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Chair

Ms. Bonnie Brown

Standing Committee on Health

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● (0905)

[*English*]

The Vice-Chair (Mr. Rob Merrifield (Yellowhead, CPC)): We'll call the meeting to order.

A few members of Parliament are a little slow in getting here, but they'll be trickling in as we get going. We have enough of a quorum to be able to start with testimony.

We are starting a marathon day with regard to legislation on Bill C-420, and we look forward to the comments of witnesses in regard to this piece of important legislation.

We have with us the Canadian Health Food Association, the Canadian Association of Naturopathic Doctors, the Canadian Treatment Action Council, the Alliance of Natural Health Suppliers, and the Canadian Council of Herbalist Associations in this first section.

I believe the witnesses are here, so let's start with the Canadian Health Food Association. I'm not exactly sure who is presenting.

Valerie Bell, we look forward to what you have to share with the committee.

Ms. Valerie Bell (President, Canadian Health Food Association): Thank you.

My name is Valerie Bell, and I'm the president of the Canadian Health Food Association.

The Canadian Health Food Association is Canada's largest organization for natural products in a $4.8-million market. We represent 1,300 members, including retailers, wholesalers, distributors, and manufacturers, and other member associations involved in supplements, vitamins, herbals, homeopathy, sports nutrition, and natural and organic products.

Our organization led the public campaign in 1990 to press the government for new and more appropriate regulations on natural health products. That campaign led to public hearings conducted by the Standing Committee on Health in 1998. The committee's subsequent report contained 53 recommendations that laid the groundwork for current natural health product regulations and for the formation of the Natural Health Products Directorate.

Although the new regulations for natural health products came into force in January 2004, two key recommendations have yet to be implemented, the primary one being to incorporate a separate definition for natural health products into the Food and Drugs Act. The former standing committee clearly recognized that natural health products were neither food nor drugs, yet today natural health products are still classified as a subset of drugs under the Food and Drug Act.

We do not, however, want to destroy what the stakeholders have created, as Bill C-420 would do, by turning back the clock to regulate natural health products as food. The Canadian Health Food Association does not support the proposal in Bill C-420 to define natural health products as food. The regulations for food and natural health products are not consistent in intent and application and are often contradictory in nature.

Legal counsel has confirmed that in cases of overlap or conflict, the food regulations would actually take precedence over the natural health product regulations were they to be moved. We would like this committee to implement the 1998 recommendation and to use Bill C-420 as a vehicle to put the existing definition for natural health products into the Food and Drugs Act. It is imperative that we strengthen and protect Canada's regulations for natural products by entrenching the definition for natural health products in law.

As the proposal for a distinct third category in law is outside the present language of Bill C-420, we have had legal counsel, including former justice department lawyers, draft the necessary amendments to the Food and Drugs Act that would allow the incorporation of the definition of natural health products. We are sharing those documents with you today.

Another key recommendation of the standing committee in 1998 was to review and amend section 3 and schedule A of the Food and Drugs Act. This piece of legislation was drafted in 1934 and has failed to keep pace with emerging science. Numerous consumer, practitioner, and industry stakeholder groups have repeatedly called for the repeal of schedule A and section 3.

Therefore, we are asking the Standing Committee on Health to reject the Bill C-420 proposal to put natural health products under the definition of food. We're requesting that you support the bill's other proposal to repeal schedule A and subsections 3(1) and 3(2) of the Food and Drug Act.

● (0910)

Mr. John Holtmann (Chair of the Board, President, J. Holtmann Holdings Inc., Canadian Health Food Association): I'll carry on. My name is John Holtmann. I'm the chair of the board of the Canadian Health Food Association, and a proud owner of eight health food stores in Manitoba.

Today, Canadians are actively taking control of their own health. They are increasingly recognizing that natural health products play an important part in health promotion and disease prevention. The recent polls show that 70% of Canadians aged 15 and over used or consumed one or more natural health products in a six-month period. Canadians spend an average of $145 on natural health products every year.

As a retailer, I've seen firsthand how the implementation of the new natural health product regulations has increased consumer confidence in natural health products. Consumers now have access to all the information they need to make informed product choices and to better manage their self-care. Under the food regulations, manufacturers are not allowed to tell consumers how or why to use their products, or even when they shouldn't use them. Labels of natural health products must now provide consumers with complete ingredient disclosure; product indications; full directions for use, including dosage information and duration of use and route of administration; as well as important warnings and contraindications.

We have drafted labels for natural health products according to the existing food regulations and the new natural health products regulations. You can see the difference for yourself and decide as a consumer which format your health care needs. I think there are some of these in your packages; they are quite different.

Mr. Carrie suggested yesterday that in the U.S.A. the market would drive the need for warnings and contraindications on product labels. However, as a retailer, I want my consumers to know that the government has evaluated the need for warning and contraindications on labels, and that their health and safety are not being left to chance.

Consumers are now assured by the presence of the natural product numbers that the products they are purchasing have been evaluated by the government for safety, efficacy, and quality. If natural health products are regulated as foods, as proposed by Bill C-420, consumers will be denied access to the information they need to make informed choices.

Bill C-420 does nothing to protect consumers or enhance their ability to effectively manage their own self-care. Although the natural health products regulations allow claims for natural health products where they are substantiated by evidence, section 3 and schedule A override this ability when the claims are related to any of the 40 diseases listed in schedule A. This prevents evidence-based knowledge on labelling and advertising from being shared with Canadians. Section 3 was introduced in 1934 to prevent fraudulent claims, where there were no known treatments or cures for many diseases. Today, many natural products, like glucosamine, and essential fatty acids, or sources of omega-3s, are globally recognized for their effectiveness in treating or reducing the risks of many diseases listed in schedule A.

To ensure that consumers have access to complete and current information, we request that you support the proposal in Bill C-420 to repeal subsections 3(1) and 3(2) and schedule A of the Food and Drugs Act to ensure that consumers have access to all the information they need to make informed choices, and to encourage self-care.

Thank you.

[*Translation*]

Mr. Gilles Houde (Vice Chair of the Board, President, GNC Canada, Canadian Health Food Association): Good morning. My name is Gilles Houde and I am the vice-chair of the CHFA and the president of GNC Canada. Through our 142 retail stores, we help ensure the well-being of hundreds of thousands of Canadians. GNC also formulates and manufactures their own line of products for distribution through our retail outlets. As a retailer and supplier we are committed to implementing the Natural Health Products Regulations. Stakeholders were consulted extensively and played an integral role in the development of the regulations. Industry now has regulations appropriate for their products and that ensure the formulation and manufacture of products for consumers that are safe, effective and of high quality.

Moving natural health products under the food umbrella, as proposed by Bill C-420, is a major step backwards that would result in regulatory and market confusion. We cannot assume, as has been suggested, that the natural health products regulations will simply slide over to the food side. If this is indeed the case then why are we going through this exercise of changing the definitions?

Bill C-420 as written would not only negate the millions of Canadian taxpayers' dollars spent in the development of the new regulations, but also the significant resources invested by industry to comply with the new regulations. Important gains for both industry and consumers such as good manufacturing practices and product claims could not have been achieved if natural health products were regulated as foods. There are no specific good manufacturing practices in food legislation.

It has been suggested that we look to our major trading partner, the USA, for a suitable regulatory model, however DSHEA—the Dietary Supplement Health and Education Act, is not meeting the needs of consumers or of industry. Consumer confidence in natural products and dietary supplements is low in the USA and product quality is questionable. The US industry and other countries are looking to the new natural health products model as a workable and practical solution. In addition, product claims, under DSHEA, are limited to structure and function, in other words health maintenance claims, and are followed by a disclaimer that they have not been evaluated by the Federal Food and Drug Administration.

Adopting the DSHEA model over our current natural health products regulations will limit consumer access to information and undermine consumer confidence. Good manufacturing practices, under DSHEA, are food-orientated and not appropriate to the natural products industry. In Canada, good manufacturing practices have been developed specific to natural health products. Canadians want natural health products regulated independently of drugs, but they also want high-quality, safe, effective products and full product information to make informed choices. They want to know that what is on the label is in the bottle.

Canadians are relying more and more on the natural health products sector to ensure their well-being. They also rely on their elected officials to do the right thing. We must continue the forward momentum established to date and continue the implementation of the natural health products regulations.

Canada has established world leadership with its natural health products regulations. Amending the Food and Drugs Act to incorporate the existing definition for natural health products will not only strengthen existing regulations, but will also give natural health product regulators the full autonomy they need to refine the current regulations to meet the needs of Canadians.

● (0915)

[*English*]

In summary, we are asking you, the Standing Committee on Health, to reject the proposal that natural health products be regulated as foods, and we call for a separate NHP definition in the Food and Drugs Act. We also ask you to support the clauses in Bill C-420 proposing to repeal schedule A and subsections 3(1) and 3(2) of the Food and Drugs Act.

Thank you.

The Vice-Chair (Mr. Rob Merrifield): Thank you very much. I appreciate that.

We'll go on now to the Canadian Association of Naturopathic Doctors, and I believe we have Paul Saunders.

Dr. Paul Saunders (Naturopathic Doctor, Member of the Government Relations Committee, Canadian Association of Naturopathic Doctors): Thank you, Mr. Chair, and thank you, members of the committee. You have a copy of our brief here, and what I want to do is just go through and highlight a few things.

The Canadian Association of Naturopathic Doctors organizations, which I'm speaking on behalf of, represents over 85% of the regulated and licensed naturopathic doctors in Canada and over two million patient visits per year. Canadian naturopathic doctors have been involved with this file for over 20 years and feel very strongly about it. They have had involvements, for example, on the health advisory committee, on the transition team, of which I was a member, and on the expert advisory committee, the schedule A committee, and so forth.

We support the repeal of subsection 3(1) and subsection 3(2) in schedule A, and I think, more importantly, what we should focus on is the issue of whether natural health products are the same as foods.

Let me give you some examples of why natural health products and foods are really different. For example, with respect to natural health products, you can make claims that there must be issues of safety and efficacy that have to be satisfied, and these claims can be made on the basis of structure function, treatment, and prevention. They can be made on the basis of traditional claims all the way up to reproducible clinical trials or med analysis of that.

On natural health products, we can have listings of contra-indications, which cannot be present on food; we can have listings of interactions, which cannot be present on food. On natural health products, we need to have the substances on the label. For example, what type of vitamin D is it? Is it D1, D2, or D3? And those have different biochemical effects. Or, for example, the species of the plant and the part that is used are very important from a clinical perspective. In addition, on natural health products, unlike on foods, we must list the amount of the actual constituent that's there—or if it's standardized to a particular constituent—or the amount or weight of the concentration of the substance is listed as well.

In addition, on the natural health products label there is a warning that says something to this effect: seek advice from your health care provider should symptoms not be resolved or side effects develop. You would not find that on a label of a health food or a food in general. One of the other things that separates foods from natural health products is the route of administration. Foods are taken orally. Natural health products may be taken orally, but they may also be applied topically—when was the last time you applied most foods topically. They may be taken by suppository—I'll leave that to your imagination—or by eye drops or ear drops and various other routes. Foods are oral, but natural health products can be used for various conditions and by various routes.

Let me give you an example of something that was raised yesterday, and that's the issue of picolinates. Chromium and zinc picolinates are two forms of a particular mineral that is essential, but they can also be available in the citrate form. The advantage of the citrate form is that there is less potential for side effects. The picolinates would be contraindicated in somebody who has kidney disease, who is a dialysis patient, or for nephritis, for autoimmune kidney disease, or even for diabetes type 1 and type 2. So if that were to be put on the market, it would have to have some warnings and labels, and if it was put there as a food, none of that information would be available, and there could be complications with that.

When naturopathic doctors work with their patients, they take a complete history, including the current medications and drugs that they're on, including over-the-counter medications, and they do a physical examination and laboratory tests in order to arrive at a working diagnosis and a treatment plan. That could include natural health products, although our recommendations for dosings may be above the RDA, depending on the patient's situation.

What's needed is to actually increase naturopathic doctor access to these items. If they become foods, then it is quite likely that with a change of administration and so forth, these would fall under Codex. If they fell under Codex, they would not be available to us and they would not be available to our patients. In other words, we would not be able to meet the needs and the health care responsibilities that we have with respect to our patients and we would not be able to look after them. Some two million patients would suffer as a result of these being defined as foods.

What are some items that might not become available or that we are interested in accessing as naturopathic doctors? Higher doses of vitamin A and vitamin K, above the RDA; single amino acids; bioidentical hormones; trace minerals—two examples are boron and lithium—and homeopathic medicines, which are, by virtue of their name, on various other schedules, such as schedule F.

As naturopathic doctors, we currently do not have access to items that we are trained for and educated on, or that we are taking licensing exams on, that exist on schedules 1, 2, and 4 of the Controlled Drugs and Substances Act and schedules D and F of the Food and Drugs Act. Yet, we are trained and able to use these substances in other jurisdictions. We ask that we actually have access to these. As a solution, we do not want to see these natural health products defined as foods, as proposed under Bill C-420, as they would not be regulated and they would not be accessible to us and to our patients.

● (0920)

What is in fact needed is for naturopathic doctors to be included as practitioners under the regulations under the Canada Food and Drugs Act. This would be for naturopathic doctors who have both graduated from four-year educational institutions and passed board exams of their respective province and territory. What we're asking for is to create a schedule of higher-risk natural health products that would be accessible to us and to others who would have suitable training in order to prescribe and be able to access these for our patients.

This will require collaborative effort between the federal government, provinces, and territories in order to ensure that naturopathic doctors are defined as practitioners, and that our patients have access to the health care products that they need.

In conclusion, I want to point out to the committee that millions of dollars, countless hours, effort, and resources have been invested not only by this association but by the Canadian Health Food Association, the public members, and so forth in order to create this file, the natural health products, and to redefine them not as food but what they truly are: products that are beneficial for Canadians for use in their health.

Should this bill pass, what would happen is that all of this effort would simply be wasted, and we would step back twenty or thirty years to when things were available on the market illegally or not available at all. We support the work of this committee, and we suggest and encourage this committee to support the work of the government, Health Canada, and allow the Natural Health Products Directorate to be able to do its job without interference—the job that some 76% in the recent Ipso-Reid poll supported when they said that the regulation of these natural health products, as they are, is what they were looking for.

In conclusion, we support repeal of subsections 3(1), 3(2), and schedule A, and we do not support the redefinition of natural health products as a food.

Thank you.

● (0925)

The Vice-Chair (Mr. Rob Merrifield): Thank you, Dr. Saunders.

Now we'll go to the Canadian Treatment Action Council. We have Tony Di Pede.

We welcome your comments.

Mr. Tony Di Pede (Treasurer, Canadian Treatment Action Council): Thank you, Mr. Chair, and thank you, members of the committee, for the opportunity to present the position of the Canadian Treatment Action Council.

We're a consumer organization, a national organization of people living with HIV and AIDS. All our members are people with HIV and AIDS.

The Canadian Treatment Action Council promotes informed public policy, public education, and awareness on issues that impact on access to treatment and health care for people living with HIV and AIDS. We define treatment very broadly to include allopathic as well as complementary and alternative medicine. This includes the use by many people living with HIV and AIDS of natural health products.

Our position is that in its present form, Bill C-420 should not be passed into law.

The bill proposes two things. One is the repeal of subsections 3(1) and 3(2) and schedule A of the Food and Drugs Act, and CTAC supports the repeal of these sections. We do not support amending the definitions of “food” and “drug” under the Food and Drugs Act.

Let me speak first about the repeal of subsections 3(1) and 3(2) and schedule A. As you've heard, it is time to repeal these outdated subsections. First introduced in 1934, these regulations were designed to curb advertising of medicines for diseases that had no known treatments at the time. The diseases listed in schedule A include cancer, arthritis, diabetes, depression, and hypertension. Today we know there is a strong body of evidence for the use of calcium supplementation for osteopenia, glucosamine in the treatment of arthritis, and St. John's wort in the treatment of moderate depression—products used quite a bit by people living with HIV and AIDS.

People living with HIV and AIDS often live with multiple conditions such as these and seek to mitigate the impact of taking many medications through the use of natural health products. People in our communities have told us strongly that they want clear information on the label, including health claims, as long as they are based on good evidence. People with HIV and AIDS want more than evidence-based alone; they want to know the potential interactions with the anti-viral drugs they are taking.

The Natural Health Products Directorate regulations presently allow manufacturers to make a full range of claims, including structure, function, risk reduction, and treatment or cure, provided there is sufficient evidence, including thousands of years of traditional use to support these claims. The present subsections and schedule A restrictions prevent Canadians from learning more about natural health products they use in conjunction with other medicines. These subsections and schedule A should be repealed.

Let me now explain why CTAC is opposed to amending the definition of “food” and “drug” under the Food and Drugs Act. What would happen if Parliament voted to amend this definition? We think there could be two outcomes. One is either that our natural health products would fall under food regulations or that the Food Directorate would administer the current natural health product regulations.

What is the problem of classifying natural health products as food? For us, there would be major inconsistencies in critical areas such as health claims and labelling; good manufacturing processes; routes of administration, topical versus ingested; and of particular importance to us, adverse event reporting. Many common self-care products that have been on the market for decades with evidence-based claims would have to be removed from the market in order to meet food regulations.

Bill C-420 does not address these inconsistencies. Dosages of vitamins and minerals, as we know them, might have to become serving sizes. Food labelling would not require the listing of medical ingredients by quantity but by descending order of presence. The result would be market and consumer confusion about the different ingredients and levels of components in a given product.

On the other hand, simply migrating the Natural Health Products Directorate into the Food Directorate cannot be the intention of the bill's proponents, as it would lead to what we believe would be legislative confusion.

● (0930)

The CTAC supports the regulation of natural health products as a distinct category, neither food nor drug. We strongly feel that the role and the purview of the Natural Health Products Directorate should be strengthened, not diluted. Consumers are looking to government for assurances that the products they buy are safe, effective, and affordable.

Thank you.

The Vice-Chair (Mr. Rob Merrifield): Thank you very much.

We have two more before we go to questions and answers.

From the Alliance of Natural Health Suppliers, we have Peter Helgason. We welcome your comments.

Mr. Peter Helgason (Vice President, Regulatory Affairs, Alliance of Natural Health Suppliers): Good morning.

I'm going to speak more to the generalities of what I call the “how many angels can dance on the head of a pin” argument. How did we get to where we are?

It always goes back to 1997 and the site licensing regulations that Health Canada tried to impose on the industry with no consultation whatsoever. I believe Mr. Dingwall was the Minister of Health at that time. The fundamental change in public policy or what have you at that time was pre-market authorization for the sale of these products. And—literally—why? That's the million-dollar question. Where is the pressure coming from? If you check the death statistics for Canada, there is no adverse event reporting. The medical community is not reporting adverse events. There are no bodies piling up anywhere.

There was an original push, an initiative. I also work for a company that's been serially prosecuted and persecuted by HPB, TPD—however you want to characterize it—and I work with a lot of people who also have been prosecuted and persecuted by the regulator. We can't find any problems. They find effective products that are, in our view, cutting into somebody else's line of profits, and they come at you with a big sledgehammer and try to smash you and destroy you.

As for the industry itself—and I certainly respect and appreciate the positions the other people here are presenting—the naturopathic doctors would like enhanced prescribing rights to schedule F products, which will be products that are moved out of the food or NHP category and for which you'll need special insight or medical training. A lot of the larger companies are publicly traded firms, and a publicly traded firm has a different financial incentive in business from what are principally, in the vast majority of the industry, small privately held companies.

Then we get into the bigger issue of where Canada fits in the international picture. I notice that we do $1.5 billion per day with the United States. If we're going to be harmonizing rules with anybody, it would seem to me that the model to emulate would be that of our single largest trading partner. I've met with numerous people from America—elected representatives, their staff, industry advocates, and manufacturers from the United States—and they're actually quite pleased with the DSHEA.

I've done some investigating on the New York Stock Exchange for that sector of products. You hear from, say, the American Botanical Council that there's a lack of confidence in the products, and actually the sector sales are up 34% over last year at this time.

This is with the largest, most powerful industry in the world planting stories in the media on a regular basis. As recently as yesterday, as a matter of fact, the CFIA was slagging nutritional supplements on a banner, screamer headline in the *Globe and Mail* on Monday. You live in a town—everybody here—is this coincidence? Come on, the committee was meeting yesterday to start considering Bill C-420, and you get a screamer headline in *The Globe and Mail* about the dangers of nutritional supplements, which are actually sport nutrition products. Jamieson had a response in today's *Globe and Mail*, buried on page 89 or something like that, saying it's not the products that are the problem; it's the stupid, bloody regulations that are the problem. The products are fine. The consumers love them. Nobody's complaining.

So what's up with that?

That kind of led us to this meeting. We met with Dr. Lunney a couple of years ago on this file. What can we do? Mr. Buckley addressed it yesterday at the committee, if you recall, and it's the use-based definition.

Just because it's in somebody's financial interest to call black white doesn't mean that I have to bury my head in the sand and agree that black is white. It's not. These products have been used by individual human beings for thousands of years. Science and technology have brought innovations, but under the existing laws, if you are fraudulent in what you claim about your product or if you're dishonest in how you label your product, there are laws to deal with that.

We've now created a new bureaucracy within Health Canada that I understand has sucked up something like $15 million over the last 16 months. There are 60,000 products in the marketplace to be licensed; 300 have been licensed.

● (0935)

I sat at a CHFA-sponsored forum last Friday night in Vancouver, and I was told by the director general of that department that the solution at NHPD is that they're going to increase their output by 50%. Imagine having somebody working for you who says,"I've been dogging it for the last year and a half, but damn, tomorrow morning I'm going to work 50 times harder". It beggars belief. And this is passing for public policy. People's lives and businesses are being destroyed. I'm reliably informed that vitamin K is going through the *Gazette* process to be removed from schedule F. There are 10 skids and $100,000 worth of vitamin K held up at customs right now because it's banned from entry into Canada.

The regulator we're supposed to trust is in the process of removing vitamin K from schedule F in two weeks, but they seized the shipment. The guy didn't have it for the big health food association show in Vancouver. As a manufacturer, how can you have faith? Like, is this leopard changing its spots?

When I started investigating this, I read all the background briefing papers from 1997 and 1998. I remember Zoltan Rona's top 10 reasons why the HPB had to go. It hasn't changed very much; it's pretty much the same old game.

Nobody here was elected by their constituents to come and represent the interests of public companies or trade associations. On this committee there's a genuine interest in the health of Canadians. The partisan nature of the Hill these days makes it difficult to reach agreements, but this is a chance to hit a home run. Canada can be a leader in the world on this file.

You could talk to the Europeans about what's happening with the Codex Alimentarius Commission or the European Union Food Supplements Directive. Nobody is hiding what's going on. Bureaucrats had been bought out by big money for decades. If we allow our natural health products to be classified as drugs in Canada today, I will guarantee you that in 10 years anything above the RDA, the recommended daily allowance, is going to be classified as a drug, exactly as it is in Germany. Anything that's effective will be available by prescription only. Those who prescribe and manufacture will be smiling, and those who pay will be getting done over both financially and physically.

That's a brief summary. I'd be happy to answer any questions.

● (0940)

The Vice-Chair (Mr. Rob Merrifield): Thank you. We have the Canadian Council of Herbalist Associations, Michael Vertolli.

Mr. Michael Vertolli (President, Canadian Council of Herbalist Associations): Thank you.

We would like to thank the committee for allowing us to make a presentation.

Five minutes really isn't a lot of time to speak on such a large and complex issue. We've provided you with a brief in which we've outlined our position, and I'm going to basically go to the heart of the brief, which is on our recommendations.

First of all, the Canadian Council of Herbalists Associations represents all of the provincial, regional, and national associations representing herbal practitioners in Canada. We have a unique perspective on this issue because we've been involved since the very beginning.

You've heard many times about how a lot of people were very upset with the regulations in the mid-1990s. As practitioners who rely on many types of natural health products, particularly botanicals, we were in a uniquely difficult situation at that time because the weight of the old regulations was having the greatest negative impact on botanicals. If you look at the products that were disappearing very rapidly from the marketplace in the mid-1990s, the vast majority of them were herbs.

Back in the spring of 1996, a group of small herbal manufacturers, who were very upset with the status quo, met with a group of herbalists at that time. I attended that meeting. It was as a result of that meeting that we prepared a report in the summer that was first tabled at the Canadian Health Food Association trade show in the fall of 1996. It was on the basis of that set of recommendations that eventually the entire campaign to have the regulatory framework for natural health products was essentially kicked off. At that point, it was initially championed by the Canadian Coalition for Health Freedom.

We've been involved in this process from the very beginning. We've participated in the Advisory Panel on Natural Health Products. We made a presentation to the former standing committee, and we participated in the office of natural health products transition team.

Getting to the matter at hand, which is the current situation, we have made six recommendations in our brief that we hope the standing committee will take seriously, because we believe these recommendations will help get this process back on track.

As you know, and as you've heard from many presenters, first of all, Bill C-420 recommends the repealing of subsections 3(1) and 3 (2) and schedule A from the Food and Drugs Act. I'm sure that just about everyone who has come before you has supported that.

You've probably heard from many presenters that these sections are interfering with the ability of consumers to get accurate information on the use of these products. We feel that the ability of consumers to be able to have access to these products, and more particularly access to accurate information on the use of these products, is critical because natural health products make a very important contribution to the health care system in Canada.

We fully support that aspect of Bill C-420, but with regard to the second part of Bill C-420, which proposes the redefinition of natural health products under the food category, like many of the presenters you've heard from, we disagree with that provision. For reasons that have been outlined in detail by many of your presenters, we feel this simply would not work.

It would eliminate the ability of the regulators to impart sufficient quality control standards to ensure the safety and efficacy of these products. It would eliminate provisions that allow for claims and contraindications to be made on the use of these products, which is very important in order for consumers to be able to make informed choices.

We feel this approach is simply not workable. It essentially amounts to the deregulation of the industry, in spite of the fact that many of the proponents of Bill C-420, and specifically the recommendation to reclassify natural health products as food, are also those who have spoken out and expressed the greatest amount of concern over the regulations that have been proposed by the Codex Alimentarius Commission. It's the actual process of moving NHPs into the foods category that puts them most at risk from the Codex regulations, because these regulations strictly deal with food products.

● (0945)

So we do not support the reclassification of natural health products as foods.

However, it was the intent of the Advisory Panel on Natural Health Products and the previous report of a former incarnation of this standing committee and the recommendations of the office of natural health products transition team that natural health products be defined in the Food and Drugs Act as a distinct category of products.

Neither the previous standing committee nor the office of natural health products transition team wanted the necessity to create legislation to redefine the definition in the act to interfere with the implementation of the natural health products regulations. Health Canada right now is undergoing a review of the Food and Drugs Act. It was hoped that when that review was complete, all the amendments to the act could be accomplished within a single piece of legislation. Unfortunately, that has led to the classification, in the interim, of natural health products as a subcategory of drugs.

If this committee goes forward with the recommendation of repealing schedule A and the related sections of the Food and Drugs Act, that legislation would have to be passed anyway in order to amend the act. Therefore, we feel this is an opportune time to make an appropriate amendment to the act that clearly defines natural health products as a product category that is distinct both from the food category and the drug category. That was our third recommendation.

Our fourth recommendation recognizes that in the Codex recommendations, which many consumers are very concerned about, natural health products are not recognized as a distinct product category. The Codex recommendations speak only to foods and drugs. So there is a concern that if natural health products are defined in the Food and Drugs Act as a distinct category, that category—natural health products—because it is not recognized by the Codex Alimentarius Commission recommendations, could potentially put the product category at risk for coming under those recommendations because they're no longer regulated in Canada as a subset of drugs.

We are aware of the fact that Canada's position has always been that natural health products are therapeutic products, not food products, and that they therefore do not fall under the jurisdiction of the Codex recommendations. If we choose to change the Food and Drugs Act and to define natural health products as a distinct category, we feel that it's very important that the Canadian delegation to Codex reaffirm Canada's position that although natural health products are no longer defined as a subset of drugs in Canada, it is still Canada's position that they are a distinct category from foods, and therefore they are not subject to the Codex recommendations. That is very important, because we don't want natural health products to get lost in this process due to the fact that Canada is the only country that actually recognizes them as a product category.

I'd now like to get to the more contentious aspects, our last two recommendations.

Herbalists in Canada recognize that the current regulatory framework is a considerable improvement over the regulations that were in existence in the mid-1990s that led to the various processes that have taken place to change the regulatory framework for NHPs. However, the fact of the matter is that a considerable percentage of consumers and many members of the natural health products industry continue to express grave concern over the current regulations.

● (0950)

Now, if you look at the current regulations, you can see that the real concern isn't with the regulations themselves. The regulations themselves are broad, and we feel that they do establish an appropriate regulatory framework. However, the problem has been with the policies that have been created in order to interpret the regulations.

We have identified in our brief three guiding principles that were established by the previous standing committee regarding the intent and philosophy of the regulations. We feel that the current policies and interpretations of these regulations, as they stand, do not adhere to those principles.

In particular, our concern is that the regulations do not recognize that natural health products as a category are considerably safer than most of the drug products that are available on the market. They have imposed onerous policies and requirements that are essentially making it difficult for small companies to continue to operate.

The Vice-Chair (Mr. Rob Merrifield): We're going to have to stop you there. Actually, you're a minute over, and I gave you a little more freedom than I did some of the others. We have your brief, so we can capture those last two points that you were attempting to make. Perhaps we can capture them in some of the questioning.

We've heard lots of testimony. It's time for the questioners.

We'll turn it over to Mr. Lunney for 10 minutes.

Mr. James Lunney (Nanaimo—Alberni, CPC): Thank you very much, Mr. Chair.

Another round has been heard today, and we had an interesting session yesterday, as we get to discuss Bill C-420.

I ask the indulgence of all members around the table for my croaky voice. I need to load up on some extra NHPs, I guess, to chase that virus.

We're glad to have you here today. It's quite interesting to hear a reflection on the whole range of use around the table here. I think as this unfolds and we hear more witnesses in the coming days, and even later today, we'll hear that there has been a wide range of use, both about how we got here and how well the regs are working now and where they're likely to take us.

There is a certain amount of confusion, certainly, in relation to Codex and what implications it will have, and also in terms of whether or not the natural health products industry is really happy being regulated as a subclass of drugs. I think that was the point Mr. Vertolli was just starting to make here. It fails to recognize that there are some very significant differences between natural health products and drugs. I tried to bring that out a little bit in my testimony yesterday.

We heard Dr. Saunders talk about the differences between natural health products and foods. Nobody wants to assume that natural health products, which are concentrated, physiologically active food products—biological, orthomolecular products, if you will—are the same as food. That's not the point. I think certainly it's disingenuous to suggest that if we took this from under drugs and put it under food, there would be no regulations, or it would destroy everything that's been accomplished.

There's one of the concerns people have, though, that I think the committee has to take a look at. With this regulation, for all of the product applications coming in and at the very slow rate that NHPD is moving in approving products, what we're finding is that there are a few large players—mostly members of the Canadian Health Food Association—who have the money and the means to advance their products. Of the very few products that have been approved so far, it's the big players who are the winners and the small ones who are being left out in the cold.

For example, we're looking at the number of product licences in backlog—about 6,300—while the number of NHPs in the marketplace is between 40,000 and 60,000. So far we've spent about $24 million over the couple of years we've been working at this. But if I look at the applications that have been approved so far.... Let me offer just one example here, Jamieson Laboratories, which owns Quest Vitamins and Wampole, has submitted approximately 200 applications, about 3.7% of the 6,300 applications, and it's received 47 product licences. That's about 14% of the 336 product licences that have been currently issued. At the rate we're going, I think we heard somebody suggest—Dr. Waddington, who was here yesterday; I don't see him in the room today—at the conference in Vancouver last week that they're going to increase by 50 times the output.

A voice: I believe it was 5,000%.

Mr. James Lunney: We're going to somehow be able to churn this through and accelerate the rate we're moving these approvals through in order to be able to accommodate this in the time period that all of these products are supposed to be approved.

I'll give you an example here that came to me from someone on Vancouver Island. I see we have others here with Dr. Watkin who will be testifying later about Recovery medicine and the trouble Biomedica has had with Health Canada.

● (0955)

The Vice-Chair (Mr. Rob Merrifield): Mr. Lunney, we heard your testimony yesterday. Do you have a question today?

Mr. James Lunney: A small aromatherapy company in British Columbia submitted 26 pounds of paper in support of their eight product licence applications in May 2004. By early 2005, they sent the owners a 25-page deficiency notice and gave the owners 30 days to supply the information. The concern is here that the big players are moving ahead and the little ones are being left out in the cold.

Mr. Helgason, one of the companies you represent is Strauss Herb Company. In dealing with the issue of subsections 3(1) and 3(2) and schedule A , Strauss Herb Company faced a very nasty experience with Health Canada. Would you review what happened with the costs that were accrued?

Mr. Peter Helgason: Big money. It cost the company about $500,000 by the time the smoke had cleared. It was a 73-count charge. There were 25 or 30 charges that were subsections 3(1) and 3 (2) violations. I saw a document floating around yesterday that I think was written by one of the EAs here. It said there's a new DM at Health Canada from the Department of Justice. What a coincidence! That's the way I view it.

When we were prosecuted, we called access to information. It took them 20 months to get the information to us. I think they're allowed 60 days under the act. The information was released four days after we were completely acquitted of all charges in a court of law. In there was a document they claimed privilege on and wanted back; it was a reference to a legal opinion that the Minister of Health had received from the deputy minister in October 2002, which was two months prior to our charges being filed. Justice was saying to Health Canada that subsections 3(1) and 3(2) would not withstand a charter challenge. But they did it anyway.

The company, my employer, is now conducting civil actions. Tragically, this is under privilege. I can't talk about the examinations for discovery. But I'll tell you, it sure makes interesting reading to understand how they targeted and whacked a small company in the middle of nowhere that's a burr in their saddle—never hurt a soul, never had a complaint.

Mr. James Lunney: What were the legal costs to your company?

Mr. Peter Helgason: All told, with legal, public affairs, travel, and all the hoop-jumping, about half a million dollars. That's about 10% of annual revenue.

Mr. James Lunney: Then, after squeezing you to the tune of half a million dollars, they dropped the charges.

Mr. Peter Helgason: No, they dropped the subsection 3(1) and 3 (2) charges. We were acquitted on the other charges.

Mr. James Lunney: Now, what has happened subsequently, with Revenue Canada being turned loose on you?

Mr. Peter Helgason: We had three CCRA audits and were whacked by the GST cops for $500,000, even though the company was in possession of documents from the GST guys saying the products were food and not GST-able. So it was a retroactive $500,000 assessment—cash or jail.

Mr. James Lunney: For committee members, if that wasn't clear, after the company had been exonerated, Health Canada turned the case over to Revenue Canada, which determined that the company should have been charging GST on the product. Now Revenue Canada is trying to collect some half a million dollars from the same little company.

How many product licence applications does Strauss Herbal have?

Mr. Peter Helgason: So far we've submitted two. That was just a test—stick a toe in the water. There has already been a decision made to drop about 30 products. We're selling 300 to 500 units a year. Herbalists will tell you, nobody is drinking adrenal tea for pleasure. Trust me, it's horrible-tasting stuff, like most of the herbal products.

Mr. James Lunney: How long have these applications been in?

● (1000)

Mr. Peter Helgason: Oh, about a year.

Mr. James Lunney: Health Canada's original applications were suggesting that this turnaround would take about 30 days. Then NHPD said they'd extend it to 60 days, which seemed reasonable when people were buying into this. But is it taking that long? Those of you who have had product applications approved, what kinds of turnarounds are you seeing?

Mr. Gilles Houde: Health Canada is telling us that if we have a compendial product, which means that we take a product to market according to a monograph they've published, we should receive our application within 90 days. They have never made a commitment for non-compendial product.

Let me also answer your question about the 5,000% increase. Having had the opportunity to set up companies myself, I can assure you that in the first year the output of a company or directorate is very low. Their claim of a 50% increase in productivity is something I'm perfectly willing to believe. The directorate has now been in place for a little more than a year, and you have to remember that nothing existed prior to the creation of the directorate. As one of the large members of this industry, I'm willing to wait for the directorate to put out the NPN number. I know the consumer will greatly benefit, and what's good for the consumer is good for the industry. So I'm willing to wait out the directorate. That's not an issue.

Mr. James Lunney: Okay.

The Vice-Chair (Mr. Rob Merrifield): Mr. Bigras, five minutes.

[*Translation*]

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

I have to say that the further we get with our study of Bill C-420, the more I find myself thinking that if it is passed, the desired results will be far from being achieved. We want natural health products to become more accessible, but supporting Bill C-420 will have the opposite effect. I would like you to consider the following questions regarding Bill C-420. How could we go about amending certain elements of the bill while ensuring that it still meets the sponsors' objectives? I will not hide it from you, what I have heard this morning has been music to my ears. You raised certain international issues which we must consider when making our decisions today.

You spoke of your determination to follow a rigorous approach in dealing with products available to consumers. You want consumers to have greater access to natural health products, a desire which consumers themselves share. Would it be possible to use Bill C-420 to repeal schedule A and the provisions set out in sections 3(1) and 3 (2), and to amend the definition by explaining the distinct nature of natural health products? Would the best approach not be for our community to amend certain provisions in Bill C-420? At the end of the day, it would be good news for you, and I am certain that consumers would also be pleased.

Mr. Gilles Houde: Mr. Bigras, I am hearing the same music that you are. This morning, we tabled a text which, where it applied, would create exactly the result that you are seeking. In the first part, it is simply a matter of repealing schedule A and sections 3(1) and 3 (2). We have also submitted wording, drafted by lawyers, to amend the Food and Drugs Act to create a new category for natural health products. It is as simple as that.

The Health Products and Food Branch has to be able to push its files through the system without necessarily having to deal with Health Canada's drug regulations. The principal difference offered by this solution is that it is far safer than having natural health products under the food umbrella, as foods are subject only to very limited regulations. It was said this morning that Canada, as well as Quebec and the rest of the provinces, has legislation to protect against fraudulent or dishonest acts. Unfortunately, it does not meet our needs. Industry is currently able to introduce any product it wants to the market, as products are only assessed once on the market. We want the assessment process to be undertaken before product launch. We want to ensure that consumers really are satisfied with the products that they are using, and that they know why they are using them. At the moment, this is not the case. Consumers have to rely on shop assistants, or they have to carry out Internet research or read extensively on the subject.

The solution is very simple: if section A were repealed, consumers would have the possibility of accessing the information they required, and the Health Products Branch could be placed in a separate category. As I said, we have prepared a text for you to this effect.

● (1005)

Mr. Bernard Bigras: If I understand you correctly, you are telling us that, thus far, the administrative cogs have been turning smoothly, but that the legislation is not in line with natural health product regulations. You support the regulations, but do not find the essence of the regulations reflected in the legislation. This is something which could prove to be very detrimental to you, and could render natural health products less accessible to the public.

Mr. Gilles Houde: I would draw your attention to what was said at the end of yesterday afternoon's meeting, when Dr. Waddington commented that the Health Products Branch had been put under drugs to create a springboard effect for the procedure. They really did this for this reason. If we had had to wait for legislation, we would have had to wait another two or three years. Because the Health Products Branch comes under drugs, it can now start to do its work. It simply needs to be transferred to its own category.

[*English*]

The Vice-Chair (Mr. Rob Merrifield): Thank you.

Ms. Dhalla, five minutes.

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

Thank you to all our witnesses for coming.

I have a couple of questions, one going back to yesterday. We've seen the intent of Dr. Lunney and Dr. Carrie to ensure that Canadians have more access to natural health care products. As we've heard, there are people who are, I guess, passionate on both sides of the issue in terms of what the process should be for Canadians to get increased access.

Valerie, you mentioned repealing schedule A along with subsections 3(1) and 3(2). Yesterday, the deputy minister of the department suggested having a modified schedule A, which they're in the process of working on and, if I'm not mistaken, having labelling that would allow for the statement of cures that are preventative in nature, and not actually for the cure or treatment itself. What would be your views on those suggestions by the health department?

Ms. Anne Wilkie (Director, Regulatory Affairs and Quality Assurance, Canadian Health Food Association): I'm Anne Wilkie of the Canadian Health Food Association.

We have worked on an external working group and put forward three different recommendations on how to move forward with schedule A. There were short-term, medium-term, and long-term objectives, but I think Ms. Gorman was only speaking to the short-term objectives at present, looking at modifying the definition of risk reduction or defining risk reduction, and then looking at some of the claims in schedule A.

We had looked at more long-term objectives, basically getting rid of it entirely because there are other frameworks in place. Under the natural health product regulations, there is already oversight to prevent you from making fraudulent claims, and to allow you to make only those claims you can scientifically substantiate.

So in my opinion, she's only looking at the short-term objectives.

Ms. Ruby Dhalla: Could you elaborate for some of us here on this committee what your experience has been working with the department in trying to meet some of these objectives? You can be honest, because I think it's important for us to—

Ms. Anne Wilkie: It's difficult, as I was only on part of the working group, so obviously.... But the process is definitely slow. I believe the working group mentioned yesterday that it took over a year to get their report posted on the website for some initial response. And again, they are looking at establishing additional advisory panels. So it is a very lengthy process.

● (1010)

Ms. Ruby Dhalla: Peter, do you want to add to that?

Mr. Peter Helgason: Well, it's being dangled as the big carrot in front of industry that you can make treatment claims; finally, we can state the truth and state the obvious.

I actually tried to ask a question at the aforementioned regulatory meeting in Vancouver a couple of weeks ago of the fellow who was speaking to DSHEA. I asked, gee, how would the FDA view a Canadian company making a treatment claim on their label, on their website, in a print publication, or in the electronic media? His response was, they will squish you like a bug. We are not going to change United States policy; it is going to be what it is.

It just seems to me, or the company that I work for, that the United States is a market ten times as big as the one we have. We speak the same language, we have a similar legal system, and we're basically the same culture. We can expand our trade opportunities exponentially in America. In Europe we're basically shut out, and most Canadian manufacturers will be.

The Vice-Chair (Mr. Rob Merrifield): Ms. Bell.

Ms. Valerie Bell: I want to make it clear that the Canadian natural health product regulations are seen internationally as being the role model, or something we should all look to internationally. As a matter of fact, Brazil has already harmonized itself to the Canadian regulations. The U.S. and the Mexican industries have both approached us, and we're already starting NAFTA negotiations to harmonize to the Canadian standards. The Australians have a drug model and New Zealand has a food model. They've actually looked at our model as being a possibility, because we're in between both. So internationally, there is a tremendous amount of interest in our regulations and in moving forward.

Perhaps I could address one other point, and that is the big and small issue. We represent both small and large companies in our membership, and we have worked actively with Health Canada to develop a small business strategy that would allow small businesses to actually come forward with the applications they need to remain in business. We have had negotiations with Health Canada on that for a considerable amount of time now, and we hope to see an announcement in the near future.

The Vice-Chair (Mr. Rob Merrifield): Thank you. Your time has gone.

Ms. Crowder.

Ms. Jean Crowder (Nanaimo—Cowichan, NDP): I want to thank you all for your presentations today. I have a couple of comments and then a couple of questions.

It seems to me what we've been hearing is that although there is some dissatisfaction over what's currently happening with the Health Canada approach to this thing, the department's approach to this thing, it almost feels as if we're using a blunt instrument in Bill C-420 to actually deal with some of the issues with Health Canada.

I would like you to comment specifically on what it is that needs to change in Health Canada in to order to meet Canadians' needs around having access to health products that they feel confident about, that have quality, that have adequate information on them so that they know what they're taking, that have quality in the manufacturing, and that have appropriate cost. I wonder if you could say specifically what needs to happen at Health Canada.

Mr. Tony Di Pede: I'm glad you raised that. There are a lot of problems with Health Canada. Even on the regulation of pharmaceuticals, they're very slow. But we're not suggesting that we don't regulate pharmaceuticals.

These aren't benign products, even though they're natural health products. They have impacts. In our community we need to know that. It may be one thing to say that if a manufacturer or a supplier makes a claim or does something that's unsafe we can sue them, but we don't have access to that information or the resources to do that. So we do need a balance. I'm sensitive to the needs of manufacturers and suppliers, because that does bring access, but consumers need some protection as well. Some of these products have interactions that, with the medications I am on, could have very serious implications.

We may have problems with Health Canada. Fix that somewhere else.

But the regulations, the directorate, and the policies that are taking place now we strongly support, because we think it's a balance and we need to be protected.

Mr. John Holtmann: I would like to add to that. As a retailer talking with consumers all the time, I can say they're looking for assurance. So it's not that what Health Canada is doing is wrong; we need it done faster. We need the natural health product numbers on products. We need the claims. Just as the previous gentleman said, people want to know the contraindications. They're coming into our stores all the time. We have trained staff. All our staff are certified natural product advisers; they have training. But what they're telling consumers is not on the label, so the consumer is confused. They read on the Internet that they shouldn't take these together, but when they buy the bottle, they don't see it on the bottle.

We need more speed. There's a big lag time out here. If you've applied...you don't have regulations in place yet. It's 2008 or 2010 before...you know, I was astounded when I saw the timetable for the new regulations. It'll take six years before it's going to be in place. My business is suffering because consumers are not getting the right answers.

So I think from the consumer's point of view, it's the time thing. They want regulation. They want to see that what's on the label is in the bottle. But they also want it soon—now.

● (1015)

Ms. Jean Crowder: Somebody mentioned the fact that the U.S. is looking at the Canadian regulations. Is there any documentation around this that you could supply?

Ms. Valerie Bell: I've just been approached by the NNFA, which is our equivalent in the United States, by the International Alliance of Dietary/Food Supplement Associations on a global basis, and by the Mexican industry, the dietary supplement association, to actually work together on this. Our counterparts in the United States have had discussions with the FDA on this. The FDA realizes that DSHEA is not working in the States and that they have to make significant changes.

One of the key areas they are looking at implementing is actually GMPs. GMPs are something that Canada already has in our natural health product regulations. So it would be logical, if they're going to make a change, that they would make it now before they start tinkering with their own laws. The DSHEA almost went down several times in the last couple of years because of opposition to it. It's not a perfect system.

The Vice-Chair (Mr. Rob Merrifield): Actually, your time is pretty well gone.

Peter, one more comment on this. We have a few seconds.

Mr. Peter Helgason: That's just not accurate information whatsoever. In fact, the NNFA is generally considered not to be the voice of anybody in the United States. No offence to Mr. Seckman, whom you have brought in—

Ms. Valerie Bell: Excuse me, the NNFA represents 9,500 manufacturers and retailers throughout the United States.

Mr. Peter Helgason: So that would make them—

Ms. Valerie Bell: It's the largest natural product association in the U.S.

Mr. Peter Helgason: Actually, we're trying to get a witness here who's an American lawyer, who speaks for 40,000 consumers.

The Vice-Chair (Mr. Rob Merrifield): Well, okay, we'll see if that happens.

Mr. Fletcher.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): My question is to Mr. Helgason.

In your testimony you stated that bureaucrats have been bought off for decades. What evidence do you have to support that?

Mr. Peter Helgason: It's the oldest saying in the world that the proof of the pudding is in the eating.

Having had an opportunity to attend the Codex meetings and discuss with national delegates from all over the world how they arrived at their positions, and even in Health Canada.... The people I sat with from Health Canada in Bonn will confirm that essentially they have a whole scattered series of working groups, and each person is unaware...it's sort of compartmentalized information. So each person has their little part of the puzzle that they work on.

When the Canadian delegates sit down at the table, they bring a position paper that represents the views of the Government of Canada. But as every member of this committee knows, nobody looked, and in fact, one of the things we've been pushing for is to get an all-party delegation in—

Mr. Steven Fletcher: But you said they had been bought off. That implies bribery.

Mr. Peter Helgason: Well, yes, and in fact, one of your predecessors on this committee, Deb Grey, mentioned actually in a committee meeting at which I was present that she'd been offered money by the pharmaceutical industry as well.

If you go to organizations like the National Institutes of Health in the United States, they have what's called the revolving-door policy, where mid-level people come in and go out, and come in and go out. They write policy, and then they go back to industry.

Mr. Steven Fletcher: Mr. Helgason, if you have evidence substantiated, I ask you to table it in front of the committee. Otherwise, I'd ask you not to make accusations about bureaucrats in Health Canada. As much frustration as we all have with the bureaucracy, they are fundamentally good people, and suggesting that they are going to be bought off or bribed is completely inappropriate.

Mr. Peter Helgason: It would be consistent with the evidence you'll be hearing from Mr. Chopra and others.

Mr. Steven Fletcher: Great. Well, then, table it.

I'm done.

● (1020)

The Vice-Chair (Mr. Rob Merrifield): Mr. Carrie, do you want to pick it up?

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

I want to thank all the witnesses for being here today.

I do think we're in agreement about a lot of things, especially schedule A, subsections 3(1) and 3(2), and the fact that how things are being regulated now under a drug-style directorate doesn't appear to be appropriate, doesn't appear to be working, doesn't appear to be fast enough. But I did have some concerns on some of your comments about the regulatory aspect of Bill C-420.

I would just like to read a quick little statement here: No one, not consumers, manufacturers, retailers or practitioners, believes that appropriate regulations are not necessary. Bill C-420 paves the way for a more appropriate regulatory approach. The Liberal government, through bringing in a drug-style regulation, has set the stage for a future where Canadians have fewer products available, with those that are available becoming more expensive. Fewer, more expensive products will hurt those who could benefit most from natural health products—low-income Canadians. Stating that labels would not be able to provide treatment, dosage or warning information is more or less blatant fear-mongering. The NHPD already has a guidance document to allow health claims for NHPs, and there's no reason that document could not serve as the basis for claims under a new regulatory regime.

One of the things you said was that if we had moved them from where they are under a food-style directorate, these regulations would have to go. What do you have to back that up? Why do you think the regulations that we've already developed could not serve as a framework under a food-style directorate?

Dr. Paul Saunders: I think the ADM answered that yesterday. I tried to make that relevant in my point, that a food is different from a natural health product, which is slightly different from a drug. Natural health products, if they were in the food category, would not be able to make claims. They would not be able to have indications and contraindications on them. They would not be required to give the species or part, or the format of the substances in it, or the amount, the weight, or advice about seeking your health care provider if you're having symptoms or side effects.

The end result would be that people would be taking these, not necessarily knowing why they're using them, having problems with them and asking for information that's not available.

Mr. Colin Carrie: But regulations, basically, are just a product of political will. So you can make the regulations the way politicians want.

Dr. Paul Saunders: But that's not the way a food is currently defined under the Food and Drugs Act.

Mr. Colin Carrie: What we can do, though, is regulate it as a subsection, to put a more stringent regulation on that, to allow your objection to be satisfied, don't you think?

Dr. Paul Saunders: No, I actually don't think so.

Mr. Colin Carrie: You don't think so.

Dr. Paul Saunders: If you actually stepped back about 30 years, we would be in a situation in which, in effect, we'd really have no regulations to deal with this category.

Then we have the issue of patients. You're a doctor, so you would understand this. Patients are wondering about how to take these products, what to use them with, and so forth.

Mr. Colin Carrie: I'm saying, though, that you could regulate it so that there would be appropriate recommendations on the labels.

Dr. Paul Saunders: It would take a considerable amount of time.

Mr. Colin Carrie: Well, I think we have a nice framework of regulations as they are right now.

Dr. Paul Saunders: I don't think you do for food.

Ms. Anne Wilkie: One of the problems is that all you have proposed in the bill is a change in definition. It doesn't say what happens after you change the definition.

When looking at the two frameworks, you see that the NHP framework and the food framework are not consistent. They're for different products. You would take food *ad libitum* for different reasons than you would take natural health products.

If you're only going to lift the NHP regulations to put it on the food side, what's the point? One has to assume that you have another agenda or another motive for doing it and that the regulations are going to change. You then have food regulations that are not compatible with the NHP.

Mr. Colin Carrie: One of the difficulties we see, and I think it has unanimous consent, is the speed with which things are moving forward for what we have now.

We basically have a petition where 140,000 Canadians are saying they do not want natural health products regulated as drugs. We need to do something to take it out of that category. My suggestion would be to put it into the food category as a subsection, but I guess that's going to be up for some argument.

The Vice-Chair (Mr. Rob Merrifield): You can ask a very quick one.

Mr. Colin Carrie: I wanted to ask Dr. Saunders this. Couldn't some of the natural health food products that are liniments or suppositories now be regulated more or less like cosmetics?

Dr. Paul Saunders: Cosmetics are not allowed to make health claims. Again, if you read a label for cosmetics, it may list the ingredients, but it does not tell you how much of any particular ingredient is there. As a doctor, I want to know how much of the ingredients is there, because that may be an issue for my patients. Regulating them as cosmetics is not appropriate, because cosmetics do not have health claims on labels.

● (1025)

Mr. Colin Carrie: But certain—

The Vice-Chair (Mr. Rob Merrifield): That's it. Thank you.

Mr. Savage.

Mr. Michael Savage (Dartmouth—Cole Harbour, Lib.): Thank you, Mr. Chair.

Thanks to all the witnesses for coming this morning. This is a very interesting study that we're doing, and your input is helpful.

I'd like to talk to Mr. Vertolli for a second. I found your submission to be very good. I always like it when people come to the health committee with specific recommendations on what they like about the bill and what they don't like about the bill. I think you've laid it out very well.

I want to give you a chance to address recommendations five and six. You didn't have a chance earlier because you ran out of time. But I want to talk about recommendation five.

You're recommending that the Standing Committee on Health propose the creation of an independent committee, composed of a representative cross-section of natural health product stakeholders, with a mandate to review the current regulations. How is that different from the process that got us to where we are now?

Perhaps the transition team could talk a little about that.

I also wanted to specifically ask you this. You mentioned that you believe the regulatory framework is vastly improved and is appropriate legislation. I think you indicated that you have a concern about the policy that has been created to interpret it. I want to hear more about that.

When you start off, could you give me an idea of what kinds of products are included? What do you sell? What does your association market?

Mr. Michael Vertolli: We're not a marketing association. We're an association of practitioners. As herbalists, we dispense herbal products. We recommend the use of other natural health products.

Mr. Michael Savage: Such as?

Mr. Michael Vertolli: It could be over-the-counter herbal products, it could be vitamin products, it could be essential oils. It really depends on the individual practitioner and what their expertise involves.

Our concern and what has led us to this situation is the interpretation of the regulations. I have to admit we were expecting to have this opportunity to speak to you later in the month. This was put together fairly quickly, and we didn't really differentiate between the regulations and the policies in the document, but really the concern is the policies. The regulations, as they stand, are fine if they're interpreted in a fair and realistic way.

The concern is that when we're looking at foods and when we're looking at natural health products and when we're looking at drugs, we have different types of products with different concerns around safety. We feel that the current interpretation of the regulations is treating many natural health products as if the degree of risk associated with their use is similar to the degree of risk associated with the use of drug products. Therefore, the interpretative policies are too onerous for the category. Therefore, the cost of implementing them is too high.

For the big players, for the large companies in the industry, it's more of an irritation. This industry, and particularly the herbal end of the industry, has largely been made up in the past of very small companies—companies that make $1 million, $2 million, $3 million a year. I have spoken with many companies that are in that category, and they've told me flat out that if the regulations and the policies as they are interpreted are fully implemented, they will not survive. That not only means that members of the industry are going to be hurt, but it also means that consumer access to products is going to be seriously affected, because much of the innovation in the industry and a lot of the product variability comes from the small companies. The larger companies that do survive are all rationalizing their inventory. They're saying, we may produce 500 products, but we can't continue to produce these 500 products because many of them don't provide us with the financial returns that justify this level of regulation.

Mr. Michael Savage: You have a specific concern, I think, which Dr. Lunney referred to earlier, that in practice these regulations are not fair to smaller companies, that they're easier to follow for larger companies.

Mr. Michael Vertolli: Definitely, yes.

The Vice-Chair (Mr. Rob Merrifield): Thank you very much.

In fact, your time has gone, but we've handled a fairly broad area.

We want to thank the witnesses for coming in and sharing their expertise with the committee.

We will now break for a few minutes.

● (1030)

(Pause)

● (1039)

The Chair (Ms. Bonnie Brown (Oakville, Lib.)): Good morning, ladies and gentlemen. Could we come to order now, please. Our witnesses are ready.

We're happy to welcome the members of our second panel, and we'll begin with the representative of the University of Toronto, assistant professor at the Leslie Dan Faculty of Pharmacy, Ms. Heather Boon.

Ms. Boon, the floor is yours.

● (1040)

Dr. Heather Boon (Assistant Professor, Leslie Dan Faculty of Pharmacy, University of Toronto): Thank you very much. I appreciate the opportunity to testify before this panel.

I'll cut right to the chase. My recommendation is that the bill in its entirety be rejected, and I'll give you the reasons why I think so.

I think if we accept this bill we'll actually decrease the amount of information available to consumers, and this will decrease their ability to make informed choices about natural health products. That may, in fact, increase the risk to their health.

I think if we accept this bill it will undo approximately 10 years of consultations—more than that, actually—and it will undo a lot of the work that's already been done on the regulations, which culminated in the development of the natural health product regulations that are currently being implemented by the Natural Health Products Directorate. You've heard this morning, and yesterday, I understand, that those regulations may not be perfect, but I think we need to work with what we already have rather than starting anew.

I think if we accept this bill it will also potentially remove an important stimulus for research into the safety, efficacy, and quality of natural health products, and ultimately I think it will cause chaos, confusion, and great expense to the natural health products industry, which is working hard to comply with the regulations we have today. I think the health of Canadians and their right to freedom of informed choice will be put at risk if this bill is accepted.

Just to go a little bit further on some of these points, the Standing Committee on Health issued 53 recommendations, including that natural health products be regulated distinctly from the existing food and drug regimens. Creating a distinct category in regulation, I believe, has effectively achieved this goal. The current natural health product regulations are the product of hundreds, potentially thousands, of consultations with stakeholders, including consumers, conventional health care providers, complementary medicine groups, and industry members.

Our recent interviews as part of a study with industry members and CAM practitioners indicate surprising agreement with the regulations. There is some frustration with the speed at which they're being implemented, but there's surprising agreement with the regulations themselves. I don't honestly believe that most groups have changed their minds about the regulations now that they're being implemented.

I think redefining natural health products as foods puts Canadians at risk in a number of concrete ways. The current natural health product regulations include specific standards for labelling information, including listing the approved claim, dosing information, potential adverse effects, drug interactions, and cautions—in other words, information about people who potentially shouldn't use the product. None of this information is currently allowed on food labels. This not only limits consumers' ability to make informed choices, but also has the potential to cause direct harm.

We know that most natural health products are safe for most people, but some do have some specific known drug interactions, for example, St. John's wort. Some shouldn't be taken by women who are pregnant. Others have adverse effects at specific doses or in specific people with specific underlying medical conditions.

This bill would create a situation where that kind of information wouldn't be allowed on the labels. So either you would have foods out there—these products would be foods—that don't carry enough information for people to be able to use them safely, or someone would decide that they're not appropriate as foods because of these safety concerns, and then they potentially wouldn't be available at all, which doesn't make sense. Then we'd be taking away access to some potentially very useful products for Canadian consumers.

Another consequence of redefining natural health products as food would be that the good manufacturing practices that are currently part of the natural health product regulations would not necessarily be implemented under the food regulations, because we don't have the same standards for foods.

Finally, this bill potentially could have a direct negative effect on natural health product researchers in Canada. Part of the research program initiated by the Natural Health Products Directorate has led to the establishment of a number of national research networks, including the Interdisciplinary Network for Complementary and Alternative Medicine Research, which I direct and which has over 800 members across Canada and internationally.

The new regulations stimulate research by requiring quality assessments of products, approving clinical trials involving humans, and allowing claims on product labels based on research. The incentives for doing this kind of high-quality research in Canada will potentially be removed if these products are regulated as foods and thus health claims based on scientific research can't be made.

● (1045)

In conclusion, Bill C-420, as currently written, will decrease the amount of information available to consumers, potentially increasing the chance they may come to harm due to misuse of products. I also think that in some ways it negates all of the consensus-building that has led to the establishment of the natural health product regulations we currently have, and it will cause chaos and great expense to the industry, which is already working hard to adopt the regulations.

The current natural health product regulations may not be perfect, but I don't think this bill solves the problems we've identified with the existing regulations. We need to work with the regulations we already have, because they're the best way to ensure free and informed use of high-quality, safe, and effective natural health products for Canadians.

Thank you.

The Chair: Thank you, Ms. Boon.

Our next witness, Mr. Patrick McDougall, is here as an individual.

Mr. McDougall, the floor is yours.

Mr. Patrick McDougall (As an Individual): May I begin by thanking the committee for giving me a hearing.

I believe the Food and Drugs Act should be left as it is until we can be sure that companies marketing products or compounds they claim can cure or alleviate scourges like cancer and bipolar disorder are not encouraging people to postpone or set aside conventional treatment. My submission draws attention to one such company, the Canadian Cancer Research Group, its founder, William O'Neill, and the CCRG's medical director, Dr. Eoghan O'Shea.

I am concerned that what I have included in my submission might lead you to believe that Mr. O'Neill and Mr. O'Shea are engaged in criminal activity or that they may be breaking Canada's laws. It's quite the contrary; in fact, I've been given every indication that both gentlemen conduct their activities free of any restraint from the agencies one might think would control such activity—Health Canada, the federal or provincial health departments, the Competition Bureau, and the College of Physicians and Surgeons of Ontario. I've approached all of these agencies, and more of them, and have received no satisfaction, except expressions of condolence for the loss of my daughter.

My submission also mentions Empowerplus. I haven't had any direct contact with this company, but my family, like so many others, has been knocked around by mental illness, and the very suggestion that Empowerplus has led some sufferers to abandon their prescriptions medicines, for even a matter of days, sends chills up my spine.

That's where I want to direct the committee's attention, to the possibility that the bill you are studying, Bill C-420, will make it easier for such companies as the Canadian Cancer Research Group and Empowerplus to operate—and, I might add, create a happy hunting ground for other snake oil salesmen to set up research groups of their own. So get ready for the Canadian Eczema Research Group, the Canadian Lower Bowel Syndrome Research Group, and so on. At least these are not life-threatening conditions.

The author of this bill, Mr. Lunney, has defended Empowerplus a number of times in the House of Commons, and suggested that the Food and Drugs Act is antiquated because some of its restrictions were written in the 1930s. I'm old enough to remember the 1930s, and Lydia Pinkham, and Carter's Little Liver Pills, and cough syrups laced with enough alcohol to make them interesting.

Some hon. members: Oh, oh!

Mr. Patrick McDougall: Some of these products are still around, and it's comforting to me to know that they are still being controlled—at least as to content. The thirties didn't lack snake oil salesmen, but few of them had the sophistication or the tools of today's representatives. I wonder what they would have done with telemarketing, TV, and the Internet.

I submit that our focus should be the same today as it was back in the 1930s, to try to deter those who would make a living out of the misery, fear, and desperation of others, or those who would knowingly put their sufferers in danger by inviting them to shun conventional treatment in favour of handfuls of vitamin pills. I don't come before you today brimming with hope.

I couldn't help but notice that three of your members on this committee are chiropractors.

An hon. member: That's scary!

Mr. Patrick McDougall: Yes, it sure is.

The Internet tells me that orthomolecular medicine and companies touting heavy doses of vitamins and minerals have found considerable support in the chiropractic and naturopathic camps, but I somehow can't imagine any of you supporting the stated views of Tim Bolen, an American who styles himself as a crisis management consultant and a consumer advocate in the health care industry. Mr. Bolen represents the extreme of the orthomolecular mob, when he declares on the Internet:

> Cancer, for instance, isn't being cured by Oncologists, cancer centers, or the American Cancer Society. Those groups only use, and promote, expensive "treatments." Cancer is being cured by individuals, in different parts of the world. All of those individuals, and their new ideas, are either being suppressed in some way, or are under outright attack. It is the same for AIDS, diabetes, heart problems, strokes, autism, MS, you-name-it.

Thank you very much for your attention.

● (1050)

The Chair: Thank you, Mr. McDougall.

Our next presenter is from York University, Dr. Joel Lexchin.

Dr. Joel Lexchin (Associate Professor, York University): Thanks very much for the opportunity to be here.

In addition to teaching health policy at York, I'm also an emergency physician. I've written guidelines for prescribing for general practitioners and emergency physicians, and I am considered a world expert in drug promotion.

I'm going to speak here about schedule A, which this bill proposes to eliminate. I'm opposed to that, and I'll tell you why in a minute. First, I want to review a little bit of the background of schedule A.

It was introduced as a health protection measure to protect the public against undue commercial influence at times when people are most vulnerable because of ill health. When you're seriously ill or caring for an ill family member, you are vulnerable in a way that significantly differs from people facing an ordinary consumer choice such as buying a new car or a new item of clothing.

Advertising is a poor mechanism for providing unbiased information related to the treatment of serious diseases. By definition, advertising aims to sell a product. It does not provide complete, accurate, and unbiased information on the pros and cons of available treatment options that people need for making informed decisions.

When schedule A was put in, there was a different set of products available. But the reasons for having schedule A are still the same—to prevent inappropriate claims being made about products. Let's review what has gone on and is going on with respect to promotion.

The last time that over-the-counter promotion in Canada was reviewed was over a decade ago. There were 51 different ads in 10 Canadian magazines that were looked at. Only 37% of those ads fully complied with the regulatory requirements of the time, 24% had minor errors,and 39% had major violations. That was for print advertising. For broadcast advertising, which had to be pre-cleared before it could be aired, 20% of the scripts that were initially submitted had major problems. These occurred while Health Canada was still regulating over-the-counter promotion. Since then, this responsibility has been transferred to a voluntary agency, Advertising Standards Canada. What we know about promotion in general is that self-regulation is much less effective than government oversight.

If you look at over-the-counter advertising, or the direct-to-consumer advertising of prescription drugs, you see large elements of deception. Recently there's been an ad running for Lipitor, which is a drug to lower cholesterol. This is usually referred to as the toe-tag ad. It has a corpse in a morgue with a toe-tag on it. One ad had the toe tag saying that it was a 52-year-old woman who had died of heart disease. This is playing on fear. The chances of a 52-year-old woman having significant heart disease are actually pretty low.

Diane-35 is a hormone treatment for women with acne, which is only approved as second-line treatment after first-line agents have failed. The ads that are running in places like bus shelters and women's toilets don't mention this kind of thing.

A few years ago, there was an ad for another cholesterol-lowering product that had Daryl Sittler in it. It said, "Daryl Sittler knows about the risks of heart attacks ... so should you". Then it went on to say that one particular medication can reduce the risk of first attacks by 31%. All of this is more or less true, but not really accurate. What the ad in fact should have said is that if you're a male, aged 55 or older, you have high cholesterol...you have a 50% chance of smoking, and you are willing to take a drug for five years and to pay a few thousand dollars, you can reduce your chances of a heart attack in that period of time from 7.9% to 5.5%. So it's a much different way of putting the same kind of information, but the former is what we generally see in ads.

● (1055)

Finally, if you want to talk about advertising, you can look at what advertising of prescription drugs does to the way doctors prescribe medications.

One of the things I've been doing over the past number of years is collecting studies that have look at the association between how well doctors prescribe, how appropriately they prescribe, and where they get their information. Over the past 30 years, 13 such studies have been done. All of them, without exception, said that the more doctors rely on information that they get from promotion or advertising, the worse they do in terms of prescribing, the less appropriate they are as prescribers. If advertising does that to doctors who already have some degree of expert knowledge, what's advertising to consumers going to do?

Finally, let me end with a quote from Jerry Seinfeld: "There's another oxymoron: sales help. You're either helping me or selling me, but they're not the same."

Thank you.

The Chair: Thank you, Dr. Lexchin.

Our next witness is from Biomedica Laboratories Inc., the chief executive officer, Mr. Jason Watkin.

Mr. Watkin.

Mr. Jason Watkin (Chief Executive Officer, Biomedica Laboratories Inc.): Thank you.

Today I want to speak under three hats. As a health-conscious consumer, I've been in the industry for 15 years, working with the industry. My background's in biochemistry, pathology, and pharmacology. As well, my company is a health manufacturer for pharmacies and health retailers and works with medical doctors, chiropractors, physiotherapists, and naturopaths.

We developed a product called Recovery. The paper you have there today on this was something I was called to submit at the last minute, so I've given something that we prepared before. I'm going to comment in addition to that. I'd just like you to see what happened to us with Recovery.

To shorten a long story, we were attacked by Health Canada. We found that it was overstepping its bounds, constitutionally. It backed off, but in the meantime it was a claims-associated issue. In a closed-door meeting with three individuals—we talk about it in there—in the western region, with Dennis Shelley as head, we were told that he believed pain and inflammation relief was not considered a claim. He said that with our lawyers present, whereas his subordinates actually attacked his opinion in that office.

So you can see the ambiguity here. What are you supposed to do when, even within their own offices, they're arguing over pain and inflammation relief?

We had a long battle with Health Canada, and it ended up costing us—we had to prepare documents for a mediation—conservatively, in the realm of $4.5 million. My mother and father mortgaged their house to start this company, so this was quite an attack. On the other end, it was possibly up to $8.2 million, working in sales figures, with direct costs of about $750,000.

In the meantime, Health Canada was stopping us from selling the product to the U.S., under seizure, which the U.S. had gladly accepted for the past three years as a dietary food supplement. Health Canada was trying to block access to any kind of sales avenue we had, knowing it would break our entire company.

Luckily, we contacted a constitutional law adviser and found out what it was doing, and it has since backed off. But since then, I want to address three points. Does the new NHPD ensure safety? I want to cover that. Does the NHPD ensure a cost-effective availability of dietary food supplements to Canadians? And the third point is what my position is on Bill C-420 and why.

First, does the NHPD ensure safety? You've already seen what happened to us. Interestingly enough, our product directly competed with COX-2 inhibitors and NSAIDs, which are recognized, extrapolated from U.S. data, to kill at least 1,900 Canadians per year, conservatively. Many of these are available in gas stations, namely Aspirin, Ibuprofen, and acetaminophen on the other side, and they're very cheap. People—little kids—can go into a gas station and literally purchase this. This is the regulation that provides safety; I don't get it.

Many people were forced off Recovery during the period of transition, when we were getting legal advice, who had tried everything and who would have had to turn to the typical conventional treatments that Mr. McDougall was talking about. Typically these would be the COX-2 inhibitors or other NSAIDs. COX-2 inhibitors are very popular. Bextra and Vioxx, namely, were supposed to be safe drugs, which were promoted to people, that caused a problem. Dr. David Graham, an FDA doctor, proposed that possibly up to 40,000 people died in a four-year span from using Vioxx alone, so this is a key thing. People were forced off Recovery to Vioxx.

We had MPs and senators who still used the product, and luckily they gave us a lot of support with the minister's office, which helped get us through the wait. Otherwise, as a small company, we would have surely drowned in the cost of what was happening to us.

I've been in the industry for 15 years, and without finding it slightly humourous, I've never had major issues with quality in Canada. Canada is noted for very high-quality products. There may be, surely, a couple of companies that may have put out a bad product, but that happens in the drug industry as well. It's happening right now with counterfeits, things like that. The issue is that this is a very low-risk thing. Even with the modernization of the industry, it's still very low risk compared to the pharmaceuticals that are available in gas stations, as I said.

The problems we had were with the TPD, the Therapeutic Products Directorate. The NHPD is modeled after the TPD and is effectively a subset of it. So right now, this proposition would take dietary food supplements closer to drugs than to foods. I'm rather amazed at some of the comments of people who haven't attained legal counsel as to what would be better, an NHPD or a food, as far as access to Canadians in the earlier group is concerned.

● (1100)

Another thing is that as far as the claims are concerned, our product was rated in animal trials by the most respected journal in the world, the *Horse Journal* in the United States, as the best product in the world, when compared to the top 18 products in the world, for arthritis, tendonitis, and back pain in horses that do not see a placebo effect. If that's not something, I'm not sure what is. If this is not a life-threatening condition, as arthritis and tendonitis are, why are we turning to drugs that are potentially lethal, and many of whose side effects were masked for four years by their manufacturer?

Again, turning people away from safe options in conditions that are non-life-threatening...and I agree with the cancer condition there and things that are life-threatening. We should have some more insight into that, but still there are a lot of effective treatments.

My best friend has a PhD in medicine. He's at one of the top cancer research facilities in the world, the Burnham Institute in San Diego. They study mostly drugs, and the accessibility and the modernization of natural health products is the more exciting avenue for them to peruse right now, since the control of cancer in the last 30 or 40 years has not been very great, except for a couple of minimal classes of cancer. So we need other options.

The second part here is, does the NHPD ensure cost-effective availability of dietary supplements?

I lived in Germany in the mid-1990s. This is the template for what's happening here, even if people don't want to admit it and say that it's a different category—not a drug category. When I lived in Germany, they effectively stripped everything but less than RDA away from the populace. So a reform house or a health food store can carry things like wheat germ, or very minimal doses, and they're very expensive.

In Germany, it is widely known that the pharmaceutical industry spearheaded proposed regulations to change the industry to hyperregulate dietary supplements as they saw the statistics of how the competition was going. They were taking industry away. What happened is that they effectively got the naturopaths on their side because they believed they would get prescription rights to those products. They would train the medical doctors, the *Arzts*, in *Naturmedizin*. For a one-year diploma on top of their medicine, they would get a degree in natural medicine. So the naturopaths were effectively thinking they would work with the doctors.

Once the programs were set up, the schooling was done, and the *Naturmedizin* program was set up, they effectively cut the naturopaths out of anything significant in the industry. So the ruse was against them in the end.

What also happened was that any doses that were effective—and really pathetic small doses were even included—were taken away, and you had to go to a doctor to get a prescription.

Not only that, but the price.... I imported vitamin C into the Netherlands, just simple vitamin C, and it was five to ten times more expensive. Nobody bought vitamin C. Do you know what they did? All they did was order it from Italy. The Italians would import it, just as we can here. The minister's office told people when they wrote, including members of Parliament, that you could order Recovery from the U.S., if we shipped to the U.S. and shipped back for a three-month supply, but you could not buy it from Canada. If that's not silly, I'm not sure what is. We have that in writing from Oli Cosgrove.

Anyway, for safety and availability, the German scenario is enough to show me as a parent that, for my kids, in 10 years this could all be an issue of taking it to doctors, raising the prices.

I want to pick up on the cost of availability next. We just did a submission for the new NHPD category. I'm talking direct experience with the German issue, and now the new one. I have a background in biochemistry, pathology, and pharmacology, yet I still could not attempt whatsoever to do the compound formulation submission to the NHPD. I had to hire out a regulatory expert, who still had major issues with Health Canada, because they were very unsure on some of these compound products.

● (1105)

It has effectively cost us, so far, $15,000-plus, just to put in the submission. Most companies are going to go through the same thing, except for the large companies that have in-house regulatory chemists. They will be favoured in this entire scenario. So $15,000 is no short amount of money when you can't sell the product until you've submitted...and that's what we're going through, the pre-submission of a very low-risk product that competes with things like Aspirin and Ibuprofen, which are available in a gas station to a child at a very low cost.

The next part is the United States issue. If we were to regulate this as an NHPD and we allowed certain claims in Canada, there is no way, as Peter Helgason brought up earlier, that the FDA will allow the claims if they go beyond simple claims that they have. I know this for a fact, because if anything is on a website and it's turned into the U.S., and it doesn't comply in the minimalist aspect, they will stop huge shipments. They did this to us on our horse product going to vets. They stopped a massive shipment until we relabelled. That meant coming back and relabelling minor infractions. Can you imagine a claim being on there?

They also routinely access websites to see, as Mr. McDougall was pointing out, if a Canadian or an international website is making a claim that doesn't fit with their regulations, and they will stop those at the border. This is our major trading partner. We do as much business in the United States as we do in Canada. It's a major issue to have them stopping our supplies that we've already paid for in product costs. It also effectively cuts off our supply costs, because we can no longer purchase if we can't pay our suppliers. So it could cut off our Canadian business if we hurt our American business.

Obviously you know my position here. I believe it should be regulated as food. Subsection 3(1) and subsection 3(2) won't stand up, as was brought up earlier. Schedule A is antiquated, definitely. Things like psoriasis and skin conditions are listed, and certain serious conditions are not, so it obviously needs an update. When we're talking about non-life-threatening conditions, I think it's logical and reasonable to think we should try the safest option first.

On a food regulated as a food, it has been brought to my attention that the concerns that were brought up by most of the former speakers here could be addressed by the Governor in Council under the health minister's assessment. You could change the Food and Drugs Act to accommodate the concerns about claims that were brought up earlier...and especially since we need to harmonize more with the U.S., since most of us do business mostly with the U.S., not with Europe and Africa and so on.

So a huge issue for me is making it available to the U.S., changing food regulations that are currently there to comply with the concerns, because they're legitimate concerns. I think this could work extremely well, instead of taking an NHPD category of more government bureaucracy that historically doesn't work too well. And I'm looking at the German model. Interestingly enough, most of the NHPD submissions for single ingredients, for monographs, are German Commission E monographs for accepting a single product like a herb—like St. John's wort.

So we're effectively modelling everything the Germans have done here, renaming it, and putting “a little bit of fluff” around it to make it look as if it's not a drug.

● (1110)

The Chair: Excuse me, Mr. Watkin, you're well over your time allocation.

Mr. Jason Watkin: I'm sorry about that.

The Chair: Thank you very much. I think you've made your three points clearly.

We'll begin with the question and answer period now, and we'll begin with Mr. Merrifield.

Mr. Rob Merrifield: I would like to thank the witnesses for coming in. The testimony we've heard this morning is interesting—the session before, and here.

My first question is actually to Ms. Boon. You actually suggested that we leave the regulations the way they are, that we leave subsection 3(1) and subsection 3(2) and schedule A the way they are.

Dr. Heather Boon: Not actually. I didn't address that in my oral presentation due to time limits. In my brief I identify that schedule A, I believe, needs to be changed, and there are committees that are looking at that. I don't think completely abolishing it is the answer, because I actually concur with many of the things that Dr. Lexchin mentioned about advertising for these products. I don't believe that schedule A should stay exactly as it is either. I do believe there needs to be some updating.

Mr. Rob Merrifield: It's interesting. The bill talks about the definition and where to place it, whether it's in food or whether it's in drugs, or in a third category, and I believe the transition team requested the third category. They also had significant problems with clause 3 and schedule A.

You said to put this bill into place would roll the clock back 10 years—I think that's what you're saying. I really wonder who we were listening to, who the department was listening to, because we just heard testimony in the last group, from the Canadian Health Food Association, from the naturopathic doctors, from small manufacturers, and from the herbalists who all said to get rid of schedule A and clause 3, and to put it in a third category.

So that's pretty consist testimony from a large group of the industry. I just wonder, from your perspective, who the department would have been listening to when they came up with what we have today as a drug, and regulated under drugs.

Dr. Heather Boon: Obviously I can't speak on behalf of that committee, but my—

Mr. Rob Merrifield: The reason I'm asking is that you're saying that it's going to roll the clock back 10 years and destroy what we've done. I don't understand. I'm trying to get a handle on where you're coming from.

Dr. Heather Boon: Okay. I'm a little confused by your question.

With respect to schedule A, I believe it does need to be updated. But with respect to moving these products to food, I was listening at the end of the session this morning, when I came to talk. There was a suggestion that we could make them food but keep all the regulations. My question is this. Why are we going through all of this? What would change if we did that?

Moving these things to food means that we'd have to make a lot of changes to the food regulations, which could take years. People are already concerned about how long things are taking to go through. We spent more than 10 years in consultations to come up with these regulations, but we haven't even seen their impact or seen them fully implemented yet.

I think we owe it to Canadians to get on with the job and work with what we have.

Mr. Rob Merrifield: When I hear of what went on over the last 10 years, what's interesting to me is that it's not so much the number of people you listen to or hear from; it's who you take your advice from to actually bring a regulation forward complying with WHO.

When you have that large a section of the industry suggesting one thing and you come up with something else, it begs this question: who were you listening to and what advice were you taking?

You're probably not the right person to ask that question to. That's fair enough.

For my next question, we are going on to Dr. Lexchin. Are you a specialist in drugs?

● (1115)

Dr. Joel Lexchin: I am a specialist in pharmaceutical policy, writing guidelines for prescribing, and evaluating the promotion of pharmaceuticals.

Mr. Rob Merrifield: That's interesting, because this committee has done a considerable amount of work in that area in the last couple of years. The number of deaths in Canada that are due to pharmaceuticals is astounding. It absolutely blows this committee away, and it should alarm every Canadian, when we see some of the studies that are coming out.

You seem to be attacking schedule A on pharmaceuticals. Yet when I look at what is actually happening on the prescribing side of pharmaceuticals, and the amount of damage and the number of deaths that are being caused, I'm trying to put the comparison into perspective.

Dr. Joel Lexchin: I think that a lot of the problems with the use of pharmaceuticals, both in terms of prescribing and in terms of use, are due to poor regulation on promotion.

On the promotion of pharmaceuticals currently, print regulation is done by the Pharmaceutical Advertising Advisory Board, which has a relatively weak system and a weak code. The regulation on what sales representatives can tell doctors and how industry deals with continuing medical education is done entirely in-house by the pharmaceutical industry.

I think that if you're talking about problems with drugs being misused or misprescribed, a lot of that is due to the fact that we do not have sufficiently stringent regulations on promotion here in Canada. Schedule A is part of that system, and taking away schedule A would make things even worse.

Mr. Rob Merrifield: That's interesting, because we actually have stringent regulations on promotion. In fact, we don't allow direct consumer advertising.

Dr. Joel Lexchin: I'm sorry, that's what the regulations may say, but companies have been skirting that quite well.

For instance, if you look at advertisements that have appeared in bus shelters for Diane-35, you see products saying that this product is good for acne, and the name Diane appears. The name Diane, though, refers to the woman who's being shown in the ad, not the product, but you can tell what it means.

If you look at advertising for Alesse, it's an oral contraceptive, although it doesn't say that it's an oral contraceptive. When you see the package, it is clearly a package for oral contraceptives.

About a year and half or two years ago—

Mr. Rob Merrifield: Okay. You've made your point. Are you saying those are too weak?

Dr. Joel Lexchin: Yes.

Mr. Rob Merrifield: The regulations are too weak on that.

Dr. Joel Lexchin: Schedule A is part of the regulations, again, around promotion. If you take schedule A away, you have even weaker controls over promotion.

Mr. Rob Merrifield: So could your concerns be handled in the regulations? That's what the other witnesses are saying.

Dr. Joel Lexchin: Schedule A may need to be modified, but it should be retained.

Mr. Rob Merrifield: Could it be repealed and then handled under the regulations?

Dr. Joel Lexchin: I don't think so.

Mr. Rob Merrifield: So you would disagree with the panel?

Dr. Joel Lexchin: I didn't hear all the panel, but if they were advocating repealing schedule A, removing it completely, then I disagree with them.

Mr. Rob Merrifield: I believe you're the only person testifying that schedule A should not be removed. Well, I guess there are two of you now.

Dr. Joel Lexchin: I agree with Dr. Boon that schedule A may need modification, but I believe it should be retained.

Mr. Rob Merrifield: So you're saying that it couldn't be addressed in the regulations?

Dr. Joel Lexchin: If you start allowing promotion for the diseases that are covered in schedule A, or the ones that should be covered—psoriasis is not generally life threatening, although if you develop psoriatic arthritis you could be in for more serious problems—the weaknesses that we currently see in our ability to control promotion, either of over-the-counter products or prescription products, will get even worse.

● (1120)

Mr. Rob Merrifield: That's your opinion.

Dr. Joel Lexchin: The recommendation to get rid of schedule A is also an opinion. I'm giving you my opinion as somebody who has developed material for the World Health Organization on drug promotion, who has written extensively on the subject, and who has given drug promotion advice to governments in Canada, New Zealand, and Australia.

Mr. Rob Merrifield: Dr. Boon, you verify the effectiveness of natural food products, is that right?

Dr. Heather Boon: I'm originally trained as a pharmacist. My medical PhD is in medical sociology, and I study health services and policy issues related to complementary and alternative medicine. I have done this for the last 10 years. I have been involved in the design of several clinical trials of natural health products, but I don't consider myself an expert in the quality of the products. I don't do basic chemistry work, if that's what you're asking.

Mr. Rob Merrifield: I wanted to ask you about the 2009 timeline for compliance of natural food products. Is that realistic?

Dr. Heather Boon: I would say it's challenging. It ultimately depends on the people power at the directorate. If you have enough people, you can certainly meet those deadlines, but it requires financing.

Mr. Rob Merrifield: They will have to speed it up, though?

Dr. Heather Boon: Yes.

The Chair: Thank you, Mr. Merrifield.

Madam Demers.

[*Translation*]

Ms. Nicole Demers (Laval, BQ): Thank you, Madam Chair. I would like to thank the witnesses for coming.

I am concerned about elderly people who may take medication along with natural products. Like Mr. Lexchin, I think that there is, unfortunately, too much advertising that is often misleading. I use a lot of natural products and I look for harmful side effects, best quality and greatest effectiveness in choosing products so as not to compromise my health.

I have already raised this matter with Mr. Helgason. What really concerns me about natural products is the possibility that, by agreeing to include them in Bill C-420, we would seem to be saying that all natural products can be approved without any verification, like essential oils. Essential oils containing sage caused two deaths in Montreal. This is serious. One death is one too many, even though you said that other pharmaceutical products have caused many deaths. Like Mr. McDougall, I believe that we must be careful what we say when we talk about natural products. Several people who were here this morning told us that a separate category, a third category, would be the ideal solution so that we can have high calibre, effective products that are known to be safe, and which are also very well regulated.

What do you think of that?

[*English*]

Mr. Jason Watkin: I think from my experience in Germany, although they are a drug category...currently, this is a drug category. I do agree, if there are deaths. However, under section 30 of the current Food and Drugs Act, again with constitutional counsel, the Governor in Council could, with the Minister of Health's approval and assessment, modify to account for these concerns.

Secondly, when you put it under this NHPD framework, it is very close to a drug—right now it is a drug. They could easily modify the doses, as they did in Germany, to pathetic—to put it quite simply—doses that don't do anything.

Again, with this NHPD, pre-submission costs a lot of money—

● (1125)

[*Translation*]

Ms. Nicole Demers: Thank you. That is important, but I would also like to hear the opinions of Dr. Lexchin and Ms. Boon.

[*English*]

Dr. Heather Boon: I'll start.

I would have no problem with the idea of a third category at the level of the act. I would support that. My main concern with moving it to the food category is that the restrictions currently in the foods act that limit the amount of information, the good manufacturing standards, those kinds of things. Creating a third category would negate many of those concerns that I have.

[*Translation*]

Ms. Nicole Demers: Thank you.

[*English*]

Dr. Joel Lexchin: This is not an area where I would claim any degree of expertise, but from what I know, I would agree with what Dr. Boon has been saying with respect to the third category.

[*Translation*]

Ms. Nicole Demers: Thank you very much, Dr. Lexchin.

Once again, we know that natural products are very popular with the elderly. Studies conducted by Forensic Accounting and Investigative Services for the Wampole company showed that 70 per cent of the St. John's Wort and Ginkgo biloba analyzed had no active ingredients.

Bill C-420 may result in a situation where we have products where concentrations are unknown, where we are not sure that the ingredients indicated on the boxes are correct, and where we do not know whether not the products present any dangers to the patients. That is one of the dangers we run if we adopt Bill C-420 as it is written.

Mr. Watkin, do you also believe that this is possible?

[*English*]

Mr. Jason Watkin: On the 70%, I find it really hard to believe that's the case in Canada. Before I got into the industry when I moved back from Germany, I wanted to see what the quality was like, because German quality is high, but it's not available. And the Canadian quality was exceptional in the test. I paid a lot of money as a student back then—$1,500 U.S.—to send it to the top U.S. labs. The results were very favourable, ranging from big to small companies, including a small company in British Columbia that I'd never even heard of. Their quality was as good as the German quality.

So when they say a 70% empty shelf, it just seems like they've taken something out of thin air to try to push an agenda. I've never seen it, and I've been in the industry for 15 years. My kids take it. I'm very proud of Canadian quality, for the most part. Of course there are exceptions to every rule, but again, these are very safe, low-risk products, and they can't prove.... I need facts to show me the harm.

Again, at gas stations you can buy anything you want, and the seniors do that a lot with painkillers. They take them for a prolonged time with other drugs, and there are a lot of deaths that result, or serious harm, including bleeding, lack of healing, and fractures of the hip.

[*Translation*]

Ms. Nicole Demers: Thank you, Madam Chair.

[*English*]

The Chair: We'll move to Mr. Savage now.

Mr. Michael Savage: Thank you very much, Madam Chair.

Again, this is very interesting. I'd like to understand for my own benefit the concern about moving natural health products from a drug category to a food category. Is all of that concern based around the idea that if people use these instead of other medications, they're harming themselves, or is there significant concern that these products themselves will do harm?

I might ask Dr. Lexchin, and then perhaps Mr. McDougall or Professor Boon might like to just take a crack at it.

Dr. Joel Lexchin: Once again, you're asking me about things that I'm not an expert in. However, I do know there are a fair number of instances of interactions between natural health products and prescription drugs. So in that sense natural health products can prove dangerous. There are instances where taking too much of certain things like vitamin A is harmful.

I'm afraid I'm going to stop there.

Mr. Patrick McDougall: I would like to add something there.

I don't bring any expertise at all. I'm in the same category as Mr. William O'Neill, the founder and operator of the Canadian Cancer Research Group in having no medical experience. But I do have this experience: I'm a cancer patient who has survived two serious operations for cancer. I suppose this would make me a believer in at least two approaches to it, but I escaped, as I didn't have to have chemotherapy or radiation.

The only thing I can add is that I'd like to limit the situation I'm bringing before you; when it becomes obvious that people are setting aside conventional treatment for cancer, these groups should be watched extremely carefully. The Canadian Cancer Research Group has an out right away, because it says that each cancer is individual to the sufferer; therefore, the group has to make up its compound to suit that particular patient.

How do you regulate that? I suggest that if it comes to that, they should have to submit each compound individually to the regulating authorities.

● (1130)

Mr. Michael Savage: Okay, thank you.

Dr. Heather Boon: I would like to comment.

We've done studies on how patients make decisions about their health care and their medical treatment. I believe it's very much an individual's decision, so I'm not concerned about people forgoing conventional treatment.

I'm concerned about the natural health products that may interact with conventional medication. I'll give you a very specific example. There is very good, high-quality scientific evidence that St. John's wort works for mild to moderate depression, but there is also lots of really good evidence that it induces some enzymes in our liver called the cytochrome P450 enzymes. These make our bodies metabolize conventional medications faster, or some of them. It makes us metabolize the birth control pill faster; we have a case of a patient in Toronto who became pregnant while taking the two together. It makes us metabolize cyclosporin faster. There are more than 30 case reports in the literature of individuals starting to reject transplanted organs because they took the two things together.

All this requires is some information on a label saying, don't take St. John's wort if you're on these medications. A food product would not allow you to put that kind of information on a label.

Mr. Michael Savage: We've heard that about St. John's wort before. Thank you for that.

I want to ask another question, so be quick, Mr. Watkin.

Mr. Jason Watkin: I just want to modify what was said, because your concern is valid. The drug industry itself has to do labelling when their drugs interact with grapefruit, because grapefruit has the same interactions as St. John's wort. In many cases, these interactions can be even more serious, but they don't remove grapefruit. If we modify section 30 of the Food and Drugs Act, we could accommodate for those, and then we could work with the drug industry. And if doctors knew, through a modified food act, some of the beneficial claims, they would hopefully be able to integrate that through the college. I know it's work, but this integration is something that needs to happen.

We cannot remove a lot of different foods. For example, you can't remove peanuts even though they certainly cause more harm than any other natural health product, just by allergies alone.

The Chair: Thank you, Mr. Savage.

Mrs. Crowder.

Ms. Jean Crowder: Thank you for your presentations.

One of the things that seem to have come up fairly often from some groups.... I don't know if Dr. Boon could comment on this specifically, but we've generally heard from some groups that the current regulations are okay. The challenge has been for small businesses to comply.

I wonder if you could comment on whether, from the research and things you've looked at, there's a way to accommodate small business in the current regulatory framework. I know you're not from Health Canada, so I'm not expecting you to speak on behalf of Health Canada.

Dr. Heather Boon: What I can tell you is that the companies we've interviewed as part of our ongoing research study, including a number of small companies, are generally in agreement with the spirit of the regulations. I can tell you that the large companies are in more compliance currently than the small companies overall.

With small companies, we believe that what needs to happen is some additional help by providing them information about exactly what they need to do; we found that it wasn't clear to a lot of small companies what they actually had to do to meet the regulations. So one of our recommendations in a forthcoming paper is that the Natural Health Products Directorate do some direct outreach to these companies, since we actually do know many of them, to help define exactly what they need to do. As I sit on the expert advisory committee of the Natural Health Products Directorate, I know there has been some discussion about creating templates to help them do the submissions online, as well as developing more monographs, which make the submissions significantly easier.

● (1135)

Ms. Jean Crowder: I want to ask a question about contra-indications. There are some challenges with certain pharmaceuticals in natural health products. Yesterday, somebody at the committee said, if a natural health product makes you feel bad, just stop taking it. But with some of these natural health products, you don't know what you're taking. For example, some of the things that women are using to deal with menopausal symptoms can be estrogen mimickers, which have some of the same impacts as estrogen. You won't know it's having an impact on you until some problem crops up. Are there silent things happening with natural health products that we may not be aware of?

Dr. Heather Boon: Sure. Your example of phytoestrogenic herbs is apt. Women who can't take estrogen probably shouldn't be taking some of these phytoestrogens, even though the research is not conclusive on this point.

Women may say, well, it's natural, so it's got to be safe. It doesn't have to be safe. The fact that it grows doesn't mean men and women are supposed to eat it. You could be doing harm to an unborn child without realizing it. It's not all about interactions with conventional pharmaceuticals.

There are adverse effects related to some of these natural products, but, bottom line, many of them are very safe. I don't want to overstate the case.

Ms. Jean Crowder: We have products that have to be labelled differently when they're shipped to the United States. I don't understand why we wouldn't just issue natural health products differently. We just heard about how alcohol labels that are shipped to the States have to carry risk warnings, which they don't in Canada. Industry is able to accommodate different labels. So why wouldn't we do that?

Mr. Jason Watkin: In industry, label is basically the same as off-label. If you make an off-label claim, it's considered part of your label. It doesn't matter if your labels change. They will recommend all the things that have to come off your website. Any literature, if it's going across the border, is part of your label in the U.S.

Ms. Jean Crowder: Aren't there ways to have your website available differently?

Mr. Jason Watkin: You can block a website, but if they can get access to it, which they can, then they're going to want to modify it.

Ms. Jean Crowder: If we block a website, the FDA still looks at it?

Mr. Jason Watkin: Absolutely, and they also take in any information about a product that passes across the border, even from a consumer. So if someone from Canada shipped a product of, say, Recovery, and it made claims not accepted by the FDA, they will put that under file. Then the next time you try to ship, they'll know that you have an infraction under file.

With regard to estrogen mimicking, estriole is about 400 times weaker than estrodial, which is typical of the hormone replacement. Estriole is what's being mimicked. A lot of times they block the sites to inhibit other estrogens from binding on the cell, so they can effectively block the effects of estrodial and estrone on the cell, inhibiting their negative effects in inducing cancer.

Ms. Jean Crowder: I'm aware of other symptoms, not necessarily related to cancer, that some of the natural health products have caused in menopausal women. The science is uncertain, but women should at least be aware of the potential.

● (1140)

The Chair: Ms. Crowder, your time is up.

Ladies and gentlemen, we were supposed to break at 11:30 a.m. Would you like to stop now, or do you have some burning questions for this panel?

Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): I have one very short question I'd like to ask, if you think it's acceptable.

The Chair: It'll be the first one of your questions that's very short.

Voices: Oh, oh!

Hon. Robert Thibault: I think I can do it. It follows up on the question from Mr. Merrifield.

The Chair: No preamble, Mr. Thibault, just a question then, and one from Mr. Lunney very quickly.

Hon. Robert Thibault: To Dr. Boon, the witnesses from Health Canada mentioned the fact that they were reviewing the question of schedule A. The suggestion was made that it might go in the direction of wiping out the effectiveness of schedule A for the question of prevention. You wouldn't limit claims on prevention, but you might limit claims on cure.

Would that satisfy your fears about the removal of schedule A?

Dr. Heather Boon: Not completely, but I would be less concerned.

The Chair: Mr. Lunney.

Mr. James Lunney: Thank you, Madam Chair.

The Chair: Be very brief, please, Mr. Lunney.

Mr. James Lunney: Yes, I just have a comment.

The Chair: Is it a comment or a question? You can make a comment later in the meeting. If you have a question for these particular witnesses—

Mr. James Lunney: It's a very specific response to Mr. McDougall, who mentioned my own interventions on behalf of Empowerplus.

The Chair: Okay. I think you have the right to do that. You've been named, so go ahead.

Mr. James Lunney: I was named.

Mr. McDougall mentioned that he has a concern for people with mental illness, and yet he went on to say he doesn't know anything about Empowerplus. He doesn't know anything about the company that produces it. He doesn't know anything about the studies that have been published in four peer review journals about the positive effects of Empowerplus.

He doesn't know about the studies at the University of Lethbridge with Dr. Bryan Kolb and the amazing regrowth of rat brains when they're given this product. He says he's concerned about mental illness, but he knows nothing about the product.

What it tells me is that, number one, he's not a scientist, which I think he admitted already, because science is not threatened by looking at things from a new angle. A scientist would simply say, wow, there's a problem here with a potential solution; maybe we should look at it. So number one, it tells me that your response, sir, is not scientific because you went on to say that it chills you to think that someone would suggest that this could possibly work.

So number one, it suggests to me that you're not a scientist; and number two, if I can quote an ancient proverb that says, he who judges a matter without first hearing it is not wise, it suggests to me that neither are you wise, to attack something that you know nothing about.

Voices: Oh, oh!

Mr. Patrick McDougall: Am I allowed to respond to that, Madam Chair?

The Chair: Mr. Lunney, that's not fair. I'm not going to let you do that again.

You may ask questions; you may not make statements. Now I have to allow Mr. McDougall to respond, and we're wasting time.

Mr. McDougall.

Mr. Patrick McDougall: What I said, specifically, was that I have experience with mental illness. Mental illness has devastated my family, okay?

And the very idea that the sufferer involved there would have put aside her medication for something that is unproven—it's unproven; the tests that you're talking about were not concluded. I know that much about the Lethbridge tests you're talking about. They were not concluded. I don't know why, but they were not.

So I'm telling you that I'm not a scientist, not a doctor; I'm a cancer sufferer. I know what fear is. I know how frightened you can get, and I don't want people to be taken advantage of because of intense fear and desperation.

Voices: Hear, hear!

The Chair: Mr. Carrie, do you want to ask a question?

Mr. Colin Carrie: It's a quick question.

We're looking at the NHP regulations in Canada, and after $24 million has been spent, there are only 336 approvals. If 95% of businesses and applications can't comply, would you say it's a problem with the regulations or a problem with the companies trying to fulfill the regulations?

Mr. Jason Watkin: Can you rephrase your question, sorry?

Mr. Colin Carrie: Well, it seems that very few applications are getting through with the regulations we have. Does it mean that the regulations are too onerous when so many applications aren't getting through?

If we have 40,000 to 50,000 to go through and we've only gone through 336, is there a problem with the companies applying for it or a problem with the regulations being too onerous?

● (1145)

Mr. Jason Watkin: I can speak to both. I spoke to Phil Waddington in person last weekend for about 25 minutes. The regulations are too onerous, but there's another side to it in that, for the initial first year anyway, even the NHPD didn't know what it really needed, unless it was a German Commission E monograph, basically.

A single product was easy. It was already done in Germany. It has great monographs for vitamin C or St. John's wort or black cohosh. But when it came to any compound formulation, NHPD didn't know what they would need as far as interactions were concerned. It's not like a drug, because you're not mixing synthetic chemicals that can interact like they can in a...it's a different kind of interaction. Traditional formulations have abounded in Ayurvedic and Chinese systems for 5,000 years.

So there were serious problems there, but also cost was a factor. This is where another interesting thing came up, and I talked to Phil Waddington about this. Dubious consulting firms are now approaching all of the companies to try to get them to pay for consultation to help them get their NHPD licence. When I consulted a couple of them—not to name names—they didn't know yet what they needed, and they admitted that, but they were going to start charging me for it. And Phil said that, yes, he was aware of this.

So the problem has been set up. Now you have people taking advantage of the health food companies, not the health food companies taking advantage of people.

The Chair: Thank you, Mr. Carrie.

I think Ms. Boon wanted to comment on this—very briefly, please.

Dr. Heather Boon: Things are just getting started. As I think was mentioned already, this is actually lightning speed, in my opinion, for government to have gotten regulations off the ground. I don't think you're being fair. Give them a couple of years, and I think you're going to see the numbers go up exponentially.

The Chair: Thank you.

On behalf of my colleagues on the committee, I want to thank the members of the panel.

I want to reassure Dr. Lexchin that we hope to get back to his favourite topic, which is pharmaceuticals and promotion, and all those kinds of things in September. So we will be calling him back for the area in which he is known worldwide.

Thank you very much.

To my colleagues, we had scheduled 11:30 to 11:45 for lunch. I'm going to suggest that we take a 10-minute break and then begin again, perhaps with our lunches still in front of us. We'll start again at 12 o'clock, people.

● (1148)

(Pause)

● (1201)

The Chair: Good afternoon, ladies and gentlemen. You can hear the bell ringing. There's a half-hour bell, and I think if we begin right away we can hear a couple of presentations, at least, before the members have to leave to go and vote.

So I'm going to call on Mr. John Biggs, who is a nutritional consulting practitioner, to begin his presentation.

Mr. Biggs.

Mr. John Biggs (Nutritional Consulting Practitioner, Optimum Health Choices): Honourable members, I'm happy to be here today to support the passing of Bill C-420. As a practitioner, I'm a registered and degreed nutritional consultant. As a retailer, I'm a member of the Canadian Health Food Association and I own four health food stores in Edmonton. As a manufacturer, our company produces over 20 of its own products. And as a consumer, I've taken supplements since I was a young child in the 1970s.

The call for regulations of natural health products is based largely on a couple of faulty assumptions. The first of these is that regulation necessarily ensures safety, but as the recall of Vioxx plainly shows, it doesn't. Yet since 1960, the grand total for all recorded deaths caused by NHPs in Canada is zero, and they have been regulated as foods for most of this time. With zero deaths on record in 45 years, the rationale for preventing the sale of natural products based on safety concerns is very shaky, to say the least, and absolutely invalid, to say the most.

So because of the overwhelming evidence that natural health products are safe, the proponents of drug-style regulations resort to the claim that they are necessary to ensure that Canadians are confident in the NHPs they are using. But according to Allen Roses at GlaxoSmithKline—he's the vice-president of genetics—approximately 90% of prescription drugs work less than half the time. And pharmaceuticals are the most highly regulated industry in the world.

So clearly, regulation does not guarantee safety, efficacy, or quality.

Now, the claim that regulations will bolster consumer confidence and that consumers are in favour of the regulations is true to some extent. Yes, people want to be assured that what is on the label is in the bottle, but as a retailer with several thousand customers, I can tell you for certain that first and foremost what consumers want is having increased and continued access to the natural health products of their choice, and they are dead set against regulations that are going to reduce this access.

As the current regulations are coming into effect, this is exactly what we are seeing, for two main reasons. One is that companies are discontinuing entire chunks of their price list because the sales of certain products don't justify the cost of compliance. The other is that we're seeing hundreds of products that we've been importing from the U.S. for years stopped at the border because they don't comply.

We've been importing some things that people rely on for a long, long time. You want to see customers get mad and think that the government is part of a pharmaceutical conspiracy? Wait until you see someone who has been using a product for several years with great results, and now they can't get it anymore because it doesn't comply. Believe me, they get mad, and rightfully so.

At an industry info session, I heard it clearly stated by Heather Throop of the NHPD that in their consultations with Canadians, by far and away the number one request from Canadians was that they wanted greater access to a wider range of NHPs.

I want to be able to choose the products that I want. I don't want the government telling me what products I can and can't use. Regulations that contravene this number one desire of Canadians in the face of an overwhelming safety record are not appropriate. After all, is Canada not a democratic nation?

It's very interesting to note that this number one desire of Canadians completely disappeared from the public dialogue of the NHPD after the regulations went into effect. No longer do we hear that the number one desire of Canadians is for increased access, only that yes, Canadians want more assurance that what is in the bottle is what is on the label, and yes, Canadians want more information on the bottle about what a product is good for. But think of it. If you were asked if you'd like to be assured that what is in this bottle is on the label, well, obviously you're going to say yes.

And by the way, having been involved in the industry for 15 years, I can tell you that Canada's current natural health industry is already one of the best and highest-quality in the world, bar none.

We always hear in the media about how we can't trust natural products, and this is simply not accurate. There are scores of companies in Canada that are doing an excellent job, that have excellent quality standards, and whose products you can absolutely trust. An extremely high percentage of Canadian companies have been following strict GMP standards for years now. I might just add that one of the things that are hard to deal with is that so many of these products are identical before and after the regulations. It's just that they're more expensive.

● (1205)

Of course, there are going to be bad apples, and there always will be, just as in any industry. But limiting consumer choice with regulations, when they're unlikely to stop the hucksters anyway, does a major disservice to the people of Canada, especially given that by far the largest percentage of adulterated products that Health Canada finds are finished products imported from China.

I don't know which consumers of those who are being polled like the regulations. I can tell you for sure that few, if any, of my customers have the slightest clue about the regulations and where they are.

In general, consumers are totally confused. While several previously restricted products, which should never have been restricted to begin with, are coming on to the market now, scores of supplements that have been used for a long time are either no longer produced, because companies can't justify the cost of compliance, or no longer shipped into Canada. You can go to ten different websites and find the words “will not ship to Canada”. That is happening over and over again.

In 1997 Canadians protested in record numbers to stop all dietary supplements from being regulated as drugs and to gain greater access to NHPs of their choosing. After a five-year consultation process with Canadians, during which I appeared in front of this committee, Health Canada went ahead and classified them all as drugs anyway, despite the recommendations of this committee and its expert advisory committee.

As a small but very knowledgeable and conscientious manufacturer, I rue the day in 2006 when the cost recovery fees from my NHP applications will drive my prices up markedly higher because my batch sizes are small. I ask you to remember that whether a consumer can't get a product or can't afford it, the net result is the same: they don't have access to it.

Moreover, what really gets me about this whole process is how simply the entire situation could be solved and still meet everyone's needs. If Bill C-420 was passed and natural products were regulated as food, but an official government seal of approval was awarded to be visibly displayed on the labels of products that had passed the NHPD process, customers would have a device to be able to tell at point of purchase which products have passed government standards and which haven't.

How do you keep crap out of the market without restricting freedom of choice? Regulate them as food, but identify, right on the shelf, the products that have passed government inspection.

Manufacturers who undertook this process would be rewarded with a large competitive advantage, but no products would have to be discontinued and/or denied entry into Canada simply because they are slow sellers or the company doesn't want to deal with the hassle of shipping them to Canada.

Canadian consumers would still have access to them, but they would more likely buy products with the government seal of approval. To understand, think of what safety-conscious consumers look for when buying a helmet. They look to see if it's CSA approved. The same could apply for natural health products, and you could preserve all of the resources and good work that has been done by the NHPD.

Health Canada always talks about striking the right balance between protecting consumers versus maintaining their freedom to choose. A visible government approval seal at point of purchase, indicating a product had passed federal inspection, would do this. It would provide consumers with a buying guideline to avoid adulterated products, while passing Bill C-420 as written, would maintain freedom of choice.

As it is, having approved less than 400 of some 60,000 natural products in one and a half years, the NHPD approval process is looking a little like the gun registry.

Last, let me say that although I'm a member of the CHFA, and understandably their views represent what is good for the large manufacturers in the association, those views are not representative of many retailers, even in their own membership, or many small manufacturers and distributors, or consumers especially, who can often no longer get products that they've been using for a long time. They definitely don't speak for the whole industry.

Honourable members, we have been here before, and the reason we are back is that Canadians don't want their health care choices restricted.

Thank you.

● (1210)

The Chair: Thank you, Mr. Biggs.

I think we might have time for one more presentation, but perhaps the time is too tight.

The health committee members don't want to sprint to the House, which might say something about their fitness levels. But I always do what they want me to do.

Mr. Réal Ménard (Hochelaga, BQ): I'm in good shape.

The Chair: They seem to feel they should leave now to go to the vote, as the bell is ringing. So we will go, and we will come back as soon as we can. We invite you to stay until you have your say, which will be after the vote. Thank you.

● (1212)

(Pause)

● (1255)

The Chair: We'll end our pause in the proceedings and go forward with a presentation by a representative of Nu-Life Nutrition Ltd., Mr. Lionel Pasen, director of regulatory affairs.

Mr. Pasen.

Mr. Lionel Pasen (Director, Regulatory Affairs, Nu-Life Nutrition Ltd.): Thank you, Ms. Brown.

I come to you wearing a few hats. I am the director of regulatory affairs of a company called Nu-Life Nutrition. It has been in the business since 1950 and has every aspect of nutritional products—vitamins, minerals, herbs, homeopathics, and such.

My second hat is that of an industry consultant. I have approximately 360 applications into the Natural Health Products Directorate. I've received about 20 NPNs at this point. I represent about 25 companies, all sizes, from minor two- or three-product companies up to some of the major weight clinics across the country—170 clinics.

My third hat is that of a 68-year-old who has been in the industry since the age of 19. That's 49 years. I've seen it all. I've been involved in manufacturing, importing, retail chains, and health stores. I own a company that my grandfather started in 1888. It's a herb company. I was a lecturer at York University, a radio talk show host, and on and on. I've been through the full gamut.

I've heard a number of presentations, some of which are dubious and questionable. This whole concept of moving herbs to foods is ridiculous. It just doesn't hold up. The arguments are usually that you ask, what are you doing? Then an answer will come that something happened in Germany, that something happened there. We're talking about Canada.

What foods do you give for menopause? What foods do you give migraines? What foods do you give for prostate? What foods to you give for...? It goes on and on. These are not foods. Foods you take orally for nutrition. So if you hear something like, oh, these are specialized foods...they're specialized drugs. We have always, as long as I can remember, been regulated under drugs. Anybody who tells you that we have been regulated under foods is either new to the industry or is lying to you.

There are some aspects of the industry that have been and are regulated under foods, and you saw them in *The Globe and Mail* yesterday—it was the Canadian Food Inspection Agency that dealt with this—and there are some problems, because the regulations are very hard to meet.

Over the years, you would bring out a product. You would come to Health Canada, and you would say, I'm going to put this product on the market. They would say, okay, it's a drug, and these are the regulations that you have to live by. But you couldn't, because they weren't appropriate to the products you were bringing out. They weren't foods. They weren't appropriate to food regulation.

Over the years, with a lot of coaching of Health Canada, they finally did the right thing. They hired a person with the correct mindset for these classifications of drugs. They are not specifically drugs, but they are certainly not foods, and anybody who tries to tell you, with gobbledygook, that they're foods, and they're this and they're that, is misinformed and is misinforming you.

I'm sure you've heard that foods only come orally. All these products—whether a patch, a suppository, an ointment, an inhalant, or whatever the case may be—are used for purposes of correcting something within the body, either stimulating an action or suppressing an action, or helping in the healing process.

You can argue that, well, foods help in the healing process, and this is true, but not to the same degree. Foods are for nutrition. You can eat them as much as you want. These products require rules and regulations, limits both at the bottom end and the top end.

● (1300)

You've probably heard some arguments, what about garlic? I want to have my garlic and it's going to be regulated, and it's going to be expensive and all that. If you're taking garlic because you have high blood pressure, there's a certain amount you have to take in order to have efficacy. If you're taking echinacea, there's a limit to how much you should take, there's a limit, both at the lower and the upper end.

I don't know whether another important point has been mentioned. Insurance happens to be a fairly important part of business, and if these things are moved from regulated drugs, which they are and everybody recognizes they are, and moved to foods, there goes your insurance, there goes your company.

We have one responsibility as an industry, and that is the consumer. Why is the consumer our responsibility? You think, oh, it's the bottom line. No, it's the consumer, because if the consumer takes your product and gets results, they'll come back. If the consumer takes your product and they don't get results, they don't say “That product is bad”, they say “Natural products are bad”. The whole industry suffers because of bad product being out there, and bad product can be a product that's insufficiently presented.

The new regulations are great regulations. There are problems. I have 360 applications in, and I'd be happy to talk about that. With 360 applications—and I have about 20 NPNs—I'm starting to realize just how great these regulations are. These are legitimate products on the market. They work well for everybody, particularly for the consumer, and that's really who our boss is.

You're going to hear stories such as, well, I've never followed regulation before, and I've got lots of products on the market and everything is fine. These products were never DINed, which were the regulations we have been living under for as long as I've been in business, and they were inappropriate drug regulations, but drug regulations nevertheless.

You've also heard how good Canadian products are. That's because they were under drug regulations. We had GMPs to follow, we had a number of things that we were told. We're a country of regulation. We're not cowboys.

There's an old story I was once told. The difference between the Americans and the Canadians is that in Canada the Hudson's Bay Company would go out and create a fort. The RCMP would come out. There was calm there, and then the settlers came out, and there was regulation. With the Americans, bang! That was the way it was done, and it still is today, the six-gun, and that's very much a part of their culture. They want freedom.

We have freedom under these new regulations. We have more products than we've ever had before. Contrary to what was said a little while ago, products are not coming off the shelves; quite the contrary, there are a lot of new products on the shelves.

The way it works right now, very wisely, Health Canada has said, look, we're new, we're upstarts; we have a new set of regulations that industry does agree with. I represent about 25 companies and all of them are saying, this is good, because I know that when I can sell the product, I can say what it really does; and I know I have the protection of the government sanctioning the claims, and I know I have to prove that the product has been properly manufactured”.

Now I've lost my train of thought.

A voice: Ginkgo.

Voices: Oh, oh!

Mr. Lionel Pasen: Isn't this amazing? I'm never at a lack for words. Okay, we'll go off on some other subject.

● (1305)

The Chair: You're almost out of time.

Mr. Lionel Pasen: The gentleman over here had about 15 minutes in the previous group. He just went on and on. I would ask that I have a few—

The Chair: No, 10 minutes is the usual, and there was one person, but he didn't take a breath so I couldn't—

Mr. Lionel Pasen: Okay, fair enough.

The cost of products is not an issue. Because he's a major distributor, Mr. Chapman will probably explain to you what is the effect of the $1,500 or $2,000 it costs to get one of these applications in and through the process. When you're talking about 10,000, 20,000, or 50,000 bottles, that cost is nothing.

I'm sure in the question period you're going to ask me questions and I'll probably address other things. But definitely schedule A should be removed, because the regulations cover all the protection that is necessary. It can be done under regulation, and very effectively, because if you don't abide by it, you lose your NPN and then you don't have your product on the market. So schedule A should go, no question. And as for putting it into food, it's just ridiculous.

I thank you.

The Chair: Thank you.

We'll move on to the representative of Purity Life Health Products Limited, Mr. David Chapman, the president.

Mr. Chapman.

Mr. David Chapman (President, Purity Life Health Products Ltd.): Good afternoon.

I'm president of Purity Life Health Products of Acton, Ontario. We're a distributor of over 600 natural health products in Canada. I'm also a director at the Canadian Health Food Association and chair of its regulatory affairs committee.

I'm totally in agreement that schedule A and subsections 3(1) and 3(2) must go. I am totally against moving NHP into foods, and I want to see natural health products as a distinct third category.

I founded Purity Life a little over 20 years ago with very little money, but with an entrepreneurial desire to bring NHPs to Canadians. Since then my wife and I have built Purity into one of the significant suppliers of NHPs to natural health food stores, mass stores, and drug stores in every province and territory in Canada, and I now employ over 160 people.

I've always believed there needed to be a bridge between allopathic or conventional medicine and the natural world, and I have worked to that end. There's too much of this fighting going on, and it's gone on for too long.

I am also a founder of the Holistic Health Research Foundation, a registered charity dedicated to researching NHPs.

Early in my time in the industry, I realized that the way the NHPs were regulated was really wrong. The drug model used by Health Canada did not fit our products. As a CHFA board member since 1990, I have worked very hard in meetings with Health Canada officials, right up to and including testifying at the last standing committee that led to the 53 recommendations. That committee did a huge amount of work and consultation, leading to what we have now. I hope you guys can go back and read what they've done; we really respect that work.

These people were opposed to the formation of the office for NHPs, and these people are behind the process we are in now. These people are part of a very small, very dedicated special interest group, and despite making a lot of noise, they do not represent the vast majority of people in the NHP world. Last weekend in Vancouver, we had a Canadian Health Food Association show where we asked for proxies in support of our position, and over 95% of the proxies supported our position. Petitions that call for freedom of choice for health care are easy to sign on to, like motherhood and apple pie, but the ramifications of moving NHPs into food are terrible—a move back into a regulatory dark age.

Many of us have spent a lot of time and money in applying, and as Lionel says, it can be expensive. But at the end of the day, if you have an NHP, you can go out and make claims that we were never allowed to make in the past. That process, although slow, was well worth it.

Mr. Biggs commented that U.S. products are no longer coming in. With all due respect, too bad. If you have applied, the current transition program allows you to bring in your products during the transition period. If the American companies who were shipping into Canada, and who had a choice, chose not to apply, I'm sorry, but people who aren't interested in applying or complying with the regulations shouldn't be allowed to compete with those of us who are complying. From the viewpoint of one of those who is putting a lot of money and effort into making this, I have no desire to see those people come in.

In the past, I have often commented to my colleagues that we've been mad at Health Canada, but with very good reason, because there are some people there with very bad attitudes toward our industry. I'm not talking about the NHP; I'm talking about the former Health Protection Branch. By the way, for some of those people, their only interest is in protecting their egos.

But to get back to this, we have worked hard to put this process in motion. The transition is allowing us many more products. Melatonin, lysine, arginine, chromium picolinate, and other products were previously banned, because someone tried to make a claim for them, and the old Health Canada thing was, let's shove it into new drug status. It was a black hole, as it would cost you hundreds and hundreds of thousands of dollars to get a product out of new drug status, and since they're not patentable, who's going to spend the money on researching when all your competitors would thank you very much for getting it out of new drug status. The old system was ridiculous, and we feel we are way better off with the new NHP regulations.

With regard to schedule A, guess what, Canadians are not children, but grown-up adults who should be able to make decisions on their own health care. We should make decisions on what we want to take, and this paternalistic attitude of Health Canada.... Though I like a lot of Diane Gorman's presentations, I was very disappointed that she said, oh, well, we're so concerned that poor Canadians might not have proper medical care. I'm sorry, but doctors as a whole, unfortunately, know nothing about natural health products and nothing about nutrition. They have almost no training in medical school. They have no knowledge of this, so they're afraid of it. Plus, there is peer pressure to say that it's all snake oil. It is not snake oil; we sell products that make a fabulous difference to people's lives.

● (1310)

One of the presentations that I think you heard this morning said that billions could be saved in health care. If everyone in this room or everyone in Canada took a multivitamin every day, I think the health care costs in Canada would be dramatically lower. A lot of the problems we have are due to a lack of real nutrition.

I'm sorry if I'm digressing from my original point, but this is the age of the Internet. Canadians are taking charge of their lives. In spite of all this opposition, as has been said, there are adequate regulations in place to be able to handle any of schedule A. I'm tired of this paternalistic attitude. Canadians should be able to do that in all aspects.

Are we totally happy with the NHP regulations? No. Lionel sounds as if he's happier than I am, but there are issues.

You have Phil Waddington, who is the head of the office and a very refreshing bureaucrat. Here is a man who actually goes out in the real world and talks to stakeholders. In his discussions with us, he is willing to make reasonable changes. This man is a real gem. He's excellent. We're very impressed.

As I said earlier, many times I've spoken to the bureaucrats. They sit in their offices and pronounce on things. He's a very good guy. I think the people he has hired in his office are good people. We want to see more changes, and Phil is willing to listen to us. I think there will be some changes made.

We have a desire to see recommendation one implemented. Give us a third category. That's really what we want.

The last thing I want to say is this. We not selling food; we're selling capsules, tablets, lotions, and suppositories. That has been well covered.

There are a couple of other things.

We have had a real problem in the last several years with insurance.

The DSHEA in the U.S. is supposed to be this wonderful catch-all. The DSHEA is under horrendous fire in the U.S. The press in the U.S. is nailing the natural supplement industry, claiming that it's poorly regulated or unregulated. That spills over into Canada. I don't know if you've heard about some of the bashing that has been going on with the products in our industry. It's wrong in Canada and, to some extent, wrong in the U.S., but it's still going on.

I feel that with our products regulated in the way they are, we won't be bashed in the same way. Our insurance rates at Purity Life went from $20,000 one year to $240,000 the next year, when the ephedrine thing was going on. We were fired by one insurance company. I had to scream and yell to be able to keep coverage until the end of the year to allow myself to find other coverage. They said they didn't want to be a part of our industry anymore.

We're very concerned that if we are shoved back into food, which, I repeat, is going backwards, we're going to have a hell of a time finding insurance. I'm very concerned about that. They see it as just not knowing about all of us, but when we're regulated and we have NHPs, I think the insurance company will be more relaxed.

Last, there would be turmoil and uncertainty, and that creates bad business for all of us. The consumers of Canada need some regulation, and I believe we're on the right track. Give Phil and his people a chance. I'm prepared to.

Thank you.

● (1315)

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

Next we have Mr. David Rowland, the owner of the Creative Nutrition Canada Corporation.

Mr. Rowland.

Mr. David Rowland (Owner, Creative Nutrition Canada Corp.): Thank you.

Everything I've heard thus far, from these presentations and other submissions, appears to me to be a turf war over profits, and the forgotten people in all of this are Canadian citizens.

Here we have two industries: pharmaceutical-based medicines, on the one hand; and natural medicines, food-based medicines, herbal-based medicines, on the other. Pharmaceuticals and the people who prescribe them kill 70,000 Canadians a year unnecessarily. That's like a jumbo jet dropping out of the sky every second day. Natural food-based medicines have killed zero people. Your chances of dying of a bee sting are greater than dying from taking a natural-based food medicine.

What happens with the Food and Drugs Act? It restricts consumers' choice to take safe substances for their own health and to preserve their lives, by restricting their access to the substances, by making it more expensive, by cutting out smaller companies like my own—and there are many like mine. I disagree with David and Lionel that they represent all of the companies in the industry. This is not so. Most of them are under $2 million in sales, like mine. These regulations are already killing the suppliers.

I'm glad you agree that schedule A should go, because to restrict a claim is to restrict the telling of the truth and is to prevent access to these safe substances. The more we prevent access to these safe substances by regulation or by making the cost prohibitive, the more people we are condemning to death, who have to take their prescription drugs as the alternative. So the Food and Drugs Act is promoting death. That's the issue here.

Canadians need free access to safe substances. If the substance is safe, then the federal government has no right to restrict it whatsoever. If Canadians don't have the right to access safe substances to protect their health, they do not have the right to their own lives, which is against the bill of rights.

Furthermore, the federal government has no business regulating health claims. This is contrary to the Constitution Act of 1867, which clearly gives powers regarding health to the provinces. What a substance does, whatever it does in the human body, is a subject for medicine or health disciplines. It's not under the jurisdiction of the federal government. That's in violation of the Constitution.

So in effect, this new health products directorate, by restricting claims—you can only make the claims that they approve of—is practising medicine without a mandate. Anything that restricts a claim, for whatever purpose, is in violation of the Charter of Rights and Freedoms—the freedom of thought, belief, and expression.

So what's happening now is that the Food and Drugs Act is promoting death. It's killing your constituents, our customers. I see the clearest way to stop this, to stop promoting death, is to allow free access to safe substances that people can choose for their own health. I see Bill C-420, in its present wording, without compromise, without adding anything to it, without creating any third category, as the clearest way to do this.

I don't see how any compromise is possible. How do you compromise on death? How do you compromise on freedom of speech? How do you compromise on human rights? You either allow them or you don't. You can't say, well, we're going to regulate some claims but not others. What is partial censorship? It's still censorship.

The effect of these regulations is that it's going to cost my company $180,000 a year to comply. I've already lost a lot of products, which means my customers have lost a lot of products. My products are largely food-based medicines. People eat oranges and broccoli for their vitamin C content, but somehow, when you put it in a capsule, this becomes a drug? No, that makes no sense whatsoever. People take prunes as a laxative. They take milk to build their bones. All these foods have medicinal effects, according to the Food and Drugs Act. According to the Food and Drugs Act, a drug is anything that you claim has an effect on the body. It may have an effect in fact, but the fact that you claim it is what makes it a drug.

● (1320)

This is a very subjective way of categorizing what is a drug and what isn't. I say if a substance is food, if the substance is safe, the public needs to have unrestricted access to it. And I agree with David Chapman, we're not dummies; we're not in kindergarten. We can make up our own minds as to what works for us and what doesn't work for us. We don't need these products restricted.

Many companies are going to go out of business or have their product lines restricted because of these regulations, and there's no need for it.

Sections 4 and 5 of the Food and Drugs Act give Health Canada all the power they need to prevent fraudulent claims that what's on the label is actually in the product, and they give them all the power to stop substances that are unsafe. We don't need more regulations; we're already overregulated.

I don't agree with David's comments about DSHEA, the Dietary Supplement Health and Education Act, in the United States. They have their own category of what they call dietary supplements, what I call food-based medicines, as a subcategory of foods. These are foods and they're allowed to make claims. So maybe we should tinker with the food regulations to emulate what they're doing.

You will notice David's glee when he wants to shut out U.S. competition for the products that he sells. This is going to happen across the board. I see the only people who are advocating for the third category are the ones who have a self-interest. They're putting their business self-interest, their professional self-interest, ahead of the concern for the public.

There are naturopaths and herbalists who covet the prescription pad; they want to have these substances declared in their own bailiwick so they can prescribe them, just like medical doctors. How does that help the consumer? How does that give them free access to safe substances?

The larger manufacturers and distributors love these regulations because they screen out their U.S. competition, they screen out the smaller competitors in the field, of which there are many—most have less than $2 million in sales. These people are putting profit mode ahead of human lives, as I see it.

Thank you.

The Chair: Thank you, Mr. Rowland.

We'll now move to Mr. DeSylva of Herb Works.

Mr. Richard DeSylva (Owner and Operator, The Herb Works): Thank you, Madam Chair.

Cognizant of the time restraints here and the late date at which I was asked to appear, I'm going to read only selected sections of my submission.

My name is Rick DeSylva. I'm been a practising herbalist since 1977, and most recently, since last year, a doctor of natural medicine.

In 1986 my company, The Herb Works, began offering for sale to natural health food stores various herbal formulae made from wild-crafted and organically grown botanicals. The business gradually increased over the years, necessitating larger and larger premises. In 1999 we moved to a 5,000-square-foot shop. Within the following two years the company was providing custom manufacturing services to a number of NHP distributors across Canada. Our company had five full-time employees and one part-time staff, not very large compared to most, but given the record of growth and substantial export sales, we felt that the company reached a certain critical mass. Concurrent with these developments was the increasing influence of the NHPD's decisions regarding the regulations that eventually came into force on January 1, 2004.

A number of issues readily became apparent: one, the recommendations from the 1998 report *Natural Health Products: A New Vision* were not going to be implemented fully; two, the cost of compliance would be unsustainable for the small to medium manufacturer; and three, products that survived would be greatly reduced in selection and subject to huge increases in the net cost to consumers. The case of tryptophan from 20 years ago comes to mind.

Costing out compliance for the 30-odd products that The Herb Works offered was approximately $250,000 to $300,000 in start-up costs, and $50,000 per year on ongoing testing, etc. With the realization that I could not afford the cost of compliance, in late November of last year I sold most of my equipment to our biggest co-packing customer, who luckily, in turn, took over the lease and hired my staff.

This is typical of the decimation that is going to affect the small to medium businesses—proportional to their inability to comply to these regulations and to future measures that will be taken by the enforcement branch of Health Canada over the next two to three years. Given the various estimates from NHPD, CHFA, and Agriculture Canada studies, and from others, the threshold for survival in this market was stated to be anywhere from a minimum of $2 million up to $5 million per year in sales, and further, a minimum of 60%, more likely 80%, of the industry would have to close their doors. This is a very disturbing scenario.

Many are the critics of Bill C-420 who dismiss this initiative as little more than a tactical manoeuvre, arguing there is no real basis for inclusion under the food side of the Food and Drugs Act. I beg to differ.

Allow me to quote from the forward in Dr. Carolyn Dean's book, *Death by Modern Medicine.*. The first of these three forwards comes from Dr. Abraham Hoffer, MD, PhD, FRCP, a man widely acknowledged as the father of orthomolecular medicine:

> For the past 50 years I have been demonstrating that the use of natural nutritional treatment is and must be the most effective form of medicine and that when it is not used and the profession depends solely on the use of toxic drugs the results are abysmal.

And further:

> Some drugs do have some value but they should be used very carefully, very sparingly, for a short a period of time as possible and they should be subservient to the use of nutrition and nutrients.

What Dr. Hoffer's observations hint at is the changing paradigm in healing today, the shifting reliance upon drugs back to natural-based food substances. This shift has its roots in socio-cultural, ethnic, philosophical, and yes, even spiritual concepts. These beliefs and value systems do not necessarily subscribe to the germ theory or model of disease advanced by modern medicine, but operate according to more holistic and integrated concepts, such as one might find in the work of Dr. Gunter Enderlein. His major work, *Bacterial Cyclogeny*, points out how disturbed pH—and by way of aside, there is a balance of acid and alkaline in the body—or overacidification of the blood and tissue sets the stage for a mutation of pathogens in a more dangerous variance, increasingly noted in medical literature today. It is here that proper foods—whether it is vegetable juices or very specialized foods such as herbs—can play an increasingly valuable role in health care today.

In the past 50 years many have been the natural practitioners who use vegetable juices and specific herbs to help shift this pH, thereby resolving conditions such as arthritis, nerve exhaustion, osteoporosis, or even cancer. That herbs are specialized foods is evident in a detailed examination of their total constituents. Using hawthorn berries as an example, yes, there are substances that have specific cardio-active properties, but of equal value are mineral salts, such as calcium chloride, that serve to tone and nourish the heart muscle, or the mucilage—to use the technical term, mucopolysaccharides or glyco-proteins—that reduce inflammation and restore degraded membranes. Each constituent in hawthorn serves to address a different facet or aspect of the disease process.

● (1325)

In the larger picture, herbal formulae—long misunderstood by modern medicine and euphemistically referred as “polypharmacy”—cry out for clarity of purpose. In any given formula, there are primary, secondary, tertiary, and even quarternary herbs.

The major herbs in a formula address the specific concerns—for example, in the lungs, the accumulation of matter in the lungs or bronchi. They help dissolve mucoid matter, facilitate its expectoration, and even eliminate pathogenic activity. Some of the herbs may lessen nerve irritation that results from this congestion; others serve to astringe tissue expanded by this matter, while others still neutralize inflammation or provide amino-sugars—the mucopolysaccharides I referred to earlier—to restore structural integrity.

In this manner, they provide phyto-nutrients that offer sanative, restorative, and nutritive factors that bring organ, gland, and tissue back to proper functioning. Again, each constituent will address a different aspect or facet of disease process, or the nutritional deficit behind the ailment, as per the comments of Dr. Hoffer.

To argue that herbs are specialized foods does not imply that one can consume large quantities of, say, steamed comfrey leaves, much as one would spinach, or drink a large glass of echinacea tincture as one would a glass of wine. Part of this construct that looks upon specialized foods and phyto-nutrients as therapeutic calls for prudence in the same manner as one judiciously uses high-octane foods such as chipotle peppers, wasabi mustard, and horseradish or avoids drinking excess coffee and alcohol, ingesting too much sugar, or even eating too many prunes.

In summary, left unchecked, these regulations and their enforcement over the next few years will result in the collapse of the small to medium-sized sector of this industry, the segment that provides most of the innovative and unique products. Two, product availability will be substantially reduced, especially from those outside Canada, that cannot or choose not to meet the regulatory requirements. Three, the net cost to consumers will rise substantially, reflecting the cost of compliance. All of these outcomes run counter to the recommendations of the 1998 *New Vision* report.

This is a breach of the public's trust and their rights in the matter of freedom of choice. As an aside, an additional note would be the potential cost savings to the government, which has been referred to earlier, given the exploding costs of health care and the public's willingness to absorb costs associated with managing their own health.

Therefore, I would ask the honourable members of this committee to seriously consider the disproportionate and inappropriate current drug model for regulating these products and the havoc it is causing this industry and, eventually, the public. I would specifically ask that consideration be given to regulating NHPs as a subset of the food directorate, much as it is now the subset of the drug directorate; that there be appropriate amendments, such as the elimination of subsections 3(1) and 3(2); that the current definition of a drug accompany this reclassification to allow for claims; and that a rigorous evidence-based risk assessment model be used, with the onus placed on regulatory authorities to provide any such evidence of harm to an independent panel for evaluation.

Given their safe history, nature, and widespread use, it is no surprise that the Center for Disease Control in the United States, in Atlanta, Georgia, found them to be much safer than foods. Regulation in this manner will overcome the inadequacies referred to above and restore integrity to the process initiated by the review in 1997.

Thank you very much.

● (1330)

The Chair: We have, of course, lost some time because of the vote, but I should also tell our witnesses that our members have to get to the House for two o'clock. That's why we had planned to end at a quarter to two. This means we have less than 15 minutes left, so I'm going to suggest to my colleagues that we have one questioner per party at four minutes each.

Is that agreeable?

Some hon. members: Agreed.

The Chair: Thank you.

We'll start with Mr. Carrie.

Mr. Colin Carrie: First of all, thank you very much for attending today.

I do have a concern that hasn't been answered very well up to this point, and it's the concern over small businesses. Dr. Rowland, you mentioned that so far this has cost you $180,000 a year. I'm curious to know what products have been lost.

Mr. Biggs mentioned a solution that I really liked. You mentioned that a government seal of approval might be a great option, because doing that wouldn't cut out the small player.

Could you comment a little bit further about what products have been lost, the costs involved, and go forward with that, please?

Mr. David Rowland: The amino acids were taken off the market in the eighties by an excuse. Durk Pearson and Sandy Shaw wrote a book called *Life Extension: A Practical Scientific Approach*, in which they advocated a whole lot of amino acids. The Health Protection Branch just went through the list and took them off the market. Then there was a problem with tryptophan, which became contaminated. People died from a disease they contracted from the contaminant in the tryptophan, but Canada took it right off the market, even though it was harmless and they knew that it was—and so on.

In my particular company, $180,000 a year is what it's going to cost me from now on. I've been spending about $10,000 a year to get my DIN numbers. I have 54 products, 14 of which were classed as drugs until recently; vitamins and minerals have been classed as drugs for a long time. For those, it cost me about $10,000 a year to get the DIN numbers and $40,000 a year to do the testing on them. It costs something like $2,000 to test one batch of multivitamins, even if I only have a few thousand bottles in that batch. It is an unfair regulatory model, because drugs have only one ingredient; for $240 they can test billions of tablets, but I have to spend $2,000 to test a small batch of multivitamins.

My lost sales from products that were taken off the market and products that I can't bring to market are probably in the order of $100,000 a year. My regulatory costs are about $50,000 a year so far —and I see them going to $180,000 now that all of my products are classed as drugs. I will have to stop selling some of them, because I don't sell enough to justify the expenses, and I can't charge the roof for them, because people aren't going to buy them. It's a function of the volume of the various products that I sell. Most of my products are in what I call food-based medicines; they're unique formulations that I create based on vitamins and minerals, gladulars, amino acids, and so on, and a sprinkling of herbs, but that's it. It's mostly in the herbal area.

It's really difficult to put a finger on this, other than that I know that my costs are going to go from $50,000 to $180,000.

● (1335)

Mr. Colin Carrie: Have you had any deaths or significant adverse reactions to any of your products over the years?

Mr. David Rowland: None, absolutely none. I have hundreds of thousands of customers and haven't had a single adverse reaction.

Mr. John Biggs: Can I add some specifics in here? There are a couple of examples, such as the shortened price lists I talked about. We get herbs from lots of different outfits, but our two main herbal suppliers are Nature's Way and Solaray, which both dramatically shortened their list simply because they knocked off all their slow sellers. They didn't want to bring them in, because they couldn't justify the cost of compliance.

I can give you another specific example—

The Chair: Excuse me, but your time is up for that questioner.

I have to move to Mr. Ménard.

[*Translation*]

Mr. Réal Ménard: I would like some clarification. I understand that, should the committee adopt this bill, some of you would have a great deal of concerns.

With respect to the allegations and scientific evidence of health benefits, I would like to know more about the ramifications of this difference between food and natural health products. What concerns do you have with respect to the alleged scientific evidence on health benefits? In addition, what is the difference between natural health products and foods?

Mr. Chapman, you maybe the appropriate witness to answer these questions.

[*English*]

Mr. David Chapman: Quite frankly, the food regulations hardly allow us to make any claims. As well, the government has the right to do this and to do that. I don't want the bureaucrats to still decide this. I'm still at a loss; the reality is that the food regulations do not allow us to make near the claims we can make under the NHP regulations. The hopefulness about the government having the right to allow and tinker with the thing is simply that; it's all hopefulness to me. I really hate it when bureaucrats are writing our legislation.

[*Translation*]

Mr. Réal Ménard: Would you therefore prefer the status quo? Would you prefer to keep the Natural Health Products Branch established in 2000? That would enable you to make these allegations. If the bill were adopted, would this mean, in your opinion, a step backwards?

[*English*]

Mr. David Chapman: If we went back to food, it would be a step backwards. I heard a comment yesterday that the NHPD could stay intact. If that's the case, then either leave it where it is, or—this would be my hope— put it in a third category.

[*Translation*]

Mr. Réal Ménard: Do you share this opinion?

[*English*]

Mr. Lionel Pasen: There are some other things to address here. First of all, amino acids are back on the market under the new regulations. They're not gone. I've got NPNs for amino acids. So that should take care of some of Dr. Rowland's losses.

As for the claims, they're based on science, which has come a long way since schedule A was written. That was 70 years ago, two years before I was born. Now there's solid evidence as to why herbs or vitamins or amino acids, or whatever the case may be, have certain actions on the body. There are levels within which they work.

But if you're just going to have them, willy-nilly, put them under... the DSHEA concept is ridiculous. They have five simple claims, that's it. They can't make claims. They have five "may do this"—it was something to do with calcium—I forget what they are, but they're insignificant.

Under the regulations for Canadian foods, the claims you can make are insignificant. Under the NHPD, you can make real claims for what the product really does at real doses.

● (1340)

[*Translation*]

Mr. Réal Ménard: You have annoyed your colleague, who wanted to speak.

[*English*]

Would you have a short comment?

Mr. David Rowland: You can still only make claims that are approved by committee, and that's still a form of censorship. We have truth in advertising laws in Canada. If someone wants to make a health claim and documents it with research, even with testimonials, that's prevented by the present drug regulations. What's to stop someone from doing this for a food? The regulations have not been challenged in that regard.

The other thing is that we don't need to copy the limitations of the DSHEA thing in the United States. Why can't people tell the truth about foods? I mean, the way the act is now, if I say that oranges prevent scurvy—or even that a sandwich prevents hunger, or water prevents dehydration—it makes those substances drugs. This can be changed very easily. It doesn't need a whole new extra set of regulations.

The Chair: Thank you, Mr. Ménard.

Mr. Thibault.

[*Translation*]

Hon. Robert Thibault: Thank you, Madam Chair.

[*English*]

Thank you all for appearing.

I just want to make a brief comment, and then I have a question for Mr. Chapman and Mr. Pasen.

We say we're mature and can make decisions, but I've seen people in many instances who get chronic pain and get desperate. Then they'll accept a testimonial, or an unproven claim, or a study by some institute we don't know as being fact, rather than this process.

I remember magnets in shoes for arthritis. I remember Matol, a liquid that would give you hair if you had no hair, take some off if you had too much—your dog would smell better if he took enough of it. A lot of people spent good money and may have put off other treatments they should have been doing because they had faith in these products.

So going to the food side, I haven't heard too many presentations supporting it. All the presentations but one or two have suggested the elimination of schedule A. Dr. Boon was one of the few who suggested keeping it, and she comes with good credentials and made good points on it.

Yesterday the Health Canada witnesses made the suggestion that the review was being carried out under schedule A. Unfortunately, they didn't give us a timeframe. One of the areas of consideration was eliminating all the restrictions on health claims under schedule A for the question of prevention, but maybe maintaining them for cures.

Now, I have concerns around cures with some of these. On prevention, I find it much more difficult to believe why there should be....

I'd ask both of you to comment on that suggestion. Would that go far enough, or do you still think we should eliminate it completely?

Mr. David Chapman: What if I could prove a cure? I haven't done that, but what if I could prove a cure for cancer? It would say no, you can't do it. And it is possible, using natural health products—and all my colleagues would agree with me here—to make a profound impact on a cancer. I would even like to say, perhaps in some cases, get rid of the cancer. So I feel that we should have the right to be able to do that.

On your concern over the issue of people having bought things that didn't work, people vote with their feet. If something doesn't work, they try something else. I'm concerned that they'll buy stuff with nothing in it.

The people in this room have integrity, everybody at the table here—and, by the way, we're friends, even though we don't 100% agree on all aspects of the issue—but there are people out there who do not have integrity. There might be people who will sell junk, and it bothers me that some people can sell anything in a bottle under the notion of freedom of speech.

Hon. Robert Thibault: I think we agree on that.

I'd like to hear from Mr. Pasen in the short time we have left.

Mr. Lionel Pasen: I agree with you totally, except that under the new regulations you can go for a cure—if you can prove it; you can go for prevention, if you can prove it; and if you can't go for anything, you don't get your licence. You can't sell alfalfa to make your hair grow, to use your example. You want to protect the consumer. They're number one—number one, two, three, four, and five. They're the important ones. If they're taken care of properly, everything is fine. And you can't do it under foods.

Hon. Robert Thibault: So with the new regulations, schedule A is not necessary?

Mr. Lionel Pasen: It's not necessary. It covers all fraudulent or exaggerated claims. Under foods, you can forget it.

● (1345)

Hon. Robert Thibault: Thank you.

The Chair: Thank you.

Mrs. Crowder will be our last questioner.

Ms. Jean Crowder: Thank you, Madam Chair.

Thank you all for your presentations.

I don't have a copy of the regulations for NHPD before me. What I do have is *A Fresh Start*, the final report from the transition team, with their recommendations around the regulations, and I have the Food and Drugs Act.

Under the foods, I'm really challenged to see how these products, if we move them into foods, would address the issues around consumer safety. We've heard a lot about costs, we've heard a lot about the impact on small and medium-sized business, but I think one of the primary concerns we have to bring to the table is consumer safety, and that includes how consumers know what's in a product, how they know what kind of dosage to take, how they know what contraindications there are, and how they know this is safe in any kind of a way.

I'd like Mr. DeSylva and Mr. Chapman to comment on it. Could you specifically comment on how we can demonstrate that products would actually be safe under the food section of the Food and Drugs Act?

Mr. Chapman, would you mind going first?

Mr. David Chapman: I actually do not have an answer for that. Under the food part of the act, I don't know how we could demonstrate safety, because I don't know where it would end with the GMPs. It goes back to this uncertainty issue. I don't know what GMPs we would work under in that case, so I don't know.

Ms. Jean Crowder: Mr. DeSylva.

Mr. Richard DeSylva: Starting with the background of the Center for Disease Control report, statistically the descending order of safety—meaning the number of deaths, as David referred to—lists drugs, then foods, and then NHPs. That would provide at least a basis on which to assess these. Science at some point will certainly be able to come out with a means of assessing—

Ms. Jean Crowder: I don't see how that's allowed or encouraged under the food section.

Mr. Richard DeSylva: You're right. It isn't currently allowed under the food section. This is why we're asking for amendments to the food side of the Food and Drugs Act, to allow for this.

Ms. Jean Crowder: But Bill C-420 does not include all the safety standards outlined in the transition team's report, and that's where my concern is—that Bill C-420, as it stands, just relabels products as foods, and the current Food and Drugs Act doesn't talk about efficacy and testing.

Mr. Richard DeSylva: The short version would be that it's a work in progress.

Mr. David Rowland: If you turn to your act, subsections 3(1) and 3(2) govern foods. The statement is that no person shall advertise any food, drug, cosmetic, or device to the general public...no, that's the wrong one. Sorry.

Ms. Jean Crowder: Those are the two sections they've asked to have repealed.

Mr. David Rowland: I understand. Sorry. It's in here.

Ms. Jean Crowder: Section 4 talks about—

Mr. David Rowland: Yes, it's section 4. Sorry.

It says:

> 4. No person shall sell an article of food that
>
> (a) has in or on it any poisonous or harmful substance;
>
> (b) is unfit for human consumption;
>
> (c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal...

Ms. Jean Crowder: Sorry. If I may interrupt, I've read those. I actually don't see how they talk about the levels that are in a product. Somebody talked about echinacea earlier today, and about how different parts of the plant—

Mr. David Rowland: If you'll let me finish, section 4 prevents adulteration of food products. It prevents harmful products, okay? Section 5 prevents mislabelling of food products to misrepresent what's in them. All you have to do is beef up the enforcement of these two sections of the foods part of the Food and Drugs Act and you will have everything you want to keep Canadians from consuming unsafe products or products that are misrepresented.

Ms. Jean Crowder: Thank you. I have limited time.

Mr. Pasen, could you please comment?

Mr. Lionel Pasen: What about effectiveness? Period.

Ms. Jean Crowder: Thank you.

The Chair: Thank you, Ms. Crowder.

On behalf of my colleagues who are members of the committee, I want to thank our witnesses for coming. Thank you for the work you do as you're trying to address Canadians' health needs, and thank you for the time you've put into your presentations.

I can assure you we will take your comments into our consideration as we review Bill C-420.

Thank you very much.

This meeting is adjourned. We will be back at 3:30 p.m.

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