House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 037 • 1st SESSION • 38th PARLIAMENT

EVIDENCE

Tuesday, May 3, 2005

Chair

Ms. Bonnie Brown

Standing Committee on Health

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● (1535)

[*English*]

The Acting Chair (Hon. Robert Thibault (West Nova, Lib.)): Order. Thank you very much. While waiting for our regular chair or vice-chair, I'll assume the duties and welcome you all.

[*Translation*]

I would like to welcome you this afternoon, for your presentations.

We will be listening to all the presentations before we begin our question period.

The first to make a presentation will be Mr. Yvan Bourgault, President, Canadian Homeopathic Pharmaceutical Association.

Mr. Yvan Bourgault (President, Canadian Homeopathic Pharmaceutical Association): Thank you.

Chairman and committee members,

[*English*]

my name is Yvan Bourgault. I am president of Heel Canada, a pharmaceutical member company of the Canadian Homeopathic Pharmaceutical Association.

[*Translation*]

The Acting Chair (Hon. Robert Thibault): Excuse me, Mr. Bourgault. I forgot to remind all committee members that we will be giving only 10 minutes for presentations since we will have lots of them this afternoon.

You may continue.

[*English*]

Mr. Yvan Bourgault: I'm also the current president of the CHPA, and I'm here today on behalf of the board of directors of the association and its 15 member companies.

You will note that the word “pharmaceutical” is used in the name of CHPA. This is because the homeopathic medicines that are manufactured, imported, and distributed by our member companies are defined and regulated as pharmaceutical products, not only in Canada but in all other industrialized countries, including the United States and member states of the European Union.

Homeopathic medicines have been regulated as pharmaceutical drug products in Canada since 1989, when Health Canada determined that all homeopathic medicine must be compliant with drug regulations and carry DINs, or drug identification numbers, as product licences. When these requirements were imposed by Health Canada, it was immediately apparent to manufacturers, importers, and distributors of homeopathic medicines that certain aspects of the existing drug regulations and related guidance documents were not appropriate for our products. By not appropriate, I mean that they were not consistent with some aspects of universally accepted and approved methods of manufacturing, testing, and labelling of homeopathic medicines.

These inconsistencies led to a dialogue between our industry and the TPD, the therapeutic products directorate, of Health Canada. These discussions spanned many years, and led to the creation of guidance documents that recognize the unique characteristics of homeopathic medicines as a subcategory of drug products. The guidance documents include good manufacturing practices, or GMPs, adopted and published in 1996; a labelling standard adopted and published in 1997; and for multi-ingredient homeopathic medicines, a policy for labelling, indications for use, and related traditional references adopted and published in 1998.

By the end of 1998, over 4,700 DINs, or drug identification numbers, were issued in Canada for homeopathic medicines that were compliant with these policies. In other words, the drug regulatory framework for homeopathic medicines was essentially complete and implemented before the development of natural health products regulation was even recommended by the Standing Committee of Health and approved by the former Minister of Health, the Honourable Allan Rock.

I would ask the current standing committee members to note that CHPA filed a brief to the committee in 1998 requesting that homeopathic medicine not be included in the natural health products category. We did so on the understanding that natural health products would be a new category, separate from both foods and drugs. We continued to oppose having homeopathic medicine included in the natural health products regulation definition until it became clear that natural health products would be recognized and regulated as drugs, and that the natural health products directorate would acquire the professional skills to competently regulate homeopathic medicine, which it so far has done.

I know that our time is very limited, so I want to emphasize just three points.

The first point is that natural health products are defined as a subcategory of drugs. This simple fact is why homeopathic medicines can be regulated as natural health products under Canada's regulatory system.

The second point is that homeopathic medicines are not foods and cannot be regulated as foods or become compliant with Canadian food regulations. This simple fact is why it is not appropriate for Bill C-420 to redefine natural health products as foods, and this is why CHPA supports removal of the provisions of Bill C-420 that would redefine natural health products as foods.

The third point is that section 3, relating to schedule A, also presents impediments to the responsible use of health claims and indications for use for homeopathic medicines in Canada. As a consequence, CHPA has long supported the removal of schedule A, and therefore supports the provisions of Bill C-420 that refer to the removal of schedule A.

[*Translation*]

If I may, since our time is very limited, I would like to sum up three points in French for the francophone members of the committee.

In our view, there are three important points. The first is that natural health products are defined in Canada as a sub-category of pharmaceutical products; in other words, they are drugs. This simple fact is why homeopathic medicines—recognized as medicines throughout the world—can be regulated as natural health products under Canada's present regulatory system.

The second point is that homeopathic medicines are not foods and cannot be regulated as foods or become compliant with Canada's Food regulations. This simple fact is why it is not appropriate for Bill C-420 to re-define natural health products as foods nor is it compatible with world regulations on homeopathic medicines.

The third point is that section 3, schedule A also presents impediments to responsible use of health claims and indications for use for homeopathic medicines. For this reason, CHPA supports the provisions of Bill C-420 that refer to the removal of schedule A.

[*English*]

I want to be clear that if this committee and the drafters and sponsors of Bill C-420 determine that Bill C-420 cannot be amended to remove the provision of the bill defining natural health products as foods, the CHPA is categorically and emphatically opposed to Bill C-420 proceeding to third reading. Under those consequences, we would hope to see the bill withdrawn and to see schedule A removed by other legislative amendments in the near future.

You will find additional information on homeopathic medicines and their use in the briefing document we have prepared for the committee.

I thank you all for the opportunity to appear and for your attention.

● (1540)

The Chair (Ms. Bonnie Brown (Oakville, Lib.)): Thank you, Mr. Bourgault.

Our next witness is from the Canadian Natural Products Association, Mr. André Gagnon, president.

Mr. Pierre Morin (Consultant, Canadian Natural Products Association): My name is Pierre Morin, and I will be intervening on our behalf.

We represent the Canadian Natural Products Association and its 30-odd members, most of whom are located in Quebec. A list of our members was also supplied.

Our members hold strongly entrenched feelings about Bill C-420. None want to see it adopted in its current version, yet every single one wants to see it become law. The contradiction is strictly virtual.

We also admit to the fact that both the association and its members are aware that the contents of the bill have come before this House before and that a version disappeared with the last Parliament. Members also felt previous iterations of the bill had little chance of being sanctioned, given the government's majority at the time. Such is no longer the case.

In 1998, in 53 recommendations, this standing committee produced a seminal report on framing a regulatory environment for natural health products. From this very report flowed government and ministerial decisions, as well as general regulations that became effective on January 1, 2004.

Without exception, CNPA members accept the constraints brought by the regulations, for they respond to the three major concerns raised. They address the issue of product safety, which has to be demonstrated for consumer security, the issue of quality control for these same products, as well as the issue of demonstrating efficacy so as to allow industry to make health claims for their products ranging from prevention to health recovery. To the best of our knowledge, the whole of Canada's natural health product industry shares our support for the regulations.

The contents of clause 1 of Bill C-420 would erase more than 10 years of efforts by consumer groups, by this very committee, and by industry to assert a rigorous and credible regulatory environment for natural health products sold in Canada. Sure, there are problems with the regulations, but they result from an outrageously bureaucratic and overly finicky application rather than from the regulations themselves. Should it remain in a sanctioned version of the bill, clause 1 would change the definition of a drug, as now specified in section 2 of the Food and Drugs Act, to exclude "food, manufactured, sold or represented for" and to change the definition of food to include

> any article, grown, manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever, including dietary supplements, herbs and other natural health products....

The resulting combination would make current regulations inoperative without providing an alternative framework to cover the three main concerns raised above.

In addition, the new definition would create intense confusion. Internationally, health claims related to beneficial effects of foods—more specifically, vitamins and minerals—are covered by the United Nations Codex Alimentarius. Canada respects the Codex Alimentarius decision that treats as a drug any food that makes a health claim. Even if Canada is not a member of the organization, it has always claimed to protect the Canadian natural health products industry through its regulatory framework. This protection would disappear should clause 1 of Bill C-420 be adopted as is.

The confusion would be all the more pervasive when one is asked to accept as food ear and eye drops and topical creams. It is worthwhile mentioning that under the current Food and Drugs Act provisions, the burden to support a health claim for food is particularly lengthy and costly. This is why CNPA members want the withdrawal of clause 1 of Bill C-420.

● (1545)

[*Translation*]

They, however, feel as strongly that Bill C-420 be adopted with, as its sole content, sections 2 and 3 as currently drafted. You will remember that this standing committee made recommendations as to the future of schedule A of the Food and Drugs Act.

The issue was shuffled from working groups to committee, to task forces neither of which had sufficient independence and ended up in a dead end. We might mention the example of glucosamine with the property to reduce symptoms associated with arthritis. This is being scientifically demonstrated but it is illegal to make this claim because the word “arthritis” is part of schedule A.

The regulations already require that any claim or allegation be supported by sufficient scientific evidence and even when that claim is satisfied, no claim may make use for an illness or condition listed in schedule A. Another example is St. John wort whose property has been known for years.

What can one put on the label since “depression”, the condition treated by this product cannot be used because of its inclusion in schedule A?

It is inconsistent to require natural health products to demonstrate their efficacy while denying them the possibility of claiming this efficacy. This is why Bill C-420 should have as its sole purpose the elimination of schedule A and be adopted with sections 2 and 3 as its sole contents.

It may well be in a new Parliament but it is high time this standing committee revisit how its recommendations have been implemented, recommendations which will soon be eight years old. In our opinion, the regulations closely reflect the objectives you set out by the bureaucratization of the process as had an undermining effect. Product licences are issued very sparingly and the vast majority of currently-marketed products cannot get an authorization to advertize their products' claims nor get an export certificate as a legally-marketed product in Canada. In this respect, we have just gone through an experience relating to a product that we were unable to advertise. We can give you more information about this later.

In addition, requirements to obtain a product licence for a product previously covered by a DIN have become much more exacting.

Our elected representatives have often demonstrated more common sense and pragmatism than public officials. That is why we wish to draw to your attention this issue of natural health products.

Thank you for your attention.

[*English*]

The Chair: Thank you, Mr. Morin.

Our next witnesses are from the Canadian Cosmetic, Toiletry and Fragrance Association, and the proponent will be Mr. Carl Carter, the vice-president of government relations.

Mr. Carter.

Mr. Carl Carter (Vice-President, Government Relations and Regulatory Affairs, Canadian Cosmetic, Toiletry and Fragrance Association): Thank you, Madam Chair and honourable members. On behalf of the Canadian Cosmetic, Toiletry, and Fragrance Association, I want to thank you for providing us with the opportunity to present our comments on Bill C-420.

CCTFA is the leading Canadian association for the personal care industry and represents virtually all of the name-brand cosmetic companies. A cross-section of the types of products we represent and on which we will focus our comments are displayed here in front of me today, none of which are to be ingested by the consumer.

CCTFA and its 175 member companies are at the forefront of a $5.3-billion industry in Canada, with more than 100,000 Canadians directly employed in the industry. The industry is highly integrated on an international basis and supports international harmonization of regulations in order to facilitate international trade and to encourage Canadian export opportunities.

Currently, personal care products are captured under three sets of regulations under the Food and Drugs Act: the Cosmetic Regulations, the Food and Drug Regulations, and now the new Natural Health Products Regulations. The current three sets of regulations—cosmetics, drugs, and NHPs—are burdensome and confusing and are costing the industry tens of millions of dollars in unnecessary administrative and compliance costs that are not needed to protect the health and safety of Canadians.

The average Canadian uses six to 12 personal care products every day, but most consumers don't realize many are drugs or natural health products. The seven categories of cosmetic-like drugs or cosmetic-like natural health products are as follows: antiperspirants, fluoridated toothpastes, anti-dandruff products, medicated skin care products, antiseptic skin cleansers, acne products, primary sunscreens, and other makeup products making an SPF claim. With the introduction of the new natural health products regulations in January of 2004, these seven classes of products have been further subdivided, with some falling under the new natural health products regulations and others remaining as drug products, depending solely on the source of the active ingredient.

To illustrate that personal care products fall under three sets of regulations, here is an example of a foaming facial cleanser, which is a cosmetic; a medicated foaming facial cleanser, which is a drug by virtue of it containing triclosan; and a pimple astringent, which is a natural health product because it contains salicylic acid. All three products are submitted to three different directorates within Health Canada.

As another example, let's examine the antiperspirant and deodorant categories. These aerosol and stick deodorants are cosmetics, while this stick antiperspirant is a drug and this aerosol antiperspirant will be a natural health product. The differences in classification are a result of the source of the ingredients and the deodorant versus antiperspirant claims that are made.

While CCTFA monitored the development of regulations specifically for natural health products, CCTFA and its members were not consulted on the inclusion of personal care products under such regulations. The natural health products directorate has acknowledged that the interpretation of the definition of a natural health product was changed at the last minute, which resulted in the inclusion of personal care products.

CCTFA members have made more than 100 natural health product licence applications since January of 2004, and to date only two NPNs have been issued for personal care products, both of which were toothpastes. Through this period, member companies have been frustrated with the lack of registrations for both drugs and, especially, natural health products, which has stymied virtually all new product launches for these products in Canada. In many cases companies have resorted to marketing the identical formulation as a cosmetic without any drug or natural health product claims in order to get their product to market.

We have serious health risk concerns with topically applied natural health products such as sunscreens, antiperspirants, toothpastes, and acne products being regulated as foods, as proposed by Bill C-420. As an example, the toothpaste before you today is one of the two personal care products that have been granted a registration as a natural health product. The directions expressly state, “Do not swallow toothpaste”. Similarly, this age-defying makeup with sun protection factor, or SPF, which will be a natural health product and no longer a drug, should of course never be ingested as a food.

● (1550)

There is already enough confusion and administrative expense for the industry to understand and comply with the current three sets of regulations, let alone a fourth, with foods being added. CCTFA therefore does not support Bill C-420 and its intent to redefine NHPs as foods.

With that said, CCTFA strongly believes all personal care products should be defined as cosmetics and not natural health products, drugs, or foods. We therefore recommend that Bill C-420 be modified to include a revised definition of cosmetic so all personal care products, whether a cosmetic, drug, or natural health product, be redefined as cosmetics, which would mimic the European definition of cosmetic. The current cosmetic regulations are fully adequate to ensure the health and safety of all personal care products we are discussing here today. Among other requirements, the Cosmetic Regulations require all marketers to submit the product formulation to Health Canada in a process known as cosmetic notification, coincident with the sale of any new cosmetic in Canada.

CCTFA's proposed definition of cosmetic would be consistent with Health Canada's legislative renewal proposal, which states that the proposed definition for a cosmetic is largely inspired by the one used in Europe. This revised definition has already undergone public scrutiny as part of the 2002-03 legislative renewal consultations. CCTFA strongly advocates adoption of the European definition of cosmetics, where all personal care products in 25 countries are regulated as cosmetics under just one common set of regulations.

Australia is also in the process of reviewing its regulatory definitions for personal care products, and the recent Newgreen report recommends the reclassification of several low-risk therapeutic categories as cosmetics.

In conclusion, let me say CCTFA does not support Bill C-420 as currently written but rather recommends that the definition of cosmetic be amended to incorporate the seven categories of personal care products we have discussed today, thus excluding them from being regulated as drugs, natural health products, or foods.

On behalf of Canada's personal care industry, we thank you again for this opportunity to share our views on Bill C-420. Thank you very much.

● (1555)

The Chair: Thank you, Mr. Carter.

Our next representative is from NDMAC, Mr. David Skinner, who is the president.

Mr. Skinner.

Mr. David Skinner (President, Nonprescription Drug Manufacturers Association of Canada): Thank you.

Members of the standing committee, ladies and gentlemen, NDMAC welcomes this opportunity to comment on Bill C-420, and is pleased to participate in its review on behalf of our members.

NDMAC is the only association that represents the full breadth of the self-care health products industry. We're dedicated to advancing Canadians' self-care, from sunscreens to pain relievers, vitamins to herbals, and toothpaste to acne treatments. Self-care health products are vital tools in the personal health management of virtually all Canadians. Our goal is to build an environment that improves the opportunities for people to manage their own health through the responsible use of safe and effective self-care health products.

My name is David Skinner, and I'm president of our 109-year-old association. My history with this issue spans more than 25 years, including participation on all of the government-appointed teams dealing with self-care and natural health products over the past 15 years.

NDMAC is fully supportive of the bill's intent to repeal the outdated provisions of schedule A, but believes that the best interests of Canadians are not well served by changing the definitions in the current Food and Drugs Act. The proposed amendment to the definition of food specifies that “dietary supplements, herbs and other natural health products” would be included in that definition. Thus the intended effect of the proposed change to the definition of food would be to recategorize the currently defined natural health products from a subset of health products under the Food and Drugs Act, to foods. This would cause very serious regulatory problems. As approximately 80% of self-care health products are NHPs, this change means that the vast majority of self-care health products would be regulated as foods. This would negate the essential advances made as a result of the implementation of the previous Standing Committee on Health's recommendations.

While vitamins and minerals are well-recognized self-care health products, so are many products with household names. For example, traditional Ayurvedic medicines such as psyllium make up the formulation for GI products like Metamucil and Swiss Herbal's Psyllium Husk. Calcium is the active ingredient in upset stomach medicine, such as Maalox, and Swiss Herbal's calcium. Menthol, eucalyptus, and other herbs make very effective cough and cold products in remedies such as Halls cough drops, Vicks VapoRub and 024 essential oil pain reliever.

The technical changes in regulatory requirements that the current bill would force are numerous, and are outlined in our written submission. For example, many manufacturers would have to undergo costly product reformulation to ensure all of the non-medicinal ingredients used for the stable formulation of the products were in compliance with the ingredient tables listed in the food regulations. The labeling requirements for age-related dosing, caution and warning statements, directions for use, and other features of health product information to ensure the safety of Canadian consumers are also not covered by food regulation.

If passed as written, this bill would also create further confusion, in that topical NHPs would not likely be considered foods, but ingestible NHPs would. Clearly, the intent of the bill is not to continue to subdivide self-care health products and create even greater disparity than exists today, as we've just heard from my colleagues from CCTFA. But what Canadians need is a stronger recognition by government that all self-care health products are valuable to the future of health care, and that these lower risk products should be regulated consistently, predictably, and differently from prescription drugs.

To illustrate the current discrepancy in the regulation, look no further than some of the examples from CCTFA and the products we use every day. As they say, antiperspirants and Vaseline are drugs. Sunscreens are regulated as both drugs and NHPs, but it seems to me there is no logical reason why all products intended for self-care should not be regulated under the same framework. The current regulatory environment for self-care products needs to be simplified.

The throne speech has on at least two occasions mentioned the need to reform the Food and Drugs Act through legislative renewal. It is within that larger project that the full context of definitions and regulatory framework needs to be addressed. We seek this committee's support for the recognition and common regulation of self-care products as a distinct class of health products under the legislative renewal initiative. We would also ask that this committee, in its report back on this bill, call for the government to proceed on the renewal of the outdated Food and Drugs Act.

Any change in the current definition of NHPs without full consideration of the impacts on the rest of the products regulated under the current act could be devastating. For example, removing NHPs from the current regulatory framework without this full review could subject them to the provisions of the joint FAO-WHO Codex Alimentarius. This would have the effect of denying most product-based health claims, and would place restrictions on vitamin and mineral dosing. It would require most NHP manufacturers to reformulate and/or relabel their products to sub-therapeutic levels, thereby penalizing consumers and unnecessarily burdening the industry.

● (1600)

To summarize the NDMAC recommendations for the first component of Bill C-420, we support a regulatory system for self-care health products that is better suited to meet the needs of Canadians, but believe that any change in definitions outside the context of a full legislative review would do more harm than good. Therefore, NDMAC recommends and would support amending Bill C-420 by deleting subsections 1(1) and 1(2). We also request that this committee send a strong message to the government that legislative reform is badly needed.

Briefly, with respect to the second component of Bill C-420, the repeal of subsections 3(1) and 3(2) of the Food and Drugs Act would remove an outdated provision first introduced in 1934. As others have said, at that time there was no known treatment for many of the diseases, and the government needed to curb the promotion of a plethora of products being sold to treat such diseases. Since that time there have been many advances in the regulation of products with health claims. Currently, to receive market authorization a product for which a health claim is made must undergo a pre-market review by Health Canada and sufficient evidence must be provided to prove the safety and efficacy of the product.

Also, since the inception of section 3 and schedule A, many self-care health products have been shown to reduce risks associated with specific schedule A diseases, yet producers are prevented by section 3 of the act from passing on that knowledge to Canadians in the most direct way possible—through product labelling and advertising.

Examples of health products prevented from being approved by virtue of schedule A include sunscreens and their use in reducing the risk of many skin cancers, ASA and its use in reducing the risk of one of the largest killers of Canadians, heart disease, and psyllium and its use in reducing arteriosclerosis due to its proven cholesterol-lowering effects. All of these are summarized in the schedule A report to Diane Gorman.

To summarize the NDMAC recommendations for the second component of Bill C-420, NDMAC supports paragraphs 2 and 3 and the repeal of section 3 of the Food and Drugs Act and the accompanying schedule A, as written.

In conclusion, we're convinced that it is the existence of schedule A, and not the definitions, that keeps valuable products off the market. It's not what we call these products, but rather how they are regulated and administered by the government. We believe that self-care products need to be regulated and recognized as a distinct class of health products.

On behalf of the self-care health products industry, I'd like to thank you for the time you've allotted us today to express our concerns and recommendations for possible amendments to this bill. We would be pleased to answer any questions you may have.

● (1605)

The Chair: Thank you, Mr. Skinner.

Now, from the Direct Sellers Association of Canada, Mr. Ross Creber, the president.

Mr. Creber.

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

Madam Chair, honourable members, on behalf of the Direct Sellers Association, I want to thank the committee for providing us with the opportunity to present our comments with respect to Bill C-420.

The Direct Sellers Association, founded in 1954, is the national association representing 41 direct selling companies and close to 900,000 independent sales contractors—and voters—who in 2004 sold more than $1.6 billion of products and services to Canadian consumers.

The direct selling companies and independent sales contractors market and distribute a wide variety of products and services directly to the consumer, usually but not exclusively in the consumer's home rather than in traditional retail establishments.

Generally, these products and services are sold by independent sales contractors in the context of group presentations, known as party plan, or on a personal consultation basis. These independent business persons represent such well-known names as Avon, Mary Kay, Tupperware, PartyLite, Weekenders, Shaklee, NuSkin, Quixtar, Nature's Sunshine, and Cutco/Vector.

The strength of direct selling lies in its tradition of independence, its simplicity, and its commitment to a free market system, providing accessible business and career opportunities to people whose entry is not restricted by gender, age, education, or previous experience. It is a significant fact that direct selling is a manageable economic opportunity that can further family income with minimal disruption and minimal investment.

Let me now turn to our views on Bill C-420.

In our opinion, Bill C-420 is a product of frustration. It is the frustration of Canadians who want ready access to safe and efficacious natural health products. It is the frustration of Canadian companies that wish to market these products to Canadian consumers.

In 1998 the Standing Committee on Health tabled its report, “Natural Health Products: A New Vision”, which contained 53 recommendations on the most effective way to balance freedom of choice with consumer safety. The report laid out the framework for a regulatory regime for NHPs. The government accepted all 53 recommendations of the committee.

Unfortunately, while the basic tenets of these recommendations were superficially incorporated into the NHP regulations, the manner in which they are currently being implemented does not reflect either the spirit or the intent of the recommendations. The goal of ensuring that Canadians have access to safe and effective natural health products has not materialized.

The DSA fully supports all efforts to achieve a truly efficient and effective regulatory regime for natural health products. We believe that Bill C-420 reflects, at least in part, an effort to revisit the original consultations and to redress the current situation with the NHP regulations.

The Direct Sellers Association supports clauses 2 and 3 of the bill, which propose a repeal of schedule A and subsections 3(1) and (2) of the Food and Drugs Act. This is in keeping with the Standing Committee on Health's recommendation that, and I quote,

> Health Canada immediately initiate a review of the diseases listed in Schedule A to ensure that only appropriate diseases are included and, where relevant, specific diseases be exempted by regulation from the broad terms found in Schedule A

Given the measures in place to protect the health and safety of Canadians in the current NHP regulations, the elimination of schedule A and the repeal of section 3 of the Food and Drugs Act in our opinion significantly enhances the health of Canadians with greater access to product-related health information.

The Direct Sellers Association cannot, however, support clause 1 of the bill, which essentially proposes that natural health products be treated as foods. We submit that classifying natural health products as foods would remove the mechanisms in place that are designed to ensure the safety and efficacy of the natural health products available to Canadians.

We fully support proper regulation of natural health products. In fact, it is the DSA's position that the problems and indeed the frustrations we spoke of earlier are not with the NHP regulations per se but the manner in which they are being implemented.

At present, Canadians are being denied access to NHPs because of a horrendous backlog in the processing of product licence applications in the Natural Health Products Directorate. Not only has this kept products from Canadian consumers, but the NHP industry has been burdened with enormous costs associated with the manner in which the NHPD is interpreting compliance with the NHP regulations.

I want to illustrate how the NHP regulations and the manner in which they are being implemented has impacted direct sales companies, especially their independent sales contractors, and ultimately Canadians who want to purchase these products.

● (1610)

The DSA undertook a small sample from 11 of our member companies to illustrate this situation. These 11 companies have submitted, to date, 86 product licence applications. The total projected retail sales for these products is in excess of $75 million. The DSA estimates a potential loss of earnings to these independent sales contractors, who are out there representing these companies, of more than $32 million. These 11 companies plan to submit an additional 437 product licence applications in the next two years, with projected sales of these products of more than $98 million and a further possible potential loss of income for independent sales contractors of some $36 million.

In total, we are talking about $175 million from our association alone in potential lost sales to these companies, and close to $69 million in lost earnings for independent sales contractors. For the government, this also translates into lost GST revenue alone in the neighbourhood of $12 million.

I want to reiterate that we have concerns with the changes proposed in clause 1 of Bill C-420. We believe there are other short- and long-term remedies available to address the shortcomings with the current NHP regulatory regime. We have detailed these in our formal submissions to this committee. These include a moratorium on product licence application requirements for NHPs for at least three years, in addition to an extension of the current deadlines for the filing of product licence applications. We believe the government must make elimination of the current backlog, which is now in the thousands, a priority.

As of April 19, 4,721 current product licence applications have been submitted, and 250 product licences have been issued. Appropriate resources and procedures could assist in that regard.

In the long term, the establishment of reasonable performance standards, adequate training of NHPD staff, reassessment of appropriate levels of scrutiny and review, and better resources for industry would be reasonable solutions. We also believe serious consideration should be given to the establishment of a distinct third category for NHPs, as opposed to a subset of drugs. This could be done as part of Health Canada's legislative renewal process.

All our recommendations are detailed in our written submission, and we would be glad to discuss these with you today.

Once again, Madam Chairman, on behalf of the Direct Sellers Association, I want to thank you and the committee for this opportunity.

The Chair: Thank you, Mr. Creber, and thank you to all the witnesses.

Ladies and gentlemen, we have seven members here. Could we agree to five minutes each and we'll just make sure everybody gets a chance to talk?

Okay, thanks.

We'll start with Mr. Lunney.

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

Well, again we're having a very interesting day today. It's interesting that most of the presenters, with the exception of our cosmetic people, are really caught in a vise.

We agree that we should get rid of subsections 3(1) and 3(2) and schedule A, so we're glad to hear we have almost unanimity, except for Health Canada, on this issue.

To the Direct Sellers Association, I wonder if you were here for some of the earlier presentations. I don't know if you were here, Mr. Creber.

Mr. Ross Creber: No, I wasn't.

Mr. James Lunney: It seems that many of the product monographs that are out there are for single-item things, like, I don't know, maybe calcium citrate—I'm just making this up—but it seems to me they are simple things. The ones that are being delayed are ones that have multiple compounds in them.

I see some nodding back there, so I think I'm on the right track, that those with multiple ingredients are the ones that are being delayed.

Did you say in there how many product applications from your companies had been approved?

● (1615)

Mr. Ross Creber: Out of the 86 that have been submitted, two or three have been approved.

Mr. James Lunney: What we heard expressed earlier, particularly from the smaller manufacturers—and this is perhaps a question for the Quebec group here, Canadian Natural Products Association, as well—is that it's smaller producers, of around $2 million, between $2 million and $5 million, that are really having a problem complying.

I wonder if you heard the suggestion that if we were to move this, for sake of argument, wherever NHPs land.... I don't know why we couldn't hive off a subcategory under that garage, put another room for cosmetics, whatever type of regulation regime eventually comes out of this. Certainly cosmetics need their own single umbrella. I think we'd agree with that.

But I wonder if you didn't hear the suggestion earlier from one of the smaller producers that since we don't have a list of bodies from natural health products—and we understand that with all the natural health products together, we probably have fewer deaths than from bee stings or peanut butter—if it would not be more appropriate to capture all the good work that has been done by the NHPD and put it under a different type of regime, where you get your product recognized as complying with these regulations, and you get a certificate like a CSA approval that it has been approved and examined, without having to take off anything or put restrictions on making sure you get your pre-approval here, create a marketing advantage for those that pursue this, and it would take the heat off, unless there's risk of harm. If there is, we certainly have regulatory regimes to deal with products that we know are harmful. Is that something you've considered or that you think might be advantageous to your members?

Perhaps we'll come back over here and ask you whether your members are large players or small, and whether some of them are having trouble getting their products approved.

Mr. Ross Creber: I don't think compliance is the problem. Getting the licence is the problem. Anything that could be done to maintain safety while making the products available in the marketplace would be welcomed by members of our association.

Mr. David Skinner: The transition team recommended something similar to the cosmetics notification system, for items with a monograph. Rather than going through a pre-approval, you do a notification and attestation that you are following the monograph. It operates by exception rather than review.

It's not so much large company versus small company as publicly traded versus privately held companies. NHPD has provided an interim compliance policy that says you don't have to stay off the market, even though they haven't reviewed you. As long as you've made a submission, you can go on the market and wait until you get your number. That is actually a pretty good tool for a company that doesn't have shareholders to report to and a legislated system of governance and by-laws. These systems require them to abide more by the letter of the law than the interpretation of it.

With this interim compliance policy, you have a notification system in play. It may be just a matter of trying to put this more formally into the recognized set of regulations.

Mr. Pierre Morin: But though you can be on the market, you cannot legally advertise your claims, nor can you get an export certificate for your product.

Mr. James Lunney: Yes, you're certainly held up by that.

Mr. André Gagnon (President, Canadian Natural Products Association): I was part of the first committee in 1997, the advisory panel on natural health products. I was a presenter for the association in front of the parliamentary commission at that time. My father was in the business for 60 years. I'm now the president of the biggest company in Quebec, Santé naturelle Adrien Gagnon, which is well known. So I have lived in this business all my life.

Actually I don't believe NHPD will be able to carry through. They won't be able to go through 50,000 products, one by one. That's impossible. From day one, I said it was not feasible, considering the limitations in budget, even with the best intentions. Nevertheless, if they're willing to find an ultimate solution, we will be willing to cooperate.

There's another aspect of this that I live with all day, every day of the week. Our company advertises a lot on TV. When you go on TV you need a pre-approval number, given by ASC, Advertising Standards Council. Before the new regulations, you could obtain your number under either the food regulations or the drug regulations, depending on your product.

I just had a phone call saying they cannot grant me a number to advertise omega-3 capsules on TV because now it's an NHP. Before the regulation, I could advertise. So Natrel, which makes omega-3 milk, can advertise, but I cannot get a number to advertise my omega-3 capsules. It doesn't make sense. It will take probably more than a year to get my NPN number for a simple omega-3 capsule. That's not acceptable.

In the interim, we have to find solutions. The simplest solution is to say to those people, “Listen, as long as I don't have my NPN, just continue to apply your criteria under the food, because meanwhile it still is a food”. By the way, they asked me to change my label. It's interesting to note that.

Initially I tried to get my number under the NHP. They said, “You don't have NHP, so do a food labeling”. So I changed my labeling for omega-3. I sent that back and started to do my commercials, because they said, “You can produce your commercials as long as you have food labeling. We'll give it a number.” Just yesterday they said, “We went up to NHPD. Now that it's an NHP, we can do nothing about it.”

I'm for appropriate regulations. We can cooperate with a system, but it cannot work this way. I'm also opposed to the amendment of Bill C-420 because it does not resolve the major issue, which is the application of regulations rather than the spirit itself. I think this comment could be useful in your consideration.

Thank you.

● (1620)

Ms. Wendy Hulton (Legal Counsel, Direct Sellers Association of Canada): If I may just follow up on that point, you can, in fact, actually get an advertising standards number, because they're now sort of trying to bend the law. Because technically you can't sell or advertise without an NPN, without a product licence.

What it has forced the Advertising Standards Council to do is now assess product advertisements on a case-by-case basis. So we're getting into this sort of grand conspiracy about how we're all going to sort of circumvent the law so we can continue to sell these products, which is just ridiculous. Whatever number you toss around, whether there are 40,000 products or 50,000 products on the market, the reality is there are 5,000 licence applications that have been submitted, and anywhere from 200 to 300 licences are all that have been issued. So technically there should be only 200 to 300 products on the market—technically, legally.

So if there's ever a problem, I think there are a whole bunch of products that are on the market illegally in Canada. And that's the problem—the backlog at NHPD with respect to getting the licences out for these products.

The Chair: Thank you.

Mr. Bigras.

[*Translation*]

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

When I look at the bill, I get the impression, and that is what our witnesses have just told us, that it has to be seen in two ways. On one hand, there is schedule A that makes out the last part of the bill. On the other hand, there are the definitions and the categories. I will not be talking much about schedule A since there seems to be a consensus. I would like to come back to categories and definitions and find out with you how we could amend this bill in order to make it more acceptable. It has at least the advantage of taking natural health products out of the category of drugs. I think that it is possible to improve it so that people can be fairly satisfied with it.

Mr. Bourgault, you told us that in 1998 you presented a brief asking that homeopathic medicines not be included in the same category as natural health products but rather constitute a new category. Could you elaborate on your intention? Were you in favour of amending the drug category in order to create a sub-category for natural health and therapeutic products? Is that what you are asking for?

I will also put my second question since I may forget to ask it later. I am rather surprised to see that the Canadian Natural Products Association did not go along with the proposal of the Canadian Health Foods Association which claims to be the voice of the natural products sector and which call for the creation of a separate third category. I did not hear you call for it today. Wouldn't the creation of a distinct new category having no relationship to either food or drugs be a more appropriate approach? That would mean amending the bill we have before us. In your view, would that be an approach worth examining?

● (1625)

Mr. André Gagnon: I will answer your second question. I do not think it is a question of categories. Under the Canadian legislative system, the government is responsible for food or drugs. I do not think that there would be a willingness to accept a regulation allowing for claims to be made for products without any type of control. Once again, I do not think it is a question of categories but rather how the regulations are to be applied. It must be decided what the criteria will be to allow a claim for product X. The fact that it is considered to be a food or a drug belonging to a sub-set of the drug category will not change anything.

It would be perfect if the minister accepted less demanding or rigourous criteria to make a claim for foods. Nonetheless, I do not think that the minister would agree to a manufacturer being able to make a claim tomorrow morning as he sees fit without submitting it to any form of proof or without complying with any particular criteria. I sincerely believe that it is not a question of sub-categories. It is a question of applying the regulation. It is necessary to come to an appropriate agreement so that the problem of unacceptable time delays can be settled. I do not know if my answer is clear enough.

Mr. Bernard Bigras: There may be a danger. There is a risk that natural products will be classified under the category of drugs in the legislation. Consequently, you will probably be asked to submit more thorough evidence and monographs, as is the case for medicines.

Mr. André Gagnon: No. Curiously enough, the present criteria are actually more rigorous than they were previously under the heading of drugs. It is quite absurd and this is not how things should have developed.

As a matter of fact, it is just as difficult at the present time to obtain claims for foods. To a certain extent, they are very limited. It is not any better when it comes to foods. It was extremely complicated to come up with regulations. I do not think that the regulations are yet complete. There may be two or three claims that are allowed in the case of food. It is not any easier.

If a product is advertised with a claim on the market, the minister monitors whether there is sufficient justification to allow for such a claim. That is where the problem lies.

My colleague, Mr. Skinner, says that there should be an across the board application and he is right. It is not logical that a drink like Red Bull is able to make more significant claims than those that we can make at the present time. There are now what is known as health enhancing or functional foods. Guarana will be added to certain beers. Soon energy claims will be made. The reasoning or the regulations should be applied in a consistent manner across the board. It is not a question of categorization but rather of applying the appropriate regulations.

We can provide you with more details if necessary but that is where the problem is. I do not think that we will be able to solve it by evaluating one by one all the products in Canada. It is materially impossible. It would take 10 years. Already, last year, in 2004, I made applications for 120 products. So far, I have received two monographs for two products with single ingredients. It does not make any sense.

Mr. Yvan Bourgault: I would like to answer the first question dealing with the sub-category. I did in fact mention that we resisted this. We mentioned that we did not want our products to be part of a new category. At the time, there was some question of then falling into a category that was not medicine or drugs but rather a third category.

Throughout the world homeopathic medicines are regulated as medicines. We have recognized pharmacopoeia in Canada, Germany, France and the United States that define and oversee the manufacture of such medicines and ensure that they are of appropriate quality. We do not think that things should be done differently in the Canadian market. It is our view that we should attempt to harmonize, as much as possible, Canadian regulations on homeopathic medicines with those to be found in other countries.

That is why the category "medicines" is very important for us. When we saw that natural health products were to be defined as a sub-category of medicines, we expressed our agreement but noted that in this case we would prefer to work with people who had a better knowledge of natural health products rather than working with the therapeutic products directorate which was very reluctant to recognize the differences of our products, from the point of view of safety, for example.

For us, the "medicine" or "drug" aspect remains very important so that our regulations can be harmonized with those in the United States, among others, where a medicine is defined as being a substance to be found in the United States Pharmacopoeia or in the Homeopathic Pharmacopoeia of the United States. That is how it is defined in the U.S. Of course, in Canada we are seriously influenced by what takes place in the U.S.

The term "drug" is clearly associated with homeopathic medicines in the United States as well as in Europe. That is why we would like to see our products included in the "medicine" category in Canada.

● (1630)

[*English*]

The Chair: Thank you, Mr. Bigras.

Mrs. Chamberlain.

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

One of the things that's been coming out over and over again in these hearings is that we need faster approval. I think everybody would agree that along with that, though, we need safety. I know there have been various people presenting, right from some people with the point of view that there is absolutely no harm that can come from these to other people saying that these are not totally benign. Obviously, people buy them because they want to cure something, so there's truly a health component in this.

You talked, Mr. Creber, about some of the mechanisms that you would propose for faster approval. I wonder if you'd go over those again. And then I'd like to hear if anybody else has anything to augment that, because I think this is a very serious component in this bill that we need to address for people.

So if you want to lead off, Mr. Creber, we'll go from there.

Mr. Ross Creber: Thank you very much.

I refer to our formal submission. We have our proposed solutions in two categories, an interim solution and a long-term solution.

Under the interim solutions, the DSA would recommend that Health Canada formally grant a moratorium on the product licence requirement for NHPs for at least three years, and grant an extension of the current deadlines for the filing of PLAs by at least one year.

Our second recommendation is to eliminate the backlog of product licence applications by implementing the following: reduce the delay associated with the review of all PLAs by hiring more Natural Health Product Directorate staff to assess and review PLAs; fast-track conversion of NHPs with DINs to NPNs and compendial submissions; and thirdly, to outsource preliminary screening of PLAs to NHP expert consultants.

A third recommendation on an interim basis is to amend the NHPD's and the inspectorate's compliance policies to formally acknowledge introduction of new products to the market, upon receipt of a submission number, which would be assigned following preliminary screening to ensure sufficiency of the PLA submission, to permit new products to legally enter the Canadian market.

In terms of our long-term solutions or recommendations, our first recommendation is to make more resources available to industry—for example, the NHPD's internal checklist for initial PLA screening; more product monographs; an updated non-medicinal ingredient list; and templates for acceptable evident safety and efficacy reports for common products or NHP ingredients.

The second long-term solution would be to set reasonable performance standards for the PLA and site licence review process—for example, 120 days to the issuance of a licence.

The third recommendation is to provide more training for NHPD staff performing the screening and the reviewing of PLAs to ensure a more consistent and even-handed approach to the evaluation of PLAs.

Our fourth recommendation is to reconsider the implementation of a more appropriate level of scrutiny or review for lower-risk NHPs, as recommended in the report of the Standing Committee on Health.

Our final recommendation is to give serious consideration to revisiting the concept of NHPs as a distinct third category, as opposed to being a subset of drugs, as part of the legislative renewal process.

Hon. Brenda Chamberlain: Thank you.

Mr. Morin, you wanted to add to that?

Mr. Pierre Morin: Yes. I think that you've just raised a most important question.

If one goes back to the committee's 53 recommendations, I think there was no intent to declare products that were safely on the market illegal, and yet on January 1 this is exactly what happened. I don't think it was the intent of this committee to see that happen.

So while you're sitting, it may be a good thing to look into the current bill and see if it isn't possible to reinstate the legality of products currently marketed that are safe—they have to remain safe—and the current regulations that provide for the removal of any product that is deemed unsafe, which is quite all right. But basically reverse the process that occurred on January 1, 2004, and still go through and approve a process, so at least the products currently on the market can be sold legally, can be exported legally, and can be advertised legally.

Thank you.

● (1635)

Hon. Brenda Chamberlain: Thank you.

Is there anything further? Yes, Mr. Carter.

Mr. Carl Carter: If I can comment on that as well, I think we need to keep in mind that our members, for years and years, have complied with the drug requirements, and we were instrumental, I think, in setting up what's called the category IV product monographs to expedite approval of products like sunscreens, for example, in a 45-day period. As soon as the natural health product regulations came into effect, that avenue of getting these types of products registered dried up. In other words, the Therapeutic Products Directorate said, "No, we can no longer review these types of products; they have to go over to NHPD." Now, that took about a year to decide which active ingredient went into which camp so we could know where to submit it. So basically both avenues dried up.

We have advocated on two occasions, the most recent of which was earlier this year, and suggested that in fact to help with the backlog, perhaps TPD could be allowed to continue to approve these types of products. This sunscreen is currently on the market as a drug, and has been for years. It will, by virtue of the fact that it contains zinc oxide, become a natural health product. Now it's staying on the market, but if somebody wanted to launch this same product, they'd get caught up in the same queue over and over again, and yet, bingo, within 45 days, through the Therapeutic Products Directorate.... And I'm sorry, this is not really a health-and-safety issue, because there are a lot of products that contain zinc oxide and titanium dioxide as the active ingredient.

What's frustrating for us is that I think the government, and the Natural Health Products Directorate in this case, or Health Canada in general, has not stepped up to the plate and said, "You know what, there is some reason to this in terms of dealing with our backlog". Not only is it a way to help industry get its products forward, but I think it's an opportunity for government as well to focus on its true priorities.

Hon. Brenda Chamberlain: Thank you.

Does anybody else wish to comment?

Mr. Skinner.

Mr. David Skinner: There is just one quick thing they could do. It seems silly to us that a product that has been on the market, and pre-approved, and reviewed, and carrying a DIN for 10 or 15 years, now has to go through the process all over again. Just almost grandfather those by assigning them, as we said before, the same number, and put the letters NPN in front of DIN, and you clear up a lot of them.

But even more so, we've heard from everybody that there are very many quirks in definitions and subdefinitions, and fine slicing, and you have shades of grey. We'd really encourage HPFB to take a hard look at their regulatory environment for all these lower-risk products. They're all used by people for things they are doing for themselves, and the regulatory environment needs to be simplified and basically rationalized.

The Chair: Thank you, Mrs. Chamberlain.

Mr. Carrie is next.

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

Thank you very much for coming today and testifying before us. This is something that.... I've heard from thousands of Canadians who are frustrated with this issue. Mr. Gagnon was saying it really doesn't matter what category you're under; if you apply the regulations in such a way that it is going to be disruptive and onerous on the industry, there's going to be a cost to that.

You mentioned there was a cost to you recently, because of the way they're applying it and changing it. Do you mind letting us know approximately how much the cost was? You mentioned, I believe, the omega-3 oils. You had to change the labels and go through different things.

Mr. André Gagnon: When we had, under the new regulations, to submit our applications, filing applications for about 100 or so products.... Right now we're into more than $200,000 in time, consulting time, and scientific persons to file those applications. That's important to state again.

When the regulations were out, there was no mention of a phase-in period to send in your application. This was a surprise that came afterward. It's understandable, because they didn't want the companies to wait five years to send their applications in. That's fine.

So they came up with some deadlines for sending out your application. The problem was that because those dates were so close, we had to invest the money, but the problem is that even after spending more than $100,000, you didn't even have a clue if one, two, or three would pass, so we asked them to push back those priority dates so at least we have some kind of feedback about whether it's worth while investing money to send in our applications.

They said no to that, but in a way they said that legally speaking, our product could still be on the market. This was my opinion from the first day. In the policies that came out initially, they said you could not put a new product on the market if you didn't have an NPN, but because they could not meet their deadline, they finally said—they could not write it in the policy because it's illegal to do so—if you read between the lines, the products are no more illegal if you have an NPN or not after January 1, 2004. This is technical.

To answer your question directly, yes, we've invested a lot of money with no feedback as of now.

● (1640)

Mr. Colin Carrie: When I was looking at this problem, one of the things is because they originally decided to classify them as drugs. I do see that as a problem, because automatically you're looking at a very safe product. Natural health products—as one gentleman said earlier today, there have been no deaths in Canada. Why should we be regulating them under this drug model?

Mr. André Gagnon: The problem is not safety, basically, because it was recognized in the parliamentary commission, the report—

Mr. Colin Carrie: In 1998.

Mr. André Gagnon: They were generally recognized as safe.

Mr. Colin Carrie: One of the arguments we've been getting, over and over, is we've got to keep them safe, we've got to keep them safe.

Mr. André Gagnon: Yes, but it's the claim. The problem is the claim.

Mr. Colin Carrie: The claim?

Mr. André Gagnon: Yes, that's where the problem is. It's not safety.

Mr. Colin Carrie: No, but this is what people are bringing up—this is a safety issue.

Mr. André Gagnon: It's not a safety issue. It should not be a safety issue.

Mr. Colin Carrie: It should not be a safety issue. It should be a claim issue.

Mr. André Gagnon: It should be a claim issue.

Mr. Colin Carrie: It should be a claim issue, and have the best to follow these.

The difficulty, as we were mentioning, is what to do with it now. There's been a lot of talk of bringing it into a third category, but if the regulations are pretty much the same, and you're going to have to go through the same thing, as you were saying, it's not going to help the industry and it's not going to help Canadians.

Hence came the solution to bring it as foods, to make it less of a regulatory burden, but that in itself—I see there are going to be problems as well.

Mr. André Gagnon: It is the same problem with claims, again.

I want to add one comment to Mr. Creber's comments. In an ideal world where funds were unlimited, I would agree with the suggestion Mr. Creber made, but I do believe there are some limits in the treasury in order to hire staff—more and more staff—in order to fill out the applications and the backlog.

Right now I'm not in a solution mode within HPFB, because they still think they can accomplish their goal—meaning that, one by one, they go through all those applications. It's not a lack of goodwill or cooperation that those people have in HPFB. Again, I've been working with them since day one. It's just that I don't believe they'll be able to achieve this. It's too big a task. It will end up like the firearms, actually.

Mr. Colin Carrie: And the concern is we are driving all these small companies out of business by overregulating them.

Mr. André Gagnon: What they'll answer is that they can still be in business. That's true, because as long as they're not giving you a licence, they have the right of remaining on the market. That's fine, but still we cannot advertise legally. This is a problem, because under the old regime I could advertise legally. At least we need to resolve that problem in the interim.

Mr. Colin Carrie: If we talk about advertising, too, because I think most of the witnesses are in agreement about schedule A, subsections 3(1) and 3(2).... Mr. Skinner, would it make any difference at all if we eliminated those?

Mr. David Skinner: In terms of eliminating schedule A, are you asking what difference it would make in terms of protecting the consumers against fraud, so to speak?

Mr. Colin Carrie: Exactly. Are there any issues there?

Mr. David Skinner: There aren't. Schedule A really doesn't do anything under the framework of regulation to protect the consumer against fraud. It's what you say as your claim that's allowed in your product licence, and since that's all reviewed, schedule A is meaningless in that context. As for organizations like Advertising Standards Canada, they utilize that approved claim to approve the advertising, so schedule A doesn't give anybody any of the tools they need to address the advertising issues.

There are two things about advertising. We did hear a lot this morning from Dr. Lexchin about our Rx advertising, but quite frankly schedule A has nothing to do with Rx advertising. The prohibition that exists in the regulations is what keeps Rx advertising at the level it's at.

One thing I might encourage the committee to do is to contact ASC. Linda Nagel is the president of that organization. Perhaps you could ask for her comments on how advertising and schedule A work, or don't work, together.

● (1645)

The Chair: We'll now go to Ms. Dhalla.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Once again, thank you to all our witnesses who've come here today.

As a health care provider, I'm a big believer in ensuring that Canadians and patients do have freedom of choice, but I think that safety and quality of product are tremendously important. One of the things we've heard consistently over the last two days is having a repeal of subsections 3(1), 3(2), and schedule A. I've also heard some of the challenges people like Mr. Gagnon have had in the application process.

Could you please tell us as committee members, and for my own personal knowledge—do you think the repeal of the subsections and of schedule A will reduce the timelines involved in the whole application process?

Mr. André Gagnon: No. Again, as Mr. Skinner said, it has nothing to do with it, because you have other customs in order to address the claim issue. Whether schedule A is there or not, you would still have to go through the application process and submit your backup documentation in order to get your claim. Again you have different mechanisms in order to act as a customs—to say yes or no, you can or cannot do that claim, if you have sufficient proof that the product is good for treating this or that disease, or reduces the risk of having disease, or treats the symptoms associated with those diseases—so it's very important to understand that whether schedule A is there or not, it won't hurt the safety of Canadians. Unless I'm wrong, it has nothing to do now with the other means of controlling the claims, of the approval of the claims.

Mr. David Skinner: To put a finer point on that in relation to schedule A, plenty of data in the public realm show that utilizing this product here regularly and frequently can help reduce the risk of skin cancer. You could put all that data in to NHPD or TPD or wherever you end up sending it—in this case, TPD—and you would tell them all the data are there. They'd say they agree, but schedule A says we can't let you on the market with that claim. That is one big impediment. To go back to André's point, if schedule A goes away, they'll at least allow it on the market, but it will still probably take a year and a half.

Ms. Ruby Dhalla: I have another question, in terms of the claims submitted. I don't know, but perhaps through dealing with your member organizations you would have the information. We know about 6,000 applications were submitted, and about 300 applications have been approved thus far. Is there a breakdown of whether small or mid-sized or large-sized businesses are receiving them?

Mr. André Gagnon: It has nothing to do with the size. It's simply to do with whether it has been monographed or not. Most of the granted applications—95% or 96%—were granted based on their monographs.

It does not address the bulk of the marketplace, which is in product combinations, so when they give numbers—yes, we're up to the 300th application number—it doesn't mean anything. It's monographed products. You don't even need that system of pre-approval to give NPN approval for monographed products. You could deal with a post-notification system, which was suggested by the transition committee. It would be as safe for the consumer anyway, because the inspectorate, right now, acts afterwards in the industry.

Whether you're pre-approved or not, if you go through a notification system, it would address at least the single monographed ingredients, but again it does not address the bulk of the marketplace and the growth of the market. They are into combination products. Again, I would go into solution mode if everybody agrees that we need to find an alternative solution. We can find a solution. Right now, I cannot, because there's no use to it.

Ms. Ruby Dhalla: There's nothing off the top of your head that you would give our committee members as a solution?

Mr. André Gagnon: Not really right now, because we have to discuss that.

Ms. Ruby Dhalla: Anything else from...?

Mr. Carl Carter: I think in terms of our experience with only two products registered, it's pretty tough to categorize whether they're small or big companies. Certainly Colgate is one of the larger companies we have, but I would suggest for us that the problem is much more systemic than just the resources available to a particular company. Certainly what we're finding in our industry is a lot of members, I think, based on the fact that we're used to registrations happening fairly, quickly, and predictably, and it's very important for our sector.... The fact that this has not been happening has caused many companies, I think, to question their own technical people who do the registrations, and do they really know what's going on?

The answer is yes, I think the industry knows what's going on, and I'm not sure that NHPD is capable of following through. I think the point is that they are actually going out and hiring consultants. I think we were quite surprised about a survey we did of our members that one of our consultant members is actually processing between 30 and 40, has made 30 to 40 of the applications of the roughly 100 that our sector has applied for. It's coming through one particular consultant. I suspect that they're working mainly with smaller companies, as opposed to larger, but it's from our perspective, and once again it's based on only two products, regardless of the size of the applicant.

● (1650)

The Chair: Thank you.

We'll now go to Madame Demers.

[*Translation*]

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

Mr. Carter, I was very surprised to hear that cosmetics are considered as natural health products. In your presentation, you made reference to the recently adopted European regulations, a copy of which you have provided as an annex to your submission.

Are the European regulations similar to the United States regulations in terms of how the term cosmetics is defined?

[*English*]

Mr. Carl Carter: In terms of similarity to the U.S., no, they're not. The European definition is actually quite unique compared to the American definition, and it's really I think unique within the world. I think what we're seeing, and as evidenced by what Australia is doing as well, and really independent of what Europe is doing, is they're revisiting their definitions and have recommended that some of their therapeutic products be shifted over to the cosmetic regime.

[*Translation*]

Ms. Nicole Demers: Would you be able to send us a copy of the Newgreen report, which you have also mentioned? How do you feel the term cosmetics would be best defined?

I have read the European definition, and found it to reflect my viewpoint. From a legislative point of view, what do you perceive as being the best solution for Bill C-420?

[*English*]

Mr. Carl Carter: We would certainly be pleased to provide a copy of the new green report, whether it be to the clerk of the committee or to you directly. We will probably plan to do both.

With respect to the definition, and back to a point that Mr. Skinner made about the legislative renewal initiative, the fact that a lot of this information and a lot of these issues have really been vetted somewhat through the legislative renewal process, I think this is one issue that has been discussed. Within those discussions, a specific definition was not put on the table per se, but what we would advocate with respect to the definition that should be adopted here in Canada would be similar to what the European Union has done, and actually listed and stated an illustrative list by category of cosmetic products. So in the case of deodorants, it actually states deodorants and antiperspirants. With respect to toothpaste, for example, it states "products for care of teeth and the mouth", so it eliminates this fine line defining, if you will, between "does it modify a body function", and so on. We would essentially advocate that the wording of the definition be adopted similar to what it is within the European Union—

[*Translation*]

Ms. Nicole Demers: Thank you.

[*English*]

Mr. Carl Carter: —and we have included a copy of that as appendix B.

[*Translation*]

Ms. Nicole Demers: Thank you, Mr. Gagnon.

If I have understood you correctly, your primary concern regarding the current legislation is that it prohibits advertising products which have not yet being granted an identification number.

Mr. André Gagnon: Allow me to give you a more precise explanation.

Ms. Nicole Demers: Please do.

● (1655)

Mr. André Gagnon: There have always been two different ways of advertising, one of which is a little less stringently regulated than the other. Since the ASCs became a voluntary system, a change of which not everybody is aware, television companies have become a lot more sensitive to the issue. TV companies will not broadcast any advertisement that does not carry an ESC. In theory, the same rule ought to apply to radio and print media; but that is not actually the case. While it depends on the level of risk that media owners are willing to take, today's reality is that regulations governing print and radio offer more freedom and are therefore less stringent. Radio stations are willing to carry advertisements which do not have a pre-approval number.

Ms. Nicole Demers: Why do television broadcasters accept to advertise products which contain additives such as omega 3 or vitamins?

Mr. André Gagnon: Because these products are considered to be food, both under the legislation and the regulation.

Ms. Nicole Demers: They are not defined as being natural health products, even if they contain natural health products?

Mr. André Gagnon: Exactly.

I think that it is unreasonable that they are allowed to do so while I am not even allowed to benefit from my status under old system, which recognizedmy products as food, during the transition.

Mr. Skinner remarked earlier that, as a private company is accountable to its shareholders, it would sometimes choose to sidestep the regulations. We have no choice but to sometimes deviate from the regulations, because we cannot survive in the current system; we do not take any side steps which will put consumer health at risk. We simply find ourselves in a legal dead end which sometimes leads to us taking measures which will eventually result in the system being changed.

Ms. Nicole Demers: Thank you.

[*English*]

The Chair: Thank you, Madam.

Mr. Thibault.

[*Translation*]

Hon. Robert Thibault: Thank you very much. I would like to thank our panellists once again; you have brought a lot to our discussion, offering an alternative perspective to what we heard all day yesterday.

Do you believe that Health Canada has a role to play in terms of advertising, or is it not a matter which comes entirely under the jurisdiction of Advertising standards Canada

Mr. André Gagnon: The Advertising Standards Council of Canada does not make a decision by itself. It could do so, but it takes a look at the NPN, because since January 1, a product is not legal unless it has an NPN. The council cannot assume responsibility for authorizing wording for a product that does not have an NPN, if it is categorized as such. I do believe that it could, given that products are still legally sold on the market, accept or consider wording according to two categories: drugs, and therefore there is the DIN, or food. David, correct me if I'm wrong, but if we want to obtain advertising wording or approval for a product containing several vitamins, we still have to specify the DIN when we submit the application.

Hon. Robert Thibault: I do not want to keep you too long. I understand the issue better now.

Mr. Morin, you said that since the products already on the market were safe, they should be grandfathered so we could continue...

Mr. Pierre Morin: No. I simply said that if you could change what happened—and this is something you do not want—, you should ensure that products currently on the market, which have been regulated since January 1, be declared legal on the market.

Hon. Robert Thibault: These are the ones that have the DIN?

Mr. Pierre Morin: No, those with the DIN are already legal. I'm referring to all of these products that are said to be natural health products and which, since January 1, 2004, are in a no-man's-land: they have not received the NPN and will not be able to do so for several years, but this needs to happen before they can be legally sold on the market. It is absurd.

Hon. Robert Thibault: It would therefore be up to the entrepreneur to prove that he is on the market.

Mr. Pierre Morin: He is always compelled to prove it. We are not trying to avoid that.

Hon. Robert Thibault: I would add: if he wants to benefit from this clause.

Mr. Pierre Morin: You will recall that your 1998 recommendations said that the products should continue to be sold on the market. You stated that. However, legally, all these products that do not have an NPN—I'm not talking about the DIN—could, right now, be taken off the market.

[*English*]

Hon. Robert Thibault: This is the last question I have.

From what we've heard pretty well from everybody who has presented—or the vast majority—migrating to the food is not the answer. The question of a third and separate category for natural health products is not.... Some people would like it—it might be the ideal—but the regulations create it, so we in effect have it. So that's not the priority.

In your case, Carl and David, you're talking about personal care products that are in another no-man's land, and you're talking about creating a separate category again. If we had the third, this would be the fourth. Do I understand correctly?

Mr. David Skinner: No, not necessarily. You can have as many subcategories as you desire. The classic one is whether it is a food-like health product or a health-like food product. Those kinds of shades of grey become interesting arguments for cocktails—and I'm not sure whether that's a natural health product myself.

Hon. Robert Thibault: If it fizzes, it's a drug, I guess.

Mr. David Skinner: What we're saying is that there are whole categories of products that are of lower risk, that are used for everyday purposes, to either maintain your health, help reduce the risk of further illnesses, or in response to minor health concerns, or even personal hygiene. They're all of lower risk, they're all used daily, they're not part of drug plans and the big-cost components of health care, but they can stand to help with health care.

What we haven't had is this kind of a systematic review of our regulations for lower-risk products. We've done a little piecemeal, here and there. We did the NHP thing, and now we have issues with cosmetic and personal care products, and so on. Until we actually grasp what is self-care, what can it do for people, and how are these lower-risk products appropriately regulated as a class, within that class of self-care you can have natural health products, cosmetic, OTC, whatever categories you choose.

● (1700)

Hon. Robert Thibault: But perhaps where you lose me is when you talk about the self-care subclass or category. I think of self-care as antiperspirant or shampoo, or things like that, but I can also think of self-care as Metamucil, or as vitamins or amino acids, or all these other ones—

Mr. David Skinner: They all are—

Hon. Robert Thibault: —that I'm seeing as natural health products that could be used to treat or prevent diseases, as opposed to keeping yourself fresh and smelling nice.

Mr. David Skinner: Actually, that's where you get into all the shades of grey. As Carl was mentioning, a sunscreen can either be a natural health product or a drug, depending on whether your active ingredient is zinc oxide or PABA, or something like that. It doesn't make any sense.

It's very similar to what André was saying with respect to the advertising. It doesn't make any sense that Health Canada will allow you to have the product on the market with the claim that is absolutely consistent with their published standard on their website, and so on, and when you take that to get advertising, some other part of Health Canada, the Marketed Health Products Directorate, says, "Well, not according to us." So you have this dichotomy. It's not just in the regulations, but it's the administration of these regulations.

I've always said it doesn't bother me what people call anything. It's, on the day-to-day basis, what do you do with the products from a regulatory and administrative practice standpoint? It needs to be simplified. It's way too complicated.

Hon. Robert Thibault: I know I'm getting near my time.

You're working on the transition team. Do you see that solution coming, or do we need new legislation that legislates the renewal process that we've been holding back? Do you see something on the horizon that can take care of a problem like this?

Mr. David Skinner: I've always said I've seen light at the end of the tunnel, but it's a pinhole, and it doesn't seem to be getting any bigger. That was why one of the things I was mentioning was that legislative renewal went through a multi-year consultation phase. A lot of these questions have been raised, and we just can't seem to get on with it. There's always something else that takes a bigger priority.

As much as I recognize other priorities, the future of health care in Canada really rests on a sustainable system where people can do more things for themselves so we don't end up spending a whole lot more money and emerge from our 10-year plan with as much debt and future obligation as I'm sure we're going to end up with. So from the standpoint of where we're going to go, yes, there are possibilities, but it just never seems to get the priority. That's what we're asking this committee to send the message on.

Hon. Robert Thibault: Thank you very much.

Madam Chair, perhaps it would be wise at one point to invite these panellists to present to us in written form—or maybe we have it within their documentation—what elements we could move on that would assist in that.

The Chair: Yes. Your line of questioning has interested me too.

Mr. Skinner, you said the light at the end of the tunnel is a pinprick, and yet you serve on the committee that is trying to get somewhere. What in your view—if you could be frank with us—is the barrier? Is it groups of public servants trying to protect their own turf and keep these separate silos going, or...?

Mr. David Skinner: I'd say there's an element of that, but it's very systemic. The regulations themselves set up silos that are protected by a group of people who are designed to administer that silo. So it's self-perpetuating.

André would remember from day one, way, way back when, and I was saying, how can we be talking about certain claims for calcium in a pill and not talk about them as calcium in a food, in milk and so on, and how could we have different sets of claims in one and different standards of evidence in the other? What you're talking about is the delivery format. One is in a liquid form that you would drink, and the other is in a capsule that you would take.

So I've always said there needs to be a simplification and boiling it down to basic principles. I think it was Will LaValley who said first principles are the most important.

● (1705)

Mr. André Gagnon: It makes me old when you talk about the old times.

Mr. David Skinner: Slow progress.

Mr. André Gagnon: The point is that we need to address the claims. I do remember saying that. I don't think legislative renewal would resolve the issue, because whatever legislation you do, you end up with regulation, regulation, and policy.

Again, the way in which the policy is administered is where we need to focus our attention, I think, and try to find some workable solutions. That's my personal belief, actually. Going through legislative renewal would take about five to ten years, and I still don't think it would resolve the issue.

Mr. Pierre Morin: Not unless you were to write it into a piece of legislation that any substance having the same effect, whichever form it's delivered in, should be regulated the same way, no matter which directorate is charged with regulating it. Coming back to calcium, whether it's food, whether it's TPD, or whether it's NHPD, we'd be regulating it the same way. That is where you get your silos. The moment you create a directorate, or allow for the creation of a directorate, then it wants its own regulations, its own regime.

Mr. David Skinner: It's the need for a single window, yes.

Mr. Pierre Morin: It wants its own definitions, its own policies, and it needs to be self-perpetuating.

Ms. Wendy Hulton: Madam Chair, if I may, I think you put your finger on it when you were asking Mr. Skinner about the timing. I think the problem is that it's getting to be a big problem, and it's getting to be a big problem very quickly. The regulations took effect January 1, 2004. We've tossed around a lot of numbers, but the problem is that in the interim, we have only 200 to 300 legal products on the market right now. So whatever the solution is, it's got to happen sooner rather than later.

I know that the natural health products directorate has a number of plans in place to address the backlog, and they think very optimistically about the backlog. If you talk to them, they think they're going to have a breakthrough at any moment to address the backlog. But the reality, I think, is that they're overly optimistic about that. It's not going to happen. Just the sheer numbers involved, as Mr. Gagnon has pointed out, means it just can't happen, even with all the goodwill in the world.

So whatever the light is at the end of the tunnel, we have to speed up the train to get there more quickly or we're just not going to have any products left on the market. The reality is that if someone picks up the phone, calls the inspectorate, and says, “I bought this product at a corner store, I think it's a natural health product based on the definition, but it doesn't have an NPN on it, and I'm not sure what to do”, the inspectorate has to obey the letter of the law. They have no choice. They have to say, “Well, that's an illegal product”, and they have to go and knock on the door of the company that's marketing that product and tell them to take that product off the market. They don't have any choice.

I've never seen Health Canada put it in writing that you can go to market with a product without an NPN on it. They can't say that. They can never put that in writing. They can do the wink-wink, nudge-nudge, “Bring your product to market and we won't take any compliance action against you”, but the reality is that the product is not legally on the market. That's why the solution needs to happen quickly.

The Chair: In that big backlog of about 4,000, how many of them already have a drug identification number, or DIN?

Ms. Wendy Hulton: Not many; about 300, Madam Chair, we've been told.

Mr. David Skinner: That's in the current backlog. Since the DINs are five-year transitional, you can be sure that by the time you hit the end of the five years, some 11,000 DINs out there might qualify. So it's not a matter of how many are in the backlog now; there's a big bubble waiting out there, too.

The Chair: Okay, but that grandfathering.... If they've been through the drug process to get a DIN, I can't imagine why they have to go through this process again.

Hon. Brenda Chamberlain: I don't know either, and I think this is key.

The Chair: It's not covered in this bill, but we as a committee could write a letter to the minister about that.

Hon. Brenda Chamberlain: We could ask for a date to report back, just like we did.... Do you know what I mean?

The Chair: Yes.

Mr. Pierre Morin: But there's another major problem. As of next year, the good manufacturing practices applied to natural health products come into force. Some DIN products, which are drugs, will shift over in terms of their good manufacturing practices, or GMPs. There are mutual recognition agreements, or MRAs, in place with Europe and Australia, where the inspection certificate done in one country is accepted as is in the other country. This is true of Europe. This applies to drugs.

So we're going to change the GMP regime for those that will be becoming NHPs, and they lose that status. We've been raising this issue with NHPD for a number of years.

● (1710)

Hon. Brenda Chamberlain: It's crazy.

Mr. Pierre Morin: Yes, it is crazy, and there's a major issue there.

Hon. Brenda Chamberlain: I think the least we can do when we identify something like that as a committee is to put it forth.

Mr. David Skinner: Even if a company that has been producing its natural health product to GMP standards says it wants to continue to do that so it can continue to export, it won't be allowed to as of the end of this year.

The Chair: That's crazy.

Ladies and gentlemen, on behalf of my colleagues on the committee, I would like to thank all the witnesses for coming and throwing all these problems in our lap—

Voices: Oh, oh!

The Chair: —even though they're beyond the scope of Bill C-420.

Just how much we might be able to move forward on this all depends on how long this Parliament lasts. Of course, we wouldn't move forward without some guidance from our researchers. However, you certainly have given us interesting things to think about.

Thank you very much for your efforts and for coming to us today.

I will ask my colleagues to stay for a minute. Maybe we could just do this before there's a hubbub in the room.

We need a motion passed to give ourselves a budget that has to do with the study of Bill C-420. I think we've spent part of it already, so we need to replace it, and I need a mover for that. It says that the proposed budget in the amount of $39,175 for the study of Bill C-420, an act to amend the Food and Drugs Act, be adopted.

Ms. Ruby Dhalla: I so move.

(Motion agreed to)

Hon. Brenda Chamberlain: Madam Chair, I'm just asking about the timing. I guess we're going to come back to this in the week of May 19, are we? Is that correct?

The Chair: I'm not sure, but yes, probably.

[*Translation*]

Ms. Nicole Demers: Perhaps.

[*English*]

Hon. Brenda Chamberlain: Well, we hope so. Let's put it that way.

The Chair: Those people who really want to work on this will be back. Maybe those people who don't care—

Hon. Brenda Chamberlain: I guess it will be you and me.

Some hon. members: Oh, oh!

Hon. Brenda Chamberlain: The rest don't seem to be too concerned.

I really hate for us as a committee to go through something and feel we've identified something that is really a problem and then just leave it. I'm wondering if there's any direction or if we can agree in committee that there would be some investigation done, either by the researchers or whoever on this, for a report back to us such that in case we were dissolved in some fashion, there would be something we'd leave as a committee from what we've done, because we've done some work on this.

Ms. Ruby Dhalla: Can we change the schedule around?

The Chair: Health Canada and the NHPD are coming again at the end of this.

Hon. Brenda Chamberlain: When, though? That was my question.

The Chair: I think it's the 17th.

Ms. Ruby Dhalla: Can we move that up to next week?

Mr. James Lunney: We have witnesses on the 12th.

The Chair: We have the 9th, the 12th, the 16th, and the 17th, and the last panel will be the people from the NHPD.

I might ask the researchers, if they heard what we heard, to maybe compose a letter we might send to the minister, particularly on this grandfathering idea.

Ms. Ruby Dhalla: Even the last week, when the NHPD is coming, perhaps we can combine them with another set of witnesses if there is time.

The Chair: Well, they actually had a meeting to themselves: Health Canada and the NHPD and then we make our conclusions.

I also want to raise with you the fact that we're supposed to do the clause-by-clause on Bill C-28 on Thursday, and with all this about Bill C-420, I'm feeling I can hardly remember what Bill C-28 was about.

The clerk has not received any amendments. Is that as you understand your party's position? Do you know, Madame Demers, that there haven't been any amendments received by the clerk?

[*Translation*]

Ms. Nicole Demers: I believe that we will be moving an amendment, Madam Chair.

[*English*]

The Chair: The deadline was actually yesterday, but I don't feel we're ready to swing back into clause-by-clause on something we haven't heard about for three weeks. At the Thursday meeting, I think what we'll do is have a little review of Bill C-28 by Health Canada, and then we have another little task on helping the minister design the membership—

Hon. Brenda Chamberlain: Are you proposing a review on Thursday?

● (1715)

The Chair: I'll try to get us a little review of Bill C-28 as opposed to doing the clause-by-clause, and we'll extend the opportunity for amendments to Thursday night, maybe.

Ms. Ruby Dhalla: Madam Chair, couldn't we call in NHPD on Thursday, or is that too soon for them?

The Chair: That's too soon, and we have these other people lined up.

Ms. Ruby Dhalla: We can't alternate or switch them at this point?

The Chair: No, because they need time. You have to give your guests warning.

[*Translation*]

Ms. Nicole Demers: Madam Chair, we will not be moving an amendment to Bill C-28; we are against it. I thought that you were talking about Bill C-420.

[*English*]

The Chair: Oh, you're not having amendments.

I still think we need a little review by Health Canada on what Bill C-28 is about before we start the clause-by-clause.

Mr. James Lunney: Madam Chair, before we close here, in spite of Madam Chamberlain's pessimism about the committee's being able to complete its work on Bill C-420, I'm sure all members have an interest in seeing this accomplished so we can make a significant difference toward solving the problems associated with this bill.

The Chair: Thank you, Mr. Lunney.

We all hope so.

Hon. Brenda Chamberlain: I'm not pessimistic at all. I'm quite optimistic.

The Chair: This meeting is adjourned.

Thank you, ladies and gentlemen.

Published under the authority of the Speaker of the House of Commons

Publié en conformité de l'autorité du Président de la Chambre des communes

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