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Thursday, May 8, 2008

Chair

Mrs. Joy Smith

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● (1105)

[*English*]

The Vice-Chair (Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.)): I call the meeting to order. You've all had an opportunity to have a look at the agenda. I understand there's a notice of motion from Monsieur Thibault.

Hon. Robert Thibault (West Nova, Lib.): Rather than presenting this motion and having an extended debate on it—we have a lot of witnesses today—we've had discussions amongst the parties, and I think there is agreement to have a one-session study on the question of the Insite program before the date on which funding ends. So the meeting would be in the month of May.

The Vice-Chair (Mr. Lui Temelkovski): Mr. Fletcher.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Discussions have taken place. We'd be happy to facilitate that meeting with the minister before the end of May, provided the Liberals, the Bloc, and NDP don't defeat us on any confidence measures between now and then.

The Vice-Chair (Mr. Lui Temelkovski): Okay. Are we looking at May 27?

Mr. Steven Fletcher: Yes, I think it's May 27 or 29.

The Vice-Chair (Mr. Lui Temelkovski): Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Mr. Chairman, had we debated the motion, I would have wanted us to go much further than merely discussing the issue of safe injection sites in Vancouver as part of an AIDS prevention strategy. I would also have wanted to discuss the book and the one million dollars wasted.

Why does Health Canada feel that it is irrelevant to publish a book on AIDS prevention that includes a foreword written by Mr. Couillard? I would like to shed some light on this issue.

Also, I would like us to discuss the lack of funding for HIV-AIDS and hepatitis C sufferers. The AIDs question should be expanded. Injection sites in Vancouver are not the only issue here.

Although we won't be hearing from any witnesses on this subject, it would have been an important topic. If we want to do some AIDS prevention, we need to do more than just talk about injection sites in Vancouver.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Madame Gagnon, maybe I can encourage you to look at the motion and submit some friendly amendments for May 27.

Mr. Fletcher.

Mr. Steven Fletcher: I think we are fine with the Bloc raising those issues on May 27 or 29. I have had discussions with the Bloc health critic in this regard. If you would like to raise those issues with the minister at that time, that's fine. I don't know if we have to get into all the formalities of motions and that sort of thing.

Some hon. members: Agreed.

● (1110)

The Vice-Chair (Mr. Lui Temelkovski): Moving right along, pursuant to Standing Order 108(2), we have a briefing on natural health products.

From the Department of Health, we have Philip Waddington, director general.

From the Direct Sellers Association of Canada, we have Ross Creber, president; and Mark Priemer, president of MMP Enterprises Ltd.

From L'Apothicaire-Consultant, we have Jean-Yves Dionne, pharmacist. Welcome.

From the University of Montreal, we have Pierre Haddad, professor, department of pharmacology.

From the Canadian Cosmetic, Toiletry and Fragrance Association, we have Darren Praznik, president and chief executive officer.

I understand that each organization has been asked to speak for five minutes. If there are going to be two speakers, we'll let you divide the pie of five minutes yourselves.

We'll start with Philip Waddington.

Mr. Philip Waddington (Director General, Natural Health Products Directorate, Health Products and Food Branch, Department of Health): Thank you very much for the opportunity to come here to speak with you once again, Mr. Chair and members, about the natural health products regulations.

I believe everybody has the notes in front of you, so I won't read them word for word. I'll speak to the various points, and hopefully I'll be able to keep this within the five minutes we'll be held to.

As people know, the regulations came into force in 2004 for natural health products. We looked internationally at how products were regulated, we looked within Canada, we consulted, and we came up with regulations that we believe provided Canadians with what they asked for. They wanted products that were safe, effective, and of high quality.

When we met with people to look at how the regulations should unfold and what they should achieve, people basically said three things. They wanted to know that the products they were taking were safe—in other words, that they were not toxic and not contaminated. They wanted to know that what it says on the label is what is in the bottle. So if it says it is echinacea on the label, it has to be actually echinacea in the bottle, and if it says 100 milligrams, it should actually contain 100 milligrams. And they wanted to know that the product had a reasonable assurance that what it said it would do is what it would actually do.

That is what we believe we have achieved with these regulations.

If you look internationally, there are quite a number of different ways in which products are regulated. In some countries they are regulated as foods and in some countries they are regulated as drugs. In a few they are regulated with specific regulations, but the trend is toward having specific regulations for natural health products.

These regulations recognize that the products are generally of low risk. Under the framework we have, products are able to come to market with incredible evidence that the products are safe and effective in humans. This does not mean that every product has to have a clinical trial on that individual product, but it does mean there has to be evidence that the product is safe and effective in humans.

The standards of evidence that are applied in reviewing the products are proportional to the risk associated with them, and that's what we try to achieve with these regulations. For example, with traditional medicines, such as traditional Chinese medicine, some of these have had a long history of safe use, and we would turn to that safe use in evaluating the products. In other products we have done more modern or scientific research on them, and we've produced monographs, where people are able to look to the monograph that we have published on the web and make an application referencing that monograph for coming forward. So that is another way in which products can come forward.

In these monographs we outline what the appropriate dosages are, what claims are allowed within that dose for that product, and what the warnings are that should be applied to the product if it comes to market. For example, we now have a multi-vitamin, multi-mineral monograph, which covers the product that you would find under the product in that category. When an application is made for one of these products, we review the product application and respond with a licence or a refusal, depending upon how they've submitted it, within 60 days. We are getting back to these people who are making the applications in a rapid manner.

Under the natural health product regulations there are also a number of products that are now available in the Canadian marketplace that were not available before these regulations came into place. For example, licensed products can now be found on the market for melatonin, which has been used to help with sleep, for glucosamine sulfate, which is helpful with different types of joint pain, for 5-HTP, which is 5-hydroxytryptophan, and for L-lysine, which is used for cold sores. There are a number of products that people now have access to because of these regulations that they did not previously have access to.

Recognizing the risk profile of these products, in that they are relatively safe, we also apply our compliance and enforcement against these products, taking into account that risk profile. It is a risk-based approach as to how we're going to approach compliance and enforcement. We take action against those products that are of the highest concern, but we're not taking action against all products where there is any concern.

We do have to be aware that even though the products themselves, in general, are safe, we have to have some level of oversight. There are, for example, issues with respect to contamination or adulteration. There have been benzodiazepines found in natural sleep products, and these things can be addictive and habit forming, and they are products that we want to make sure we have oversight on. There are some companies that are repeat offenders in this regard, and we want to make sure we have oversight of them. With sildenafil and erectile dysfunction, there are a number of products that we find where there has been adulteration in that regard as well. So we want to make sure that while the original ingredients may be safe, we want to make sure that the entire product that has come to the market is safe.

Another example is with Kava. There has been an example where there were 14 accounts of liver failure associated with Kava, which is a herb that is used to help people calm down. The issue with Kava is that it was originally brought to market as a water-based extract. That's the way in which it was used traditionally. Over time that water-based extract was then moved to an alcohol-based extract. Later it became a pressurized acetone-based extract, and what gets drawn out of the herb is different under modern manufacturing conditions from what was originally drawn out of the herb when it was under its water-based extract. Simply because Kava may be safe, the way in which it comes to market has to be well looked at.

● (1115)

There are also increasing imports from China and India, and we want to make sure that the products—

The Vice-Chair (Mr. Lui Temelkovski): Can you wrap up, please? Thank you.

Mr. Philip Waddington: Wrap up?

The Vice-Chair (Mr. Lui Temelkovski): It's been five minutes. It goes fast when you're having fun.

Mr. Philip Waddington: I'll turn very briefly then to the performance within the natural health products directorate.

When I was here approximately two years ago, we had approved around 1,000 products and we had 100 site licences that had been processed by the directorate. Now we're at about 7,000 product licences and around 700 site licences. There isn't a backlog in the site licensing, and we're getting through the backlog in the product licensing.

It's estimated there were around 40,000 to 42,000 products when the regulations came in, in 2004. We received applications for just over half of those, and we've processed about half of those as well. We're now moving through this with a speed at which the number of licences for processing is greater than the applications coming in, and the backlog is in reduction.

The work that is under way, that we have put in place with respect to SOPs, with respect to batching products, grouping them together, with faster means of processing them, and electronic processing, have led us to a situation where we are confident that we'll be able to get through this backlog.

Thank you.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

We'll go to Mr. Ross Creber from the Direct Sellers Association of Canada.

Mr. Ross Creber (President, Direct Sellers Association of Canada): Thank you, Mr. Chairman.

Mr. Chairman and honourable members, on behalf of the 45-member companies of the Direct Sellers Association and our 600,000 independent sales contractors across the country, I want to thank you for the opportunity to participate in this consultation.

Our independent businesspeople represent such well-known names as Avon, Mary Kay, Shaklee, NuSkin, and Quixtar, whose retail sales in 2007 approached $2 billion. Some of the products sold include those regulated as natural health products, and as such, the efficient and effective regulation of these products is of great importance to our industry.

I last appeared before this committee three years ago as it studied Bill C-420. At that time, I suggested that the bill was a product of the frustration of Canadians who wanted ready access to natural health products and of the companies who wanted to market those products to Canadian consumers.

Three years later, the frustration continues, with long delays in the approval process and a significant application backlog. However, there have been improvements, and NHPD has certainly made real efforts to increase efficiency in product approvals. These are laudable efforts, but the situation remains bleak.

So what has caused the backlog? We believe that Health Canada was never prepared for the number of applications that came in, and we believe that the directorate is optimistic to think it will have the backlog cleared by April of 2010. To date, the directorate has received product licence applications for approximately 27,000 products.

The reality is that the backlog has led many companies to delay submitting product licence applications or even to pull out of the marketplace altogether.

Let me give you a snapshot of our NHP experience. Our member companies have submitted 380 applications. Of these, 369 have been acknowledged and only 131 completed. However, “completed” does not mean approved; it means dealt with. In this case, 70 of the applications are now licensed, 34 have been refused, and 27 have been withdrawn. So far, only 18% of member applications have been approved and licensed.

Part of the backlog has to do with the standards of evidence required by NHPD. While compendial applications do increase the efficiency of the process, they only work for single-ingredient products, whereas the market is largely made up of multiple-ingredient products. And the evidence required is, in our opinion, excessive. The directorate's statistics confirm that their biggest challenge is dealing with non-compendial, non-traditional product licence applications for multi-ingredient products. Without improvements in this area, all available products will have the same materials, dosages, benefits, and wording on the labels. There will be no perceived difference from one company to the next.

I want to focus now on the thousands of product licence applications that have been rejected by the directorate. While the regulations provide for appeals, the actual process is, seemingly, known only to Health Canada. The directorate continues to promise that this policy will be released, but it has been almost four and a half years since the regulations took effect. Given the lack of transparency about the appeals process, it is no wonder that the industry is frustrated.

I want to offer you one more illustrative example of how deep the problems have become for the direct selling industry. The distribution channel of our industry, multi-level marketing, is regulated by the Competition Bureau under sections 55 and 55.1 of the Competition Act. Some provinces in Canada require a written opinion from the Competition Bureau on the marketing plans of a company before they will issue a licence to the company to operate in their respective province. The written opinion covers all of the provisions in the act pertaining to the operation of an MLM plan.

The bureau is now invoking its powers under other sections of the act to review all materials and product claims relating to product performance, and in order to provide the written opinion it is requesting similar evidence to that required for licensing of NHPs. This is new and troubling for an industry sector that is already regulated in a number of different areas, both federally and provincially. In our discussions with the bureau on this matter, we asked if they were aware that Health Canada regulated these products under similar criteria. The response was that, in their opinion, the process at Health Canada was not working and that they were fulfilling their mandate under the act.

Of course, it makes no sense whatsoever to have two agencies of government duplicating the work of each other. But the inadequacies of the process at the NHPD have driven our industry to this point, and as such, I can see no greater proof of a problem than this.

The DSA is encouraged by the recent activity on Canada's food and consumer safety action plan. The frustration of our industry is matched only by our willingness to work with the government and this committee to effect constructive changes to the Food and Drugs Act and the natural health product regulations.

● (1120)

Mr. Chairman, on behalf of the Direct Sellers Association and its members, I want to thank the Standing Committee on Health for the opportunity to participate in this consultation process.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Mr. Creber. You were right on time.

I would like to note that I omitted mentioning one of the groups with us today, the Option consommateurs, and Geneviève Reed and Anu Bose, who will also be presenting.

Now we will continue with Jean-Yves Dionne.

● (1125)

[*Translation*]

Ms. Christiane Gagnon: Mr. Chairman, could you possibly ask the witnesses to speak more slowly. I'm having a hard time keeping up with the interpretation.

Mr. Jean-Yves Dionne (Pharmacist, The Apothecary-Consultant): Good morning.

This time around, I will be making my presentation in French.

As a pharmacist, I believe the product licensing problem stems from a dispute surrounding the scientific data. There was an attempt made to impose a pharmaceutical model on products the use of which has nothing to do with the pharmacological model of one molecule—one receptor—one effect. We're talking here about extraordinarily complex products. A single plant can contain several active ingredients. When we're dealing with complex products—and Mr. Creber alluded to this—we're getting into a complex area where stakeholders tend to get completely confused by all the regulations.

Pharmaceutical products are patented products. The patent guarantees a protected market which makes return on investment possible and generates revenues to cover the cost of the research required by Health Canada. The problem with small companies—and in Canada, barring exception, companies that make natural products are small—is that they simply do not have the resources, whether it be to obtain scientific data or to keep pace in terms of financial and human resources. A number of small companies are thinking about closing their doors because of the cumbersome legislative requirements.

As I've already said, I'm a pharmacist and from my vantage point, I see both sides of the issue. When reviewing this whole question, it is very important to look beyond the people who are armed with university degrees, however knowledgeable and amazing they may be, and look to people with genuine ability in the area of product formulation. These people know why a given ingredient is used in a product, but they do not rely solely on lists. They also have practical skills that cannot be acquired in a classroom. They understand why a particular formula must contain a certain ingredient, or why another formula is totally harebrained, despite the accompanying scientific data.

One example I have for you is Red Bull, the leading energy drink on the market. To my knowledge, this product received the first ever NPN licence awarded in Canada. The pharmacological file on this product is extensive. However, is the safety of the product guaranteed? Has any follow-up been done with young people? Has anyone checked to see what happens when the product is combined with alcohol, or what the effects can be from an overdose or from chronic use of the product? No one has looked into this. I repeat, this is a well made, legitimate product, but it may not be as safe a product as it should be. You can read about this in my notes. I have made copies for everyone.

Do we need the same protective criteria for totally new, synthetic, biotechnology compounds as we do for organic echinacea tea formulated by the local herbalist? Of course, there will be a product monograph for the echinacea. However, when two plants, or native plants are combined and there is no product monograph, the poor herbalist will not have the resources to complete the file. The product will therefore be lost.

Summing up, I have to admit that the NHPD has done a very admirable job indeed. The creation of a third category is a first of its kind, or almost, in the world. This initiative deserves to be supported because in my estimation, natural products are neither drugs nor food substances. They fall into both categories.

Thank you.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): *Merci, Monsieur Dionne.*

Now we move on to the University of Montreal. We have Pierre Haddad.

[*Translation*]

Mr. Pierre Haddad (Professor, Department of Pharmacology, University of Montreal): Good morning. I too will be making my presentation in French, if that's fine with you.

I would especially like to thank Christiane Gagnon for inviting me here, as well as her team and the clerk for helping me prepare my presentation. I would also like to extend my congratulations to Health Canada and to the NHPD in particular for trying to be rigorous from a scientific standpoint and at the same time for keeping an open mind when broaching the subject of natural health products. I agree with you that a separate category should be created for these products.

I will come back to the very laudable principles behind the regulations, which are now recognized as a model around the world. As Philip Waddington stated, these principles are based on freedom of choice and access to natural health products, as well as on the assurance of safe and high quality natural health products.

Today, I want to touch on three main points: safety, natural health product and drug interactions and the importance of research. I am the only witness here today from the world of academia. As you will see, many things are directly related to research.

The first thing I want to discuss is safety. Health Canada and the NHPD have issued many guiding principles, but there are four areas in particular that I want to touch on. The first relates to evidence. Health Canada has demonstrated its innovative spirit by including as evidence information stemming from medical and traditional knowledge. That is very laudable. Of course, this information is at the bottom of the evidence scale, but it is important to include it as health evidence.

According to the second guiding principle, all of the evidence must be weighed from every angle. This brings me to the third point, namely risk management. Basically, the Health Canada approach consists of assessing risk against benefits. I will give you an example of this later. Another guiding principle is that when in doubt, a person should abstain from using a product. If there is any risk, a person is better off not using a product.

I'd like to discuss the use of natural health products. In Canada and around the world, between 65% and 80% of the world's population use natural health products, compared to a much smaller proportion of people who must use synthetic drugs. This is an important statistic to remember.

From the standpoint of pharmacovigilance, natural health products are considered to be safe and available information shows that unwanted side effects are very rare. In the majority of cases, poor product quality is to blame. For example, the side effects could be caused by a bad plant, cutting or contaminants, as Mr. Waddington mentioned. The regulations governing sound manufacturing practices already address many of these problems because they call for the identity of the plant and the presence of contaminants to be verified.

Another thing to consider is that some available over-the-counter drugs such as acetaminophen also pose a real, serious risk. If a person ingests 10 to 20 times the recommended dosage, death could ensue, although this is not in fact noted anywhere on the label. The manufacturer relies on consumers.

I also think that the Natural Health Products Directorate is being somewhat alarmist about natural health products. This attitude is fueled to some degree health care professionals. It also stems from the lack of knowledge of health care professionals and from the lack of evidence on natural health products. Research in this area is therefore very important.

● (1130)

The principle whereby a person should abstain from using a product when in doubt takes precedence over all the others. I would say that when in doubt, a person should rely on human experience and on traditional medicine.

I wanted to touch on several other points, but I will move directly to drug interactions. Here again, there is a disconnect between the perceived risk and the real risk. People often use theoretical evidence to issue a warning against the danger of combining natural health products. However, if we consider the real evidence, we see that there is very little evidence that this is in fact the case. I strongly recommend that solid evaluation mechanisms be developed to weigh both risks and benefits.

Finally, I would like to talk about the importance of research. The NHPD is the only regulatory body with the funding to promote research and the mandate to promote research on natural health products. Unfortunately, its funding has been withdrawn. While the $1 million in funding was not a large sum of money for Canada, it still had an important effect in terms of leverage. I strongly urge you to restore this funding to promote research so that we are better equipped to assess both the risks and the benefits.

Thank you.

● (1135)

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Professor Haddad.

Now we'll move on to Mr. Darren Praznik, the president and chief executive officer of the Canadian Cosmetic, Toiletry and Fragrance Association.

Mr. Darren Praznik (President and Chief Executive Officer, Canadian Cosmetic, Toiletry and Fragrance Association): Thank you very much, Mr. Chair and honourable members of the committee.

On behalf of the CCTFA and our more than 160 member companies, which represent about a $5.4 billion industry in Canada, we'd like to thank you for the opportunity to speak to you on this very important particular matter. We have already forwarded copies of our brief, I understand, in both official languages to your office and staff, and we have distributed copies here as well.

First, let me just say that the member companies of our association continue to be and always have been supportive of Health Canada in its efforts to ensure the health of Canadian consumers. We know that Health Canada takes its job very seriously and strives to make decisions on the basis of sound science. We as an association also very much share the belief that regulation should be both effective in achieving its health outcomes and efficient as well in its operation. That's why as an association we support the amendments to the Food and Drugs Act that are being proposed by Bill C-51.

It is in the area of efficiency of operation, however, that we have our particular issues with the natural health products directorate. The first one I want to address, and it's been talked about already, is the backlog.

I very much appreciate the position Mr. Waddington is in. I know they work very hard at addressing that backlog. He keeps us well informed. We know as well that earlier this year we were looking actually at more applications coming in for non-compendial products than were being processed every day, so the backlog was expanding. We're glad to hear that you may have turned that corner.

But it really is unacceptable. Although they're trying very hard, they need to be sufficiently resourced and supported to be able to manage this particular backlog. We have member companies who don't even bother now bringing products in, if they have to wait a year or two to go through the process. We very much share the views that were expressed by the Direct Sellers Association of Canada.

Our recommendation to you today is that you don't want to get in their way to ensure that they're spending more time answering for what they're doing than addressing the backlog; that would be an unintended consequence of this committee's interest. But we think they need to be brought back on a regular basis to this committee to report on their progress and be able to get that backlog eliminated in as short a time as possible. That's enough said, I think, on that particular issue.

The other issue we would like to address is what we view as the unintended consequence of creating a third branch of regulation for what in essence are personal care products. When the NHP branch or division was set up under drugs, it was intended to address what were lower-risk products within the drug category.

All of the products that were in personal care products had traditionally been regulated under cosmetic regs or drug regs. When NHP's were created, the drug regs created a further subcategory. Our products were already regulated under drugs; they included antiperspirants, fluoridated toothpaste, anti-dandruff products, medicated skin care products, antiseptic skin cleansers, acne products, and primary sun screens, including makeup that had an SPF. These products were regulated under drug regs but were moved, because of their composition, under the NHP regs, which were intended really for a lower category of risk.

Because our products are generally very low-risk, I don't think enough attention was paid to the detail in similar regulatory regimes. The result is that we ended up with two very odd—I would argue unexplainable—and costly differences in regulation.

One, of course, was tamper-proof or tamper-evidence security packaging. I want to illustrate with the two products I have with me. I didn't bring them today because Phil and I thought it would be a hot debate and we needed extra antiperspirant, but these are antiperspirants. One is a drug; the other is a natural health product.

When the regs for the natural health products were set up, they followed pretty similarly the packaging requirements for drugs, except that they didn't include...the technical term, I guess is the "exclusion for topical products". The result is, if you buy a drug antiperspirant in Canada, you do not need tamper-evidence packaging, but if you buy an antiperspirant that is a natural health product, with supposedly a lesser degree of risk, you need to put on a tamper-evident package.

I don't think anyone ever intended that to happen, but it was an unintended result of not matching the same level of regulation.

Manufacturers both in Canada and abroad who ship antiperspirants that are NHPs into Canada spend literally millions of dollars putting tamper-evident protection on your antiperspirant that adds really no value but that costs the companies and consumers millions of bucks.

Is that really what we're intending to do: have an unintended consequence of not making sure regulations match?

● (1140)

The second area that we just flagged is heavy-metal testing. Again, for NHPs, heavy-metal testing is required for our level of low-risk products. Nowhere in the world has that yet been required, but for drugs, supposedly a higher-risk heavy-metal testing is not required. Again, we have two sets of regulations applicable to drugs, which are supposedly higher-risk, and NHPs, which are supposedly lower-risk, and they don't match. The consequence to Canadian industry and Canadian consumers is having to pay a lot of extra money for, I would argue, no additional value. Again, there are unintended consequences and some oversight. We've been raising this issue for four years. I think there's some progress on addressing the antiperspirants issue, but we raise it and bring it to your attention again.

Thank you for your time, Mr. Chair.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Mr. Praznik.

Now we have, from Option consommateurs, Geneviève Reed.

[*Translation*]

Ms. Geneviève Reed (Head, Research and Representation Department, Option consommateurs): Mr. Chairman, honourable vice-chairs and members of the committee, good day. I want to thank you for this opportunity to share our views on the main concerns that consumers have about natural health products. We will be focusing in particular today on licensing, evaluation and risk communication, consumer information and marketplace monitoring.

Established in 1983, Option consommateurs is a non-profit organization that has a mandate to promote and defend the interests of consumers and to ensure that they are respected. Our organization speaks out on regulations and on federal and Quebec policies. Our interest in the use of natural health products dates back to 2000 when we published an initial article on natural health product and drug interactions. We observed that consumers underestimated the risk of combining natural health products with drugs and that few pharmacists and doctors were in a position to give them information about possible interactions.

Through Health Canada's Population Health Fund, we have compiled for consumers a guide to natural health product and pharmaceutical interactions. We have produced two editions of this guide and over 500,000 copies have been distributed in Quebec alone. Since May 2006, we have also represented Canadian consumers on the advisory committee of Health Canada's Natural Health Products Directorate.

I would like to begin by focusing on product licensing. On April 15 last, we learned that a Quebec pharmaceutical company by the name of Neurochem, now known as Bellus Santé, was planning to market by year's end a product called Vivimind which is used to treat memory loss. In fact, Vivimind is the new name for Alzemed, a product used in the treatment of Alzheimer's which the US Food and Drug Administration refused to license. No doubt this will not be the only case of this kind in the coming years. Given that pharmaceuticals sales are declining sharply in wealthy countries, other pharmaceutical companies may decide to turn their attention to the natural health product market to finance research into new pharmaceuticals, particularly since the licensing of a natural health product in North America takes considerably less time than the licensing of a pharmaceutical.

However, how will pressure from the large pharmaceutical companies affect the natural health product licensing system?

We believe it is critically important to allocate additional resources to the risk assessment and communication process, particularly with regard to more vulnerable clients such as seniors and children. In 2005, the Canadian Paediatric Society expressed concern about the lack of scientific evidence as to the efficacy and safety of NHPs when used by children. We believe that issues such as deciding on the optimum dosage for young children as well as health product interaction with pediatric pharmaceuticals must be addressed.

Quite apart from the risks, consumers also need to know about the regulations governing NHPs and how they can file a complaint if a problem arises. Consumers must have access to clear information at the point of sale about the identification number of natural and homeopathic products. The consumer needs to be aware of the ingredients contained in these products.

Problems with the advertising of NHPs also top our list of concerns. The advertising of these products must be better regulated to avoid situations where Canadian consumers are misled. We also believe that the study of and research into natural health products should be part of the curriculum and ongoing training of doctors and pharmacists.

Finally, not only should NHPs be subject to rigorous trials prior to licensing, they should also be monitored after they go on the market.

The following guiding principles should apply when it comes to protecting consumers from natural health products: compliance with strict licensing rules, independent risk assessment and communication in clear and simple terms, regulation of advertising and marketplace monitoring.

Thank you for having us and for listening to our concerns. We will now be happy to answer your questions. Thank you.

● (1145)

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Madame Reed.

Now we will continue with questions and answers. Due to the heavy schedule today, there will be one round of questions of five minutes.

We'll start with Madam Kadis.

Mrs. Susan Kadis (Thornhill, Lib.): Thank you, Mr. Chair.

Welcome to all our guests.

I'm interested to know a few things today, very briefly. One would be your rate of refusal for applications. I know that many, it's been suggested, are voluntarily withdrawn. I'm interested to know how many are failing the approval process and why.

Also, I'd like to know where the data is going. We have recently been discussing post-market surveillance and adverse drug reactions and how industry has that information, as well as doctors, but not on a mandatory basis. Hospitals will have it shortly. Where is this information going so that we know whether there are adverse reactions to natural health products? Who is collecting the data?

I am a little bit concerned that research has been withdrawn from the directorate. I'm also interested to know about that. Why was that withdrawn? I would think it would be very important, considering that so many Canadians are using natural health products, probably more so, in particular, with an aging population. It's a very important area.

Mr. Philip Waddington: I think that one goes to me.

There were three parts, as I understand it, to your question.

The first was about where the data goes with respect to ADR—adverse drug reactions. The reports of serious and unexpected adverse drug reactions or adverse product reactions for natural health products go to the same database as the ones for drugs. The marketed health products directorate would collect that data and do the same thing they would do for drugs. They would look for a signal and whether there is something that should be a concern, and they would raise that up through the same process. So it's collected and processed in the same manner. Companies are required to submit the severe and unexpected adverse reactions but not the ones that are anticipated, such as, for example, flushing and things like that. So it's a similar process.

With respect to research, when we came into play we were funding research. A lot of it was seed funding that would go towards helping other applications for research down the road. It was considered successful by many. But it was anticipated to be a four-year program, and it has wound up. Now, there could be debate about what happens with that. We respond to the will of Canadians. When it was put in, it was a four-year program, and that has finished. So that's what happened there.

With respect to the refusals and the ones we've not licensed, we've licensed approximately, in total today, about 7,000. We've refused about 6,400. So it's close to 50-50, but it is just over to the positive side.

The reasons we refuse a product are varied. And I'll be honest; the reason we refuse them is usually not because the product is found to be toxic. That is why we use a risk-based compliance approach. If a product application comes to us and we're not aware of the toxicity, we don't take action against that product. It would only be if there was a toxicity or a concern about it in that regard. When an application is refused, the usual reason is that they have not provided the data we asked them to provide. For example, they may have a product that has three medicinal ingredients in it, and they will only provide the data to support one. We will write and ask them to provide data for the other two, and they'll come back and say, “How about this claim?” That happens all the time.

We're working with industry. I will say for sure that the quality of the applications we've been receiving over the last year has been better than it was for the applications we received previously. The training sessions and the dialogue with industry and working together to come up with an improved process is working. But we still have to process those applications that came in back when we first started the regulations. And that's why there's some delay.

The usual reason for refusing an application is because we have been unable to obtain the required data on the ingredients listed for the product.

● (1150)

Mrs. Susan Kadis: Okay.

If I have a little more time, Mr. Chair, there's some reference to adding resources to clear out the backlog and move these along or facilitate that. What types of resources have you added in terms of applications? Is it personnel?

Mr. Philip Waddington: There were a couple of comments around resources. I would like to reiterate that a number of the members felt that we should be better resourced. I just want to put that back on the table.

What we've been doing with our resources internally is twofold. We've been trying to allocate people off more of the processing tasks and onto the ones where they actually have to review an application. So we're trying to be more efficient in our oversight.

The other thing we're spending a lot of time on, that we think is going to become beneficial for us, is electronic processing. What that does is twofold. It makes it less of a burden for industry, because they are able to fill things in electronically. I'd like to take a moment to talk about this.

We've recently piloted a process—and if you speak to any of the members who have been involved in this pilot, it's around 100 or 120 of them—where companies can download with Adobe, which is free to the applicant, and fill in an application to Health Canada, submit it through epost, and we can receive it on our desktop. This is the first time in the branch you're able to go from the desktop of the applicant to the desktop of the reviewer electronically.

I wish this meeting were happening two weeks from now, because next week we're going to be putting out the next version of our database, which references all the warnings and claims that are known around it, so people will be able to incorporate that into the applications that are coming forward. The week after that we're going to be putting out the version that will allow them to tie the compendial applications to that database.

The movement we have been putting towards having this electronically available and working with industry to make sure we reduce the requirements on them, but also, at the same time, to make sure that the products are safe and efficacious, is really coming to fruition right about now.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much. I would encourage you to submit the information within two weeks to our clerk. That will be very helpful to us.

We'll move on to Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: Thank you all for shedding some light on this very important issue in terms of the safety of natural health products.

I am concerned to see that several products on the market have not yet been assigned a number by the Natural Health Products Directorate.

Mr. Waddington, you analyse these products when a licensing application is made. It would appear that the level of risk is not the same for all products. Do you prescreen the applications, or do you review them as they come in? How do you proceed?

[*English*]

Mr. Philip Waddington: We receive information around the risk of the product from a number of situations. When an application is made to us, we have a list of the ingredients. There are also products for which, unfortunately, applications have not been made, so those would be found in the marketplace. We hear about them through competitors, usually, who will say, “There's a product on the market that contains an ingredient about which I'm concerned.” Those come to us as well.

When we review them, we look at them on a case-by-case basis, but at the same time, to improve our efficiencies, we batch them together. Using the example of glucosamine sulfate, we will gather those applications together and process them as a group to try to move it ahead more quickly. So we do both things. We look at them individually, we screen them when they come in, we look to the marketplace for what is available and what may be of concern out there, and then we group them together and process them as a unit to try to gather as much efficiency into that evaluation as we can.

● (1155)

[*Translation*]

Ms. Christiane Gagnon: Several witnesses brought up the subject of labelling. It seems that quite often, consumers are not given enough information about the effects of taking a drug in combination with a natural health product. For example, taking garlic and ginkgo along with a drug like Coumadin can produce some side effects that can adversely affect people's health.

Do we need to be much more proactive and adopt regulations governing the labelling of natural health products?

Other witnesses besides the Health Canada officials can answer this question.

Mr. Jean-Yves Dionne: I believe we're already seeing such warnings on product labels. For example, the label on a product containing ginkgo biloba will warn users not to take this product with an anticoagulant or a drug. Labels already contain warnings. Of course, this is not true of all product labels. Last year, there was a case of St. John's-wort interacting with a drug and causing a pregnancy. Health Canada and the industry are still feeling their way on this. However, the warnings are going out on product labels.

Ms. Geneviève Reed: Labelling is very important, but consumers also need to check with their practitioner, doctor or pharmacist. Consumers have trouble admitting that they are taking a natural health product along with their drugs, whereas this is a very important consideration.

Mr. Pierre Haddad: It is also important to weigh the evidence. In many cases, the analyses do not reveal as high a level of risk as anticipated. With respect to ginkgo, meta-analyses, that is an analysis of all information contained in literature, did not result in a finding of a clear association. One of the criticisms I had about the guide had to do with the small image of a microscope appearing alongside very theoretical or in vitro trials. So then, it is important to proceed with caution when passing messages along to consumers.

Ms. Geneviève Reed: I simply want to point out that this image was removed from the second edition.

Ms. Christiane Gagnon: Like many other people, I too use natural health products. These are viewed as a miracle cure for a number of health problems. Some believe that if they use these products, they will not have to see their doctors.

The impression we have is that people are not taking the warnings about natural health products seriously. Yet, they should be taken seriously. What can we do to make people understand this?

Mr. Pierre Haddad: As the representative of Option consommateurs said, education is the key. It's all well and good to tell people to check with their doctor, but if the doctor is not properly informed, then what is the point? Pharmacists, on the other hand, are slightly better informed. It is also time to debunk the myth that because a product is natural, it is harmless and at the same time, better for you.

It would be important to point out that natural health products help a great deal to prevent illness. People take these products to stay healthy, which is not the case with pharmaceuticals. What people are in fact doing is trying to stay healthy and not get sick.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Thank you.

Madam Charlton, welcome to the committee.

Ms. Chris Charlton (Hamilton Mountain, NDP): Thank you, Chair.

I appreciate the submissions you made here today. It's clear that there's a real tension between effective regulation and efficient regulation. I also recognize that we're talking about these issues at a particular point in time.

Bill C-51 is just around the corner. None of you has mentioned it today. I know that you're probably going to be back here chatting about it some more. I wonder if I could lead you there now, though, in light of some of the concerns you've been raising.

I've heard from a lot of people in my community and across the country who are worried about the impact of Bill C-51 on natural health products. In that bill, it seems to me that what we're doing—

● (1200)

The Vice-Chair (Mr. Lui Temelkovski): We've had discussions about that, and we'd prefer not to ask questions on Bill C-51.

Ms. Chris Charlton: So we'll just pretend that we don't even know about it?

The Vice-Chair (Mr. Lui Temelkovski): We will have subsequent meetings devoted to it—that's the only reason.

Ms. Chris Charlton: Fair enough. I'll ask the same questions in a different way, then. I'll ask it in a more open-ended way.

Hypothetically, if there were some regulatory changes coming, what improvements would each of you be looking for in the regulatory environment?

Mr. Mark Priemer (President, MMP Enterprises Ltd., Direct Sellers Association of Canada): Working on behalf of many of the client companies and members of the Direct Sellers Association, we've been involved in submitting many applications. One of the things we complain about most frequently in our internal chats is that the regulations now seem to be a bit of a moving target.

We appreciate that regulation must be in place. We support the notion of safety above all other things. But with respect to proving efficacy, we have often found that matching the scientific literature to the products and the product licence application has been exceptionally difficult. In many cases, it is virtually impossible. We are hoping that there will be some measure incorporated to permit either extrapolation from the scientific literature or interpolation within the scientific literature. This would ease our path.

I said that the regulations sometimes seem to be a moving target. We have submitted perhaps more than 100 submissions for vitamins and mineral supplements, yet we frequently find new things appearing in information request notices. We're looking for the opportunity to learn from experience, which sometimes is not possible. Three or four years into the process, just when we thought we'd started to master it, we find we are still facing things for the first time.

Mr. Darren Praznik: Mr. Chair, if I could address that as well, I would say, very simply, if we're looking for regulatory change.... We live in a world with regulation or a regulatory structure that is 50 years old, so if there's one thing we need, it's a modern regulatory structure that allows the department to do a couple of things. One is to structure its regulations, whether they're for NHPs, or drugs, or cosmetics, or food, what have you, in a way that assesses risk and applies the appropriate level of caution, concern, or oversight to the appropriate level of risk. Their hands are tied today. They're limited in what they can do, because Parliament hasn't empowered them with modern enabling legislation.

The second thing I would suggest is that as the science-based regulators in a world with changing product lines, changing knowledge of risk, they need the ability to adjust those regulations from time to time—with the oversight of cabinet, at the political level—to be able to respond in a timely way to emerging product lines, emerging risk, emerging levels of knowledge. Currently, we all suffer from a regulatory regime that is 50 years out of date because the Parliament of Canada has not dealt with that issue. So if you want a regulatory regime that works, it needs to be modernized to meet the modern world.

Mr. Pierre Haddad: I would say it's to add to your listing methods, because natural health products cannot be evaluated with the pharmacology model that Dr. Dionne mentioned. I think new tools are necessary, and new approaches need to be considered scientifically.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much. That was a very good question.

Mr. Fletcher.

Mr. Steven Fletcher: Thank you, Mr. Chair.

I'd like to thank all of the witnesses for coming. In particular, I'd like to recognize Mr. Praznik, who was a former health minister in Manitoba and did a great public service for our province.

My questions are for Health Canada. After I have asked the questions, I would like to open the floor to comments on Health Canada's answers. You've been warned.

Could you expand on the initiatives and describe how they have sped up the review of licences and reduced the regulatory burden on industry, if that has indeed happened?

Also, I wonder if you could expand on what the standards of evidence for NHPs are and how they reflect the relative risk of the products.

I'd also like to ask about the issue that Mr. Praznik raised—the difference between the container protection between the two products. Why is that, and is it necessary?

● (1205)

Mr. Philip Waddington: Thank you for those questions. There were three, if I understood, and I'll answer them in the order you delivered them.

The first was whether you could have a little bit more detail on the processes we've been undertaking and what we're doing around that. There are many and they are varied, but I will summarize them.

Regarding the comment we heard earlier about a moving target, while I might have chosen different wording on that, I understand what's happening. It's a new directorate. We've been trying to work with industry to develop things that go forward. As we do that, we've been evolving in our understanding of what's coming in. As well, industry has been evolving in their understanding of what to deliver.

We've now come to a point where we think that moving target has been solidified. We have SOPs—standard operating practices—in place in-house for any application that comes in. What are the details that are required to be there up front? What are the things we can ask for? When would it be considered efficient for us to go out and look for information, and when should we turn to facts? We're much more consistent in the decisions we make, and therefore we spend less time debating whether we should be proceeding down one path or another.

We're also looking to expand what we're talking about as our risk-based approach. So instead of just looking into Canada for the information we can have within our walls, we're looking to other regulatory agencies. We look to Australia, which has a regulatory framework similar to Canada's—not the same, but similar—to see what kinds of decisions they're making and how we incorporate them into the decisions we're making here.

We're looking to groups in places like Singapore where they are regulating traditional Chinese medicine specifically. If we can look to the decisions they're making and incorporate them into Canada, we'll be able to process things much more quickly.

Probably the most significant thing we're doing to decrease the burden on industry is, as I mentioned, putting forward electronic processing. If companies are able to point to data we've collected, which summarizes for them the information that we believe is pertinent, and make an application based on that, then it really reduces the amount of work they will have to put forward. If a company wishes to use a dose beyond what we have collected, or to come up with a claim beyond what we have understood from the literature we've reviewed, they're not prevented from doing so. They would just have to provide additional data in doing so. So it allows for the variation that any applicant would want to have, but at the same time it could speed up the application and decrease the workload for those who wished to follow those routes.

On the second question, regarding standards of evidence, there is what we always refer to as the totality of evidence. We look at everything. We look at clinical trials. We will look at that data when it's presented. We look at meta-analyses in which data is brought in from a number of different trials and summarized together. We look to cohort studies or epidemiological studies that look at how products are used in people but not necessarily with the same randomized crossover consideration that you'd have for a clinical trial. We look at traditional use. We look at animal studies. We look at all of the data to determine whether there are indicators that there may be associated risks and whether there are indicators that the benefits there would outweigh those risks.

People often indicate to us that they believe there is a clinical trial required for every product. Now we do require the submission of data showing that the product is safe in humans, for sure, and that it's effective in humans, for sure. But there is not a clinical trial on every product. We've approved approximately 110 clinical trials over the regulations, and we've approved approximately 7,000 products. So clearly the linking of a product to a trial is not what's going on. We're really looking at the totality of evidence, what's available in the public domain, and what individual evidence a company can gather and bring forward as well.

With respect to the differences in the packaging, the regulations around natural health products are more modern than the regulations around other product categories out there. When we brought in the regulations, we decided there were a number of things we should be looking at. Tamper-evident packaging is something consumers want. If you're buying something, you want to make sure somebody else hasn't been using it.

We applied it across the full range of natural health products. We did not, as has been suggested, exclude one category from another, because there have been situations in which there can be concern around anything that can be tampered with. If it's going to be put on your body or consumed in your body, there can be differences. So we've looked at this, and we may be able to come to conclusions that will work for people. But as we stand right now with the more modern approach to this than the other regulations that apply, we have said that tamper-evident packaging is something that in general, from what we have heard, Canadians would still want.

● (1210)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

I'm sorry, that concludes the—

Mr. Darren Praznik: I can't defend my antiperspirant?

The Vice-Chair (Mr. Lui Temelkovski): I think you've done a great job.

Thank you to all the panellists.

We'll move into the second panel now. We'll take a one-minute break to change the panels.

Thank you.

● _____ (Pause) _____

●

The Vice-Chair (Mr. Lui Temelkovski): We will start with our second panel.

On the second panel we have the Canadian Health Food Association, Penelope Marrett and Anne Wilkie; Truehope Nutritional Support Ltd., Ian Stewart; the Canadian Coalition for Health Freedom, Trueman Tuck; the Natural Health Products Protection Association, Peter Helgason; and the Canadian Men in Nursing Group, with James D'Astolfo and Branden Shepika. Welcome.

We'll start with Penelope Marrett for five minutes, please. If you have additional information that you may not get through in the five minutes, please do supply it to us. We look forward to receiving more.

Thank you.

● (1215)

[*Translation*]

Ms. Penelope Marrett (President and Chief Executive Officer, Canadian Health Food Association): Good day, ladies and gentlemen. Thank you.

The Canadian Health Food Association, or CHFA, is Canada's largest national trade association dedicated to the natural products industry.

[*English*]

CHFA is Canada's largest national trade association dedicated to the natural health and organic products industry. Our 1,300 members represent the entire supply chain, including growers, manufacturers, retailers, wholesalers, distributors, and importers. Our members are involved in a variety of subsectors, such as vitamin and mineral supplements; herbal products; homeopathics; sports nutrition products; and natural and organic foods, fibres, and health and beauty aids. Natural health products have become increasingly popular as Canadians look for better ways to manage their health. In fact, over 75% of Canadians purchase natural health products. The Canadian NHP industry is currently valued at over $2.5 billion.

I would like to speak immediately today about the challenges our industry currently faces as well as the recommendations we propose as the voice of the natural products industry.

Specifically, our members have serious concerns around the current interpretation and implementation of the natural health products regulations. The 1998 Standing Committee on Health's report, *Natural Health Products: A New Vision*, laid the groundwork for the creation of a unique framework for natural health products founded on the acknowledgement that natural health products were of low risk and were neither foods nor drugs. The government is to be commended for its timely implementation of some of the 53 recommendations from this report.

In 2004, the natural health products regulations came into force. However, the regulatory requirement to license some 50,000 products and over 800 domestic sites has led to serious disruptions in the marketplace, including decreased product innovation, loss of products, inability to advertise, and consumer confusion. In addition, the current instability of the marketplace is driving business away from Canada and restricting product choice.

The government is to be acknowledged and recognized for providing additional funds to the natural health products directorate—NHPD—in its most recent budget to assist in dealing with this enormous backlog. However, it will be important for these funds to be used in a manner that will enable the backlog of submissions to be reviewed and licensed in the most expeditious manner possible.

The CHFA is very concerned that with the increasing pressure on NHPD to deal with the backlog, an inordinate number of submissions are being rejected due to administrative issues that we believe could be easily solved with direct contact between the directorate and the applicant.

Further, changing and increasingly rigid policy interpretation continues to frustrate applicants and drive businesses away from Canada. As an industry dedicated to the health and well-being of Canadians, we want to ensure that Canadians can continue to rely on safe and effective natural health products. This can only be realized if the directorate has a clear direction on how to move forward, has the support of the department and stakeholders, and is provided with the necessary resources and expertise.

Furthermore, on the issue of the 53 recommendations, despite the implementation of many of these over the past 10 years, there are still many recommendations that our members have identified as being inconsistent with the standing committee's intent in the way they are interpreted and/or applied by the directorate. In CHFA's brief we discuss a number of recommendations that have not been addressed. I will highlight only one, the one that we believe is most critical to our industry.

Specifically, it is important that the government consider creating a separate category for natural health products, which is the very first recommendation in the 1998 health committee's report. Currently, natural health products are considered to be a subset of drugs; this is clearly contradictory to the findings of the Standing Committee on Health, which stated that NHPs are neither food nor drugs.

We believe this legislative classification places an unrealistic burden on an industry that manufactures, imports, distributes, or sells products that are of low risk. If the establishment of a separate category for natural health products is in legislation, we believe the low-risk nature of these products will be appropriately reflected in the implementation and interpretation of the NHP regulations.

Thank you very much.

Merci beaucoup.

● (1220)

The Vice-Chair (Mr. Lui Temelkovski): We'll now move on to Ian Stewart.

Mr. Ian Stewart (Director, Regulatory Affairs, Truehope Nutritional Support Ltd.): On behalf of Truehope, we express our gratitude for being able to be here today and to be heard.

Truehope Nutritional Support Ltd. is an Alberta-based non-profit organization that provides a unique nutritional supplement and program to Canadians who suffer from bipolar and other mood disorders. Truehope has had a long struggle with Health Canada. Co-founders Anthony Stephan and David Hardy appeared before this committee on May 16, 2005.

Truehope was charged by Health Canada for unlawfully selling a drug without a drug identification number and appeared in 2006 before the Provincial Court of Alberta. The following is an overview of the principal points of the decision of Judge Gerard M. Meagher in awarding Truehope their defence of necessity and due diligence.

Point 1: The evidence presented by Truehope was credible and compelling. When the supplement was removed, violent behaviour, mood swings, and the possibility of suicide quickly returned.

Point 2: The Alberta head of the Canadian Mental Health Association expressed grave concern for the conduct of Health Canada, and there would be suicides if the supplement was prevented from reaching those in need. He testified that he knew of cases and even attended the funeral of one of the people who chose suicide rather than go back to the treatment Health Canada had directed him to do.

Point 3: The court found it reasonable that Truehope participants were in imminent peril or danger without the supplement.

Point 4: Ample evidence was presented to the court that Health Canada was aware of the possible harm to participants, especially evidenced in Health Canada's conduct in setting up a 1-800 crisis line.

Point 5: Truehope was overwhelmingly compelled to disobey the regulation in order to protect the health, safety, and well-being of participants.

Point 6: A double standard existed where Truehope could get no resolution. Yet the Canadian Mental Health Association was successful each time it intervened on behalf of its members.

Point 7: Health Canada's response to the public outcry was to encourage psychiatric treatment with medications that had negative side effects.

Point 8: Truehope was under a duty to provide the supplement as described in sections 216 and 217 of the Criminal Code of Canada, where complying with regulations is no defence to charges of criminal negligence.

Point 9: The harm that was sought to be avoided in disobeying the regulations was significant and severe. The harm inflicted in the circumstances of disobeying the regulations was insignificant when compared to the harm avoided. Truehope is granted a defence of necessity.

Point 10: It was evident that Truehope took all reasonable care to comply with the law in the circumstances and is awarded a defence of due diligence.

Point 11: While not the clearest case of abuse of process, the court found that some of the conduct of Health Canada would influence Truehope's belief that no legal alternative was left to it, and it had to disobey the regulations, although all reasonable care was taken to comply with the law.

I'll bring your attention to just some of the points in these excerpts from the court's decision.

In section 102, near the end of the paragraph:

> They [Health Canada] were aware of the letter of March 6, 2003 from the Defendants [Truehope] to Health Canada voicing concerns that denial of the supplement would jeopardize the health of the participants in the program.... The Crown witnesses maintained that they were just taking orders and following the policies and directives of their superiors. The Crown witnesses were unaware of any mechanism to deal with circumstances where an enforcement action could be harmful to health nor did they investigate this matter further. Unfortunately, none of their superiors testified at the trial.

Section 103:

> Another example of the conduct of Health Canada that contributed to an abuse of process was that representatives of Health Canada were not forthcoming with the Defendants by failing to tell them that it was not possible for the Defendants to obtain a D.I.N. [drug identification number] for the supplement under the existing drug approval regime, even though this belief was known at different levels of Health Canada. Health Canada had this knowledge as demonstrated in various emails and other dealings with Dr. Kaplan.

● (1225)

In closing, the conclusion by the court was this: the defendants are not guilty of count three in the information; the defendants are entitled to rely upon a defence of necessity and due diligence.

The questions we bring to the committee today are these. In light of the fact that a market authorization has not been granted to Truehope, recognizing their legal and moral duties to continue, what is Truehope to do? Second, can Health Canada and Truehope be summoned to appear before this committee to review and discuss this file and receive this committee's recommendations?

Although Truehope has engaged the new NPN process on all levels, a market authorization has not been granted. Communication has broken down, and Truehope continues to be characterized as non-compliant. Some may say, in reviewing the 2003-2006 struggle, “that was then and this is now”, but Truehope says that what was then continues now, only in a lesser degree.

Based upon the long history of this struggle with Health Canada, Truehope and the thousands of Canadians who rely upon the supplement and program feel vulnerable. If new laws were ever passed that gave sweeping new enforcement and seizure powers to Health Canada, Truehope is concerned that we would become subject to biased and retaliatory actions.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Mr. Stewart.

Now we move on to Trueman Tuck.

Mr. Trueman Tuck (Coordinator, Canadian Coalition for Health Freedom): Thank you very much.

The last time I appeared here was three years ago, on Bill C-420. I think it's very important that we understand that whether we're talking about what we're not supposed to talk about, Bill C-51 as Bill C-52, or whether we're talking about Bill C-420 and the natural health products regulations, we're talking about a continuous process that I first encountered, as did more than 10,000 small businesses and the million-plus consumers whom I represent....

I think it's very important that we understand that since I started in 1972 on a holistic, spiritual lifestyle choice—I did not believe in medical doctors, did not believe in pharmacists, did not believe in synthetic drugs—I've lived a lifetime. I'm 60 now and I work 14 hours a day, seven days a week. There are a million-plus consumers who worked with our Canadian Coalition for Health Freedom in 1997 to stop the July 1, 1997, attempt to make drugs out of our nutrient-rich foods, food extracts and food concentrates, and our foods that are rich to begin with, the healthy foods.

This whole world is upside down. We want people to be eating healthy foods, we want them to be eating nutrient-dense extracts and concentrates, we want them to be going to naturopaths, chiropractors, herbalists. We don't want big pharma ruling the world; we don't want the natural health products regulations to be forced on us, in complete contradiction to the 1998 study process.

I appeared last before this committee in 1998. If you check our coalition's message then, it was quite simple. We created the largest grassroots uprising in Canadian history, by the admission of the Liberals, and started working with the Liberal government. They did a great job. The 1998 report was one of the most extensive stakeholder consensuses in the history of this country. From a consumer and a micro small business point of view, the natural health products regulations are illegal, outside of authority, were never brought to this committee, and need to be cancelled immediately. The majority of our membership in small business is ignoring them. Increasingly, the large businesses are ignoring them.

Health Canada is a set of federal criminal investigative police officers. Their actual act started in 1884. All that is in federal jurisdiction is to charge people with a crime under the Criminal Code or under the criminal powers of item 27 of section 91 of the BNA Act, if there's a serious adulteration or harm causing serious national death or adverse events. That's all there is.

Eighty per cent of what Health Canada does, including the entire work of the natural health products directorate, is outside of federal jurisdiction. Of any party in this country, the Bloc have been the greatest champion of keeping the feds out of provincial jurisdiction, and I'm surprised they would allow the natural health products regulations and/or Bill C-51 and Bill C-52 to intrude upon exclusive civil property. There are a dozen things it's intruding on.

There won't be time for me to go through our paper, but we've identified in it the 12 reasons that no party and no member should support Bill C-51 or Bill C-52. It ties into getting rid of the natural health products regulations and ties into going back to the standing committee reports and getting this committee to do an update of that wonderful report.

Dr. Grant Hill, whom I worked very closely with, is highly respected. He introduced a private member's bill to create reverse onus to try to get control of Health Canada. Judy and Grant and others who were involved with me at that time, including the Liberals, all knew that Health Canada was out of control. There's no administrative review process for Health Canada, there's no police internal affairs process, and we have documented cases of criminal activities that the RCMP will not investigate, including what was raised here.

We're requesting that this committee reconvene the same type of format as in 1998 to give the victimized small businesses, the victimized consumers who are suffering because of this bureaucratic nonsense that exists illegally in Health Canada.... We would like the opportunity to bring this out into the open again, as was done in 1998.

Thank you very much.

● (1230)

The Vice-Chair (Mr. Lui Temelkovski): Thank you, Mr. Tuck.

We'll now go to Peter Helgason.

Mr. Peter Helgason (Vice-President, Natural Health Products Protection Association): I'd like to thank the committee for inviting me here today.

I apologize on behalf of our president, who was unable to attend. He's dealing with a legal matter in Calgary on Friday and was unable to be here. We got a late invitation, and I don't have a written submission because we were unable to get it translated.

The question that was asked is, sort of, why are we here? I'd reiterate very much what the CHFA had to say and much of what Mr. Tuck had to say, which is that about 10 years ago the largest public consultation in parliamentary history was held. A very thick report, called *Natural Health Products: A New Vision* was published, and synthesized from that report were the 53 recommendations.

The very first recommendation was that there shall be a new third category legislatively created by Parliament, not by regulation. If you go to the Health Canada website or the NHPD website, it will claim that this wasn't done because it was too complex procedurally to amend the act.

I note with interest the legislative history of a recently introduced bill, whose name shall go unmentioned; the process started in 1998. This was prepared by the Library of Parliament, presumably an objective source of information, which coincidently coincides with the publication of the *New Vision* report. Ten years, three prime ministers, and five ministers of health later, it comes out that the will of this committee, expressed as a policy expression by the Minister of Health's office in 1998, has been completely ignored.

Many of the members here weren't even elected to Parliament at that time, weren't privy to the consultations. I'm sure you could consult with your caucus members who were present for the consultations or have retired. It's pretty clear that what we're dealing with today was not the intent of this committee 10 years ago or the wish of the industry, the consumers, or the practitioners.

We have an opportunity, I believe, to go back to page one—not deal with the problems that have been created over the previous 10 years, but let's go back to page one and ask, where did we go wrong?

I'm deeply gratified to hear that the CHFA and the NHPPA are in complete agreement. I don't think we need to go any further than to look at the first recommendation of the committee from 10 years ago. Let's start fresh.

I thank you for the time.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Mr. Helgason.

Now to James D'Astolfo.

Mr. James D'Astolfo (President and Founder, Canadian Men in Nursing Group): Thank you to the committee for the opportunity to speak before you.

The Canadian Men in Nursing Group is a national organization that supports men in the nursing profession, educates the public, and is involved in supporting men's health and the health of all Canadians.

I'll be sharing my time today with Mr. Branden Shepika, our organization's chapter director, a nursing student from Sudbury, Ontario.

Nurses play an active role in all aspects of health and well-being of Canadians and in many different health organizations across the country. Because nurses are front-line health professionals, many of them come across patients taking natural health products. For this reason, we feel it is important that nurses should have an important role in all discussions surrounding natural health.

According to Health Canada in a recent survey, approximately 71% of Canadians use some form of natural health products. With this high percentage, it is important that government ensure that Canadians are well protected.

● (1235)

Mr. Branden Shepika (Chapter Director, Canadian Men in Nursing Group): Our recommendations are the following.

Recommendation 1, ensure that both the general public and health professionals are made aware, through educational programs, of interactions between natural health products and pharmacological drugs.

The public generally considers natural health products to be safe and beneficial. These substances are largely unregulated, and this contributes to the misconception that they are innocuous. Patients don't feel the need to tell their physicians that they are using them, and physicians do not often ask their patients if they are using them. Education in these areas should also help to increase the degree to which the public trusts the information they receive from their health care professionals with regard to natural health products. According to a 2005 study by Health Canada, less than half of Canadians trust information from their health professionals about natural health products.

Recommendation 2, create a reporting system so that front-line health professionals can report adverse reactions to Health Canada directly. Adverse reaction reporting is mandatory for companies that make natural health products. However, serious adverse reactions are generally dealt with by front-line workers such as nurses and doctors. The recommended system should also be mandated, since reporting is necessary to protect the best interests of the public.

Recommendation 3, because natural health products are being sold over the counter with little or no monitoring, both pharmacies and health food stores should be mandated by the government to have qualified health professionals at their disposal. Certain natural health products should be prescribed only by qualified health professionals who have knowledge and training in the area of nutraceuticals. Some natural health products can cause serious adverse effects if not used by individuals who require them or if used by patients who have allergies to the natural health product.

Recommendation 4, since 2004, Health Canada has employed the use of natural health product numbers and homeopathic remedy drug identification numbers to identify products. The public should be educated on how to find these numbers and what they mean. According to a 2005 study conducted by Health Canada, 60% of people do not look for drug identification numbers on homeopathic medicines, and 66% of people do not look for natural health product numbers.

Mr. James D'Astolfo: Recommendation 5, ongoing research in the area of nutraceuticals is important to ensure that the health of Canadians is protected. Companies should ensure that clinical trials are conducted on their products and that these clinical trials are safe and ethical. It is important that government increase funding in the area of nutraceuticals. Because of the high number of Canadians using well-researched natural health products, it is important that government work with provincial governments to ensure that the industry is reimbursed for health insurance plans and that costs are covered in part or in full.

I would like to thank the committee for their time in allowing our organization to put forth these recommendations on the subject of natural health products. We look forward to answering any questions you may have.

The Vice-Chair (Mr. Lui Temelkovski): Thank you.

Madam Fry.

Hon. Hedy Fry (Vancouver Centre, Lib.): Thank you, Mr. Chair, and my thanks to everyone for your submissions.

I think I'm hearing some clear lines coming out of this. One is that there should be a third category. The other is that there needs to be more resources for the health protection branch to be able to look at proper research.

Mr. D'Astolfo, you talked about front-line health care professionals reporting adverse reactions to natural health products. You said this reporting should be mandated. So you also want to make it a requirement for everyone to be asked if they are taking natural health products, because if people don't tell their physicians or their nurses, then no one knows. In the past, when anyone has suggested mandatory adverse drug reporting, the health care professionals have always argued that it would take up too much of their time. How do you see them making that time?

Second, you talked about 60% of consumers not looking for homeopathic drug ID numbers. Are you suggesting, therefore, that Health Canada do a public awareness campaign, or some sort of education campaign, to let people know that they should look for these numbers? Checking the numbers would allow people to know that the product is safe and has met the requirements of Health Canada.

With regard to the category, anyone can answer this who sees fit. If natural health products are neither food nor drug, establishing a separate category would seem a reasonable thing to do. I don't argue with you on that. But if a natural health product generates claims to therapeutic value, it could move out of the natural category and into a drug category. It would then have to be subjected to clinical trials. Do you see this as a possibility?

● (1240)

Ms. Penelope Marrett: Thank you very much. I'll respond to a couple of things, and then perhaps my colleague can further expand.

We believe it is important right now that there is a separate category for natural health products so that the lens for the interpretation of the regulations is appropriate for low-risk products.

We are also aware that it is possible to make therapeutic claims now within some restrictions of the various schedules, and there has been a demonstrated benefit for natural health products on claims.

Hon. Hedy Fry: Are you saying you shouldn't be required to do clinical trials if you're making major therapeutic claims? That was the question I asked.

Ms. Anne Wilkie (Vice-President, Head of Regulatory Affairs, Canadian Health Food Association): Clinical trials would be required, depending on the strength of the claim. The understanding with the natural health products regulations is that the level of evidence required is based on the strength of the claim. So if you're making it a structured function that basic calcium helps build strong bones, you can rely on textbooks, for example. If you want to go beyond that and start talking about treatment of cancer, for example, you would most likely need clinical trials. The concern now is that the NHPD is not looking at that broad range of evidence.

Mr. James D'Astolfo: To touch on your point, Dr. Fry, that 60% of patients are not aware of the drug identification numbers, we feel that the government should put in place some sort of media campaign or education to make patients aware that these numbers exist on products such as vitamins or nutraceuticals.

I think you had another question.

Hon. Hedy Fry: It was on mandatory reporting of adverse—

Mr. James D'Astolfo: Yes, it was on adverse reports for health professionals. We believe it's up to the patient to tell their provider that they are taking natural health products. But at the same time, we need to provide tools so that health professionals can talk with their patients effectively about natural health products and identify for them and work with them on reporting adverse reactions and on whether the product is safe enough and won't interfere with other treatments they're getting.

I think it's very important that health professionals are mandated to report to Health Canada, with support and education coming from Health Canada, to try to deal with adverse reaction reporting.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

Mr. Trueman Tuck: May I add to those last questions? I have an answer to them too.

The Vice-Chair (Mr. Lui Temelkovski): You have 30 seconds.

Mr. Trueman Tuck: Okay. That's tough.

The consumer wants to have informed freedom of choice. The whole regulatory system is geared to the assumption that the drugs are safe, properly risk benefited, and everything.

I co-authored a book called *Death by Modern Medicine* with a naturopath and a medical doctor. You can look it up. We proved that in North America the most heavily regulated professions, nurses, doctors, and pharmacists, in the most heavily regulated facilities, hospitals and care homes, with the most heavily regulated products, prescription drugs, were killing the equivalent of seven jumbo jets full of people a day. I can provide scientific evidence to this committee. We've used it in court, and we commissioned a risk study that I'll provide to every member.

So the whole paradigm that there's some big bogeyman that consumers have to be protected from is not only outside of federal jurisdiction, it's a violator of our most basic human rights.

Thank you.

● (1245)

The Vice-Chair (Mr. Lui Temelkovski): Thank you, Mr. Tuck.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): You can respond, Ms. Wilkie.

[*English*]

She wants to answer, so take it on my time.

Ms. Anne Wilkie: *Merci*. I have a couple of things to clarify.

There is mandatory reporting of adverse events for the industry within the natural health products regulations. So there is a requirement on industry to report adverse events.

We fully support the education of consumers, but based on the fact that there are currently only 7,000 licences in the marketplace out of 40,000 or 50,000 products, trying to educate the consumer at this time is going to cause more confusion than not.

[*Translation*]

Mr. Luc Malo: Mr. Chairman, I would like to come back to something Mr. Tuck said.

If I understand correctly, the members of the public should be free to inform themselves and choose from all of the products on the market the ones best suited to their situation. The marketing of these products should not, therefore, be regulated.

Is that in fact what you said? If it is, I would like to get the reaction of the Canadian Health Food Association and the other panellists to your comment.

[*English*]

Mr. Trueman Tuck: When Dr. Carolyn Dean and I were here we met with a number of you—we gave you copies of our book, *Death by Modern Medicine*, and we'll provide copies to any member. We requested that there be a federal death registry created that would provide mandatory coroners' forms to ensure that the cause of death, regardless of whether it was from parachuting, or prescription drugs, or cosmetics...to provide not an opinion-based, but an evidence-based mandatory death registry with an input form that makes sure the data is as accurate as possible. So whether my daughter wants to go parachuting or skydiving, or whether someone wants to take a drug or not, or a mammogram, or fluoride, whatever it is.... There are so many issues that families are trying to make informed choices on now. Without having an evidence-based federal death registry, it's impossible. You have a bureaucrat with one viewpoint; you have a naturopath with another; you have a consumer. It's all opinion-based, which is very dangerous when you're making decisions that could be life-threatening to you or your loved ones.

So we strongly suggest that a federal death registry be set up. Obviously, the confidential information would be hidden, but it would be web-based so that everybody could go in and look at the risks.

We commissioned a study in 2004 that did the risk management across all activities in society, and our group would be pleased to provide a copy of that report to each of the members of this committee so they can see what we're talking about.

Then there have to be proportionate risk regulatory regimes. Take, for instance, peanuts. You probably don't realize that peanuts kill an average of 3.5 people in Canada a year. We suggest that we need to have a peanut standard so that anything that causes deaths equal to or greater than peanuts is in federal regulations and anything less is in provincial regulations—or not regulated at all if it's below a 0.5 threshold. It would sort out the jurisdictional issues between the provinces and the feds, and it would sort out the appropriate way to truly protect Canadians.

Thank you.

Ms. Penelope Marrett: *Merci beaucoup, Monsieur Malo.*

The Canadian Health Food Association was involved when the regulations came into force. Our members said, and continue to say, that with a separate category we believe the regulations could be seen and interpreted in an appropriate manner for low-risk products. From that vantage point, if I understand your question, our members have said that with a separate category we do support it. We believe that regulations are what consumers are asking for in order to ensure the products that are available are safe and effective.

Do you want to add any more on that?

Mr. Peter Helgason: The regulations themselves.... It's what's happening with natural products, and this is why the third category is probably necessary.

For example, you can go out and buy a Ferrari Testarossa or you can buy Le Car. They're both regulated products and they're both for transportation. And then you can get a two-wheeled scooter like my kids ride out on the street. They all serve a purpose, but clearly there's a significant difference in the potential risk between the scooter my son is on, on the street, and the Ferrari Testarossa. How do you balance that? The suggestion the committee arrived at 10 years ago was to have a third category.

In terms of the standards of evidence, etc., that are used to make therapeutic claims or what have you, the gold standard, as I hear it talked of all the time, is the double-blind placebo control clinical trial, which will give you a very good statistical predictor of how effective that product will be in any given situation. There's the old joke about the statistician; he has his head in the oven and his feet in ice water, and when you ask him how he feels, he says, “Well, on average I feel fine.” But the fact is, the statistics don't speak to the individual case.

I think even the more scientifically inclined here would look at genomics and begin to understand that there are dramatic differences between individuals, even out of the same cultures. For instance, a product that I can take that makes my symptoms go away, be it cancer or heart disease, may not work for somebody else. But the fact is it works for me, and I don't think I should justify my better health to anybody. It is my body, after all.

● (1250)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much. I get the message.

Madam Charlton.

Ms. Chris Charlton: Thank you, Chair.

It's quite obvious that all of you who are here today are motivated by what's in the best interest of consumers, and obviously product safety is a concern for you all as well. Nonetheless, there's a pretty significant disagreement about what kind of regulatory framework gets us there.

I have knack for stating the obvious, so I just thought I'd do that.

I wonder, though, in light of that context—and you started to get at this answer a little bit—how important is it that we maintain that third category between food and drugs? Some of you have expressed some pretty significant concerns about that category as it exists and how regulations that apply within that category are applied and implemented.

I think I heard all of you say that the third category is important, yet you're raising concerns. So I wonder if you can comment about whether you want to maintain that separate category, and what kinds of changes in the regulations would you like to see to make that category work from each of your very different perspectives on this issue?

Ms. Anne Wilkie: Following on the previous comments, the industry has always been supportive of appropriate regulations. We're finding the challenge is the interpretation of the regulations and the implementation of them, and we find that it's biased by the very fact that we are a subset of drugs. We feel that once we're out from that category of drugs, there's a more balanced lens and a more balanced view of how these products are reviewed.

When you're talking about amendments to the regulations, there are some that we would like to see: the opportunity for post-market notification of some of the lower-risk products within that overall low-risk category, so going to market without a review, a post-market notification; removing some of the requirements for specifications right now, because whereas they're in product licensing right now, they belong with good manufacturing practices; and the ability for inspections versus attestations for site licences.

So there are some amendments we'd like to see in the regulations, but in general it's the interpretation and implementation of them.

Ms. Penelope Marrett: At the same time, I think we need to make it clear that in the legislation that exists today, there is no separate category for natural health products. There was a recommendation in the 1998 report, but in the current Food and Drugs Act, there is no separate category.

Mr. Ian Stewart: On behalf of Truehope, a third category is not only sought after, it's necessary. How can a vitamin-mineral supplement, which we typically would take just to maintain good health, fit into the categories that exist today, when a vitamin-mineral supplement has a profound therapeutic value to correct disorders that are typically treated with medications?

We don't fit in either category, and our struggle through this whole process is to maintain our purpose and to continue what we do to help people, especially those on the threshold of suicide, those who have tried all other treatments within the medical model and have failed. We do take those people and get them turned around. So how can we fit into the categories that exist today?

Aside from that, the big concern for us is not just the category but the abuse of process within the categories, and the means by which we can address those concerns and that evidence that comes forward during the process.

● (1255)

Mr. Trueman Tuck: It's very important to understand that the U. S. had this same issue in the early 1990s, and they resolved it by creating, in 1994, the Dietary Supplement Health and Education Act. They basically recognized exactly what Truehope has just said, that the vitamins had a powerful, necessary, and positive....

It was so powerful a movement, as it was in Canada, that in 1994 it was put through both the Congress and the Senate with 100% consensus. That's what we were hoping in 1997 when we invested the time and money, as over a million consumers and tens of thousands of small businesses. We were hoping that with the 1998 report—and they did start the legislative renewal, by the way, and I attended one of them—we would get a harmonization of this category with the U.S. third category, which was food and which was appropriate for what we had. That did not happen, and the regulations came out of the blue and sabotaged it.

On the second question, from a consumer point of view, we feel we need to be able to have informed freedom of choice, and the point has been made around the table that this doesn't mean having a federal bureaucrat telling me that I can or can't take a product, but it does mean that the federal government has a responsibility to provide me with the statistics so that I can make informed choices from evidence-based statistics of what's likely to harm me or what's likely to kill me or my family or loved ones.

The Vice-Chair (Mr. Lui Temelkovski): Thank you.

Mr. Brown.

Mr. Patrick Brown (Barrie, CPC): Thank you, Mr. Chairman. My first question is for the men in nursing. What types of comments are you hearing from members of your association in regard to regulations? Are they looking for stricter regulations? What exchanges have they had with patients about this? What sense do you get?

Mr. James D'Astolfo: I think stricter regulations are necessary to protect the best interests of patients throughout Canada. I think there were some comments made about identifying them in different categories versus a vitamin or herbal supplement. You have to take a look at history to see that herbs are very potent products and should be treated very carefully when patients are taking drugs along with those herbs.

I think to add a different category would be kind of disruptive. I think you should take a look at grouping them, herbs and vitamins, together in one category. I think that would be in the best interests of patients.

Mr. Patrick Brown: This is a general question. When the regulations came into force, there were an estimated 42,000 natural health products and non-compliance was a big issue. They estimated 32,000 would be non-compliant. Do you view non-compliance as still being an issue today?

Mr. James D'Astolfo: Do you mean non-compliance in terms of mandatory reporting for health professionals?

Mr. Patrick Brown: For the regulations.

Mr. James D'Astolfo: I think mandatory reporting and compliance should be enforced. I think companies should be responsible and conduct clinical trials in terms of their products. We also believe in education of the public and making sure the public is aware of what they're taking. Consumers have a choice in terms of what kinds of products they take, but they have to be informed that there are clinical trials out there that support the effectiveness of those products.

Mr. Patrick Brown: Is enforcement currently adequate, in your opinion, Peter or Trueman?

Mr. Trueman Tuck: Basically, what happens is that.... I'll confess, from Health Canada's point of view, I'm a criminal, because I have a family business, Tucksdiscountvitamins.com. I import from the U.S. kava kava, alcarnatine, which is on schedule F, and our group of small businesses that has included Truehope, Strauss, Bell Lifestyle, BIE.... We have a group of businesses. Four of our businesses have faced Health Canada in massive criminal trials over the last five years. Our small businesses have invested over a million dollars in legal fees to basically tell Health Canada that if they can't convict us of a criminal offence in front of a jury, they have no federal jurisdiction so they should leave us alone.

In the U.S., the Dietary Supplement Health and Education Act.... We did a study. If you go to New York State, you have about 70,000 products on the market. So when they started these illegal health regulations.... We complained, by the way, for three years that within REGS—the scrutiny of regulations committee—these are illegal and outside the criteria, and that committee hasn't heard any of this in three years either.

● (1300)

Mr. Patrick Brown: Peter, do you have a comment on that as well?

Mr. Peter Helgason: Well, I kind of get it. Are the regulations strict enough? I would go back to the Direct Sellers Association's point that somehow often the goalposts are moving, so what's sufficient on one submission.... I will apologize. I hang out with way too many PhDs and lawyers. That said, these are people who are experts in their own fields, and they see that what they did last time is rejected the next time and they're scratching their heads trying to figure out why.

Then there's an exceptionally complex bureaucratic process that you have to go through. You know, you wait in line, wait in line, wait in line, punt it to the back, and before you can even ask your question as to why you were punted to the back of the line, you have to wait in line for six months to a year again.

The other part of the regulatory impact is something that was brought up here, a herbal sleep product that was spiked with benzodiazepines. Something I was surprised to learn, and I think most lay people would be surprised to learn, is that about 75% of the prescription drugs on the market are actually derived from plants. There is a sub-branch of science called ethnobotany where drug companies hire scientists to go out in the wilds and study indigenous cultures to find out what cool plants they use, and then they isolate molecules from those plants, run them through the clinical trial and patent process and have very profitable products.

Well, when you sell a natural herb that that product is extracted from, when you run a mass spec or a high-pressure liquid chromatograph on it, yes, that molecule is there. That's where it came from. But it has been patented by someone else. So it's a complex issue.

The Vice-Chair (Mr. Lui Temelkovski): Ms. Wilkie, could you make a short comment, as we're wrapping up.

Ms. Anne Wilkie: Thank you.

Just in terms of compliance, it's very difficult to go out there. The industry is desperately trying to comply with the regulations now. But the way the regulations were written, as of January 1, 2004, when they came into effect, all 50,000 products on the market had to be licensed—unless they had DIN numbers. And as you heard, four years later, the NHPD say they are still wading through a huge volume and backlog of submissions.

So to go out there and proactively enforce the regulations and look for NPNs is not doing anybody a service.

And the industry wants those licences as desperately as the consumer does. They are in a very tenuous position right now, but they are aggressively trying to comply with the regulations.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Mr. Brown, and thank you to all of the panellists. This concludes our meeting today.

The meeting is adjourned.

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