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Chair

Ms. Bonnie Brown

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● (1535)

[*English*]

The Chair (Ms. Bonnie Brown (Oakville, Lib.)): Good afternoon, ladies and gentlemen.

It's my pleasure to welcome you to meeting 42 of the Standing Committee on Health. We will continue our study of Bill C-420.

It's my pleasure to introduce you to our first witness, who is the co-founder of Truehope Nutritional Support Ltd., Mr. Anthony Stephan.

Mr. Stephan, the floor is yours.

Mr. Anthony Stephan (Cofounder, Truehope Nutritional Support Ltd.): Thank you very much.

Madam, would it be okay if I turned the time over first to David Hardy, who also works with Truehope, for his part of the presentation?

The Chair: David Hardy is representing Synergy Group of Canada. Do you want him to represent that group first?

Mr. Anthony Stephan: Yes, he could represent Synergy first. Would that be okay with you?

The Chair: I suppose, yes.

Mr. Hardy, go ahead.

Mr. David Hardy (Cofounder, Synergy Group of Canada): Our purpose for being here regarding Bill C-420 is the work we've done over the last nine years producing a supplement that we feel has incredible power, as do many of the researchers who have worked with it.

Dr. Kaplan made the statement regarding the supplement we've produced that it has the potential to be the most significant breakthrough in the field of mental health since the beginning of time. She made that statement because in her experience and in looking into the literature, no other supplement or any kind of intervention, including medication, has ever shown the power in research that this has.

Our experience has been unique. Although we're proud to be Canadians, we became very concerned with what we were experiencing as we came up with what we felt was something very significant to address perhaps the most significant problem in health care in the world, which is mental health. As far as we can tell from the statistics, mental health is the number one cost to the world health care system, and it's certainly the most disabling.

What we ran into with this really bothered us, and we've fought back, because literally our families' lives were at stake. We felt that something very significant should be allowed to come forward, in a free country, to assist people.

We first saw the effect of what we had run across with Tony's family—his children. Some of you may not know the history, but his children were suffering from bipolar illness. His wife had taken her life a number of years before, and his children were in serious shape. They were on medications that weren't working for them, as is very common, as we've observed over the last nine years. They were both ready to either be institutionalized or lose their lives to this illness. At that time I suggested we try something simple, like nutrition. My experience has been for 20 years as an animal feed nutritionist, and we provided nutrition for animals.

Animal nutrition research is 20 years ahead of that for humans. I thought that since his children had been normal when they were younger and had experienced these tremendous changes in their lives, there had to be some underlying cause of that, and it certainly wasn't a lack of Prozac in their bodies, because that's not normal to the body.

So we decided to try some research, and in January 1996 we put together a combination of nutrients that were quite complete—something a little different from what had been done perhaps in most nutritional supplements that are on the market that are not nearly as complete. We also chose products that we felt were very bio-available—that is, very useful to the body.

The results with his children were just astounding, even to me. I thought this might have some positive effect, but this made his children well and gave them their lives back. We felt something that significant wasn't just meant for us, so we started to approach researchers who might be interested in taking a look at this. We felt that a hog feed salesman and an engineer weren't going to be believed by the populace, so we wanted this to be researched. Having been a high school biology teacher, I was familiar with the scientific process and research, and I thought it would be a good idea if we could get someone to look at this.

Well, we did, and as we went forward with this some very significant things were found. We approached Dr. Bryan Kolb, who is one of the most recognized neuroscientists on earth. He has lectured all around the world. He looked at what we had, and he interviewed Tony's children.

We presented a little bit of information to him on some children we'd dealt with. He did some analysis on what we had come up with, and found it to be very statistically significant in terms of the changes it had induced in those children.

So we went forward from there. He introduced us to Bonnie Kaplan, a behavioural research scientist from the University of Calgary. She looked at this very skeptically at first, but then took it upon herself to measure what the effects were, by standard outcome measure, in a number of bipolar patients. To her surprise, and to ours, the effect size was absolutely huge; every outcome measure showed an effect size of 0.8 or greater. If you're not familiar with scientific research, that may not mean anything to you, but effect size is a measure of the effectiveness of the treatment, and most medications don't show an effect size greater than 0.3. There is no medication or combination thereof we could find in any literature that has ever shown an effect size beyond less than half of the 0.8 out of 1.0 in the study we're familiar with. So that's huge. Dr. Kaplan said that's it like growing corn that all of a sudden is 10 feet taller than anybody has ever seen grow before; it's that significant.

Most people say this was a small study. Well, that's true, but when you have such a huge effect in the treatment, you don't have to have large numbers to show very great statistical significance. That's what this study showed—statistical significance at a level that none of the researchers had ever seen before, or even seen purported in the literature.

As we looked at this, we basically developed a theory that some of these illnesses could indeed be caused by something as simple as nutritional deficiency. I think it's important that we understand the potential of this in order to determine the significance of Bill C-420.

We have scanned the research over the years, looking into the literature to see if this idea had ever been come across before. We found evidence that other scientists had said.... For instance, I can quote from one abstract: “Current evidence suggests that a disturbance in the concentration of trace elements can produce various psychiatric symptomology”. We found works like those of Melvyn Werbach, the assistant clinical professor of medicine at UCLA, who wrote a book called *Nutritional Influences on Mental Illness*, a compendium of more than 2,500 studies showing the effects of nutrition on mental illness.

I'll take this earphone out of my ear, because it's very confusing to hear myself. This is really confusing: I'm hearing voices. I thought that all of a sudden I'd developed schizophrenia.

● (1540)

The Chair: Too much Empowerplus.

Mr. Hardy, you only have a minute left. I'd like to know whether you support Bill C-420 and why, and if you don't support it, why? That's what we're here for, to discuss Bill C-420.

Mr. David Hardy: Okay. I obviously don't have time to go through this and the significance of all of this research.

As we went forward and looked into this, we knew we had something very significant, but we were prevented from bringing this further forward. Health Canada used every opportunity to kibosh this. We just couldn't believe the responses we got. The response that Dr. Kaplan got to her very scholarly submission to Health Canada presenting all kinds of evidence showing that it might be effective was a statement like this: “There is no scientific basis presented or any evidence to indicate that bipolar disorder may be caused by or is due to deficiencies in the ingredients present in the E.M. Power formula”. Even though she'd done a very scientific study showing incredible statistical significance, we got this kind of response from Health Canada. We couldn't believe it, and neither could she.

Eventually the study was shut down, interfering, we felt, not only with health freedom in Canada, but also with academic freedom. The University of Calgary was close to suing the government for that action.

● (1545)

The Chair: Thank you, Mr. Hardy.

Mr. David Hardy: We think that on Bill C-420 somebody in government has to allow these kinds of things to come forward when they could be of so much benefit to Canadians.

The Chair: Thank you.

Mr. James Lunney (Nanaimo—Alberni, CPC): Madam Chair, if I may...?

The Chair: Yes, Mr. Lunney.

Mr. James Lunney: Thank you.

Inasmuch as we have only three witnesses before us today—

The Chair: We also have two motions to debate at the end of the meeting, so we don't have two hours. We're lucky we have only three witnesses today.

Mr. James Lunney: Perhaps, but that takes only a little time at the end of the meeting. I'm sure members will be very agreeable to dealing with those matters quickly.

The Chair: You need unanimous consent to extend Mr. Hardy's time.

An hon. member: Give him a couple more minutes.

The Chair: He can have two more minutes then. He has already used eleven and a half.

Mr. David Hardy: Thank you, Madam Chair.

The Chair: You have two minutes, Mr. Hardy. Please make your position on Bill C-420 known.

Mr. David Hardy: Our position on Bill C-420, if that's all that we have time to present, is that whatever is done with Bill C-420, or whatever legislation comes forward, has to take this out of the control of those who have a biased approach and who would prevent major breakthroughs in science coming forward. That's our whole contention. Bill C-420 would make this a food rather than a drug. This was obviously being classified as a drug, and there was just no oversight in what we had brought forth. We didn't have any way to get back at this injustice that we felt we were enduring in a free country. Because of that, Bill C-420, which would take this out of the drug category and out of the clutches of those who obviously show a bias, is a very significant thing.

If another category could accomplish that, I suppose we would be happy with that, but that's our position on Bill C-420. This has to be taken out of the control of those who operate, in our view, in a corrupt manner, to prevent these things from coming forward. We feel that any government that allows major research like this to be flushed down the toilet because of someone's bias is actually compromising their own lives and their own health in the future, because none of us knows when we're going to be the one who experiences adverse mental health. It just seems that something needs to be done to allow this approach to come forward.

The Chair: Thank you, Mr. Hardy.

Mr. Stephan, go ahead, please.

Mr. Anthony Stephan: It's wonderful to be here. Thank you very much. My partner and I are humbled by the fact that we're able to present this information.

We come here for a number of reasons. Of course, it all circles around Bill C-420. We're glad that this bill is before Parliament at this time. We come not only as businessmen, that's a lesser opportunity, but rather as fathers and husbands.

This is a picture of my family. I lost my sweetheart, who I was married to for 23 years, to a suicide 11 years ago. She suffered with bipolar affected disorder one, with rapid cycling. She really lost it about six to eight weeks after going on Prozac. By the way, we're not anti-medication here; we're looking for better answers. Her father's suicide was 16 years before hers, by taking a drug overdose of psychotropic medication that destroyed his liver.

This was a sweet, wonderful person. She is one of the 25% of people in this nation who suffer with mental illness, according to the World Health Organization. Health Canada has indicated it is 20%; the 2001 *World Health Report* has indicated 25%. The only thing we've had for therapy, to date, on these issues is medication.

Very quickly, I want to show you a brief document. I know you can't read it from there, but it's a comparison between Empowerplus, which was developed to help my family.... My four children, who suffer with bipolar disorder, no longer show any symptoms. His son, who suffered with schizophrenia, and his bipolar daughter no longer exhibit any symptoms. These are taxpayers. They function in marriage. They're normal and well because of this.

People who are in the system, unfortunately, do not get well like this. There's much data to support that.

Here is a little chart showing the four side effects of a nutrient protocol. This is what Bill C-420's about. It's a nutrient protocol for vitamins, minerals, amino acids, and the side effects as listed in the *Journal of Clinical Psychiatry*. We have had five medical journal publishings about Empowerplus showing that 86% of people with a mental illness who take this product will become normal. The four side effects are flatulence, constipation, diarrhea, and stomach upset on a temporary basis, which affects about 5% of the population taking this vitamin and mineral supplement. It's like Flintstones or One-A-Day vitamins. These are not dangerous or weird or strange commodities: 33 of the 36 nutrients in this protocol are taken daily, when you eat your steak, fish, eggs, carrots, tomatoes, whatever.

I want to show you, for instance, one of the medications that has been approved for use in Canada, called Paxil. We're not here to criticize it, but in the year 2000 there were three million prescriptions, according to IMS, in Canada. Here, on the right-hand side of the page, are the side effects, all 285, which are monographed. I'll read them: tachycardia, angina pectoris, cerebral vascular accidents, congestive heart failure, mild cardio infarct, rectal hemorrhaging, depression, depersonalization, euphoria, hallucinations, hostility.... These are just a few of the 285 side effects that have been listed in the monographs of this drug. This is not our creation.

The evidence does not support what this drug is supposed to do. The *British Medical Journal* published February 19, 2005, did a study on suicide, depression, and anti-depressants. The study showed that out of 702 reporting studies and 87,000 patients, suicide risk doubled using the SSRI anti-depressants—Paxil is one of them—compared to sugar pills or placebos.

Clinical reviews completed and published in the *British Medical Journal* showed that the adverse effects of these medications have been downplayed, that anti-depressant drugs cannot confidently be recommended as a treatment option for childhood depression, that there needs to be a more critical approach to ensuring the validity of published data, and that investigators' conclusions on the efficacy of the neuro anti-depressants in childhood depression have been exaggerated.

● (1550)

We found that when there was a comparison made between Empowerplus in the five clinical publishings and the SSRIs, the effect size of Empowerplus was greater than 80% and the newer anti-depressants were 0.26.

This is in a *British Medical Journal* publishing as well as in other journals. In the study called “Efficacy and safety of anti-depressants for children and adolescents”, published in volume 328, April 10, 2004, there was a meta-analysis of five published clinical studies and nine non-published ones. They said the effect size was small, 0.26; a placebo is 0.28. Here is the statement from the study: “As regards unpublished studies, we note from a report from the US Food and Drug Administration...that only one of nine showed a statistical advantage for drug over placebo.” Overall, the drug and placebo difference was less than two points on the Hamilton depression scale.

What we have developed, we believe, is a major breakthrough, and we've been assailed by Health Canada. Studies have been shut down. There were three ethics committees, at the University of Alberta, the University of Calgary, and the ASRA group, which is the Alberta Science and Research Authority; it's a government department. Their ethics committees reviewed the use of Empowerplus in studies.

The study began and started to show marvellous effects. The CTV national news carried an article on it, and from that time forward Health Canada put forth its assailing process. They shut down the study, destroyed the research, and prohibited the research from going forth for three years.

Fortunately, we now have an office of natural health products, and we do have to give credit where credit is due by saying they now have allowed the clinical study to proceed. They now have allowed us to have an NPN, but Health Canada continues to bitterly oppose what we're doing through the TPD, the drug directorate.

What we're saying is here's a copy of our NPN under the regulations; we have grave concerns about the regulations as well, and we'll indicate that to you. That's why Bill C-420 is critical if you want to see a change in health care.

This program we offer is—

● (1555)

Hon. Robert Thibault (West Nova, Lib.): I'm sorry to interrupt you, but you have used a few acronyms that aren't getting over here.

Mr. Anthony Stephan: No problem. Please feel free.

Here we have the natural health product number for Truehope EMP, which we just received. Yesterday I went on the website, and here we have Health Canada advising Canadians not to use Empowerplus, claiming it's dangerous. The ONHP is saying that it's safe, and that it can be used for a continuous duration, while the drug directorate is saying to people, “Don't do it, it's dangerous”.

They've indicated in here, on another web program they have out there with the TPD, that some of the products we have in Empowerplus are dangerous. Take phenylalanine, for instance; they've indicated that this compound can affect mood and the nervous system, and therefore DLPA, or phenylalanine, which we have in turkey, chicken, yogurt, and fish, should only be taken under medical supervision.

It's ridiculous. We're antiquated, and we've allowed the drug directorate to basically control this.

We recommend that Bill C-420 move ahead, good people. We believe it will enlist health freedom and will put the nation in a state where our health care system can be corrected. Billions of dollars are going into buying such things as Paxil, which is showing an effect size of 0.26. We're not helping people.

My wife disappeared under the use of Prozac. According to the World Health Organization, one million people, every year—suicide. If you were to line those people up, shoulder to shoulder, that would represent a line over 700 kilometres long. This is a huge disorder.

Health Canada has hidden the evidence of the danger of these drugs. There are many, many articles. There's one here about a journal that warns that Health Canada is endangering patients. The Canadian Medical Association has said that Health Canada has failed miserably to protect Canadians from harmful drugs, and the bar for approval is so low that the agency has approved medicine without adequate proof of safety.

Our recommendation to you is to unfetter the Canadian public. Do not allow Health Canada to attack researchers as well as groups that are trying to bring forth new therapies that would reduce the costs. Our therapy is less than 10% of the cost of orthodox treatment, and 86% of people who take it get better. You must unleash this and let this go. You must take away the authority of the drug directorate to destroy this.

We had to sue them. We spent over $380,000. They charged our company. They charged Strauss Herb Company, as you're well aware, with 256 charges. Health Canada was not successful in winning one of those charges.

You must unfetter this. You must protect this. We must look for a new day for the people of Canada. These are not dangerous nutrients. Why would we want to overregulate these kinds of products when we have this staring us in the face every day, that the Paxil users who bought over 3 million prescriptions in the year 2000 have to face up to every day? This is not health. If we fed this to people in another form, you would say that we were poisoning people. But we call this a medication.

We're not saying it's wrong. The medications have taken us to a new vista. The vista in the past was the view that people used to be chained up in the institutions. I have children who used to suffer with mental illness. I have a great and powerful desire to see this change. The medications have at least brought people into the community setting, but they are not functional. It's killing our health care system, as the number one cost.

Global Burden of Disease, a massive study completed by Harvard University and the World Bank, found that 6.5% of hospitalizations were due to cardiovascular disease, and 46.9% were due to mental illness.

Unfetter this and let it go. Please.

A voice: Bravo!

● (1600)

The Chair: Thank you, Mr. Stephan.

We will now move on to our next witness, Ms. Debra Oxby, who is appearing as an individual.

Ms. Oxby.

Ms. Debra Oxby (As an Individual): Thank you, Madam Chairperson.

[*Translation*]

I would like to thank my member of Parliament, Robert Thibault, for helping me appear before your committee today.

[*English*]

My name is Debra Oxby, and I live on a small farm in Nova Scotia's Annapolis Valley. I am neither a health products manufacturer nor a health food store owner. I am the mother of a child who has been directly impacted by the legislation that Bill C-420 seeks to change, a child who depends upon a vitamin and mineral supplement not only for his mental health, but also, I believe, for his life.

In September 1998, days after my son began grade two, he was diagnosed with ADHD. Cognitive testing would reveal that he has an IQ in excess of 150, not unexpected in children with ADHD, who are frequently of above average intelligence. A severe learning disability was also revealed. We were told he would never learn to read. However, the educational psychologist who administered the tests went on to say that of the nearly 5,000 children she had assessed over the course of her career, his scores on some of the tests were among the highest that she had ever seen. He is, in a word, brilliant.

At the age of seven and a half he was about to embark on a journey that would lead him into that dark abyss of the mind that we so casually call mental illness, a journey that would eventually threaten his very life on a day-to-day basis. I have a family history of bipolar affective disorder. My only other sibling has struggled to survive this disorder for 12 years. Two months after my son's diagnosis he walked up to my mother and me, at the age of seven, raised an imaginary gun to his temple and intoned "I am stupid, I am stupid. I don't deserve to live."

Children have no frame of reference for mental illness. He knew he was different from the other kids; they took every opportunity to remind him of this, not that he would ever forget. He was ostracized, ridiculed, beaten up, and bullied relentlessly. He told me his teacher made him feel like a crumpled up piece of paper. He had no friends, no children who would even tolerate him. Being the butt of jokes and ridicule were the only social interactions he had. They called him stupid and he believed them. As smart as he was, he thought he was so stupid that he didn't deserve to live.

The disorder continued to tighten its grip, and his life and the lives of the rest of our family became increasingly more unbearable. He floundered in school and it was a daily battle to get him to return to the classroom each day to face the misery again. As much as possible I took time off work and kept him home to teach him. Fortunately, I only worked half-time as it was.

Over the next two years, my son would come to exhibit all of the symptoms of my brother's bipolar disorder as well, especially the suicidal ideation. He would eventually come to constantly waiver between threatening suicide, on the one hand, or begging me to kill him. He never laughed or even smiled. He didn't play minor league sports, or take music lessons or martial arts like his brother before him. While his classmates were worrying over whether or not they would make the team in hockey, he was busy drafting a plan by which he would end his misery, end his life.

In October 2000 I chanced to hear a report on the national news about an experimental vitamin and mineral therapy being used to treat bipolar disorder in Alberta. I got in touch with the company immediately. I clung to the hope that there was a nutritional component to his disorders. He began taking Empowerplus in early November 2000. By this time he was taking Ritalin on school days to try to control some of the behaviours that made his life in the classroom so difficult. By Christmas I took him off the Ritalin, but it would be nine more months before he was well enough to attend school again without the drugs. Once again, I taught him at home.

The following September, for grade five, he transferred to a small private school near our home. He was becoming well and he needed a fresh start. My son is now well. His marks continue to improve and they are now creeping up into the nineties. He shows no signs of ever having had a learning disability. He has friends and he loves driving tractors and farm machinery and reading Clive Cussler novels. His self-esteem has soared from absolute zero to absolutely amazing.

I have a bachelor of science degree in animal nutrition from McGill University. I have worked as a research technician for Agriculture and Agri-Food Canada for the past 22 years as a member of the food safety and quality team. I have researched the nutrition behind Empowerplus and I know that it is safe and I have seen that it is indeed extremely effective. The drugs made my son sit down in just 15 minutes. They would have the same effect on each and every person in this room. That is how psychotropic drugs work; they mask the symptoms of the disorders.

It would be ten months before Empowerplus would provide all of the nutritional building blocks that my son needed in order for his body to produce the chemical messengers in the correct balance to achieve and maintain mental health and freedom from the horrendous symptoms of the disorders that led him to become convinced, at the age of seven, that death would be preferable to life with the disorders.

● (1605)

My son was not mentally ill because he had a Ritalin deficiency. He was ill because he has much higher nutritional requirements than the average North American upon whom daily recommended intake levels are based. By stopping all entry into the country of Empowerplus on two separate occasions, Health Canada in its zeal to uphold the Food and Drugs Act has put my son's life in great peril. Canadian laws have been used and could continue to be used at any time to deny my son access to simple vitamins and minerals, and yet the only alternative treatment available to him would be anti-depressants that have themselves been demonstrated to cause suicides in children.

In light of the growing body of evidence of the therapeutic effects of vitamins and minerals—niacin for high cholesterol, boron for calcium metabolism, folic acid for heart disease, and vitamin C for cancer, to name just a few—Canadians are being harmed by the very legislation that was drafted 70 years ago to protect them. Though traditional definitions of food and drugs harken back to a time when little was known about the therapeutic effects of vitamins and minerals, it makes no sense to be broadening the definition of drugs to encompass foods with medicinal properties. Food and food-based nutrients are still food, just as they have always been. They don't suddenly become drugs just because scientists learn more about their role in treating and preventing diseases.

Passing Bill C-420 as it is written will give all Canadians—not just those of us with degrees in nutrition and access to scientific journals, but all Canadians—the access they deserve to health claims on natural health products, which will allow them to choose nutrition therapy over drug therapy as they see fit.

My son has paid his dues. He gave the psychotropic drugs a chance. They fueled his rages, intensified his feelings of worthlessness and despair—the crumpled-up piece of paper analogy my son used—and deepened his depression. He lost much of his childhood to mental illness. I am asking you now to use the power we have entrusted in you to pass this legislation, to protect his right to unfettered access to simple vitamins and minerals. I am asking you to protect the health of all Canadians.

Thank you.

The Chair: Thank you very much.

We'll proceed to the question-and-answer period. We're beginning with five minutes for Mr. Lunney and then five minutes for Mr. Carrie.

Mr. James Lunney: Thank you very much, Madam Chair.

Thank you to all of the witnesses here.

Deborah, your son was here when we presented some 40,000 signatures on a petition on behalf of Bill C-420. He's a lovely lad. It was so wonderful to see a young man functioning normally and proud to be who he was and proud to be here with others who felt their lives were actually being threatened because Empowerplus was being withheld by Health Canada at the time. Some of you will remember the red umbrellas, the ladies who came here and stood asking for attention before the House.

Colleagues, this particular product illustrates why Bill C-420 was drafted in the first place. It's because as soon as a health claim was made for something as powerful as this to help ameliorate disease, Health Canada said it's a drug. It's vitamins; it's minerals, it's in the feed stores. It's in the health food stores one day and is available to anyone, and the next day, as soon as the health claim is made that it's helping somebody, it becomes a drug.

You, Deborah, explained a little bit about what you went through as you were threatened with the loss of this product when Health Canada was trying to shut this down. I would ask the Truehope people to comment on Health Canada's response. Not only, you mentioned, did they shut down the study at the University of Calgary, but they also sent the RCMP to visit you. Is that correct?

● (1610)

Mr. Anthony Stephan: Yes. They refused to.... We sent them letters, we tried to communicate, we were prepared to come down to Ottawa to visit with them. They basically closed the door. There was no discussion whatsoever on anything. They did send the RCMP and they did shut product off.

Interestingly enough, there's a good man in Alberta whose name is Ron LaJeunesse who was the executive director of the Canadian Mental Health Association. He attempted to work at that time with Anne McLellan, who was then health minister, to no avail as well. Reported in the *Calgary Herald* after Health Canada put an embargo on and shut the product off, he said this. Remember, this is the man who wrote the book called *Political Asylums*, who also sat as the chairman of the Alberta Mental Health Board. He was responsible for millions and millions of dollars' worth of budget. He had all of the mental institutions under his authority in the province of Alberta, and also sat on the Edmonton City Police Commission as the chairman. Ron LaJeunesse, executive director of the Canadian Mental Health Association's Alberta division, says he knows many people who have been essentially cured of mental illness after taking Empowerplus. “It's going to result in dozens of suicides. I know of two already”, he said. “If there's no opportunity for people to take it, at best we're going to see some mental patients going back to hospital. At worst, they'll die.” And that's exactly what occurred.

Health Canada continued, and we had no response whatsoever. We couldn't visit with them or work with them.

Mr. James Lunney: Time is tight, and I want to get another question in here.

You did mention Dr. Bryan Kolb from the University of Lethbridge, an internationally known neuroscientist. I know he has an international reputation. In terms of the work he was doing with rats, you didn't get a chance to talk about the results that Bryan Kolb had when he began to introduce this product to his animals. This man is an expert in lobotomies on rats. Could you please tell us those findings, and have those findings been published yet?

Mr. David Hardy: They haven't been published yet, but they soon will be. Bryan does studies in brain plasticity. What he does is he takes the brain of a four-day-old animal and completely removes the frontal lobe, denying the animal any cognitive function. Over a period of time that actually restores, and on the Purina rat chow diet, which is a diet highly fortified with minerals and vitamins, they get about 20% of their cognitive function back.

Bryan had heard of the results of Empowerplus in humans and decided to try this in animals. To his amazement, animals on this supplement, Empowerplus, recovered 100% of their cognitive function. In fact, they actually performed better after having had the entire frontal lobe of their brain removed, and 100 days after recovery they actually performed better in cognitive tasks than normal animals. They also found, in doing a blinded trial, staining the neurons in the brains of these animals, that without exception the animals on the supplement showed statistically significant increases in dendritic endings. Those are the little endings on the nerves that pick up the signals and make it more efficient as a nerve.

It's just unbelievable. They've never seen results like that with anything they've tried. It was restoring brain and brain function.

The Chair: Thank you, Mr. Lunney.

Mr. Carrie.

Mr. Colin Carrie (Oshawa, CPC): Thank you very much, Madam Chair.

I've never heard about that frontal lobe removal. After reading what Health Canada did to you, I wonder if you thought maybe that would be something we could suggest to the people who shut down your company.

Voices: Oh, oh.

Mr. Colin Carrie: I think everybody who's heard your story sees how the status quo right now is just an absurd enforcement of these regulations. One of the things with Bill C-420 is that by changing it into the food directorate, I think we could alleviate some of the problems that a lot of the vitamin manufacturers are having with these regulations.

During the testimony here we've heard some people suggest that we just take the regulations almost as they are and move it into a third category. I was wondering if you could comment directly on whether you would prefer to have Empowerplus regulated as a food. What would be the difference between regulating it as a food or as a distinct category, if the distinct category had similar regulations?

Mr. Anthony Stephan: We don't care where they put it. Our concern is that it must be removed away from the drug directorate, which has an absolute bias. It has been criticized, even by the Minister of Health, for the lack of transparency. It must come away from the drug directorate.

You can call it food; you can call it a dietary supplement. I don't think we really have an opinion there as much as we do about taking it away from those people who have a bias, and letting this thing grow and flourish.

● (1615)

Mr. David Hardy: Whatever legislation comes forward, we want to see it exclude the possibility of the treatment that we received in what is supposedly a free country. I can't imagine what happened to us happening in a free country. I just couldn't imagine it.

Mr. Colin Carrie: 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.

I'm wondering, if we categorize this as a food, compared to a third category, how would it affect your health claims and what you could put on the labels for your product?

Mr. Anthony Stephan: Our understanding is that the food directorate basically uses subsections 3(1) and 3(2) as well, and with subsections 3(1) and 3(2) being repealed it would allow for truthful claims.

Please don't take this as being an irresponsible statement. We believe that people should have to support what they say, yes, but truthful claims should be allowed. To date, that's been the whole problem here—it's been denied. But yes, definitely.

Mr. Colin Carrie: Could you tell me a little bit more about the research? Mr. Hardy talked a little bit about research, and I found Ms. Oxby's story about her son astounding, particularly for children with psychological problems.

Have you done specific studies with ADHD, autism, and things along these lines? How much research has been done?

Mr. David Hardy: One of the studies that Dr. Kaplan put forth was a combination of a number of diagnoses. I think there were nine different diagnoses of children. And the results once again, with all of those varied diagnoses, regardless of the diagnoses, came back with effect sizes greater than 0.8, similar to what we'd seen in adults. So this is obviously effective for a number of things, and that's exactly what you would predict; multiple deficiencies are absolutely expected in what the literature provides. If you look at the U.S. Department of Agriculture information that shows the amount of these nutrients that are being taken in by the population, there are at least five major ingredients that are being missed by 50% or more of the population on a daily basis. There are another five that 30% or more miss on a daily basis and others as well. And the multiple deficiencies that we see in animals are certainly there in humans. This addresses those multiple deficiencies.

I think we're just beginning to see the potential effect of nutrition on many forms of illness. Recovery from brain injury, for instance, which the rat study projected, we've definitely seen that; and there are people recovering from strokes long after you would expect any further recovery. We can give people this supplement and expect them to further recover from that damage.

Mr. Colin Carrie: Are these research projects in peer-reviewed journals? Have they been published?

Mr. David Hardy: Yes, we have five peer-reviewed, published articles in peer-reviewed medical journals. Dr. Kaplan has produced two of those in *The Journal of Clinical Psychiatry* and one in *Journal of Child and Adolescent Psychopharmacology*; Dr. Charles Popper, from Harvard, has one in *The Journal of Clinical Psychiatry*; Dr. Miles Simmons, another independent psychiatrist from the U.S., has one published in *The Journal of Clinical Psychiatry* .

Mr. Colin Carrie: Would your classifying your product as a food hamper any of your research projects at all?

Mr. Anthony Stephan: No.

Mr. Colin Carrie: Would it move it forward more quickly, that much more quickly?

Mr. Anthony Stephan: It could work very well. Our only concern is that there would have to be oversight on the food directorate to make sure that the same abuse we've experienced from the drug directorate didn't reoccur. That's all.

Mr. David Hardy: These products are of course classified as foods in the United States, and it hasn't prevented the same bias, so whatever we come forward with, there needs to be regulation that prevents this. And in regard to the current regulations in the Office of Natural Health Products, although we've certainly received far fairer treatment from that office than the other office, we're a little bit concerned about the way those regulations are written, because there is no oversight there either. And if the same kind of bias came up, people like us could suffer exactly what we suffered once again.

The Chair: Thank you, Mr. Carrie.

Monsieur Bigras.

● (1620)

[*Translation*]

Mr. Bernard Bigras (Rosemont—La Petite-Patrie, BQ): Thank you, Madam Chair.

Before coming here today, I went quickly through your documents. The treatment you received since June 2003 is unfortunate, especially with the six charges against you. I think the product you developed was not treated fairly. The fact that your product is being classified as a drug is certainly one explanation of the unfair treatment you experienced in the last few years. This is the dark side of this case.

But we should recognize that real progress has been made in the last few years, thanks to the new Natural Health Products Directorate. It gave you a licence that allows you to make about your product claims that it can improve physical and mental health.

Should we not go further in that direction and amend the Food and Drugs Act to create a third category for natural health products? The new approach that opened things up for you in the last few months would be reflected in the legislation.

Also, if products like yours were put in the food category, it would be unfair for the product you are marketing, since Health Canada recognizes its benefits for physical and mental health. Besides, you would lose the minimal protection afforded by the licence you have been given by the Natural Health Products Directorate under a guideline of the Codex Alimentarius Commission. If your products are included in the food category, do you not run the risk that their real value is not recognized? And do you not run the risk of losing the minimal protection you get from the future implementation of the Codex Alimentarius?

[*English*]

Mr. David Hardy: I suppose that's a possibility. One of the things we have been told by the therapeutic products branch is that because this product is so effective in alleviating elements of mental illness, they would like to control it as a drug. I think that's just completely unacceptable.

There either has to be a redefinition of the word “drug”, which Bill C-420 definitely emphasizes, or some way that the therapeutic products branch cannot have control over this. When you start making claims and treatment claims, under the current regulations it appears we're going to be put right back into that category, and that's unacceptable.

Mr. Anthony Stephan: Is it any different from the beginning, in French Canada, when the settlers here suffered with scurvy and the Iroquois Indians taught them that if they tore off the maritime white pine bark, stewed it, made a bitter broth, and drank it, that it would cure their scurvy? Is this not a form of scurvy, in a sense, of the brain? If this is real, why do we have to put limitations on it?

I take vitamin C every day in my food, and I also supplement. We no longer have rickets or scurvy among us, as a people. It's well accepted that if you nutrify you won't have those issues. Yet for someone who suffers from mental illness, we want to limit it, so it has to be in the medical system; it has to be applied here, instead of just taking the nutrients and becoming better. That's our belief. Unfetter this and let this thing go.

[*Translation*]

Mr. Bernard Bigras: I agree with you, but I would like you to tell me what the ingredients in your product are. If I got it right, it includes vitamins and minerals.

People from the natural health products industry appeared before us, and they told us they radically oppose Bill C-420. The representatives of this industry which markets natural health products, vitamins, minerals, and so on are telling us they do not want this bill. I am trying to figure out how these two visions can be reconciled, when the marketing and products are very similar.

How can we make sure your product is classified in the food category and other products with minerals and vitamins are included in a different category? I am trying to figure out how we could create distinct categories and put one product in the food category, another one in a different category and other products in the drugs category. How can we make such a distinction?

● (1625)

[*English*]

Mr. David Hardy: If you're going to put minerals, vitamins, and other natural health products in a category, I think you need to put it in a category. There are a number of regulations in the current Food and Drugs Act that make certain things drugs over a certain level, absolutely unsupported by scientific evidence. Whatever category is determined for this, as far as we're concerned it all needs to come under one.

Every mineral should be regulated by the group that regulates minerals. Right now lithium is a mineral, but it's regulated as a drug. It needs to be regulated as a mineral. Even though it has a therapeutic treatment at very high levels, it has a better therapeutic treatment at much lower levels. We wish we could put a little lithium in our product, because at low levels Dr. Popper from Harvard has found it's more effective to have a tiny bit of lithium—not the amount that would cause your liver or your kidneys to shut down, as often happens with lithium now in the use of bipolar illness. It needs to be regulated as a nutritional supplement in the same way everything else is. Of course, the safe upper limit of lithium is far exceeded in its current use as a drug.

It's a complex issue, but we need to put these in a single category of some sort. Right now they're not. There's still too much control from therapeutic products that have some of these at certain levels, absolutely unsupported by science as drugs over a certain level.

The Chair: Which regulation are you referring to, the natural products regulations, or the pharmaceutical drug regulations? On this whole thing about above a certain level it's a drug, are you sure?

Mr. David Hardy: Schedule F is, I suspect, not in the...that's part of the drug regulations. It's schedule F that some of these minerals and vitamins are included in.

Mr. Anthony Stephan: For instance, if you exceed 10,000 IUs per day in a supplement of vitamin A, then it becomes schedule F, by prescription only; yet there are hundreds of studies showing that 100,000-plus for years has no negative effect on the human body.

The Chair: Thank you.

I think it's Mr. Thibault's turn.

Hon. Robert Thibault: Thank you very much.

I thank Ms. Oxby for making the trip out here. I became aware of your product through her. She made a very good presentation and got me aware, and then there were these ladies who were on the Hill, and some other clients who successfully used it, who made me aware of the product. It was enlightening to me, in that I don't think we disagree on any of the basics that we all discussed. There is value in natural health products and nutritional supplementation to good health.

The question is, how do we make it available in a safe manner, and in a reasonable regulatory fashion? It creates a lot of problems. There are two parts to Bill C-420. There is the question of the schedule and subsections 3(1) and 3(2), and the other part deals with the reasons for putting it under food. If we put it under food, then you can't make health claims; but if we take out the other parts and make health claims, then there are a whole bunch of other regulatory problems that are of concern to the natural health products people who are here.

As a consumer, I'd have a hard time, not being as knowledgeable as Ms. Oxby, and not knowing which ones are good, which ones are dangerous, which ones are not good. So the Natural Health Products Directorate, as a stand-alone body, or, as the department suggested, as a third party, has some reasonable sides to it.

On the question of Paxil, I should say, however, that Paxil is a controlled product available by prescription only. It's not on the shelf where I could put my hands on it and harm myself.

Dr. Hoffer was here last time. He is a psychiatrist with some 60 years in practice, who uses natural health products and nutritional supplements, as well as therapeutic drugs. He agreed that there was a danger with having a product on the market that makes a claim that is untrue. There would be some danger of a person self-medicating, when they should have the assistance of a physician or a psychiatrist.

So I want to point to two things. I had a discussion about this with Ms. Oxby. Before Matol was on the market, it was sold door to door. It was sold in my community. It made all sorts of health claims. It was going to cure you of everything: your dog would smell better; you would have less hair if you had too much, more hair if you didn't have enough. Then there's your product, which I believe works, from everything that I've seen. You deserve to have a way of getting a chance to prove that you can make a health claim. By definition, that calls for some sort of regulation.

So what we have seen, or most of the people who have appeared before the committee seem to be telling us, is that it is not a food. It is in another category, whether associated with drugs or stand-alone. Schedule A is antiquated, where it says that in all these things, you can't make health claims. So a lot have suggested to us we should change subsections 3(1) and 3(2) in schedule A and permit substantiated health claims with scientific information, so I would know the dosage information. As in the case of lithium, as you say, at low dosage, I can't hurt myself; at high dosage, I can do great harm to myself.

I wonder if you would agree with those general lines.

● (1630)

Mr. David Hardy: It's pretty difficult to categorize this as separate from food, because each of the 36 ingredients in our product, with the exception of one, you take in every day, or at least every week if you eat grapes and citrus fruits.

Hon. Robert Thibault: But you don't necessarily in the same concentrations. We can't just talk about your product. We have to think of all the products in that area of medicine or of health care.

Mr. Anthony Stephan: There has to be a classification that's either food or separate because of the relative risk. For instance, we have three publications in the *Journal of the American Medical Association* and the Johnson and Bootman study in *Archives of Internal Medicine* that indicate that over 200,000 people lose their lives every year in the United States as a result of taking properly prescribed medications. We're not talking about drug abuse here.

In Canada we have 24,000 deaths on an annual basis. A good number of them—as identified in the *Canadian Medical Association Journal*—are the result of properly prescribed medications. That's a risk, so those medications have to be treated in a very careful way, and people need to give informed consent. They need to understand the dangers of taking these.

On the other hand, we have foods that we've taken for hundreds of years that have negligible side effects, like, for instance, Empowerplus. Peanuts in the U.S. have been identified in the *Archives of Emergency Medicine* as causing over 200 deaths per year due to anaphylactic reactions, yet we don't classify peanuts. You don't see a big warning on the label. There should be, I think, but there isn't, and we say it's a food and we just understand that we have to be careful.

In my home we have a bottle of bleach that we use in the laundry. I've taught my children that you don't drink bleach.

Hon. Robert Thibault: We are not promoting either bleach or peanuts as a cure.

Mr. Anthony Stephan: No.

Hon. Robert Thibault: We're not promoting them as having health effects.

Mr. Anthony Stephan: The point I'm trying to make, though, is that the relative risk is less than that of peanuts, and certainly less than that of bleach. What we're saying is inform the public, teach the public how to use these products.

Nobody stops me from buying a pack of cigarettes or a bottle of alcohol. Health Canada has identified that there are 80,000 hospitalizations every year due to the use of alcohol. And I'm not saying we shouldn't use it. That's up to people. People have a choice. You have to unfetter this and allow people to do it and not overregulate it. That's what's happened with the new regulations. They're overregulated and there's a way they could be abused. So we're saying park it in the food category.

Hon. Robert Thibault: I think if we marketed cigarettes as a treatment for weight loss, then we'd be talking about something else again.

Mr. Anthony Stephan: Yes.

Mr. David Hardy: We do promote foods, by the way, as a means of staying alive, and I'd say that's a pretty good treatment effect, wouldn't you? We can't do without it.

● (1635)

The Chair: Ms. Crowder is next.

Ms. Jean Crowder (Nanaimo—Cowichan, NDP): Thank you for your presentation.

I think it clouds the discussion when we are talking about some of the challenges in the Therapeutic Products Directorate, and many of us have spoken out quite vocally about the lack of transparency in the directorate. I think it clouds this discussion about Bill C-420, because many of your challenges arose out of the Therapeutic Products Directorate, not out of the Natural Health Products Directorate. I'm going to set that aside, because I appreciate your presentation on that, but that's not really what we're here to talk about. We're here to talk about Bill C-420.

I have a couple of questions, but first I just want to correct a piece of information for the record. Mr. Stephan, you said that the only thing used for therapy for mental illness is medication, and because this is a public record, I want to be clear that there are many other therapies for people with mental illness, including counselling and cognitive therapy. So it's not just drugs. I think it's really important that we're on record saying that, because many people do benefit from a number of other therapies that don't include medication. So I think it's important to clarify that.

I'm a little uncomfortable about language like “unfettered access”. We've heard from a number of witnesses about the dangers of taking some herbs and other natural products. There can be contra-indications. Some herbs have a direct impact on things like high blood pressure—licorice, for example, feverfew, black cohosh. There can be other complications. So when I hear about unfettered access, it makes me very nervous.

My understanding of it is that what we have under the Natural Health Products Directorate right now is an interim measure. The intent is to amend the act, as Monsieur Bigras has indicated, so that eventually we would have a separate category for natural health products, with some regulation.

What I understand is that if we move these things into foods, we lose the ability to have good manufacturing practices, which would then not guarantee things like dosages and potency and things like that. And these are the experts who are telling us that foods can't be regulated in that way.

Many of us feel we need a third category to ensure that people are getting what's on the label, that they know what the contraindications are—I don't want my mother taking licorice, because she's got high blood pressure—that they're getting the dosage that's on the label, that the health claims have some sort of veracity. So I wonder if you could comment on the third category.

Mr. Anthony Stephan: First off, licorice is unfettered; you can buy it at any food store.

Ms. Jean Crowder: Sorry, that is the problem. You can actually buy concentrated dosages of licorice that can cause severe problems for people with high blood pressure. I would argue that it needs to be labeled appropriately.

Mr. Anthony Stephan: Okay, just like the peanut thing needs to be labeled.

Ms. Jean Crowder: You don't buy peanuts for a medical problem, but you do buy concentrated licorice for medical problems.

Mr. Anthony Stephan: That's true. Rephrase your question for me.

Ms. Jean Crowder: How do we protect people so they have accurate information about what they're taking—dosages, potency, and so on? We know from studies on vitamins and minerals that not all companies manufacture them in the same way. Sometimes you're not getting what you think you're getting out of these dosages.

Mr. Anthony Stephan: There should be standardization, no question. If I produce milk, I have to use good manufacturing processes. I have to make sure that it's clear of bacteria, that it's processed appropriately, and that there aren't any harmful chemicals. In the food industry, there is GMP. It's a big part of the food industry.

Ms. Jean Crowder: I don't think they're actually GMPs. There are rules in the food act that talk about adulteration, but they're not GMPs. It's misleading to say that they're GMPs.

Mr. Anthony Stephan: Okay, but there are required manufacturing practices. For instance, I used to have a water-bottling plant in Alberta. There were certain guidelines we had to follow. I had to send away a water sample every week, checking for E. coli and other bacteria. I had to ensure that the bottles were sterilized at 170 degrees Fahrenheit and above. I could use a hydrogen peroxide mist as well. There were certain procedures I had to follow. These procedures must also be evident in the health food dietary supplement industry.

In addition, the label must indicate if there are any dangers. If black cohosh presents a danger, then it has to be clearly stated, as it should be in any other product. When I buy a bottle of bleach, it has the skull and the crossbones warning us that it's a caustic agent. So labeling is important.

● (1640)

Mr. David Hardy: We have no problem with good manufacturing practices.

The Chair: Thank you.

Ms. Dhalla.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Thank you for coming.

I wanted to touch upon a couple of issues that I think are important. Like Ms. Crowder, I believe that some of your frustration has been with the drug directorate. But we need to focus on Bill C-420. I wanted to get your comments on the safety of health care products. Do you think putting them into the food category is going to compromise the amount of safety information that Canadians receive?

Mr. David Hardy: I don't know. These products are traditionally safe. Every ingredient in our product has been used safely for 40 to 100 years. That's something we can never achieve with drugs. Before Vioxx was put on the market, there was no long-term study of it done with humans, and it was taken off the market after only five years of use. This is true of almost every drug on the market.

These are inherently safe products. They have caused fewer problems than a year's worth of deaths from peanuts, which we consider food. There is an exaggerated sense of danger associated with taking these products. People, for the most part, are smart enough to take them appropriately. Minerals and vitamins aren't like drugs. You don't generally reach a toxic level. The only deaths from vitamins have occurred when doctors injected one million IUs into babies. It's quite a different thing from drugs. Yet we're made to think that these things are toxic and dangerous, when they're really very safe.

Mr. Anthony Stephan: Emergency room statistics do not indicate that NHPs, natural health products, are causing a substantive problem.

Ms. Ruby Dhalla: Have either of you had interactions with the Natural Health Products Directorate?

Mr. Anthony Stephan: We have an NPN that we received last week on a product called Truehope EMP, which is 99.998% volume by weight the same as in Empowerplus, the product we've been discussing. We've had a lot of interaction with them. We have to say that they have kept their word, to their credit. The drug directorate did not, and it was very vindictive.

Ms. Ruby Dhalla: But because you've had a positive experience with them, don't you think, moving forward, that is going to address a significant part of the issues and the problems you face?

Mr. Anthony Stephan: Not at all, because it's open to abuse. If you were to study the actual regulations, you would find that if somebody was in authority there, they could very quickly begin to abuse the position. There's no oversight and there's absolutely no—how would I put that—recourse; none.

There needs to be a complete review of the legislation. It needs to be altered, changed, or whatever.

Mr. David Hardy: If indeed it were to stay in that category, those regulations would need to be looked at, because the same potential for abuse is there as was present in the other category. I suppose it is in the food category as well. The U.S. sees some of this same thing, and it is a food in the U.S.

Ms. Ruby Dhalla: You say that, despite having had a positive experience with the directorate.

Mr. Anthony Stephan: We've had a positive experience with Mr. Waddington, but he didn't give us any more than what anybody else would have received. Don't take us wrong there. We applied and it took us a year and four months to receive our NPN, which is quite a while.

I think our NPN was number 383, and there are probably another 3,000 to 5,000 NPNs that will have to be listed. It's going to take them a number of years at the current rate. We're not being critical; we're just being observational.

But overall, when you study those regulations, once again, there is an area where there could be abuse. In our estimation, having been through the courts a number of times and having seen the drug directorate and the inspectorate of Health Canada actually deceive a judge—they were actually chastised in Calgary by a justice of the Court of Queen's Bench for not being truthful and not making full disclosure—we see that a position of abuse could come out of this, no question. It was the drug directorate's desire to bankrupt us and actually destroy this.

● (1645)

Ms. Ruby Dhalla: I'm sorry, I don't want to get into a discussion on the drug directorate.

Perhaps I'll just ask one last question. Another important concern that has been mentioned by many Canadians who do take natural health product supplements—and I myself am a big promoter of them when they're used in the proper manner—is that what's stated on the bottle is not necessarily what's in it. With having it put into the food category, how would you, based on your particular experiences and window of expertise, try to alleviate that concern for many Canadians?

Mr. Anthony Stephan: We've had to jump through hoops proving to the Office of Natural Health Products that when we say there are 200 milligrams of calcium per three caplets, there are. We've had to prove it to them.

There must be a system put in place to ensure there isn't a deception to the public. When you buy an extract of echinacea and it says that it's 55% or 95% extract, it has to be so. So yes, there is room for regulation.

We're not saying that there shouldn't be good manufacturing practices or that there shouldn't be regulation. We're saying there should not be abuse of those regulations and a bias against bringing forth new answers for Canadians.

Mr. David Hardy: One of the problems of just listing what is in the bottle, however, is that it doesn't necessarily mean it's helpful. For instance, you can legally put iron oxide in a human supplement and guarantee the iron is there, but it's absolutely useless. It goes in one end and out the other, and it's absolutely useless. There is a whole variation in terms of effectiveness those labels don't address or indicate at all.

Ms. Ruby Dhalla: The Natural Health Products Directorate, I think, is going to ensure that as we move forward, the claims listed on the bottle are going to be able to be verified.

That's it. Thanks.

The Chair: Thank you, Ms. Dhalla.

We'll move now to Mr. Fletcher.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Thank you, Madam Chair.

I hope my NDP colleague isn't going to fetter my access to red licorice. Black licorice can be banned as far as I'm concerned, but not red licorice.

Hon. Robert Thibault: We don't like red licorice.

Some hon. members: Oh, oh!

Mr. Steven Fletcher: In the comment about access, Mr. Stephan, you made the analogy to tobacco and alcohol and so on. The argument we've heard on other issues is, what about the children? Children and young people are not supposed to have access to tobacco and alcohol. I wonder if there are cases or situations where younger people could be exposed to harm if we move it to the food category.

Mr. Anthony Stephan: I think it's necessary to have childproof containers, as we do with our ratchet lid, but I think you still have to use care and caution on any substance. We know that if we take too much of any food, of any substance, it's not good for the body. We have to use the same care and caution here, with childproof containers and warnings on the labels that require it.

Ephedra, which is now back on the shelves in the U.S., where the courts ruled in favour of it, unlike up here, is a very powerful herb. We know that. You have to use it with wisdom and prudence.

So there have to be childproof containers and warnings, yes.

Mr. Steven Fletcher: What about a 16-year-old going in and buying something that may be harmful right off the shelf? Is that something that would be of concern?

Mr. Anthony Stephan: I don't think so. We've never heard of abuse of dietary supplements. Don't take me wrong—I'm not being smart—but I've never read a case, ever, where dietary supplements were abused.

Mr. Steven Fletcher: No, and that may be the case, but I don't know about the concentrations. Kids seem to be combining things in ways that weren't foreseen, and causing themselves a lot of harm. I would hate to see that unintended consequence.

Mr. Anthony Stephan: Yes.

Mr. Steven Fletcher: Health Canada has implemented, I understand, a third category for natural food products. I'm wondering what your position is on the third category.

● (1650)

Mr. Anthony Stephan: Personally speaking, I would prefer to see it go into foods. I would still want to see GMP on those types of things. Maybe it could be a classification of food, as a dietary botanical supplement or whatever, but I believe it should go to food so that it can be somewhat more unfettered.

I believe the risk factor is very, very low in these. Emergency medicine journals do not demonstrate that there is ever a high risk. And I think there needs to be education.

Mr. David Hardy: Can I comment on that, and give one of the reasons why we think this needs to be unfettered?

Mr. Steven Fletcher: Yes, sure.

Mr. David Hardy: First let me just give you a comment from my perspective of the animal industry. I think we treat our pigs better than we treat our wives and our children. The use of this supplement in women who are pregnant is considerably discouraged, because when you put it in this category of treatment, everybody is worried about a pregnant mother taking this supplement. We have numerous women who have chosen to do that, and all they see is benefit. Just as in the rat brain study, what we see is a more healthy child, a more thrifty child, and we never see a mother who undergoes any postpartum depression. Not a single mother who has taken this has postpartum depression.

That's incredibly powerful. I just see that there is a stigma attached, with ethics committees and everything else. We're willing to give our pigs these supplements so that they can be productive and operate effectively, but we're not willing to give our women that benefit. To fetter it in any way, and to put it in a category that has a certain amount of regulation to prevent that from happening, I think is ridiculous.

Mr. Steven Fletcher: One last thing. I'm wondering if someone could pass on to me, or table for the committee, that study about the frontal lobe. That is quite fascinating.

I'm going to yield the rest of my time to Mr. Merrifield.

The Chair: You don't have any time left.

They almost got me. You have to pay attention here.

Thank you, Mr. Fletcher.

Ms. Chamberlain, do you want to ask a question?

Hon. Brenda Chamberlain (Guelph, Lib.): Sure.

I just want to say to Ms. Oxby, who no one has let speak at all, that I heard everything you said about your child, and about how difficult it has been for you. Is there anything you want to talk about with regard to Bill C-420? Are you in support of it the way it is? Or do you feel that a third category is perhaps in order to classify these, with some restrictions and some boundaries around it? How do you feel?

Ms. Debra Oxby: I feel that the system we have now is not working. Twice now, as I said in my presentation, my son has been denied access to these vitamins and minerals. This shouts volumes to me, that the system we have in place now is not working.

I'm faced with a situation with him where if the health minister decides on a whim that this product is dangerous, he or she has the power to take my access to it completely away without providing proof of harm. I believe that is the situation we are in now with this supplement. This terrifies me, because there is nothing that will keep my son alive if he doesn't have access to this supplement.

I don't know what the answer is, and I don't think there is a simple answer, but the system we have in place now is dangerous. It's far more dangerous than the supplements you're trying to protect us against.

That's all I would have to say.

Hon. Brenda Chamberlain: I think we recognize there are lots of flaws in the system; there are things that are not right. We're trying hard to look at those.

We also know this is a growing market where there are all kinds of natural things out there that are helping and are really good for people. Again, different people react differently to each product.

But as a mom, you must feel that you want safety around your product, I would suspect. That would be true, would it not?

Ms. Debra Oxby: Absolutely, absolutely, and I want to know that what they say is in the bottle is in the bottle. If the people who manufactured this product suddenly changed the ingredients in any way, it would not work as well for my son. So there does have to be truth in labelling, but I believe that would apply to any food; even for Kraft Dinner, you have to put all of your ingredients on your label. This applies to foods, drugs, and natural health products. It's in the Food and Drugs Act, that you must have truth in labelling, so even if they go into the food category, they still must be labelled as to what their ingredients are. So I'm not sure why that's a concern.

● (1655)

Hon. Brenda Chamberlain: Well, it's because you would get different things, like calorie content, with labelling under food. That's a concern, as opposed to it being something else that would be helpful as far as being medicinal. So you see there's a marrying of these two things. That's why I think at least some of us on this committee would like to investigate a third category in some fashion; it may be that these should be looked at a little differently than a drug or food.

Ms. Debra Oxby: As long as we—

Hon. Brenda Chamberlain: As long as you can get it, and it's the way it is, and it helps your child.

Ms. Debra Oxby: As long as no one can take it away from my son on a whim. I say that because it is safe.

Hon. Brenda Chamberlain: I hear what you're saying. Thank you.

The Chair: Thank you, Ms. Chamberlain.

Madame Demers.

[*Translation*]

Ms. Nicole Demers (Laval, BQ): Thank your, Madam Chair.

I am also concerned. I am using natural products a lot myself. I have been taking Strauss drops for a few months, and I feel fine. But I am worried when you talk about complete freedom for natural health products. Not all manufacturers really want to market, like you do, a quality product that really meets the needs of people and can be effective.

There are a lot of quacks. If we have a third category, I think it is important that we have some regulation just to make sure that consumers will get products that have been approved and evaluated beforehand. One can never know.

You were talking about the 36 ingredients in your product Empowerplus, 33 of which are taken daily. What are the three other ones?

[*English*]

Mr. David Hardy: The 36 ingredients in our product are taken on a daily basis. The only ingredient that you would never eat is gingko biloba; most people don't chew on gingko biloba leaves. But there is wonderful science showing that it has the ability to dilate blood vessels and to assist collapsed blood vessels in the brain, making the nutrients more available. That's why it's there.

[*Translation*]

Ms. Nicole Demers: It is okay. I just wanted an answer about this product.

You said that 86% of those who use your product become normal. Does that mean that it has no effect on 14% of those who use it? Could you explain briefly what the impact is on this 14%?

[*English*]

Mr. David Hardy: Well, in the studies that Dr. Popper and others have come forward with they've actually improved on the statistics they published in the medical journals. We're just quoting those statistics, since they have studied the use of this product and found things that would mitigate the interferences. For instance, if you have a candida problem, or a parasite, in your body, this supplement feeds the candida or the parasite very effectively, and you don't see all of the benefit of the nutrient.

In the studies they did, the response wasn't necessarily worse with the supplement; it just wasn't better than the drug regimen those people were on.

[*Translation*]

Ms. Nicole Demers: Okay.

Last week, I met an hepatologist at a social function. He told me that, since natural products are metabolized more rapidly than drugs, most cases of liver transplant at the CHUM, which is the university hospital of the University of Montreal, are due to an excessive intake of natural products without medical advice.

Do you have evidence to the contrary?

[*English*]

Mr. David Hardy: Actually, the doctors have done blood work on probably over 100 patients now who've taken Empowerplus, some of whom were liver compromised and kidney compromised from taking medications in the past. So you'd think if there was any compromise from taking this product, it would show up in those who've already been compromised.

In fact, they were not compromised at all. Their liver and kidney function improved on the supplement—it did not decrease—in spite of what people say is a reasonably high level of minerals and vitamins.

● (1700)

[*Translation*]

Ms. Nicole Demers: This is true for your product, but I am talking about all natural health products, and not just Empowerplus. Some of them can have a positive impact, but not all of them.

[*English*]

Mr. David Hardy: There is the potential with every product, I suppose, to create some liver misfunction. We just talked about lithium. That's a mineral. But at the nearly toxic levels at which doctors use it to treat bipolar illness, it definitely does compromise liver and kidney function and will often kill people because of that. It happens all the time.

So every one of these products of course has to be used within the safe upper limits that science has set. We don't know all of those limits very well yet, but we have many of them set by science, and I think that's important. You can't abuse those levels.

[*Translation*]

Ms. Nicole Demers: Mrs. Chamberlain, Mrs. Crowder, Mr. Bigras and myself would prefer a third category for all natural health products, just to make sure these products are analysed, regulated and put under a certain framework. This framework does not need to be as tight as that of therapeutic products like drugs, but they should be regulated.

Would you agree with that?

[*English*]

Mr. David Hardy: We're not against monitoring, as we've stated, but we are against the current position of the Office of Natural Health Products because we see the potential for abuse just like the abuse we've experienced in the past. It can't be a subset of drugs, which it currently is. That's the whole purpose of Bill C-420, to bring to the attention, I think, of everyone in Canada that foods are not drugs.

[*Translation*]

Ms. Nicole Demers: In what category would you put essential oils?

[*English*]

Mr. David Hardy: They're very clearly foods. To me, they are. Those products are a part of our diet, and I don't see any great problem with taking essential fatty acids at all.

Mr. Anthony Stephan: Why can it not be listed as a food and still support good manufacturing practices, appropriate labelling, and truthful claims? All that can be resident within a food directorate.

[*Translation*]

Ms. Nicole Demers: It is too dangerous. I know senior citizens who used essential oils because they were convinced of their therapeutic virtues, and there were many negative impacts. Contrary to what you said, some people died because of this. I do not think essential oils should be included in the natural health products that have no effect, and are not dangerous. They do have an impact and are dangerous.

[*English*]

Mr. David Hardy: You're not talking about essential fatty acids, then, you're talking about—

Mr. Anthony Stephan: Essential oils, yes.

Mr. David Hardy: —essential oils. Okay.

The Chair: Thank you, Madam Demers.

I want to say to our witnesses that I think all of us feel badly about the experience you had. We had many letters from witnesses who wrote to us, such as Madam Oxby. There were some very sad stories that we heard from people who were denied access to your product.

I hope you realize that you are the only manufacturer of a single product who has been invited here. I think this is our way of making a gesture to you that we do feel that you underwent some pretty unpleasant times.

I want to say that the unpleasant times you went through were at a period of time when your product was under drug evaluation in the drug directorate. The research was shut down because it was not fulfilling some of the criteria required.

If that research were being done today, if you'd just started a year or so ago and just got the research going, today, under the new category—it's not a third category, but it almost is a third category because it has its own bureaucracy, its own regulations, and its own rules—I don't believe you would have run into that.

Do you think we're making some progress?

● (1705)

Mr. Anthony Stephan: Yes. In fact, there is a double blind study operative right now at the University of Calgary. The FDA has approved double blind studies in the U.S. This is a major step; it's a step forward. But once again—

The Chair: We have to ask you to kind of now separate yourself from your own history and look at what is being presented today. I have heard your commentary that you think the regulations are a little too tight. It's possible that when we have a new Food and Drugs Act, which might be coming up in the next few years, we will get a look at those. We'll have had a few years of experience with applying them, and we may as a committee actually suggest some amendments to them. We would be interested in your comments about those regulations more in a couple of years than now.

If we move this to food, you realize you couldn't make any claims at all, unless you were saying something like this will not cause tooth decay.

Mr. Anthony Stephan: Right now, the Health Canada approved claim through the Office of Natural Health Products is that Truehope EMP supports mental and physical well-being, so there is a minor claim there right now.

The Chair: That's a pretty good claim. And particularly if your product is as popular as the letter writer seemed to suggest, I'm sure it will do well, even under that claim.

Mr. Anthony Stephan: We're okay on that part, because a product needs to prove itself. It needs to be able to stand up on its own.

But once again, I hold up in my right hand the NPN that has been provided to us as of last week, and then yesterday's report off the website, where the drug directorate is saying don't take Empowerplus.

The Chair: I believe that report on the website—it probably should be taken off—is dated 2003, which was prior to your issuance of an NPN.

Mr. Anthony Stephan: This is true.

Hon. Robert Thibault: I think the product included boron, didn't it?

Mr. Anthony Stephan: It included boron. The new product does not include boron, because the drug directorate had control over it as a new drug. Our understanding, as of last week, is that boron is now up for evaluation at the Office of Natural Health Products.

The Chair: So actually, in quoting that thing being on the website you didn't quite tell us all of it. It was an issue in 2003, when they said that, because that's what they thought at that point. Now you've moved well beyond that. If I were you, I'd write to them and say could you please clean up your website and get that particular evaluation off, and put instead that we have been issued an NPN and we are undergoing clinical trials at the moment.

Mr. Anthony Stephan: Unfortunately, because of their website and the oversight that's required, we had a query last week from the Norwegian government, and they had put out a press bulletin to the people in Norway not to take Empowerplus because severe side effects that could even include death had been identified.

The Chair: I think rather than complaining about that I would take that Norwegian press release and a copy of what was on the website and send it to them and say, "You are actually putting out poor information and this is causing us trouble. Please remove it." That gives you a good thing to use.

You're next, Mr. Merrifield.

Mr. Rob Merrifield (Yellowhead, CPC): I know, but your time has gone.

The Chair: Thank you very much, Mr. Merrifield.

By the way, I'd just like to make one point.

Mr. Rob Merrifield: It had better be a good one.

The Chair: It is a good one.

Somebody said we treat our pigs better than we treat our wives and our children. That's impossible, because you own your pigs; you don't own your wives and your children.

Mr. Merrifield.

Mr. Rob Merrifield: I've learned from experience that a happy wife is a happy life, and that's all I can say on that subject.

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 the law. That's not where I wanted to go with my questioning.

My question is really with Bill C-420 and how we're going to move forward so that this never happens to you or to anybody else again. From my perspective, it looks as if it could be acceptable if we could move it under a food and apply Bill C-420 as written—but it may not be to everybody around the table. It seems to me the real irritant isn't so much whether it's in a food, drug, or separate category; it's the application of subsections 3(1) and 3(2) and schedule A.

● (1710)

Mr. David Hardy: Absolutely.

Mr. Rob Merrifield: The transition team recommended getting rid of them, in testimony before this committee.

Mr. Anthony Stephan: 1997.

Mr. David Hardy: Yes. We were told that they were going to disappear, but they didn't. We're not happy with this at all.

Mr. Rob Merrifield: This is where Health Canada has picked up the law and used it as a hammer. If this committee could get rid of subsections 3(1) and 3(2) and schedule A, would this satisfy you?

I ask you because you've had experience in a court of law in this country.

Mr. Anthony Stephan: It would be a major step forward. It would take us out of archaic standards into an area where we can speak and not be in violation of an act. Actually, we weren't in violation. All along the charter allowed us the freedom of speech.

Mr. Rob Merrifield: I believe we're going to clause-by-clause tomorrow. Could our researchers come tomorrow and give us some recommendations on how we could make this happen.

The Chair: Make what happen, the elimination of subsections 3 (1) and 3(2)?

Mr. Rob Merrifield: That's right.

The Chair: We can't do that.

Mr. Rob Merrifield: We've had almost consensus from all sides, even the transition team. I'm wondering if our researchers have a way of doing this. I've asked them if they could share this with us tomorrow before we go to clause-by-clause.

The Chair: You asked them for a private meeting where we could meet in camera and thresh some of this out, but I don't think they understood it to mean how to get rid of subsections 3(1) and 3(2).

Mr. Rob Merrifield: I'm asking them right now how we can remove subsections 3(1) and 3(2), so that they won't apply to natural food products. I'm asking them if they would give us some recommendations on this before we go into clause-by-clause tomorrow.

The Chair: If that is your question, I'm sure they can be ready with an answer by tomorrow. This is just a proceeding—an injection into tomorrow's meeting whereby the researchers try to guide us on what their thinking is.

Hon. Robert Thibault: Madam Chair, I agree with proceeding like that. But we had suggested last time that before we get to the decision-making part, we hear one last time from Health Canada on the question of schedule A.

Mr. Rob Merrifield: They're coming tomorrow, right?

The Chair: Yes.

Mr. Carrie or Mr. Lunney will do a little sum-up. You fellows will be ready?

Mr. Rob Merrifield: Tomorrow?

The Chair: Yes.

So the question will be the order in which we do this.

Will we have Mr. Carrie and Mr. Lunney give their sum-up first? No? Health Canada first? Okay. Then we'll have Mr. Carrie and Mr. Lunney. After that, we'll go in camera and ask the researchers to answer your question. Then we'll come out of camera and go into clause-by-clause.

Mr. Rob Merrifield: That's fine.

The Chair: Everybody happy with that plan?

Thank you for coming. We hope that you're feeling better about your relations with the Government of Canada.

We're going right into a motion now.

Hon. Robert Thibault: I think, Madam Chair, that I can save you some time. I'm willing to withdraw the motion. I believe the clerk has said that Thursday would be available for Mr. Bernstein to appear. The others have agreed as well.

The Chair: So you're not ready to do the motion?

Mr. Rob Merrifield: He's withdrawing the motion.

The Chair: I understand that the other motion has been withdrawn until Thursday as well.

● (1715)

The Clerk of the Committee: It's to be dealt with on Thursday.

The Chair: Because Mr. Ménard isn't here today.

The Clerk: Notice is 48 hours, so it's Thursday.

The Chair: Okay.

Yes, Mr. Lunney.

Mr. James Lunney: On the question of whether this product would have been treated differently under the new regulations, there's no guarantee of that. The reason is that even with the new regulations, schedule A and subsections 3(1) and 3(2) still exist. Mental illness is on the list. It is against the law to mention that a vitamin, mineral, or herb can influence anything on schedule A, which includes mental illness. So they would still be violating subsections 3(1) and 3(2) with those clauses in place.

If Bill C-420 was not on the table, pushing the NHPD to get some work done, we'd have no guarantee that their product would be treated any differently under their existing regime than it was before.

The Chair: My understanding was that one of the reasons it was under siege when in the research stage was that the regulations required that it be under the supervision of a medical doctor or a dentist, and they only had a psychologist. That is why the research was shut down. However, the new regulations under natural health products allow someone such as a psychologist to be the supervising scientist.

Mr. James Lunney: On a point of order, it's actually not so. Under the new NHPD regulations in part II of the *Canada Gazette*, to do research on an NHP you have to be a medical doctor or a dentist. That's in the new regulations.

The Chair: You still do?

You told me that under drugs, they shut it down because it wasn't under a medical doctor. He's saying those same things apply under NHPs.

Ms. Sonya Norris (Committee Researcher): Under subsections 3(1) and 3(2), the trials would have been allowed to continue.

Mr. James Lunney: So I just wanted to address that.

As far as claims being made under food are concerned, it is simply a matter of political will. There was no provision for natural health products to make claims under the drug style until the new regulations in part II of the *Canada Gazette* came into place. So the same procedure could be followed under a food directorate, allowing for good manufacturing practices, office inspections, and claims.

Ms. Sonya Norris: Not claims.

Mr. James Lunney: Well, it's a matter of political will. There were no claims either under the drug side before.

The Chair: It's in the act that you can't make claims under food, other than to say that it won't cause dental caries, and that kind of thing.

Anyway, there's lots of time tomorrow to go into some of these details.

Mr. James Lunney: Thank you very much.

The Chair: Thank you, everybody, for your attention. We actually finished a bit early. I'm sorry, but I thought I had two motions to go through and was trying to allow 15 minutes for each one.

This meeting is adjourned.

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