No. 040608200P1

THE PROVINCIAL COURT OF ALBERTA

HER MAJESTY THE QUEEN

- v -

THE SYNERGY GROUP OF CANADA and
TRUEHOPE NUTRITIONAL SUPPORT

Accused

T R I A L
(EXCERPT)

Calgary, Alberta
28th July, 2006
Transcript Management Services, Calgary

I N D E X

Excerpt of Proceedings taken at Trial, in the Provincial Court of Alberta, Provincial Courts Building , Calgary, Alberta

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*July 28, 2006 a.m. Session

The Honourable Judge Meagher	The Provincial Court of Alberta
K. Brown, Esq.	For the Crown
S. Buckley, Esq.	For the Accused
J. Isaac/J. Boyd	Court Clerk

THE COURT CLERK: Calling the matter of the Synergy Group of Canada.

THE COURT: Thank you. All right, for the record, Mr. Brown, you are appearing on behalf of the Federal Crown?

MR. BROWN: That's correct, sir.

THE COURT: Mr. Buckley, you are appearing on behalf of the defendants?

MR. BUCKLEY: Yes, sir, I am.

THE COURT: All right. This matter is set today for a decision. Before I go to that, are there any further comments or motions or applications that either counsel wish to make at the present time?

MR. BROWN: Sir, I don't have anything further at this time, sir.

THE COURT: No.

MR. BUCKLEY: I don't have, Your Honour.

THE COURT: All right, thank you.

I have prepared a written decision that might assist, and it is in the process now of putting the finishing touches on and making copies. It will be ready in about a half an hour. So what I am going to do is I am going to stand this matter down for about a half an hour, I will make that until 20 after 10:00, and I will return at that time and deliver the decision.

I do not intend to read the decision verbatim into the record, because it is 40 pages long, but what I will do is I will highlight parts of the decision and copies will be given to both counsel and will be attached to the Court file as the official decision of this Court with regards to the matter before it.

All right.

MR. BROWN: Yes, sir.

MR. BUCKLEY: Thank you, Your Honour.

THE COURT: All right, very good.

MR. BROWN: Thank you, Your Honour.

THE COURT: We stand adjourned for a half an hour.

THE COURT CLERK: Order in Court, all rise.

Court is adjourned for a brief period of time.

THE COURT: Thank you.

(ADJOURNMENT)

THE COURT CLERK: Calling the Synergy Group of Canada Incorporated and TrueHope Nutritional Support Limited.

THE COURT: First of all I would like to thank counsel, both Mr. Brown on behalf of the Crown and Mr. Buckley on behalf of the defendants for the excellent work they did, both over the course of the two to three week trial that was conducted in this matter and in the arguments that were presented to the Court with regards to the issues. It was apparent that the work was thoroughly researched, the cases were thoroughly prepared and the case was very well presented. So thank you both, gentlemen, for the work that you have done on this matter.

As I stated earlier, I have a written decision which taken down from double spaced is only 29 and not 40 pages, so it will be a little lighter reading than you might have initially thought. Nonetheless, I do not propose to read the entire decision into the record. The original of the decision has been signed and will be attached to the Court record, I have copies for Crown and defence counsel, and in due course the decision will be available on the

Alberta Justice website.

However, the issues that were raised and the circumstances of this case were complex and unique and I'm going to take some time now to review and to summarize the decision so that people here have the benefit of hearing first hand of how the facts and evidence were considered by the Court and the arguments that were made and the decisions that I have arrived at.

By way of background, and I would think that most of you are very aware of the story, but I am going to touch on a number of matters that you have heard before, but I think are relevant to the outline of the summary of this decision.

Mr. Stephan and Mr. Hardy are the principals of the defendants, TrueHope and Synergy, and Mr. Stephan had lost his wife to bi-polar disorder through suicide and two of his children were apparently suffering from the same disorder. He spoke with Mr. Hardy who had experience in the livestock feed business, and they came up with the idea that perhaps a vitamin mineral supplement used with pigs to reduce rage and aggressive behaviour might be of some assistance in dealing with Mr. Stephan's children.

So they tried this and within a few weeks there were observable improvements, initially in his son's

behaviour and then with regards to his daughter. Over the next while other persons started taking the supplement for depression or bi-polar disorder, with significant results and Synergy was incorporated as a research company.

Over the next several years the significant results of treating depression and bi-polar disorder with vitamin mineral supplements, rather than conventional pharmaceutical treatments attracted interest from potential patients and experts in the field of depression and bi-polar disorder, both in Canada and the United States.

By 2002/2003, Synergy, the research organization was raising funds and TrueHope was running a support program required for the product, which over time had become more refined and was known as EMpowerplus. There were approximately 3,000 people across Canada participating in the use of the supplement and the TrueHope Support Program, and the program administered a 24 hour a day -- was administered on a 24 hour a day basis with call takers assisting in the screening, monitoring and support of participants in the program.

By 2002 the defendants had attracted the attention of Health Canada, since the defendants made claims that EMpowerplus was used for the treatment of depression and bi-polar disorder,

Health Canada took the position that this brought the supplement within the meaning of the definition of a drug within the Food and Drugs Act and Regulations, even though the product was a vitamin mineral supplement.

There were discussions in which Health Canada suggested, representatives of Health Canada, suggested that the product couldn't be sold without a drug identification number or a DIN. However, in order to get a DIN the product would be required to undergo extensive testing designed for drugs or pharmaceuticals and which process was not suited towards health food products or vitamin mineral supplements. The drug testing regime in the normal course, one or two active ingredients would be tested, but with a vitamin mineral supplement such as EMpowerplus had approximately 24 ingredients.

There was expert evidence at trial that it would have been impossible for the defendants to obtain a drug identification number for the supplement.

In any event, in June 2002 the defendants wrote to Health Canada expressing their concerns that Health Canada may require a DIN for the supplement, and looking for a resolution to the problem. The defendants referred to new legislation being developed for health food products and the

encouraging finding of medical professionals who patients were using the supplement and were involved in the TrueHope program. The defendants provided testimonials on letters from over 200 supporters at that time.

Mor 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 for the continuance of the sale and distribution of the supplement and the operation of the program. The defendants at that time, this was June of 2003, repeated earlier requests for a meeting with the Minister of Health.

A meeting did occur in mid January 2003 in Burnaby with representatives of Health Canada where the defendants pleaded their case to continue the sale and distribution of the supplement and specifically asked for a Ministerial exemption. The defendants claim to have contacted Health Canada and the office of the Minister of Health on numerous occasions and numerous instances, but have 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 the meeting with Health Canada were either stop selling the supplement until

they obtained a DIN, which Health Canada knew they could not do, or leave the country and move to the United States.

The defendants continued to request meetings by correspondence and telephone with the Minister of Health, but none were forthcoming. In early March 2003 the defendants again wrote to Health Canada and the Minister of Health outlining their concerns and asking for a response to their written inquiries from June of 2002.

However by the end of March Health Canada had already issued directions to Canada Customs to stop all shipments of the supplement from the United States into Canada.

There was panic and confusion amongst the participants in the TrueHope Program, Health Canada's response was to set up a 1-800 crisis line which callers were advised that they should go see a psychiatrist.

In April 2003 the defendants wrote to Health Canada warning Health Canada of serious risk of harm and possible deaths by suicide from Health Canada's actions. Numerous previous warnings had been expressed in writing to Health Canada, but the seizures continued.

In the meantime Canadian citizens took to smuggling the supplement into Canada for their own

health and for the health, safety and well being of their family members. The defendants continued to take orders for the supplement and to maintain the TrueHope support program, which was essential 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 the supplement was a drug, it was not to be sold without a DIN. A DIN which was impossible to obtain.

The defendants pressed on with their efforts, in addition to phone calls and faxes and correspondence, attempts to meet with the Minister, attempts to meet with representatives of Health Canada. They also went to Court in May of 2003 to the Federal Court of Canada in an attempt to challenge the seizure actions being taken by Health Canada and Canada Customs.

In June of 2003 a group of women known as the Red Umbrellas gathered on Parliament Hill, they were either members of the TrueHope Program or had family members associated with the program. They were protesting the lack of response from Health Canada to their concerns for their well being or for the well being of their family members and for other persons taking the supplement and being supported through 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 against the business premises of the defendants.

The defendants pressed on looking for legal resolutions and in September 2003 they challenged the validity of the search warrant and sought the return of all goods that had been seized pursuant to the search warrant.

At the same time that this was going on the Minister of Health in 1998 and 1999 had accepted 53 recommendations from a Standing Committee on Health, many of which dealt with the natural health food products industry. There was developing legislation in which Health Canada itself recognized that the therapeutic products directorate and the drug testing regime or process was not suited to the health food industry and legislation had been developed and was making its way through Parliament that would amend the legislation to provide for a natural health products directorate and a different form of testing regime. And in the course of 2003 there was a transition team in place and this new directorate was in the process of being set up.

The new legislation and regulations was gazetted to come into force on the 1st of January of 2004. That is a relevant backdrop to the circumstances that the defendants found themselves in, because they were hopeful that under a new regime their product, EMpowerplus or a similar product would be readily approved. Certainly they were not up against the impossible situation of trying to get a drug identification number for a vitamin mineral supplement under a drug testing regime.

It is also significant that in early 2004, in March of 2004, after the federal election in December of 2003, a new Minister of Health entered into an agreement or made an agreement that in effect exempted the defendants from the application of the regulation, the DIN regulation and permitted the defendants to continue to sell and distribute the supplement and to operate the TrueHope Program, and that agreement remains effective today, and my understanding from the evidence at trial was that the defendants continue to operate under that agreement today, with the approval of Health Canada.

Regardless of the foregoing, in particular the new regime and the agreement with the Minister, in May of 2004 Health Canada instituted six charges against the defendants for breach of the Food and

Drug Act and Regulations, from January 1st, 2003 to December 31st, 2003. At the commencement of this trial the Crown entered stays of proceedings on five out of six charges and proceeded on only one Count, that is Count number 3, which is unlawfully selling a drug for which a drug identification number had not been assigned. This offence carries a maximum penalty on summary conviction for a first offence of a fine not exceeding $500 or to imprisonment not exceeding three months or to both, and the Crown conceded at the outset of the trial that in the event of conviction the Crown was only seeking a fine.

The offence charged is a strict liability offence and the Crown has proven the actus reus 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. Stephan 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.

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 I will make in this analysis. 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, a consultant on drug approval process and classification of substances under the Food and Drug Act and Regulations.

The expert evidence 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 actions or the lack of action by Health Canada was compelling and persuasive.

There are four issues in this case, first are either or both the defendants a manufacturer within the meaning of the Food and Drugs Act and Regulations. Secondly, are the defendants entitled to the defence of necessity, thirdly, are the defendants entitled to a defence of due diligence,

and fourthly, was the conduct of Health Canada an abuse of process sufficient to justify a stay of proceedings.

The first issue or argument that was presented by the defence dealt with the meaning of manufacturer within the Food and Drug Act and Regulations, and the argument was that since another company was a holder of the trademark during the relevant charge period in 2003, that the defendants could not be found to be manufacturers and therefore selling in contravention of the regulation.

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, wordmark, trademark or other name or wordmark controlled by them sells a food or drug. On the evidence presented at the trial the Crown has proven beyond a reasonable doubt that the defendants were manufacturers who under their own name sold the vitamin mineral supplement known as EMpowerplus. This was more of a technical argument based upon the wording of the definition, but in any event, I'm satisfied that the defendants are included in the plain meaning of that definition.

The substantive arguments in this case dealt with the defence of necessity, the defence of due diligence and an abuse of process.

With regards to the defence of necessity the onus of proof is on the Crown throughout. There is an evidentiary burden on the defendants to place sufficient evidence before the Court to raise the defence, 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. There is no onus of proof on the defendants.

Counsel for the defence referred to R v. Perka, and some of the comments of Mr. Justice Dixon. One of the characteristics of a defence of necessity involves voluntariness and in describing voluntariness, Justice Dixon said as follows:

> The criterium is the moral involuntariness of the wrongful action.

And then further:

> This involuntariness is measured on the basis of society's expectation of

appropriate and normal resistance to pressure.

The Supreme Court of Canada went further in describing the defence of necessity, it said:

> 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 overwhelming impel disobedience.

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 others from harm.

The defence of necessity has three elements, these elements include that there must be imminent peril or danger, that there must be no reasonable legal alternative, and that there must be proportionality with regards to the harm inflicted and the harm avoided.

The Supreme Court of Canada in R v. Latimer

described the perfect case that I have just mentioned as being the leading case on the defence of necessity, and it is important to appreciate as well that the Court approved a statement that it is well established law that the defence of necessity must be of limited application.

In any event, in dealing with the defence of necessity the first two elements that I have described, the test to determine -- to make a determination is one called the modified objective standard, whereas the proportionality test has to be made on a completely objective basis.

The modified objective standard basically means that, and I will quote from one of the cases here:

> That that standard will take into account the particular circumstances of the accused, including his or her ability to perceive the existence of alternative courses of action.

So dealing first with the element of imminent peril or danger. The evidence presented by the defendants was credible and compelling with regards to imminent peril or danger. Mr. Stephan testified that individuals who came to the defendants for assistance were often the most severe cases to whom

EMpowerplus and the TrueHope Program were the last resort. He has had first hand personal experiences with the ravages of depression and bi-polar disorder. He has also had personal experience with the dangers associated with removing individuals from the supplement, and his evidence was that when the supplement was removed an individual regressed very rapidly, and within a matter of a few days to aggressiveness, violent behaviour, mood swings and also the possibility of suicide quickly returned.

His evidence in this regard was supported by the personal and testimonial evidence of Ms. Coulson, Stringam, Ms. Oxby and Ms. Stanley, who all testified that the symptoms of -- the negative symptoms associated with depression, bi-polar disorder, rapidly returned when the supplement was not taken. This effect was also observed by Dr. Bonnie Kaplan, psychologist at the University of Calgary who had been conducting case studies in the use of the supplement before her work was shut down by Health Canada.

There is expert and objective evidence from Dr. Charles Popper, psychiatrist at Harvard University, who also taught other psychiatrists. He testified that when the treatment was withdrawn the symptoms returned. His 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.

There is also evidence from Ron LaJeunesse of the Canadian Mental Health Association, of his grave concerns with the conduct of Health Canada in preventing the supplement would result in suicides.

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. And the Court is satisfied that this was a reasonably held belief.

The Crown argued on the other hand that there was no imminent peril or danger and argued the case of R v. Morgantaler, which was a decision 20 years ago in first of all in the Ontario Court of Appeal and then in the Supreme Court of Canada. And in dealing with imminent harm or danger the response of an individual was described as having to be an uncalculating response essential to involuntary conduct.

And the Crown argued that since the conduct in this case was planned and deliberate, disregarding Health Canada's directions, that the conduct was not involuntary.

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, that was R v. Perka, the act of smuggling heroine under threats of harm to a family member was not immediate in the sense of immediate time frame, yet the Supreme Court of Canada allowed the common-law defence of duress in R v. Ruzic.

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 program.

Regarding the argument that the defendant's conduct was planned and deliberate, the actions of the accused persons in both R v. Perka and R v. Ruzic, 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. And this Court is satisfied that the defendants have presented sufficient evidence, applying the modified objective test, to establish that their conduct in disobeying the DIN regulation was in this sense

involuntary.

The Crown also argued the case of R v. Krieger, the medical marijuana case and in that case the Courts found that there was no air of reality to the defence of necessity.

In this case I have found that 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.

The Crown argued that the defendants themselves were not facing imminent peril or danger, however the law is clear that it's not just the defendants, but the protection of the defence of necessity extends to the protection of other people from harm, and that's R v. Perka.

So with regards to imminent peril or danger, that element of the defence of necessity, I am satisfied that the defendants have presented sufficient evidence to place the onus on the Crown to prove beyond a reasonable doubt that this element did not exist.

The Crown, in my decision, the Crown has failed to prove beyond a reasonable doubt that the defendant's conduct, viewed through a modified, objective standard was not involuntary in the sense of moral involuntariness. The defendants were

overwhelmingly compelled to disobey the DIN regulation in order to protect the health, safety and well being of the users of the supplement and the support program.

The second element with regards to the defence of necessity is no reasonable legal alternative, that the defendants has no reasonable, legal alternative, but to conduct themselves the way they did.

Once again, this is the modified objective test that takes into account the situation and characteristics of the defendants. And the test is also whether they were reasonable legal alternatives, not whether there were any alternatives.

The alternative set out by Health Canada was that they just -- the defendants just stop selling the product in 2003 and the defendants have said this was not a reasonable legal alternative. There were people involved in taking the supplement since 1996, these people were dependent upon the supplement and on the TrueHope Support Program and against the backdrop of a transitional regulatory scheme, it was in the view of the defendants, not a reasonable legal alternative to stop selling the product, particularly when considering the significant harm and danger that would arise to

participants in the program.

Dr. Popper, whom I have previously referred to, 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 program. Dr. Popper also testified that he learned from the defendants how to manage the transition for individuals on medications to the supplement.

So the defendants argued that with approximately 3,000 participants effectively using the supplement and the TrueHope Program in 2003, that with the harm that these individuals faced if denied access to the supplement or the support program, with the regulatory regime undergoing a state of transition, in all of those circumstances there was no reasonable legal alternative but to consider selling the supplement and maintaining the support program.

In the arguments of both the Crown and the defence, a number of alternatives were proposed that could or could not be considered to be reasonable legal alternatives. I have just addressed that the defendants did not believe that stopping selling the supplement was a reasonable legal alternative.

One alternative was that the defendants could

get a drug identification number for the product. This was not a reasonable legal alternative because the evidence at trial was clear that it was not possible to get a drug identification number for this product.

Another alternative was to negotiate with Health Canada, and I am satisfied on the evidence that the defendants made numerous efforts to meet with Health Canada to work out a resolution to this developing problem. Health Canada's response when the seizures of the product, of the supplement, at the border started, was to establish a 1-800 crisis line, which received over a 1,000 telephone calls and the callers were advised to go see their psychiatrist. It should be obvious from that, that Health Canada recognized that there was potential harm that could accrue to the users of the supplement.

And just on that point, there was evidence at trial as well that going to a psychiatrist and taking pharmaceutical medications for the treatment of depression and bi-polar disorder was seen by many not to be a reasonable alternative. However that was the advice by Health Canada.

Another alternative was that the defendants could obtain a Ministerial exemption. They made numerous efforts to meet with the Minister to try to

obtain a Ministerial exemption in 2002 and in 2003. They made numerous telephone calls, they wrote letters, they went to Ottawa, they supported protests on Parliament Hill, they appeared before the Standing Committee on Health, they worked with a Member of Parliament developing a private members bill to change the definition of the Food and Drug Act to allow the supplement to be sold as a food, not as a drug. There was a rally at the Minister of Health's office in Edmonton. All of these 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 a Ministerial exemption were apparently ignored or disregarded.

The only alternative proposed by Health Canada besides to stop selling the supplement was for the defendants to leave the Country and go to the United States.

Now there is more than one way to look at this particular alternative that was proposed by representatives of Health Canada. But I will only address the defendants' reaction. And the defendants' reaction was that they took this alternative seriously, that they considered it, but that there were numerous problems with it. First of all they did not know if the United States would

allow them to emigrate or get working Visas in order to carry on their business there, and they did not have the financial resources in order to move their businesses 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 that relationship and its viability was not clearly established in evidence by the Crown. Leaving the country was not a reasonable legal alternative.

Another possible suggestion by the Crown was that the defendants somehow direct the users of the supplement to make their own product with off the shelf products. This is not a reasonable legal alternative in dealing with 3,000 participants attempting to obtain the supplement and to have access to the TrueHope Support Program to assist them in dealing with their mental health issues. The product would not be consistent, there would be no knowledge of who was necessarily on the program and how to assist them. There would be questions as well about the viability of maintaining the support program. It is not a reasonable legal alternative.

A further alternative was to employ the personal use exemption. There is 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 as well. There was evidence of inconsistent application of the exemption and there was evidence before the Court that attempts to use the exemption still resulted in seizures at the border. So that was not a reasonable legal alternative.

Counsel for the defendants also argued that the defendants were under a duty or duties as described in Section 216 and 217 of the Criminal Code, to continue to provide the supplement and to maintain the support program or face the consequences of being charged with criminal negligence. The defendants provided several cases in this regard. Now I will address that particular argument later. There are certain factors that deal with the possibility of a charge of criminal negligence that I will address later in this decision.

Another alternative, while I am talking about reasonable legal alternatives, 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 legal alternative at the time. It is noteworthy, however, that by March of 2004 it was and an agreement was made with the 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 TrueHope Support Program and this agreement remains in affect today.

So I have found that the defendants took numerous steps to seek a resolution of the problem, the defendants considered or attempted numerous alternatives regarding how to continue the supply of the supplement and to maintain the support program without running afoul of the existing legislation and Health Canada.

The Crown on the other hand argued that there were reasonable alternatives, legal alternatives. The Crown argued that economics was not a defence. However, the 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 provided financial means for persons who were not able to afford to go on the program. 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 conventional treatment for

depression and bi-polar disorder.

The supplement and the support program were and are inextricably connected.

The Crown suggested the off the shelf alternative, and I have already addressed that, that that in my view, was not a reasonable legal alternative. But it also suggests as well that the Crown did not consider that the vitamin mineral supplement itself was harmful, it also casts doubt on the assertion that Health Canada had concerns for the safety of the supplement if they are making the suggestion either use the personal use exemption or make the product yourself off the shelf.

This argument also disregards the necessity of the TrueHope Program and disregards the fact that the product, the supplement, must be controlled and managed through that program. It is not a reasonable legal alternative to somehow suggest that people make their own and are somehow going to be maintained on a support program.

The Crown also suggested that it was a reasonable alternative for the defendants to remove Boron or Germanium from the supplement. However this argument only goes so far as to state that these were Health Canada concerns. There is no evidence before the Court that the removal of either or both of these ingredients would have resulted in

obtaining a DIN or would have prevented the enforcement actions taken by Health Canada. In fact, the evidence was that regardless, the defendants were not going to get a DIN.

Another argument that the Crown made was that it would have been a reasonable legal alternative for the defendants to stop making treatment claims. Again, there is no evidence that if the defendants modified or stopped their treatment claims that this would have resulted in the defendants obtaining a DIN or would have resulted in the cessation of enforcement proceedings. However there was evidence that the defendants sought to obtain advice from Health Canada regarding amendments or modifications to their website but that no such assistance was forthcoming.

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. And the Crown pointed to the fact that a relationship had existed with a corporation called Evince in the United States until 2002.

I have found that there is not sufficient evidence before the Court of the details of the past

relationship with Evince, or why that relationship ended. There is also insufficient evidence before the Court to determine if it was indeed possible to sell rights in the supplement to a company in the United States and be able to negotiate a contractual relationship for a financial percentage to continue the support program.

Applying the modified objective test I must consider whether or not reasonable legal alternatives existed, taking into account the perception, experiences and circumstances of the defendants. The evidence 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 there was no reasonable legal alternative but to disobey the DIN 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.

The third part of the test of necessity or defence of necessity is proportionality, and this is an objective test. The Court clearly stated in Latimer, R v. Latimer, that the evaluation of the seriousness of the harms must be objective.

The harm that the defendant sought to avoid was the rapid return of 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 side effects was also a harm that the defendants sought to avoid. The defendants in argument characterized the harm to be avoided as being the most serious harm of all, that is serious incapacitation and possibly death due to mental illness.

There was ample evidence presented from both ordinary and expert witnesses that the symptoms associated with depression and bi-polar disorder returned rapidly, within the matter of a few days.

There was expert evidence before the Court as well, from Dr. Kaplan, who observed the rapid return of symptoms once the supplement was discontinued. And Dr. Charles Popper, who I have referred to earlier, who testified that if the supplement was unavailable there would be aggressive behaviour, assaults, hospitalizations, incarcerations and death.

The defendants argued that there was no harm in not having a DIN since 90 percent of the health, the natural health product industry, is not in

compliance. There was also an interim DIN directive by Health Canada that exempted products. There was a new regulatory regime under the Natural Health Products Regulations that was being developed. Health Canada itself classified the product as type 2, meaning that the risk of health consequences was remote, and Health Canada itself was prepared to allow the purchase of the supplement under the personal use exemption, and ultimately the Minister of Health in 2004 agreed to the sale and distribution of the supplement and the operation of the program in an arrangement that continues to operate to the present day.

So on a purely objective basis, based upon 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.

The Crown argued that the Court should take into account the bigger picture, that is the importance of the regulatory system in order to govern the conduct of people in businesses in Canada. And referred to the R v. Wholesale Group case and that the ability of government effectively

to regulate potential harmful conduct must be maintained.

The Crown argued that the purpose of the DIN was to protect the public from a company or companies who would develop a drug and place it on the market without going through the testing requirements of an appropriate regulatory body.

In assessing the harm inflicted on the regulatory process it is important to note a couple of things. One is that the DIN was a requirement relating to drugs under the Therapeutic Products Directorate, primarily related to pharmaceuticals. The regulatory process itself was in a state of transition while the new Natural Health Products Directorate was coming into place.

Also the Minister of Health in 2004 sought to enter into an agreement to permit the sale and distribution of the product and the support program.

Health Canada itself considered the product a type 2 category, which meant the risk of serious consequences was remote. Health Canada itself recommended that the product could still be obtained under the personal use exemption. The legislation itself provided for a maximum $500 fine on first offence summary conviction or imprisonment or both.

In these circumstances little harm would have been inflicted on the regulatory process. So 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. And we are referring to a regulatory process that was in transition and changing and was about to change to recognize a new product, and so the harm in my view, to the regulatory process, is minimal in the circumstances of this particular case.

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 elements of requirements of the defence of necessity has not been met. On my analysis the Crown has failed to satisfy the burden of proof and the defendants are entitled to the defence of necessity.

Turning now to the defence of due diligence, the offence for which the defendants stand charged under the Food and Drugs Act and Regulations is a strict liability offence. The leading case of R v. Sault St. Marie describes a strict liability offence

and the defence of due diligence as follows:

> For this type of offence there is no necessity for the prosecution to prove the existence of a mens rea or mental element of the offence. All the Crown has to do is prove the actus reus, which is that the acts occurred, and then what that leaves open to a defendant to avoid liability is to prove that the defendant took all reasonable care.

As stated by the Court in R v. Sault St. Marie, the accused to avoid liability must prove that he took all reasonable care, and this involves consideration of what a reasonable man would have done in the circumstances. The onus in this case is different than the defence of necessity where the onus was on the Crown beyond a reasonable doubt. The onus with regards to the defence of due diligence is on the defendants on a balance of probabilities, to satisfy the Court that the defendants took all reasonable care in the circumstances.

Some of the comments I am about to make will overlap on comments I have already made with regards

to whether or not there were any reasonable legal alternatives.

First of all there was evidence before the Court that it would have been impossible, expert evidence before the Court that it would have been impossible to obtain a drug identification number. Not only was there expert evidence to this affect, but also that this was known to representatives of Health Canada, although they were not forthcoming in telling the defendants that they were not going to get a DIN. This is also supported by the experiences and dealings that Dr. Kaplan had with representatives of Health Canada when they stopped, when Health Canada stopped the clinical trials that she was attempting to conduct.

So what would a reasonable man have done in the circumstances? Well a reasonable man would have tried to obtain a Ministerial exemption or to reach an agreement with Health Canada to permit the continued sale of the supplement and the maintenance of the support program while the new natural health products regime was scheduled to come into force on the 1st of January, 2004.

The defendants made considerable efforts to bring to the attention of Health Canada the seriousness of the actions of stopping the supplement at the border. They also made

considerable efforts to meet with the representatives of Health Canada and to the Minister of Health.

As stated earlier, there were protests on Parliament Hill, there were questions raised by Members of Parliament in the House of Commons, there was a private members bill sponsored by I believe Dr. Lunney, in order to amend the definition. There was a rally at the office of the Minister of Health in Edmonton, and all of these efforts made by the defendants during 2003 were unsuccessful in obtaining a meeting with the Minister or a Ministerial exemption or agreement that was being sought by the defendants, so that they would not as I have said, run afoul of the Food and Drug Act and Regulations.

It is noteworthy as well that the eventual solution that was available was through the next Minister of Health in March of 2004, which was an agreement to permit the sale and distribution of the supplement and the operation of the program, and as I have said earlier and as I will say again, I have found that this agreement by the Minister of Health in March of 2004 is evidence of what would be expected of a reasonable person in the circumstances.

Besides the matters that I have just referred

to there were other actions taken by the defendants that would be considered reasonable and fall into the category of taking all reasonable care to comply. The defendants took legal proceedings in Federal Court of Canada to try to prevent the stoppages of the supplement. The had to take action in the Court of Queen's Bench of Alberta in September with regards to the search warrant.

The Court has found that the defendants followed a course of conduct from 1996 to 2003 that involved the development and the refinement of the supplement and the sale and distribution of the supplement and its monitoring through the TrueHope Program, and this course of conduct had been accepted by Health Canada until March of 2003.

I am going to address for a moment when considering reasonable legal alternatives and whether or not the defendants took all reasonable care. The issue of the argument, the issue or argument, that the defendants were under a duty of care to continue to provide the supplement and the support program, and defence counsel had referred to Section 216 and Section 217 of the Criminal Code.

I will just briefly refer to Section 217, it says:

Everyone who undertakes to do an act

is under a legal duty to do it, if an omission to do the act may be dangerous to life.

The defendants could have been at risk of criminal prosecution if they stopped providing the supplement and providing the support program. They had undertaken this course of conduct over the course of the past several years.

Ignorance of the law would have afforded them no excuse. The Crown had raised the fact that it was not clear that they were even aware of this at the time. That is fine, ignorance of the law is no excuse.

Secondly, claiming that they had to comply with a DIN regulation would not have provided them with any defence.

And 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 supplement, that they had to continue distributing the supplement and monitoring the progress of those persons through the TrueHope Support Program.

The Crown suggested that the defendants did not take all reasonable care in the circumstances. They could have moved to the United States, I have dealt

with that argument already. The personal use exemption argument or the off the shelf argument, I have dealt with those arguments as well. The moving to the United States, in my view, was not what a reasonable person would do in the circumstances. The personal use exemption or the off the shelf solutions, in my view, were not reasonable legal alternatives and would not have been the acts of reasonable persons because they disregard the necessity of tracking, monitoring and maintaining persons on the support program, which I have said I have found is inextricably connected to the supply of the supplement.

The Crown also suggested that they could have just waited for the new Natural Health Products Directorate to be established in early 2004. That is the same thing as saying, well they should have just stopped selling the product, and I have already indicated that I do not consider that to be a reasonable legal alternative or a reasonable course of action.

Other suggestions by the Crown was that the defendants could have stopped making the treatment claims or withdrawn the Boron or Germanium from the supplement, however there is no evidence before the Court that taking these steps were measures that would have led Health Canada to change its position

that the defendants required a DIN.

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 and the Food and Drugs Act and Regulations.

The backdrop of circumstances include that it was not possible for the defendants to obtain a DIN 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. That their numerous efforts to obtain a resolution to the concerns of Health Canada regarding the sale and distribution of the product were being largely ignored, 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 the product and to maintain the support 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 program that continues to this present day is evidence that the defendants acted reasonably in 2003 and that there was no other reasonable legal alternative at the time.

Therefore I find that the defendants took all due care to comply with the Act and Regulations. The defendants have established on a balance of probabilities that the defendants took all reasonable care to comply with the Food and Drug Act and Regulations that would be expected of a reasonable person in these circumstances, and are therefore entitled to the defence of due diligence.

I turn now to the last remedy sought by the defendants, and that is abuse of process. A stay of proceedings for abuse of process.

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. But it is actually more than that, it is a very high threshold, it is a high standard, and I will refer back to that again in just a moment.

The defendants specifically referred to R v. Jewitt and R v. Young, and in R v. Young, that case spoke of a particular situation where:

> The executive action, meaning

> government action, where 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.

The defendants argued that in 2003 approximately 90 percent of the health food products industry was not in compliance. Evidence was presented that the DIN regulation didn't fit the natural health products industry and that the regulatory process itself was in a transitionary period with new regulations 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 supplements, 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 proceeding for abuse of process. Health Canada's efforts were directed at stopping the sale and distribution of a product that purported to treat mental illness. According

to the Food and Drug 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.

The defendants also argued that this prosecution is an abuse of process because it is an attempt to make the defendants stop selling the supplement.

Since the charge before the Court was laid after the present agreement was made by the Minister of Health to permit the sale of the product and the operation of the program and that the product and the program continue to be available under this agreement today, I do not accept that argument that this prosecution is an attempt to stop the sale of the product.

However, there is a further argument that was made by the defendants and that is that commencing this prosecution following the agreement with the Minister was an abuse of process, and the defendants referred to the case of R v. Young and argued that this case, the present case, is even stronger than that. The defendants argued that this case was even stronger because firstly, the same branch of the executive was involved, as opposed to a different branch in the Young case. And secondly, that in the present case an agreement had already been reached

to resolve the issues with the Minister and that that agreement continues to today.

While these matters were resolved by an agreement with the Minister in March 2004, which continues to the present time, the fact remains that in 2003 the defendants were in breach of the DIN regulation and have admitted as much.

So is this prosecution commenced after the agreement in 2004 an abuse of process amounting to the clearest of cases? The Court in R v. Reagan refers to the remedy being sought here as:

> One where a prosecution has been 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.

And further in the Reagan case at paragraph 52 another case is referred to in which the Supreme Court of Canada stated that:

> The abuse must have caused actual prejudice of such magnitude that the public's sense of decency and

fairness is affected.

The quote went on to state that:

> The prejudice caused by the abuse in question will be manifested, perpetuated or aggravated through the conduct of the trial or by its outcome that no other remedy is reasonably capable of removing the prejudice.

Further at paragraph 55 in R v. Reagan, the Supreme Court of Canada said that:

> The remedy of a stay of proceedings for an abuse of process must be considered in the context of this statement. That when dealing with an abuse which falls into the residual category, generally speaking, a stay of proceedings is only appropriate where the abuse is likely to continue or to 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 likely to be continued or to be carried forward, in particular in view of the agreement that has been in place since March of 2004.

So as I have stated, 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 there is an abuse of process, but that it is the clearest of cases.

The Crown referred to R v. Reagan and R v. Power in the Supreme Court of Canada and there are various phrases there that talk about the extent of an abuse of process and what constitutes an abuse of process of such a degree as to warrant the stay of proceedings in the clearest of cases.

One statement is that:

> 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 page 16 to state that:

Cases of this nature will be extremely rare.

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 maintenance of the program, while that prosecution may amount to an abuse of process, this Court is not prepared to find that the commencement of the 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 in order to warrant the remedy of a stay of proceedings.

The defendants had further arguments, however, on abuse of process. The defendants argue that there were other instances of conduct by representatives of Health Canada that should be considered as contributing to an abuse of process. They included the endorsing the blind following of policy where enforcement or compliance officers apparently have no regard or do not consider it to be any of their concern of the possible harm or consequences that could arise by enforcement

proceedings, and they were not aware of any mechanism of which such information could be brought forward in Health Canada.

Another instance of conduct of Health Canada officials that could have been considered an abuse of process the defendants argued, was that the Health Canada officials were not forthcoming with the defendants by failing to tell them that it was not possible to obtain a DIN.

There was also the double standard that was employed once the seizures started and the defendants were trying to get the supplement through the border and trying to ensure access to the participants in the TrueHope Program. Their experiences versus the -- that they were not always successful, versus the experiences of Mr. Ron LaJeunesse of the Canadian Mental Health Association, who testified that in every case that he intervened he was successful in getting the product released. A double standard.

Another example that the defence argues is conduct amounting, or that could contribute to abuse of process, was that Health Canada had its own health hazard evaluation that had this product described as type 2 and the possibility of harm as being remote. And even when that health hazard evaluation was being prepared the defendants have

asked to meet with Health Canada, but Health Canada was reluctant to meet with the defendants, even without information from the defendants, Health Canada's evaluation was still that the risk of harm from the use of the supplement was remote.

Another example that the defendants argued was conduct that could lead to the finding of an abuse of process was that the conduct of Health Canada was forcing otherwise law abiding Canadian citizens to become smugglers and 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 their family members.

In reply the Crown argued that neither the conduct of Health Canada through 2003 nor this prosecution should be seen as an abuse of process.

The Crown argued that there was an interim DIN directive in place to assist with transitional matters, there was a policy that provided for a personal use exemption for individuals to obtain the supplement, the fact that 90 percent 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.

Health Canada had expressed other concerns with regards to Boron and Germanium in the product.

The Court has also noted that the defendants were in breach of the DIN regulation, and although the Minister of Health and Health Canada were approached on numerous occasions unsuccessfully by the defendants, the Minister of Health and Health Canada were not required by law to provide a Ministerial exemption or to enter into an agreement with the defendants. And while the seizures of the supplement at the Canada/US border has been challenged in the Federal Court of Canada and the search warrant has been challenged in the Court of Queen's Bench of Alberta, there have been no findings that these actions taken by Health Canada were not taken within the strict letter of the law.

While this Court is not prepared to find that the various instances of the conduct by the representatives of Health Canada amounted to the clearest of cases of an abuse of process in order to warrant a stay of proceedings, this Court does find that some of the conduct would have influenced the defendant's beliefs that there was no reasonable legal alternative, other than to disobey the DIN regulation and that the defendants had taken all reasonable care in the circumstances to comply with the law.

The defendants are therefore not guilty on Count number 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 Drug 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 support 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 program, which agreement continues to the present day.

So in those circumstances I find the defendants not guilty of the offence as charged.

MR. BUCKLEY: Thank you, Your Honour. And my understanding because this is a summary conviction proceeding is that basically ends the Court's jurisdiction and so our constitutional obligations have also ended. That is my

understanding. If that is not the case --

THE COURT: Just before you go there.

MR. BUCKLEY: Okay.

THE COURT: Madam clerk, that is the original decision, attach that to the Information.

THE COURT CLERK: thank you, sir.

THE COURT: There is two copies for the Crown and two copies for the defence. All right.

All right, now, Mr. Buckley.

MR. BUCKLEY: If that is not the case, Your Honour, I will advise the Court in light of the decision this morning that we would be abandoning our constitutional application in any event.

THE COURT: My understanding from previous discussions with counsel was that if there had been a finding of guilt on one or more of the charges before the Court, then a further part of this trial would then be proceeded to that would deal with I believe it is a constitutional challenge on the definitions within the Food and Drug Act?

MR. BUCKLEY: Yes.

THE COURT: But that in the present circumstances with the finding of not guilty, that you would not be proceeding further?

MR. BUCKLEY: Yes, that's correct.

MR. BROWN: Yes, that's certainly my understanding as well, sir.

THE COURT: Is that your understanding as well?

MR. BUCKLEY: Yes.

THE COURT: All right. All right, once again, gentlemen, thank you for the effort that you have both put into this very unique and challenging trial, and your arguments that were presented were thoughtful and well presented to the Court and I thank you both for your efforts.

MR. BROWN: Thank you as well, sir.

THE COURT: And we will stand adjourned.

MR. BUCKLEY: Thank you, Your Honour.

THE COURT: Thank you. We will stand adjourned now until 2:00 this afternoon, madam clerk.

THE COURT CLERK: Thank you. Order in the Court all rise. This Court stands adjourned until 2:00 p.m. this afternoon.

THE COURT: Thank you.

THE COURT CLERK: Thank you, sir.

EXCERPT CONCLUDED

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*Certificate of Record

I, Jane Isaac, certify that the recording herein is a record of the oral evidence of these proceedings taken at the Calgary Provincial Court, in courtroom 414, on July 28th, 2006, and that I and Jacqueline Boyd were in charge of the sound-recording equipment.

*Certificate of Transcript

I, the undersigned, certify that the foregoing pages are a true and faithful transcript of the contents of the record, including the certificate of record given orally by the court official, recorded by means of a sound-recording machine.

Paige Young

Paige Young, Ms.

Page by Paige Transcribers

sw/Date July 30, 2006