In the Provincial Court of Alberta

Citation: R. v. Synergy Group of Canada Inc. 2006 ABPC 196

Date: 20060728
Docket: 040608200P10103, 0203
Registry: Calgary

Between:

Her Majesty the Queen

- and -

The Synergy Group of Canada Inc.
and
Truehope Nutritional Support Ltd.

Decision of the Honourable Judge G. M. Meagher

I. BACKGROUND

[1] Anthony Stefan and David Hardy are the principals of the Defendants - The Synergy Group of Canada Inc. and Truehope Nutritional Support Ltd. ("Synergy" and "Truehope"). Mr. Stefan had lost his wife to bi-polar disorder through her suicide and had two children apparently suffering from the same disorder and becoming more and more unmanageable. Conventional pharmaceutical treatments were unsatisfactory. Mr. Hardy, with twenty years experience in the livestock feed business, informed Mr. Stefan of a vitamin/mineral supplement that had been used successfully with pigs over the years to reduce their rage and aggressive behaviour. They prepared a similar vitamin/mineral supplement and administered it to one of Mr. Stefan's children. Within weeks, the child's behaviour had returned to normal, without the drastic side effects often associated with drugs used to treat depression or bi-polar disorder. Similar results were observed with regards to Mr. Stefan's daughter when she started taking the vitamin/mineral supplement. Similar results were observed in other subjects and in May 1996, Synergy was incorporated as a research company.

[2] Over the next several years the significant results of treating depression and bi-polar disorder with vitamin/mineral supplements rather than conventional pharmaceuticals attracted interest from potential patients and experts in the field of treatment of depression and bi-polar

disorder in Canada and the United States. The vitamin/mineral supplement went through several refinements and became known as "Empower Plus".

[3] Because the treatment of depression or bi-polar disorder could have serious side effects when an individual was reducing dependence on drugs while commencing treatment with the vitamin/mineral supplement, it was necessary to establish a unique screening, monitoring and support program called the "Truehope program" operated by a non-profit organization, the Defendant, Truehope.

[4] By 2002 - 2003, Synergy, the research organization, was raising funds, and Truehope was running the support program required for Empower Plus for approximately 3,000 people across Canada. The Truehope program was administered on a twenty-four hour a day basis with a staff of 25 experienced call-takers to assist with the screening, monitoring and support for participants in the Truehope program taking the vitamin/mineral supplement. The business conducted by the Defendants took orders from individuals in Canada and imported the vitamin/mineral supplement from a United States' based manufacturer. Empower Plus was then re-distributed in Canada to the participants in the Truehope program.

[5] In 2002, the Defendants had attracted the attention of Health Canada. Since the Defendants made claims that Empower Plus was useful for the treatment of depression and bi-polar disorder, Health Canada took the position that this brought the supplement within the definition of a "drug" within the meaning of the *Food and Drugs Act,* even though the product was clearly a vitamin/mineral supplement. Health Canada advised the Defendants that they could not sell or distribute the supplement in Canada without a Drug Identification Number or "D.I.N.". However, in order to get a D.I.N., the product would be required to undergo extensive testing designed for drugs or pharmaceuticals through the Therapeutic Products Directorate of Health Canada. In the normal course this would typically involve the testing of one active ingredient over the course of several years and at considerable expense. Such a drug testing regime was not suited to a vitamin/mineral supplement, or other health food products, which typically could have numerous active ingredients. The vitamin/mineral supplement in Empower Plus, for example, has approximately 24 ingredients. It would not be possible for the Defendants to obtain a Notice of Compliance and then a D.I.N. for Empower Plus, and Health Canada was well aware of this fact.

[6] At the same time, Health Canada had been working for several years to develop a Natural Health Products Directorate to regulate health food products because it was well known that the testing of health food products was not compatible with Health Canada's drug testing regime. Legislation establishing the Natural Health Products Directorate had been prepared and was making its way through Parliament, and a transition team had been established by Health Canada to oversee the establishment of this new regime more suited to dealing with health food products.

[7] Even though approximately 90% of the health food products sold in Canada were not required to conform to Health Canada's legislative regime for drugs, Health Canada insisted that

the Defendants obtain a D.I.N. or stop selling and distributing Empower Plus to the thousands of participants in the Truehope program in Canada.

[8] At this time, the users of Empower Plus were being monitored through the Truehope program. If an individual stopped taking the supplement, or was denied access to the supplement, that person would revert within a matter of days to an earlier state of depression or bi-polar behaviour characterized by aggressiveness, mood swings, and violence to one's self or to others with a very real risk of personal injury and, in some cases, death. Conventional treatment with various drugs or pharmaceuticals and regular attendances with psychiatrists was not considered to be a viable or desirable alternative because of the serious negative side-effects associated with such medications.

[9] In June 2002 the Defendants wrote to Health Canada expressing their concerns that Health Canada may require a D.I.N. for the supplement and seeking a resolution to the problem. The Defendants referred to the new legislation being developed for health food products and to the encouraging findings of medical professionals whose patients were using the supplement and were involved in the Truehope program. The Defendants provided testimonials and letters of support from over 200 supporters. Most importantly, the Defendants requested a dialogue with Health Canada to work with the Defendants for a resolution such as a Ministerial Exemption or an agreement to continue to the sale and distribution of the supplement and the operation of the Truehope program. The Defendants also repeated an earlier request for a meeting with the Minister of Health.

[10] Representatives of the Defendants initiated a meeting with representatives of Health Canada in mid-January 2003, in Burnaby, British Columbia, to plead their case to continue to sell and distribute their supplement as monitored through the Truehope program and specifically requested a Ministerial Exemption for the supplement. The Defendants claimed to have contacted Health Canada and the office of the Minister of Health on numerous instances but had not received any responses. According to the Defendants, who were seeking to remain in compliance with the requirements of Health Canada, the options available to the Defendants arising from this meeting with Health Canada officials were to stop selling the supplement until they obtained a D.I.N. (which Health Canada knew the Defendants could not obtain under the then current drug approval regime) or move their business to the United States.

[11] The Defendants continued to request meetings by correspondence and by telephone with the Minister of Health but none were forthcoming. In early March, 2003, the Defendants again wrote to Health Canada officials and the Minister of Health outlining their concerns and requesting a detailed response to their correspondence from June 2002. Representatives of the Defendants continued to approach Health Canada officials on numerous occasions in an effort to find a solution to the sale and distribute of the supplement and to continue the Truehope program. Participants in the Truehope program wrote to Health Canada and to the Minister of Health to find a way to continue the supply of the supplement and the operation of the support program. Representatives of the Defendants made several trips to Ottawa attempting to meet with the Minister of Health and Health Canada officials but to no avail. They met with various

members of Parliament to discuss their concerns and supported Bill C-420, a private Member's bill, to amend the *Food and Drugs Act and Regulations* to permit the sale of the supplement as a food and not as a drug.

[12] However, by the end of March 2003, Health Canada had issued directions to Canada Customs to stop all shipments of the supplement from the United States at the Canadian border. Only such supplement that was strictly proven to fall within the "personal use" exemption would be permitted to enter Canada. There was confusion and inconsistency with the application of this direction. There was panic and confusion amongst the participants of the Truehope program. Health Canada's response was to set up a 1-800 crisis line on which callers were advised that since the vitamin/mineral supplement would no longer be available they should contact their psychiatrists and return to conventional pharmaceutical treatments.

[13] In April 2003, the Defendants wrote to Health Canada warning Health Canada of the serious risk of harm and possible deaths by suicide from Health Canada's action to stop the importation of the supplement by ordering seizures of the supplement by Canada Customs at the Canada/United States border. Numerous previous warnings had been expressed in writing to Health Canada, including correspondence in June 2002 and in March 2003, but these warnings were apparently disregarded by Health Canada. The only witnesses called by the Crown were three compliance officers, one of whom merely assisted in the execution of the search warrant in July 2003. The other two compliance officers testified that they were aware of the warnings of harm but that this was not their concern. They testified that they were simply following orders from their superiors to strictly enforce the D.I.N. regulation against the Defendants.

[14] The Minister of Health had accepted numerous recommendations in 1999 from the Standing Committee on Health, many of which referred to the health food industry. The federal government had been slow to act on any of these recommendations. There was a transition team in place at Health Canada to establish the new Natural Health Products Directorate but the legislation and implementation had been bogged down. However, the new legislation and regulatory regime for the Natural Health Products Directorate was scheduled to come into force in January 2004.

[15] In the meantime, Canadian citizens took to smuggling the supplement into Canada for their own health or for the health of family members. Fearing for the health, safety and well-being of their participants in the Truehope support program, the Defendants continued to take orders for the supplement, transmit the orders to their manufacturer in the United States, and distribute the supplement in Canada. The Defendants continued to operate the Truehope program which was vital to the safe and effective use of the supplement. This conduct by the Defendants was contrary to the direction from Health Canada that, since Health Canada had determined that the supplement was a drug, it was not to be sold without a D.I.N.

[16] Also, over this period of time, the Defendants brought an application in the Federal Court of Canada in May 2003 for judicial review of decisions made by Health Canada with respect to the supplement and the seizure actions by Health Canada and Canada Customs.

[17] In June 2003, a group of women known as the "Red Umbrellas" gathered on Parliament Hill. The women were either members of the Truehope program or had family members associated with the Truehope program. They were protesting the lack of response from Health Canada to their concerns for their well-being and the well-being of their family members caused by the border seizures, and the lack of response to the numerous concerns raised about the availability of the supplement and the operation of the Truehope program. In July 2003, they also protested Health Canada's conduct at the constituency office of the Minister of Health in Edmonton. No direct response was forthcoming from the Minister of Health or representatives of Health Canada; however, in July 2003 Health Canada executed a search warrant and raided the business premises of the Defendants.

[18] In September 2003, the Defendants brought an application in the Court of Queen's Bench of Alberta in response to a search and seizure operation by Health Canada on their businesses, seeking an order quashing the search warrant and returning all goods that had been seized pursuant to the search warrant.

[19] Under the new legislative and regulatory regime for natural health products that came into force in January 2004, a similar product to Empower Plus was submitted and eventually received approval. More significantly, in March 2004 the new federal Minister of Health granted an exemption to the Defendants for the Empower Plus supplement pursuant to the terms of a ministerial agreement that remains in force today. The supplement continues to be sold, distributed and monitored in Canada by the Defendants, Synergy and Truehope, under this agreement.

[20] Regardless of the foregoing, in May 2004, Health Canada instituted six charges against the Defendants for breaches of the *Food and Drugs Act* and *Food and Drug Regulations* during the period of January 1, 2003 and December 31, 2003. At the commencement of this twelve day trial on March 13, 2006, the prosecution entered Stays of Proceedings on five out of six charges. This Health Canada prosecution has proceeded on count number 3 - that the Defendants, between January 1, 2003 and December 31, 2003, unlawfully sold a drug for which a Drug Identification Number (D.I.N.) had not been assigned contrary to the provisions of the *Food and Drugs Act and Regulations.* The charge carries a maximum penalty on summary conviction for a first offence of a fine not exceeding $500.00, or for a term of imprisonment not exceeding three months, or to both. The Crown conceded at the outset of the trial that, in the event of a conviction, the Crown was only seeking a fine.

[21] The offence charged is a strict liability offence and the Crown has proven the *actus reas* of the offence. On the evidence, the Defendants were selling a drug as defined in the *Food and Drugs Act and Regulations* without a Drug Identification Number. This finding is based on the documentary evidence admitted as part of the Crown's case, the evidence of the Crown's witnesses and the evidence and admissions of Mr. Stefan and Mr. Hardy on behalf of the Defendants. This case is one of whether or not one or more of the defences claimed by the

Defendants is available to them. The Defendants have argued for the defence of necessity, the defence of due diligence and for a stay of proceedings based on abuse of process.

[22] The evidence presented by both Health Canada and the Defendants was credible, with no significant inconsistencies or contradictions, and has been accepted subject to the further comments in the analysis that follows. In particular, the expert evidence presented by the Defendants - - Dr. Charles Popper, psychiatrist at Harvard University, Dr. Bonnie Kaplan, psychologist at the University of Calgary, and Mr. Bruce Dales, consultant, on the drug approval process and the classification of substances under the *Food and Drugs Act and Regulations* - - was clear and persuasive in support of the Defendants and not significantly affected by cross-examination. Also, the evidence of numerous witnesses called by the Defendants on the effects of the supplement on their lives or on the lives of their family members, and the effects of the actions or lack of action by Health Canada, was compelling and persuasive.

II. ISSUES

[23] There are four issues in this case, generally described as follows:

(1) Are either or both of the Defendants a "manufacturer" within the meaning of the *Food and Drugs Act and Regulations*?

(2) Are the Defendants entitled to the defence of necessity?

(3) Are the Defendants entitled to the defence of due diligence?

(4) Was the conduct of Health Canada an abuse of process sufficient to justify a stay of proceedings?

III. ANALYSIS

(1) MEANING OF "MANUFACTURER"

[24] The definition of "manufacturer" in the regulations under the *Food and Drugs Act* is found in section A.01.010 of the *Regulations*[1] and states:

> 19-12-96 | "manufacturer" or "distributor" means a person, including an association or partnership, who under their own name, or under a trade -, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug: *(fabricant or distributeur)*

[25] The Defendants argued that, for all of 2003, the trademark under which the supplement was sold was controlled by True Hope Institute Inc. and at no relevant time did the Defendants, Synergy or Truehope, have control of the trademark under which the supplement was sold. The

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1 *Food and Drug Regulations*, p.29, April 10, 2003 - Part A, Administration - General; Interpretation - A.01.010

Defendants argued that this evidence demonstrated that the "manufacturer" was True Hope Institute Inc. because of its control of the trademark and that the Crown had failed to prove beyond a reasonable doubt that the Defendants, or either of them, were manufacturers within the meaning of the *Act* or *Regulations*.

[26] This argument attempts to limit "manufacturer" to the person or persons controlling the trademark under which a food or drug is sold. While this describes one of the persons or persons in the definition in the *Regulations*, in the plain wording of the definition "manufacturer" also means a person who under their own name sells a food or drug. The plain meaning of the definition of "manufacturer" in the *Regulations* contemplates two different categories of persons - in one case, a person, including an association or partnership, who under their own name sells a food or drug; or, in the other case, a person who under a trade -, design or word mark, trademark or other name, word or mark controlled by them, sells a food or drug. On the evidence presented at trial, the Crown has proven beyond a reasonable doubt that the Defendants were manufacturers, who under their own names, sold the vitamin/mineral supplement known as Empower Plus.

(2) DEFENCE OF NECESSITY

A) Onus of Proof

[27] There is an evidentiary burden upon the Defendants to place sufficient evidence before the Court to raise the defence of necessity. However, once there is sufficient evidence before the Court, the defence of necessity is raised and the Crown has the burden to prove beyond a reasonable doubt that the Defendants were not acting out of necessity. In ***R. v. Perka et al***, [1984] 2 S.C.R. 232 at pp.257-258:

> Although necessity is spoken of as a defence, in the sense that it is raised by the accused, the Crown always bears the burden of proving a voluntary act. The prosecution must prove every element of the crime charged. One such element is the voluntariness of the act. Normally, voluntariness can be presumed, but if the accused places before the court, through his own witnesses or through cross-examination of Crown witnesses, evidence sufficient to raise an issue that the situation created by external forces was so emergent that failure to act could endanger life or health and upon any reasonable view of the facts, compliance with the law was impossible, then the Crown must be prepared to meet that issue. There is no onus of proof on the accused.

[28] Justice Dickson for the majority went on the summarize a number of conclusions regarding the defence of necessity in terms of its nature, basis and limitations at p.259. In particular, the Court spoke of "moral involuntariness" in the following terms:

> (4) the criterion is the moral involuntariness of the wrongful action;
> (5) this involuntariness is measured on the basis of society's expectation of appropriate and normal resistance to pressure;

[29] The Supreme Court of Canada in ***R. v. Perka***, *supra,* at p.248 described the defence of necessity and moral involuntariness in the following words:

> Conceptualized as an "excuse", however, the residual defence of necessity is, in my view, much less open to criticism. It rests on a realistic assessment of human weakness, recognizing that a liberal and humane criminal law cannot hold people to the strict obedience of laws in emergency situations where normal human instincts, whether of self-preservation or of altruism, overwhelmingly impel disobedience. The objectivity of the criminal law is preserved; such acts are still wrongful, but in the circumstances they are excusable.

This statement was cited with approval by the Supreme Court of Canada in ***R. v. Latimer***, [2001] 1 S.C.R. 3 at para. 26. Furthermore, Dickson J. at para. 27 stated ". . .It is well established law that the defence of necessity must be of limited application."

[30] In this case, the Defendants had the choice of stopping selling the supplement and operating the Truehope program or of disregarding the regulation requiring a D.I.N. The Defendants maintain that they were in a situation of emergency and were compelled by normal human instincts to disobey the regulation in order to protect other persons from harm.

B) Elements of the Defence of Necessity

[31] The Supreme Court of Canada in ***R. v. Latimer,*** *supra,* described ***R. v. Perka***, *supra,* as the leading case on the defence of necessity. The Court stated at para. 28:

> *Perka* outlined three elements that must be present for the defence of necessity. First, there is the requirement of imminent peril or danger. Second, the accused must have had no reasonable legal alternative to the course of action he or she undertook. Third, there must be proportionality between the harm inflicted and the harm avoided.

[32] The Supreme Court of Canada in ***R. v. Latimer***, *supra,* at para. 32 stated that, before applying the three requirements of the defence of necessity to the facts of a particular case, it was necessary to determine what test or tests governed the elements of the defence of necessity. The Court concluded at para. 33 that:

> The first and second requirements – imminent peril and no reasonable legal alternative – must be evaluated on the modified objective standard described above. As expressed in *Perka*, necessity is rooted in an objective standard: "involuntariness is measured on the basis of society's expectation of appropriate and normal resistence to pressure" (p.259). We would add that it is appropriate, in evaluating the accused's conduct, to take into account personal characteristics that legitimately affect what may be expected of that person. The approach taken in *R. v. Hibbert,* [1995] 2 S.C.R. 973, is instructive. Speaking for the Court, Lamer C.J. held, at para.59, that
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> > it is appropriate to employ an objective standard that takes into account the particular circumstances of the accused, including his or her ability to perceive the existence of alternative courses of action.

[33] While stating that a modified objective test should be applied to the first two elements of the defence of necessity, the Court in ***R. v. Latimer***, *supra,* at para. 34 went on to state:

> The third requirement for the defence of necessity, proportionality, must be measured on an objective standard, as it would violate fundamental principles of the criminal law to do otherwise. Evaluating the nature of an act is fundamentally a determination reflecting society's values as to what is appropriate and what represents a transgression. . . . The evaluation of the seriousness of the harms must be objective.

C) Analysis

[34] The Defendants have presented sufficient evidence to the Court on the three elements of the defence of necessity to establish an air of reality to the defence. The Crown must therefore prove beyond a reasonable doubt that one or more of these elements does not apply on the facts of this case. The Crown based its case on proving that the supplement was sold without a D.I.N. and relied on the evidence of the compliance officers from Health Canada. The Crown further relied on evidence of the witnesses for the Defendants, and the Crown's cross-examination of those witnesses, to attempt to satisfy the onus on the Crown to prove beyond a reasonable doubt that the Defendants were not acting out of necessity.

i) Imminent Peril or Danger

[35] The test applicable to this requirement is a modified objective test which involves an objective evaluation, but one that takes into account the situation and characteristics of the Defendants (***R. v. Latimer,*** *supra*, at para. 32).

[36] The evidence presented by the Defendants was credible and compelling with regards to imminent peril or danger. Mr. Stefan testified that the individuals who came to the Defendants for assistance were often the most severe cases to whom Empower Plus and the Truehope program were the last resort. He had had first-hand, personal experience with the ravages of depression and bi-polar disorder having lost his wife to suicide and having two children suffering from the same mental illness. He also had personal experience with the dangers associated with removing the supplement from such individuals. When the supplement was removed an individual regressed very rapidly and within a matter of a few days aggressiveness, violent behaviour, mood swings and the possibility of suicide quickly returned.

[37] His evidence was supported by the evidence of Sabine Colson, Autumn Springham, Debra Oxby and Sheila Stanley based on their personal experiences or observations of close family members regarding how depression and bi-polar behaviour rapidly returned when the supplement was not taken. This effect was also observed by Dr. Bonnie Kaplan, a psychologist at the University of Calgary, who had conducted case studies on the use of the supplement before her work was shut down by Health Canada.

[38] Dr. Charles Popper, a psychiatrist at Harvard University, who also teaches psychiatry to other psychiatrists, testified that when treatment was withdrawn the symptoms returned. Dr. Popper has most impressive qualifications. Although he was initially extremely skeptical with regards to the supplement, by the time of trial approximately 100 to 150 of his patients were using the supplement. He testified that he would have difficulty managing his practice if his patients had to return to conventional treatment by frequent interviews and the use of medications which lack the stability experienced by patients on the supplement. In addition to his patients, Dr. Popper testified to having consulted on 300 to 500 hundred additional patients on the supplement. Dr. Popper's expert evidence was that if the supplement became unavailable, symptoms associated with depression and bi-polar disorder, which would include aggressive behaviour, assaults, hospitalizations and suicides, would return.

[39] Ron LaJeunesse, the Alberta head of the Canadian Mental Health Association, was very knowledgeable of the risks facing persons with mental illnesses. He expressed grave concern for the conduct of Health Canada in preventing the supplement from coming into this country. He testified that death was a consequence of bi-polar disorder and that he was concerned that there would be suicides if individuals could not get access to the supplement.

[40] The evidence presented by the Defendants establishes that the Defendants believed that the persons in the Truehope program were in imminent peril or danger if they no longer had access to the supplement or to the Truehope program. The Court finds that this was a reasonably held belief.

[41] The Crown argued that there was no imminent peril or danger in the sense that the harm was not immediate or unavoidable. However, the onus is on the Crown to prove beyond a reasonable doubt that this requirement has not been met. The return of symptoms of depression and bi-polar disorder within a matter of a few days, with the attendant behaviours of aggression,

assaults, hospitalizations and suicides was, in the eyes of the Defendants, imminent peril or danger to the persons who relied upon the Defendants to supply the supplement and administer the Truehope program.

[42] The Crown argued ***R. v. Morgentaler et al*** (1986), 22 C.C.C. (3d) 353 (Ont. C.A.) with regard to voluntariness. The Crown maintained that this portion of the decision of the Ontario Court of Appeal was upheld in the Supreme Court of Canada. At p.428 of the decision, the Court referred to an ". . . uncalculating response essential to 'involuntary' conduct." The Crown argued that since the conduct in this case was deliberate and planned - - disregarding the direction of Health Canada to stop selling the supplement with out a D.I.N. - - the conduct was not involuntary.

[43] However, the grounding of a ship after mechanical problems and deteriorating weather was found to be imminent peril or danger, even though the time frame involved could not be said to be immediate as in ***R. v. Perka***, *supra.* Also, the act of smuggling heroin under threats of harm to a family member was not immediate yet the Supreme Court of Canada allowed the common law defence of duress in ***R. v. Ruzic,*** [2001] 1 S.C.R. 687. Likewise, this Court finds that the return of devastating, possibly life-threatening behaviours within a few days constituted imminent harm or danger that the Defendants reasonably believed was unavoidable if access was prevented to the supplement and the Truehope program. Regarding the argument that the Defendants' conduct was planned and deliberate, the actions of the accused persons in ***R. v. Perka***, *supra* and ***R. v. Ruzic***, *supra,* were also planned and deliberate yet the Supreme Court of Canada found that the accused persons in those cases were entitled to the defences of necessity and duress respectively. Involuntariness means moral involuntariness. The Court is satisfied that the Defendants have presented sufficient evidence, applying the modified objective test, to establish that their conduct in ignoring the D.I.N. regulation and continuing to supply the supplement and operate the Truehope program was, in this sense, involuntary. As stated by the Supreme Court of Canada in ***R. v. Perka,*** *supra,* at p.248:

> . . . a liberal and humane criminal law cannot hold people to the strict obedience of laws in emergency situations where normal human instincts, whether of self-preservation or of altruism, overwhelmingly impel disobedience.

[44] The Crown also argued the case of ***R. v. Kreiger***, [2000] ABQB 1012 and ***R. v. Kreiger***, [2005] ABCA 202 in which case the Courts found that there was no air of reality on the evidence presented in support of the defence of necessity. In the present case, there is an air of reality to the defence of necessity sufficient to require the Crown to prove beyond a reasonable doubt that one or more of the requirements of the defence was not satisfied.

[45] The Crown also argued that the Defendants themselves were not facing imminent peril or danger. However, in 2003 there were approximately 3,000 individuals in Canada taking the supplement and being monitored by the Truehope program who were being placed in imminent peril or danger and the defence of necessity does extend to the protection of others from harm (***R.***

v. Perka, supra, p.248). There was ample evidence presented by the Defendants that Health Canada was aware of the possible harm to the participants including hundreds of letters of support, numerous correspondence, faxes and telephone calls, protests on Parliament Hill, questions in the House of Commons and a rally at the Minister of Health's constituency office in Edmonton. Health Canada's own conduct in setting up a 1-800 crisis line once the seizures commenced at the Canada/United States border is evidence that Health Canada was aware of the possible harm or danger to the participants. Health Canada received over 1000 calls on the crisis line.

[46] The Defendants presented sufficient evidence on the requirement of imminent peril or danger to the persons using the supplement and the Truehope program. The Crown has failed to prove beyond a reasonable doubt that the Defendants' conduct, viewed through a modified objective standard, was not involuntary in the sense of moral involuntariness. The Defendants were overwhelmingly compelled to disobey the D.I.N. regulation in order to protect the health, safety and well-being of the users of the supplement and the support program.

ii) No Reasonable Legal Alternative

[47] The second requirement for the defence of necessity is that there must be no reasonable legal alternative to disobeying the law. The test for this element is also the modified objective test. While this involves an objective evaluation, it should also take into account the situation and characteristics of the Defendants. The test is whether there was a "reasonable" legal alternative considering the situation and characteristics of the Defendants, not whether there was "any" alternative.

[48] The Defendants argued that the alternative sought by Health Canada, that the Defendants stop selling the supplement in Canada in 2003, was not a reasonable legal alternative. The Defendants pointed out that the conduct of the Defendants was not merely selling a vitamin/mineral supplement but also maintaining an absolutely necessary support program for persons who were treating mental illness with the supplement. The evidence presented by the Defendants was that it was vital to the health, safety and well-being of the persons on the supplement to be managed through the support program. The Defendants presented evidence that up to 40% of the persons who applied for the program were not accepted and that the Defendants only took participants that could be effectively managed within the support program. The Defendants also established a fund to provide the supplement and support program to persons who could not otherwise afford it. In fact, two of the Crown witnesses who were compliance officers with Health Canada gave evidence as to the thoroughness of the screening process and the continuous monitoring within the support program when they were investigating the Defendants.

[49] Dr. Popper gave evidence on behalf of the Defendants supporting the Defendants' contention that this was the only program of its kind at the time and that only the Defendants had the expertise to effectively screen and monitor participants in the support program. Dr. Popper testified that he learned from the Defendants how to manage the transition for individuals on medications to the supplement. Only persons who were screened and accepted into the Truehope

program were provided with the supplement. The supplement and the support program worked together, for the health, safety and well-being of the persons taking the supplement. There had to be a support program. Therefore any reasonable legal alternative would be required to include this support program.

[50] The Defendants argued that with approximately 3000 participants effectively using the supplement and the Truehope program in 2003, with the harm that these individuals faced if denied access to the supplement or the support program, and with the regulatory regime undergoing a transition to a new health products regime more suited to vitamin/mineral supplements, there was no reasonable legal alternative but to continue selling the supplement and maintaining the support program. A number of alternatives were examined.

[51] The Defendants argued that getting a D.I.N. was not an alternative. The Defendants presented credible and reliable evidence that it would have been impossible to obtain a D.I.N. for a vitamin/mineral supplement because the drug testing regime to which D.I.N.s applied was not suited to the testing of a vitamin/mineral supplement which was a health food product. The Defendants presented expert evidence in this regard through Mr. Dales, on the classification of substances and on applications for approvals under the *Food and Drugs Act and Regulations*. Also, Mr. Stefan understood from his dealings with representatives of Health Canada that the Defendants would not be able to get a Notice of Compliance (a pre-requisite to obtaining a D.I.N.) and that the Defendants should not bother applying for a D.I.N. In addition, Dr. Kaplan's experiences in dealing with Health Canada was that the Defendants would not get a D.I.N.

[52] Another alternative was negotiations with Health Canada. The Defendants made numerous efforts to met with Health Canada to work out a resolution to this developing problem. According to Mr. Stefan, the Therapeutic Products Directorate of Health Canada was not prepared to work towards a resolution with the Defendants. The only alternative suggested by representatives of Health Canada was to stop selling the supplement or leave the country and take the business to the United States. Despite numerous and various attempts to negotiate a solution with Health Canada, the Defendants were not successful in negotiating a resolution such as a Ministerial Exemption or an agreement with Health Canada. However, when Mr. LaJeunesse of the Canada Mental Health Association intervened with Health Canada on behalf of specific individuals to continue to obtain access to the supplement, his interventions were successful in every case.

[53] Health Canada's response to the public outcry was to establish a 1-800 crisis line that received over one thousand telephone calls. The callers were advised to go to a psychiatrist. By this action, Health Canada recognized that there could be serious consequences and harm for individuals no longer able to access the supplement or the Truehope program. Because of the harm associated with conventional psychiatric treatment with medications that had negative side effects and the fact that participants would refuse to undergo such treatments, the Defendants did not consider referring the 3000 participants in the Truehope to psychiatrists to be a reasonable legal alternative.

[54] Another alternative explored by the Defendants was to obtain a Ministerial Exemption. The compliance officers from Health Canada called as witnesses by the Crown were not aware that such an exemption was possible. Mr. Stefan testified that he made numerous telephone calls and wrote several letters attempting to get a meeting with the Minister of Health but to no avail. Mr. Stefan made trips to Ottawa and supported protests in favour of the continued supply of the supplement and the maintenance of the Truehope program. He appeared before the Standing Committee on Health and supported Bill C-420 which was a private member's Bill intended to amend the definitions on the *Food and Drugs Act* to allow for the supplement to be sold in Canada as a food and not as a drug. Attempts were made to reach the Minister of Health at her Edmonton office but they were not successful. All of the efforts undertaken by the Defendants to meet with representatives of Health Canada and to meet with the Minister of Health to make their case for an agreement or for a Ministerial exemption were ignored.

[55] The only alternative proposed by Health Canada (besides to stop selling the supplement) was for the Defendants to leave the country and to move to the United States. The Defendants indicated that this alternative was seriously considered but that there were numerous problems. These problems included not knowing if the United States would permit them to immigrate or obtain working visas, and not having the finances to move their business and their families to the United States. The only evidence presented by the Crown was that at one time the supplement had been provided through a corporate agent in the United States but the circumstances regarding this relationship and its viability were not clearly established in evidence by the Crown.

[56] Another possible alternative suggested by the Crown in argument was to direct the users to prepare their own supplement with "off the shelf" products. This was not a reasonable alternative when dealing with 3,000 participants attempting to obtain the supplement and the maintenance of the Truehope program to assist these persons with their mental health issues.

[57] Another alternative attempted by the Defendants was to take legal proceedings. The Defendants also testified that they took legal proceedings in the Federal Court of Canada in May 2003 to challenge the order or direction by Health Canada to stop the importation of the supplement at the Canada/United States border. Legal proceedings were also taken in the Court of Queen's Bench of Alberta to challenge the search warrant under which Health Canada entered the business premises of the Defendants to seize computers and business records in July 2003.

[58] A further alternative was to employ the "personal use" exemption. There was insufficient evidence before the Court on the effectiveness of this exemption and whether or not the support program could have been maintained under such a scheme. There was evidence of inconsistent application of this exemption. There was evidence before the Court that attempts to use this exemption still resulted in the supplement being stopped at the Canada/United States border.

[59] Counsel for the Defendants also argued that the Defendants were under a duty or duties described in s.216 and 217 of the *Criminal Code of Canada* to continue to provide the vitamin/mineral supplement and to maintain the support program or possibly face the consequences of being charged with criminal negligence. The Defendants provided several cases

in support of their argument, ***R. v. LeBlanc***, [1977] 1 S.C.R. 239; ***R. v. Nelson***, [1990] O.J. No. 139 (Ont. C. A.); ***R. v. Sullivan*** (1986), 31 C.C.C. (3d) 62 (B.C.S.C.); ***R. v. Rogers***, [1968] C.C.C. vol. 4 278 (B.C.C.A.); ***R. v. Homeberg*** (1921), C.C.C. Vol. XXXV 250 (Alta.S.C.A.D.). Further, the Defendants argued that it was established law that it was no defence to charges of criminal negligence to say that one had to cause harm because one had to comply with licensing requirement.

[60] Another alternative was to obtain an agreement with the Minister of Health to permit the supplement to be brought into Canada. Given the conduct of Health Canada officials and the Minister of Health in 2003, this was not a reasonable alternative at the time. It is noteworthy, however, that in March 2004 such an agreement was made with a new Minister of Health. This agreement is evidence that by early 2004 the Minister of Health thought that there was no other reasonable legal alternative for resolving the supply of the supplement and the operation of the support program. This agreement remains in effect today, permitting the sale of the supplement and the operation of the support program.

[61] The Defendants took numerous steps seeking a resolution to the problem. The Defendants considered or attempted numerous alternatives regarding how to continue to supply the supplement and to maintain the support program without running afoul of existing legislation and Health Canada.

[62] The Crown argued that there were reasonable legal alternatives to the conduct of the Defendants in continuing to sell the supplement and to maintain the support program. The Crown initially argued that it was not up to the Crown to suggest reasonable legal alternatives. However, once the Defendants presented sufficient evidence to raise the defence of necessity, then the onus was on the Crown to prove beyond a reasonable doubt that there were no reasonable legal alternatives, bearing in mind the modified objective test for this requirement.

[63] The Crown argued that economics was not a defence. However, evidence led by the Defendants established that the business of the Defendants was more than just selling the supplement but included a vital and essential support program. The Defendants also provided the financial means for persons who wished to take the supplement and be on the program but could not afford to do so. The Defendants' evidence was clear and credible that their business was never about earning a profit but in developing and delivering a vitamin/mineral supplement and support program that provided a viable alternative to the conventional treatment of depression and bi-polar disorder without the significant negative side effects of such treatment. The supplement and the support program were and are inextricably connected to each other.

[64] The Crown suggested the "off the shelf" alternative, that individual users of the supplement cobble together their own vitamin/mineral supplement from existing "off the shelf" products. The Crown suggested that the Defendants should have encouraged the participants to do so and somehow maintained the support program. This argument suggests that the Crown agreed that the vitamin/mineral supplement was not harmful and casts doubt on the Crown's

assertion that Health Canada had concerns for the safety of the supplement. This argument also disregards the necessity of the Truehope program and disregards that the sale and distribution of the product must be controlled and managed through the support program. It is not a reasonable legal alternative to suggest that thousands of people make their own supplement and somehow maintain the support program.

[65] The Crown suggested that it was a reasonable alternative for the Defendants to remove the boron and or germanium from the supplement. However, this argument only goes so far as to state that these were Health Canada concerns. There was no evidence before the Court that the removal of either or both of these ingredients would have resulted in the Defendants obtaining a D.I.N. or would have prevented the enforcement actions being taken by Health Canada. In fact, the evidence before the Court was that regardless the Defendants were not going to get a D.I.N. for the supplement. Lastly, the supplement is still being sold today under the agreement with the Minister of Health containing the same ingredients that it contained in 2003.

[66] The Crown submitted that a further alternative was that the Defendants could have stopped making treatment claims. Again, there was no evidence that if the Defendants modified or stopped their treatment claims that this would have resulted in the Defendants obtaining a D.I.N. or would have resulted in the cessation of the enforcement proceedings by Health Canada. However, there was evidence that the Defendants sought to obtain advice and assistance from Health Canada regarding amendments or modifications to their website but that no such assistance was forthcoming.

[67] Another course of action suggested by the Crown as a reasonable legal alternative was that the Defendants could have sold their rights in the supplement to a company in the United States and negotiated a contractual relationship for a percentage of profits to continue the support program. The Crown pointed to the fact that a relationship had existed with a corporation called Evince in the United States until October 2002. However, there was not sufficient evidence before the Court of the details of the past relationship with Evince or why that relationship ended. There was also insufficient evidence before the Court to determine if it was indeed possible to sell the rights in the supplement to a company in the United States and to negotiate a contractual relationship for a financial percentage to continue the support program.

[68] Applying a modified objective test, the Court must consider whether or not reasonable legal alternatives existed, taking into account the perception, experiences and circumstances of the Defendants. The evidence presented by the Defendants established that the Defendants did not consider that stopping the sale and distribution of the supplement, because they had not or could not obtain a D.I.N., was a reasonable legal alternative. The evidence also established that the Defendants considered and attempted to find a number of alternatives. The Defendants believed that to protect the participants in the Truehope program from harm that there was no reasonable legal alternative but to disobey the D.I.N. regulation. This was a reasonably held belief. The Crown has failed to prove beyond a reasonable doubt, based on the modified objective test, that there were reasonable legal alternatives available to the Defendants.

iii) Proportionality

[69] The third element of the defence of necessity is the requirement that there is proportionality between the harm inflicted and the harm avoided. The Supreme Court of Canada in ***R. v. Latimer,*** *supra,* at para. 34 stated:

> The third element for the defence of necessity, proportionality, must be measured on an objective standard, as it would violate fundamental principles of criminal law to do otherwise. Evaluating the nature of an act is fundamentally a determination reflecting society's values as to what is appropriate and what represents a transgression. . . . The evaluation of the seriousness of the harms must be objective. . . .

[70] The harm that the Defendants sought to avoid was the rapid return of the symptoms associated with depression and bi-polar disorder which could result in aggressive behaviour, assaults, hospitalizations and suicides. The alternative of being placed under psychiatric care with regular interviews and medications that had serious negative side-effects was also a harm that the Defendants sought to avoid. The Defendants in argument characterized the harm sought to be avoided as being the most serious harm of all, that is, severe incapacitation and possibly death due to mental illness.

[71] There was ample evidence presented from both ordinary and expert witnesses that the symptoms associated with depression and bi-polar disorder returned rapidly, within a matter of a few days. Mr. Stefan had observed this personally through his son and daughter, and on a broader scale with the thousands of Canadians who were participating in the Truehope program. Ms. Springham described her severe incapacitation prior to the supplement and was fearful and concerned that without the supplement she would not be able to care for her children and her family and that she could not go out in public for fear of her behaviour. She feared being medicated and consumed with drugs, and becoming suicidal and hospitalized. Ms. Oxby described the harm as having to hear her son beg her to kill him several times a day and watching her son deteriorate as he lost his mental health, his friends, his self-esteem, his dignity and his will to live. Ms. Stanley expressed similar concerns with regards to her daughter and her husband. Ms. Colson described self-inflicted injuries, being involuntarily committed, and becoming useless to the point where she had formulated a plan to kill herself before she lost her mental health again.

[72] The expert evidence before the Court with regards to the objective harm that could occur included the observations of Dr. Bonnie Kaplan, a psychologist from the University of Calgary, who observed the rapid return of symptoms once the supplement was discontinued and Dr. Charles Popper, a psychiatrist from Harvard University, who testified that if the supplement became unavailable there would be aggressive behaviour, assaults, hospitalizations, incarcerations and suicides. He testified that his patients would have to be returned to medications which lack stability and had negative side-effects. Overall, Dr. Popper testified that

he would not be able to manage his practice at the level to which it had grown and he would have refer patients away from his practice.

[73] The Defendants argued that there was no harm in not having a D.I.N. since 90% of the natural health product industry was not in compliance. Also, there was an interim Drug Identification Number directive in place by Health Canada exempting products. There was a new regulatory regime or system being developed, *The Natural Health Products Regulations*, that were more suited to the natural health product industry and were to come into force on January 1st, 2004. Health Canada itself classified the product as Type II, meaning that the risk of serious health consequences was remote, and Health Canada was prepared to allow the purchase of supplement under the "personal use exemption" in any event during this period. Ultimately, the Minister of Health agreed to the sale and distribution of the supplement and the operation of the support program and the Defendants continue to operate under this agreement today.

[74] On a purely objective basis, based on the evidence of ordinary witnesses and expert witnesses, the harm sought to be avoided to the thousands of participants in the Truehope program was significant and severe. The existence of this harm was not seriously questioned by the Crown and any possible harm from the use of the supplement appears to be of little concern to Health Canada today.

[75] The Crown argued that the Court should consider the bigger picture of the importance of regulatory schemes to the governance of the country and the potential harm if this method of governance was undermined. The Crown referred specifically to ***R. v. Wholesale Travel Group Inc.***, [1991] 3 S.C.R. 154 at pp.221-222. In particular at p.221 the Court stated:

> Statistics such as these make it obvious that government policy in Canada is pursued principally through regulation. It is through regulatory legislation that the community seeks to implement its larger objectives and to govern itself and the conduct of its members. The ability of the government effectively to regulate potentially harmful conduct must be maintained.

The Crown argued that this must be taken into consideration in determining the proportionality between the harm inflicted and the harm avoided. The Crown argued that the purpose of the D.I.N. was to protect the public from a company or companies that would develop a drug and place it on the market without going through the testing requirements of the appropriate regulatory body.

[76] In assessing the harm inflicted on the regulatory process it is important to note that a D.I.N. was a requirement relating to drugs under the Therapeutic Products Directorate and primary related to pharmaceuticals. The regulatory process itself was in a state of change and transition while the new Natural Health Products Directorate more suited to health food products like the supplement, was being established. The new regulatory scheme was scheduled to be brought into force on January 1st, 2004. Also, from March 2004 to the present the Defendants

have continued to sell and distribute the supplement and to operate the support program under an agreement with the Minister of Health. Health Canada itself considered the product to be in its Type ll category which meant the risk of serious health consequences was remote. Health Canada made the product available under its "personal use exemption" provisions. The legislation and regulations provided that on a summary conviction proceeding for a first offence of selling a product without a D.I.N. a defendant is liable to a fine not exceeding $500.00 dollars or to imprisonment for a term not exceeding three months or both. In these circumstances, little harm would have been inflicted on a regulatory process that was not suited to health food products like the supplement and that was in the process of being replaced.

[77] The Crown argued that the Defendants were responsible for creating the risk and described their conduct as a complete failure to attempt to abide by the Regulations. However, the evidence established that the Defendants, from 1996 on, developed a vitamin/mineral supplement that was effective for the treatment of some mental illnesses without the negative side-effects of medications associated with conventional psychiatric treatments. The supplement served to reduce the risk to individuals taking the supplement, provided they participated in the Truehope program. The risk that arose was in preventing these individuals from having access to the supplement or, having access to the supplement, not having access to the Truehope program. Rather than a complete failure to abide by the Regulations, the Defendants undertook extensive efforts throughout the course of 2002 and 2003 to meet with the Minister of Health and to work with the representatives of Health Canada in order to find a resolution to the problem within the existing and pending legislative and regulatory framework.

[78] On a purely objective basis, the harm inflicted in the circumstances of this case was insignificant when compared to the harm avoided. The harm avoided was clearly and unquestionably greater than the harm inflicted. The onus was on the Crown throughout the trial to prove the case against the Defendants beyond a reasonable doubt. Since sufficient evidence was presented by the Defendants to raise the defence of necessity, the onus was on the Crown to disprove the defence of necessity beyond a reasonable doubt. To do so, the Crown had to establish beyond a reasonable doubt that one of the three elements or requirements of the defence of necessity had not been met. On the foregoing analysis, the Crown has failed to satisfy the burden of proof and the Defendants are entitled to the defence of necessity.

(3) THE DEFENCE OF DUE DILIGENCE

[79] The offence for which the Defendants stand charged under the *Food and Drugs Act and Regulations* is a strict liability offence. In the leading case of ***R. v. Sault Ste. Marie (City)***, [1978] 2 S.C.R. 1299, (1978) 40 C.C.C. (2d) 353 at p.374 the Supreme Court of Canada described a strict liability offence and the defence of due diligence in the following terms:

> 2. Offences in which there is no necessity for the prosecution to prove the existence of *mens rea*; the doing of the prohibited act *prima facie* imports the offence, leaving it open to the accused to avoid liability by proving that he took all reasonable care. This

> involves consideration of what a reasonable man would have done in the circumstances.

The Supreme Court of Canada at p.373 stated that the onus of proof was on the defendant to establish the defence on a balance of probabilities when it stated:

> . . . While the prosecution must prove beyond a reasonable doubt that the defendant committed the prohibited act, the defendant must only establish on the balance of probabilities that he has a defence of reasonable care.

[80] The evidence presented by the Defendants established that the Defendants were not going to obtain a D.I.N. for the supplement. The expert evidence of Mr. Dales, consultant, with regards to the classification of substances and the approval process under the *Food and Drugs Act and Regulations* was that the process for the approval of a new drug through the Therapeutic Products Directorate of Health Canada, was a process which would take several years and cost millions of dollars. In the end, Mr. Dales evidence was that it would have been impossible to obtain a D.I.N. for this vitamin/mineral supplement because of the nature of the product as a health food product with multiple ingredients going through a therapeutic drug testing regime which typically tested products with only one or two ingredients.

[81] Other evidence presented by the Defendants also established that representatives of Health Canada knew that the Defendants would not obtain a D.I.N. for the supplement but did not clearly state this to the Defendants in meetings, in numerous telephone conversations, in e-mails and in correspondence with the Defendants. Nonetheless, the Defendants, understood they were not going to obtain a D.I.N. from the Therapeutics Products Directorate of Health Canada. It was also apparent from the discussions and e-mails between Dr. Kaplan and representatives of Health Canada that the Defendants would not be able to obtain a D.I.N. Health Canada would not give permission to Dr. Kaplan to continue to conduct clinical trials that Dr. Kaplan and the Defendants hoped would assist in the approval process.

[82] As a result, the Defendants focused their efforts to obtain approval from Health Canada for the continued sale and distribution of the supplement and the operation of the Truehope program by trying to obtain a Ministerial Exemption, which was provided for in the *Food and Drugs Act and Regulations,* and by trying to reach an agreement with Health Canada or the Minster of Health under which these activities could be continued. The Defendants were made numerous attempts to approach the Minister of Health directly and through representatives of Health Canada to plead their case for a Ministerial Exemption. In fact, the head of the transition team establishing the new Natural Health Products Directorate, had recommended this course of action. For whatever reasons, in 2003 the Defendants were unable to successfully pursue this alternative.

[83] Considerable efforts were made to bring attention to the plight of the participants and to obtain a meeting with the Minister of Health. A group of women called the "Red Umbrellas",

who either personally or through members of their families had experienced the successful treatment of depression and bi-polar disorder with the vitamin/mineral supplement, protested on Parliament Hill. Questions were raised by Members of Parliament in the House of Commons. A private member's bill, Bill C-420 was presented to amended the *Food and Drugs Act and Regulations* to permit the sale and distribution of the supplement. Dr. Lunney, a Member of Parliament, attempted to intervene on behalf of the Defendants to obtain a meeting with the Minister. Supporters of the Defendants staged a rally at the constituency office of the Minister of Health. All of these efforts made by the Defendants during 2003 were unsuccessful in obtaining a meeting with the Minister of Health or a Ministerial Exemption or an agreement with the Health Canada to permit the sale of the supplement and the operation of the support program. However, the eventual solution that was available through the next Minister of Health by March 2004 was an agreement with the Defendants to permit the sale and distribution of the supplement and the operation of the Truehope program on certain conditions that today are largely ignored. The decision of this Minister is evidence that the Ministerial Exemption or agreement was the only reasonable legal alternative to resolve the problem against the background of the existing legislation. It is also noteworthy that the Defendants continue the sale of the supplement and the operation of the support program under the terms of this agreement to the present day. It is also evident that the Defendants took all reasonable care to comply with the law in the circumstances.

[84] The Defendants presented other evidence to establish that the Defendants took all reasonable care. The Defendants made numerous attempts to have Health Canada negotiate with the Defendants for a resolution of these matters. Numerous telephone calls, correspondence and e-mails were directed towards Health Canada to raise Health Canada's awareness of the problems that could be and were created by the stoppage of the supplement at the Canada/United States border. Significant actions were taken in Ottawa, in the House of Commons, and in Edmonton but the Defendants' pleas and requests were ignored.

[85] In their continuing efforts, the Defendants took legal proceedings in the Federal Court of Canada in May 2003 to prevent the stoppages of the supplement at the Canada/United States border. When Health Canada executed search warrants against the business of the Defendants in July 2003, the Defendants brought an action in the Court of Queen's Bench of Alberta challenging the validity of the search warrant.

[86] The Defendants had followed a course of conduct from 1996 to 2003 that involved the development and refinement of the supplement, the sale and distribution of the supplement, and the monitoring of its use through the Truehope program. This course of conduct had been accepted by Health Canada until March 2003. Counsel for the Defendants in argument referred to s.216 and 217 of the *Criminal Code* regarding the duty of persons undertaking acts. These provisions state as follows:

> **DUTY OF PERSONS UNDERTAKING ACTS DANGEROUS TO LIFE .**
> **216.** Every one who undertakes to administer surgical or medical treatment to another person or to do any other lawful act that may

> endanger the life of another person is, except in cases of necessity, under a legal duty to have and to use reasonable knowledge, skill and care in so doing.
>
> **DUTY OF PERSONS UNDERTAKING ACTS.**
> **217.** Every one who undertakes to do an act is under a legal duty to do it if an omission to do the act is or may be dangerous to life.

[87] While the Defendants may not have been specifically aware that they may be subject to criminal prosecution for a breach of these sections of the *Criminal Code*, three points are relevant. Firstly, ignorance of the law would afford them no excuse or defence. Secondly, claiming compliance with the D.I.N. regulation would not have afforded them a defence. Thirdly, the evidence is overwhelming that the Defendants considered themselves under a duty to protect the health, safety and well-being of the thousands of persons taking the vitamin/mineral supplement, to distribute the supplement and to monitor those persons through the Truehope program.

[88] The only alternative suggested by Health Canada representatives, other than stopping selling the product, was that the Defendants move to the United States. The Defendants provided evidence that Mr. Stefan and Mr. Hardy gave serious consideration to this possibility but in the end determined it was not financially feasible and there were too many questions to be resolved with regards to re-locating their families and businesses to another country. In any event, the Defendants did not consider this to be a reasonable legal alternative in order to comply with a regulation that 90% of the natural health product industry was not required to comply with, and where the regulatory regime governing the supplement was scheduled to be changed January 1st, 2004.

[89] Other alternatives such as relying upon individuals through the "personal use exemption" or by purchasing the ingredients "off the shelf" to make the supplement themselves were not reasonable in the context of thousands of individuals who were successfully using the supplement that had been refined over several years and who required support through the Truehope program.

[90] The Crown argued that the Defendants did not take all reasonable steps to comply with the law. The Crown maintained that the Defendants could have stopped selling the supplement. Considering the duty of care that the Defendants considered that they were under, this was not what a reasonable person would have been expected to do in the circumstances. Another suggestion was that the Defendants could have waited for the new Natural Health Products Directorate to be established in 2004. This was not a reasonable course of action because thousands of people were already using the supplement and this would have had the same effect as stopping selling the supplement and operating the support program. Another suggestion was that the Defendants could have hired an expert such as Mr. Dales to go through the drug approval process. However, Mr. Dales' expert evidence was that the product would be considered a new

drug, would be required to go through numerous steps in a process that would take a minimum of five years and at a cost of millions of dollars, and ultimately be unsuccessful because of the nature of the product and the requirements of the drug approval process. To expect the Defendants to embark on such a process in 2003, when the new Natural Health Products Directorate and a new regulatory regime was to come into force on January 1st, 2004, was not reasonable.

[91] Other suggestions by the Crown of reasonable steps that the Defendants failed to take were that the Defendants did not remove the treatment claims or the boron or germanium in the supplement. However, there was no evidence that taking these steps were measures that would lead to Health Canada to change its position that the Defendants required a D.I.N. It was also suggested that the Defendants could have made changes to their website to comply with the Regulations but there was no evidence that taking such a step would have been effective. In fact there was evidence that the Defendants sought assistance from Health Canada regarding suggestions and advice regarding changing the website but none was forthcoming.

[92] The Defendants took all reasonable care that could have been expected of a reasonable person in the circumstances to comply with the requirements of Health Canada under the *Food and Drugs Act and Regulations*. The backdrop of circumstances include that it was not possible for the Defendants to obtain a D.I.N. for the supplement, that a new Natural Health Products Directorate with an approval process suited to natural health food products was about to come into force on January 1st, 2004, that their numerous efforts to obtain a resolution to the concerns of Health Canada regarding the sale and distribution of their product were being largely ignored by Health Canada, and that the thousands of individuals who had found relief from mental illness through the supplement without the negative side effects of conventional medications were relying upon them to continue to sell and distribute their product and to maintain the Truehope = program. The fact that the Minister of Health in March 2004 made an agreement for the sale and distribution of the supplement and the operation of the Truehope program that continues to this day is evidence that the Defendants acted reasonably in 2003 and that there was no other reasonable legal alternative at the time. Therefore, the Defendants took all due care to comply with the *Act and the Regulations*. The Defendants have established on a balance of probabilities that the Defendants took all reasonable care to comply with the *Food and Drugs Act and Regulations* that would be expected of a reasonable person in these circumstances and are entitled to the defence of due diligence.

(4) ABUSE OF PROCESS

[93] It is established law that the Defendants, to obtain a stay of proceedings for an abuse of process, whether by common law doctrine or by *Charter* breach, must establish on a balance of probabilities that to allow the Crown to proceed against the Defendants would violate the community's sense of fair play or decency or that the proceedings would be oppressive. The Defendants in this case seek a stay of proceedings based upon the common law doctrine of abuse of process. The Defendants referred to the Supreme Court of Canada decision of ***R. v. Keyowski***, [1988] 1 S.C.R. 657 which summarized the test for abuse of process at pp.658-659 as follows:

> The availability of a stay of proceedings to remedy an abuse of process was confirmed by this court in *R. v. Jewitt*, [1985] 2 S.C.R. 128. On that occasion the Court stated that the test for abuse of process was that initially formulated by the Ontario Court of Appeal in *R. v. Young* (1984), 40 C.R. (3d) 289. A stay should be granted where "compelling an accused to stand trial would violate those fundamental principles of justice which underlie the community's sense of fair play and decency", or where the proceedings are "oppressive or vexatious"([1985] 2 S.C.R. at pp. 136-137). The Court in *Jewitt* also adopted "the caveat added by the Court in *Young* that this is a power which can be exercised only in the 'clearest of cases'" (p.137).

[94] The Defendants further referred to the case of ***R. v. Young,*** *supra,* at p.290, that one case to which abuse of process applies is:

> . . . [W]here the executive action leading to the institution of proceedings is offensive to the principles upon which the administration of justice is conducted by the courts. . .

[95] The Defendants argued that in 2003 approximately 90% of the natural health food products industry was not in compliance with the *Food and Drugs Act and Regulations*. Evidence was presented that the D.I.N. regulation did not fit the natural health products industry and that the regulatory process itself was in a transitionary period with new regulations to govern the natural health products industry scheduled to come into force in January, 2004. The Defendants argued that since there was evidence that withdrawing the supplement would cause harm to the users of the supplement, the efforts of Health Canada to stop the sale of the supplement in 2003 were an abuse of process. This Court is not prepared to find that the efforts of Health Canada to stop the sale of the supplement in 2003 constitutes the "clearest of cases" in order to justify a stay of proceedings for abuse of process. Health Canada's efforts were directed at stopping the sale and distribution of a product that purported to treat mental illnesses. According to the *Food and Drugs Act and Regulations* in force at the time the supplement was therefore technically a drug which had not been tested and approved within the existing regulatory scheme for a drug product.

[96] The Defendants argued that this prosecution is an abuse of process because it is an attempt to make the Defendants stop selling the supplement where there is clear evidence that to stopping the sale of the supplement and/or the operations of the Truehope program could cause serious harm and possibly death. Since the charge before the Court was laid after the present agreement was made by the Minister of Health to permit the sale of this product and the operation of the Truehope program by the Defendants, this prosecution is clearly not an attempt to stop the sale of the supplement and a conviction for breach of the D.I.N. regulation will not

result in stopping the sale of the supplement or the operation of the Truehope program today. Therefore this argument of abuse of process is rejected.

[97] A further argument advanced by the Defendants was that the commencement of this prosecution following the agreement that was reached with the Minister in March 2004 is an abuse of process. The Defendants referred to the case of ***R. v. Young,*** *supra,* where the Court found that it was an abuse of process to proceed with a prosecution on an issue that the Executive had already resolved. The Defendants argued that their case was even stronger because, firstly, the same branch of the Executive was involved, as opposed to different branches of government in ***Young,*** *supra,* and, secondly, in the present case an agreement had already been reached with the Minister of Health to resolve the issues which continues to the present day. While these matters were resolved by an agreement with the Minister in March 2004 which continues through to today, the fact remains that in 2003 the Defendants were in breach of the D.I.N. regulation and have admitted as much.

[98] Is this prosecution, commenced after the agreement in 2004, for conduct from 2003, an abuse of process amounting to the "clearest of cases"? The Supreme Court of Canada in ***R. v. Regan***, [2002] 1 S.C.R. 297 at para. 50 cited with approval the statement of L'Heureux-Dubé J. in ***R. v. O'Connor***, [1995] 4 S.C.R. 411 at para 73 as follows:

> This residual category does not relate to conduct affecting the fairness of the trial or impairing other procedural rights enumerated in the *Charter*, but instead addresses the panoply of diverse and sometimes unforeseeable circumstances in which a prosecution is conducted in such a manner as to connote unfairness or vexatiousness of such a degree that it contravenes fundamental notions of justice and thus undermines the integrity of the judicial process.

At para. 52 the Supreme Court of Canada referred to ***Blencoe v. British Columbia (Human Rights Commission),*** [2000] 2 S.C.R. 307, 2000 SCC 44 at para. 133 where Bastarache J., stated that the abuse "must have cause actual prejudice of such magnitude that the public's sense of decency and fairness is affected." The Court went on to discuss, at paras. 53 and 54 that a stay of proceedings for abuse of process has a very high threshold which has been frequently described as the "clearest of cases". The Court stated at para. 54 that two criteria must be met:

> (1) the prejudice caused by the abuse in question will be manifested, perpetuated or aggravated through the conduct of the trial, or by its outcome; and
>
> (2) that no other remedy is reasonably capable of removing that prejudice. [*O'Connor,* at para. 75]

[99] In particular, at para. 55 of ***Regan,*** *supra,* the Court stated:

> . . . When dealing with an abuse which falls into the residual category, generally speaking, a stay of proceedings is only appropriate when the abuse is likely to continue or be carried forward.

That is not the case with the prosecution that is before this Court. The actual prejudice is not of such a magnitude nor is it likely to be continued or carried forward. The onus is on the Defendants in advancing this argument to satisfy the Court on a balance of probabilities, not only that this is an abuse of process, but that it is the "clearest of cases".

[100] The Crown relied upon ***R. v. Regan,*** *supra,* and ***R. v. Power***, [1994] 1 S.C.R. 601 decisions of the Supreme Court of Canada to demonstrate that the conduct of Health Canada was not an abuse of process, and even if such conduct was found to be an abuse of process, this was not the "clearest of cases" for the Court to direct a stay of proceedings. The Crown referred to ***R. v. Powers,*** *supra,* at p.615:

> . . . [C]ourts have a residual discretion to remedy an abuse of the court's process but only in the "clearest of cases", which, in my view, amounts to conduct which shocks the conscience of the community and is so detrimental to the proper administration of justice that it warrants judicial intervention.

The Court went on at p.616 to state:

> To conclude that the situation "is tainted to such a degree" and that it amounts to one of the "clearest of cases", as the abuse of process has been characterized by the jurisprudence, requires overwhelming evidence that the proceedings under scrutiny are unfair to the point that they are contrary to the interests of justice. . . . Where there is conspicuous evidence of improper motives or of bad faith or of an act so wrong that it violates the conscience of the community, such that it would genuinely be unfair and indecent to proceed, then, and only then, should courts intervene to prevent an abuse of process which could bring the administration of justice into disrepute. Cases of this nature will be extremely rare.

[101] While the prosecution of the Defendants was commenced in 2004 after an agreement had been entered into with the Minister to provide for the sale and distribution of the supplement and the operation of the Truehope program may amount to an abuse of process, this Court is not prepared to find that the commencement of this prosecution after the agreement by the Minister is the "clearest of cases" which would entitle the Defendants to a stay of proceedings. The onus is on the Defendants on a balance of probabilities to satisfy the Court that this is the "clearest of

cases" of an abuse of process to warrant the remedy of a stay of proceedings and the Defendants have not satisfied this onus.

[102] The Defendants argued that there were other instances of conduct by representatives of Health Canada that should be considered as contributing to an abuse of process. One such argument was that the Court was being asked to endorse the blind following of policy in the face of evidence that following such policy would cause harm. The Crown witnesses were compliance officers who were not concerned with the consequences the seizure of the supplement on the thousands of persons using the supplement and involved in the Truehope program. They steadfastly maintained that the product was a drug that did not have a D.I.N., that the Defendants were in breach of the D.I.N. regulation, and that Health Canada was entitled to take enforcement proceedings against them to stop the sale and distribution of the supplement in Canada contrary to the *Food and Drugs Act and Regulations*. They were aware of the letter of March 6th, 2003 from the Defendants to Health Canada voicing concerns that denial of the supplement would jeopardize the health of the participants in the program and the April 29th, 2003 letter warning that the seizures were putting such people at risk. The Crown witnesses maintained that they were just taking orders and following the policies and directives of their superiors. The Crown witnesses were unaware of any mechanism to deal with circumstances where an enforcement action could be harmful to health nor did they investigate this matter further. Unfortunately, none their superiors testified at the trial.

[103] Another example of the conduct of Health Canada that contributed to an abuse of process was that representatives of Health Canada were not forthcoming with the Defendants by failing to tell them that it was not possible for the Defendants to obtain a D.I.N. for the supplement under the existing drug approval regime, even though this belief was known at different levels of Health Canada. Health Canada had this knowledge as demonstrated in various emails and other dealings with Dr. Kaplan. Furthermore, when the Defendants attempted to obtain information under the *Access to Information Act*, information demonstrating this knowledge was edited from the communications with Dr. Kaplan. Then, only edited copies were provided to the Crown for purposes of disclosure to the Defendants. The Court directed that unedited copies be provided. Also, Health Canada had collected materials with regards to calls to the 1-800 crisis line that had been established by Health Canada but failed to disclose this information in the disclosure provided to the Defendants before trial. When the Defendants requested these materials they were still not disclosed. The materials were ultimately found and provided to the Defendants within two hours of this Court ordering the production of the materials mid-way through this trial.

[104] Another example of the conduct of Health Canada that the Defendants argued amounted to an abuse of process was the double standard that applied to people seeking the release of the supplement through Ron LaJeunesse of the Canadian Mental Health Association. The evidence established that in every case where Mr. LaJeunesse intervened to obtain the release of the supplement that had been seized at the Canada/United States border he was successful. This was not the case for the Defendants or other persons seeking release of the supplement seized in the same circumstances.

[105] Another example of the conduct of Health Canada alleged to contribute to abuse of process was that Health Canada did not provide the Defendants with an opportunity to contribute information to the Health Hazard Evaluation and Health Canada's assessment of risk of the supplement. The Defendants argued that Health Canada even resisted meeting with the Defendants for the purpose of sharing information for the evaluation. Even without the participation of the Defendants, the Health Hazard Evaluation of Health Canada for the supplement was that the risk of harm from the use of the supplement was remote. The Defendants argued that the conduct of Health Canada, in the face of their own findings and with the knowledge that the withdrawal of the supplement and the termination of the support program could have serious health consequences to the participants, amounted to an abuse of process.

[106] A further argument advanced by the Defendants was that it was an abuse of process for Health Canada to attempt to enforce a regulation that did not fit the natural health product industry and that by its conduct Health Canada was forcing law-abiding citizens to break the law by smuggling the supplement into Canada for their own health, safety and well-being or for the health, safety and well-being of family members.

[107] A further argument advanced by the Defendants was that the Defendants could have been subject to criminal prosecution for criminal negligence if they had stopped the sale and distribution of the supplement and the operation of the support program. The Defendants argued it would be no defence for the Defendants to argue that they were merely complying with the D.I.N. regulation.

[108] Overall, the Defendants argued that the foregoing conduct of Health Canada taken together should be seen to offend the community's sense of fair play and decency and that this prosecution should be seen as oppressive and vexatious thereby amounting to an abuse of process by Health Canada.

[109] In reply, the Crown argued that neither the conduct of Health Canada throughout 2003 nor this prosecution should be seen as an abuse of process. The Crown argued that there was an interim D.I.N. directive in place to assist with transitional matters. There was a policy that provided a "personal use exemption" for individuals who wished to obtain this supplement. The fact that 90% of the natural health product industry was not in compliance did not justify the Defendants' lack of compliance where the Defendants were making treatment claims associated with the product. Furthermore, Health Canada had expressed some concerns with the existence of boron and germanium in the product. The Court has noted that the Defendants were in breach of the D.I.N. regulation. Also the Minister of Health and Health Canada were not required by law to provide a Ministerial Exemption or to enter into any agreement with the Defendants. While the seizures of the supplements at the Canada/United States border have been challenged in the Federal Court of Canada and the search warrant for the business premises of the Defendants was challenged in the Court of Queen's Bench of Alberta, there have been no findings to date that these actions by Health Canada were not taken within the law.

[110] While this Court is not prepared to find that the various instances of the conduct of the representatives of Health Canada amount to the "clearest of cases" of an abuse of process to warrant a stay of proceedings, this Court does find that some of this conduct would have influenced the Defendants' beliefs that there was no reasonable legal alternative other than to disobey the D.I.N. regulation and that they had taken all reasonable care in the circumstances to comply with the law.

IV. CONCLUSION

[111] The Defendants are not guilty of Count #3 in the Information. The Defendants are entitled to rely upon the defence of necessity, which once raised was not disproved beyond a reasonable doubt by the Crown. Furthermore, this being a strict liability offence the Defendants are entitled to the defence of due diligence. On a balance of probabilities the Court is satisfied that the Defendants took all reasonable care that would be expected of a reasonable person in the circumstances to comply with the *Food and Drugs Act and Regulations* as evidenced by their considerable efforts to obtain a Ministerial Exemption or agreement during 2003. The findings that the Defendants had no reasonable legal alternative and took all reasonable care to comply with the law in the circumstances are supported, in part, by the fact that by March 2004 the new Minister of Health entered into an agreement to permit the sale and distribution of the supplement and the operation of the Truehope program, which agreement continues to the present day.

Heard on the 13th day of March, 2006 to the 24th day of March, 2006 and the 28th day of March, 2006 to the 29th day of March, 2006.
Dated at the City of Calgary, Alberta this 28th day of July, 2006.

G. M. Meagher
A Judge of the Provincial Court of Alberta

Appearances:

K. Brown
for the Crown

S. Buckley
for the Defence