Federal Court		Cour fédérale

Date: 20100120

Docket: T-880-03

Citation: 2010 FC 63

Toronto, Ontario, January 20, 2010

PRESENT: The Honourable Mr. Justice Campbell

BETWEEN:

TRUEHOPE NUTRITIONAL SUPPORT LIMITED AND DAVID HARDY

Applicants

and

THE ATTORNEY GENERAL OF CANADA AND THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] In the present Application, the Applicants challenge the constitutionality of the seizure provisions of the *Food and Drug Act*, R.S., 1985, c. F-27 (*FDA*) as offending Section 7 and Section 8 *Charter* rights.

[2] The Applicant, Mr. David Hardy, is a co-founder and the operating mind of the corporate Applicant TrueHope Nutritional Support Limited (TrueHope). TrueHope manages the production, sale of, and consumer support for a natural health product called EMpowerplus which is promoted

as a treatment for mental illness. The conduct which grounds the constitutional challenge is the seizure of two shipments of EMpowerplus by officials of Health Canada which, under the auspices of the Minister of Health, is the Federal Department responsible for helping Canadians maintain and improve their health.

[3] Section 23 of the *FDA* allows a Health Canada inspector to seize articles which he or she believes, on reasonable grounds, contravene the *FDA* and its regulations at any given point in time (the *FDA Regulations*). Section 26 of the *FDA* allows the detention of articles seized until the inspector who executed the seizure is satisfied that they comply with the *FDA* and the *FDA Regulations*. The seizures of EMpowerplus under review occurred in April and May, 2003, and the product in the April shipment seized has remained in detention since that time.

[4] The seizures are the seminal event in a history of conflict between Mr. Hardy and Health Canada over the sale in Canada of EMpowerplus. In April 2001, Health Canada served notice that TrueHope's conduct of offering the product for sale in Canada is unlawful, and Truehope's refusal to cease the practice resulted in the seizures. At the time of the seizures, hundreds if not thousands of people were dependent on EMpowerplus as a treatment for their poor mental health. Because the seizures were perceived by these users to be a direct threat to secure access of the product, an immediate intensive public informational campaign was launched against Health Canada's enforcement action. The campaign proved to be effective; within a year of the seizures an agreement was reached between TrueHope and Health Canada with respect to the conditions of sale

of EMpowerplus and which resulted in the same access by users to the product that existed prior to the seizures.

[5] Nevertheless, the present Application which was launched immediately after the seizures has been pursued to hearing. The critical relief sought are two declarations: the Section 7 and 8 *Charter* rights of Truehope and Mr. Hardy are infringed by the seizures; and s. 23(1)(d) and s. 26 of the *FDA* infringe Sections 7 and 8 of the *Charter* and are, therefore, of no force and effect. The constitutional challenge to the seizure provisions of the *FDA* is advanced in an effort to reduce the restricted access to health products imposed by the *FDA* and the *FDA Regulations*. While the present Application does not challenge the statutory and regulatory control measures directly, the objective is to reduce their effectiveness by fundamentally altering the provisions used for their enforcement.

[6] The Applicants argue that the seizure provisions of the *FDA* offend Sections 7 and 8 of the *Charter* because the provisions do not provide, before a seizure takes place, statutory access to argue the health risks that will be caused by the seizure. The necessary change to the *FDA* regime is argued to be the introduction of a form of procedural fairness that will provide a measure of judicial control over the enforcement of the *FDA* and the *FDA Regulations*.

[7] Mr. Hardy is not a user of EMpowerplus for a treatment purpose; his purely personal *Charter* challenge is based in his Section 7 right to security being his right to be free from the psychological stress he suffered as a result of the seizures. Thus, to achieve success in introducing

procedural fairness into the seizure process under the *FDA* it is necessary for the Section 7 rights to life, liberty, and security of users of EMpowerplus for a therapeutic purpose to be brought into play. To achieve this result, Counsel for the Applicants argues that Mr. Hardy's personal *Charter* standing in the present Application opens an opportunity to argue that the presently deficient enforcement provisions breach the *Charter* rights of non-Applicant users of EMpowerplus and, thus, they are unconstitutional.

[8] For success, Mr. Hardy's personal *Charter* claim depends on the quality of the evidence on the record, and the argument that *Charter* claims of non-Applicant users can be considered depends on a correct interpretation of the law with respect to standing to bring a *Charter* challenge. For the reasons which follow, I find that the Application fails on both grounds.

[9] At the outset, a preliminary matter requires attention. In the course of oral argument, Counsel for the Respondents argued that a question exists as to whether, because of events which have transpired since the seizures took place, the present Application is moot. However, given that Health Canada concedes that because the product seized in 2003 is still in detention and a live controversy still exists as to whether it should remain in detention, I find that the Application is not moot on any ground.

I. The Factual History Leading to the Present Application

[10] For clarification, in the narrative of these reasons the spelling of EMpowerplus and TrueHope is that used by Mr. Hardy in his affidavit. The spelling and format used by other participants are variable in the documents referred to in these reasons.

[11] The history of the development and marketing of EMpowerplus, and Health Canada's involvement in restricting access to the product, is not contested. However, because the history provides the basis of Mr. Hardy's *Charter* challenge, the major events in his relationship with Health Canada are necessary to state to support the reasons for the final determination of the present Application.

A. *The development of EMpowerplus*

[12] As an animal nutritionist, Mr. Hardy discovered that feeding certain nutrients to pigs helped alleviate their ear and tail biting syndrome. Mr. Hardy observed that certain behaviors in humans such as hyper-irritability as well as symptoms related to bipolar disorder are similar to what he observed in pigs and speculated that if people were given certain nutrients, their symptoms could also be alleviated.

[13] In 1995, Mr. Anthony Stephan, also a co-founder of TrueHope, sought Mr. Hardy's advice about treating the poor mental health of his children: his daughter Autumn was delusional and suicidal, and his son, Joseph suffered from bursts of uncontrollable rage. Given Mr. Hardy's positive experience with treating similar conduct in pigs as a nutrient deficiency, they placed

Autumn and Joseph on a course of off-the- retail-shelf nutrients. The mental health of both improved.

[14] In 1996, the positive experience with using nutrients to help people deal with their mental problems led Mr. Hardy and Mr. Stephan to develop the Quad Program, a treatment protocol of supplement vitamins and mineral nutrients. In 1996, Mr. Hardy and Mr. Stephan incorporated the Synergy Group of Canada Inc. (Synergy) to promote research into the Quad Program and observe its results. A Quad Program study at the University of Lethbridge and the University of Calgary revealed that due to inconsistency in the mineral supplements, people on the protocol faltered. Mr. Hardy and Mr. Stephan sought to improve the Quad Program and did so by developing a single and consistent product, being EMpowerplus.

[15] In 1998, Mr. Hardy's son and daughter started on the Quad program: for his son Landon, it was to treat his schizophrenia and psychotic episodes; and for his daughter, Cherilea, it was to treat postpartum psychosis after having her first child. Both benefited and continue to use EMpowerplus for a therapeutic purpose.

[16] In 1999, Mr. Hardy and Mr. Stephan founded TrueHope as a program to support users of EMpowerplus. An essential feature of the program is that EMpowerplus is only sold to persons who agree to enroll in the TrueHope program and the product is only made available for sale to users enrolled in the program.

[17] The rationale for the management structure developed is that EMpowerplus requires users to reduce or eliminate entirely their intake of psychiatric medication on the belief that the transition from psychiatric medication to EMpowerplus causes symptoms of mental disorders to return temporarily. Because of safety concerns arising from the transition, TrueHope addresses these concerns by helping new users adapt to EMpowerplus through counselling and nutrient management. TrueHope also provides continued support through trained staff to help manage participants and trains psychiatrists and physicians to help their patients adapt to EMpowerplus.

[18] Early development of EMpowerplus took place in the United States in cooperation with American partners. In late 2002, TrueHope moved its support program to Raymond Alberta, and TrueHope's corporate partner Synergy started to be used as a revenue bearing company to manage sales of EMpowerplus. At all times material to the seizures under review, warehousing, and distribution occurred in the United Stated through the Utah firm Pharos DTB LL (Pharos) and manufacturing took place in the United States. However, it is uncontested that EMpowerplus was sold to users in Canada by Synergy through offering the product for sale on the TrueHope website as a treatment for mental disorders.

[19] At the time of the seizures, the selling practice was as follows: Synergy took orders through a toll-free number advertised on TrueHope's website; the orders were relayed to and filled by Pharos; Pharos shipped the orders to Synergy in Canada through United Parcel Service (UPS) as a customs agent; to save shipping costs, many orders were shipped together as a single shipment but

each shipment contained separately-invoiced packages each addressed to TrueHope users; and once in Canada each package was delivered to each user by UPS.

[20] The fact that TrueHope offered EMpowerplus for sale in Canada for the treatment of mental disorders proved to be highly contentious to Health Canada.

B. *Health Canada's enforcement action and TrueHope's response*

[21] It is not contested that, in 2003, Truehope was offering EMpowerplus for sale in Canada through its website without the required Health Canada authorization. It is also not contested that the seizures under review were conducted as a direct result of TrueHope's failure to comply with Health Canada's demand, first made in 2001, that it cease its unauthorized conduct. Therefore, apart from the *Charter* challenge aspect of the present Application, there is no question that Health Canada had sound legal reasons to perform the seizures for breaches of the *FDA* and the *FDA Regulations* as they existed in 2003.

[22] Because the reasons for the seizures are not contested, it is unnecessary to elaborate on the various provisions of the *FDA* and *FDA Regulations* that ground the seizures. Indeed, these provisions are clearly summarised in Health Canada's April 27, 2001 warning letter from Health Canada Inspector Mr. Miles E. Brosseau to Synergy that it was operating in violation of the law:

> Mr. Anthony Stephan
> Synergy Group of Canada, Inc.
> 635 – 2nd Avenue West
> Cardston, Alberta T0K 0K0
>
> Attention: Mr. Stephan

RE: WARNING: Violation of Sections 3(1), 3(2), 9(1), 9(2), C.01.003, C.01.005, C.01.004.1, C.01.014(1), C.01A.004.(1), C.08.002, and C.08.005 of the FOOD AND DRUGS ACT AND REGULATIONS.

It is apparent that the **Synergy Group of Canada Inc.** is **advertising and selling** the **unapproved drug product, "E.M.Power",** through your website at www.truehope.com.

The website solicits participation in a **clinical trial research** and seeks to attract parents of children with mental illness with statements such as **"finding true hope in despair"**. The product is being promoted for the study and treatment of serious disorders such as **anxiety and panic disorder, bipolar affective disorder, fibromyalgia, schizophrenia, attention deficit hyperactive disorder, clinical depression, Tourett's Syndrome**, etc. which are not amenable to self diagnosis or self-monitoring.

The activities of the Synergy Group of Canada Inc. are considered violative of the above noted sections and compliance with the regulatory requirements is necessary.

The sale and advertisement of a drug, and in this case a new drug, prior to receipt of a **Notice of Compliance (NOC)** and a **Drug Identification number (DIN) is in violation of sections C.01.014(1), and C.08.002.**

E.M.Power has not received a DIN or NOC for any of the indications for which it is being sold and advertised and is not properly labelled. Consequently, the false, misleading, and deceptive selling/advertising of this unapproved and improperly labelled drug product is **in violation of sections 9(1), 9(2), C.01.003, C.01.004.01, and C.01.005.**

As well, marketing E.M.Power for diseases that are listed in **Schedule A is a violation of sections 3(1) and 3(2).**

As per section **C.01A.04(1),** no person shall distribute a drug product in Canada without an **establishment licence**.

You were previously advised [by letter dated October 20, 2000] that the Food and Drugs Act and Regulations require that an **Investigational New Drug Submission (IND) be filed for**

evaluation prior to initiating a clinical trial. A **"No Objection Letter"** would be issued, should review of the proposed clinical trial be considered satisfactory. **Failure to submit an IND with respect to the research conducted with E.M. Power is in violation to section C.08.005.**

A copy of definitions, Schedule A, and the violated sections is attached for your reference. It is my recommendation that you disseminate this information to the parties involved (ie. Corporate directors, clinical trial investigators, the manufacturer, and Synergy research assistants).

It is imperative that the sale, distribution, any form of advertising, and research with the product E.M.Power be concluded immediately. I am requesting, by May 31, 2001, your written response confirming that the violative activities have ceased and that the Synergy Group of Canada Inc. will maintain compliance with the Food and Drugs Act and Regulations.

If you have further questions or wish discussion please call […]

[Emphasis in the original]

(Respondents' Record, Vol. 2, p. 382)

[23] The key provisions of the *FDA* mentioned in the April 27, 2001 letter are as follows:

Foods, drugs, cosmetics and devices	*Aliments, drogues, cosmétiques et instruments*
3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A. (2) No person shall sell any food, drug, cosmetic or device (*a*) that is represented by label, or (*b*) that the person advertises to the general Public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical	**3.** (1) Il est interdit de faire, auprès du grand public, la publicité d'un aliment, d'une drogue, d'un cosmétique ou d'un instrument à titre de traitement ou de mesure préventive d'une maladie, d'un désordre ou d'un état physique anormal énumérés à l'annexe A ou à titre de moyen de guérison. (2) Il est interdit de vendre à titre de traitement ou de mesure préventive d'une maladie, d'un désordre ou d'un état

states referred to in Schedule A.	physique anormal énumérés à l'annexe A, ou à titre de moyen de guérison, un aliment, une drogue, un cosmétique ou un instrument : *a*) représenté par une étiquette; *b*) dont la publicité a été faite auprès du grand public par la personne en cause.

[…]

Drugs	*Drogues*
9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. (2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).	**9.** (1) Il est interdit d'étiqueter, d'emballer, de traiter, de préparer ou de vendre une drogue — ou d'en faire la publicité — d'une manière fausse, trompeuse ou mensongère ou susceptible de créer une fausse impression quant à sa nature, sa valeur, sa quantité, sa composition, ses avantages ou sa sûreté. (2) La drogue qui n'est pas étiquetée ou emballée ainsi que l'exigent les règlements ou dont l'étiquetage ou l'emballage n'est pas conforme aux règlements est réputée contrevenir au paragraphe (1)

[24] Health Canada's enforcement powers are provided by s. 23(1) and s. 26 of the *FDA*:

23. (1) Subject to subsection (1.1), an inspector may at any reasonable time enter any place where the inspector believes on reasonable grounds any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged or stored, and may

23. (1) Sous réserve du paragraphe (1.1), l'inspecteur peut, à toute heure convenable, procéder à la visite de tout lieu où, à son avis, sont fabriqués, préparés, conservés, emballés ou emmagasinés des articles visés par la présente loi ou ses règlements. Il peut en outre :

(*a*) examine any such article and take samples thereof, and examine anything that the inspector believes on reasonable grounds is used or capable of being used for that manufacture, preparation, preservation, packaging or storing;

a) examiner ces articles et en prélever des échantillons, et examiner tout objet qui, à son avis, est utilisé — ou susceptible de l'être — pour la fabrication, la préparation, la conservation, l'emballage ou l'emmagasinage de semblables articles;

(*a.1*) enter any conveyance that the inspector believes on reasonable grounds is used to carry any article to which section 6 or 6.1 applies and examine any such article found therein and take samples thereof;

a.1) procéder à la visite de tout moyen de transport qui, à son avis, est utilisé pour le transport d'un article visé par l'article 6 ou 6.1, examiner l'article qui s'y trouve et en prélever des échantillons;

(*b*) open and examine any receptacle or package that the inspector believes on reasonable grounds contains any article to which this Act or the regulations apply;

b) ouvrir tout contenant ou emballage qui, à son avis, contient un article visé par la présente loi ou ses règlements;

(*d*) seize and detain for such time as may be necessary any article by means of or in relation to which the inspector believes on reasonable grounds any provision of this

d) saisir et retenir aussi longtemps que nécessaire tout article qui, à son avis, a servi ou donné lieu à une infraction à la présente loi ou à ses règlements. L'avis de

Act or the regulations has been contravened.	l'inspecteur doit dans tous les cas être fondé sur des motifs raisonnables.
[…]	[…]
26. An inspector who has seized any article under this Part shall release it when he is satisfied that all the provisions of this Act and the regulations with respect thereto have been complied with.	**26.** L'inspecteur, après avoir constaté que les dispositions de la présente loi et de ses règlements applicables à l'article qu'il a saisi en vertu de la présente partie ont été respectées, donne mainlevée de la saisie.

[Emphasis added]

[25] During the course of conduct leading to the present Application, Health Canada also expressed concern about the safety of the composition of EMpowerplus and whether it met the *FDA Regulations*. It is agreed that this concern is not relevant to the present Application.

1. Events leading to the seizures

[26] Health Canada's warning letter of April 27, 2001 was the lead event in an adversarial relationship in which Health Canada attempted to gain TrueHope's compliance, and to which TrueHope objected.

[27] In response to the April 27, 2001 letter, Mr. Hardy and Mr. Stephan contacted Mr. Dennis Shelley and Mr. Rob Neske of Health Canada by teleconference to discuss the issues raised in the letter. As a follow-up to the teleconference, Mr. Hardy and Mr. Stephan sent a letter to Mr. Shelley

dated June 17, 2002 explaining the merit of their activities and expressing the desire "that this letter may be only the beginning of an ongoing dialogue with yourself and others in government who may have an interest in the health and well being of Canadians specifically those who suffer the stigma of mental illness". Attached to the letter were letters of support from over 200 TrueHope participants and letters and articles from psychiatrists outlining the "significant" effects of EMpowerplus on users. However, the fifth page of the letter reads as follows:

> Of course, Synergy – Truehope is not seeking for a product endorsement but rather a clearing of the roadblocks which impede the progress of this critical research. Legislation should never be used as an excuse for extending human suffering to protect the vested interests of a small minority, however powerful that minority might be perceived.
> […]
> We do not feel we should have to heap embarrassment upon the government nor any of its departments in order to obtain the confirmation that we are being heard in this request. Nor do we feel that we should have to stir the ire of thousands of Canadian families who continue to be aggravated with both the government action and inaction in this matter to date.
>
> (Applicants' Record, Vol. 3, p. 705)

[28] Health Canada's response to the June 2002 letter came from Mr. Shelly by letter dated December 4, 2002. Mr. Shelly reaffirmed the continuing *FDA* and *FDA Regulations* violation by Synergy and TrueHope with the statement that "Synergy/Truehope is required to immediately stop all sale, offering for sale, exposing for sale, promotion or advertising of E.M.Power+". The letter concludes by stating that "*FDA* compliance is requested not later than the close of business on December 18, 2002" (Respondents' Record, Vol. 2, p. 390).

[29] Mr. Hardy and Mr. Stephan wrote a responding letter dated December 10, 2002 in which they mention that they had had telephone conversations with Mr. Shelly on December 9th, 10th, and 11th and confirmed that they would attend a meeting with him on January 14, 2003 in the Health Canada office in Burnaby, B.C. They also made the following statements:

> […]
> In light of the content of your letter of December 4, 2002, we reiterate that it is not our desire to violate the law. We find ourselves very confused as we had requested assistance (please see our June 17th letter) from your department as to what would be acceptable, and have received nothing but a cease and desist order. Our efforts to set up a meaningful dialogue with your Minister, requested now three times in writing and with at least a dozen phone calls have like wise [sic] been met with no response. We are, therefore, very happy to be able to meet with you.
>
> In the second paragraph of your letter you indicate that we have a Canadian Website. Please be advised that there is no Canadian website. The website is now operated in the U.S. by a U.S. corporation.
>
> You also claim that we are in breach of the law. As we have explained previously, it is our view that we are not in violation of the Food and Drugs Act. We have provided you with the case law that indicates that we are not involved in selling a product within Sec. 2 of the Food and Drugs Act.
> […]
>
> (Applicants' Record, Vol. 3, p. 932)

[30] Indeed the meeting did take place on January 14, 2003 attended by Messrs. Hardy, Stephan, Shelley, Brosseau, and Ms. Lorill Zandberg who was a TrueHope participant and EMpowerplus user. A report prepared by Miles Brosseau after the meeting explains what was discussed. At the meeting, Mr. Stephan and Mr. Hardy expressed their wishes to be compliant with the *FDA* with respect to the sale of their product but also expressed their frustration over the response Health

Canada gave them to their request for assistance to ensure their compliance. They also expressed concern over the clinical trials on EMpowerplus being "sandbagged". Further, they requested a Ministerial exemption for their product, adding that they have tried communicating with the Minister to this effect but were ignored. Ms. Zandberg attended the meeting to describe her poor experience with prescription psychiatric drugs and how she had improved with using EMpowerplus. There were discussions about the way in which sales of EMpowerplus were transacted. Ms. Zandberg explained that "she paid for the product by cheque written to Synergy" and "Mr. Stephan stated that since November 2002, cheques for the product are written to Synergy Group of Canada" (Respondents' Record, Vol. 2, p. 393).

[31] Health Canada representatives at the meeting requested a specific commitment from Mr. Hardy and Mr. Stephan to comply with the legislation and to stop the sale of the product in Canada. They also made a suggestion that "Synergy / Truehope" move its operations to the United States. At the conclusion of the meeting, Mr. Stephan requested seven to ten days to prepare and submit a plan of action (Respondents' Record, Vol. 2, p. 394).

[32] Following the January 14, 2003 meeting, Mr. Hardy telephoned Mr. Shelley and told him that TrueHope would not be able to comply with the *Regulations*, and that he was frustrated and wanted to write-up what he was thinking. He asked Mr. Shelley if he could send his drafted thoughts to Ottawa to which Mr. Shelley replied he could (Applicants' Record, Vol. 2, para. 91). As a result, the next step in the relationship was Mr. Hardy and Mr. Stephan writing an "Open Letter" to Health Canada on TrueHope letterhead dated March 6, 2003 and addressed to Mr. Neske:

AN OPEN LETTER TO HEALTH CANADA

March 6, 2003

Mr. Rod Neske, Compliance Officer
Health Canada
Health Products and Food Branch Inspectorate
3155 Willingdon Green
Burnaby, BC
V5G 4P2

Dear Mr. Neske,

It appears that our letter for clarification dated June 17, 2002 to Mr. Shelly copied to your Minister and to Director General Phil Waddington (ONHP) was completely ignored since we received no response to it whatsoever. In addition to this, we have sent three letters to your Minister and placed over twenty logged telephone calls to which we have received no reply either.

Nevertheless, further to our January 14, 2003 meeting in Burnaby, B.C. with Mr. Dennis Shelly and Mr. Miles Brosseau of the inspectorate, we provide the attached information.

Mr. Shelly has recognized that the communication with us has not been appropriately handled and has requested that we outline all of our concerns in letter form and forward them to him.

It is with the continuing desire to receive a detailed response to our concerns that we submit them to you.

Sincerely,

Anthony F. Stephan	David L. Hardy
Co- Founder	Co-Founder

XC: The Honourable Anne McLellan, Minister of Health.

ATTACHMENT: 6 PAGES

[The Attachment]

PROLOGUE:

Truehope Nutritional Support Ltd. is an Alberta company which has developed a protocol addressing nutrient deficiencies which are the evident cause of some mental disorders. The efficacy of the protocol is supported by three peer reviewed publications in medical journals, as well as a number of studies awaiting publication. Experiential observation of many doctors worldwide, as well as over 2,500 published studies showing the positive influence of nutrients on mental disorders, also contribute to the weight of scientific evidence supporting the discovery. Truehope offers support to the mentally-ill at no-cost by way of telephone and internet and also provides free nutrients to the mentally-ill who cannot afford them. Over four thousand people in Canada have been touched through the use of this support system. Many of these individuals have been able to find normality and have returned to their families, careers, and educational pursuits. Although the supplement has not worked for all who have taken it, an increasing number of participants are finding total relief from their symptoms.

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1. CURRENT CONDITION: Truehope's seven-year search for answer to the causes of mental disorders and the ensuing independent but parallel scientific research has clearly confirmed that addressing nutritional deficiencies ameliorates symptoms of mental illness [footnotes omitted]. Our results are consistent with a worldwide movement towards treating mental illness with natural remedies, a topic that is drawing much attention in North America (Note: the first ever university conference on the treatment of mental disorders with nutrient supplementation will take place at Harvard University on April 25-27, 2003.)

CONCERN: It's obvious that a government department entrusted with the health of Canadians should be interested in fostering, expediting, and assisting such research so clearly important to the health of Canadians. Instead of investigating and confirming our breakthrough research, Health Canada has criminalized both the efforts of Truehope and the University researchers. An Alberta Government funded double blind study has been shut down at the University of Calgary and Truehope has been issued a cease and desist order. Health Canada employees have shown their bias as demonstrated in comments while turning back university clinical trial

applications and within their own internal communications referring to us as “TRUEDOPE” for example. Health Canada has further violated the privacy rights of Truehope and its founders by releasing confidential information to parties outside of Truehope, without due process under access to information legislation. Is Health Canada really concerned with improving the access to health for all Canadians? Are they appropriately respectful of academic freedom in Canada as well as the rights of Canadian citizens?

2. CURRENT CONDITION: Health Canada has issued a cease and desist order against Truehope which effectively denies to every Canadian the access to our supplement.

CONCERN: For hundreds of Canadians who have found restored mental health through the Truehope program, this action denies them their right to health as guaranteed by the Charter of Human Rights. Such action forces these individuals back onto [sic] less effective and more dangerous medications (medications that are clearly addictive or which dramatically increase the risk of cancer or liver or kidney failure for example. See CONCERN #7). Does this seem to be a responsible action by those entrusted with the responsibility to ensure the health of Canadians?

3. CURRENT CONDITION: Health Canada is using Schedule “A” and Section 3(1) and 3(2) of the outdated Food and Drugs Act to eliminate alternative treatments that effectively alleviate various health concerns.

CONCERN: Over a million consumers across Canada sent a strong message to government in 1997, making it clear such legislation as Schedule “A” and Section 3(1) and 3(2) of the antiquated Food and Drugs Act could no longer be used to deny Canadians health freedom or relegate foods to a drug status. The government responded in November of 1998 by setting up the Standing Committee on Health which sought input from citizens across Canada before bringing forward 53 recommendations for change. These recommendations were tabled in the House of Commons and accepted on March 26, 1999 by the Minister of Health, the Honorable Allan Rock on behalf of Parliament [footnote omitted]. Further to that process the government set up the Office of Natural Health Products Transition Team (a committee of experts formed from Health Canada, consumers and consumer groups) and accepted their clarification and expansion of the 53 recommendations as

submitted in their March 31, 2000 report [footnote omitted]. One important segment of the Transition Team report reads as follows:

Natural Health Products: A New Vision
Section 3 and Schedule A (As They Currently Stand)
3(1) "No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases or disorders or abnormal physical states referred to in Schedule A."

3(2) "No person shall sell any food, drug, cosmetic or device
(a) that is represented by label, or
(b) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A."

In Response to the above quoted section of the act the Transition Team comments:

"Sections 3(1) and 3(2) and Schedule A of the Food and Drugs Act are no longer relevant. They do not serve any purpose that cannot be accomplished adequately by other sections of the legislation or regulations.

More importantly, the schedule does not reflect contemporary scientific thought. The weight of modern scientific evidence confirms the mitigation and prevention of diseases and disorders listed in Schedule A through the judicious use of NHPs. It is time that the legislation and regulations reflect the prevailing science.

Section 30(1) (m) of the Act grants the authority to add anything to, or delete anything from, the Schedules of the Act.

The Transition Team recommends that:
Section 30(1) of the Food and Drugs Act should be invoked to remove all diseases listed in Schedule A; sections 3(1) and 3(2) should be revoked through the Legislative Renewal Initiative."

Health Canada was then charged with the responsibility to translate these recommendations from the Transition Team report into law in Gazette1 submitted Dec 22, 2001 and in Gazette 2 due by June 22, 2003. Glaring omissions in Gazette 1 such as the recommended elimination of Schedule "A" and Sections 3(1) and 3(2) of the act and Health Canada's sudden renewed attempts to enforce selectively

and unfairly these sections clearly demonstrate their abrogation of the spirit and intent of the aforementioned recommendations. Indeed it is difficult to not see this as an attempt on the part of certain civil servants within Health Canada to become a law unto themselves, ignoring the will of Canadians by implementing their own agenda in contempt of parliamentary process. Their actions certainly fly in the face of the stated intent of Parliament and once again are raising the ire of consumer groups across Canada. Does Health Canada know something more about the intent of government in this issue than we are being told?

4. CURRENT CONDITION: Health Canada is imposing sanctions against those who speak the truth about the effectiveness of nutrient supplements and other alternative health remedies.

CONCERN: True statements made about the efficacy of treatments other than pharmaceuticals but which clearly are supported by the weight of scientific evidence are within every Canadian's right of expression according to constitutional law. Health Canada is acting out of synch with the constitutional guarantee allowing "freedom of thought, belief, opinion, and expression including freedom of the press and other media of communication" [footnotes omitted]. Isn't it time that we hold such rights (outlined in the Canadian Bill of Rights and the Canadian Charter of Rights and Freedoms) inviolable and amend all old legislation to so conform [footnote omitted]? In relation to a similar constitutional consideration, if it's deemed unconstitutional to deny Canadians the right to use marijuana (a controlled substance) for medicinal purposes, why would Health Canada deny Canadians the right to use vitamins and minerals for the same purpose? [footnotes omitted]

5. CURRENT CONDITION: Health Canada sustains the indefensible position of allowing products to be sold into Canada without DIN numbers under NAFTA but denies Canadians the right to produce or sell these same products in Canada.

CONCERN: Such action is a slap in the face to Canadians who experience this as a clear attempt to legislate an unfair trade practice, allowing foreign vendors to rob Canadian business. Many of the products banned in Canada for sale are sold in supermarkets in the U.S. The fact that these products are imported into Canada for personal use says that there is no health concern, but rather Health Canada is involved in a discriminatory trade practice outside of its stated mandate. In addition, the practice of selective enforcement of

this discriminatory regulation is proof that it cannot be administered equitably or fairly. How can Health Canada continue to sustain such a policy?

6. CURRENT CONDITION: Health Canada is making it difficult if not impossible for academic research to proceed in Canada on products for which there are no health concerns.

CONCERN: Health Canada is in contempt of the constitutional rights of Canadians by blocking academic freedom in research and the potential benefit of the research to the health and well being of all Canadians. They have successfully terminated a double blind study, using minerals and vitamins, at the University of Calgary which was showing impressive benefits of nutritional supplementation in the alleviation of psychiatric disorders. Further, they have held up that research for over a year and a half. Their attempts to muzzle efforts to educate the public on such important findings are another breach of constitutional rights and are a discriminatory practice against the mentally disabled [footnote omitted]. (Section 15 (1) of the Charter specifically states: "Every individual is equal before and under the law and has right to the equal protection and equal benefit of the law without discrimination and, in particular without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability") One must ask why it is Health Canada's agenda to drive such research out of the country when expectation from Canadians would be to foster and expand research showing such promise?

7. CURRENT CONDITION: Health Canada is inadequately informing the public of both the lack of efficacy and of the significant dangers of psychiatric medications.

CONCERN: The above stated reality is the very reason for the existence of Truehope. As we have looked into the current system of treatment of those suffering with mental illness it is little wonder that so many seek help in vain. Hundreds of studies over the past twenty years identify the addictive natures and carcinogenic effects of many medications [footnotes omitted]. (Note: the authors have over **400 studies** that demonstrate the addictive – carcinogenic effects of commonly used psychiatric medications). Health Canada continues to ignore current research identifying these realities, hence, the drugs become a significant part of the problem with many Canadians being put at increased risk by Health Canada's inaction. We advised you of this in our June 17, 2002 letter and no action was taken to reduce

> the risk to Canadians. For a public service body which is supposedly set up to enhance and protect the health and well being of Canadians, this could be viewed as a criminal action or a " Breach of Public Trust" as defined in Section 122 of the Canadian Criminal Code. Does this seem a responsible act by those entrusted with the responsibility to ensure the health and well being of all Canadians?
>
> 8. CURRENT CONDITION: Truehope exists because it is literally fighting for the health and well being of family members of both the co-founders and employees. We have sought clarification in the past on these issues from both Health Canada and the Minister of Health with no response whatsoever other than a cease and desist order.
>
> CONCERN: Who is going to be accountable for the above concerns? Will this letter like all of the other correspondence to Health Canada be ignored? Who is going to face up to the reality of mental health treatment in Canada?
>
> **CONCLUSION**:
> ***In summary it is clear that our work needs to go forward. With evidence in hand, we therefore demand that the unjust cease and desist order issued by you to us be immediately rescinded. More important is a similar demand that you allow research to move ahead unimpeded on our product and every other product like it where there is a well established history of safety. These nutrients are not drugs and we and hundreds of thousands of Canadians demand that you quit treating them as such.***
>
> [Footnote References omitted]
> [Emphasis in original]
>
> (Applicants' Record, Vol. 3, pp. 937 - 943)

[33] In response to the "Open Letter", Mr. Hardy and Mr. Stephan received the following letter from the Executive Assistant to the Minister of Health, Anne McLellan, dated March 26, 2003:

> Mr. Anthony F. Stephan and
> Mr. David L. Hardy
> Co-Founders
> Truehope Nutritional Support Ltd.
> P.O. Box 1254
> Cardston, Alberta T0K 0K0

Dear Mr. Stephan and Mr. Hardy:

On behalf of the Honourable A. Anne McLellan, I wish to acknowledge receipt of correspondence/communication from you and representatives from your company, concerning EM-Power - Truehope and Synergy.

Regulatory compliance and enforcement action is underway with respect to the sale of drugs by your company. Therefore, it is inappropriate for the Minister or any member of the Minister's staff to discuss the concerns you raise. Regulatory decision-making are matters that are delegated to departmental officials. Please note that, as of the date of this letter, any subsequent communication of this nature either by telephone, facsimile, or e-mail will be forwarded directly to the appropriate departmental official for response. No reply from the Minister's office will be provided.

For your reference, I enclose a list of regional officials whom you may wish to correspond with concerning compliance and enforcement actions. I also enclose a list of officials you may wish to contact to obtain information of a general nature regarding market authorizations, establishment licensing, and clinical trials.

Under the *Food and Drugs Act* and Regulations, manufacturers, distributors, and importers of drugs are subject to comply with its requirements. Departmental officials will be pleased to assist you in understanding all regulatory requirements related to your company's products.

Thank you again for writing.

Yours sincerely,

Hilary Geller
Executive Assistant

(Applicants' Record, Vol. 3, p. 944)

[34] Mr. Neske's response to the "Open Letter" is dated April 8, 2003:

Mr Anthony Stephan
Co-Founder
Truehope Nutritional Support Ltd.
P.O. Box 1254
Cardston, Alberta T0K 0K0

WARNING LETTER

Dear Sir:

This is further to your correspondence of March 7, 2003 concerning EMPowerplus formerly known as EM Power Plus and EM Power. Reference in this letter will be made to EM Power and is intended to apply to all the above names.

Synergy/Truehope continue to be in violation of the *Food and Drugs Act* and *Regulations* due to promotional activities being conducted at the Lethbridge office. The activities at the Lethbridge office are considered to be "offering for sale" the product EM Power. "Sell" as defined in the *Food and Drugs Act* includes "offer to sell" and "expose for sale" and does not necessitate possession of any drug product. Please refer to the definition of "sell" in Section 2 of the *Food and Drugs Act*.

E.M.Power is considered to be a drug and a "new drug" as defined by the *Food and Drugs Act* and Division 8 of the *Food and Drug Regulations*. As such, any sale, promotion and advertising of this product prior to obtaining an [sic] Notice of Compliance is a violation of this legislation. Furthermore, E.M.Power, and its suggested dosage, has been reviewed by Health Canada and has been determined to be a Type 2 health risk to Canadians.

Synergy/Truehope must immediately stop all sale, offering for sale, exposing for sale, promotion or advertising E.M. Power to Canadians.

Given that the Action Plan requested at the January 14, 2003 meeting with Mr. D. Shelley explaining how you intend to comply with the *Food and Drugs Act* and *Regulations* has not been received, the Health Products and Food Branch will be undertaking further compliance and enforcement activity in keeping with its mandate under the *Food and Drugs Act*. Unless future correspondence demonstrates clear evidence of compliance with the *Food and Drugs*

> *Act and Regulations*, you should not expect a reply to every future communication received by Health Canada.
>
> Yours truly,
> Rod Neske
> A/Operations Manager
>
> (Respondents' Record, Vol. 2, pp. 396 - 397).

2. <u>The seizures themselves</u>

[35] Two seizures of EMpowerplus are the subject matter of the present Application.

[36] The first seizure was of the April 17, 2003 shipment of 72 bottles of EMpowerplus sent to Canada by Pharos via UPS to fill orders from 22 TrueHope participants. The shipment was accompanied with a Master Invoice and a Consolidated Invoice Detail. The Master Invoice states where the shipment originated, to whom it was sold, to whom it was to be shipped, and details of the total quantity of the product shipped with both the unit value and total value of the products in U.S currency. The Consolidated Invoice Detail is a breakdown of the Master Invoice, with the total quantity of the shipment divided into separate invoices addressed to individual buyers or contacts. Each invoice lists the specific quantity and value of the buyer's order.

[37] The April shipment was evaluated as follows: as the customs agent for Synergy, UPS alerted the Canadian Border Services Agency (CBSA) that the shipment was not in compliance with Canadian laws and regulations including the *FDA*; the CBSA consulted with Health Canada to determine next steps by faxing the Master Invoice and Consolidated Invoice Detail; and, as a result, Mr. Neske recommended that the shipment be seized because " Empowerplus is a drug and the fact

that, in my opinion, it was being imported into Canada for sale" (Respondents' Record, Vol. 2, p. 376).

[38] On April 28, 2003 Mr. Stephan received a faxed letter from Mr. Neske containing this message:

> Re: E.M. Power +
>
> Further to the shipment of 72 bottles of the above named product presently being detained, this shipment will not be released at this time. The product is currently under investigation for importation prohibited under the Food and Drugs Act Regulation A.01.040. We hope to conclude this investigation quickly with your cooperation.
>
> (Applicants' Record, Vol. 3, p. 1034)

Regulation A.01.040 reads as follows:

> Subject to section A.01.044, no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations.

[39] On April 29, 2003, Mr. Hardy and Mr. Stephan wrote to Mr. Neske confirming receipt of his letter:

> Dear Mr. Neske:
>
> We are in receipt of your letter indicating that the shipment of 72 bottles is being detained and will not be released at this time. You have indicated the product is under investigation. This particular shipment has now been detained for eight days, since Tuesday, April 22, 2003.
>
> Please be advised that your actions in detaining this product are jeopardizing the health and lives of those persons who have ordered the vitamin/mineral product EMPOWERPLUS for their personal health. Many of these individuals have suffered with suicidal symptoms in the past and your actions are placing them at risk.

> We wish to advise you that if any harm comes to any of those persons, whose product is being detained that we will seek for CRIMINAL and or CIVIL redress on their behalf against you personally. The Canadian charter of rights and freedoms, sec 7 states: 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. You are effectively denying the rights of life, liberty and security of those suffering with mental illness by detaining the product shipment.
>
> Govern yourself accordingly,
>
> Anthony F. Stephan, Co-Founder — David L. Hardy, Co-Founder
>
> [Emphasis in original]
>
> (Applicants' Record, Vol. 3, p. 1035)

[40] On May 1, 2003, Mr. Neske, received a demand letter from legal counsel retained by Synergy and TrueHope requesting "the immediate release of this unlawfully detained shipment" (Applicants' Record, Vol. 3, p. 1037). In reply, by letter dated May 9, 2003, Mr. Neske outlined Health Canada's lawful conduct with respect to the seizure pursuant to s. 23 and s. 26 of the *FDA* and confirming that the shipment would not be "released immediately" as requested (Applicants' Record, Vol. 3, p. 1039). The April shipment was formally seized on May 8, 2003 by completion of a "Report of Examination for Customs Entry" (Applicants' Record, Vol. 4, p. 1203).

[41] The second seizure was of the May 16, 2003 shipment of 57 bottles of EMpowerplus and three bottles of EMpowerplus powder. While Inspector Sandra Jarvis initially seized this shipment on the same basis as the April shipment, she later released it on her own interpretation of the Master and Consolidated Invoice Detail that the product was not being imported into Canada for sale. As a

result, Ms. Jarvis notified UPS that Health Canada no longer had an objection to importation of the shipment (Respondents' Record, Vol. 2, p. 331).

[42] However, over the next number of months, several shipments of EMpowerplus were deemed to be in violation of the *FDA* and *Regulations*, and, consequently, individuals named on the Consolidated Invoice Detail who ordered the product received a letter notifying them that the shipment was refused entry into Canada (Applicants' Record, Vol. 4, pp. 1043 - 1185).

3. Events subsequent to the seizures

[43] At the time of the seizures there were some 48,000 users of EMpowerplus in 50 countries (Applicants' Record, Vol. 1, p. 26) many of whom were dependent on EMpowerplus as a treatment for a mental disorder. A number of discrete actions were taken for the purpose of pressuring Health Canada to end its restriction on access to the product: users engaged in a massive letter writing and telephone calling campaign to government officials; the support of Member of Parliament, Dr. James Lunney, was solicited to act as an advocate for the users and lobbied government on behalf of the users; and a group of women users called the "Red Umbrellas" publicly declared that, by travelling to Parliament Hill in Ottawa to demonstrate, speak to Members of Parliament, and holding a press conference, their health was being jeopardized

[44] To deal with user telephone complaints, Health Canada set up a 1-800 Crisis Line. According to data produced by Health Canada tracking the calls received by the 1-800 Crisis Line, a

total of some 484 calls were received between June 2, 2003 to June 25, 2003 (Hearing Exhibit No. 1 filed November 10, 2009).

[45] As a result of the actions taken, on March 18, 2004 an "Agreement" was reached between Health Canada and TrueHope to formally allow users then, and now, to import EMpowerplus directly from Pharos in Utah under the "Personal Use Importation Directive" (PUID); orders for personal use are placed directly with Pharos, the money to pay for the orders is transmitted directly to Pharos, and the orders are allowed to come across the border unimpeded. EMpowerplus is available for sale in the United States without restriction. Health Canada takes the position that its mandate is to only restrict sales of the product in Canada in the interest of public safety and it does not have a legal interest in the use of the product if it is lawfully brought into Canada for personal use. However, to enforce the existing restriction of sale of EMpowerplus in Canada, under the PUID only a three-month supply of the product is allowed to be imported.

[46] With respect to access to EMpowerplus, the Agreement has resulted in peace between Health Canada and TrueHope to the present day. There is no evidence that this condition will not continue to be in effect into the future.

II. The User of EMpowerplus Aspect of the *Charter* Challenge

[47] From the early development of EMpowerplus in 1998 to the time of the seizures, TrueHope had achieved a high degree of marketing success: people by the hundreds if not thousands had become dependent on the product for their mental health treatment. It is this group of people that

Mr. Hardy feels responsibility for, and it is this group of people to whom the present Application is intended to serve.

[48] In service of users of EMpowerplus for a therapeutic purpose, an objective of the present Application is to establish that EMpowerplus does treat the underlying mental illness for which it is taken. Mr. Hardy made this admission in the course of examination on his affidavit:

> That's why this case is so significant, because -- either it's true, either we're telling you the truth, which I swear that we are, or -- and this is a major breakthrough and a great benefit to humanity in the future, your kids and my kids; or this is a hoax and needs to be exposed. So I hope this court case does that, but if it is the case, that this is a breakthrough, then we want to see it pushed forward.
>
> (Applicants' Record, Vol. 5, p. 1414)

[49] The Applicants' ultimate objective is to force an amendment to the seizure sections themselves to address the wrong which is described in paragraph 43 of the Notice of Application:

> Seizures under section 23 of the [*FDA*] 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.
>
> (Applicants' Record, Vol. 1, p. 9)

The effect of the wrong in the circumstances of the present Application is described as follows:

> As a result of the seizures, other users of Empowerplus are 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.
>
> 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.
>
> As a result of the seizures, Hardy and other users of Empowerplus suffered serious psychological stress.
>
> As a result of the seizures, the physical and/or mental health of Hardy and other users of Empowerplus was put in jeopardy.
>
> (Applicants' Record, Vol. 1, p. 7, paras. 27 to 31)

The Applicants argue that, to correct the wrong, a due process feature must be introduced into the operation of s. 23 to provide that a judicial hearing be conducted before a vital health product is seized. The object of the hearing would be to provide an opportunity to a user, potentially deprived of a vital health product by the seizure, to make an argument. The argument would be that a health risk will result to him or her if the seizure takes place, and if this argument is well received by the judicial officer conducting the hearing, the seizure would not be allowed. The nature of the hearing that will meet this expectation is proposed to be some form of warrant process either by teleconference or in person (Hearing Transcript, Vol. 13, pp. 3249 – 3272).

[50] As a result, paragraphs 74, 94, and 95 of the Notice of Constitutional Question propose questions with respect to s. 23 and s. 26 as they relate to Section 7 and Section 8 *Charter* rights of the Applicants as well as the Section 7 rights of users of EMpowerplus for a therapeutic purpose. Paragraph 74 reads as follows:

> 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.

Paragraphs 94 and 95 read as follows:

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

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*.

The Applicants argue that answers to these questions in their favour will result in a finding that s. 23 and s.26 are unconstitutional. However, the focus of the argument is on the health risk to users, and the infringement of the life, liberty and security *Charter* rights of users and, therefore, the evidence which will support the argument can only come from users who make a personal *Charter* claim. With respect to the present Application, Mr. Hardy is not a user of EMpowerplus for a therapeutic purpose and, therefore, has no claim to make and no evidence to offer as a user. The success of the argument depends on a determination with respect to the nature of a constitutional challenge launched pursuant to s. 52 of the *Constitution Act, 1982*.

[51] Counsel for the Applicant argues that a claim that a provision is unconstitutional because it breaches a *Charter* right pursuant to s. 52 of the *Constitution Act, 1982* is different in kind to a claim for relief under s. 24 of the *Charter* for breach of a *Charter* right: that is, the former is not a claim for a remedy and, therefore, is not limited by the nature of an Applicant's personal claim. These provisions are as follows:

Enforcement	*Recours*
24. (1) Anyone whose rights or freedoms, as guaranteed by this Charter, have been infringed or denied may apply to a court of competent jurisdiction to obtain such remedy as the court considers appropriate and just in the circumstances.	**24.** (1) Toute personne, victime de violation ou de négation des droits ou libertés qui lui sont garantis par la présente charte, peut s'adresser à un tribunal compétent pour obtenir la réparation que le tribunal estime convenable et juste eu égard aux circonstances.
General	*Dispositions générales*
52. (1) The Constitution of Canada is the supreme law of Canada, and any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect.	**52.** (1) La Constitution du Canada est la loi suprême du Canada; elle rend inopérantes les dispositions incompatibles de toute autre règle de droit.

[52] With respect to this argument there are two issues to address: Mr. Hardy's legal ability to rely on the evidence of users to somehow add to his own personal claim the risk to life or liberty or security of users; and his legal ability to have the *Charter* claims of users considered as a feature of his own personal claim.

A. *The Applicants' argument*

1. <u>The legal ability to add to a personal claim</u>

[53] In written argument, Counsel for the Applicants frames Mr. Hardy's legal ability to add to his own personal claim this way:

> The striking down of legislation affects not only the parties, but the public at large. It is inappropriate to strike down legislation based on a narrow fact pattern specific to the parties in a review, without considering the effect of the decision broadly (see paragraph 181). Similarly, courts must look at both the "purpose" and the "effect" of the legislation in determining its constitutionality (see discussion beginning at paragraph 175). This obligation to consider the broad effect of the legislation dictates a broad review of effects beyond those on the parties.
>
> A fuller discussion of the scope of evidence mandated in this review follows the ss. 7 and 8 analysis. However, in considering the evidence relevant to ss. 7 and 8, it is important to note that it was open to the applicants to lead evidence of the effect of the law on others that is unconnected to the seizures and detentions under review. So for example, the Applicants could have led evidence of seizures with no connection to the Applicants to demonstrate that the "effect" of the law is unconstitutional. It just happened in this case that there was ample evidence of the broad "effect" of the law on others with a factual nexus to the seizures under review. Such a factual nexus is not a requirement for "effect" evidence. The only requirements are that courts should not make constitutional determinations on the effect of legislation without broad "effect" evidence, and there is an obligation on the party seeking to have legislation struck to lead such evidence.
>
> […]
>
> **There is no question there has been an infringement of life liberty or security of the person**. As indicated above, to get past the first hurdle, it is only necessary to show on a balance of probabilities that there has been an infringement of life, liberty **or** security of the person. In this case it is clear that there has been an infringement to life, liberty **and** security of the person. The seizures and detentions were likely to impair health. The right to make fundamental health decisions was clearly interfered with. The right

> of access to a treatment was interfered with. The State's action caused severe psychological stress. The real issue is whether these infringements occurred in accordance with the principles of fundamental justice.
>
> [Emphasis in the original]
>
> (Applicants' Record, Vol. 20, Memorandum of Fact and Law, paras. 111, 112, 124)

Thus, as the argument goes, evidence of the infringement of the right to life, liberty, and security of "others" who are not themselves *Charter* claimants, can be imported into Mr. Hardy's personal right to security *Charter* claim to expand the merit arguments of his claim.

2. <u>The legal ability to allow the *Charter* claims of non-Applicants to be considered</u>

[54] With respect to Mr. Hardy's legal ability to allow the *Charter* claims of users to be considered as a feature of his own personal claim, in oral argument at the hearing of the present Application, Counsel for the Applicants advanced the proposition that, because Mr. Hardy has standing to advance his personal Section 7 challenge, it is possible to use this standing to argue a *Charter* breach of each of the Section 7 rights and the Section 8 right of other persons who are not a party to the present Application. This category of other persons is argued to be: the 21 users of EMpowerplus, apart from Mr. Hardy, who have a property interest in the product seized; three users who have filed affidavits in the present Application attesting to the beneficial effect that the product has had on their mental health and expressing concern for their health if deprived of the product; and all users who relied on the product at the time of the seizures and who complained to Health Canada as part of the campaign to end the enforcement action. This argument is based on a second

proposition: with respect to a constitutional challenge pursuant to s. 52 of the *Constitution Act, 1982*, the effect of the seizures on Mr. Hardy as an Applicant is irrelevant and what is relevant is the effect on the users.

B. *The Respondents' argument*

[55] Counsel for the Respondents argues that there is no difference in kind between a *Charter* claim brought under s. 24 of the *Charter* and one brought under s. 52 of the *Constitution Act, 1982*. Either claim is a claim for relief and the same legal rules with respect to standing and evidence applies. In oral argument, this submission was made:

> We submit the case has to be decided on evidence specific to the parties; that this case falls under the general rule of standing whereby a person alleging infringement of a Charter right has standing to plead that infringement and is limiting to asserting a breach of his own rights. Cases need to be resolved on evidence specific to the parties. The scope is properly limited to the Charter rights of the parties. The failure of a diffuse challenge or a wide-spread challenge could prejudice other challenges to the same rules by parties, which specifically and factually are able to establish complaints. It always must be kept in mind that the evidence heard has to be from -- in relation to the parties most affected by the decision. Someone who is affected who is not a party has no standing, and their complaint cannot be voiced through a party with standing. To do so, it would compromise the need for Charter cases to be decided in a proper factual context.
>
> [Emphasis added]
>
> (Hearing Transcript, Vol. 10, pp. 2326 - 2327)

[56] With respect to the s. 52 arguments under consideration, Counsel for the Respondents' position with respect to both is as follows:

This judicial review is about whether or not the seizure, or the law permitting the seizure, violated the rights of the Applicants. It is not an abstract exercise as to whether or not the seizures, or the law permitting the seizures, might violate:

(a) the rights of others not party to this judicial review;
(b) the rights of others to any natural health product; or,
(c) the rights of others to anything regulated by the *Food and Drugs Act*.

The references to "others" in the Applicants' application and evidence, purporting to show impacts or effects on others, is not relevant to the issues in this proceeding. The impacts or effects on others are not proper contextual elements to consider in the adjudication of the *Charter* claims raised by the Applicants.

As an Applicant, Hardy can not meet his burden of proof of establishing a limit to his own rights without evidence of the effect of the law or action on his own rights. Hardy does not allege that he relies on Empowerplus to treat an illness.

The proper scope of this judicial review is to determine whether or not government actions or legislation violated the Applicants' *Charter* rights. Standing to bring a *Charter* challenge may be granted under four broad heads. First, the general rule is that a party alleging an infringement of their *Charter* rights and freedoms, has standing to plead those *Charter* infringements, but are limited to asserting a breach of their own rights and not those of others.

Second, where a party has been brought involuntarily before the courts, the party may, as of right, challenge the constitutionality of the statute under which the party is being prosecuted: *R.* v. *Big M Drug Mart and Canadian Egg Marketing Association ("CEMA"), infra.* Third, a court may exercise its discretion to grant standing where the test for public interest standing has been met. Fourth, a court may grant standing under a residual discretion in respect of matters of national importance: *CEMA, infra.* Thus while *R.* v. *Big M Drug Mart Ltd.*, and *CEMA, infra,* provide exceptions to the general rule, those exceptions do not apply in this case.

[Case citations omitted]

The requirement of a full and proper evidentiary record in constitutional cases is nonetheless limited to evidence that is relevant

> to the adjudication of the claims before the court. Thus, evidence about the effects of the impugned government actions or legislation on others who are not before the court is not required. The Applicants' evidence - that there was an impact on others in a variety of circumstances, is not relevant to Hardy's and Truehope's claims. On this basis, it is not admissible.
>
> [Case citations omitted]
>
> The issue in this judicial review is about the impact of [Health Canada Inspector] Neske's seizure and detainment [of the April 2003 shipment], pursuant to sections 23(1)(d) and 26 of the *FDA*, on the Applicants. The issue is not about the hypothetical potential impact that a warrantless seizure under section 23(1)(d) may occasion.
>
> In addition, [Health Canada Inspector] Jarvis' initial recommendation to Customs to refuse entry [of the May 2003 shipment] does not implicate the seizure power under section 23(1)(d) of the 2003 FDA or s. 26 of the FDA. There was no seizure in this instance that withheld the product from the Applicants or any other consumer.
>
> [Emphasis in the original]
>
> (Respondents' Record, Vol. 19, pp.127 - 129)

C. *Analysis of the arguments*

[57] As a rule, a *Charter* challenge is only available to a person. However, in *R. v. Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295 (*Big M Drug Mart*) the Supreme Court allowed a criminal law exception to this rule by providing standing to a corporation to maintain a Section 2(a) challenge to the constitutional validity of the legislation which compelled it to Court. In *Big M Drug Mart* the reasoning of Chief Justice Dickson is provided at paragraphs 36 - 41:

> Standing and jurisdiction to challenge the validity of a law pursuant to which one is being prosecuted is the same regardless of whether that challenge is with respect to ss. 91 and 92 of the

Constitution Act, 1867, or with respect to the limits imposed on the legislatures by the Constitution Act, 1982.

Section 24(1) sets out a remedy for individuals (whether real persons or artificial ones such as corporations) whose rights under the *Charter* have been infringed. It is not, however, the only recourse in the face of unconstitutional legislation. Where, as here, the challenge is based on the unconstitutionality of the legislation, recourse to s. 24 is unnecessary and the particular effect on the challenging party is irrelevant.

Section 52 sets out the fundamental principle of constitutional law that the Constitution is supreme. The undoubted corollary to be drawn from this principle is that no one can be convicted of an offence under an unconstitutional law. The respondent did not come to court voluntarily as an interested citizen asking for a prerogative declaration that a statute is unconstitutional. If it had been engaged in such "public interest litigation" it would have had to fulfill the status requirements laid down by this Court in the trilogy of "standing" cases (*Thorson v. Attorney General of Canada*, [1975] 1 S.C.R. 138, *Nova Scotia Board of Censors v. McNeil*, [1976] 2 S.C.R. 265, *Minister of Justice of Canada v. Borowski*, [1981] 2 S.C.R. 575) but that was not the reason for its appearance in Court.

Any accused, whether corporate or individual, may defend a criminal charge by arguing that the law under which the charge is brought is constitutionally invalid. Big M is urging that the law under which it has been charged is inconsistent with s. 2(*a*) of the *Charter* and by reason of s. 52 of the *Constitution Act, 1982*, it is of no force or effect.

Whether a corporation can enjoy or exercise freedom of religion is therefore irrelevant. The respondent is arguing that the legislation is constitutionally invalid because it impairs freedom of religion--if the law impairs freedom of religion it does not matter whether the company can possess religious belief. An accused atheist would be equally entitled to resist a charge under the Act. The only way this question might be relevant would be if s. 2(*a*) were interpreted as limited to protecting only those persons who could prove a genuinely held religious belief. I can see no basis to so limit the breadth of s. 2(*a*) in this case.

> The argument that the respondent, by reason of being a corporation, is incapable of holding religious belief and therefore incapable of claiming rights under s. 2(*a*) of the *Charter*, confuses the nature of this appeal. A law which itself infringes religious freedom is, by that reason alone, inconsistent with s. 2(*a*) of the *Charter* and it matters not whether the accused is a Christian, Jew, Muslim, Hindu, Buddhist, atheist, agnostic or whether an individual or a corporation. It is the nature of the law, not the status of the accused, that is in issue.
> […]
>
> [Emphasis added]

[58] However, the "effect on the challenging party is irrelevant" phrase emphasized in the passage just quoted is the basis of an interpretation argument made by Counsel for the Applicants in response to the Respondents' argument that the *Charter* rights of "others" cannot be brought into the present Application. Counsel for the Applicants gave the following explanation in oral argument:

> And the Applicants' position is, is that the case law is crystal clear. Well, for instance, we have the Applicant Truehope, we have the Applicant David Hardy. And the Applicants are absolutely crystal clear that when you're challenging constitutionality of legislation under Section 52 of the Constitution, and very important, Section 52, and that's -- we've listed that in our Notice of Application, that not only must the Court look at the purpose and effect, but so broadly that it's to look at the purpose and effect of others.
>
> And the reason for that is quite simple, if a party could come before you and show a personal Charter violation and ask the Court to strike down the law as unconstitutional, but the laws have an application to everyone. And so courts are not supposed to strike down laws as unconstitutional under Section 52 without having an appreciation of broad purpose and effect.
>
> Often what happens is some people can bring an application under Section 24 of the Charter, which is a personal thing. They have to show personal violation before the Court can grant a remedy. But

under Section 52 that's not necessary. And so, I'd like the Court to refer to tab 193. Now, this is Big M again. And this is a very important point. So I've just referred to Big M where they said purpose and effect. You need to look at purpose and effect.

And now, this is where, at paragraph 38, the Court is drawing this distinction between when you're seeking relief under Section 24 of the Charter and you're seeking relief under Section 52. So at 38:

> Section 24(1) sets out a remedy for individuals whether real persons or artificial ones, such as corporations, whose rights under the Charter have been infringed, is not, however, the only recourse in the face of unconstitutional legislation, whereas here the challenge is based on the unconstitutionality of the legislation, recourse to Section 24 is unnecessary, and the particular effect on the challenging party is irrelevant.

And I cannot stress this more. So what the Supreme Court of Canada is saying here is, yeah, Section 24 of the Charter, that's an avenue that people have for relief. And usually you're applying to have evidence excluded, it's used in criminal trials all the time, and a lot of my friend's case law, they're Section 24 cases. But it's absolutely crucial for the Court to appreciate what we're applying for here is a declaration under the authority of Section 52 of the Constitution, which is the section that basically says the Constitution is the supreme law of Canada, and any law that is inconsistent with it is of no force and effect. And I do reproduce that in mine.

So the Supreme Court of Canada here is making clear, and I've emphasized it and marked it in red: <u>That when you're challenging the constitutionality of the legislation, recourse of 24 is unnecessary, and the particular effect on challenging party is irrelevant</u>.

So what that means is, is I don't have to show the Court that Mr. Hardy's personal rights were violated. I don't have to show that Truehope's rights were violated. And -- but I can't -- now, this is the case that says you have to show purpose and effect. So when they're saying we have to show the effect, well, they're not talking about the effect on Big M.

Sorry, they carry on in paragraph 39:

> Section 2 sets out the fundamental principle of constitutional law that the constitution is supreme. The undoubted corollary to be drawn from this principle is that no one can be convicted of an offence under an unconstitutional law. The Respondent did not come to Court voluntarily as an interested citizen asking for a prerogative declaration that a statute is unconstitutional.

> Now, this is an early case that began this principle, and everyone agrees back in 1985 when this came out, this only applied to if you were charged. So a corporation could challenge the constitutional validity of legislation if they're charged. This has now been expanded, and I'll show that.

> [Emphasis added]

> (Hearing Transcript, Vol. 3, pp. 760 – 765)

> [...]

> Well if you have to look at the effect and the effect on the challenging party doesn't matter, well, the effect on who then is the obvious question, and it's clear it's the effect on others.

> (Hearing Transcript, Vol. 3, pp. 777 – 778)

[59] I reject this argument. I find that the "effect on the challenging party is irrelevant" phrase has been given a meaning which can only be derived by reading it out of context. The leading words of the passage in which the phrase is stated sets the context; that is, the words "where as here" must be read as referring to the situation being addressed in the case which is, where a person or a corporation is facing a criminal prosecution the personal circumstances of the person or the corporation are irrelevant because the whole focus is on the constitutionality of the law upon which the prosecution is based.

[60] There is no question that where the constitutionality of legislation is in issue, the well established principle that the "purpose" of the legislation must be defined, and the "effect" of legislation challenged on *Charter* grounds must be broadly considered before a determination is made; it is not contested that the effect of the legislation, beyond the effect on the parties, must be considered (see *Big M Drug Mart*, para. 80; *Mackay v. Manitoba*, [1989] 2 S.C.R. 35 at para. 9). Therefore, application of the principle is an evidentiary imperative in determining a constitutionality issue. However, Counsel for the Applicants seeks to somehow extend this evidentiary principle to establish a right of legal standing in a constitutional challenge.

[61] Counsel for the Applicants cites the following cases for the point that, in each, insufficient effect evidence was provided to succeed in a constitutional challenge of the legislation concerned: *Mackay v. Manitoba*, [1989] 2 S.C.R. 357, *R. v. Edwards Books and Art Ltd*., [1986] 2 S.C.R. 713, *Danson v. Ontario (Attorney General)*, [1990] 2 S.C.R. 1086 and *R. v. Rao* (1984), 46 O.R. (2d) 80. The argument arising from these cases as an “expansion” of the ratio in *Big M Drug Mart* is that the principle that sufficient effect evidence must be produced allows the evidence of the effect on “others” to somehow give standing to the “others” to maintain their own personal *Charter* claims in an application to which they are not a party. In my opinion, this is an erroneous use of the principle. The evidentiary principle has nothing whatever to do with the legal principle that standing must be first established before a person can maintain a *Charter* challenge.

[62] The "expansion" argument also relies on what I find to be an unsupportable interpretation of the decisions in *R. v. Parker* (2000), 188 D.L.R. (4th) 385 (Ont.C.A.) (*Parker*) and *R. v. Morgentaler*, [1988] 1 S.C.R. 30 (*Morgentaler*).

[63] In *Parker*, the Ontario Court of Appeal found that: the epileptic defendant, who was charged with possession of marijuana contrary to s. 4 of the *Controlled Drugs and Substance Act*, S.C. 1996, c. 19, used marijuana for medicinal purposes and therefore was forced to choose between a life-threatening health condition and the threat of imprisonment; the marijuana prohibition impaired Parker's Section 7 rights; and the prohibition impaired the rights of others who use marijuana for medicinal purposes. It is this last finding upon which Counsel for the Applicants puts reliance to argue that the decision in *Big M Drug Mart* is expanded to conclude that the "onus under Section 52 is to show *Charter* violations and it can be *Charter* violations of other people and it can be *Charter* violations of yourself" (Hearing Transcript, Vol. 3, p. 787). The finding in *Parker*, read in context, is in paragraphs 77 to 80:

> In the companion case of *R. v. Clay*, I have already dealt with the submission that, broadly speaking, the marihuana prohibition violates s. 7 because it criminalizes people who have done nothing wrong. This case raises the narrower issue of the impact upon individuals claiming a need for marihuana as a matter of medical necessity, not recreational use.
>
> This aspect of the case raises an issue akin to the standing issue that I have touched upon in the *Clay* case. The Crown's approach to this appeal was to try to demonstrate that as a matter of fact Parker did not need marihuana to control his epilepsy. I deal with that issue below. <u>However, it is also open to Parker to challenge the validity of the legislation on the basis that it was overbroad or unconstitutional in some other way in its application to other persons</u>. The Crown respondent appeared to concede this in the Clay appeal. In any event, that conclusion follows from the

> decisions of the Supreme Court of Canada in *R. v. Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295 and *R. v. Morgentaler*. In both cases, the accused were held to have standing to challenge the law under which they were charged although the alleged infringement of the Charter concerned the rights of some other person.
>
> The decision of the Supreme Court of Canada in *Morgentaler* is of particular assistance because the issues in that case were similar to the issues here. The accused physicians relied upon s. 7 of the Charter to challenge a criminal offence based upon the interference with the health of pregnant women seeking abortions. In his dissenting reasons at p. 133, *McIntryre* [sic] J. suggested that the question of the s. 7 violation was hypothetical since, "[t]here is no female person involved in the case who has been denied a therapeutic abortion". However, Dickson C.J.C. was satisfied that the accused physicians had standing. As he said at p. 63:
>
> > As an aside, I should note that the appellants have standing to challenge an unconstitutional law if they are liable to conviction for an offence under that law even though the unconstitutional effects are not directed at the appellants per se: *R. v. Big M Drug Mart Ltd.*, at p. 313. The standing of the appellants was not challenged by the Crown.
>
> Therefore, it is open to Parker to challenge the validity of the marihuana prohibition not only on the basis that it infringes his s. 7 rights because of his particular illness, but that it also infringes the rights of others suffering other illnesses.
>
> [Emphasis added]

In my opinion it is clear that neither *Parker* nor *Morgantaler* expands upon the decision in *Big M Drug Mart* to serve the purpose of Counsel for the Applicants' argument.

[64] Indeed, an attempt is made to obtain a finding that Mr. Hardy is in the situation of a person compelled to challenge the constitutionality of the seizure provisions of the *FDA* on two grounds: he was not a volunteer in bringing the present Application because he felt the responsibility to do so to

the benefit of users of EMpowerplus and he had no other choice but to do so to gain the return of his EMpowerplus seized in the April 2003 shipment. The decisions in *Canadian Egg Marketing Agency v. Richardson*, [1998] 3 S.C.R. 157 (*CEMA*) and *PCL Industrial Constructors Inc. v. CLR Construction Labour Relations Association of Saskatchewan Inc*., [1999] S.J. No. 151, (Sask. Q.B.) (*PCL*) are advanced in support of this argument.

[65] In oral argument, Counsel for the Respondents submitted that Mr. Hardy is not in the role of defendant or in a position to challenge a law that is alleged to be in breach of someone else's *Charter* rights. Therefore, Mr. Hardy is not compelled to act in the present Application in the same way as were the respondents in *CEMA* and *Big M Drug Mart*.

[66] While *Big M Drug Mart* provided an exception for criminal law, the Supreme Court in *CEMA* expanded the exception to civil proceedings. The Respondents in *CEMA* are private poultry producers who challenged the constitutionality of the federal egg marketing scheme. At paragraph 34, Justices Iacobucci and Bastarache wrote:

> The constitutionality of the federal egg marketing scheme is clearly an issue of national importance, as are the more specific issues raised with regard to whether ss. 2(*d*) and 6 of the *Charter* apply to corporations. These issues were addressed in the courts below and could have been dealt with by this Court based on this residuary discretion. However, this case has provided this Court with an opportunity to revisit the rules governing the granting of standing to a corporation under the so-called *Big M Drug Mart* exception. Prior to this decision, the respondents could not obtain standing to invoke the *Charter* using the exception created by this Court in *R. v. Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295, because they were not facing penal proceedings. In our opinion, it is now time to expand the exception to allow corporations to invoke the

> *Charter* when they are defendants in civil proceedings instigated by the state or a state organ pursuant to a regulatory scheme.

However, the exception was provided with the following caution at paragraph 44:

> Our expanding the *Big M Drug Mart* exception to civil proceedings in these limited circumstances is not intended to provide corporations with a new weapon for litigation. The purpose of the expansion is to permit a corporation to attack what it regards as an unconstitutional law when it is involuntarily brought before the courts pursuant to a regulatory regime set up under an impugned law. Surely, just as no one should be convicted of an offence under an unconstitutional law, no one should be the subject of coercive proceedings and sanctions authorized by an unconstitutional law.
>
> [Emphasis added]

[67] In *PCL* the Court found that a number of industrial contractors were required to commence the action for a determination of issues that pertain to their rights and obligations under the existing statutory labour relations regime and, under these circumstances, determined that the plaintiffs have standing to invoke the *Charter* on the basis of the principles set out in *CEMA*.

[68] Counsel for the Applicants argues that TrueHope can obtain standing as a corporation to invoke the *Charter* by using *CEMA*, and also argues that the findings in *PCL* establish that plaintiffs, not under threat of criminal or civil regulatory sanction, can be compelled to bring a civil action and gain standing to make a constitutional *Charter* argument. I find that this argument is irrelevant because, in my opinion, the present Application was brought and has been maintained purely as a matter of choice.

[69] The seizures were a clear signal from Health Canada that talking about TrueHope's and Synergy's failure to comply with the law was no longer an option. In the face of this fact, Mr. Hardy had choices to make: stop offering EMpowerplus for sale by re-arranging TrueHope's and Synergy's marketing practices; or attack the seizures by Court action. Obviously, the latter choice was made.

[70] Access to EMpowerplus has been provided to users under the March 2004 "Agreement" and, as mentioned, there is no evidence on the present record that this fact will change into the future. Therefore, one might question the rationale for maintaining the Application in view of this fact. The detention of the EMpowerplus seized in the April 2003 shipment as a practical matter is inconsequential. During the course of the hearing, Counsel for the Applicants stated that the rationale for maintaining the present Application is to ensure "secure" access because access under the Agreement is still at the "whim" of Health Canada (Hearing Transcript, Vol. 13, p. 3143).

[71] Thus, from the way that the Application has been structured and argued, it is apparent that introducing due process into the existing seizure provisions of the FDA is a primary rationale for maintaining the Application. In my opinion, advancing this rationale is, again, purely a matter of choice: operate within the law willingly, or operate within the law under objection and attempt to change the law. Obviously, the latter choice was made.

[72] In conclusion, I find that Counsel for the Respondents' argument on the law of standing is correct. Thus, I find that Mr. Hardy's standing can only be used for the purpose of bringing his own

personal Section 7 and Section 8 challenges on the evidence of the direct impact the seizures had upon him. I make a similar finding with respect to TrueHope's Section 8 challenge.

[73] As a result, I find that the evidence with respect to *Charter* claims of the users of EMpowerplus is irrelevant to the present Application.

D. *Do s. 23 and s. 26 of the FDA offend Section 7 and 8 of the Charter?*

[74] As set out above, the Constitutional Question framed by the Applicants attacks both s. 23 and s. 26 as offending Sections 7 and 8 of the *Charter* on the same basis. The argument is framed this way:

> This case will also address whether it is permissible to seize and detain vital health products indefinitely for regulatory violation without Court supervision.
>
> (Applicants' Record, Vol. 20, Memorandum of Fact and Law, para. 110)

As mentioned, the focus of the constitutional challenge argument is on the health risk to users, and the infringement of the life, liberty and security *Charter* rights of users and, therefore, the evidence which will support the argument can only come from users who make a personal *Charter* claim. Because the *Charter* claims of users of EMpowerplus have been found to be irrelevant to the present Application, I find that the answer to the question posed is "no".

III. The Relevance of Contested Affidavit Evidence

[75] The Applicants and Respondents have filed cross motions to strike certain paragraphs of the affidavit evidence on the principal grounds that the evidence is hearsay or inadmissible opinion. In the course of the case management process leading to the hearing of the present Application, I directed that the determination of the admissibility of the contested affidavit evidence would be resolved in the final decision for the reason that a contextual understanding of the evidence would be necessary before a final determination could fairly be made.

[76] Much of the contested evidence has been tendered in anticipation that the *Charter* claim evidence of non-Applicant users is relevant to the present Application. The determination of the narrow scope of the present Application as found in the preceding Section of these reasons has rendered this evidence as irrelevant. I find that both the Respondents' and the Applicants' strike motions can be dealt with on this basis. The law with respect to the relevance and admissibility of evidence is as follows:

> Facts in issue, which are sometimes called "principal" facts, are those necessary by law to establish the claim, liability or defence, forming the subject-matter of the proceedings; and which are in dispute between the parties [footnote omitted].
>
> […]
>
> Relevancy must be distinguished from admissibility, of which, though the primary, it is by no means the sole condition. Evidence may be relevant and yet, on grounds of convenience or policy, inadmissible. Indeed, this exclusion of matter otherwise relevant has been called the distinguishing feature of the English law of evidence. It is correct then, in deciding whether evidence is admissible, to ask first whether the evidence is relevant and, thereafter, whether there are any rules or discretions, based on convenience or policy, which nonetheless make this relevant evidence inadmissible.

> [Emphasis in the original]
>
> (*Phipson on Evidence*, 16th Ed. (London: Sweet and Maxwell, 2005), paras. 7 – 02, 7 – 05)

Further, the Ontario Court of Appeal decision in *R. v. Truscott*, [2006] O.J. No. 4171 at paragraphs 22 and 23 is instructive:

> Evidence is relevant if, as a matter of logic and human experience, it renders the existence or absence of a material fact in issue more or less likely […]. Evidence will be irrelevant either if it does not make the fact to which it is directed more or less likely, or if the fact to which the evidence is directed is not material to the proceedings.
>
> Relevance is contextual in that it depends on the facts in issue, the position taken by the parties in respect of those facts, and the other evidence adduced in relation to those facts: see *R. v. Arp* (1998), 129 C.C.C. (3d) 321 at 338 (S.C.C.). Because relevance is contextual, a court will often be unable to determine relevance at the time the evidence is proffered, but will receive the evidence conditionally and determine the relevance of the evidence after the evidentiary picture has been fully developed. It does not follow, however, that because relevance often cannot be determined when the evidence is tendered, that relevance should not be addressed when the evidence is tendered. If a court is satisfied when the evidence is tendered that the evidence is irrelevant, it should so hold and refuse to admit the evidence. A court should not hear evidence on the chance that it might somehow, at some time, in some way become relevant in the proceedings.
>
> [Emphasis added]

A. *The Respondents' motion to strike the Applicants' evidence*

[77] The evidence of the factual history underlying the present Application recounted in the affidavits of Mr. Hardy, Mr. Stephan, and Mr. Lunney is uncontested as relevant. I find that any

other evidence tendered by either Mr. Stephan or Mr. Lunney in support of the concerns of users is irrelevant.

[78] Mr. Hardy's state of mind is a fact in issue in the present Application and, therefore, evidence with respect to this fact is relevant. In his affidavit, together with his factual statements, Mr. Hardy provides opinions and hearsay evidence with respect to the entire context of the story under review, including the development of EMpowerplus, the conduct of TrueHope, his relationship with Health Canada and his relationship with users of EMpowerplus, including members of his family and Mr. Stephan's family. I find that this evidence is relevant as proof of his state of mind, but for no other purpose. Because Mr. Hardy refers directly to Landon Hardy's mental health experience in support of his own *Charter* claim, I find that the affidavit evidence of Landon Hardy is relevant, but only as recounted below in Section IV, (A), (3), (d).

[79] While it is an undisputed fact that users of EMpowerplus report an improvement in their mental health as a result of taking a recommended dosage of the product, controversy exists as to whether EMpowerplus treats mental illness and is, therefore, "efficacious", or whether EMpowerplus merely creates a placebo response because it is expected to treat, and is, therefore, only "effective". Given the limited scope of the present Application as found, I find that the question does not constitute a fact in issue because it can only be advanced if the *Charter* rights of users are in play. This was the strategy advanced by the Applicants, but it has failed.

[80] As a result I find that the following affidavit evidence is irrelevant: the evidence of Ms. Coulson and Ms. Oxby which goes to prove the positive effect that EMpowerplus has had on their lives; the evidence of Mr. LaJeunesse, a past executive with the Canadian Mental Health Association, which goes to support user claims; and the expert opinion evidence of Dr. Kaplan, a psychologist, and Dr. Popper, a psychiatrist, which goes to the treatment effect of EMpowerplus.

[81] With respect to the 1-800 Crisis Line notes, there is no disagreement that the notes prove that a certain number of calls were received voicing concern about the seizures, and while this fact is relevant as an element of the history evidence, the truth of the content of the calls is irrelevant. I make the same finding with respect to the audio and video recordings of users which includes the testimonials of the Red Umbrellas.

[82] With respect to the Applicants' application to admit the in-court testimony of Mr. Miles Brosseau, a Health Canada official, given in the Provincial Court of Alberta criminal trial of TrueHope and Synergy for breach of the *FDA Regulations*, to prove that Health Canada did not consider the health consequences of the April 2003 seizure before making the seizure, I find that this fact is not contested.

B. *The Applicants' motion to strike the Respondents' evidence*

[83] As stated above, it is agreed that Health Canada's expressed concern about the safety of the composition of EMpowerplus is not relevant to the present Application. The Applicants object to certain elements of the affidavits of Health Canada officials who address this irrelevant concern as

well as the irrelevant treatment effect of EMpowerplus. As a result, I find that the affidavit evidence of Dr. Duc Vu, Director of Marketed Biologicals, Biotechnology and Natural Health Products Bureau with Health Canada, Dr. Robin Marles, Director of the Bureau of Clinical Trials and Health Sciences with Health Canada, and Dr. Siddika Mithani, an Associate Assistant Deputy Minister with Health Canada, is irrelevant.

[84] For the same reason applied to the expert evidence of Dr. Kaplan and Dr. Popper with respect to the Respondents' strike motion, I find that the expert evidence of Dr. Silverstone, a psychiatrist, which also goes to the treatment effect of EMpowerplus, is irrelevant.

C. *Conclusion*

[85] I find that the evidence found to be irrelevant is inadmissible.

IV. The Personal Aspect of the *Charter* Challenge

A. *Mr. Hardy's Section 7 challenge*

[86] Section 7 of the *Charter* reads as follows:

7. 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.	7. Chacun a droit à la vie, à la liberté et à la sécurité de sa personne; il ne peut être porté atteinte à ce droit qu'en conformité avec les principes de justice fondamentale.

[87] Mr. Hardy is not a user of EMpowerplus for a therapeutic purpose and, thus, he cannot argue that the seizure sections are unconstitutional as a denial of health products necessary for his life or a denial of his liberty to choose necessary vital health products.

[88] Therefore, the focus of Mr. Hardy's *Charter* challenge is with respect to his right to security. His subjective and objective claim is that his emotional well-being as a security interest has been infringed by the seizures. His standing to make this argument is not contested.

1. The test to be met

[89] I find that the proper correct legal approach to evaluating Mr. Hardy's claim involves a critical analysis of not only his subjective evidence but also relevant objective evidence with respect to the content of his subjective claim in order to determine the weight to be given to his subjective evidence. This point is made clear in *New Brunswick v. G.(J.)*, [1999] 3 S.C.R. 46 at paragraph 60:

> For a restriction of security of the person to be made out, then, the impugned state action must have a serious and profound effect on a person's psychological integrity. The effects of the state interference must be assessed objectively, with a view to their impact on the psychological integrity of a person of reasonable sensibility**.** This need not rise to the level of nervous shock or psychiatric illness, but must be greater than ordinary stress or anxiety.
>
> (Emphasis added)

[90] As identified in this passage, a strong subjective and objective evidentiary base is required to prove the breach claimed.

[91] The impugned state action which is in issue in the present Application is the April and May, 2003 seizures; however, I accept Counsel for Mr. Hardy's submission that, viewed in context, the relevant objective evidence with respect to the seizures begins with the circumstances leading to the development of EMpowerplus and ends with the Agreement in March 2004.

[92] Thus, the question is: did the seizures, understood in context, have a serious and profound effect on Mr. Hardy's psychological integrity?

2. The objective evidence

[93] The objective evidence is the history recounted above in Section I.

[94] On the objective evidence, a number of facts can be found: the seizures took place within an adversarial relationship between Mr. Hardy and Health Canada; within this battle of wills Mr. Hardy was a full and competent participant; Mr. Hardy's refusal to comply with Health Canada's lawful demands caused anxiety on both sides; and Health Canada and Mr. Hardy were both frustrated by the fact that no progress could be made to resolve the existing conflict.

[95] It is clear on the evidence that Mr. Hardy was representing the interests of users of EMPowerplus; however, he was doing so as the principal of a corporation that had an economic interest in maintaining a profit from the sale of a product, the profit being necessary to maintain the company and efforts of its operatives, as well as the counselling program developed.

[96] On the evidence, the seizure was a defining moment in the enduring conflict, but it was one which could have been predicted and should have been expected. In particular, the challenge presented by Mr. Hardy should have been understood by him as an open invitation to Health Canada to take enforcement action. It is very understandable that the tone and content of the "Open Letter" was a challenge to the authority of Health Canada that could no longer be tolerated. Indeed, Health Canada's response made it clear that the negotiation process was at an end and the enforcement process was about to begin. The response was ample notice that a likely step in this new phase of the relationship would be seizure.

3. The subjective evidence

[97] There is no evidence upon which to question Mr. Hardy's credibility or his stated motives with respect to operating TrueHope and Synergy or the engagement with Health Canada. Precisely with respect to Mr. Hardy's state of mind in the course of this conduct, there are three sources of information the credibility of each is not in doubt: Mr. Hardy's own evidence, Mr. Stephan's evidence, and the evidence of Mr. Hardy's son, Landon Hardy.

[98] The affidavit evidence supplied by Mr. Hardy and Mr. Stephan makes constant reference to the two of them acting together. For example, each affidavit uses the plural pronoun "we" with respect to actions they took together. With respect to Mr. Hardy's state of mind, there are similar references with respect to their joint states of mind; for example, in speaking about Mr. Neske's letter of April 28, 2003, Mr. Stephan says that the letter "caused us a lot of anxiety" (para. 99), and "we were so concerned about the health of TrueHope Participants…" (para. 100). Thus, while Mr.

Stephan supplies confirming evidence, I put primary weight on Mr. Hardy's own evidence with respect to his own state of mind.

[99] Landon Hardy is the only user of EMpowerplus to whom Mr. Hardy directly refers in his affidavit and who has filed an affidavit in the present Application. Because of their close association, I find that Landon Hardy's own evidence is content of Mr. Hardy's state of mind; indeed, he also provides evidence confirming Mr. Hardy's evidence.

[100] In his October 4, 2008 affidavit filed in the present Application (Applicants' Record, Vol. 2, pp. 292 – 322) and in the examination conducted thereon, Mr. Hardy makes a number of statements to prove his state of mind in support of his *Charter* claim.

a. *A duty to help people who need and use EMpowerplus*

[101] By 2002, Mr. Hardy and Mr. Stephan were committed to developing EMpowerplus out of a sense of duty. Mr. Hardy makes this point under examination when speaking about treating Mr. Stephan's children:

> […] that's what we set out to do, is just put together a product. I don't know that we had in mind to make a big company out of it, but we knew we had one obligation, and that was to keep those kids whose lives were at stake, stable, and that was the thrust of it. If you have ever lived with the hell of mental illness, you'll know that it's one of the most devastating experiences of life, and that's where Tony [Stephan] had been, and that's where we didn't want to ever go back to; and what has largely driven us is the fact that we don't want others to have to experience that either.
>
> (Applicants Record, Vol. 5, p. 1400)

[102] With respect to this and the circumstances of users, throughout there is no question that Mr. Hardy functioned on a belief that the product is efficacious in successfully treating mental illness. The purpose here is to understand this factor in play as a contributor to his state of mind. Whether, in fact, EMpowerplus is efficacious or merely effective is irrelevant.

[103] Mr. Hardy expresses his belief in his affidavit as follows:

> We have always felt we have a moral duty to help people suffering from mental illness who approach us for help. I have witnessed over the years a success rate of over 80% of people suffering from bi-polar disorder who join our Program experience either a total or a substantial reduction in their symptoms. The majority of Participants who were on psychiatric medications when joining the program were able to get off of those medications or to substantially reduce them and at the same time have a total or substantial reduction in their symptoms. Many participants, like Mr. Stephan's children Joseph and Autumn were unable to effectively manage their symptoms on psychiatric medications but have a complete elimination of symptoms on EMpowerplus.
>
> It is my personal belief that if at any time, including the present, we stopped providing EMpowerplus that we would witness suicides and hospitalizations of TrueHope Participants. We would also witness the return of debilitating symptoms despite interventions by doctors and psychiatrists. I believe I would witness people close to me such as my son Landon, or Mr. Stephan's children Autumn and Joseph return from living healthy lives to being disabled by mental illness.
>
> (Applicants' Record, Vol. 2, p. 300 at paras. 37 and 38)

b. *Frustration with Health Canada*

[104] From the outset, as he explained under examination on his affidavit, Mr. Hardy knew very well that he would be held accountable for selling EMpowerplus in Canada:

> […] Q: Any time after 2000 when Dr. Peterson sent that letter, which is Exhibit 13, and the short time after, were you concerned

> that the fact that the product, according to Health Canada, did not comply with the actual regulations, that some steps might be taken to take the product off the shelves or off the market, as you've said?
>
> A: Yeah, I think when we got those letters, that we were definitely aware and concerned of what might happen. That's why we started writing letters and trying to get meetings with Ministers, all of which -- very few of which were responded to appropriately. We didn't get any answers and we couldn't get meetings. We definitely were aware that there was a problem. We just didn't know how to rectify it. And I wasn't prepared to terminate it and wait for six years while Health Canada determined that I could finally have it back for my son, who would be dead by then.
>
> (Applicant's Record, Vol. 5, p.1454)

[105] However, with respect to Health Canada's April 27, 2001 demand to stop selling EMpowerplus, Mr. Hardy in his affidavit expresses the following concern:

> We were not actually distributing the product in Canada and consequently did not believe we needed an establishment licence. The product was manufactured and shipped in the United States. We were willing to work with Health Canada to modify what was said on our website to address their [sale in Canada] concerns and so I hoped at the time that we could address that concern. […]
>
> We were concerned about [Miles Brosseau's] demand to stop selling. Our primary concern was that if we stopped selling we believed that we would cause serious harm to the Participants in the TrueHope program.
>
> (Applicants' Record, Vol. 2, p. 309, paras. 80 and 81)

[106] In the letter of June 17, 2002 as described in the history above, Mr. Hardy expressed frustration at not being able to get Health Canada to listen to his concerns. The reply which came six months later and the meeting which followed on January 14, 2003 proved that Mr. Hardy and

Health Canada were in a stalemate. Mr. Hardy makes this comment in his affidavit with respect to the meeting:

> At the January 14, 2003 meeting Miles Brosseau suggested that we move to the United States. We thought about that option and reached the conclusion that it was not feasible. Assuming the United States would allow us to emigrate and re-locate, we concluded that it was not economically feasible to do . We were also worried about finding and training new people to run the TrueHope Program if we relocated.
>
> (Applicants' Record, Vol. 2, pp. 311 - 312, para. 90)

[107] With respect to the Minister of Health's March 26, 2003 reply to the "Open Letter", Mr. Hardy makes the following comment:

> […]
> This letter was difficult to deal with. We believed that the Minister had the power under the Act to grant us an exemption so that EMpowerplus would remain available. We had repeatedly brought up the ministerial exemption option in our correspondence and meetings (for example in our June 17, 2002 letter or at the January 14, 2003 meeting). We were now being told by the Minister's Office that the Minister would not meet with us, let alone grant us an exemption.
> […]
> (Applicants' Record, Vol. 2, p. 312, para 92)

c. *Anxiety caused by the seizures*

[108] Mr. Hardy expresses his concerns about the effect of the seizures on his family as follows:

> I have never suffered from mental illness. However, after we developed EMpowerplus I began taking it regularly as a vitamin and mineral supplement. I have encouraged the rest of my family to do the same. I have not experienced any negative effects. Indeed, my own experience is that I feel well and seem to get things like colds and flues with less frequency than when I was not taking EMpowerplus.

> When, as described below, Health Canada seized the April 17, 2003 shipment of 72 bottles of EMpowerplus, they seized 15 bottles that I had ordered for myself and my family. For myself and most of my family this seizure was not going to create a health risk. However, for Landon and Cherilea, this seizure did create a significant health risk. Landon and Cherilea depended upon EMpowerplus for their mental health and stability. The seizure threatened this. I became very worried for the health of Landon and Cherilea when my order of EMpowerplus was seized. I was very concerned that I might have to witness my children revert to the psychiatric ward or worse. By that time I had plenty of experience with others becoming unstable very quickly when they quit taking EMpowerplus. I took the seizure as nothing less than a threat to their lives.
>
> (Applicants' Record, Vol. 2, p. 302, paras. 46 and 47)

However, because Mr. Hardy was fully aware of the PUID, under examination on his affidavit he admitted that members of his family were not deprived of access to the product as a result of the seizures because he was personally able to bring a sufficient supply into Canada under the PUID (Applicants' Record, Vol. 5, p. 1440 - 1442).

[109] Mr. Hardy was also concerned about the deprivation of other users of EMpowerplus; in his affidavit at paragraph 97 he states that the April seizure also "caused us great concern as we feared for the health of the persons whose shipments were detained". With respect to Mr. Neske's letter of April 28, 2003 stating that the April shipment would not be released, in his affidavit Mr. Hardy gives his reasons for responding as he did in his April 29th letter:

> The April 28, 2003 letter caused us a lot of anxiety. The 15 bottles of mine that were seized were for my family, some of whom used EMpowerplus to control serious mental illness. The other 57 bottles were for 21 separate TrueHope Participants, many of whom had suffered from severe mental illness before using EMpowerplus. We believed that this detention posed a significant threat to the health and safety of these 21 Participants and my family. We responded

> promptly with a letter dated and sent on April 29, 2003 to communicate our concerns.
> […]
> The purpose of the letter was to clearly communicate to Health Canada that they were creating a serious health risk by detaining the shipment. We believed that his dangerous action was a violation of the Participant's section 7 rights under the Charter and we wanted Health Canada to consider this. We hoped that by sending this letter Health Canada would realize that they were creating a dangerous situation and release the shipment.
>
> We were so concerned about the health of the TrueHope Participants whose EMpowerplus was seized, that we sought legal help […].
>
> (Applicants' Record, Vol. 2, pp. 314 - 315, paras. 99 and 100)

[110] Following the April seizure, Mr. Hardy states:

> For much of this period TrueHope was flooded with calls from TrueHope Participants who were worried that they were not going to get EMpowerplus. Many of the calls were from Participants who had not yet had shipments seized, but who called to communicate to us they were worried. Many of the callers were in a panic. […]
>
> We felt obligated to do everything we could to change Health Canada's mind and to ensure that TrueHope Participants could access EMpowerplus.
>
> We also decided to publicize what was happening and the steps we were taking in an effort to create political pressure on the Government to allow access to EMpowerplus.
>
> (Applicants' Record, Vol. 2, pp. 317 - 318, paras. 114, 116, and 117)

d. ***Concern about Landon Hardy's condition***

[111] Landon Hardy gives the following description of his mental condition, its treatment, and his reaction to the seizures:

The first problems I recall having were at age 17, in late 1997, around exam time. I recall having racing thoughts that would keep me awake at night, and paranoid thoughts that armed government or military people were coming to get me, and that helicopters were coming after me. The symptoms got worse over the next few months.

I suffered perhaps my worst psychotic episode in March 1998. My symptoms got to a point that I felt trapped and wanted to escape, so I bolted from the house. I thought I could run all the way to see my brother who was in Russia. I put on two or three housecoats, several pairs of shoes and other pieces of clothing, and ran out of the house. I ran through town, across fences, through fields, across a highway, and through an irrigation canal filled with broken ice and knee deep water. I recall throwing snowballs at some horses, and waving at cars on the highway. As I became hot from running, I started to throw off my clothing. After running a fair distance, I ran up to a house that was unfamiliar to me and knocked at the door. By that time, I was naked. The residents of the house appeared shocked, but handed me a blanket. Just when I was at the door, my father and brother showed up, and also the police. I do not know who called the police, but I noticed a woman in the house on the telephone. My father and brother were able to calm me down, and took me home. Fortunately, the police did not lay any charges.

I also recall that I became very psychotic for a few days and could not sleep. One particularly bad night, March 20, 1998, I had two or three songs in my head, all at the same time, which I could not shut off. I was hallucinating, and thought there were saws trying to cut me in half, snakes biting me, and that I was being chased by helicopters. My parents brought me into their room to try to calm me down. Eventually I got through the episode. However, I did not feel well enough to go back to school, so I stayed home and tried to recuperate.

My father suggested that I try taking four supplements, on a consistent program, that he was involved in manufacturing. Given the seriousness of my behaviour, and how frightening the experiences of my breakdown had been, I agreed to try the supplements. Slowly, my state of mind improved. After four or five months on the program, I started to feel better. The racing thoughts slowed down, and the frightening images went away. I was calmer, and could sleep. I did not have an urge to escape from something.

I was well enough to go back to school in September, and finished my year and graduated. I was careful to keep on the supplement program, and felt completely normal. I functioned very well for a year and one half.

In February 2000, my father provided me with a newly formulated supplement to try, Empower-plus, produced by Evince, at Cornerstone Labs. I understood this formulation to be more stable than the previous one.

I started on this program before I traveled to Salt Lake City, Utah, for a missionary project I was involved with. After a few weeks, I moved to Toronto for the project. I found this work very time consuming, and often was out for many hours of the day. I was doing really well. I was very involved in my work, and started to get careless with taking the supplement. I began to think that my problems were behind me and that I did not need to continue taking the supplement. I was skipping the lunch time doses, and just sporadically taking the EMPowerplus.

Just before I left Ontario, I caught a gastroenteritis, which gave me diarrhoea. This went on for a few weeks, and any EMPowerplus that I did take would not have been absorbed. I returned to Alberta in December, back to my parents home. The diarrhoea continued for a few more weeks. I found that I was feeling worse and worse and that I was quick to lose my temper. I found I got more and more angry, and the outbursts got worse. I began to have disturbing hallucinations, the same images as in 1998, but they were more violent. My thought processes were not coherent, and I was not functioning well. I recall periods of extreme anger, I began to lose control, and at one point, I recall smashing a chair in an angry rage. I set a couple of fires in the house. My parents could no longer cope with my behaviour, and took me into the Raymond Hospital, on February 5, 2001, where I was certified as a formal patient under the Mental Health Act, and moved to Lethbridge Regional Hospital.

[…]

I was diagnosed with schizophrenia. In the hospital I was given Flanksol for the first month, and later put on Haldol. I was also put on Zyprexa. I recall some anger outbursts in the hospital, such as flipping over a puzzle table. I threw a piece of pizza at another patient. I wanted to get out, but they would not let me leave. Initially,

I felt worse, but after the doctors changed the medication, I stabilized somewhat. I slept up to 18 or 20 hours at times. […]

I gained 50 – 65 lbs. on the hospital medications and I felt that my brain was in a fog. I found that although my thoughts were no longer racing, I was drowsy. I did not actually feel better. I was not violent anymore, and found myself feeling very mellow. However, I did not feel functional. On the EMPowerplus, I do not have the drowsiness, and I feel functional.

After I was in the hospital for a time, I started back on EMPowerplus. My family would bring it in for me, and there were two nurses who reminded me to take it. I recall that I told the treating physicians at the hospital that I was on EMPowerplus.

After I was released from the hospital, I continued taking the supplement, and was careful with my diet to avoid bowel problems, and eventually went off the Zyprexa. I went back to the psychiatrist who treated me in hospital six months later to follow up. I was not having any problems at all, and I have not gone back. I have had no relapses since that time. I have never stopped taking EMPowerplus as I do not want to ever go back to the psychiatric ward or to experience the racing thoughts, confusion, paranoia, or hallucinations again.

In April 2003, I heard through my family that the government had seized shipments of EMPowerplus. When I heard that the shipments had been seized at the border, I became extremely anxious, and fearful of what could happen to me and my family if I were unable to obtain the EMPowerplus. I have experienced severe mental illness and, since being on the EMPowerplus program, I have been completely healthy and well. After I became ill in 1997, and started on the EMPowerplus in 1998, I only had one relapse or breakdown, just after I completely stopped taking the EMPowerplus around December, 2000.

I was still single, and living in the family home with my parents in 2003. I know that I threatened my family and was a danger to myself back in early 2001, and I was fearful of becoming ill again. I could see that the seizure of the EMPowerplus shipments at the border caused my parents a great deal of stress and concern, as I had been violent with them in the past when I was not taking the supplement. I also saw that my parents were angry and frustrated about the seizures.

(Applicants' Record, Vol. 8, pp. 2345 - 2449, paras. 6 – 13, and 15 - 20)

e. *Conclusion*

[112] The principal impression that arises from Mr. Hardy's evidence is that he is a strong, dedicated, creative, and very determined person. At the time of the seizures he filled many roles: entrepreneur with substantial business development and management skill; visionary leader and supporter of the use of natural health products for a therapeutic purpose; challenger of government authority perceived to be unfair and uncaring; dedicated supporter of persons in need of mental health care; and supportive and caring father of his own unwell children.

[113] The evidence of activity within each of these roles is difficult to separate. The evidence of Mr. Hardy's disappointment and frustration as a builder of a successful and trusted natural health care business in the challenging atmosphere of conflict with government regulation is difficult to separate from the evidence of his personal feelings of caring and concern for users of EMpowerplus who felt threatened by the seizures.

[114] I have no doubt that throughout Landon's life, Mr. Hardy suffered a great deal of emotional anxiety over his son's poor mental health, and that the seizures produced some immediate fear for his son's safety. However, with respect to Landon's continuing access to EMpowerplus after the seizures, when viewed realistically and on the basis of Mr. Hardy's own evidence, Landon's access was never in doubt. Mr. Hardy knew of options to assure supply, and, in fact, did take up these options to ensure supply.

[115] With respect to the seizures, Mr. Hardy's resilience is impressive. His immediate response was to help facilitate and manage a very successful campaign to provide continuing access to EMpowerplus for TrueHope participants through an agreement with Health Canada. Indeed, in an effort to secure access into the future, as a principal in TrueHope and as an Applicant in these proceedings, he has fought hard during the past six years to bring his health care concerns to hearing through the present Application.

[116] Therefore, given Mr. Hardy's proven strong character, and given the complexity of the factors in play in the history of TrueHope's and Mr. Hardy's experience with Health Canada leading to the seizures as described, I cannot find that the test for Mr. Hardy's Section 7 challenge has been met; I cannot find that the seizures, understood in context, had a serious and profound effect on Mr. Hardy's psychological integrity.

[117] Thus, I dismiss Mr. Hardy's Section 7 *Charter* claim.

B. *Mr. Hardy's and TrueHope's Section 8 Charter challenge*

[118] Section 8 of the *Charter* reads as follows:

8. Everyone has the right to be secure against unreasonable search and seizure.	**8**. Chacun a droit à la protection contre les fouilles, les perquisitions ou les saisies abusives.

[119] It is agreed that only the seizure of the April 2003 shipment is relevant to the present Section 8 claim because, while the May 2003 shipment was inspected, in the end result it was not in fact or law seized.

[120] The recent law with respect to determining whether a “seizure” engages a Section 8 right is expressed by Justice Lebel at paragraph 53 of the Supreme Court’s decision in *Quebec (Attorney General) v. Laroche*, [2002] 3 S.C.R. 708 (*Quebec v. Laroche*):

> However, just as an overbroad interpretation of the word "seizure" might defeat the purpose of s. 8, so too might a strict literal interpretation of that concept. In interpreting the word "seizure", we cannot look only at the process. We must examine the context and the objective of the guarantee. By ignoring the purpose and context of the provision, we might deprive it of part of its effect in numerous situations in which constitutional interests in privacy, not to mention the regularity and fundamental fairness of criminal procedure, are in issue. Accordingly, if there is to be any limit on the definition of the word "seizure", it must not relate to the process *per se*, but rather to the context in which it is carried out. The issues involved in interpreting and applying s. 8 are clearly explained in the following comments by S. C. Hutchison, J. C. Morton and M. P. Bury:
>
> > One limitation ought to be put on the scope of "seizure" under the Charter. The "enjoyment of property" as a specific right, as protected in the Canadian Bill of Rights, is not protected in the Charter. The prohibition of unreasonable search and seizure is designed to promote privacy interests and not property rights. Hence, Charter protections against unreasonable seizure should not apply to governmental actions merely because those actions interfere with property rights. Specifically, where property is taken by governmental action for reasons other than administrative or criminal investigation a "seizure" under the Charter has not occurred. A number of cases illustrate this view of seizure. A detention of property, in itself, does not

> amount to a seizure for Charter purposes -- there must be a superadded impact upon privacy rights occurring in the context of administrative or criminal investigation.
>
> [Emphasis added]
>
> (S. C. Hutchison, J. C. Morton and M. P. Bury, *Search and Seizure Law in Canada* (loose-leaf), at p. 2-5; see also: F. Chevrette and H. Cyr, "La protection en matière de fouilles, perquisitions et saisies, en matière de détention, la non-rétroactivité de l'infraction et la peine la plus douce", in G.-A. Beaudoin and E. Mendes, eds., *The Canadian Charter of Rights and Freedoms* (3rd ed. 1996), 10-1, at pp. 10-8 and 10-9).

Therefore, a contextual analysis is required to determine the purpose of the seizure: was it for criminal investigation as argued by the Applicants; for administrative investigation as argued by the Respondents; for both purposes; or for neither purpose?

[121] The Applicants' primary argument is that this Court has already determined that *FDA* seizures are for the purpose of criminal investigation. The following passage at paragraph 150 of Justice Muldoon's decision in *C.E. Jamieson v. Canada*, [1988] 1 F.C. 590 (*C.E. Jamieson*), which focussed on the predecessor provision to s. 23, is relied upon as support for this argument:

> It is true that paragraphs 22(1)(a), (b) and (c) create powers which appear to provide for regulatory inspections, but paragraph 22(1)(d) which the inspectors invoked, provides that such official "may ... seize and detain ... any article by means of or in relation to which he reasonably believes any provision of this Act or the regulations has been violated". (Emphasis added.) Those are the words in which section 26 is expressed. The legislative intent to make paragraph 22(1)(d) an enforcement adjunct to the prosecution of offences pursuant to section 26 is too clear to merit further discussion.
>
> [Emphasis added]

Given the requirement for a contextual analysis in answering the question as stated by Justice Lebel in *Quebec v. Laroche*, with respect, I find that the evidence on the record of the present Application does merit further discussion about Health Canada's reasons for performing the seizure.

[122] In the course of the examination on his affidavit, Mr. Neske provided a policy directive containing the following statement with respect to enforcement of the *FDA* and the *FDA Regulation* by way of seizure:

> 6.5.12. Seizure and Detention
> An administrative seizure and detention is an immediate enforcement tool for controlling non-compliance. The Inspectorate may take control of non-compliant articles (eg. drugs or medical devices) under the authority for administrative seizure and detention provided in the applicable legislation. When determining whether to implement an administrative seizure and detention, the Inspectorate will consider the risk to health and safety and the compliance history of the regulated party.
>
> Evidentiary seizures are used to gather evidence for a prosecution. The Inspectorate may seize non-compliant articles as evidence under the authority of a search warrant obtained pursuant to section 487 or 489 of the *Criminal Code* as evidence.
>
> 6.5.13. Prosecution
> A prosecution is a legal proceeding in which the courts determine whether the applicable legislation has been contravened and if so, apply an appropriate penalty. The Inspectorate will consider recommending that charges be laid if non-compliance:
>
> - creates a significant health or safety risk;
> - is continuing in nature;
> - was premeditated, indifferent, reckless or a marked departure from a reasonable standard of care;
> - other enforcement activities have proven unsuccessful.
>
> (Applicants' Record, Vol. 8, p. 2589)

Thus, as a matter of practice, the policy make a clear distinction between an "administrative seizure and detention" as an immediate enforcement tool for controlling non-compliance and an "evidentiary seizure" used to gather evidence for a criminal prosecution.

[123] Indeed, in May 2004, TrueHope and Synergy were criminally charged with contravention of the *FDA* and the *FDA Regulations* for selling EMpowerplus in Canada during the period of January 1, 2003 and December 31, 2003. For the purposes of that prosecution, a warrant application was made for a search of TrueHope's business premises in Raymond Alberta which was conducted in July 2003. The Applicants argue that, because the action taken with respect to the April and May 2003 shipments are mentioned in that warrant application, it is conclusive that the April seizure was conducted for the purpose of that criminal law investigation.

[124] As quoted in Section I of these reasons, the fax from Mr. Neske to Mr. Stephan immediately following the April seizure provides a statement of the reasons for the seizure:

> Re: E.M. Power +
>
> Further to the shipment of 72 bottles of the above named product presently being detained, this shipment will not be released at this time. <u>The product is currently under investigation for importation prohibited under the Food and Drugs Act Regulation A.01.040</u>. We hope to conclude this investigation quickly with your cooperation.
>
> [Emphasis added]
>
> (Applicants' Record, Vol. 3, p. 1034)

As mentioned above, Regulation A.01.040 reads as follows:

> Subject to section A.01.044, no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations.

[125] Mr. Neske's letter makes it clear that the April seizure was with respect to the importation into Canada of EMpowerplus and not the sale in Canada of EMpowerplus. However, it is not clear as to whether the seizure was intended to be an administrative seizure and detention as an immediate enforcement tool for controlling non-compliance or an evidentiary seizure used to gather evidence for a prosecution. I find it was likely for both purposes.

[126] On the last day of the hearing of the present Application, the April shipment was inspected in open court and it was established that, subsequent to the seizure, some of the seized product was extracted and sent for analysis. Therefore, I find that this fact establishes that, in part, the seizure was used to gather evidence for a prosecution for either unlawful sale or unlawful importation.

[127] As addressed by Justice Lebel in *Quebec v. Laroche*, an important feature of a Section 8 analysis is a determination of whether the detention of property amounts to a seizure for *Charter* purposes. In order for the *Charter* to be engaged, a detention must have a superadded impact on privacy rights.

[128] In my opinion, the following factors establish that Mr. Hardy and Truehope have no credible basis upon which to make a *Charter* complaint about the seizure: in the two years preceding the seizure there was a high degree of personal contact between Mr. Hardy and officials of Health

Canada; during this period, Mr. Hardy knew that TrueHope and Synergy were acting in violation of the *FDA* and the *FDA Regulations*; Health Canada was patient in making it clear that the violations could not be disregarded and compliance with the law was required; and, most importantly, Mr. Hardy flatly refused to devise a way to put Synergy and Truehope into compliance. Thus, when all factors are considered, I find that Mr. Hardy and Truehope has no privacy right in the product seized, and, as a result, the seizure had no superadded impact on either of them.

[129] Even if some negligible privacy interest can be found in favour of Mr. Hardy and Truehope which engages Section 8 rights, on the factors cited I find that the result is the same. In this situation, it is agreed that, since the seizure of the April shipment was conducted without a warrant, a rebuttable presumption arises that the seizure is unreasonable; if a seizure is for an administrative purpose the presumption is easy to rebut, while if the seizure is for a criminal law purpose, the presumption is difficult to rebut (*Hunter et al. v. Southam Inc.*, [1984] 2 S.C.R. 145). Nevertheless, in my opinion, the presumption is rebutted on the highest standard. I find that the seizure was very reasonable for both the administrative and criminal law investigative purpose of stopping long standing illegal conduct.

[130] As the final point in the Section 8 analysis, Counsel for the Applicants argues that in *C.E. Jamieson*, Justice Muldoon decided the predecessor to s. 23 was unconstitutional and since it is agreed that there is no difference between it and s. 23, therefore, s. 23 is unconstitutional. Paragraph 155 of the decision is argued to have this effect:

> Clearly, then, prior authorization was feasible. Prior authorization would not have caused an imbalance in favour of the plaintiff's expectation of privacy and security of property over the State's valid objectives of law enforcement and safeguarding public safety. Therefore, the warrantless seizure was unreasonable, and in contravention of the [page670] Charter, section 8. To that extent, paragraph 22(1)(d) of the Food and Drugs Act is declared to be, and to have been, of no force or effect.
>
> [Emphasis added]

[131] Counsel for the Applicants argues that Justice Muldoon's use of the phrase "of no force and effect" supports a finding that s. 23 is unconstitutional. In my opinion, when the phrase is read in context, this argument must be dismissed. The legal finding in *C.E. Jamieson* is that the presumption that the seizure was unreasonable was not rebutted, and, as a result, the search was found to contravene the *Charter*. In my opinion, the comment that s. 22(1)(d) is declared to be of "no force or effect" must be read only as a statement that the *Charter* breach rendered the search to be of no force or effect.

[132] Support for this conclusion is found in paragraph 156 of *C.E. Jamieson* where Justice Muldoon says:

> The seizure is quashed as being unlawful. The seizure only is declared unconstitutional. […]
>
> [Emphasis added]

In addition, at the end of the decision under the heading "Summary of Conclusions" at paragraph 158, relief is granted in the following terms:

> ... the seizure of articles conducted on December 17, 1984, by the defendant Director, and the inspectors, officials and any other public

> servants who were then members of his staff or otherwise authorized to effect such seizures, was and is illegal, null and void, in particular, in that said seizure was unreasonable and contravened section 8 of the Canadian Charter of Rights and Freedoms.
>
> [Emphasis added]

[133] Therefore, I find that *C.E. Jamieson* does not stand for the proposition that s. 23 is unconstitutional.

[134] In the end result, I find that the April 2003 seizure does not offend Mr. Hardy's or Truehope's Section 8 rights.

V. Conclusion on the Present Application

[135] The Application is dismissed.

ORDER

THIS COURT ORDERS that:

1. The Application is dismissed.

2. The issue of costs is reserved for determination following further argument.

"Douglas R. Campbell"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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PLACES OF HEARING:	CALGARY, ALBERTA AND VANCOUVER, BRITISH COLUMBIA
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DATED:	JANUARY 20, 2010

APPEARANCES:

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