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8 August 2006

Our File: 190035003

The Honorable Tony Clement  
Minister of Health  
Minister's Office - Health Canada  
Brooke Claxton Big., Tunney's Pasture  
Postal Locator: 0906C  
Ottawa, Ontario  
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Dear: Mr. Clement

Re: Public Letter Calling for a Public Inquiry into Health Canada

This is a public letter.

I am writing this letter on behalf of the Synergy Group of Canada Inc. ("Synergy") and Truehope Nutritional Support Ltd. ("Truehope"). The purpose of this letter is to seek:

1. a meeting with you to discuss the issues raised in this letter, and
2. a public inquiry into the actions of Health Canada.

Synergy and Truehope were charged on May 24, 2004, with selling their product, EMPower Plus without a Drug Identification Number ("DIN"). On July 28, 2006, following a lengthy trial, both Synergy and Truehope were acquitted. In essence, the Judge found that Synergy and Truehope were morally obligated to continue selling EMPower Plus without a DIN. I am enclosing copies of the transcript of the judgment and of the reasons for judgment. Some of the highlights of the judgment include findings of fact by the Trial Judge that:

- following the discovery that bi-polar disorder could be effectively treated with a Vitamin/mineral supplement, Synergy was incorporated as a research company to promote research into this finding;
- because the treatment of depression or bi-polar could have serious side effects when an individual was reducing dependence on drugs while commencing treatment with EMPower Plus, it was necessary to establish a unique screening, monitoring and support program called the Truehope program. This program is operated by Truehope which is a non-profit organization;
- by 2002-2003 approximately 3,000 Canadians were taking EMPower Plus through the Truehope program;
- although Health Canada was demanding that Synergy and Truehope get a DIN for EMPower Plus, it was not possible for them to get a DIN. Further, Health Canada knew that it was impossible for them to get a DIN;

- at the time the Natural Health Products Directorate was being set up by Health Canada to regulate products such as EMPower Plus because the drug testing regime required to get a DIN was not compatible with natural health products such as EMPower Plus;
- at the time Synergy and Truehope were being told to stop selling EMPower Plus without a DIN, a full 90% of the natural health products in Canada did not *have* DINs. Despite this EMPower Plus was singled out for enforcement action;
- Synergy and Truehope took many efforts to communicate with Health Canada that stopping the sale of EMPower Plus would put the health of thousands of Canadians at risk. These efforts included:
  - letters to Health Canada and the Minister of Health;
  - letters from Truehope program participants and medical professionals;
  - providing copies of peer-reviewed journal publications on EMPower Plus showing tremendous efficacy and safety;
  - meetings with Health Canada officials;
  - requests for meetings with the Minister of Health;
- despite all of the communications, Health Canada issued directions to Canada Customs in March of 2003, to stop shipments of EMPower Plus from crossing the border from the United States unless the shipment was proven to fall within the "personal use" exemption;
- the stoppage of shipments at the border caused panic and confusion amongst the participants of the Truehope program. In response Health Canada set up a 1-800 crisis line. The notes taken by Health Canada employees of calls to this line were entered as Exhibit 65 in the trial;
- Synergy and Truehope warned Health Canada that the stoppage of shipments at the border created a serious risk of harm including possible deaths by suicide. These warnings were expressed in writing and verbally;
- two of the Health Canada employees who testified at trial said they were aware of the warnings of harm, but that this was not their concern. They were simply following orders to enforce the DIN regulation;
- in response to Health Canada's action to stop shipments at the border, Canadian citizens took to smuggling the supplement into Canada for their own health or for the health of family members;
- in June 2003, a group of women known as the "Red Umbrellas" gathered on Parliament Hill to protest against Health Canada's actions. In July 2003, they also protested at the Minister of Health's office in Edmonton;
- on January 1, 2004, the Natural Health Products Regulations came into force. The DIN regulation no longer applied to Synergy and Truehope;

- in March 2004, the new Minister of Health, Pierre Pettigrew, granted an exemption to Synergy and Truehope allowing EMPower Plus to be sold under the ministerial agreement. Dr. James Lunney, Member of Parliament, negotiated the agreement with the Minister. This agreement remains in force;
- despite all of the above Health Canada laid the DIN charge in May of 2004;
- there was clear evidence corroborating the warning by Synergy and Truehope that taking EMPower Plus off of the market was dangerous. For example:
  - Dr. Bonnie Kaplan, a psychologist from the University of Calgary, had observed the rapid return of the symptoms of bi-polar if EMPower Plus is Withdrawn;
  - several lay witnesses testified of the return of bi-polar symptoms to themselves or to family members if EMPower Plus is not taken;
  - Dr. Charles Popper, a psychiatrist at Harvard University, testified that if EMPower Plus became unavailable, symptoms associated with depression and bi-polar disorder would return including aggressive behavior, assaults, hospitalizations and suicides;
- Ron Lajeunesse, the Alberta head of the Canadian Mental Health Association in 2003, expressed grave concern for the conduct of Health Canada in preventing EMPower Plus from coming into Canada. He was concerned that there would be suicides if individuals could not get access to the supplement;
- Synergy and Truehope were overwhelmingly compelled to disobey the DIN regulation in order to protect the health, safety and well-being of the users of EMPower Plus;
- Synergy and Truehope would have been liable under the Criminal Code for criminal negligence if they had stopped selling EMPower Plus in accordance with Health Canada's direction.

All of these actions by Health Canada took place before you became the Minister of Health. In fact, the Conservative Party was extremely critical of the then Liberal Government for Health

Canada's actions. For example:

- On June 2, 2003, the Honorable James Lunney addressed the House of Commons stating:

"Mr. Speaker, one in five Canadians experiences mental illness at some point in their lives. The cost to family and society is enormous.

Bipolar disease results in manic-depressive swings, and people in the depressive phase of the illness are at high risk of suicide. Recently, a natural health product was developed in Alberta that has brought hope to thousands of sufferers. Researchers at the University of Calgary, led by Dr. Bonnie Kaplan, have documented the phenomenal results. The findings have been published in peer reviewed psychiatric journals and repeated by Harvard researcher Dr. Charles Popper.

Unbelievably, Health Canada has ordered the study stopped and is withholding

product at the border because of an antiquated clause in the Food and Drugs Act that prevents claims about natural health products.

I was in Edmonton last week to meet with concerned citizens who feel their personal health and security are threatened by these actions of Health Canada. The minister and her department are being sued for obstructing the well-being of people affected by the seizure of their nutritional products.

Why does the minister defend antiquated and unscientific clauses in the Food and Drugs Act to obstruct freedom of choice in health care?"

- On June 12, 2003, the Honorable James Lunney addressed the House:

"Mr. Speaker, visiting Parliament today is a courageous group of women, the women with the red umbrellas. They came from across the country to share their stories of recovery from the debilitating disease of bipolar depression.

These women lived through tragedy until they discovered a simple vitamin and mineral supplement which helped them to recover their lives and restore them to their families. Over the past year Health Canada has initiated progressive restrictions on their supplement. The simple vitamin and mineral formula has been turned back at the border and people calling Health Canada are being told the product has been banned.

Clinical studies have been published in peer-reviewed journals like the Journal of Clinical Psychiatry, and the Journal of Child and Adolescent Psychopharmacology. Unbelievably, research at the University of Calgary which was funded by the Alberta Science and Research Authority was shut down by Health Canada, even though there is no evidence of harm to anyone taking this product. These people are here representing thousands across the country who feel their health and security are being threatened by this Health Canada embargo.

Will the minister ensure access to this product is not impeded and that the right to freedom of choice in personal health care by Canadians is respected?"

- On October 20, 2003, while debating Bill C-420, the Honorable James Lunney said:

"A mineral supplement, which was developed in Alberta, called EMPower+ , has been helping Canadians with a mental illness known as bipolar disease or manic depression. There is a tremendous cost to the individuals and there is a high risk of suicide.

We actually have people in the House today who are here because they are concerned. They are watching the debate and many are watching across the country because they are concerned. They feel their lives are being threatened because Health Canada is taking the products off the market simply because people begin to tell others that this could help them with their mental illness. There are over 3,000 Canadians receiving help from this product and yet Health Canada would move to take it off the market. They want to know, why would Health Canada do this when there is evidence of benefit?

I would like to give an example. There was a lady from Ontario who had been on psychiatric drugs for 18 years. Her husband had been on suicide watch for many

years. She has been taking this vitamin and mineral product for about two and a half years and she is off her psychiatric drugs. She is not trying to kill herself or her husband any more. She is holding down a job, paying taxes and she is volunteering. She wants to know, why would Health Canada take this away from her? Frankly, so do I...

In times when health costs are spiraling, Canadians would expect Health Canada to have an interest in a product that might lower the cost, lower the morbidity of a serious disease, and improve clinical outcomes. That was the approach of the Province of Alberta when it heard about the effect that EMPower+ was having on Albertans, it asked to look into this. There are huge costs associated with it. A \$544,000 study was set up at the University of Calgary under the leadership of Dr. Bonnie Kaplan. Canadians feel betrayed and certainly the people taking the product who have their lives back feel betrayed when Health Canada hears about this and moves in to shut down the study...

This is made even worse if Health Canada is complicit in maintaining that which is contrary to the public interest. It seems to me that Health Canada ought to be on the forefront of advancing opportunities to advance health care in Canada. If a natural health product can do that, Canadians have a right to know and have a right to access low risk products."

- On November 20, 2004, while debating Bill C-420, the Honorable Colin Carrie said:

"Let us take, for example, a product developed in Alberta; Empower Plus. This product has been helping patients with bipolar disease and manic depression. People with these problems are at a high risk of suicide and are sometimes not very productive in their lives. There are over 3,000 Canadians finding a benefit from this product.

The Province of Alberta initiated a scientific response to this product and the Alberta Science and Research Authority approved and funded a \$544,000 study. Preliminary results have already been published in at least four peer-reviewed psychiatric journals. Amazingly, Health Canada interpreted news of this success as a subsection 3(1) violation and shut down the study. Last July, Health Canada, while accompanied by the RCMP raided the company's offices and began obstructing access to the product. This makes no sense at all."

Later in that debate the Honorable James Lunney said:

"A couple of members mentioned Empower Plus. We had principally women come here who had been impacted by bipolar disease, as well as many men. An 11 year old boy was here. He came with his mother from Nova Scotia. He had only been able to go to school for a year and a half because prior to that he was trying to hurt himself all the time. This product has had a phenomenal effect on people with bipolar disease in particular.

Why is it that Health Canada would send in the police to raid this little company, with no evidence of harming anybody and tremendous evidence of benefit, steal its computers, and contact 3,000 Canadians to tell them to get back on their psychiatric drugs and off this natural vitamin and mineral based compound?"

- On May 16, 2005, at the Standing Committee of Health, the Honorable Colin Carrie said to Mr. Stephan and Mr. Hardy from Truehope:

"I think everybody who's heard your story sees how the status quo right now is just an absurd enforcement of these regulations...

I think, if you talk to the members here, we'd all be totally offended - we are offended - that you went through what you did here. We'd like to see that not happen to anybody else."

The Honorable Rob Merrifield said:

"Actually, you don't have to convince me at all of your product, and it's not that I've used it, but I've certainly talked to enough individuals who have testified to me the value of your product. We fought hard over the last number of years as you've gone through your difficulty to try to add some sanity into Health Canada in the way they've applied that law..."

It is clear, that the Conservative Party has been consistent in viewing Health Canada's treatment of Synergy and Truehope which culminated in the Court proceedings as abusive and wrong. At the same time, I understand that with the Court process under way when you became Minister, it may have looked inappropriate to intervene regardless of the position of the current Government.

Now that this matter is no longer before the Court, we feel it is appropriate to at this time request an inquiry. It is now time to answer questions such as that posed by the Honorable James Lunney above, namely:

Why is it that Health Canada would send in the police to raid this little company, with no evidence of harming anybody and tremendous evidence of benefit, steal its computers, and contact 3,000 Canadians to tell them to get back on their psychiatric drugs and off this natural vitamin and mineral based compound?

Indeed, considering that Conservative Party's criticism of Health Canada's actions in this matter have been completely validated by the Court decision, it would be inappropriate not to have an inquiry.

### **The question of whether Health Canada caused deaths in this matter.**

One of the witnesses at the trial was Ron LaJeunesse. Mr. LaJeunesse was the head of the Canadian Mental Health Association in Alberta. He has an impressive history of working with the mentally ill. This included being in charge of all of the mental health programs run by the Province of Alberta.

Mr. LaJeunesse testified that the Canadian Mental Health Association investigated EMPower Plus and determined that it was beneficial. When Health Canada started stopping shipments of EMPower Plus at the border, the Canadian Mental Health Association was active in intervening on behalf of its members to ensure the product could cross the border.

As the stoppages continued, Mr. LaJeunesse **publicly blamed Health Canada for two suicides caused by Health Canada's stoppage of the product at the border.** He publicly blamed Health Canada for the two suicides in his capacity as the head of the Alberta Branch of the Canadian Mental Health Association.

It is important to note that neither Mr. LaJeunesse nor the Canadian Mental Health Association had any connection with either Synergy or Truehope. Their involvement was motivated by their

mandate to protect persons with mental health issues.

I was counsel for Synergy and Truehope at the trial. As their counsel, I did not try to prove to the Court that these suicides happened. That was not necessary to the defense case. Also, in speaking with Mr. LaJeunesse, I was advised that the families of the two victims did not want to be identified or to testify. I was not going to force the families to be identified or to testify at the trial where this was not necessary. Different considerations apply, however, to a public inquiry into whether Health Canada actually caused deaths in this matter.

I think it would be fantastic to suggest that Mr. LaJeunesse and the Canadian Mental Health Association were lying when they publicly blamed Health Canada for two suicides. I do not believe for a moment that either would make the allegations unless they believed them to be true.

I am also mindful based on all of the testimony at the trial, that suicides would be expected if EMPower Plus became unavailable. It became unavailable to some due to Health Canada's action of stopping shipments at the border. Dr. Charles Popper, psychiatrist at Harvard Medical School, made it abundantly clear that there would be suicides if the product became unavailable.

We also know from the absolutely bone-chilling notes of the 1-800 crisis line calls, that the participants pleading to Health Canada for their lives were worried of suicide.

Finally, we have the testimony of some of the participants at trial that they would have killed themselves rather than to go back to the despair of mental illness.

In light of the foregoing, it is very likely that the actions of Health Canada in this matter caused suicides. It is also possible that these suicides may not be limited to the ones that Mr. LaJeunesse blamed on Health Canada.

Honorable Minister, we are calling on you to hold a public inquiry to:

- A. determine if Health Canada's actions led to suicides in this matter as has been publicly alleged by the former head of the Alberta Branch of the Canadian Mental Health Association.

### **Was Health Canada and/or employees of Health Canada acting criminally?**

It is clear from the Trial Judge's decision that Synergy and Truehope had a duty under the *Criminal Code* to ignore Health Canada's direction to stop selling. If Synergy and Truehope had taken EMPower Plus off of the market, they would have been liable under the criminal negligence provisions of the *Criminal Code*.

It is clear from the trial evidence and judgment, that taking EMPower Plus off of the Canadian market would have caused deaths and hospitalizations. Synergy and Truehope would have been criminally liable if they had done so. At the same time Health Canada, despite numerous warnings and in the face of evidence that taking the product off of the market would cause harm, pressed ahead.

The trust Canadians have in Health Canada to protect them from harm has been shaken. If in this case Health Canada deliberately or recklessly caused harm, the public's confidence can only be restored by holding Health Canada to account.

Honorable Minister, it cannot be that Health Canada and Health Canada employees are immune from the law. We are calling on you to hold a public inquiry to determine:

- B. whether Health Canada and/or any employees of Health Canada were acting criminally when taking action to remove EMPower Plus from the market.

### **How can it be that Health Canada does not consider suicides by Canadians as relevant?**

At least two Health Canada Inspectors were involved in stopping shipments at the border. These were Sandra Jarvis and Miles Brosseau. Both made it clear they did not consider evidence that their actions were causing harm was relevant.

When Sandra Jarvis learned of the news stories in which Mr. LaJeunesse of the Canadian Mental Health Association was publicly blaming Health Canada for two suicides, she did nothing. She continued to stop shipments. She testified that she took no steps because she did not believe the news of suicides was relevant to the investigation of the prosecutions. This can be found at page 130 of the Court Transcript.

Similarly, on September 18, 2003, both Ms. Jarvis and Mr. Brosseau had a telephone call with their supervisor Dennis Shelley and Tony Stephan of Truehope. Mr. Stephan spoke of two families who had suicides because of their inability to get the product. Amazingly there was no response by Health Canada to look into these allegations of suicide. Indeed, Ms. Jarvis testified that her role was to gather evidence for the case. There was no evidentiary value in looking into allegations of Suicide. This is found at page 128 of the Court Transcript.

When Ms. Jarvis read the testimonies of the Ladies with Red Umbrellas, she ignored it. She testified:

"I was under the understanding that they were taking that action because they believed in the -- the -- you know, the effectiveness of the product, It did not have an impact on I didn't believe it had any support to the evidence of selling a product that was unapproved which was essentially my role." (Transcript page 119).

When learning of a similarly impassioned plea for access to the product from another participant Ms. Jarvis said:

"You know, I -- I thought of it personally, it concerned me personally. I didn't feel it was really relevant to the fact that this drug does not have DIN number. Whether or not it, you know, did amazing things or not, the fact of the matter is, it was in violation of the law." (Transcript page 44).

The evidence of Mr. Brosseau was equally frightening. Mr. Brosseau seemed to go out of his way to avoid looking into evidence that Health Canada's actions were causing harm. He was questioned about a June 17, 2002 letter that had been sent warning of harm and attaching 200 letters from participants and medical professionals pleading for continued access to the product. Mr. Brosseau explained that he did not read it in depth because it was not a directive to take action. It had no bearing on how Health Canada acted. If he had a document indicating people were dying he would ignore it because it is not a policy or a directive (Transcript page 250).

On September 18, 2003, Mr. Brosseau had a conference call with his supervisor Dennis Shelley, Ms. Jarvis, Tony Stephan and David Hardy. Mr. Stephan read a story from the Medical Post about severe angst about the product not being available. He also spoke of two suicides. Mr. Brosseau testified that he did not verify the Medical Post story as it would not have allowed him to make any changes to his enforcement action. Further, it did not alarm him that his enforcement actions may be leading to deaths and hospitalizations. This is because he did

not have first hand knowledge (Transcript p. 263).

This is a small sample of the evidence of harm that these Health Canada Inspectors ignored.

It is clear on the evidence that Ms. Jarvis and Mr. Brosseau were taking orders from above. Other than Dennis Shelley, the supervisors actually responsible for this matter have not been identified. Some documents leave the impression that Joan Korol was involved in this matter.

Honorable Minister, how can it be that Health Canada Inspectors that are supposed to be protecting the health of Canadians, can consistently ignore evidence that their actions are causing harm and even death because it is not relevant: because there is no evidentiary value in looking into allegations of suicide?

Honorable Minister, ordinary Canadians who have no idea that Health Canada would not consider their deaths to be relevant, would be shocked at the revelations that came out at the trial.

We are calling on you to hold a public inquiry to determine:

- C. how can it be that Health Canada does not consider harm and suicides caused by Health Canada's actions to be relevant to an investigation?

**Why would Health Canada shut down the University of Calgary clinical trial when it was approved by three ethics committee boards and funded by the Alberta Science and Research Authority?**

As you are aware, following the very successful case series trials at the University of Calgary, the University approached the Alberta Government seeking funding for a large clinical trial. The Alberta Science and Research Authority agreed that it was in the public interest to run the clinical trial and provided over \$500,000 of funding.

The clinical trial was run by the Faculty of Medicine at the University of Calgary. For the trial to run, the Alberta Science and Research Authority, the University of Calgary, and the Faculty of Medicine had to satisfy themselves that the design of the trial was safe. The trial design also had to get the approval of multiple ethics committees. All of the groups involved were satisfied that the trial was safe and ethical.

The trial was progressing without any evidence of harm to the trial participants when Health Canada intervened to shut the trial down. Health Canada's reasons were that the University did not seek prior Health Canada approval. There were three problems with Health Canada's approach:

**First**, Health Canada was of the opinion that the University would not be able to get Health Canada approval for the clinical trial. This is because the approval process for clinical trials is similar to the approval process to obtain DINs. For the same reasons Synergy and Truehope could not get a DIN for the product, the University of Calgary would be unable to get approval from Health Canada to run a clinical trial. We know from documents and evidence that came out at trial that Health Canada believed the University would not be able to get approval. Despite this Health Canada had the University go through a long and involved process of trying to get approval. This ultimately proved unsuccessful and the clinical trial was stopped.

The absurd outcome of this was that Universities could not run clinical trials on vitamin and mineral supplements containing ingredients ordinary Canadians could purchase in

Health Food stores because such supplements did not fit the chemical drug testing model. If the University of Calgary had wanted to run a clinical trial on the effect oranges have on scurvy, they would not be able to get pre-approval as an orange would never pass the chemical drug testing model. This leads to the second problem;

**Second**, it was not the practice of Universities to seek Health Canada approval for nutrition research. If a University wanted to study the effect of oranges on scurvy, they would not ordinarily seek Health Canada approval. In this case the University was studying a vitamin and mineral supplement with ingredients readily available in health food stores. In Health Canada's world the supplement was a new drug. In the real world it was a multi-vitamin;

**Third**, although the clinical trial was sponsored and ran by the University of Calgary, Synergy and Truehope had made inquiries of Health Canada concerning whether preapproval from Health Canada was necessary. At the time the Natural Health Products Directorate was in the process of being set up. They were told that pre-approval was not necessary.

If you inquire of the researchers at the University of Calgary as to the reasons Health Canada gave to shut down the study, you will find that the University has grave concerns about the low quality of Health Canada's science.

Health Canada's actions in shutting down a safe provincially funded clinical trial is inexcusable in light of the fact that Health Canada later gave permission for the clinical trial to proceed. Once the Natural Health Products Directorate was established, they granted the University of Calgary permission to proceed with the clinical trial. The clinical trial is currently running without evidence of harm.

We are calling on you to hold a public inquiry to determine:

- D. why Health Canada would shut down the University of Calgary study when there was no evidence of harm and when Health Canada could not realistically criticize the design of the trial or the quality of the doctors and researchers running the trial;
- E. why Health Canada would have the University of Calgary go through the exercise of trying to get approval for the clinical trial when Health Canada believed that the University could not meet Health Canada's chemical drug requirements for approval;
- F. how the Alberta Science and Research Authority and the University of Calgary should be compensated for the hundreds of thousands of taxpayer dollars that were wasted when Health Canada wrongfully shut down the clinical trial.

### **How could Health Canada and the former Minister of Health ignore thousands of Canadians who begged and pleaded for their lives?**

When Health Canada began stopping shipments of EMPower Plus at the border, the 1-800 crisis line was set up. It became clear through the evidence at trial that this line did not actually help Truehope participants. It was patronizing and demeaning. Fortunately, however, the Health Canada employees taking the calls made detailed notes of the conversations. These notes were entered as Exhibit 65 at the trial.

Although there are over 700 pages of notes, it is essential that you read them. I can tell you that you will be shocked and horrified. I could only read bits at a time because they are too

troubling. They document scores of vulnerable Canadians Who had finally found health pleading with Health Canada for their very lives and sanity. As a human being I find it inconceivable that these notes did not cause Health Canada to re-evaluate what it was doing.

In addition to the crisis line notes, there were hundreds of letters sent by Canadians pleading for access to the product. Ordinary Canadians who rely on a product for their health, can really only communicate with Health Canada by calls and letters. Yet these were systematically ignored. There seems to be no mechanism within Health Canada to take the views of Canadians seriously.

Honorable Minister, I am calling on you to personally read the 1-800 crisis line notes and to hold a public inquiry to determine:

- G. how Health Canada and the former Minister of Health could ignore the input of vulnerable Canadians who called, wrote and protested on a life and death issue, and
- H. how is it that ordinary Canadians are to have a voice in Health Canada decisions that affect their health?

### **Why is it that evidence was suppressed prior to trial?**

We know from the Judgment of the Trial Judge that Health Canada knew that Synergy and Truehope could not get a DIN. We also know that 90% of the natural health product industry did not *have* DINs and that there was no reason to single EMPower Plus out for enforcement action.

Health Canada ran a criminal trial calling *evidence* that Synergy and Truehope did not have a DIN. Health Canada *never* explained to the Court that it was impossible for Synergy and Truehope to get a DIN and that Health Canada knew this. This fact goes to the core of the most obvious defense available, that of due diligence, and yet it was suppressed.

We also know that when Health Canada shut down the clinical trial run by the Faculty of Medicine at the University of Calgary, that Health Canada knew that they were not going to grant approval to the University to run the clinical trial. *However*, documents showing this were not disclosed as they should have been as part of the criminal disclosure process. What is worse is that documents obtained by Synergy under the *Access to Information Act* were edited so that this information was deleted. It was only after the Trial Judge ordered disclosure during the trial that the truth became apparent. Copies of some of the edited and unedited versions of documents *have* become trial exhibits.

Finally there are the notes of the 1-800 crisis line calls. These should *have* been disclosed prior to trial as part of the disclosure process. They should also *have* been disclosed under the Access to Information Act request. We had specifically requested them prior to the trial. At a pre-trial conference the Judge made it clear they should be disclosed. On the third day of trial when they had still not been disclosed, we made an application to the Court for a disclosure order. Health Canada's lawyer explained to the Court that the documents were "undiscoverable". That Health Canada had searched and searched for them and they could not be found. The Judge made an order they be disclosed. The Judge also made it clear that if the documents were not disclosed by the end of the Crown's case that the Court would consider stopping the trial. Within half an hour of this order the "undiscoverable" documents were *discovered*. I cannot say whether the 1-800 crisis line documents were being deliberately suppressed or whether it was just an amazing coincidence that after weeks of searching they happened to be

*discovered* within minutes of the disclosure order. What is clear, *however*, is that there was a pattern whereby Health Canada withheld evidence from Synergy/Truehope, and the University of Calgary. We are calling on you to hold a public inquiry to determine:

- I. whether Health Canada withheld evidence from Synergy, Truehope, the University of Calgary and the Court.

**Why did Health Canada carry on a public charade that Synergy and Truehope should have obtained a DIN without telling the Court or the public that getting a DIN was impossible?**

The Trial Judge found as a fact that Health Canada knew that Synergy and Truehope could not have obtained a DIN. Health Canada also knew that 90% of the natural health product industry did not have DINs when it singled Synergy and Truehope out.

In issuing public warnings and statements, and in charging Synergy and Truehope with selling without a DIN, Health Canada *never* communicated to the public or to the Court that it was impossible for Synergy and Truehope to get a DIN. Nor was it communicated that Synergy and Truehope were in the company of 90% of the natural health product industry who also did not and could not get DINs. Synergy and Truehope were unfairly vilified by Health Canada's statements.

As discussed above, Health Canada ran a trial charging Synergy and Truehope of selling EMPower Plus without a DIN number and yet did not call evidence to explain to the Court that Health Canada believed it was impossible for them to get a DIN. This issue went straight to the primary defense for this type of offense, the defense of due diligence. It appears as if Health Canada was more concerned with getting a conviction at any cost, than with being fair to Synergy, Truehope, and the Court.

Considering that Health Canada knew that Synergy and Truehope could not get a DIN, Health Canada's directions to stop selling until they get a DIN can only be interpreted as veiled directions to stop selling forever. Why was Health Canada hiding that its real intention was to take EMPower Plus off of the market permanently?

We are calling on you to hold a public inquiry to determine:

- J. why Health Canada would direct Synergy and Truehope to stop selling until they have a DIN when Health Canada knew they could not get a DIN. Why was Health Canada not upfront with its intention to have the product permanently withdrawn from the market?

**Why was the charge laid to enforce a regulation that no longer applies?**

The offense date was 2003. As of January 1, 2004, the DIN regulation no longer applied. The product EMPower Plus is a natural health product which became subject to the Natural Health Product Regulations on January 1, 2004 (the "NHP Regulations"). The NHP Regulations came into force because of the recognition that the drug regulations, such as the DIN regulation, did not suit the natural health product industry.

Despite the facts that:

- the DIN regulation no longer applied, and
- 90% of the industry did not comply with the DIN Regulation,

the charge was laid and proceeded with. This raises question as to why Health Canada would proceed. Does it not create disrespect for the legal system when that system is used to enforce a regulation that no longer applies because it could not be adhered to in the first place?

Synergy and Truehope are not the only examples of this bizarre approach. I am aware that Biomedica in Duncan, B.C., is also facing charges alleging offenses in 2003 of the old drug regulations Like Synergy and Truehope, Biomedica is now regulated under the NHP Regulations.

We are calling on you to hold a public inquiry to determine:

- K. how the public interest is served by charging companies with violations of drug regulations that were inappropriate and which no longer apply because they were inappropriate?

**How could the charge be laid after an agreement was reached with the Honorable Pierre Pettigrew permitting the sale of EMPower Plus?**

In March 2004, the new Minister of Health, Pierre Pettigrew, granted an exemption to Synergy and Truehope allowing EMPower Plus to be sold under the ministerial agreement. A Minister of Health will only grant a ministerial exemption under the Act if it is in the public interest to do so.

A couple of months after the Minister of Health agreed that EMPower Plus could be sold without a DIN, Synergy and Truehope were charged with selling without a DIN.

We are calling on you to hold a public inquiry to determine:

- L. how could the charge be laid after an agreement was reached with the Honorable Pierre Pettigrew permitting the sale of EMPower Plus?

**When faced with evidence that EMPower Plus could be a breakthrough in treating bi-polar disorder, why didn't Health Canada contact the researchers involved?**

This may be the largest Health Canada investigation ever. If it is not the largest ever, it is certainly one of the largest. The investigation went on for two years prior to the charge being laid. The raid of the Truehope call center with Health Canada employees and the RCMP was a well organized and large undertaking. It may be that several man years of time were devoted to this file.

Despite the size and complexity of the investigation, it appears that no Health Canada inspector took the time to ever call researchers such as Dr. Charles Popper at Harvard University, or Dr. Bonnie Kaplan at the Faculty of Medicine at the University of Calgary to determine whether EMPower Plus was safe or effective. Health Canada had been given the journal publications of these doctors on EMPower Plus.

Honorable Minister, EMPower Plus may be the single biggest breakthrough in the treatment of mental illness in history. Rather than confirm that this was a breakthrough that needed to be supported by Health Canada, Health Canada took all means in its power to stop the breakthrough.

We are calling on you to hold a public inquiry to determine:

- M. how it came about that Health Canada took all means in its power to stop what may be the most significant breakthrough in the treatment of mental illness ever;
- N. how it can be that Health Canada can conduct such a large investigation without ever contacting the researchers for information?

### **How could the former Minister of Health have practiced a double standard in 2003?**

Ron LaJeunesse testified at the trial that when Health Canada began stopping shipments of EMPower Plus at the border the Canadian Mental Health Association ("CMHA") intervened. When a client of the CMHA complained that a shipment was stopped, Mr. Lajeunesse would intervene. He was given a contact person in the Minister's Office to contact. Every single time he called to get a shipment released, the shipment was released. This meant that if you were a client of the CMHA who was lucky enough to ask the CMHA for help, you had access to EMPower Plus.

Contrasted against this were the hundreds of Canadians who pleaded with Health Canada as documented in the 1-800 crisis line notes, the hundreds of letters sent to Health Canada, or the press conferences following political protests. These Canadians were told the product was dangerous and were denied access.

This meant there were two groups of Canadians treated very differently. There was the CMHA group who was given access every time Mr. Lajeunesse intervened. There was the other group whose cries for help were ignored. If Health Canada actually believed that the product posed a real health risk, there would not have been an elite group of Canadians whose access to the product was protected.

We are calling on you to hold a public inquiry to determine:

- O. how it was that a double standard was applied to who could access the product?

### **How can it be that Health Canada stood by while otherwise law abiding Canadians became smugglers to protect their health or to protect the health of family members?**

When Health Canada began stopping shipments at the border, many Canadians who had found freedom from mental illness were not willing to return to being sick. Family members of persons being helped by EMPower Plus were not willing to allow their children or loved ones return to mental illness. Rather than allow this to happen, otherwise law abiding Canadians formed smuggling rings to protect their health or to protect the health of family members. Some of them testified at the trial that they felt degraded having to resort to smuggling.

These smuggling rings became necessary because Health Canada ignored their calls, letters and political protests.

We are calling on you to hold a public inquiry to determine:

- P. how can it be that Health Canada stood by while otherwise law abiding Canadians became smugglers to protect their health or to protect the health of family members?

### **How can it be that Health Canada is still stopping shipments of EMPower Plus?**

After a long trial in March in which it became obvious that there was a real and immediate danger to denying Canadians access to EMPower Plus, Health Canada appears to have stopped

a shipment in July 2006. This was four days before the Court decision was set to be delivered.

At this time I cannot confirm that it was Health Canada that had the shipment stopped. All we know is that on July 24, 2006, there was a shipment of EMPower Plus stopped at the border. The shipment was then released on August 3, 2006. It seems that the shipment may have been released due to the timely intervention of your Office.

Honorable Minister, we are deeply troubled that in July 2006, when it is clear that thousands of Canadians rely upon EMPower Plus for their mental health, that Health Canada would be taking any action to stop shipments at the border.

We are calling on you to hold a public inquiry to determine:

- Q. whether Health Canada is still taking action to stop shipments of EMPower Plus at the border, and
- R. what safeguards can be put into place to ensure that the access of Canadians to EMPower Plus can be protected from Health Canada?

### **How can Health Canada be refusing to license EMPower Plus with Boron?**

Synergy and Truehope have applied to the Natural Health Product Directorate for a license for EMPower Plus with boron. To date, a license has not been granted with boron because Health Canada is voicing concerns about boron.

All of the leading experts on boron state that not only is boron safe but it is an essential mineral for health. Indeed, not only is boron essential for health, but several studies have shown that boron dramatically reduces the incidence of prostate cancer. Prostate cancer is the leading cancer in men. Rather than restricting boron, Health Canada should be actively promoting boron. The world standard is to allow up to 20 mg of boron a day. The amount of boron in EMPower Plus is well below the world standard.

I would be willing to put you in touch with the leading experts on boron. It appears that Health Canada is once again ignoring science in the position it is adopting. Canadians are being denied access to a mineral that is essential for health.

We are calling on you to hold a public inquiry to determine:

- S. why Health Canada is refusing to allow Canadians access to boron when the leading scientists have shown boron is an essential mineral, and
- T. whether Health Canada's refusal to approve a license for EMPower Plus with boron was motivated by Health Canada's unrelenting drive to try to convict Synergy and Truehope of selling EMPower Plus without a DIN?

We are making this letter public, because although the Conservative Party has consistently criticized Health Canada's actions in this matter, there is still a large number of Canadians who are completely unaware of what has happened. We believe that it will strengthen the position of your colleagues who called for these questions to be answered while in opposition if the Canadian public is educated on what you were fighting for. Indeed many Canadians will be unaware that it was matters such as this that led the Conservative Party to put into its policy document a call for greater access to natural health products.

We are grateful that the Conservative Government is emphasizing openness and accountability. This is a welcome change from the Liberal Government of Jean Chretien and Anne McLellan who refused to hear pleas for help from vulnerable Canadians and from the Conservative Opposition.

I am inviting you to contact me so that we can set up a meeting to discuss the issues raised in this letter between yourself, David Hardy, Tony Stephan and myself. I would also look into seeing if the University of Calgary would send someone like Dr. Bonnie Kaplan to attend. Finally, I would contact Ron LaJeunesse to see if he could attend.

I look forward to hearing from you.

Yours truly,

A handwritten signature in black ink, enclosed within a large, hand-drawn oval. The signature consists of several overlapping loops and lines, characteristic of a cursive or stylized signature.

Shawn P. Buckley  
Law Corporation

cc. Prime Minister Stephan Harper  
The Honorable James Lunney  
The Honorable Colin Carrie  
The Honorable Rob Merrifield

enclosures