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Chair

Ms. Bonnie Brown

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● (1535)

[*English*]

The Chair (Ms. Bonnie Brown (Oakville, Lib.)): Good afternoon, ladies and gentlemen. It's my pleasure to welcome all to the 35th meeting of the Standing Committee on Health.

Today the orders of the day are, pursuant to the order of reference of Wednesday, March 9, Bill C-420, an act to amend the Food and Drugs Act, which includes the definitions of “drug” and “food”.

Our first witnesses are the sponsors of the bill, Mr. Colin Carrie, the member of Parliament for Oshawa, and Mr. James Lunney, the member of Parliament for Nanaimo—Alberni.

Gentlemen, you may present now.

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

I'd like to start by saying thank you to members from both the Bloc and the NDP for their support to date and also to my friend and colleague Dr. James Lunney for his continued assistance and perseverance in his support of Bill C-420.

It honours me to be here today bringing forward this important piece of legislation. Since this bill was first introduced, I have received an overwhelming amount of support from all across Canada. The original sponsor of the bill during the last session of Parliament, Dr. James Lunney, along with colleagues Carol Skelton and Dr. Grant Hill, submitted petitions totalling over 130,000 signatures, all rejecting the current drug-style regulatory regime. Since then, thousands of signatures have been added, including 9,000 alone on an online petition I have hosted. These numbers indicate Canadians want Parliament to know their foods are not drugs and natural health products should not be regulated as such.

Modernizing the way natural health products are regulated has been an issue many Canadians have advocated over the past decade. Those who support change feel betrayed by Health Canada's empty promise to ensure Canadians have ready access to natural health products that are safe, effective, and of high quality while respecting freedom of choice and philosophical and cultural diversity, as stated in the 2001 *Canada Gazette* part I.

When this bill was first introduced, MPs heard from many consumer groups, small companies, and individual Canadians who argued these drug-style regulations resulted in a limited number of products on the Canadian market and higher prices for the consumer. Sixteen months after the regulations came into force, it appears those people were right.

Canadians have sent a clear message. They do not want their natural health products regulated like drugs. Natural health products are derived from food and are found in nature. The Advisory Panel on Natural Health Products, the 1998 health committee, and the office of natural health products transition team have all recognized that natural health products are not drugs.

To argue that natural health products are not food because they are not taken for caloric purposes or to satisfy hunger is a weak argument. Canadians today are constantly adjusting their diets as a way of improving their health. For many, natural health products are instrumental in achieving personal health goals. The existing excess of government control, licensing, and regulation of such products needs to be modernized and simplified. Regulating natural health products under the purview of Health Canada's food directorate would do just that.

On March 26, 1999, former Minister of Health Allan Rock accepted all 53 recommendations from the health committee's final report. The government set up the office of natural health products transition team and began clarification and expansion of the 53 recommendations that resulted from the health committee's 1998 comprehensive review.

The first recommendation of the committee was to set out an appropriate definition of natural health products and amend the Food and Drugs Act accordingly. It has now been over six years since this recommendation, and the government has yet to amend the act. Although Health Canada has created a regulatory definition, it has failed to act on the committee's eighth recommendation, which stated that amending the Food and Drugs Act was a necessary process.

Instead, it seems Health Canada had its own agenda when accepting 53 recommendations of the committee. The natural health products directorate's website stated that while creating another category distinct from both food and drugs was considered, an amendment at the level of the act would have been necessary. Due to the timelines and legislative process required for a change of this magnitude, it was decided that natural health products would be considered drugs under the act but with a set of regulations specific to natural health products. Health Canada consequently ignored the recommendation to allow elected representatives to oversee the process and ensure the needs of Canadians were being met.

The health committee's 1998 report made recommendations specific to the new regulatory agency that was established to deal with natural health products. The report stated:

> ...over the course of this study, the Committee has become aware of the level of information, equipment and personnel needed to support regulatory activities aimed at ensuring safety for Canadians. Still, the need for a new entity with a separate, small body of permanent staff is supportable. This can best be achieved without replication of existing bureaucracy and without significant cost if the new regulatory authority is placed within the HPB

—health protection branch—

> where it can have proximity and access to existing regulatory resources....
>
> The structure envisioned by the Committee reports directly to the Assistant Deputy Minister of the Health Protection Branch. With reference to lower administrative costs, the Committee members see it as consisting of a small number of permanent, full-time staff drawing external support as needed from the newly-created NHP Expert Advisory Committee and appropriate working groups.

What the committee clearly recommended was a fairly small bureaucracy with low administration cost, a recommendation supported by the majority of Canadians.

However, between April 2001, when the NHPD became a distinct unit, and April 2004, the NHPD cost Canadian taxpayers $15 million. In the last fiscal year alone, the NHPD came at a cost of $9.2 million. What about the small bureaucracy? As of April 11, 2005, the NHPD had a total of 132 people on staff. These staggering numbers—almost $25 million—and a bureaucracy that has ballooned to 132 people would perhaps be justifiable if supported by a strong performance record. Unfortunately, the performance of the NHPD has been a disaster.

Back in 1998, the health committee envisioned a smooth pre-market assessment of natural health products. The report stated:

> As indicated earlier, the Committee favours a licencing system based on monographs containing previously agreed, standardized product information against which other products could be assessed.... The person marketing the product should notify the regulator before the product is marketed. The regulator would have a short time, for example, 30 days, to approve the application and issue an NHP number.

Health Canada allowed themselves some latitude when drafting the regulations and came up with a 60-day performance standard, section 6 of the regulations. The regulations have been enforced since January 1, 2004, and the 60-day deposition clause since July 1, 2004.

As of April 11, 2005, the NHPD had approved 312 products under this new regulation. Health Canada now estimates there are 40,000 to 50,000 products in the Canadian market. Even with a 1,000% increase in productivity in the next year, the NHPD will not make it through half of the 6,300 applications currently in backlog. It is virtually impossible that all these products will be approved by the target date of January 1, 2010. What does this mean for the small businesses in the industry?

Health Canada's business impact test that accompanied the regulations concluded that roughly 50% of the micro and small firms will experience increased costs, in terms of facilities, software, equipment, training, and employment. In addition, 50% of the medium-sized firms felt the regulations would have a negative impact on product availability and variety. A brief example may illustrate. A small aromatherapy company in Cranbrook, B.C., submitted 26 pounds of paper in support of the product licence application for eight products in May 2004. In early April 2005, they received a 25-page fax from the NHPD detailing the information that the company had to produce to have the product approved. The NHPD also informed the company that they had 30 days to submit all the required information or the submission would be withdrawn.

Large manufacturers support the regulations because a heavy regulatory burden makes it difficult for smaller and new manufacturers to compete and enter the market, thereby increasing the market share for large firms. As illustrated, small businesses are negatively affected by a regulatory regime that results in wait times of over a year for product approvals. Is this how small businesses in Canada should be treated by government?

Once the government accepted all 53 recommendations from the committee, the Office of Natural Health Products transition team was assigned the task of examining sections 3(1) and 3(2) of the Food and Drug Act. These sections are blanket prohibitions against making claims that a product may treat, prevent, or cure any disease or disorder found in schedule A. The final report of the ONHP transition team, "A Fresh Start", clearly spelled out their view. The report stated:

> Sections 3(1) and 3(2) and Schedule A of the Food and Drugs Act are no longer relevant. They do not serve any purpose that cannot be accomplished adequately by other sections of the legislation or regulations.
>
> More importantly, the schedule does not reflect contemporary scientific thought. The weight of modern scientific evidence confirms the mitigation and prevention of many diseases and disorders listed in Schedule A through the judicious use of NHPs. It is time that the legislation and regulations reflect the prevailing science.

The transition team went on to recommend that

> Section 30(1) of the Food and Drugs Act should be invoked to remove all diseases listed in Schedule A; Sections 30 (1) and 30(2) should be revoked through the Legislative Renewal Initiative.

● (1540)

Instead of implementing the transition team's recommendation, another working group was struck to study the issue. The final report of the external working group made three recommendations: one, a short-term option involving administrative amendments to Health Canada's guidance document on section 3 in schedule A; two, a medium-term option involving regulatory changes such as replacing the current schedule A with a shorter list of diseases and establishing a set of criteria for the review of schedule A diseases; and three, a long-term option involving legislative changes including removing schedule A and amending section 3 of the Food and Drugs Act to establish controls on advertising to any member of the general public for products covered by the act, to diagnose, prevent, treat, or cure a disease or condition.

A notable paragraph on page 13 of the report states that

> While some members supported continuing and extending current advertising prohibitions, some had concerns about the existing regime and its likely incompatibility with the Charter of Rights and Freedoms.

This paragraph is significant because at the time the external working group was investigating the issue, Health Canada charges under sections 3(1) and 3(2) were being challenged as unconstitutional in the case against Strauss Herbs. The legal counsel in the case will be appearing before the committee. At the eleventh hour and after a year and a half in court, Health Canada dropped the section 3 charges.

Under the Access to Information Act, we have obtained a memo dated October 4, 2002, from then Deputy Minister of Health Ian Green to Minister Anne McLellan regarding section 3 and schedule A of the act. In the memo, Mr. Green states that

> ...the Department of Justice considers that the current provisions would probably not withstand a Charter challenge. Forthcoming under separate cover is a legal opinion of a possible Charter challenge on the grounds of free speech.

Months before the company was charged with section 3 violations, Health Canada and Minister of Health McLellan were in receipt of information regarding the section's problems under the charter. They proceeded to charge the company regardless, costing the small B.C. business half a million dollars in legal fees. None of the charges stuck and Strauss Herbs was cleared on all counts.

Health Canada has not only failed to take actions on modernizing sections 3(1) and 3(2) in schedule A but has addressed the issue in a manner inconsistent with the recommendations of the health committee and a transition team. Bill C-420 will repeal these sections in accordance with the recommendations.

In closing, I would like to say I sincerely hope this committee gives careful consideration to this bill and to the many health benefits that will result should it successfully pass. Canadians deserve freedom of choice in personal health care, something that NHPD fails to provide. In compliance with the 1998 recommendations of the health committee, Bill C-420 will provide natural health products with a desperately needed modernized regulatory regime that recognizes their long history of safe use.

Thank you for your time and consideration of Bill C-420.

● (1545)

The Chair: Thank you, Mr. Carrie.

Mr. Lunney, do you wish to comment at this time?

Mr. James Lunney (Nanaimo—Alberni, CPC): Yes, please. I'll add to my colleague's comments.

Thank you, Madam Chair and colleagues.

It's a pleasure to be with you today to discuss this issue. We've had a lot of private discussion on this. It's good to be back before the committee again to discuss Bill C-420 and why we're interested in changing the way we regulate natural health products.

I will start a little differently. I'd like to review and mention that the perspective I always try to get across to patients in my clinical practice is that you're dealing with a body of some 80 trillion to 100 trillion cells. Each one of us represents a universe of activity. That's huge.

There is a notion that if you're 39 years old, then your whole body is that old. That is certainly not the way it is. There's a constant turnover of cells in the body, and for that reason the nutrients that you eat determine the body that you're building. It's also true that exercise and lifestyle determine the type of body you're building as well. But the turnover rate is more surprising than most people realize.

For example, 25% of your red blood cells are replaced every month. Your skin is falling off all the time. It has to be replaced. Bone takes seven to ten years. The hard cortical bone takes a little longer, about ten years. The intramedullary bone takes about seven years.

I believe there is a myth that over-regulators of natural products continue to work with that is based on what I would say is a false premise, which is that you can get everything that you need to be healthy from food alone. I would suggest to you that is stated over and over again, but there is a premise that you can get what you need from food alone. Therefore, if you need a vitamin top-up, it takes only a little to top you up, when you might be deficient or your diet might be a little low in vitamins.

I would suggest to you that there's compelling scientific evidence that this is not the case. To maintain proper health in a human being, you need to supplement your diet with good nutritional supplements, vitamins, minerals, and probably amino acids. Given the challenges that we face today with a high-stress environment, lots of microbes, lots of new super-germs that we have to deal with, and so on, you need a good healthy immune system to deal with that.

My colleague Mr. Carrie has already covered a lot of the details, so I'm going to bypass that and go on with a little review. I want to mention a couple of points.

It's clear that Canadians did not want a type of drug regulation for natural health products. If we go back to the original health committee report that was generated out of consumer concern, they tried to bring out a type of drug regulation back in the 1997-98 era. In essence, that is what we have arrived at, a type of drug regulation.

I would be concerned that you have things that would advance health care. We are all concerned about waiting lists, sick people waiting for surgeries and waiting for doctors, and the need for more doctors and health care workers. But when we have simple strategies that would enhance a person's health and reduce the necessity to even be on a waiting list, I'm concerned that Health Canada would participate in making simple strategies unavailable.

For example, chromium picolinate is a simple blood sugar regulator. You cannot metabolize blood sugar without chromium, and you should be getting about 200 to 400 micrograms a day. That's not happening for most Canadians, and yet we have an epidemic of diabetes.

The sections that we're trying to get rid of, sections 3(1) and 3(2) and schedule A, go back to 1934. How did we know in 1934 that vitamins, minerals, herbs, and natural products couldn't possibly influence the course of a disease listed on schedule A, which includes arthritis, diabetes, mental illness, heart disease, and some 40-odd diseases, including cancer? How would we know that in 1934? Were we so advanced scientifically in Canada in 1934 that we already knew none of these things would work?

I would say that's not very realistic. As my colleague has pointed out and the transition team has mentioned, the abundance of scientific evidence today shows that vitamins, minerals, and natural products help to influence the course of many of those diseases.

I'm concerned about continuing with a type of drug regulation for many of the diseases on schedule A. Forty years later, we're still looking for cures for heart disease, arthritis, diabetes, cancer, and mental illness. I would suggest that if we continue with a type of drug regulation, 40 years from now we'll still be looking for cures for these things, because they won't have materialized. The answers are sometimes found outside the box.

You were talking about arthritis. Health Canada is trying to shut down a product called Recovery medicine, from Duncan, B.C., on Vancouver Island. It's a vitamin mineral product that helps people with arthritis. It won an award internationally for treatment of racehorses, and it has been tested on ballet dancers in Denmark. They are doing phenomenally well on that. I know people on the Hill who are taking Recovery medicine, yet Health Canada is trying to obstruct them through these clauses.

● (1550)

With regard to mental illness, most of you are familiar with the story of Empower Plus and the way this product has been treated. Truehope is another case in point. The RCMP raided a little company in Raymond, Alberta, taking their computers and asking 3,000 Canadians to get back on their psychiatric drugs—even though there were published, peer-reviewed information confirming that these people were doing very well on a simple vitamin and mineral supplement.

The final one I want to mention is folic acid. As most of the women around the table would know, you take it when you're pregnant to prevent neurotube defects. We have reason to believe it is the best defence against heart attack and stroke. It's cheap. One milligram a day would help most people. I take six milligrams a day, about six cents a day in product, because my homocysteine is high. Homocysteine seems to be the culprit that damages the lining of the vessels, and it's managed with a simple folic acid supplement. This is an effective, low-cost product. But because we're not allowed to tell people this, we're running into very expensive strategies for heart attacks and strokes.

Less than a year ago, there was a huge article that appeared in most of our national papers that talked about a new “polypill” for heart attacks and strokes. Some doctors proposed that they would create a super-pill containing the five drugs they would put you on if you had a heart attack. They figured that, used with folic acid, the pill would reduce heart attacks and stroke by about 80%.

So our concerns are that this type of regulation is overzealous for low-risk products. The Fraser Institute looked at these regulations and called it a cure worse than the disease. We want good manufacturing practices; there's no question there. We want office inspections. We want to make sure that what's on the label is actually in the bottle. But we also want to produce shorter waiting lists and healthier people. We want to encourage the proper use of NHPs to improve health.

Multiple sclerosis can be reduced by about 40% with 400 international units of vitamin D. Right here in our committee, in considering Bill C-206 on the labelling of alcohol, we heard that 10 to15 studies show that when rats are given antioxidant vitamins, like vitamin C and vitamin E, the risk of fetal alcohol changes in rats is greatly reduced. CIHR has now advanced this.

These are low-risk, low-cost options. We should make them available to Canadians rather than restrict them.

Thank you, colleagues.

The Chair: Thank you, Mr. Lunney.

We have a small problem, and you can probably see it by examining your agendas. There are many witnesses. I'm going to suggest to you that, owing to the leadership shown by our two colleagues, we have one round of questioning. I would suggest one speaker per party, at about four minutes each, in order to keep on schedule and hear all the witnesses. Any objections?

No? Then we'll begin with Mr. Merrifield.

● (1555)

Mr. Rob Merrifield (Yellowhead, CPC): I want to thank you for the initiative shown in Bill C-420. Over the years, you have looked at natural health products given the public the opportunity to access them safely. I don't think you are compromising your position in Bill C-420.

We've been wrestling with this for quite a while in Canada. Bill C-420 is saying the system's not working, especially with respect to the number of products waiting to be approved. It appears that we will never be able to get these products through before the allotted time of 2009. Obviously we have a problem. Is there any country with a model we could learn from? Can you tell us what is happening in the United States, Europe, and some of the other countries?

Mr. Colin Carrie: Different countries handle it in different ways. In some places, these natural health products are likely to be labeled as drugs.

One of the best models is the United States, right next door. They had something called the DSHEA regulation, in 1992 or thereabouts. They had natural health products regulated more or less as foods. They found that the cost tended to come down and the quality went up. In some of the European countries, where there was more regulation under a drug-type directorate, costs rose and availability was reduced. In the last 10 to 15 years, we've learned that the United States is a good model. It is also our main trading partner. I'm not saying we should adopt everything the United States does, but this is certainly something to consider.

Mr. James Lunney: We're concerned with the drug-style regulation in Europe. You have many of the countries moving toward restrictive maximum levels for nutrients before they have to be controlled by prescription. For example, I believe it's Norway where you can't get vitamin C over 200 milligrams without a prescription, which would put many people at a great disadvantage.

I've taken several grams in the last couple of days, because I'm a little croaky right now. So I would take five or six grams a day, or 1,000 milligrams, and I'd need a prescription for that. Why? It's low risk. So we're concerned about that.

The U.S. model with DSHEA is a closer model. Maybe it's not perfect, but I think we can adopt our own model here. Perhaps we could lead the world in doing a food-style model that's for low-risk, low-cost, natural products.

Mr. Rob Merrifield: Are there any changes proposed to the United States model? How long have they had their model? Maybe you can bring the committee up to speed on what's going on there.

Mr. Colin Carrie: They've had DSHEA for about 14 years. Theirs is more like a legislative solution, whereas ours would be a small change and mostly done by regulations. So the regulations could change quite quickly, as the science improves.

Mr. Rob Merrifield: Are they proposing any changes, do you know, or is everything working a hundred percent there? Is there research to that at all?

Mr. Colin Carrie: No, I haven't.

Mr. James Lunney: I have a copy of the DSHE Act here. It was in 1994, the 103rd Congress, when it came in.

I think there are a few challenges down there. I'm not exactly sure. People are not a hundred percent happy with that scenario as well. I'm sorry, I can't speak specifically—

Mr. Rob Merrifield: Maybe some of the other witnesses will help us with that.

Thank you.

The Chair: Thank you very much.

Mr. Bigras.

[*Translation*]

Mr. Bernard Bigras (Rosemont—La Petite-Patrie, BQ): Thank you, Madam Chair. I will try to be brief.

First of all, I would like to repeat that my party supports Bill C-20 in principle. I think that natural health products should not be included in the category of drugs, because they are certainly not drugs. However, you are suggesting that these products be included in the food category.

There are regulations that were put in place in 2004, but the danger is that they apply to the two definitions: the definition of "drug" and the definition of "food". Given that there are negotiations underway at the moment at the Codex Alimentarius Commission and that some directives have been denounced by the natural health products industry, given that a recommendation was made to define natural health products, and given that the products to be regulated by the directives are foods, your proposal could mean that these natural health products would be governed by the Codex Alimentarius. Would it not be simpler to establish a third category, which we would define? In this way, the recommendations of the committee would be taken into account, and we would avoid having natural health products put into the food category and governed by the Codex Alimentarius. I think a proposal of this type would achieve a greater consensus.

● (1600)

[*English*]

Mr. Colin Carrie: That's a very good question.

When we're talking about the Codex Alimentarius commission, one of the misconceptions about it.... Each separate country has its own regulations; it's not a mandatory adoption of codex. As codex is implemented here in Canada, we can have certain exclusions based on our own legislation and our own regulations.

Originally in the report "Natural Health Products: A New Vision", back in 1998, they did recommend a third category. At that time, it was decided by Health Canada not to have a third category. They decided to put natural health products under drugs.

What I'm proposing here—we have foods at one end, drugs at another end—is that by making a subsection of the foods, food would be less regulated, and then you'd do a subsection with greater regulations. Once you have a product aligned with the drug directorate, you can't go back and make it less regulated; it has to be under the drug directorate. Whereas if you have it under the food, you can tighten up the regulations. It would be like a de facto third category, without having to change the act.

Mr. James Lunney: I think there's a lot of confusion about what codex does entail, and I think Mr. Carrie's comment is probably appropriate. Right now, what we have is a third category, as Health Canada wants to say it's a third category. It happens to be a garage appended to the house, under drugs. We'd like to saw off that garage and move it over under the food style, where the people we have been relating to who are particularly concerned about where we've landed right now feel that we're safer. And I personally feel it's safer that way too.

The reason I feel natural products are more akin to food than to drugs is this. You are familiar with that word xenobiotic—like xenophobia, a fear of strangers. Drugs are foreign to the body, whereas vitamins, minerals, and amino acids are orthomolecular: they're normal components of all biological systems.

For a xenobiotic product, the difference between the therapeutic level and the toxic level is very close. With an orthomolecular, you have a wide therapeutically effective range before you reach a toxic level, if you can find one. For example, 30 or 60 milligrams of vitamin C can prevent scurvy, but at three or four grams a day, you can start to interfere with viral infections and so on. So there's a huge range on the orthomolecular side before they are toxic.

That is why we feel that these are foods; they're natural. There's another difference. In the drug world, they like to find the active molecule and take it out of the natural context and then change it somehow. They find that active molecule and then they hydrogenate it or methylate it or carboxylate it, and then they can patent it. But in nature it doesn't work that way; as in EMPowerplus, you find that vitamins and minerals work together. It's a little bit like taking the quarterback out of the team. You have a winning team and then you tweak him a little bit, to put his head under his arm, and send him out to play by himself.

So we find there's quite a difference between xenobiotic products and drugs and orthomoleculars, which are natural and therefore non-toxic and therefore more appropriately aligned with food than with drugs.

The Chair: Thank you, Mr. Bigras.

Now we'll go to Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): Thank you very much for appearing and explaining your proposed bill.

I think all of us agree with what you are attempting to do, which is to make sure that consumers can make their own choices and that these products are available to them. I just want to raise a few points and give you a chance to comment on some things I have to think about before I can consider supporting, or whether there should be amendments.

Number one, as was mentioned, is the question of the manufacturing details—the safety of these products, the efficacy of these products, the dosage, the risk in these products at the wrong dosage, as Mr. Lunney just mentioned, and the question of vitamins. I can't even spell the words or pronounce the words you were saying, so I can't necessarily make those choices for myself. I wouldn't know what the amount is that becomes risky, so if they're under drugs, I'm assuming that there's some system to tell me.

I want to refer to two cases that I know of from my community, from my wider community. One is a child who uses EMPowerplus and has done remarkably well. It's amazing and it's regrettable that there are so many loopholes for him and his family to go through to get it. I understand and share your concern and his family's concerns about getting it, and I understand that some remedial action is happening now and that this will be available to Canadians much more easily.

The second is a case of a gentleman in my riding who was very ill. He had cancer. His family, well-meaning, working with the homeopath, was treating him with natural medicines. Well, he passed away after a long period of suffering. He wasn't under the care of a medical practitioner. They were treating him with these things. Maybe these drugs would have worked. I don't know. Maybe they needed to be used in the right amounts or in the right way. I don't know. But as a consumer, I don't have a way of making those decisions, and if they're under food.... I know I can't hurt myself with food, except to gain a little bit of weight.

You mentioned Bill C-206. I think it's another good example, because we had somebody appear who told us that alcohol, taken in moderation, could have some beneficial health effects. Then I listened to him further, and if I'm not mistaken, he was talking specifically of red wine, because of the tannins in it, taken in moderate amounts. And I believe the amount he was talking about was three-quarters of an ounce per day, and any greater amount started to have a negative health effect.

The consumer doesn't necessarily know all that information. I think the Natural Health Products Directorate helps us to get or to have access to the information that might help us to manage our situation better.

Now perhaps, as you were mentioning, the speed at which the transition is happening is not fast enough, and perhaps there can be a look at schedule A, but I just wanted you to comment on those.

● (1605)

Mr. Colin Carrie: Thank you very much for the question.

The Chair: You have a minute and five seconds to comment.

Mr. Colin Carrie: Five seconds? Okay.

The Chair: One minute and five seconds.

Mr. Colin Carrie: Under the food directorate, you still have good manufacturing practices. All we would need to do is make sure we start enforcing the regulations. When you're looking at a health food product—a supplement—quite often there's a history of safety with the product that has been going on for years. What I would recommend is that we look at what has been out there, the history of the product, and see what's reasonable. If, for example, a product's been used in the United States for the past ten years and there are no adverse effects, you would assume that product at that dosage is safe.

We also have to look at common sense and labelling issues. You can take any product, and it can be dangerous—for example, Aspirin. Every year.... Well, the last result was that 45 people, I think, in 1998 died of taking Aspirin. Every year we know of people who take Aspirin incorrectly, or Tylenol—even over-the-counter cough medicine—incorrectly. There can be fatalities because of it—with any product around the house: bleaches, and things like that. You have to use some common sense and trust an individual will make his own health choices.

Hon. Robert Thibault: We're not suggesting to consumers that bleach is beneficial if ingested.

Mr. Colin Carrie: Absolutely. But I'm saying to use common sense on product labelling. You have to have a level playing field. If you have an over-the-counter medication such as a Tylenol or an Aspirin and people, if they don't read the label, take more than what's recommended on it, you're not going to have the desired effect, whether it is an over-the-counter drug or an over-the-counter health food product.

You mentioned a really good case, too, if I may bring that up, about the cancer patient. I had a cancer patient who was told he had a very short time to live. He went on the natural health food products. He actually wrote a letter to the editor in support of this in my local newspaper and said “Thank you very much for the work you're doing”, because he credits his life right now—he's had a remission of his cancer—to health food products.

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

Mrs. Crowder.

● (1610)

Ms. Jean Crowder (Nanaimo—Cowichan, NDP): Thank you, Madam Chair.

Thank you, Mr. Lunney, for bringing this bill. I think it's an important piece of discussion for the committee to have.

I have a couple of comments and then a question.

I think what we hear from Canadians is that they want to have access to natural health products that are cost-effective, and they want to be assured of the quality. Unfortunately, in *The Globe and Mail* today, it was reported that a blitz found 71% of nutritional supplements didn't comply with regulations, and that there were things that shouldn't have been in these supplements. I think that's the point for many Canadians. They want to be comfortable that whatever they take is actually what it says on the label. I want you to comment specifically on that.

I also would like you to comment on what you said, that this experience in the United States has been going on since 1992. Are there any specific studies that have actually looked at these health products in the States since 1992? In the case of adverse reactions, I would suspect most Canadians and most Americans don't have a mechanism to actually report it. There's no way of gathering that information on a national basis.

Licorice is a really good example of an extract that actually you should not take if you have high blood pressure, and I don't know if people actually know that about licorice, for example.

So I wonder if you could comment on the quality and how you maintain it, and on the U.S. studies.

Mr. James Lunney: I'll take a stab at that. Thank you, Ms. Crowder.

First of all, as far as the article went, I don't believe it specified that there was any risk or concern; it just said it wasn't in the regulations. I noticed this morning on *Canada AM*, when the reporter asked the person who did this study, "Is it dangerous?", he said, we don't know. So I don't know that danger is really an issue in that particular case; it simply doesn't conform to the regulations.

Ms. Jean Crowder: But they had non-permitted ingredients in them. I think that's a bit of an issue, if they have ingredients that aren't permitted under the current regulations.

Mr. James Lunney: Yes. Well, right now, folic acid over one milligram isn't permitted. I have an issue with that, because I take six milligrams myself right now, which is technically illegal. Phil will probably want to arrest me afterwards.

As far as adverse reactions with natural health products are concerned, when people take a natural health product and it doesn't agree with them, they just generally don't feel good and they stop. I had that experience as a clinician for 24 years. There is no list of body bags, where you find people actually dying; they just don't feel good.

Ms. Jean Crowder: I'm not looking for body bags. I'm actually looking for things that perhaps have contraindications that people should be aware of. You don't want people to actually take things if they're not good for them, for whatever reason that might be.

Mr. James Lunney: Can I just jump in on that?

I know the regulations say that people want complete and accurate information. It will probably be a hundred years, if we devote some research into this, before we have complete and accurate information—and that's if we devote a lot of research to it. It's simply that complete and accurate information is not available right now, and it certainly is not on any drug, because as I said, the human body is an extremely complicated thing. The last word hasn't been said on any of these things. But in terms of adverse reactions with serious consequences, as the Fraser Institute remarked here, they called this a cure worse than the illness.

The number of reported adverse reactions is so low that it's fewer than certainly the adverse reactions to Aspirin or Tylenol alone, either one, and we don't overregulate them.

Mr. Colin Carrie: I have one quick comment. You asked a question about what's happening in the United States. They've found that it's a market-driven thing. In other words, they'll label certain natural health products that have known interactions with drugs, because they want their products to sell. They don't want to sell them irresponsibly.

Ms. Jean Crowder: How do they gather that information, then? What's the mechanism to do that?

Mr. Colin Carrie: I can't tell you offhand how they're doing it, but I would suggest that anything we would put on a hotline, just as we try to gather data.... We talked about this earlier in the health committee about drugs and how the interactions with drugs are a real problem. We don't know exactly, and we may never know, how drugs interact with each other. It's such a complicated thing. We can never have it fully understood. But as time goes on and with good market practices, the labelling should just flow with that.

Ms. Jean Crowder: But they haven't specifically done studies, then.

Mr. Colin Carrie: I believe some studies have been done, but I couldn't comment exactly.

The Chair: Thank you very much, Ms. Crowder.

To our colleagues at the end of the table, congratulations on getting your private member's bill to this stage.

We thank you for your presentation, and we know you are available for our questions over the next period when we are studying this bill. Thank you very much for all the work you've done.

I'll now ask the next set of witnesses to come to the table.

I would like to hear from everybody who is going to present, and then we'll start questioning after that. There are so many people listed that I will ask only those people who are actually presenting to come to the table, and those who are here as resource persons to just arrange themselves in seats so that they can assist the presenters with the answering of questions.

I think the order is Mr. Dugas, Ms. Herringer, Mr. MacWilliam, Ms. Bryanton, Ms. Stewart, Ms. Gorman, and then Mr. Buckley.

Ms. Gorman, I'm not sure if you're doing the total presentation or whether there is somebody else. Okay, good, it's just Ms. Gorman, then.

● (1615)

[*Translation*]

Mr. Réal Ménard (Hochelaga, BQ): Are we having another round of questions?

[*English*]

The Chair: I'm not sure. I think we'd better wait to see how long we have left, because we actually took more time than was allocated for our colleagues' presentation.

But I thought, Mr. Ménard, for example, when we finally get to questions, I'll start with Mr. Fletcher and then go to you, and then go to Mr. Savage, and so on, so that we're sure that by the time we're finished, everybody has had a chance. Does that sound good?

Mr. Rob Merrifield: We normally start with ten minutes. We only went five minutes on the last one.

The Chair: Why don't we just see how much time we have? We might not even have five minutes for everybody, so we'll just see.

Since we're a bit short of time, I'm going to ask the representatives of the Office of Natural Health Products Transition Team to begin. I believe Mr. Dugas is the first presenter.

Mr. Dugas, the floor is yours.

[*Translation*]

Mr. Ronald Dugas (Member of the Transition Team, Consumer Advocate, Office of Natural Health Products Transition Team): Madam Chair, on behalf of the Office of Natural Health Products Transition Team, I would like to thank you for giving us this opportunity to meet with the members of the Standing Committee on Health.

[*English*]

My name is Ron Dugas, and I have been a consumer health advocate for over 25 years. It has been my privilege to sit on a number of committees relating to natural health products since 1997.

I have with me Donna Herringer, David Skinner, and Alicja Wojewnik-Smith. All of these colleagues are from the transition team.

The increasing regulation of NHPs as drugs, and the accessibility of herbal remedies, sparked an intense public outcry back in 1997. The government's response at the time was to set up the Advisory Panel on Herbal Remedies. Right after the election, the health minister asked the Standing Committee on Health to conduct public hearings.

On November 4, 1998, the Standing Committee on Health tabled 53 recommendations. Among the key recommendations were the following: regulate products separately from foods and drugs; set out an appropriate definition and amend the act; and establish an expert advisory committee and transition team.

On May 19, 1999, the Minister of Health announced the appointment of a 17-member transition team to help establish the new directorate and its regulatory framework. The team included 14 members from the private sector, as well as consumer representation, and three representatives from Health Canada. The transition team worked diligently for ten months and produced six reports, and the final recommendations were tabled in March 2000.

Several of us have gone on to sit on the expert advisory committee, the management advisory committee, and Health Canada's schedule A external working group. As spokesmen and representatives of consumers on the transition team, and presidents of a number of consumer groups over the years, we have taken the position that Canadian consumers are intelligent, independent, and capable of making responsible choices with respect to their health. However, in order to make informed decisions, consumers feel that regulators must ensure that full and accurate information is readily available to protect their health and to guarantee product safety and quality. The consumers recognize that this is essential to a regimen of prevention, treatment, and health optimization.

Let me just point out that as former president of these organizations, I remember way back that when I met with Monique Bégin, and subsequently with Jake Epp and Alan Rock, I tried to get the message across that something actually had to be done with regard to natural health products, and that there should be some type of regulations in place to protect the consumers and to ensure there is freedom of choice with regard to selection of these products.

● (1620)

The Chair: Excuse me, Mr. Dugas. If you have three other speakers, you have already used up half of your time.

Mr. Ronald Dugas: I appreciate it, Madam Chair.

The Chair: You have ten minutes in total.

Mr. Ronald Dugas: I will now turn it over to Donna Herringer.

The Chair: Thank you.

Ms. Donna Herringer (Member of the Transition Team, Office of Natural Health Products Transition Team): Thank you, Ron.

We're here today as the transition team to request that the committee support the Bill C-420 proposal to repeal schedule A and section 3, an antiquated measure introduced in 1934 to prevent fraudulent claims. Today we know that many NHPs are globally recognized for their effectiveness to treat, and reduce risks of, disease.

Current regulations allow claims, yet section 3 prevents manufacturers from sharing this information with consumers. We recommended the repeal of schedule A and section 3 in the year 2000. This position is almost unanimously supported by many NHP organizations.

I doubt you will have many parties come to disagree with this, so I want to turn to the other portion of Bill C-420, that the definition within the Food and Drugs Act be amended so as to treat natural health products as foods. The transition team is categorically opposed to this proposal.

Regulating NHPs as foods could destroy Canada's world leadership in NHP regulation. We are the first country to regulate these products separately from foods and drugs. Australia and New Zealand have reviewed our model. The U.S.A. and other associations are currently studying our model as a means to set common standards for international trade agreements like NAFTA.

In effect, Bill C-420 contravenes the vision we set out for the regulations and the Natural Health Products Directorate. The Natural Health Products Directorate is led by a naturopathic doctor, and staff have expertise in natural health product disciplines. These are answers to what were major problems in Health Canada in 1998.

Regulating these products as foods will not improve on, and indeed may jeopardize, the expertise now available within Health Canada to regulate natural health products appropriately.

Secondly, the current regulations set out requirements for manufacturers to provide products that consumers can have confidence in, high quality, safe, and effective products and greater product information for the consumer. The regulations provide mandatory good manufacturing practices to give assurance of safety and greater product information so that what's on the label is in the bottle. They provide standards of evidence to allow products to make product claims based on supporting evidence, as well as product instructions, warnings, and contraindications. Many of these measures could not be achieved under food regulations.

Codex guidelines affect foods, not natural health products. Codex would have no relevance for natural health products in Canada. In our recommendations we've requested that Canada disseminate this position to all government officials responsible for international trade.

Finally, while natural health products are regulated as a separate category, natural health products remain classed as a subset of drugs under the Food and Drugs Act. Following on the former standing committee's recommendation that the act be amended, we recommended that the directorate and Health Canada work toward appropriate legislative or regulatory change to ensure that the legal interpretation of natural health products clearly differentiates these products from foods and pharmaceuticals.

It was the intention of the transition team that, in the longer term, NHPs be set out as a separate definition and a category within the context of a revised act. Health Canada assured us that the act would be amended as part of its legislative renewal expected to be completed in 2003.

Health Canada's legislative renewal is now projecting a new act to be tabled in 2006. It is not clear whether the proposed act will provide a separate definition for natural health products. That is worrisome, but it's also another matter.

I've provided you with a brief overview of the technical reasons why the transition team opposes the amendment proposed in Bill C-420. I now want to turn you over to David Skinner, who will discuss the implications on the vision for natural health products.

● (1625)

Mr. David Skinner (Member of the Transition Team, Office of Natural Health Products Transition Team): In the interests of the quickly diminishing time and on behalf of Mr. McWilliam, who sends his regrets—he was held up at the airport—I'd simply like to conclude by saying that wellness and self-care are growing trends. Canadians are increasingly demanding a greater role in the management of their own health.

Critical to the future of sustaining health care in Canada is empowering Canadians to manage their own health. Canadians want choice, but that means informed choice. The government needs to ensure that its regulatory frameworks and healthy living initiatives provide Canadians with the tools they need to manage their own health.

Thank you very much.

The Chair: Thank you.

We'll now move to the Canadian Food Inspection Agency, Ms. Debra Bryanton, executive director of food safety.

Ms. Bryanton.

Ms. Debra Bryanton (Executive Director, Food Safety, Canadian Food Inspection Agency): Thank you, Madam Chairperson.

In the interest of time, although we have distributed some comments, we won't really be delivering all of the content here today.

CFIA is responsible for enforcing the food safety and nutrition policies established by Health Canada. We also establish and enforce policies and standards that relate to packaging and labelling of foods, including provisions to prevent misleading or deceptive statements or claims regarding those products. While we do not enforce regulations relating to natural health products, we do work closely with Health Canada and the natural health products directorate to ensure that products are properly categorized.

We do feel that the regulatory regime that is currently in place for natural health products works well. We know that these natural health products are intended to be used differently from foods. It's important that they're safe and effective and that accurate information relating to appropriate quantities or doses is available to consumers in making appropriate choices.

Under the natural health products regulations, a wide range of health claims are permitted that would not be appropriate for foods. It is important that consumers do not confuse natural health products, which may have recommended doses or limitations, with more freely consumed foods.

We won't really add any more comments to that. We are here mainly to respond to any questions you may have that relate to the food area as opposed to natural health products, or perhaps some of the challenges there have been when natural health products were more closely associated with food.

Thank you, Madam Chair.

The Chair: Thank you, Ms. Bryanton.

From the Department of Agriculture and Agri-Food, we have Lynn Stewart, director of the cross-sectoral food industry affairs division.

Ms. Stewart.

Ms. Lynn Stewart (Director, Cross-sectoral Food Industry Affairs Division, Department of Agriculture and Agri-Food): Good afternoon, and thank you for inviting me here today to speak on behalf of Agriculture and Agri-Food Canada.

[*Translation*]

Natural health products include nutraceuticals, herbs and botanicals, all of which are of interest to the agriculture and food sector because of the diversification and industry growth opportunities they afford.

● (1630)

[*English*]

The global market for health and wellness products is large and growing rapidly. In fact, it is growing at a faster rate than the traditional food market. In 2003 the global nutrition industry was estimated at over $182 billion, with an annual growth rate of 8.4%. In a study done for our department in 2003, it was estimated that in Canada up to $800 million worth of raw agricultural commodities is used in the production of functional foods and nutriceuticals. The medicinal plant industry in North America is believed to be growing at a rate of 20% annually, with trade in medicinal plants surpassing $3 trillion globally and $100 million in Canada.

Canada is well positioned to be a leader in the natural health products sector. Estimates suggest at least 300 Canadian companies, from small start-ups to multinationals, are competing in the nutriceutical marketplace, with an estimated market size of $4 billion.

Some of Canada's globally recognized nutriceutical companies include Ocean Nutrition Canada in Nova Scotia, omega-3 fatty acids; Institut Rosell in Quebec, probiotics; Bioriginal Food & Science Corp. in Saskatchewan, essential fatty acid oils; CV Technologies Inc. in Alberta, botanical extracts; and Forbes Medi-Tech Inc. in British Columbia, plant sterols.

Agriculture and Agri-Food Canada's research centres are also doing research in areas like the neuroprotective properties of flavonoids from blueberries, high-lutein varieties of ancient wheats, phenolic compounds in barley, cancer-fighting properties of flax lignans, and herb extraction platforms for ginseng. Our department is providing financial support to industry for the Flax 2015 and the pulse innovation projects, which are looking at the health benefits of these crops through further research on their bioactive components and clinical trials in collaboration with the medical community.

In recent consultations, industry leaders have spoken of the important role the regulatory environment plays in competitiveness and innovation. Companies have emphasized the importance of a clear, predictable regulatory framework in which to operate, and in this context have spoken positively about the natural health product regulations.

Over the last few years, our department has worked with the industry and the provincial governments to develop a new agricultural policy framework. Branding Canada as a world leader in the provision of innovative, safe quality products is a cornerstone of this framework. Canadian companies have embraced research and innovation as a way of differentiating their products from competitors around the world. They have developed and enhanced value-added constituents from plants and animals and have become market leaders in the production and encapsulation of omega-3 fatty acids and in the processing of flax, soy, and oats into starches, proteins, and fibres. They understand the importance of demonstrating standardized product potency and quality, safety, and efficacy to the consumer.

What we have heard from industry is that they believe the current natural health products regulations contribute to Canada's being recognized as a producer of safe, efficacious, high-quality natural health products by requiring product licensing, pre-market approval, adverse reaction reporting, site licensing, and good manufacturing practices. These requirements enhance the safety and efficacy of natural health products and provide assurances to customers in Canada and around the world.

Finally, under the natural health products regulations, product labels may bear risk-reduction or treatment claims, dosage information, and warning statements when necessary. In contrast, foods are subject to different—and, in some areas, more restrictive—labelling requirements. For example, for foods, Canada currently allows only five generic risk-reduction claims associated with specific nutrients. Food labels may not carry treatment statements.

Industry is concerned that Bill C-420 would reduce the information that facilitates informed choice about natural health products in the marketplace, and could hamper the kind of industry development it thinks is possible in Canada.

● (1635)

[*Translation*]

In closing, I would like to thank you for the opportunity to share these views about the role the current Natural Health Products Regulations play in supporting the growth of this sector.

Thank you.

[*English*]

The Chair: Thank you, Ms. Stewart.

We now go to the representative of the Department of Health, Ms. Diane Gorman, assistant deputy minister, health products and food branch.

Ms. Gorman.

Ms. Diane Gorman (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Thank you, Madam Chair and members of the committee.

Although I will provide Health Canada's remarks, I would like to begin by introducing colleagues from the health products and food branch: Dr. Phil Waddington, director general of the natural health products directorate; Omer Boudreau, director general of the therapeutic products directorate; and Paul Mayers, director general of the food directorate.

In my remarks I would like to address the two separate parts of the bill because I think, as others do, it's important to separate the part that deals with the definition from the part that deals with schedule A and section 3.

Health Canada is opposed to the first portion of the bill with regard to the definition. During my remarks I will indicate why the natural health products regulations are an appropriate regulatory framework for these products. I will discuss how these regulations ensure the safety, efficacy, and quality of natural health products and will address the fact that these regulations reflect the views and opinions expressed by Canadians. I will also provide the status of Health Canada's work with regard to schedule A and section 3.

As it is currently written, the Food and Drugs Act recognizes two categories of products, namely foods and drugs. However, under this legislative umbrella, regulatory frameworks are developed that are appropriate to the risks and benefits provided by different types of products. For example, there are distinct regulations for foods, drugs, medical devices, and natural health products. The natural health products regulations were developed specifically for natural health products and address the safety, efficacy, and quality in a manner that is appropriate for this class of products. In effect, this has created a third category separate from either foods or drugs, through regulations. This approach ensures Canadians have access to the products they need while ensuring the products' safety and efficacy.

Ensuring safety is an essential element of the natural health products regulations. I am sure no member of this committee would argue that simply because a product is natural, it must be safe. Cocaine and opium are both natural products, yet clearly they are not safe. Likewise, while generally safe at lower dosages, many natural health products can have serious adverse affects at high dosages.

For example, the herb St. John's wort is traditionally used as a sedative for relief of restlessness or nervousness. However, there is a risk of severe interactions with conventional medication such as drugs to prevent organ rejection, contraceptives, HIV-1 protease inhibitors, antidepressants, migraine therapies, SSRIs, and/or anti-epilepsy drugs.

[*Translation*]

This is but one of many common examples of safety information relevant to natural health products. The effects of those that are less common are generally less understood, and therefore require thorough review before they can be safely and effectively used.

[*English*]

Natural health products are not foods. Foods are intended to be eaten to nourish and to satisfy hunger. NHPs, in contrast, are taken by Canadians for therapeutic reasons, for example, as sleep aids, as antiseptics, to relieve fevers, and to prevent the flu. These are but a handful of the thousands of therapeutic uses for these products.

[*Translation*]

The Natural Health Products Regulations ensure a balanced approach to the regulation of these products and acknowledge that one size does not fit all. They recognize the long history of safe use for many natural health products but also ensure that risks to consumers are identified and appropriately responded to.

Ensuring an appropriate level of pre-market review is an essential aspect of the Natural Health Products Regulations. For example, generally safe products such as echinacea and glucosamine require an attestation to a Health Canada monograph in order to receive market authorization. These monographs are available to applicants on the Health Canada website and are based on information obtained from both scientific and traditional sources with regard to safety and efficacy.

● (1640)

[*English*]

Furthermore, a broad range of health claims can be made for natural health products, providing there is supporting evidence. The regulations also ensure that appropriate information is on the label and that it is an accurate reflection of the contents of the package. In some, these regulations aim to ensure that natural health products are both safe and effective while providing consumers with information to make informed choices.

If natural health products were regulated as foods, manufacturers, importers, distributors, and packagers would not be able to make the same health claims, and product labels would not be able to provide the required treatment, dosage, or warning information. The natural health products regulations also respond to the risks associated with these products by setting out requirements for adverse reaction reporting.

[*Translation*]

The Natural Health Products Regulations also respond to the risks associated with these products by setting out requirements for adverse reaction reporting. The regulations ensure that natural health products are manufactured to appropriate standards of safety and quality. They establish outcome-based requirements for good manufacturing practices, which apply to manufacture, packaging, labelling and importation for sale. This is important because many of the safety issues associated with herbal medicines are due to adulteration, mislabelling or misidentification of ingredients.

[*English*]

Health Canada has received over 5,000 applications for natural health products. Over 350 NPN licences have been issued, and over 6,000 homeopathic products and 4,000 herbal and other products with DINs will soon be transitioning to the natural health products regulations. Significant work has already been undertaken by small and large companies to come into compliance with these regulations.

A change, as recommended by this bill, would come at considerable cost to Canadians who would not be able to have confidence in the safety of these products and who would no longer have access to the product information they desire, the very things Canadians expressly wanted in the natural health product regulations.

Moreover, there would be a cost to industry, which would be required to switch to an inappropriate regulatory framework. Indeed, these regulations reflect the will of Canadians. The natural health product regulations were developed based on extensive consultations spanning several years. Canadian consumers, health practitioners, and industry representatives were given the opportunity to express their views and to provide guidance on the appropriate regulations of these products.

In just one phase of the consultations, Health Canada distributed over 21,000 workbooks, answered over 2,300 phone calls, and visited 11 cities across the country where over 2,100 participants were given the opportunity to voice their opinions. Targeted consultations were also held on specific areas of the regulations and with specific groups, such as aboriginal healers; complementary and alternative health care practitioners, including homeopaths, naturopaths, and chiropractors; and industry.

Following the publication of the regulations in the *Canada Gazette* Part I, Health Canada received an additional 600 submissions indicating general support, and the draft regulatory framework was revised to reflect stakeholder comments. Canadians continue to support the existing requirements for regulating natural health products in a manner that takes into account the risks and benefits to consumers.

A recent survey conducted for Health Canada by Ipsos-Reid found that 76% of Canadians support regulating natural health products in the same manner as they are regulated today.

[*Translation*]

This poll result reflects what Canadians have said time and again: natural health products should have regulations designed specifically for these products. They should not fall under the current food regulations. Health Canada listened to what Canadians need and responded by creating the Natural Health Products Regulations, which are administered by the Natural Health Products Directorate.

● (1645)

[*English*]

The directorate is staffed with experts in the areas of complementary and alternative health care, including naturopaths, herbalists, traditional Chinese medicine practitioners, Ayurvedic medicine, and scientific researchers with extensive knowledge of natural health products. The natural health products regulations provide the regulatory oversight to mitigate the risks associated with natural health products and make these products safe for self-care use.

Bill C-420 would remove this oversight and expose Canadians to significant risks. It would restrict the health claims that these products can currently make when supported by valid evidence, eliminate the pre-market review requirements and appropriate cautionary labelling already in place, and deny consumers access to important information regarding the safety, efficacy, and quality of natural health products. I fail to see how this portion of this bill could be in the interest of Canadians.

The bill also seeks to revoke section 3 and schedule A of the Food and Drugs Act. This provision was introduced in 1934 in order to protect consumers against fraud, from treatment claims where no treatment existed, or from self-treatment or self-medication when it was considered unsafe or that professional intervention should be sought.

[*Translation*]

In response to requests from Canadians, and from the Standing Committee on Health, we have undertaken a review of these provisions. While all stakeholders support modernizing Schedule A, different approaches have been suggested. Some people have said that there is no longer a need for Schedule A; others feel it should be strengthened.

[*English*]

With the support of external advice, including consumers, Health Canada is actively reviewing schedule A. We expect this will result in changes or the removal of the restrictions relating to the pre-disease state for continued application for treatment or cure of a disease. In this way consumers would have access to information regarding prevention or risk reduction of developing certain diseases and consumers would be encouraged to seek professional advice for treating serious diseases.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): *Votre temps est écoulé. Merci beaucoup.*

I will now give the floor to our next witness, Mr. Buckley.

[*English*]

Mr. Shawn Buckley (Lawyer, Buckley and Company Law Office): Thank you, Mr. Chairperson, members of the committee.

I've handed out some written submissions, which are green in colour so they should be easy to identify. I would invite the committee to turn to tab one.

The first point I wanted to make, and it was touched on a little by Mr. Carrie at the beginning, is that the committee needs to appreciate the history of Bill C-420. It didn't appear out of thin air, and in fact it's part of the largest consumer movement probably in the history of Canada. I became involved back in March 2003. There was a national meeting in Calgary that involved consumer groups, consumers, retailers, and manufacturers. The meeting was called to deal with, first of all, the new regulations that at this stage were in the *Canada Gazette* part I, and then also to deal with the fact that some companies such as the Strauss Herb Company and Truehope Nutrition were being attacked with section 3 of the act.

As a result of that national meeting it was determined that the best approach to take would be to propose legislation abolishing section 3 of the act and to also change the definition of food and drugs so that natural health products were not over-regulated as drugs. A draft bill was actually proposed at that national meeting. Consensus was reached among the various stakeholder groups, and that draft bill has become Bill C-420. The bill before you is actually a grassroots bill that sprang up from different stakeholders in the communities.

I'd like you to turn to tab 2. I want to deal with the section 3 part of the bill first. The point that I want to make that probably isn't going to be made is that section 3 is an unconstitutional section; it's an illegal section. The committee can debate all it wants about what to do with section 3, but it's very important to understand that it violates a very fundamental principle of our Constitution, the right of freedom of expression. And that's found in both the Canadian Charter of Rights and Freedoms and in the Quebec Charter of Human Rights and Freedoms.

I'm not going to go through in detail the discussion part of that because of time reasons, but I've outlined for you several reasons why that section wouldn't stand up in court. I think it's quite germane that the last time Health Canada brought that against one of my clients and we challenged them in court, they were not willing to basically let a court rule on it. It's probably because the Department of Justice is of the opinion that it wouldn't stand up.

I could take questions on that later on, but I wanted to move on to tab 3, because most of the criticism of Bill C-420 is not focused around section 3, it's focused around these definition changes. I think it's important for the committee to appreciate that basically what Bill C-420 does is bring common sense to what has become a very absurd and inconsistent regulatory environment created by the current definition.

The current definition of drug is purely use-based. Any substance, regardless of whether it's harmless or poses great risk, is a drug if any health claim is made. This leads to very inconsistent results in the regulatory environment, because we know that several foods have therapeutic uses. You can have a food that is regulated as a food safely for Canadians to consume as food when no health claim is made, but all of a sudden when magically a health claim is made, the drug regulations kick in. There's no way around that. The definition of drug is use-based. We can say that the natural health products regulations created a different category—it's a drug.

To give you an example, you could have a grocer who buys a shipment of oranges and he divides them in half. He sells half of his oranges as foods, and they are purchased and sold safely under the food regulations. But this grocer for the other half makes a truthful claim and says, you know what, these oranges will help prevent and treat scurvy. He's now made a health claim, and the very same oranges now have become drugs under the act and need to be regulated as drugs under the act. The substance hasn't changed, the risk hasn't changed; all that's changed is that now you have two different sets of regulations governing the exact same product because a claim has been made, and a truthful claim.

● (1650)

I can go into some real-life examples of natural health products that fit into that category, but I think it's important for this committee to understand that there's actually some genius in Bill C-420, in that for the first time in 71 years there's a bill before Parliament to basically carve out an exception from this use-based definition for things that are safe, such as foods and natural health products.

It's also, I think, important to note—there was some talk earlier about the United States experience—that what Bill C-420 does is basically mirror what has occurred in the United States. If you look at section 3 of their Dietary Supplement Health and Education Act of 1994, the act defines “dietary supplements”, which for our purposes are natural health products, and exempts them from the drug category and basically states that they should be treated as foods. The act goes on to allow structure/function claims. The U.S. courts have subsequently enlarged that and allowed further claims, providing there are disclaimers, and it's working.

Another beauty about the DSHEA is that the regulatory body is not allowed to step in unless there's some evidence of harm, because the problem with natural products is the vast majority of them are completely harmless. People bring up names like St. John's wort, and say, “Well, there's some evidence...”. Well, regulate St. John's wort; pass regulation and govern it.

We're imposing some regulations on the industry that are quite onerous without evidence of harm.

I'll turn to tab 4 of my brief.

When there's opposition to Bill C-420, the concern really isn't with the definition change, the concern is that it's going to torpedo the natural health product regulations. That's the concern. I think that's a false alarm and I think it's a red herring. If you look at section 30 of the act, you'll see the Governor in Council has plenty of authority to regulate foods in a very similar fashion to how we find natural health products regulated in the regulations that everyone is worried are going to be torpedoed if Bill C-420 passes. This committee has to understand, when considering Bill C-420, that the act already provides for the regulation of drugs in a very similar way as these products are being regulated now.

It's not the end of the world; the sky isn't falling. As I say, look at section 30 of the act. It's fairly clear.

But what this committee does need to understand—and why I would urge this committee to move more to a U.S. model that is harm-based—is because, in my submission, Parliament doesn't have the jurisdiction to pass regulations such as the natural health product regulations. The power of Parliament in the area of health for these regulations is the criminal law power. And the courts have been very clear that in criminal law, you can protect against fraud, you can protect against adulteration, but if you're going to go beyond that and just control substances, there has to be some evidence of harm.

I can give you an example. Parliament, in its wisdom back in the thirties, prohibited the sale of margarine because it was harmful to Canadians. When that was sent to the Supreme Court of Canada, the court found that actually, it wasn't harmful, and it went on to say if we allowed Parliament to use the criminal law power to ban things such as margarine for the good health of Canadians, then basically the government could prohibit the sale of milk or the raising of cattle or the growing of wheat. They basically said no, there has to be some harm.

Now, the milk example is fairly germane because we know that milk causes adverse health reactions in Canadians. I'm allergic to milk. If you gave me a glass of milk, in about 40 minutes I'd need Ventolin. If I were having a bad day, I'd have to go the hospital. But milk does not cause enough significant adverse health reactions for Parliament to have jurisdiction under the criminal law power.

I cite in my brief the example of peanuts. We know that peanuts kill Canadians yearly and create numerous hospitalizations—similarly, shellfish. But probably Parliament couldn't come down with a national peanut strategy to make peanuts illegal and allow SWAT teams into people's houses to take their peanut butter out of their cupboards to protect us. It's not that there isn't harm, but it's not enough harm to bring it into the area of criminal law.

My point is that this committee needs to be very careful. If we follow the U.S. example, where the onus is on the regulator to step in only where there's evidence of harm, the advantage is, first of all, it doesn't unfetter the industry. It also allows the regulatory body to catch up on its evidence and to step in when it's appropriate. Also, it keeps us on the right side of Parliament's jurisdiction. It's very important to note that there's no point passing regulations that are beyond Parliament's competence. I would also add that would just simply make good public policy.

● (1655)

I would suggest that when members attending before this committee say that we shouldn't support Bill C-420 because the natural products regulations are going to die, you should be asking, where is your evidence of—

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Unfortunately, your time is up. I want this to be a genuine discussion among all members of Parliament. We will therefore be asking some questions.

We will begin with Mr. Fletcher and Mr. Lunney, who have five minutes each.

You have the floor, Mr. Fletcher.

[*English*]

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

I'd like to start with a statement. I'd like to congratulate my colleagues Mr. Lunney and Mr. Carrie. They've obviously put in a lot of work here, and have touched a chord with Canadians.

I do take exception...or I wonder if the regulations, as Health Canada has stated, are the consensus. Between Bill C-420 and same-sex marriage, I've received a lot of mail.

I'm also concerned by the statement by Health Canada that made an analogy about cocaine and heroin being natural substances. I don't believe for a moment that my colleagues are in any way trying to make it easier to access any of those substances, so that extreme example I'm not sure was appropriate.

To Health Canada, let's start off with the example of the orange, and what the gentleman said about the orange becoming a drug as soon as someone makes a claim about it. Is that accurate?

Ms. Diane Gorman: No, that's definitely not accurate.

Mr. Steven Fletcher: What's your response, then? Do you want to elaborate on that?

Ms. Diane Gorman: If the committee is interested in having a description of the differences between food regulations, drug regulations, and natural health products regulations, we'd be happy to do that, but I can assure you that an orange is an orange, and was intended to be eaten as food.

Mr. Steven Fletcher: So when a claim is made about an orange being able to prevent scurvy, that doesn't bring it into the drug category.

Ms. Diane Gorman: It would not be regulated as a drug.

Mr. Steven Fletcher: Okay.

Then I'll ask the witness who made the suggestion in the first place to respond to that.

Mr. Shawn Buckley: Well, there's no question when you look at the definition in the act. You have to appreciate, whether Health Canada chooses to enforce the law as it's set out, the definition of drug is clear: any substance. And it basically sets out a use-based definition.

Certainly Health Canada would be laughed at if somebody made a health claim for an orange and Health Canada tried to step in and regulate. It doesn't change the fact that under the law, under the act, that orange is now a drug.

One of my clients, Strauss Herb Company, manufactures Heart-drops. There's clinical evidence showing that it reduces risk factors for heart disease, such as cholesterol and blood pressure. It's mainly garlic and some herbs and spices—

● (1700)

Mr. Steven Fletcher: Sorry, I'm short of time here, so I'm going to try to fire off a few more questions.

Again to Health Canada, do the provisions of the act and its regulations already provide for the protection that was intended by subsections 3(1) and (2) and schedule A?

Ms. Diane Gorman: Different elements of the act deal with fraud, deal with adulteration, and so on. However, the intent of schedule A was somewhat different, in that it dealt with claims with regard to treatment, prevention, cure.

As I said, there is great debate about the value of schedule A, but its intention was certainly different from other elements of the act. As I said, views on it are quite polarized. There are those who would like to have it repealed entirely. There are others who feel that there are certain types of conditions for which individuals should not be self-medicating and need to be identified there.

Mr. Steven Fletcher: When is the study on schedule A going to be completed? You mentioned that one was under review.

Ms. Diane Gorman: Yes. A working group was put together that had experts as well as consumers on it. They provided a majority and a minority report to the department. The department is looking at what are those things we can do, absent an amendment to the regulations or to the law, and move quickly on. So we're now convening a scientific panel, which would look at what are the criteria one would use to identify diseases that might be included on such a schedule.

Mr. Steven Fletcher: Are we talking three months, six months, ten years?

Ms. Diane Gorman: There are elements that can move quite quickly, and there are others that may require regulatory or legislative change. As you know, that would take longer.

The Vice-Chair (Mr. Réal Ménard): Ten seconds.

Mr. Steven Fletcher: You're a tough guy. I'm going to need some natural health products after this meeting.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Thank you, Mr. Fletcher. You have our sincere friendship.

Mr. Lunney, even though you have joined the government side, this is not a new alliance. You have five minutes.

[*English*]

Mr. James Lunney: Thank you. It's nice to take a look from the other side of the table.

We have heard that we wouldn't be able to make claims under food. It seems naive to think we'd assume that the regulations for food are going to be any more applicable to natural health products than the regulations for drugs were.

You said you consulted many thousands of documents and a whole range of experts—naturopaths, doctors of all kinds, even chiropractors. Typical of Health Canada, though, I don't believe you actually followed their advice.

You went on to say that if we adopted Bill C-420, it would remove oversight, eliminate regulations, and prevent office inspections. You said you failed to see how that would serve Canadians' interests. There's an old proverb that says, “There are none so blind as those who will not see”. It's convenient for Health Canada and for the opponents of Bill C-420 to say, “Oh, we'll lose everything if we do that”. What we're talking about is hiving this garage off of the drug side and moving it over to the food side, along with appropriate regulation that would be tweaked as required. As Mr. Buckley has correctly mentioned, according to section 30 of the Food and Drugs Act, the Governor in Council has the right to regulate.

No one is saying that we don't want good manufacturing practices, office inspections, or labelling. Those are totally false notions, and it's disingenuous to suggest that any mischief in these areas would result from Bill C-420. We want appropriate regulations.

Mr. Buckley, you were in the process of explaining regulations of this kind. Would you care to go on?

Mr. Shawn Buckley: I notice that the opposition to Bill C-420 seems based on the notion that all of a sudden we'd have a regulatory void, and that the natural health product regulations would fall. Have a look at the act. Section 30 makes it clear that the Governor in Council has ample authority to regulate good manufacturing practices.

I would hope that the Governor in Council would look at its jurisdiction and try to limit its regulation to areas where there's evidence of harm. This would keep the industry from fighting the government in court and make the government a little more responsive to the concerns of the stakeholders.

● (1705)

Mr. James Lunney: I noted Agriculture and Agri-Food's interest in promoting omega-3 fatty acids and other healthy crops. I would think that Health Canada might want to partner with Agriculture and Agri-Food in promoting our natural health industry. Such a new model could help the world by advancing more appropriate use of natural health products, rather than restricting their availability.

On labelling of alcoholic beverages, we heard that antioxidant vitamins may reduce the risk of fetal alcohol syndrome. Should we wait 15 years to advise women to take antioxidant vitamins to reduce that risk?

Would you like some cooperation from Health Canada in advancing a new industry that might set the world on a new course toward low-risk treatment of disease?

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): You have 30 seconds to reply.

[*English*]

Ms. Lynn Stewart: At Agriculture and Agri-Food Canada, we believe there are tremendous opportunities, in both function of foods and nutraceuticals, for diversification and growth in the industry. But at the same time, we believe that a strong regulatory environment is important for the long-term sustainability and credibility of the sector. Maybe I should defer to Health Canada for—

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): I would ask you to keep your answer brief, because the time is up. However, since I am known for my flexibility and kindness, I will allow you to reply briefly.

Ms. Diane Gorman: Do you want me to answer?

The Vice-Chair (Mr. Réal Ménard): Please reply quickly.

[*English*]

Ms. Diane Gorman: In fact, Mr. Lunney made a number of statements during his previous remarks that I wasn't allowed to respond to, so I'm going to respond to those.

What Canadians want to know, whether they're consuming a food, a natural health product, a drug, whether they're using a medical device in hospitals, is that there has been evidence of the benefits and the risks of those products. So if natural health products have benefits, those should be known, and consumers should be able to have access to those products.

To say that the regulations were not developed taking into account the opinions of Canadians is a false statement. It was due regulatory process, with publication in *Canada Gazette* Part I, publication in *Canada Gazette* Part II. The transition team is here to speak to the advice that they provided over that period of time, so it's a false statement to say that we did not listen to Canadians.

Certainly our interest is access availability and protecting Canadians where there may be harm.

Mr. James Lunney: Mr. Chairman, please tell us, though, were any Canadians asking for drug-style regulation?

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): I am sorry, Mr. Lunney, it is not your turn. It is already 5:10 p.m., and there are three members who have not yet had an opportunity to ask their questions. We will therefore hear from Mr. Bigras, Mr. Savage, Ms. Crowder, Ms. Dhalla and Ms. Chamberlain. Be brief so that everyone can have a turn.

You have the floor, Mr. Bigras.

Mr. Bernard Bigras: Mr. Chairman, the more I hear this afternoon, the more I have the impression that the big winner in this is the pharmaceutical industry. On the one hand, there is a change to the legislation that would mean that natural health products are considered to be food. In that case, the Codex Alimentarius would apply and ultimately, there could be some danger with that. On the other hand, the government should have been consistent and acted on the committee's recommendation to amend the act to create a new category.

I would remind you that the pharmaceutical industry established the Codex Alimentarius in 1962. There are pressures coming from all sides. I have not yet heard you, but in order to ensure best practices and that these products are healthy and accessible to the public, would it not be simpler to establish a third category? Then we would really be sure that the Natural Health Products Regulations do not apply because of the definition of drug or food, but because of a definition of natural health products that recognizes their unique features.

I am afraid that these natural health products may be put into the drug category, that we will impose rules and control procedures and require monographs for certain products. That would mean that they would be excluded from the market. Would it not be simpler to establish a third category?

● (1710)

The Vice-Chair (Mr. Réal Ménard): To whom is your question directed, Mr. Bigras?

Mr. Bernard Bigras: It is directed to all those who care to answer it, but also to the deputy minister.

The Vice-Chair (Mr. Réal Ménard): Let us begin with Mr. Skinner, followed by the deputy minister. Please be brief.

[*English*]

Mr. David Skinner: In terms of the separate category, when I sat in front of the previous standing committee—and a lot of this discussion went on at the same time—I found very much that we focused on what the rest of the world is doing.

Now, I don't think anybody's actually given you your answer on DSHEA, but there are some things about DSHEA...it's not as simple as it sounds. If you make a drug claim for a natural health product in the United States, you do become subject to FDA, and you become subject to theirs. There are very specific types of claims, with disclaimers and so on, that go with DSHEA, so please understand that.

The second part of it is that we looked at DSHEA. We've heard already about the EU not being a good model. We decided that probably the best thing to do would be to come up with a third class in Canada that would be a Canadian-made solution. It would address all of the concerns we heard back then and we're hearing again now.

Our view on the third class was that the act, at some point in time, should be amended, but within the context of all the other things that this would bring along with it. So in the interim, to create a regulatory context for these things would actually be beneficial to be able to get to the point where we want to.

As to whether we're they're yet or not, the answer is no, but the strong belief was that natural health products are products people use, either in conjunction with their health care practitioner or on their own, that are of lower risk and deserve their appropriate regulatory category.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): It is your turn, Ms. Gorman.

Ms. Diane Gorman: In my opinion, the fact that there are three types of regulations, one for food, one for therapeutic products and one for natural health products, creates three categories of products.

[*English*]

I fail to see how categorizing these as food creates a third category; however, I'll leave that to others.

The natural health products regulations are different from the drug regulations. It would be infrequent, for example, that you would have clinical trials in the area of natural health products, where you do in the area of drugs. Good manufacturing practices are different for natural health products from what they are for drugs. The evidentiary base is different. And if there has been a long tradition of safe use and the products pose low risk, then they will be regulated with less stringent requirements than the ones required for therapeutic products. So in effect, the three regulations are quite different, and in my opinion they create the three classes of products.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Mr. Bigras, you have 10 seconds remaining.

Mr. Bernard Bigras: The act is not as specific. It talks about foods and drugs. There is no mention of natural health products.

Is there not a danger, at some point, that these products might be considered to be drugs or medicine, or food? Would it not be better to clarify the situation so that we can be sure that people will be able to have access to the products but with the guarantee of good practices, as provided for in the regulations?

The Vice-Chair (Mr. Réal Ménard): We will take that as a comment to be brought in when you ask your next question.

We will now go to Mr. Savage.

[*English*]

Mr. Michael Savage (Dartmouth—Cole Harbour, Lib.): Merci, Monsieur Ménard.

This is very interesting to me. It seems to me that there are a lot of people on perhaps both sides of this proposed bill who are very knowledgeable and understand this issue. It seems to me there's a much larger group of people out there who are trying to figure out exactly what we're talking about.

Health promotion and healthy living is very important to me. It's one of the things we've talked about at this health committee, and Mr. Lunney and Mr. Carrie know that I share their view on the fact that there are ways for us to live healthier lives. I suspect that natural health products are a piece of that, so what I'm trying to figure out is if this bill helps or hurts. I think I'm like a lot of Canadians, sitting here. I'll have an opportunity to be involved in asking questions of people over the next little while, but I think there's some confusion about this.

So the first thing I'm interested in is the process that got us to the regulations. We've heard that there was some wide consultation, and that's been disputed, so perhaps my question would be for Ms. Gorman.

Maybe you could just talk to me a little bit about the consultation process that was employed. Were the people who are now proposing Bill C-420, the supporters of this bill, involved in that consultation process?

● (1715)

Ms. Diane Gorman: The consultation process, in effect, goes back to the Standing Committee on Health's review of natural health product regulations. There were 53 recommendations coming out of that, which the department was asked to consider. We accepted all 53 recommendations, and we believe we've implemented all 53 recommendations.

Some of the other witnesses who are here today were part of that process. Coming out of that, we created a natural health products directorate. There was a request that the head of that directorate be hired through a process that involved outside people as well. As a result of that, we have Dr. Waddington.

I can't speak to the position others would have taken on that bill at that time.

Mr. Michael Savage: There was national consultation throughout this process.

Ms. Diane Gorman: There was. It was very extensive in terms of material provided, opportunities for people to comment, meetings and hearings held in 11 cities across the country, which led to the *Canada Gazette* process. During the *Canada Gazette* Part I process, again, as I said, we had a number of comments, which we reviewed and incorporated into *Canada Gazette* Part II.

Mr. Michael Savage: I was interested to hear about omega-3 fatty acids and Ocean Nutrition, a company based in Nova Scotia that seems to me to have a real opportunity to expand its business worldwide in an underdeveloped market. How would a company like Ocean Nutrition be affected by this bill?

Anybody could answer that.

Ms. Donna Herringer: I can answer that, being in the industry. We actually purchase from Ocean Nutrition, and they supply us raw material. They themselves are probably not going to be affected. Those people that they sell to will be affected, whether you sell this product as a food, or whether you sell this product as a natural health product.

In order to make health claims as a natural health product—and we sell many of the omega-3s, and there is a lot of science behind the fish oils—there has to be evidence to substantiate those claims. We support the natural health product regulations so that Canadians can be assured the claims that are made are supported by scientific evidence.

In going with that, I also have to tell you, as a manufacturer, some of the practicalities. I really appreciate what Dr. Lunney is saying. I absolutely support that natural health products are low risk and are safe, but what I think the concentration has to be and what I hope you understand is about assuring the quality of these products. The quality, to me, as a manufacturer, is the issue.

I'm just going to tell you a quick little story about something that actually happened to a manufacturer. A product was formulated.... No time? Okay.

Mr. Michael Savage: I'm going to let you answer, but I'm going to be cut off. As he said, he's a very mean person.

Ms. Donna Herringer: I'll do it real quick.

● (1720)

Mr. Michael Savage: One thing I wanted to say is I'd very much like to see that Ipsos-Reid survey that indicated that 76% of Canadians support the regulations. If we don't have that already, I'd very much like to see that.

Ms. Donna Herringer: Yes, that's available.

Mr. Michael Savage: Please carry on.

Ms. Donna Herringer: I'll just tell you quickly.

A formulation was put together for an antioxidant formula. I'm sure all of you have been around long enough to know what an antioxidant formula is. It contained other ingredients, but two of the ingredients this formula contained were vitamin C as ascorbic acid and coenzyme Q-10. It was an expensive formulation. This product was manufactured in the U.S. by one of the biggest soft gel manufacturers.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): There are still four people who wish to speak and we only have 10 minutes left. I will give everyone a chance. Ms. Chamberlain and Ms. Dhalla have not have a turn yet. I want to give everyone a chance to ask questions, but you can share the time among yourselves.

Ms. Crowder, go ahead, please.

[*English*]

Ms. Jean Crowder: Merci.

Before I get to my main question, I have one quick question.

I have seen, in the transition report, Bill C-420, and you reference it as well, about repealing section 3. But sometimes it's subsection 3 (1) and 3(2) and other times it's section.... I wondered specifically about subsection 3(3), which talks about "...general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception". Is subsection 3(3) also recommended for repeal?

Ms. Donna Herringer: No, it's 3(1) and 3(2).

Ms. Jean Crowder: So why wouldn't we actually talk about advertising contraceptive devices? We advertise everything else. Why can't we advertise contraceptive devices? It's just a question.

Has Health Canada considered it at all?

Ms. Donna Herringer: We will consider it.

Ms. Jean Crowder: Thank you.

This is my real question. I had my assistant run down the *Fresh Start* final report of the ONHP transition team—the executive summary. I took a quick glance through the regulatory framework in here, and it seems to actually make sense. Has this full regulatory framework been in place? Is it currently in place?

Mr. David Skinner: Yes, with the exception of the things we're talking about today in terms of the schedule A. That was one of the very early recommendations. Of course, we're still here to talk about how we move on to looking after an over 70-year-old provision of the act. The regulations themselves, I would say, are virtually in play, but there are still some outstanding legislative issues, such as schedule A.

Ms. Jean Crowder: So my understanding of the regulations, as I quickly glance through them, is that they do make some allowances for products that are generally deemed to be safe and that there is a quicker process in order to get them through this approval process. Am I accurate on that so far?

Mr. David Skinner: Yes. I think NHPD would be best qualified to answer about all those streams. I know, for example, there are at least three or four different kinds of streams, things that are brand-new, novel claims for existing products, which people have never heard before.

Traditional claims are things like ginger for upset stomach. I remember my mom giving me ginger ale. There are at least two to four streams that review these different kinds of claims.

So traditional goes faster; new, innovative claims take a little longer.

Ms. Jean Crowder: Part of what we seem to have heard is that there is a backlog in Health Canada, or that for the smaller businesses this has been an onerous process.

Ms. Alicja Wojewnik-Smith (Member of the Transition Team, Office of Natural Health Products Transition Team): Could I speak up? I didn't have a chance to speak.

There is a backlog, definitely, and I think this is the reason why some are getting frustrated. But getting frustrated after a year since the office actually was formed is unrealistic, in my opinion. The office has to deal with the regulations for a completely unique model that does not exist anywhere else. Obviously, they are in a process of development and of finding the best ways for the interpretation of the regulations. That's why we cannot expect that within a year they would issue the number of registration numbers sought for the products. They have to review the safety, the efficacy, and the quality of the product.

What I wanted to also add here, because there's a lot of discussion about DSHEA in the States, and on the other hand we are talking about access and freedom of choice, is that I think DSHEA in the States is actually limiting access to the products, because the only type of claims allowed there are the structural function claims, which means for health maintenance.

The Canadian model is actually very open, and that's the beauty of this model. You can bring to the market any product you want to, as long as you have the evidence for safety, quality, and efficacy. There is no real limitation, and that's the beauty. Many other models around the world are based on setting limits, and the limits are set up for today with the knowledge we have today. This model allows us to just move on and keep moving.

Thank you.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Thank you very much.

Ms. Dhalla.

● (1725)

[*English*]

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Thank you very much to all of our witnesses. Again I just want to take a minute to congratulate Dr. Carrie and Dr. Lunney on bringing forward something that I think speaks to their promoting prevention and healthy lifestyles for Canadians.

I have a couple of questions. I'm a big promoter as well of prevention, and of promotion to Canadians of healthy lifestyles. One of the major issues I've seen as a health care provider is that of the safety and efficacy of drugs. People want—Canadians want—to know that for the products they're taking as natural supplements, what's labeled on the bottle is actually in the bottle.

I think Donna was speaking to the quality issue when she was cut off. Perhaps you could just finish your story quickly, and then I have a question for the lawyer who prepared a great presentation for us.

Ms. Donna Herringer: I will try this really quickly, because I think it's important for you to understand the practicalities in the manufacturing world.

As I said, one of the largest manufacturers in the U.S. was manufacturing this product. There were two ingredients in it, one of them coenzyme Q-10 and the other one ascorbic acid. The product arrived in Canada to our manufacturing facility in Vancouver, and because in the DSHEA law they didn't have to test it when they released it, they formulated it. It's a safe product. They formulated it exactly according to our formula, but they didn't test it, because that's not their requirement, because of U.S. law.

It came to Canada. We tested it, and the most amazing thing happened—this is going to be written up in a publication. The ascorbic acid actually reduced the coenzyme Q-10. When the coenzyme Q-10—and this is the most expensive ingredient in the product—was tested at the end of the day, there was no coenzyme Q-10 left. The pH balance in the ascorbic acid reduced the quality of the coenzyme Q-10. We fixed that by using calcium ascorbate, because the pH level is different.

The reason I'm telling you the story is, if we had DSHEA law, that product would not have to be tested the way it is. It would be bottled and labeled exactly as it was formulated. On the label would be exactly what was put in there. But once those products are mixed together, there's activity that happens, and unless you test it, you don't know the results of that. The reason we're so adamant that there needs to be quality testing is that this would go out and it would take years before anybody would recognize that this product wasn't working. But it would in fact eventually come out, or somebody would test it and see that it wasn't working, and the credibility of this industry would go down the tube.

That's my story on the quality issue. Does that answer it?

Ms. Ruby Dhalla: Yes, thank you very much.

For Mr. Buckley, who is supporting the bill, how do you think Canadians will be affected in terms of ensuring the quality and safety of a product?

Mr. Shawn Buckley: It's funny, because Ms. Herringer was just speaking to credibility. If we back up a year or two, before the regulations came into force, has there been a change in consumer confidence?

If you look at the regulatory impact statement accompanying the *Canada Gazette* Part II, in part of the survey of manufacturers, they suggest there might actually be a decrease in consumer confidence or no change at all. I really don't know, as I haven't done a survey, but there's no evidence that consumer confidence has changed at all.

Ms. Ruby Dhalla: Do you think Canadians need to know that what's on the label is actually in the product?

As my colleague, Mr. Savage, was saying, unfortunately, not all Canadians are aware of the types of products they should be taking. As a provider, I know that you have individuals who are taking natural health products that conflict with each other or with current medication.

Mr. Shawn Buckley: On the question of whether a label should indicate that what's in the bottle is in the bottle, that's in the act. It's not even in the regulations. If you move it to the food category in section 4 of the act, it can't be changed by regulation. It has to be a specific label. There's actually significant protection. Nobody's suggesting that should change. So I support a label indicating what should be in the bottle.

I'm very concerned, though, as I was indicating earlier, that we're creating a bureaucracy. We have regulations. We have a new directorate. We're spending a large amount of money. But next year, when this committee meets, I would ask the committee this. How many lives have those regulations saved? How many Canadian lives have been saved? Ten years from now, will we know whether we've saved any lives? Will we know whether it has cost lives?

There's no question that when you impose a regulatory burden on the industry, some of the players are going to fall out of the industry. It will operate as a barrier.

● (1730)

Ms. Ruby Dhalla: Thank you.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Thank you.

I will take the initiative of extending the meeting so we can fit in our last two people, Mr. Carrie and Ms. Chamberlain.

Mr. Carrie.

[*English*]

Mr. Colin Carrie: Thank you very much, Mr. Chair.

I wanted to mention that I would like to challenge the comment that said Health Canada was listening to Canadians.

In 1998, with the report from the Standing Committee on Health, Canadians were initially upset because Health Canada wanted to regulate these products as drugs. There were 140,000 Canadians who signed a petition that said they didn't want these products to be drugs, that they wanted them to be food. We have absolutely zero Canadians telling us that they want these products regulated as drugs.

Health Canada wanted to regulate them as drugs. They set up this committee. The committee said there would be a third category, as Mr. Bigras was saying. Then they went along and put them in a drug category anyway.

On the argument that it's actually a third category under the drug category, if that argument is true, you could move that whole regulation, put it under the food category, and the whole argument is lost, because it would mean the same thing. You could have a third category under food.

One of the things I wanted to talk about specifically was the report mentioned that subsections 3(1) and 3(2) of the Food and Drugs Act and schedule A should be deleted. The transition team—and we have some members here—actually said:

> Section 30(1) of the Food and Drugs Act should be invoked to remove all diseases listed in schedule A; Sections 3(1) and 3(2) should be revoked through the Legislative Renewal Initiative.

When my colleague asked about the report that was supposed to be finished—and unlike what Health Canada said, that it wasn't finished yet, it was done in January 2004—one of the options was a complete elimination of section 3 and schedule A.

Mr. Skinner, could you comment on that? If Health Canada was listening to Canadians, obviously this would be over and done with.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Is your question for the Health Canada officials?

[*English*]

Mr. Colin Carrie: No, it's for the transition team, please.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Very well.

[*English*]

Mr. David Skinner: Actually, for the information of the committee, I also sat on the schedule A expert advisory committee you're referring to, which delivered our report. Donna was there as well.

The report was sent to government around the time the election was called. Since then, we've been pressing the government to try to move forward on the issue of schedule A, as well as on another initiative that actually deals quite quickly with the definition side. That is the legislative renewal project that has been in at least two successive throne speeches.

As a transition team, I'd have to say we're quite disappointed that we haven't seen faster action on this, because in fact there has been an awful lot of consultation on all of these issues, including legislative renewal. We continue to wait.

The Vice-Chair (Mr. Réal Ménard): Last question.

Mr. Colin Carrie: I have a question for Mr. Buckley. You started with an example of what Health Canada says and what it does. You had an example of a company and Health Canada saying what they want to do, but what they're actually doing is using the regulations to enforce. Could you finish that example?

Mr. Shawn Buckley: Was that in relation to the definitions?

Mr. Colin Carrie: I believe you had mentioned.... Was it Empire Plus or something?

Mr. Shawn Buckley: It was probably Strauss Herb Company. I was outlining that they have a product called Strauss Heartdrops, which basically is garlic and cayenne pepper and a few other herbs, and which could easily be sold under the food regulations as a seasoning, and I'm not even sure that that's not the case under a separate company. They make health claims. They've had clinical studies done to show that this product reduces cholesterol and blood pressure—two factors leading to heart disease. So we have a product that falls under food regulations if it's sold for one purpose. As soon as a claim is made-and they're not shy of making claims—it becomes a drug and it's subject to much heavier regulation. That was the product that Health Canada was targeting with the prosecution.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Thank you very much.

I will now give the floor to our last questioner, Ms. Chamberlain, and I would like to thank her for her patience.

[*English*]

Hon. Brenda Chamberlain (Guelph, Lib.): Thank you.

Ms. Stewart, you had said that this bill would reduce the information on natural products. Is that correct?

Ms. Lynn Stewart: Yes, our thought process on that was that if these products were regulated as food, the kinds of information that are currently on products under the natural health products regulations would not be there.

● (1735)

Hon. Brenda Chamberlain: Okay, I'd like you to give me an example, because I, like Mr. Savage, have trouble with these big words and what you mean. So let's take a product like echinacea. Could you tell me, if you know, what might be in it now and what it would look like under Bill C-420? Could you tell me that?

Ms. Lynn Stewart: Actually, with your indulgence, Mr. Chair, I'd like to ask maybe Health Canada to comment on that, because they have more regulatory expertise than I do, and I think it's really that.

Mr. Philip Waddington (Director general, Natural Health Products Directorate, Health Products and Food Branch, Department of Health): Under the current food regulations, you have to identify what the product is, so you would say echinacea. Under the current natural health product regulations, you have to identify the species, so you'd say echinacea angustifolia or echinacea purpurea. People who know the products know that you have to select a specific part of the plant, and it's going to have a different activity if you're using the purpurea or the angustifolia. Under the current regulations, the consumer wouldn't know which one they're selecting and therefore they would be misinformed potentially on the products they're going to be purchasing.

Also with respect to the claims, if I can comment potentially on what Mr. Buckley said, you have to read this act—the proposals, the changes that are there—and not what you anticipate it will say. So for example you would say, “I think it should employ good manufacturing practices. I think it should include statements for claims that are going to be on the labels.” If you look at what's there, it doesn't do that. All it does is say the definition of a natural health product will fall under the definition of a food, so the food regulations as written would apply. You can't presume what's going to happen. You have to take what's actually on there, and the Canadian consumer would be poorly served by that kind of a situation.

Hon. Brenda Chamberlain: So following on that, one of the things I'm very concerned about with natural health products—and I'm actually a great supporter of them, and Mr. Lunney and I had this conversation quite some time ago, whether he remembers or not—is for instance, for people using three, four, five natural health products, if there's less information, then it seems to me that there's more of an opportunity for harm to happen. Would it be correct to assume that there is harm in using a bunch of products? Somebody says, "I'm feeling a little depressed today, so I'll go out and buy some St. John's wort", and "I'm feeling a cold coming on, so I'll get some echinacea". Can you tell me about that?

Mr. Philip Waddington: You're exactly correct. The more products that have an activity such as these that we're talking about, the higher the likelihood is there's going to be an interaction.

Mr. Lunney himself said, coincidentally, "I'm feeling a little bit hoarse, so I'm taking extra vitamin C". He didn't say, "I'm feeling a little bit hungry so I'm taking extra vitamin C". He's using it for a therapeutic purpose, and the reason why we do so is because these products have therapeutic action. The more products with therapeutic action that you mix together, the more likely it is that you're going to get an interaction that you hadn't anticipated. It's only with clear labelling of what is in the product and what it's anticipated to do, to inform people where there are known concerns that they should take into account, that you're going to be able to have consumers make informed choices about products in a timely and accurate manner.

Hon. Brenda Chamberlain: Just on a further note, when you do go into natural health stores, some people are fairly well versed, I think, but some people quite clearly don't have a clue, they really don't. They say you could take this or that, you could try this, but they really don't know.

It seems to me this third category Mr. Bigras talked about is perhaps an option. Have we thought about that at all?

Mr. Philip Waddington: The third category has been considered since the onset. It was in the Senate committee on health support, and the transition team has discussed it. In each of those situations they said we should explore a third category, but should not let the length of time required to make changes at the level of the act slow down the process and benefits that can be achieved by the changes in the level of the regulations. That's why we pursued that.

We have regulations in place right now that have been there for over a year. Obviously when you're making changes to the act it's a much more complicated process. It has ramifications on regulations far beyond the initial intent, and you have to do it with very careful consideration as to what those outcomes are going to be. That's why we pursued the natural health products regulations the way we did.

[*Translation*]

The Vice-Chair (Mr. Réal Ménard): Thank you very much, Ms. Chamberlain.

Before adjourning the meeting, I will remind you that we will be meeting tomorrow at 9 a.m., in room 209, for the whole day, until 5:30 p.m.

The meeting is adjourned.

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