must be capable of being identified with some precision and applied to situations in a manner which yields an understandable result;
- (3) there must be consensus that they are vital or fundamental to our societal notion of justice.

71. When trying to identify principles of fundamental justice concerning health:

- (1) it is not enough to look at the history of the law. The rationale behind the law has to be examined;
- (2) in arriving at the principles the Court must balance the interests of the State and the interests of the individual. Where the violation of the individual's s. 7 rights does little to enhance the State's interest, a breach of fundamental justice is made out;
- (3) in balancing the interests of the State and of the individual, the risk of side effects or increased risk to the individual if forced by the State to turn to other treatments must be considered;
- (4) if the law causes illegal behaviour in that persons must break the law to protect their health, then the law violates the principles of fundamental justice;
- (5) the rationale behind the defence of necessity applies to whether denying access to a health product people depend upon for their health is antithetical to our notions of justice;
- (6) the State's interest in regulating the use of new drugs cannot override the individuals interest in health products that they depend upon for life and health.

72. When considering what principles of fundamental justice exist where the criminal law intersects with medical treatment, the Courts have determined the following:

- (1) there is a consensus that it is a fundamental principle that human life must be respected;
- (2) The principles of fundamental justice are breached where the deprivation of the right in question does little or nothing to enhance the state's interest;
- (3) A blanket prohibition will be considered arbitrary or unfair and thus in breach of the principles of fundamental justice if it is unrelated to the state's interest in enacting the prohibition, and if it lacks a foundation in the legal tradition and societal beliefs that are said to be represented by the prohibition;

- (4) The absence of a clear legal standard may contribute to a violation of fundamental justice;
- (5) If a statutory defence contains so many potential barriers to its own operation that the defence it creates will in many circumstances be practically unavailable to persons who would prima facie qualify for the defence, it will be found to violate the principles of fundamental justice;
- (6) An administrative structure made up of unnecessary rules, which result in an additional risk to the health of the person, is manifestly unfair and does not conform to the principles of fundamental justice.

73. The rules of natural justice apply to determining whether a Charter violation is in accordance with the principles of fundamental justice.

74. This case presents a factual pattern that has not been considered by any Court. Applying the principles above, the Court will also have to consider:

- (1) whether it is vital to a system of justice for the Respondents to take away products people rely on for their health without:
  - (a) considering the health risk of removing the products, and
  - (b) a review mechanism to challenge the seizure and detention;
- (2) whether it is vital to our system of justice for persons with no health training to be making decisions that directly impact upon health;
- (3) whether the State has the right to have effective treatments removed without compelling reasons to justify the removal;
- (4) whether the State has the right to detain essential health products indefinitely without any review or judicial oversight;
- (5) whether the risk of removing Empowerplus exceeded the risk of leaving it on the market (this is the balancing of the individual and State interests);
- (6) whether the seizure and detention powers which violate s. 8 of the Charter can be considered to be in accordance with the principles of fundamental justice;

- (7) whether the seizure and detention powers which violate the principles of procedural fairness can be considered to be in accordance with the principles of fundamental justice;
- (8) whether the seizures and detention violated the criminal negligence provisions of the *Criminal Code* R.S.C. 1985 c. C-46;
- (9) if the seizures and detention were criminally negligent, whether they could be considered to be in accordance with the principles of fundamental justice.

75. **The third question:** whether the deprivation of life, liberty or the security of the person has occurred in accordance with the relevant principles of fundamental justice.

76. Based on the material facts set out above, the deprivation of life, liberty and the security of the person has not occurred in accordance with the principles of fundamental justice.

77. Both the purpose and the effect of subparagraph 23(1)(d) violate s. 7.

78. Both the purpose and the effect of section 26 violate s. 7.

## **II. The Section 8 Violation of both subparagraph 23(1)(d) and section 26.**

79. Section 8 of the *Charter* provides:

"Everyone has the right to be free from unreasonable search and seizure".

80. For seizures that are characterized as criminal in nature, the following three conditions must be met for a seizure power to comply with s. 8:

- (1) a search warrant, or other authorization, must be obtained in advance of the search;
- (2) the warrant or other authorization must be issued by a person who

- is capable of acting judicially, and
- (3) the issuance of a warrant or other authorization must be based upon an objective standard, and not merely the subjectivity of individual adjudicators.

(the "Hunter Requirements").

81. Seizure powers that are administrative may not need to comply with the Hunter Requirements.

82. If there are two common themes to seizures that have been classed as "administrative" by the Courts, they are:

- (1) administrative seizures are limited to information gathering only as opposed to the seizure of private property (which with the exception of taking samples for analysis are almost always classed as criminal), and
- (2) the information being gathered is for administrative purposes, as opposed to confirming that an offence has occurred (which would be a criminal purpose).

83. There are at least two clear themes Courts have used to classify seizures as criminal. Seizures are criminal if either:

- (1) private property is seized (with the exceptions of: (a) taking samples for analysis or (b) emergencies), or
- (2) the property is seized because it is believed that an offence has been committed in relation to that property.

84. Even if a seizure power is administrative, once an inspector under a regulatory regime possesses reasonable grounds to believe that an offence has been committed, a threshold is crossed and the Hunter Requirements need to be met (see *R. v. Inco Ltd.*, [2001] O.J. No. 2098 (C.A.)).

85. The threshold set out in *Inco Ltd.*, is written into s. 23(1)(d) of the *Food and*

*Drugs Act*. Subparagraph 23(1)(d) only allows the seizure and detention of articles "which the inspector believes on reasonable grounds any provisions of this Act or the regulations have been contravened." Because the subparagraph crosses the threshold at which the Hunter Requirements apply, the section cannot be in compliance with s. 8 as none of the three minimum Hunter Requirements are met.

86. In the case at bar, the seizures were made because the inspectors believed that an offence was occurring. Even if subparagraph 23(1)(d) was administrative, once the inspectors believed an offence was occurring, it would not apply and the Hunter Requirements would have to be met. They were not met rendering the actual seizures in violation of s. 8.

87. The seizures were part of the Enforcement Initiative which can only be described as a criminal as opposed to an administrative process.

88. In this case there was not an emergency, nor was the seizure in a public place.

89. The seizure power in subparagraph 23(1)(d) and the detention power in s. 26, are linked. Both depend upon an inspector's belief in an offence. This makes it clear the powers are criminal and not administrative.

90. The *Act* is a criminal law act. The Federal Government does not have jurisdiction over foods, drugs or cosmetics. Rather the Federal Government is exercising its criminal law power. The seizure and detention powers are criminal and not administrative powers.

91. Both the seizure and detention powers are predicated solely upon whether there has been an offence, regardless of whether it is serious or minor. The fact that actual health concerns are not to be considered strongly suggests that the powers are criminal in nature as opposed to administrative. If they were supposed to protect health then health would be a consideration.

92. The seizure and detention powers do not require any judicial oversight and as a result are unreasonable within the meaning of s. 8.

93. Subparagraph 23(1)(d) permits detention for "such time as may be necessary". Under s. 26 an inspector is only obligated to release when satisfied the Act and Regulations have been complied with. There are no defined time limits. This is unreasonable.

94. When addressing whether a seizure is unreasonable within the meaning of s. 8, the Court must consider whether the harm caused by the seizure is excessive in relation to the harm sought to be avoided by making the seizure.

95. It is not "reasonable" within the meaning of s. 8 of the *Charter* to seize and detain products that people rely upon for their health:

- (1) without any notice;
- (2) without any mechanism to review the seizure and continued detention;
- (3) without balancing the health risk of the seizure and detention against the interest to be served by the seizure and detention;
- (4) without any prior authorization;
- (5) by persons who are not qualified to assess the health risks of the seizure, and/or
- (6) in violation of s. 7 of the Charter.

96. It was unreasonable to risk the health, both mental and physical, of Hardy and others over violations of the Act and Regulations that were normal for natural health products. Most were non-compliant and it was unreasonable to create a health risk by singling Empowerplus out.

97. Once the Court acquitted Truehope of the charge under the Act, and found it was necessary for Truehope to continue selling to prevent deaths and hospitalizations, it was unreasonable for the Respondents to continue to detain the April 17, 2003 shipment.

98. Based on the material facts above, there been an unreasonable search and seizure.

**Summary**

99. Subparagraph 23(1)(d) and section 26 violate both ss. 7 and 8 of the *Charter*. Neither can be saved by section 1 of the *Charter*.

100. The actual searches and seizures violated both ss. 7 and 8 of the *Charter*.

Dated this 9th day of June, 2009.



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