HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

Standing Committee on Health

HESA • NUMBER 034 • 2nd SESSION • 41st PARLIAMENT

EVIDENCE

Thursday, June 12, 2014

Chair

Mr. Ben Lobb

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● (0845)

[*English*]

The Chair (Mr. Ben Lobb (Huron—Bruce, CPC)): Good morning, ladies and gentlemen. We're continuing our study of Bill C-17.

We have a full schedule here today, so we'll get right at it. We have a number of witnesses here for the first hour, and then we'll have some for the second hour. As we always do in these meetings, we'll try to start with our guests who are here by video conference.

Can you guys hear us okay?

Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association): Yes, I can.

The Chair: You can go first. You have 10 minutes or less to make your presentation.

We have Jim and Jody.

Go ahead, please.

Mr. Jim Keon: Thank you, Mr. Lobb.

Welcome everyone. Thank you for the opportunity for Canada's generic pharmaceutical industry to contribute to your study of Bill C-17, Vanessa's law. Thank you for accommodating our need to appear via video conference this morning.

I am Jim Keon, the president of the Canadian Generic Pharmaceutical Association. I'm joined today by Jody Cox, our vice-president for federal and international relations.

I'll say just a couple of words about the CGPA, the Canadian Generic Pharmaceutical Association. We represent companies that specialize in the research, development, and production of high-quality generic medicines, fine chemicals, and new chemical entities. We are Canada's primary pharmaceutical manufacturers and exporters and are among the top research-and-development spenders across all industrial sectors. The generic pharmaceutical industry employs more than 12,000 Canadians in highly skilled scientific and manufacturing positions and operates large life sciences companies in Ontario, Quebec, and all of Canada.

The generic pharmaceutical companies have an essential role in Canada's health care system. Generic pharmaceutical products provide safe and proven alternatives to more expensive brand-name prescription drugs. In 2013 alone, the use of generic prescription medicines saved governments, employers, and consumers approximately $13 billion. Today, four or five prescriptions for generic medicine can be filled for the cost of one brand-name prescription. We are proud of the fact that two out of every three prescriptions in Canada are now filled with generic medicines.

Generic drugs are approved for sale by Health Canada and are identical or bioequivalent to the brand-name version. Each product must also meet the rigorous and internationally accepted standards established by the Food and Drugs Act and its regulations. Generic medicines are required to have the same quality, purity, efficacy, and safety profile as branded drugs.

By the time a generic version is licensed for sale in Canada, the drug has generally been on the market for between 12 and 15 years in Canada and other jurisdictions, and the safety profile of the drug is generally well established. Even so, Canada's generic drug companies take our responsibilities with respect to patient safety very seriously. For us, patient safety is paramount.

I'd like to make a few comments on the bill.

On behalf of the association and our member companies we would like to congratulate member of Parliament Terence Young for championing Bill C-17 and the minister for bringing it forward.

In general, the CGPA supports Bill C-17. We note that it is enabling legislation and that many of the finer details will be provided for in regulation, which we will of course follow very carefully. I will briefly address a few certain aspects of the bill.

First, I will address the new powers for the minister. Bill C-17 provides several new powers to the Minister of Health. They give the minister expanded powers to obtain safety information, modify labelling, recall drugs or take other corrective actions, and obtain a court injunction on 48 hours' notice or no notice at all in the event of a perceived health risk.

During their testimony to the committee, the minister and Health Canada officials pointed to a specific instance where it was felt that undue delays were created in negotiations with a manufacturer. In most instances, however, manufacturers voluntarily comply with the requests from our Canadian drug regulator, Health Canada. The CGPA is of the view that a thoughtful, risk-based dialogue between the manufacturer and the regulator generally brings out the best outcome for patient safety. As such, it is our view that a voluntary approach is appropriate and should be maintained. That said, we do support the minister having the ultimate power as a last resort.

Next is adverse drug reactions, ADRs. There is no question that information is a key component of assessing the risks associated with a medicine. While drug companies have had a mandatory reporting requirement for many years, the health care professionals who are the primary point of contact for patients have had no such obligation. As such, the CGPA supports a mandatory requirement for prescribed health care institutions to report adverse drug reactions. This new requirement will help to narrow an important information gap and will improve both the quality and quantity of ADR information available.

We have a comment about post-market surveillance. As previous witnesses have testified, Health Canada has been moving towards a life-cycle approach to drug regulation for several years.

● (0850)

While the current regulatory scheme focuses on drug review prior to and leading to market authorization, the amendments allow the minister to order a manufacturer to "compile information, conduct tests or studies or monitor experience in respect of the therapeutic product".

While CGPA welcomes this approach, we look forward to consulting with Health Canada on the specific details of the regulation and guidance that will be associated with these changes. In particular we recommend that the regulations and guidance specifically clarify any shared duties or actions between generic and brand manufacturers of the same drug. I'm going to stop here, Mr. Chair.

In conclusion I would like to reiterate our support for the bill, and Jody and I will be pleased to answer any questions you may have this morning.

Thank you.

The Chair: Thank you very much.

Next up from Rx&D are Walter Robinson and Keith McIntosh.

Go ahead, guys.

Mr. Walter Robinson (Vice-President, Government Affairs, Canada's Research-Based Pharmaceutical Companies (Rx & D)): Mr. Chair and honourable members, thank you for inviting Rx&D to appear before Bill C-17 today.

My name is Walter Robinson. I'm vice-president of government affairs at Rx&D, and I'm joined by my colleague, Keith McIntosh, our senior director of scientific and regulatory affairs.

By way of background, Rx&D is the national trade association that represents 55 research-based pharmaceutical companies and members who discover, develop, and deliver innovative medicines and vaccines to Canadians. To be perfectly clear we support Bill C-17.

Legislative and regulatory modernization of the Food and Drugs Act that enhances and promotes patient safety is good public policy. We have been consistently supportive of these efforts and those of previous governments.

By way of background as well, we invest over $1 billion each year into Canada, with approximately 75% of this amount directed to over 3,000 clinical trials across the country. As you have heard before, clinical trials are required to bring safe, innovative, and effective medicines, vaccines, and devices to the Canadian marketplace. These trials are conducted in highly controlled, monitored, and regulated settings. The successful completion of trials provides the confidence to bring new drugs and procedures into clinical practice. Clinical trials also provide hope to patients and their families who have failed on or do not respond to conventional therapies.

[*Translation*]

We are proud of our long-standing partnerships with the Canadian Institutes of Health Research (and its predecessor, the Medical Research Council of Canada) and various provincial and para-public agencies.

[*English*]

But our most important contribution is working together to better the lives of all Canadians. It is here where the proper diagnosis, appropriate prescribing, and optimal utilization of medicines enable health system sustainability by reducing the need for physician visits, unnecessary hospitalizations, or avoiding costly and invasive surgical procedures.

Our industry is also on the front lines of health care provision with our federal and provincial partners in the delivery of vaccination campaigns. And we play a key role in supporting provincial health system strategies, such as primary care reform, age in place efforts, and community delivery of health care through pharmaceutical and other services.

As we have highlighted to this committee before, our members' activities are guided by a clear code of ethical practices. Acceptance of and adherence to this code in letter and in spirit are mandatory conditions of membership in Rx&D.

Rx&D and its members support Bill C-17, as I have stated, and other related efforts to improve patient safety across all stages of the development, approval, and use of all therapeutic products. And we agree with you that Health Canada must have a modern, efficient, and effective compliance and safety regime, a regime that is world-leading in its scope and receives the confidence of Canadians.

We also note that prior to any specific powers now proposed in Bill C-17, which essentially codifies the way we have been working with government, Rx&D members work closely with Health Canada to recall products, update or change labels, and implement any other important safety-related actions, either of their own accord or these warranted by Health Canada.

[*Translation*]

The foundation of any decision or regulatory intervention must be evidence-based and arrived at through rigorous scientific inquiry and standards.

[*English*]

Critical to this line of inquiry is a fulsome exchange of information among manufacturers, Health Canada, health care professionals and, increasingly, Canadian patients.

We pledge to work with the government, parliamentarians, and all stakeholders to make Bill C-17 and its adoption, if passed into law, as clear, efficient, and effective as possible. We would also suggest that the committee consider a number of aspects to further enhance and strengthen patient safety within Bill C-17. These include improving the exchange of information around reporting adverse events, which we support; encouraging and promoting the consistent dispensing of approved Canadian labels in pharmacy settings for innovative and generic medicines; additional oversight regarding counterfeit medications; and at a more practical level, more collaboration with international regulators such as the U.S. FDA, the European Medicines Agency, and their peers. As you heard in testimony before this committee, in several aspects they are further ahead than Health Canada on present safety regimes.

● (0855)

Every product has benefits and, yes, risks that are determined on the best available information and scientific practices. These benefits and risks are studied throughout a product's life cycle, and as the committee is aware, the vast majority of developmental therapeutic products fail for a wide variety of reasons, including unacceptable safety profiles, lack of efficacy, or situations where established risks clearly outweigh the benefits of a given therapy. Only one of 10,000 molecules in study ever makes it to market and to patients.

Vigorous and continuous attention to safety is a fundamental part of the development process from the early stages of drug development through to the entire life cycle of product even after discontinuance or product withdrawal. As other experts have testified before you, this process can span 30 to 50 or more years.

[*Translation*]

Mr. Walter Robinson: Rx&D members seek to meet or exceed all legal and regulatory requirements regarding safety, product quality, and the information that is provided to patients, their families and healthcare providers.

[*English*]

In conclusion and in reviewing your work today, we are encouraged by your commonality of passion and the solidarity of your commitment to patient safety. We share this number one priority. We look forward to your questions on specific aspects of Bill C-17 during today's session, and we'll be active participants during the gazetting and comment process if it's passed into law. At the beginning of our remarks, we noted that we support Bill C-17 and we sincerely urge Parliament to pass it into law.

Thank you.

[*Translation*]

Thank you for your attention.

[*English*]

The Chair: Thank you very much. Next up from MEDEC is Nancy Abbey. Go ahead, please.

Ms. Nancy Abbey (Executive Director, Reuse of Single-Use Devices Task Force, MEDEC - Canada's Medical Technology Companies): Good morning.

On behalf of MEDEC, I want to thank the health committee for providing me with the opportunity to be here today.

My name is Nancy Abbey, and I am the executive director of the MEDEC Reuse of Single-Use Devices Task Force.

MEDEC is the national association representing the medical technology industry in Canada. Our members are committed to providing safe and innovative medical technologies that enhance the quality of patient care, improve patient access to health care, and help enable the sustainability of our publicly funded health care system.

The industry in Canada employs over 35,000 Canadians in approximately 1,500 facilities, and we have sales of over $7 billion per year.

We are committed to supporting the growth of a strong and vibrant medical technology industry that contributes to Canada's innovation economy.

Our member companies are fully supportive of Bill C-17, an act to amend the Food and Drugs Act, in order to improve patient safety by introducing important measures that will strengthen safety oversight and improve reporting of serious adverse events.

We have an opportunity to work together to further strengthen this legislation. Unfortunately, in the time we have today, I will not be able to review with you the full list of our recommendations, but they are contained in appendix 1 of our submission. I do, though, want to focus on two of our recommendations that would address a long-standing medical device issue that warrants particular attention by the committee, which is the reason I asked to appear before you today.

This issue is the reuse and reprocessing of single-use medical devices and the fact that there is no federal regulatory oversight regarding this practice, a fact that raises serious concerns regarding patient safety. It's important that I briefly outline this issue for you.

In an effort to save money, hospitals in Canada are reusing medical devices that are licensed by Health Canada for single use only. This practice is widespread. In 2008 the Canadian Agency for Drugs and Technologies in Health, better known as CADTH, reported that 28% of hospitals in Canada and 42% of hospitals with over 250 beds were reprocessing single-use devices either in-house or through a third party reprocessor.

Single-use devices are not designed, validated, or licensed to be disassembled, cleaned, reassembled, and reused, and doing so can jeopardize their performance, safety, and effectiveness.

In 2014 the vast majority of hospitals that are using reprocessed single-use devices are doing so by outsourcing this activity and signing contracts with third party reprocessing companies. The fact is there are no third party reprocessing companies for single-use devices based in Canada. This has resulted in a situation of hospitals across the country shipping used devices, licensed for single use only, to U.S.-based companies for reprocessing without any federal regulatory oversight of the reprocessors and the devices that are then being shipped back for use in our Canadian hospitals.

This is a long-standing issue.

In March 2004, over 10 years ago, the Auditor General of Canada recommended that Health Canada take action, such as regulating the reprocessing of single-use devices, to manage the health and safety risks related to the reuse of single-use medical devices.

The Health Canada Scientific Advisory Panel on Reprocessing of Medical Devices and the Canadian Orthopaedic Association have repeatedly called for Health Canada to regulate this activity.

Health Canada has concluded that the Food and Drugs Act, from which the medical device regulations derive their authority, is not intended to apply to the use of a device after its sale; therefore, Health Canada does not have the authority to regulate the reprocessing of single-use devices by hospitals or third party reprocessing companies.

Health Canada has been unable to take action given the current Food and Drugs Act and medical device regulations. With Bill C-17, there is an opportunity to change this situation.

Why are amendments important? Canada's medical device regulations require original equipment manufacturers to present substantive evidence of a device's safety, effectiveness, and quality prior to being given authorization to sell and market a device for its intended use in Canada. There are also specific requirements for documenting and reporting adverse events, with clear guidance on how to issue a recall should the situation warrant such action.

● (0900)

Third-party reprocessing companies are not required to comply with Canada's medical device regulations, a fact that raises important concerns regarding Health Canada's role in ensuring patient safety. For instance, Health Canada does not require third party reprocessing companies to submit any safety, effectiveness, or quality data for the devices they are selling and/or shipping back for use to our Canadian hospitals. Third party reprocessing companies are also not required to maintain any records of reported problems related to a device, nor are they required to report adverse events to Health Canada. They are also not required to provide a proposed strategy to the health minister as to how a device recall would be conducted and a proposed plan to prevent a recurrence of the problem.

Amendments to Bill C-17 provide an opportunity for Health Canada to be granted the authority to regulate reprocessed single-use devices and address these important patient safety concerns. It is our recommendation that Health Canada regulate third party reprocessing companies as manufacturers in the context of Canada's medical device regulations, as has been the case in other countries, including the United States.

We're recommending that amendments be made to section 30 of the act, as this is the section addressing regulation-making authority for therapeutic products, including medical devices.

With regard to the bill, our first recommendation is to modify the regulation-making power in proposed paragraph 30(1.2)(a) to include reprocessing as a listed activity in respect of which authorizations may be issued.

Our second recommendation is to add a subsection—adding to proposed subsection 30(1.2)—providing for the authority to make regulations requiring that reprocessors of devices licensed for single use obtain therapeutic product authorizations in respect of those reprocessed devices.

It's important to point out to committee members that neither of these recommendations would actually require Health Canada to regulate, but would grant them the option to regulate both the reprocessing companies and reprocessed devices without dictating when or in what matter. The decision before you today is a relatively easy one. Time would allow the right regulations to be developed. Without these amendments, however, that discussion about how to regulate couldn't take place.

I want to be clear on the benefits of your making these amendments to Bill C-17 to strengthen patient safety. There would be clear, appropriate requirements for evidence to demonstrate that reprocessed devices will perform as intended and are safe for patients when used by a trained health care professional. There would be the ability to ensure that patients, doctors, industry, and other stakeholders have access to clear information about the medical devices they use. Very importantly, it would allow for rapid identification of adverse events and ensure coherent and timely action in the event a recall is required.

In summary, MEDEC wants to reiterate its full support for Bill C-17. It is important to MEDEC members that patients and health care providers have confidence in the safety of our health care system. We all benefit when public trust is at its highest. Bill C-17 helps to build that public trust and grow Canadians' confidence in our health care system. We believe these amendments can address a long-standing issue and enhance this important piece of legislation to further improve patient safety.

Over the years, I have talked with many government officials about this issue. There is always an interest in seeing a sample of a single-use device that is currently being reprocessed, so today I've brought with me a harmonic scalpel. This is a device that is used during surgery to cut and seal tissue. On the back you can see what a fully assembled harmonic scalpel from the original equipment manufacturer looks like. On the reverse are the individual components that would actually happen as part of a resterilization. The reverse shows you the individual components when it's disassembled and what would have to happen in order for it to be then reprocessed and come back.

I'll pass it around for you to see it, if you would like.

Thank you for your time. I would be pleased to answer any questions.

● (0905)

The Chair: Thank you very much.

We'll begin our round of questions with Ms. Davies.

Ms. Libby Davies (Vancouver East, NDP): Thank you very much to the witnesses who came today. There's been a lot of interest in this bill, so we're glad to hear you today. Unfortunately, there are a lot of other witnesses who also wanted to be heard, but we're rushing through at this point, so this is the last day of witnesses. As you probably know, we'll be going directly through to clause by clause on the bill when we've finished hearing the witnesses today.

I have just a couple of questions I'd like to put to all of you. In terms of overall drug safety, one of the issues we heard in a previous study of this committee when we were looking at the misuse or abuse of prescription drugs was the whole issue of marketing and the practice of providing samples to physicians, advertising in journals, and so on.

This is directed to Mr. Robinson, but others can respond to it too. What is your view of the legislation we've seen in the U.S., generally referred to as the "sunshine legislation", that puts very strict parameters on the kinds of practices that can take place in terms of marketing, particularly with samples. In fact, as I understand it, the legislation in the U.S. requires full disclosure; there's a registry of what is provided to physicians. This is done in order to ensure there's a degree of transparency so that it's very clear what's being passed through. I think it's an attempt to ensure there isn't misinformation directed to prescribers.

I just wonder if you could comment on how the industry views that kind of legislation. We don't have it here in Canada, but because we are talking about drug safety, is this something we should be contemplating in this country?

Mr. Walter Robinson: Through you, Mr. Chair, I thank Ms. Davies for the question. I would point out that our code of ethical practices in chapter 16 shows how we work in concert with the Food and Drugs Act regulations that are already in place for the distribution of clinical evaluation packages, or as they're more commonly known, samples. I can also tell you that there is a diversity of opinion amongst our membership based on certain international practices of where companies are moving in one direction or another with respect to the appropriate promotion of the benefits of medicines.

If I could speak to that, we can only promote a medicine with respect to the approved Health Canada indication and product monograph. What has also happened in concert with a variety of clinicians is that there's much more security placed in doctors' offices or family clinics in terms of locking up, tracking samples, tracking the use. There has been a movement away, as well, from having stock of those clinical evaluation packages or samples to an actual invoicing or card system so that there is an audit trail of those.

They still have a very legitimate role, especially for people who only have access to limited public insurance plans, with clinicians making that choice to try a therapy, the appropriate diagnosis, the appropriate prescribing of a sample. So they have a role to play in clinical practice. We are working with clinicians, and we follow the Food and Drugs Act and our own code of ethical practices to ensure they are distributed and promoted in a law-abiding and ethical manner with physicians and other prescribers.

● (0910)

Ms. Libby Davies: So you think your own code of practice is sufficient, that it covers all situations? There might be misinformation being provided or inappropriate prescribing, because I can certainly tell you what we heard when we were studying this issue. The misuse of information or erroneous information that's provided to prescribers is a pretty major issue.

Mr. Walter Robinson: Through you again, Mr. Chair, we followed the testimony closely. There are four things that cover our conduct in Canada.

First is the Food and Drugs Act, the law of the land. As we've noted, we support the improvements proposed before this committee in Bill C-17. Second is our code of ethical practices. When it comes to the distribution of information and promotion, we are also guided by the parameters of the Pharmaceutical Advertising Advisory Board, or PAAB, and Advertising Standards Canada.

There is a great degree of rigour in the context of what our members can do. Again, by law and by our code, we can promote only the approved indication and label.

Ms. Libby Davies: Do I have a little more time?

I have another question. I think at our last meeting we had a number of witnesses who spelled out the need for independent research in terms of evaluating the safety and effectiveness of drugs. What's your opinion on that, in terms of whether or not there should be third-party evaluation to make sure there's proper oversight?

Mr. Walter Robinson: As you've heard, and as we noted in our testimony, about 75% of our activity in this country is in clinical trials. That mirrors about 75% to 80% of global activity of the pharmaceutical industry funding clinical trials. It's in our interest to do so, to bring new medicines to patients.

I'd like to point out, though, that there is a lot of independent research, and Health Canada must approve every clinical trial that happens in this country. There is also posting of those trials in the context of ClinicalTrials.gov, and the new initiative that Minister Aglukkaq started and that Minister Ambrose has picked up.

There's a lot of transparency and disclosure of those results. They are conducted—if we have more time, I can walk through the steps—with a high degree of regulator rigour and independence in evaluating the results of the trials. Again, as I pointed out, most clinical trials fail for the reasons of unacceptable safety profiles.

The Chair: Next up, for seven minutes, Ms. Adams.

Ms. Eve Adams (Mississauga—Brampton South, CPC): Thank you.

I'm picking up on that point. Clinical trials are something that we've been addressing extensively during these hearings.

Can you tell me—succinctly, please, if you would be so kind, because I'd like to split my time with Mr. Young—what you feel are the key elements to ensuring that there is transparency for patients and consumers across Canada.

Mr. Walter Robinson: There are a variety of things.

I would also—very succinctly, Ms. Adams—point you to the work of your colleagues in the Senate. The Standing Senate Committee on Social Affairs, Science and Technology is lead by your esteemed colleague Dr. Kelvin Ogilvie, whom I know many of you hold in high regard. Its first report lays out the framework for improving the transparency, uptake, knowledge,and informed consent around clinical trials, and how Canada can have a very ethical and rigorous approach to that. The key elements are rigorous safety, a key line of scientific inquiry, and ensuring that we share those results globally, including adverse events that happen in those clinical trials. These things happen on a global stage, and Canada is one player in that regard.

That's as succinct as I can be, and I would direct the members of this committee to Senator Ogilvie's work in his committee—the phase one report. I've brought copies with me. It clearly spells out how we can improve and strengthen and enhance the safety of Canada's clinical trials regime.

Ms. Eve Adams: Thank you, Mr. Robinson.

I'd like to also thank Mr. Young for the amendments that he has brought forward to this legislation. We are certainly supportive of those amendments.

Without further ado, I will pass the remainder of my time to Mr. Young.

Mr. Terence Young (Oakville, CPC): Thank you.

Mr. Robinson, you said that decisions to market prescribed prescription drugs are based on the best available evidence. Yet, the common practice amongst your members is to start clinical trials on new drugs by asking researchers to sign a contract. If they're ordered to stop the trial of the drug because the drug isn't working very well or it turns out that it's harming patients, they have to stop it and never talk about it again. There are very serious sanctions, which we've heard about publicly, if they ever do that.

The evidence that's covered up when those trials are stopped is often life-saving information, for example, if it's harming patients. In fact, the normal business practice amongst your members is to cover up the best available evidence on drugs. Can you please explain that to the committee?

● (0915)

Mr. Walter Robinson: Through you, Mr. Chair, to the honourable member, to start, I commend your work on patient safety.

As I pointed out earlier in our remarks, all clinical trials that are conducted in Canada by industry must be registered with Health Canada, and we need to report the adverse events and the outcomes of those clinical trials. The best available evidence is not only decided with respect to the conduct of the clinical trial, but is also moved through the rigorous Health Canada scientific and regulatory drug approval process to get a notice of compliance. They pronounce on the safety and the clinical efficacy of a product.

Further data and further requirement is usually found in Canada through our health technology assessment regimes, including pCODR, for cancer drugs; the common drug review, through CADTH; and even INESSS, in Quebec. There is not a one-point review of clinical safety information; it is an ongoing process through the drug reimbursement process.

That is the best answer that I can give you.

Mr. Terence Young: You talked about your members' products reducing unnecessary hospitalizations, which, in some cases, is no doubt true. Yet, researchers tell us that one out of the nine hospitalizations in Canada—that's admissions to hospital for internal medicine, which aren't planned—are related to an adverse reaction to a prescription drug. Clearly, thousands of patients are taking prescription drugs when the benefits do not outweigh the risks. They're not getting proper safety warnings; they're taking them as prescribed and still ending up in hospital.

Your products lead to unnecessary hospitalizations. It's the exact opposite of what your members claim their products will do. Why does that happen so often?

Mr. Walter Robinson: Through you, Mr. Chair, to the honourable member.

It is true that adverse events happen with medication. One of the things we pointed out, and which we believe could be improved in the bill, is that when adverse events occur, we would like to see not only a notification to Health Canada—and I'm glad that the sanctions for institutions and prescribers are higher now to report those adverse events—but also would suggest that they simultaneously be reported to the global manufacturer. Then we can update the global adverse event databases that our own members keep to ensure that the labels or contraindications, which you've talked about very knowledgeably at this committee, can also be changed.

That's why we also pointed out that we'd like to see the product label and monograph that Health Canada approves to ensure that when a patient goes to their local pharmacy and gets their prescription and perhaps an information sheet, it mirrors in plain language the Health Canada approved product label and monograph. We need that to happen more consistently.

The other thing we're doing, and we're quite proud of, is that with British Columbia's and other governments, we're participating in a personalized medicine initiative to reduce those adverse events, especially in seniors' populations. We know they may be on multiple medications, and by using biomarkers or pharmacogenomic markers, we ensure that a senior—my mother or somebody else's mother who is on five or six medicines and is prescribed the new ones—has a better profile so that we can reduce those adverse events.

Mr. Terence Young: Thank you.

From an analysis in the *Canadian Medical Association Journal* written by five leading experts on prescription drug safety, I have a list of drugs that have been withdrawn from the Canadian market for safety reasons. That means they were killing or injuring patients, and this is just since 2004: Vioxx was approved in 1999 and taken off the market in 2005; Bextra approved in 2002 and taken off the market in 2005; Mellarill approved in 1959 and taken off the market in 2005; Climacteron, 2005; Tequin, 2006; Zelnorm, 2007; Permax, 2007; Prexige, 2007; Raptiva, 2009; Meridia, 2010; Darvon, 2010; Thelin, 2010; Calcitonin, a nasal spray, 2013; and MEP, a Meprobamate-containing medicine, 2013.

This is just since 2004. Since 1997, I think the total I've always used and the best total I can find is that 27 drugs have been taken off the market for killing and injuring patients.

● (0920)

The Chair: We're over time.

Mr. Terence Young: Okay, I'll continue later.

Thank you.

The Chair: Thank you.

Mr. Scarpaleggia.

Mr. Francis Scarpaleggia (Lac-Saint-Louis, Lib.): Thank you, Mr. Chair.

Mr. Robinson, my understanding is that in the act there's no current way to protect the minister from potential lawsuits. For example, if the minister were to recall a drug pre-emptively, believing that its distribution were detrimental to the health of Canadians and then it were discovered that the drug was safe for distribution, the minister and the government could be sued for loss of product sales during the duration of the recall. Is that your understanding?

Mr. Walter Robinson: I'll defer to my colleague, Mr. McIntosh, who has a much more detailed knowledge of that aspect of the act.

Mr. Francis Scarpaleggia: Mr. McIntosh.

Mr. Keith McIntosh (Senior Director, Scientific and Regulatory Affairs, Canada's Research-Based Pharmaceutical Companies (Rx & D)): I believe it is correct that there is no specific immunity provided to the minister in that regard.

Mr. Francis Scarpaleggia: Do you feel that perhaps limits the minister's resolve to act in the best interest of Canadians?

Mr. Keith McIntosh: I think our system generally provides ministers great discretion in delivering their mandate for enabling legislation, and I think any citizen or corporation would want to have the ability to have a judicial review for actions that were unnecessary, but certainly—

Mr. Francis Scarpaleggia: But taken in good faith—

Mr. Keith McIntosh: —I think the bar in Canada is quite high to demonstrate that in the courts.

Mr. Francis Scarpaleggia: Okay. So the minister would be protected if it were in good faith, or would he or she still be sued?

Mr. Keith McIntosh: I believe so.

Mr. Francis Scarpaleggia: I'd like to turn to you, Ms. Abbey.

You've raised a fascinating subject. Let me see if I understand. Are you saying that these products should not be reused in any circumstances, or that if they are reused, they should be reprocessed here in Canada under federal government oversight?

Ms. Nancy Abbey: We need the regulatory oversight in Canada. The position of the MEDEC members is that it's difficult for us to tell a hospital what or what not to do. They're doing it in an effort to save money. The gap right now is that nobody is looking at these devices from a safety, efficacy, and quality standpoint, which is what we're asking for. Other jurisdictions have taken that step and have called these reprocessing companies "manufacturers".

Mr. Francis Scarpaleggia: You seem to be saying that when they create these products, there has been research done and the manufacturer has established that these should not be reprocessed under any conditions. Yet you're saying that they can be reprocessed as long as it's being done in Canada in federally regulated companies. There's a bit of a contradiction there.

Ms. Nancy Abbey: I agree. The term "reprocessed single-use device" actually doesn't often make sense. The reality is that an original equipment manufacturer, at the point where they are starting to think about a new device, goes through a rigorous exercise of how to design it, how to develop it, and how to validate it. That leads to licensing. As for the point at which they are looking at what materials, how the device is going to be used, and what sort of durability there is, that whole exercise is a pretty rigorous one.

The fact is that we now have reprocessing companies that are regulated in the United States and think they can now, through their proprietary technology and expertise, take a single-use device and reprocess it. Our view is that we should be asking them to prove it. Right now, Health Canada—

Mr. Francis Scarpaleggia: Prove it to the government, yes.

Ms. Nancy Abbey: Yes, prove it to the government in the same way that original equipment manufacturers need to prove what their devices are.

Mr. Francis Scarpaleggia: It's interesting. Why has the government not acted on this? You mentioned an Auditor General's report from 2004. We still haven't gotten to the point where the federal government is regulating drug compounders in this. So really, why are there these gaps? In your view, why hasn't the government acted?

● (0925)

Ms. Nancy Abbey: I think that initially when they first concluded they didn't have the authority, it was a challenge because most of the reprocessing was being done in-house by hospital staff—

Mr. Francis Scarpaleggia: That doesn't necessarily make it any safer.

Ms. Nancy Abbey: I agree, but to regulate hospital staff would be very difficult with the federal-provincial jurisdiction.

Mr. Francis Scarpaleggia: Right. I understand.

Ms. Nancy Abbey: The fact that these reprocessing companies are now doing the vast majority of the work makes it much easier.

Mr. Francis Scarpaleggia: It's time for the federal government to act on it.

Ms. Nancy Abbey: Totally.

Mr. Francis Scarpaleggia: I'm wondering why this wasn't mentioned in the bill, but maybe we'll be informed of that over the course of today.

Mr. Robinson, you mentioned that clinical trials have to be registered with Health Canada. I believe this bill would make it mandatory to register them publicly. I'm a guest to this committee. I'm subbing for another member, so I'm just getting up to speed.

Mr. Walter Robinson: The ones that are approved by Health Canada, which are our trials, are already public.

Mr. Francis Scarpaleggia: Registration?

Mr. Walter Robinson: They're publicly.... There is a portal on the Health Canada website today with those trials.

Mr. Francis Scarpaleggia: With the registration of each trial?

Mr. Walter Robinson: As I understand it, yes.

Could I add, though, that one of the challenges—and I refer back to the work done in the Senate committee—is that these are global trials involving multiple companies, multiple countries, 5,000, 10,000, or 12,000 patients, and multiple sites across Canada. One of the things to come back to, because it relates to Ms. Adams' question, is to ensure that we have harmonization of research ethics boards or simplification of that, so that everybody has the same standards and the same research protocols and so on and so forth.

Mr. Francis Scarpaleggia: So there are standard research protocols that are published?

A voice: Yes.

Mr. Francis Scarpaleggia: Well, then, I'm at a bit of a loss here, because we have people who have testified at the committee and were saying—and it was mentioned here today, I think by Ms. Davies—that sometimes a trial will be abandoned if it's not going well, but the public is not aware of that. One would think that a standard research protocol would require the company doing the trial to report if something was abandoned because it wasn't giving good results, or whatever the reason, but you're saying that this is all hunky-dory, that these are standard protocols that come with the registration—

The Chair: Mr. Scarpaleggia?

Mr. Francis Scarpaleggia: Yes?

The Chair: You're over your time.

Mr. Francis Scarpaleggia: Okay. That's fair enough.

The Chair: Thank you.

Mr. Young, go ahead, sir.

Mr. Terence Young: Thank you.

Mr. Robinson, Mr. Keon made a comment, and I'd like to hear your comments as well, after I explain what my question is. Referring to safety issues with drugs, he said that thoughtful, risk-based dialogue is the best way to approach these matters. Yet, through a journalist that did a film about Vanessa's story, back in 2001, I was able to get copies of e-mails that went back and forth between the vice-president of Janssen-Ortho—part of Johnson & Johnson—and senior Health Canada officials. Health Canada officials were asking them to either take the drug off the market or put a very clearly worded warning or do their utmost to make sure the drug wasn't prescribed to patients it shouldn't be.

I have those emails back and forth. Of course you can imagine it broke my heart reading them and seeing the Health Canada officials struggling to get Janssen-Ortho to recognize that this drug should be taken off the market. This was prior to Vanessa's death. These emails went back and forth right into March 2000, and Vanessa died on March 19, 2000.

I was shocked to find out that this is normal in the industry. This happened with the other 26 drugs that have been taken off the market since 1997. This is supposed to be thoughtful, risk-based dialogue. In fact it is the pharmaceutical companies, your members, trying to keep a blockbuster on the market longer because they're selling $100 million a month or something and pretending that the drug can be prescribed safely. The hands of Health Canada officials and the minister were tied prior to this bill. In fact, thoughtful, risk-based dialogue was really just a way to delay the withdrawal of the drugs so the companies could make more money.

Could you please comment on that?

Mr. Walter Robinson: Through you, Mr. Chair, to the honourable member, I cannot comment on specific product decisions or specific company dialogue. I can speak at a policy level with respect to risk-based communications.

I'm going to ask my colleague Keith McIntosh to walk us through what some of that communication would look like and the principles around that, but I would agree with Mr. Keon's comment in that regard.

● (0930)

Mr. Keith McIntosh: First I would note that we support the authorities that are proposed in Bill C-17 to provide the minister with the authority to compel label change or to compel a recall if that thoughtful dialogue isn't conclusive.

I think that reasonable scientific debate is a valid exercise, and I know that our members have patient interest at heart when they have that debate, regarding what the label should contain or when to conduct a recall. I think if we only require a mandatory recall or a mandatory label update, the regulator is not necessarily the most rapid vehicle. The manufacturer is in the best position to initiate one of those changes quickly.

Mr. Terence Young: Thank you.

Mr. Robinson, I previously read to you a list of drugs that have been taken off the market just since 2004 for having injured or killed patients. You say you support Vanessa's law, which I'm very glad to hear, but I want to ask you whether there is anything in Vanessa's law that your members, the big pharma companies, could not have implemented on their own, voluntarily, years ago. Was there anything stopping them from having plain language labelling and issuing proper safety warnings? Was there anything that stopped them from acting sooner to get dangerous drugs off the market in order to reduce injuries and deaths? Was there anything to prevent them, to stop them, from reducing the injuries to Canadians caused by their products?

Mr. Walter Robinson: I would start by noting that many aspects of Bill C-17 already codify the manner in which Rx&D member companies have been interacting with Health Canada and other regulatory bodies, not only here in Canada but similarly with Health Canada's peer agencies, for a long time.

Regarding the issue around the specific article you mentioned—and I think that had to do with Dr. Lexchin and a few other journalists—you were cut off before when listing some of those products. As I noted, I can't speak to individual product issues. It would be best to address the companies to speak to those. From reading about it and from the research, I can tell you that some of those recalls were voluntary. They were not mandatory recalls. The companies themselves pulled them from the market.

You had a very clear question around plain-language labelling. I'd like to ask my colleague Keith McIntosh to speak to the things we've done around that and the things we've urged Health Canada to do. Some of these things have the best weight of suasion with regulatory authority.

Mr. Terence Young: I'd like to get another question in first, if you don't mind.

If you can, please explain the thinking within your member companies when the FDA or the European Medicines Agency orders a drug off the market for injuring and killing patients. What is the thinking in your companies that they can still leave that drug on the market in 100 other countries, including Canada sometimes?

They have essentially been ordered to take the drug off the market, or they put up a facade that they voluntarily took it off the market because they're about to be ordered to, and they maintain this facade that the drug can be prescribed safely and they just keep it on the market until they're ordered to take it off. What is the ethical thinking in those companies?

Mr. Walter Robinson: I can't speak, again through you, Mr. Chair, to individual products. The question is more of a broader policy question. I appreciate that, and I can speak to recent examples where you're seeing more global recalls or voluntary withdrawals of product.

I'll ask Keith if he has anything further to add on that—and he did want to answer the other question, because it was an important one, on plain language labelling.

Mr. Keith McIntosh: On this last question, I will only add that when there is a change in market status in a foreign country, in Europe or the U.S., for example, the first thing that a manufacturer in Canada will do is notify Health Canada and have a discussion with them about what the appropriate response for the Canadian approval would be.

Mr. Terence Young: What is the thinking behind changing the drug label, which is a 50-page or 60-page document, in 8 point size print that doctors don't even read—

The Chair: Just give a brief response, and then we're over time.

● (0935)

Mr. Keith McIntosh: I think that point 8 font size is a very important question, and we have supported plain—

Mr. Terence Young: It's on the label, but you know doctors don't read them.

The Chair: Okay, thank you very much.

Next up is Mr. Morin.

You're ready to go, sir.

[*Translation*]

Mr. Dany Morin (Chicoutimi—Le Fjord, NDP): Thank you, Mr. Chair.

My first question goes to Mr. Robinson.

To what extent do pharmaceutical companies conduct safety trials once the medications have been approved for the market? In your opinion, do the new clauses in this bill encourage that kind of regular study after a medication is on the market?

Mr. Walter Robinson: There are trials during and after a drug's lifecycle. Before it is put on the market, during the clinical trials, there is a safety program. There is—

[*English*]

real world evidence that we collect,

[*Translation*]

Those are the requirements of regulatory bodies like Health Canada or the FDA. After the end of a drug's lifecycle, we have to keep providing information that it is not harmful for 25, 30 and even 50 years. We exchange all the details with Health Canada and other public bodies. It is important to mention that a drug's profile can change over time because of its use in clinical situations.

Mr. Lexchin did not criticize our industry, but he did mention a very important point. Let me give you one example. A product is approved by Health Canada and goes onto the market. It is well used clinically and works very well for the patients. However, as Mr. Young well knows, after five or six years, a new drug or natural product may appear on the market and is contraindicated because of its interactions with the drug already on the market. There can be adverse effects because of that contraindication. We have to keep providing all those details.

As we mentioned in our remarks, the dialogue with Health Canada and the manufacturers must be enhanced when a case of adverse effects is reported by a hospital or another clinical institution.

Mr. Dany Morin: When a drug has been approved by Health Canada, when preauthorization trials have been done and it is being sold on the market, do pharmaceutical companies continue to conduct studies on the drug, or do they wait until adverse effects have been reported by the public before more investigation is done?

Mr. Walter Robinson: Yes. Both. Under the legislation, Canada's Medical Technology Companies and the Canadian Generic Pharmaceutical Association are required to do that.

Let me continue in English.

[*English*]

By law, we've always been required to report adverse events. We have safety studies in the clinical phase and in the regulatory approval phase. We follow good clinical practices and good research practices. Health Canada and the FDA have reciprocal abilities to do good manufacturing inspections of our facilities. Then, in a post-approval world, we have adverse event reporting, risk management plans that continue to be updated, post-market surveillance that either the manufacturers undertake on their accord or regulators order—they both work—and label updates and safety communication, which are some of the things we've already pointed to.

[*Translation*]

Mr. Dany Morin: We have talked about the general situation in the pharmaceutical industry. However, in your opinion, are there pharmaceutical companies that neglect to conduct long-term studies after a product is on the market? If the answer is that, unfortunately, some companies do the bare minimum in that regard, do you believe that Health Canada's requirements should be a little higher as a result?

● (0940)

[*English*]

Mr. Keith McIntosh: I think the important point here is that, as I think you said, the standards do need to be high, and they need to be to the highest standard internationally. On good manufacturing processes, we've been working with Health Canada to make sure that documentation and inspections for products that come into Canada are of the highest quality and to make sure that their systems are effective to make sure that's the case.

Certainly we expect and we hope that...and we work with Health Canada to ensure that for the review mechanisms as well the highest standards are met.

The Chair: Thank you very much.

Mr. Lunney, you have about four minutes.

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

Mr. Robinson, we talked briefly about the situation with proton pump inhibitors, common acid-suppressing drugs, that have been clearly linked to a hospital infection called Clostridium difficile. The risk has increased on the order of 40% to 275%.

Now, that information wasn't available when these products were approved, but over 20 years research has been accumulating. It was at least 10 years ago, when the first evidence came out in Montreal, which was considered the epicentre for this new infection, that I started raising questions with then Minister of Health Ujjal Dosanjh.

In terms of the risk of infection, we now know, through further studies, that people on those medications have not only an increased risk of infection of 40% to 275%; among those infected, they also have an increased risk of the worst complications, about 300%. They also have an increased risk of death, about 500%.

When I asked that question of the Honourable Ujjal Dosanjh in 2005, Health Canada contacted your member companies, four of which produce PPIs, although there may be more by now. The response I got back was that they weren't aware of any connection between their products and hospital infections.

Can you provide any evidence, since I know you're aware of this issue, that any of your member companies actually did any research to establish, voluntarily, whether there was a connection between acid suppression and hospital-based infections? That's 1,400 deaths a year currently; so over 10 years, at least 14,000 Canadians have perished, with hundreds of millions of dollars expended in hospital costs.

Mr. Walter Robinson: Through you, Mr. Chair, to Dr. Lunney, as we had a conversation earlier, I won't speak to specific products, but the therapeutic class I know very well. I take two PPIs a day for a hiatus hernia, because they are avoiding an unnecessary and invasive surgical procedure that is 50% effective, not 100% effective.

In the context of coming back to my earlier testimony with respect to the changing safety profile of the medication, which is right at the heart of your question, I do not know of any studies that may or may not have been undertaken. Those questions would be best addressed to the member companies.

I do know as well, though, that C. difficile and MRSA, another of these hospital-borne and very antibiotic-resistant infections, are a key issue occupying health care institutions and health integration networks. Several of our member companies are pursuing vaccines.

Perhaps Keith could speak a little more to the science around that.

Mr. James Lunney: Before you do I would like to say that perhaps unlike you, who may be one of the 30% who should be taking them, there is compelling evidence that at least 60% to 70% of the patients taking them should not be taking them for just GERD, or esophageal reflux.

Mr. Walter Robinson: Many of those products are now in the generic realm and have lost their market exclusivity, which comes back to the point that I made earlier in my testimony. It is about how we're in a continuum here of health care of proper diagnosis, appropriate prescribing, optimal use, real-world surveillance, and measuring outcomes to move us back to a virtuous circle of medicine —which you know well as a physician—back to proper education and diagnosis. I think we all have a role to play there.

Mr. James Lunney: Thank you.

The Chair: Thank you very much.

I want to thank all our guests here for our first hour.

We're going to suspend for a minute to bring on our next panel. We'll just keep moving right along.

Thank you very much for taking the time.

● (0940)

(Pause)

● (0945)

The Chair: Welcome back, ladies and gentlemen.

We're in the second hour of our meeting here. We have Linda Wilhelm by video conference. We'll do a technology check here.

Can you hear us okay, Linda?

Ms. Linda Wilhelm (Chair, Operations Committee, Best Medicines Coalition): I can hear you. Wonderful.

The Chair: We can hear you too. That's good.

Ms. Linda Wilhelm: I can hear you just fine.

The Chair: We'll get right into it. Seeing as how we always like to test our technology first, you're first up by default. You have 10 minutes to present. Go ahead, and welcome.

Ms. Linda Wilhelm: I want to thank the committee for having me and for including patients in the review and discussion on this legislation. I'm representing the Best Medicines Coalition, which is a national alliance of patient organizations. We're very interested in health policy and involving patients in the development of health policy, and our focus has been primarily around pharmaceutical issues in Canada. We try to make sure the patient voice is heard and listened to. I am a member of our board and I'm also a past chair of the organization. I'm also president of the Canadian Arthritis Patient Alliance, which is a national organization of arthritis patients from across the country.

We've been working with Health Canada for a number of years on developing this legislation. We think it's very important for patients, and BMC and CAPA are very supportive of this legislation.

I've been living with rheumatoid arthritis for almost 40 years, and part of living with this disease day to day is taking medications. Throughout the years there have been issues around some of our medications, and we've always had discussions with Health Canada about the limitations they have right now when there is an issue with a drug. The biggest example I can think of is Vioxx and all the issues around that. Vioxx was a drug that many patients benefited from. When there were issues with it, it was withdrawn. As somebody living with inflammatory arthritis, I can tell you we take far more dangerous drugs than Vioxx on a daily basis. Patients lost access to this drug. Had Health Canada had the powers that this bill will give them, patients who knew the risks and benefits and the possible uncertainties around Vioxx would still have access to the drug, and those who shouldn't be taking it would not have access to it.

As I said, we've been closely involved with Health Canada for a number of years on the consultation end of this legislation and everything it entails. I'd like to give credit to them for including all the stakeholders in this and listening to everybody's perspective, which, at times, surely got messy. Again, the Best Medicines Coalition and the patients I represent support this legislation under which Health Canada can have a regulatory framework that's modernized, and not operate under the constraints of legislation that was developed almost 40 or 50 years ago. We need to have better post-market surveillance in Canada. Health Canada has made great strides in the last number of years with MedEffect and with some of its initiatives, but they need to be able to get information when they need it and not be under the constraints they are currently working under.

We really believe this legislation is long overdue and very important for patient safety going forward. It's very important to involve patients, as has been done with this, to hear the broader perspective that we can bring to the table as people who actually have to put these drugs into our bodies to be able to live a healthy life.

We look forward to continuing to work with Health Canada going forward. Again, this is very important in the future for patients and post-market surveillance.

That's really all I have to say.

● (0950)

The Chair: Well, thank you very much. That's great.

Next up, from the Canadian Pharmacists Association, we have Jeff Morrison and Barry Power. Go ahead.

Mr. Jeff Morrison (Director, Government Relations and Public Affairs, Canadian Pharmacists Association): Thank you, Mr. Chair, and good morning to the committee. Thank you to the Standing Committee on Health for the invitation to appear this morning. My name is Jeff Morrison. I'm director of government relations and public affairs with the Canadian Pharmacists Association. With me—I'm very happy—is Barry Power, a pharmacy consultant with CPhA, an adjunct assistant professor at the school of pharmacy with the University of Waterloo, and a pharmacist himself.

As you know, CPhA is the national association representing the pharmacist profession in Canada.

[*Translation*]

Drug safety is a priority for the Canadian Pharmacists Association and for all pharmacists in Canada. Although it is not possible to completely eliminate all risks associated with the use of prescription drugs, pharmacists spend a lot of time counselling patients on the appropriate and safe use of the drugs they are taking. That is why the CPhA supported the general spirit and thrust of Bill C-17, Vanessa's Law, when it was introduced by the minister in December 2013.

[*English*]

In particular, the CPhA supports the bill's intent to increase penalties for unsafe products and to provide Health Canada with new powers to recall unsafe products and to compel companies to do further testing on a product when issues are identified with certain at-risk populations, as well as the requirement for drug companies to revise labels to clearly reflect health risk information, including potential updates for health warnings for children.

However, there are some concerns and outstanding questions we have with regard to the bill. Although these questions and concerns may be addressed during the regulatory development process, we still wish to raise them with the committee this morning.

First, the bill provides a blanket exemption for natural health products. As NHPs are medicinal products and have the ability to cause harm, and given that Health Canada and several provinces state that between 60% to 70% of therapeutic products consumed by Canadians are in fact NHPs, the CPhA feels that NHPs should be included within the scope of the bill.

Second, the bill mandates the need for adverse drug reporting by stating the following, which I'm sure you know:

> A prescribed health care institution shall provide the Minister, within the prescribed time and in the prescribed manner, with prescribed information that is in its control about a serious adverse drug reaction that involves a therapeutic product or a medical device incident that involves a therapeutic product.

However, this clause raises several questions that frankly the bill doesn't clarify.

● (0955)

[*Translation*]

For example, what is a prescribed health care institution? Is a pharmacy a health care institution? Will the downtown community health centre, of which I was the president, be considered a health care institution?

It would be helpful to specify the definition of a prescribed health care institution that is required to provide information.

[*English*]

Also, what is a serious adverse drug reaction? How is that to be defined? For example, is it necessary to report a well-known but serious reaction? All health care professionals know of many of the serious adverse reactions caused by chemotherapy, for example, during cancer treatment. Would they be expected to report these? Where do we draw the line between what is to be reported and what is considered well-established fact? Again, clarification within the bill would be useful.

Also, what will happen with this information? Will it be analyzed? Will all the information that is reported be made publicly available? If so, how so? As pharmacists we believe that Health Canada should be transparent in the provision and aggregation of the information it receives from this mandatory reporting, but at present, the legislation as written is unclear on whether this information will be properly analyzed and shared with health practitioners and with Canadians.

The same issue regarding transparency can also be applied to the bill's requirement that the minister may order the manufacturer to conduct additional assessments and tests of a questionable product or drug in regard to health and safety. The legislation states that the results of these tests will be provided to the minister. However, there is no allowance currently in the bill for providing that information more publicly, including to pharmacists, other practitioners, and Canadians. As you can probably guess, we feel it should.

Last, the bill also states that this reporting requirement “shall take into account existing information management systems, with a view to not recommending the making of regulations that would impose unnecessary administrative burdens”. However, this clause would appear to be at odds with the reality of the situation on the ground.

By its inclusion in the bill, the requirement for prescribed health care institutions to report adverse drug reactions will impose additional administrative burdens. Although technological solutions can and should help, the fact remains that additional human resources will be required to collect and provide this data. If the definition of prescribed health care institution is broad in scope—as I mentioned earlier, we don't have that—then the administrative requirements will likely increase. As a result, we're uncertain about how the bill can reconcile what would appear to be two contradictory goals of, on the one hand, increasing reporting, but on the other hand, without imposing administrative burdens.

In short, Mr. Chair, the Canadian Pharmacists Association is very supportive of Bill C-17. Given pharmacists' preoccupation with safe and effective use of medications, the CPhA believes the legislation is a step in the right direction. However, as I've outlined, we feel that there are clauses within the bill that could benefit from greater clarity and certainty in terms of how they will be applied.

[*Translation*]

Thank you, Mr. Chair.

We are ready to answer the committee's questions.

[*English*]

The Chair: Thank you very much.

Next up, from the Canadian Health Food Association, is Helen Long.

Please go ahead.

Ms. Helen Long (President, Canadian Health Food Association): Thank you. Joining me today is Carl Carter, our director of regulatory affairs and policy development.

It's with great pride that I appear before you today as president of the Canadian Health Food Association. CHFA is Canada's largest trade organization dedicated to the natural health and organic products industry.

As MPs, you should also have pride that Canada has a robust natural health product sector contributing $3 billion annually to the Canadian economy. CHFA represents over a thousand predominantly small and medium-sized businesses across Canada. Our members include manufacturers, retailers, importers, and distributors of natural health and organic products, and these can include foods, vitamins and supplements, herbal products, and more.

As members of the committees know from your own constituents, over 70% of Canadians use natural health products to improve the quality of their lives. The majority of Canadian families consume NHPs as part of a balanced healthy lifestyle and our sector has worked hard to ensure that Canadians continue to have access to these safe and effective products. CHFA members across the country applaud the Standing Committee on Health for their important work on Bill C-17 and its specific targeted focus on drug safety. CHFA fully supports the government's approach in this bill.

After an extensive and thorough review in 1998, this very House of Commons Standing Committee on Health concluded, as number one of its 53 recommendations, that NHPs are not drugs and should not be legislated as such. In line with this recommendation, NHPs have been regulated since 2004 under the natural health product regulations and these regulations are among the most rigorous and advanced in the world. Simply put, we support the exclusion of NHPs, as defined in the natural health product regulations, from Bill C-17. It's just common sense. Vitamins are different from pharmaceuticals and we commend the government for recognizing the relative low-risk profile of NHPs.

I am proud to highlight for committee members that NHPs are subject to extensive legislation and regulation in Canada, much more, for example, than in the U.S. According to Health Canada's most recent quarterly report, over 85,000 product licence applications have been submitted over the 10 years since the regulations were put into effect, and some 52,000 product licences issued. This is not a rubber stamp process. Before an NHP is authorized for sale, a company must complete a product licence application that is reviewed by the natural health products directorate. This is an entire section of approximately 100 staff dedicated to NHP safety. An application must demonstrate that the product is safe, effective, and high quality. Each application must provide information about the product, including medicinal and non-medicinal ingredients, evidence supporting any health claims, product labelling, and information about the manufacturing site. Many are unaware of, or perhaps take for granted, the lengthy pre-market assessment process required for NHPs. In addition, all NHPs licensed for sale in Canada must comply with Health Canada's good manufacturing practices and the natural health product regulations require a site licence issued by Health Canada to demonstrate compliance.

GMPs are a system designed to ensure NHPs are packaged, manufactured, stored, and monitored appropriately to ensure high-quality products are available to Canadians. All NHPs that have been assessed by Health Canada for safety, effectiveness, and quality have an NPN or natural product number on the label, which a consumer can easily find. It is worth noting again that Health Canada is a global pioneer in the regulation of natural health products and in pre-approval requirements of a product being sold in Canada. In contrast, the U.S. has a post-market system that clearly lags behind Canada in consumer safety of NHPs.

The licensed NHP database is a public, fully transparent government database of licensed products, approved label copy, claims, warnings, and the name of licence holders. Consumers, retailers, and medical professionals can and do consult the site regularly.

Serious adverse reactions to NHPs licensed for sale in Canada are rare. Health Canada monitors the safety profile of all products sold in Canada to ensure consumer safety. In addition, the marketed health products directorate provides a reporting and review framework for any adverse events to medicines or NHPs experienced by Canadians. NHP regulations under section 24 expressly require companies to report serious adverse reactions to the minister. As noted, Health Canada does not approve all NHP applications it receives and routinely requests additional safety information, formulation changes, or additional warnings.

● (1000)

Consumers and health care practitioners are encouraged to report any suspected adverse reactions to Health Canada through the online reporting system. Through this system, we know that adverse reactions to NHPs are rare, especially in comparison to pharmaceutical drugs. Information collected from adverse reaction reports is assessed to determine the most appropriate measures for risk management and intervention. When there are any changes to the conditions of use for a product, or if a product is withdrawn altogether, this information is conveyed to Canadians through communications, such as advisories online and other resource materials.

We commend the government for recognizing the relative low-risk profile of NHPs. In line with the Standing Committee on Health's 53 recommendations, in 1998, NHPs are not drugs, and they should not be treated as such.

Thank you.

The Chair: Thank you.

That concludes our presentations, and now on to the questions.

First up is Ms. Davies.

Go ahead.

Ms. Libby Davies: Thank you very much for coming today.

There are some very specific issues that you've raised, and I think I'll begin with the natural health products. You've both raised it. Pharmacists say they should be in; the Canadian Health Food Association says they should be out.

We questioned the minister on this issue when she came before the committee. She said that at the end of the day they decided not to put them in because they were considered low risk. We've certainly had a lot of e-mails and correspondence from people both ways: people saying they should be in, and others saying they should be out.

I will go to Mr. Morrison. I think people really trust pharmacists; they're the go-to people. Pharmacists are more accessible to ask questions about safety. You have this prescription, or you want to buy something in the drug store, but you don't know what you should be using. You're the kind of go-to person to get that information.

You're saying that natural health products should be included. I guess it comes down to an issue of what we consider to be the risk relative to what is covered in the bill. I want you to think about that in terms of these major pharmaceuticals, the drugs that can have enormous side effects and adverse effects and can cause death.

In terms of natural health products, my understanding from all of the research I've done is that basically they're not going to kill you. In fact, I'm not aware of information that's says a natural health product, whether it's a vitamin or a herbal remedy, is going to kill you or severely injure you.

When you consider the risk, where do you place that in the spectrum relative to other things that are covered in this bill?

● (1005)

Mr. Jeff Morrison: Thank you, Ms. Davies, for the question.

I would add that polls show that pharmacists are the most trusted profession in Canada and are the most accessible health care providers. You are correct in that.

With respect to the question regarding NHPs, Ms. Long detailed quite extensively the process that NHPs go through, essentially to be approved, and as you've both mentioned, the risk tends to be somewhat lower.

Ms. Libby Davies: Somewhat lower, or a lot lower?

Mr. Jeff Morrison: It tends to be lower.

We would argue that if that were the case, that the risk is significantly lower, then by including NHPs within the bill, there's probably not a lot they would need to worry about. However, the risk still does exist.

I think what Bill C-17 does is to acknowledge that there is risk with all medication, that there needs to be processes in place to address that risk and identify it. Therefore, by putting it in—and I'll pass it over to my colleague in a moment to finish off the response—you are essentially covering the range of possible risk associated with consumption of any of these products. It's probably better to put them in than not.

Ms. Libby Davies: Okay.

Before you turn it over, I want to follow up with you and ask you another question about prescribing health institutions.

You're basically saying it's more of a precautionary principle. That's what I hear you saying.

Could you give us an example of where you think a natural health product has posed a risk or does pose a risk? Let's be concrete about this. Is there stuff out there that pharmacists are aware of for which there should be a greater warning, other than what's provided in the labelling and product information?

Mr. Jeff Morrison: I'll ask my colleague Dr. Power to address that.

Dr. Barry Power (Pharmacy Consultant, Canadian Pharmacists Association): There are a number of natural health products that have been shown to interact either with mainstream medications or to pose a risk for certain things such as bleeding. There has been an increased use of natural health products, and as more people use them, we need to collect data that will show all of the risks.

We need to keep in mind that low risk does not mean no risk, and natural does not mean safe. By including natural health products in the bill, it ensures that health care professionals and consumers in Canada have access to better information, that they can make better decisions for their health, and make sure that everybody has a good understanding of the actual risks associated with the products. The current databases that we have are fairly thin on the risk side.

Ms. Libby Davies: I'm going to go back to Ms. Long, but before I do, I want to sneak in one other question for Mr. Morrison.

You raised the question of the definition of a prescribed health care institution, and you're right. In the bill that's all it says, so what does that mean?

I'm going to throw it back to you, because we're at the eleventh hour now with regard to making amendments and so on. What would you cover? What are your suggestions? I'll leave it to you.

● (1010)

Mr. Jeff Morrison: Thank you.

When we posed that question to Health Canada officials, I think it was made very clear that hospitals would be considered, but beyond that we're into some grey territory. As I said in my comments, there was an open question. For example, would a prescribed institution include community health centres? Would it include pharmacies? Would it include family health teams?

Ms. Libby Davies: Should it? Would it be helpful if it did?

Certainly community health centres should be included, but what about pharmacies? Is that something you're suggesting we include?

Mr. Jeff Morrison: The challenge with broadening the scope of the definition is whether these institutions will have the human resources and the capability to in fact do the work necessary to report these.

In theory it would be advantageous for all of these various institutions to report on such a basis, but in reality do they have the capacity to do so? That's the challenge for all of these various institutions.

Ms. Libby Davies: Quickly then, Ms. Long, would you like to respond to anything the pharmacists have said about the issue of risk?

Ms. Helen Long: Yes. Thank you.

Mr. Morrison commented on the act and the risk with all medication. I'd like to go back to my first and my key point.

In 1998 this Standing Committee on Health made 53 recommendations, number one of which was that NHPs are not drugs and they should not be treated as such.

I think anything that's too risky requires a prescription. When we talk about this issue, we talk about consumer education. We work extensively and we collaborate with Health Canada and we speak in our public pieces about consulting with your health care practitioner. I think working on a collaborative message around that education and making consumers aware is where we would like to go.

Patients and consumers do need to take some responsibility, and we would certainly like to educate them, but as you indicated, Ms. Davies, the risk is so minimal that's not where we think we need to be.

The standing committee agreed that these products are not drugs, and I think that's where we should rest.

Thank you.

The Chair: Thank you.

Ms. Adams.

Ms. Eve Adams: Thank you.

Would you be kind enough to perhaps highlight for us which aspects of the bill before us should not be amended? Which aspects do you feel are the most critical and should certainly move forward?

I ask you this question in the general context of this really not having been updated by the federal government for 50 years now. So we do need to move the ball forward. We hope to create one of the most transparent systems in the entire world, a system that is genuinely focused on consumer safety and on patient safety, for the betterment of all Canadians' health.

So would both of you be kind enough to provide me with some insight into which aspects of the bill you think are great the way they are and should not be subject to amendment?

Mr. Jeff Morrison: Thank you for the question, Ms. Adams.

I identified in my opening comments a number of the aspects of the bill of which we are extremely supportive. I'll just mention some of those.

First of all is the inclusion of increasing penalties on those manufacturers who essentially wilfully put unsafe products on the market. Obviously the recall powers for Health Canada have long been absent, as you mentioned. The requirement for companies to revise labels to clearly reflect health risks is important. We welcome the reporting of adverse reactions, although again perhaps with some greater clarity in terms of how that would actually be applied. There is also the notion or the power to compel companies to do further testing of products, especially when at-risk populations are identified.

We think all of these are extremely welcome aspects of the bill.

Ms. Eve Adams: Thank you.

Ms. Helen Long: And thank you.

CHFA does support the bill as it is written. We support the exclusion of natural health products, and we do feel this addresses a number of areas that have been open since 1953. With a regulated system on natural health products, the benefits of which we enjoy in Canada on, we are pleased to fully support the bill as it is written.

Ms. Eve Adams: Thanks very much.

Would you be kind enough to provide some insight into the type of stakeholders you have consulted with and the membership you have reached out to in developing your remarks for today?

Ms. Helen Long: We have a membership of over 1,000 businesses across Canada, everything from the very small mom-and-pop independent health food store to one of the largest vitamin manufacturers in the country, and we reached out to all of those members, our stakeholders. We have worked and discussed with some collaborative organizations, and of course we are always in ongoing discussion with the natural health products directorate. That's the group we have reached out to.

Ms. Eve Adams: Thank you.

Mr. Jeff Morrison: I would to add that we've consulted with our board, with our provincial pharmacists associations, and with individual members. When the bill was introduced back in December, we issued a public statement.

As many of the members around this table know, we've worked on various issues related to drug safety. For example, we've worked with Mr. Wilks on prescription drug take-back days. A number of issues involve the broader issue of drug safety, and we've worked with and consulted with our members about them.

As I said in my opening comments, this is priority number one for pharmacists.

● (1015)

Ms. Eve Adams: Thank you.

You have been outstanding in coming forward with information for consumers.

When patients pick up their medicine from you, you said very plainly that you're the ones who are advising patients what they can and can't take, how they should take it, what it might interact with. But when we do have the most adverse drug reactions, typically those people are being rushed into emergency rooms. That's why, obviously, we're having the reporting focus on our hospitals and asking our doctors to fill out those reports.

This is a collaboration, and we need to ensure that we work with all industry stakeholders and the entire health profession to ensure that Canadians are receiving the best possible information to make the most informed choices. We are never going to be able to eliminate all risk. It's a matter of making sure that people are informed and that we mitigate all possible risk.

Thank you very much.

The Chair: You still have two and a half minutes.

Ms. Eve Adams: Oh, we have plenty of time.

Mr. Jeff Morrison: Mr. Chair, one of the things that pharmacists have been trying to do over the past several years is to advocate with their provincial governments to increase the scope of practice, increase the service they can provide to patients. In pretty much every jurisdiction in this country, pharmacists now can do more than they could even five years ago. The primary reason we've advocated for that, and I might add we've done so quite successfully, is to broaden the ability of the pharmacist to interact with the patient to ensure better drug safety.

For example, one of the new services that pharmacists can now provide that they couldn't a couple of years ago is a comprehensive medication management review, whereby a pharmacist can sit down with a patient, review the medication history of that patient, review what they are and are not taking, and come up with a care plan. That service has only been in place for several years.

Again, it's not just something that pharmacists are talking about from a legislative standpoint, but in their day-to-day interactions with patients. Safety is paramount. It is priority number one, and we are trying to provide ourselves and pharmacists with the tools to ensure better drug safety for that patient.

Ms. Eve Adams: As you may know, this committee is studying the scope of practice and is particularly supportive of increased scope of practice for pharmacists, in particular, the ability to provide immunizations. I'm of European descent, and in Europe for quite some time now you've had the traditional apothecary where you could have your medication provided by the pharmacist at hours that are convenient to you or to young families and so on. It's certainly much more efficient for the entire health care system.

We of course suspended that study to bring forward this critical piece of legislation. I think you would concur that this legislation is imperative to deal with so that we may proceed. It's been waiting now for decades. Obviously there are lives to be saved potentially by enacting this legislation. I think we can certainly all agree around this table that this was critical to bring forward.

The Chair: Thank you very much.

The bells are ringing and there is a vote, as I'm sure you all know, at a quarter to 11. As always, I'm at the will of the committee. Mr. Scarpaleggia would be next. Does anybody have any thoughts if we want to do Mr. Scarpaleggia's round or suspend now? I'm open to suggestions.

Ms. Davies.

Ms. Libby Davies: With all due respect to Mr. Scarpaleggia, I'd love you to have your question, but because of the time needed to get back I feel we should suspend now.

The Chair: Okay, is everybody in agreement with that?

By the time we get back it'll likely be about a quarter to 11, so at that point does the committee have any interest in asking more questions of the witnesses or do you want to get to the clause by clause?

Mr. Francis Scarpaleggia: What time are we coming back? Will I have my question when we get back?

The Chair: We'll probably get back at a quarter to, but I'm not sure.

Mr. Francis Scarpaleggia: You mean back to the committee room at a quarter to?

The Chair: We'll be back at around quarter to 11, maybe 11 o'clock.

● (1020)

Mr. Francis Scarpaleggia: So I'll get my question in.

The Chair: What does the committee want to do?

Ms. Eve Adams: May I suggest the following? Just so that we don't have these witnesses stay here for such a long period of time, I would prefer that we suspend. You know, we do have a walk to make.

But would you perhaps like a one- or two-minute round?

Mr. Francis Scarpaleggia: Sure.

Is that okay, Chair?

The Chair: Go ahead.

Mr. Francis Scarpaleggia: Ms. Wilhelm, you mentioned something that I didn't fully understand or didn't quite catch. You said that if this bill had been in place, those who needed Vioxx would have had access to it.

Did I misunderstand what you said?

Ms. Linda Wilhelm: Vioxx as a drug was intended for people like me, those who take non-steroidal anti-inflammatory drugs. We see those over the counter with ibuprofen and naproxen drugs. They have the same risks as Vioxx had, but because Vioxx was withdrawn, people like me now have fewer options. If you can't take the one remaining drug, which is Celebrex, you can get a stomach bleed, which is far riskier for my health population than the high blood pressure and cardiovascular risks of Vioxx.

What was happening was that it was being prescribed for everything from tennis elbow to PMS. It should have been reserved for people like me. We take drugs like Methotrexate, which is a cancer drug. We take biologics. We take all these serious drugs.

Mr. Francis Scarpaleggia: How would this bill being in place have allowed it to be on the market for your condition?

Ms. Linda Wilhelm: Health Canada would have had the power to call for more studies, and we could have had the label changed to say that this drug is only prescribed for people with inflammatory—

Mr. Francis Scarpaleggia: I understand. Thank you so much.

One more minute?

The Chair: Sure. Go ahead.

Mr. Francis Scarpaleggia: In terms of natural health products, there have been some questions about manufacturing sites overseas. This is not just an issue for natural health products but also for drug manufacturers everywhere. For example, there's some suggestion that some sites may not be up to standard, that some drugs have come in with things in the bottle that should not be in the bottle, and so on and so forth.

I don't know how this bill will fix that, necessarily, but is this also an issue with some natural health products? You say that you need.... The government looks at the manufacturing site, but how rigorous is the government in ensuring that manufacturing sites overseas are up to scratch, up to par, with the manufacturing sites here?

Ms. Helen Long: The natural health product regulations, the good manufacturing practices requiring a site licence, do apply to facilities used for Canadians overseas, and are still subject to the same requirements.

Mr. Francis Scarpaleggia: So they are the same requirements as drug manufacturing sites overseas.

Ms. Helen Long: No, the same requirements as natural health products in Canada.

Mr. Francis Scarpaleggia: In Canada. Okay, I understand.

That's fine, then. Thank you for your patience.

The Chair: Thanks very much.

At this point in time, we'll suspend our meeting.

Thanks to our guests for taking the time. You're now excused.

When we get back, we'll get into the technical portion of our meeting and the clause by clause.

Thank you.

● (1020)

(Pause)

● (1105)

The Chair: Welcome back. We're back in session.

We'll start going through the clause by clause portion of Bill C-17. We have the departmental officials at the table, at the ready, if there are any questions. So feel free to ask questions or for clarification.

In addition to that, similar to what we did for Bill C-442, the Lyme disease bill, we'll take our time and make sure everybody knows exactly what clause and what amendment we're talking about, so everybody feels good about what they're voting on.

There's lunch at the back and recognizing the fact that everybody wants to pay attention to the clauses and the amendments and to which way to vote, we can suspend at some point, when the committee feels like it, for five to 10 minutes, just to have a quick lunch so that everybody can stay focused on the clauses and the amendments, if that's okay with everybody.

We have two legislative clerks here to help us along the way if we have any technical questions. Karin is also still here as our analyst.

If everybody's ready to go, we'll get at it.

Similar to the case with the Lyme disease bill, the title and the preamble will wait until the end, and we'll get right at it.

(On clause 2)

The Chair: We have amendment CPC-1. On that, I'll say that if this amendment is adopted, so will be amendment CPC-2 since they are consequential. Would somebody like to talk about the amendment?

Ms. Adams.

● (1110)

Ms. Eve Adams: I'm moving amendment CPC-1 to clause 2.

The Chair: Is there any comment or debate on—

Ms. Libby Davies: Are we not going to hear any explanation from the movers of the amendment on what it's about?

The Chair: You can if you like.

Ms. Libby Davies: Well, normally, we would.

The Chair: Sure, it's okay.

Ms. Eve Adams: We're keen to allow you to continue through this as quickly as possible.

Ms. Libby Davies: So we're not going to hear any explanations?

The Chair: No, we're just going to let Mr. Young get ready here. There are a lot of papers flowing around for everybody, so that's why we'll just take our time and—

Mr. Terence Young: With regard to the definition of confidential business information, the definition sets out the three conditions that must be met in order for information to be considered confidential business information and appropriately safeguarded by the minister. The definition entrenches common-law principles and is consistent with the definition of the same in other domestic legislation, for example, the Canada Consumer Product Safety Act. It is also consistent with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights— TRIPS—and the North American Free Trade Agreement.

The conditions set out in the definition are also consistent with the practice by regulators in other jurisdictions, such as the United States Food and Drug Administration, the FDA, and the European Union's European Medicines Agency. The definition is necessary to support the minister's power to disclose confidential business information for the purpose of identifying or responding to a serious risk of injury to human health—as identified in clause 3—to persons from whom the minister seeks advice or to a government or to a person who carries out functions related to the protection or promotion of human health —as identified in clause 3—and, for regulation-making authority, as identified in clause 6.

The Chair: Ms. Davies.

Ms. Libby Davies: We have what we hope is a friendly amendment. Just by way of explanation, I did have a discussion with Mr. Young earlier and we tried to go over some of these amendments where we think there might be some agreement. So I hope that we can make some progress.

The Chair: So you're proposing a subamendment then to Mr. Young's amendment?

Okay.

Ms. Libby Davies: Yes, a subamendment.

I also want to note that this process has been made very difficult by having the committee meet today instead of Monday—or maybe we're meeting Monday as well—and having the amendments basically go in at noon yesterday. We've been scrambling. As we go through them today, I hope you will be accommodating just because it's been a lot of stuff to get in order in less than 24 hours. So I just want to make that note.

In terms of our friendly amendment, what we would like to do is to add a paragraph (d). Mr. Young has got paragraphs (a), (b) and (c). We would like to add a paragraph (d) and the subamendment would be:

> For greater clarity, confidential business information does not include safety and efficacy information including phase 1 to phase 3 pre-market trials or post-market safety assessments, clinical study reports and periodic safety update reports.

So we just want to make it clear that confidential business information doesn't include those things that I've just listed. That's just for greater clarity. We support the amendment but think that the subamendment would bring greater clarity.

● (1115)

The Chair: Okay.

Ms. Libby Davies: I think we have a copy to hand out.

Do you have a copy?

We've got a copy to hand you. We don't have a lot of copies but at least the parliamentary secretary and the legislative counsel will have one.

The Chair: So is everybody clear on what the subamendment is to Mr. Young's amendment, which is CPC-1? Does anybody have any discussion or debate on that subamendment?

Mr. Terence Young: Mr. Chair, we have a number of concerns about it.

The first one is that by providing a list of what types of information the minister can order to be released courts at some point would look at the list and decide if something wasn't on the list that it therefore could not be ordered to be released by the minister. So that's a primary concern.

The secondary concern is that the government has amendments. I've presented amendments that deal later with when the minister can exercise the power. So Government amendment number 2 determines that:

> (2) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the Minister believes that the product may present a serious risk of injury to human health.

It's a very all-inclusive power. It further says:

> (3) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public and the disclosure is to
>
> (a) a government;
>
> (b) a person from whom the Minister seeks advice; or
>
> (c) a person who carries out functions relating to the protection or promotion of human health or the safety of the public.

It's an undefined and broad definition. So the minister has power to direct anyone who carries out functions relating to the protection and promotion of human health. Then it defines further in the section:

> Government means any of the following of their institutions, the federal government, a corporation named in Schedule 3 to the Financial Administration Act, a provincial government or public body established under the act, legislature of the province. An aboriginal government is defined in Subsection 13.3 of the Access to Information Act, a government of a foreign state or subdivision of a foreign state or an international organization of states.

It's a very broad power given to the minister to issue cautions. By adding this amendment, it would appear that we're providing a list that the courts could interpret more narrowly.

The Chair: Yes, Ms. Davies.

Ms. Libby Davies: I have a very brief response.

I do understand the argument that Mr. Young is making about this being disputed in court and that if you added something to the list, it could possibly narrow it. But actually the reverse is true here, because with this subamendment we're just specifying that confidential business information does not include.... So it's actually not what's on the list; it's just making it clear that this would not be covered.

I do understand the argument he's making, but I don't think it would be a problem with this particular subamendment.

The Chair: Thank you, Ms. Davies.

Are there any other comments on the subamendment?

Mr. Terence Young: Chair, I'd like to defer to the legal counsel from Health Canada to describe their thinking on this.

Thank you.

Mr. David Lee (Director, Office of Legislative and Regulatory Modernization, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Department of Health): Mr. Chair, the inclusion of a list in this definition may be a very vulnerable way to introduce what the member is suggesting. There is a commonly understood international approach to what is protected, and that's really expressed in this definition. By saying what is not on that list.... Much of what's on that list would be considered protected in most countries, so it could attract international challenge.

What Mr. Young has gone through in terms of the appropriate way to deal with that information is really what flows to the other motions.

● (1120)

The Chair: Ms. Davies.

Ms. Libby Davies: I'd like to ask you a question. In terms of the international list that you refer to, would safety and efficacy and what's listed there in our subamendment normally be considered part of confidential business?

Mr. David Lee: Yes, typically it would. If you look at article 39 in TRIPS and its equivalent article 1711 in NAFTA, it does contemplate that companies have to invest quite a bit of money to get the data that they would submit—and this is health-related, so it's safety and efficacy data—but then they have to give it to a third-party regulator, as it they wouldn't normally disclose that to competitors. So it is contemplated as being protected, and again, most people in the world would understand that this definition catches that.

What you do to disclose it, though, is a different issue.

Ms. Libby Davies: Okay. My response would be that I know this came from one of the witnesses we heard. When you look at this information, which we've now heard would normally be considered confidential business information, this is actually information that the minister does need to be aware of, so it's actually a very important point. I would still stand by our subamendment.

The Chair: Is there any further discussion on Ms. Davies' subamendment? Seeing none, I will call the vote.

(Subamendment negatived)

The Chair: Now we'll go back to the amendment itself, which is CPC-1. Is there any further discussion on that amendment? As I mentioned before, if this is adopted, amendment CPC-2 is as well. Does anyone want clarification on why amendment CPC-2 would also be adopted? Is everybody comfortable with that? Okay.

All those in favour of amendment CPC-1?

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: Amendment CPC-1 is carried. Accordingly, amendment CPC-2 is carried.

Next on the list we have another couple of amendments to clause 2. As long as you have that in the package, we're good. I'm working off the chair for dummies package—

Voices: Oh, oh!

The Chair: —so as long as you guys have the right package, which now reads "NDP-1", we'll all be good to go. Okay?

Ms. Davies.

Ms. Libby Davies: Thank you.

We have NDP-1 and we have NDP-1.1. They're basically dealing with the same clause or the same line. It's just that we had submitted an earlier version, which is NDP-1, but based on the testimony that we heard from Ms. Gibson very recently, we reworded it. I did have a brief discussion with Mr. Young this morning. We're actually happy with either version, so I would be happy to move either NDP-1 or NDP-1.1, if the government members are inclined to vote for whichever version they think is preferable.

The issue here is that we're concerned that the bill, as it's currently outlined, doesn't recognize the full scope of adverse drug reactions. Of course, the example that's being used is the issue of the birth control, where it was sort of characterized as a lifestyle choice. In fact, a number of witnesses did raise this. As for the language that we have proposed here, I'll actually read NDP-1.1. We would add in these lines: "injury to health" includes cases in which a drug does not have its intended effect due to mislabelling or mispackaging of the product. The issue it's related to is the example we heard about the birth control.

If there are suggestions about how to make that better, we're open to them, but we want to tackle that issue because we don't think it's properly covered in the bill.

● (1125)

The Chair: Ms. Davies, do you have a preference?

Ms. Libby Davies: I'll move NDP-1.1, because that's the latest version and it was based on Ms. Gibson's testimony, as opposed to what I think she'd written in before. So I'll use that one. But as I say, we're open to slightly different wording, if there are any suggestions on that.

The Chair: Okay. Thank you very much.

Mr. Scarpaleggia.

Mr. Francis Scarpaleggia: On the issue of different wording, we would like to propose a subamendment, simply to change the word "drug" to "therapeutic product".

The Chair: Okay, was it Ms. Adams or Mr. Young?

Ms. Adams.

Ms. Eve Adams: Thank you.

Through you, Mr. Chair, I very much understand what Ms. Davies is getting at here; however, the department has already had an independent review on this very issue. The department has accepted all recommendations. We believe that this is now captured and that certainly, this type of incident would not be happening again. So for that reason, we are not able to support this amendment.

The Chair: Mr. Young, you were next up. Did that cover it?

Mr. Terence Young: That's fine. That explanation is adequate.

The Chair: Okay, Ms. Davies.

Ms. Libby Davies: Through you, Mr. Chair, could the parliamentary secretary explain what she means that they've approved all recommendations? I don't know what she's referring to.

Ms. Eve Adams: The Alysena issue was fully independently and thoroughly reviewed. A number of recommendations came out of that independent review, and Health Canada has accepted all of those recommendations.

Ms. Libby Davies: That's fair enough, but it doesn't necessarily mean it's covered legally for the future, and that's why we have this bill. So it may be helpful in terms of that one therapeutic product, but we don't know whether it will apply to other ones. I think we have to look at it systematically, and not just in terms of one product.

This is actually a very important amendment. A number of witnesses, I think, pointed out that the bill had a shortcoming around what the definition was.

The Chair: Would it be okay if we had Mr. Lee, if he's prepared to provide a comment on it as well, just to give the committee further clarification?

Mr. David Lee: Certainly. Thank you, Mr. Chair.

On the first point, when we started discussing some of the text in the bill, this was raised by health care professionals. It's the first time you've had mandatory recall. It's very important that the threshold language be able to deal with the kind of event that we saw, a failure of a birth control pill to work.

So we went back and we pulled in our inspectors; we pulled in our legal team; and we really made sure that this new threshold, which we've never had before, would work for that. So we were satisfied that the language "serious and imminent" would do it. That was a very serious concern for us. We really made sure we looked at it.

On this other language, "injury to health", that's a phrase that occurs in the existing act in different places and in other parts of what we're trying to amend through the bill. It's very important to understand how this language would operate throughout those, so any vagueness that this would introduce could prospectively be very troubling. It's something you'd have to be very careful about in introducing brand new language.

I will say that for NDP-1.1, we would include "in an adverse event or an injury to health". Really what we're looking for there, especially if it's serious, if somebody is permanently debilitated or there's a life-threatening event to them, no matter how it happened, whether it was a package that went wrong, or the labelling, we would pick that up as a serious event.

And basically, the other thing I should mention is that in our label-change power later on, in that proposal it does contemplate changing package. So if there is a mistake around the package, if we do see that, then there's a decisive action that can be taken.

● (1130)

The Chair: Okay. Thank you for the explanation.

Ms. Davies.

Ms. Libby Davies: I don't feel very comfortable that we have an assurance—no matter what you might say verbally; we're looking at the legislation—that we wouldn't have another instance where there was a lifestyle kind of thing. I can't think of another example, but I'm sure there must be others, or something else could come up.

I don't hear the assurance that if there were a similar kind of thing, even if it was around mislabelling, that Health Canada wouldn't then make a decision because they would consider it to be a lifestyle issue as opposed to an injury.

Where's the assurance for that?

Mr. David Lee: Mr. Chair, what I can say, again, is that in our discussions on prospective language, health care professionals, among others, and patient groups brought up this issue. They raised it very profoundly with us. As a regulator, we want to have this right. It's a threshold for a very serious moment as a regulator. We did run through scenarios to make sure that the language, "serious and imminent risk", would catch anything we could think about.

It was as rigorous an analysis as we could provide for that language.

The Chair: Okay.

It's Dr. Sharma, right?

Dr. Supriya Sharma (Acting Associate Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Yes.

Just to add, in terms of the Health Canada assessment around the Alysena issue, we did actually deem it to be a serious risk when we did do the risk assessment. When the testimony was given, I think the issue was that when the company had made the assessment, they had not raised the same issue.

Certainly the Health Canada assessment was that it was a serious risk, and we've had subsequent issues around recalls of similar products since that time. Again, it has been treated as it would apply in terms of the definition that we have moving forward.

The Chair: Thank you for those explanations.

I have Ms. Adams next.

Ms. Eve Adams: Thank you. I think you've covered it.

I believe we had additional testimony from one the witnesses, who indicated that if a drug were ineffective that would then warrant a recall. We wouldn't need to engage in this debate about lifestyle or serious or adverse; it would simply be that if the drug were ineffective for the purposes it was prescribed, that would then trigger the recall.

Is that correct?

Dr. Supriya Sharma: The lack of effectiveness would have consequences. When we're looking at the definitions, we're really focusing on the consequence. Regardless of the upstream cause of it, you're looking at something that could have an impact on patient safety or endangering patient safety. Then we have the powers to do something about it, regardless of the actual cause. That lack of effectiveness, or for a drug to work, would get captured in the definition.

The Chair: We've had a good discussion on that.

Ms. Libby Davies: Could we have a recorded vote, please?

The Chair: Yes.

First, Mr. Scarpaleggia, you proposed a subamendment to the subamendment around wording. Are you still moving that subamendment?

Mr. Francis Scarpaleggia: Sure.

The Chair: Okay.

In Mr. Scarpaleggia's subamendment to Ms. Davies' amendment, he was basically removing the word "drug" in the second line, and inserting "therapeutic product".

Is that correct, sir?

Mr. Francis Scarpaleggia: Yes.

The Chair: If everybody is clear on that, all those in favour of Mr. Scarpaleggia's subamendment to Ms. Davies' amendment?

Ms. Libby Davies: Could I clarify something? If his subamendment is defeated, do we still vote on my amendment?

The Chair: Yes.

● (1135)

Ms. Libby Davies: Okay. I'll call for a recorded vote on the second one then.

The Chair: All right. All those in favour of Mr. Scarpaleggia's subamendment?

(Subamendment negatived [See *Minutes of Proceedings*])

The Chair: Now we're on to the amendment itself, which is NDP-1.1.

NDP-1 wasn't moved, so we're going to vote on the amendment NDP-1.1

Ms. Davies has requested a recorded vote on this.

(Amendment negatived: nays 5; yeas 4 [See *Minutes of Proceedings*])

The Chair: That gets us through the amendments on clause 2.

Do you have one other one?

Ms. Libby Davies: I do have another amendment as a result of hearing the testimony today. We have written it up quickly, and we'll hand it out.

Basically, I'm suggesting that this amendment would go under the definitions under clause 2, page 3, after line 8. It has to do with the definition of a prescribed health care institution, which was just raised by the pharmacist. I would like to move an amendment that we add a four—

The Chair: Just so we're clear on where we're at, you're talking about page 3 on the bill.

Ms. Libby Davies: Page 3, and it would be after line 8.

The Chair: Okay. Is everybody clear where that would be?

Ms. Libby Davies: It could go somewhere else. I didn't have a lot of time to look. I just stuck it here because it's definitions, but the gist of it is that we would add the following: "definition of prescribed health care institutions shall include hospitals, community health centres and pharmacies".

In the bill, of course, there's the provision about reporting adverse health effects, which is very important, and it spells out "prescribed health care institution" but it doesn't say what that is. I think we heard from the testimony today that it would be useful to spell it out, so that's why we're suggesting, as the witness did when I asked him, to include hospitals, community health centres and pharmacies.

The Chair: Okay, thank you, Ms. Davies.

Before we go any further on this, can our legislative clerk provide a little clarification around this amendment just to make sure it's in order?

Go ahead.

Mr. Philippe Méla (Procedural Clerk): You aim at adding a new definition. It's called "prescribed health care institution". In order to do that the term or the expression has to be in the bill somewhere.

Ms. Libby Davies: Okay, so we should put it somewhere else?

Mr. Philippe Méla: If you define a term, the term has to be somewhere in the bill, otherwise it doesn't relate to anything. The definitions, generally speaking, are to help understand the wording in the bill.

Ms. Libby Davies: The wording "prescribed health care institutions" is already in the bill, but it doesn't define what that is, so I'm suggesting we define it after line 8.

Mr. Philippe Méla: Okay, that's fine. Would you be able to tell me where it is in the bill, because...?

Ms. Libby Davies: Yes. It's on page 5, and it's line 34. It says "a prescribed health care institution shall provide the Minister", etc., but it doesn't spell out what a prescribed health care institution is. So, we're including in the definition what we believe a health care institution is. Is that adequate?

Mr. Philippe Méla: Yes, that's fine.

The Chair: You're procedurally in order.

Ms. Libby Davies: These are minor victories.

● (1140)

The Chair: Mr. Young, go ahead, sir.

Mr. Terence Young: We think this would be a mistake because by providing a prescribed list you could conceivably be excluding.... The act gives the minister the power to create a list and this might limit the minister's powers. I think our goal is the same: for the minister to have a broader power to get more adverse drug reactions reported.

The Chair: Okay. Ms. Davies, any further comments?

Ms. Libby Davies: Yes. Alternatively the minister could make it incredibly narrow and exclude community health centres or pharmacies, so I think by including it we're giving her some direction to be broad. I would worry if it's just left to the minister's discretion, which we see a lot of these days, then it could end up being very narrow. I'm sure it would include hospitals.

The Chair: Would you like to defer to Mr. Lee?

Ms. Libby Davies: No.

The Chair: Okay.

Mr. Scarpaleggia.

Mr. Francis Scarpaleggia: I understand Mr. Young's point about leaving it broad so it can be defined under regulation. If we adopt Ms. Davies's amendment, would that somehow prevent the minister or the regulations from defining it more broadly? In other words, would the fact that you start defining it in the law specifically take away the minister's ability to add to the definition in regulation?

The Chair: If it's okay, Mr. Scarpaleggia, we'll defer to Mr. Lee and have him....

Mr. Francis Scarpaleggia: Absolutely, I was hoping he would take the question.

Mr. David Lee: Thank you, Mr. Chair.

The word “prescribed” next to “health care institutions” indicates that we would use a regulation to say which ones they would be, so “prescribed” just points to the fact that the regulations will tell you which ones. If the list is up at the act level in a definition, it would to that extent bind the minister in adding on. We haven't had much time to analyze this, but, for example, if we had specialized clinics for cancer they may not be community clinics nor a hospital and yet very serious events come there that you want to see. If you have a stroke you're not going to sit with your GP; you're going to get into acute care. They're not all hospitals now. Having to go with drafters and work out the technicalities of that could be quite challenging.

Mr. Francis Scarpaleggia: So it could prevent the minister from adding, through regulation, institutions.

Mr. David Lee: It would certainly make that exercise quite difficult.

Mr. Francis Scarpaleggia: Or even adding doctors' offices, for example.

Thanks.

The Chair: Thank you very much.

Ms. Davies.

Ms. Libby Davies: I will actually make an amendment to my own amendment. I'm not quite sure how you do that.

The Chair: I don't think you can.

Ms. Libby Davies: Could somebody else do that?

The Chair: Yes.

Ms. Libby Davies: I'd like to suggest that somebody else include the words “definition of a prescribed health care institution shall”, and then the subamendment would read, “at least include hospitals, community health centres, and pharmacies”.

Mr. Dany Morin: I move that.

Ms. Libby Davies: It doesn't limit the minister, but at least these basics would be covered.

The Chair: Okay. So we have a subamendment to your amendment. Is there any further discussion? I guess we'll deal with the subamendment now. Is there any other discussion on that?

Okay. So we go to Mr. Morin's subamendment, which would insert two words, “at least”. All those in favour?

(Subamendment negatived [See *Minutes of Proceedings*])

The Chair: On Ms. Davies' amendment NDP-1.2, all those in favour?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: I think that addresses all of the amendments that we had for clause 2. Now I'll ask the question on clause 2 as amended.

(Clause 2 as amended agreed to)

(On clause 3)

The Chair: Ms. Adams.

● (1145)

Ms. Eve Adams: I would move amendment CPC-3, please, as CPC-2 has already passed.

The Chair: Thank you. Right. That's good.

Ms. Libby Davies: We now go to NDP-2, then?

The Chair: Yes. I was in the same boat as Ms. Adams. I forgot that the other one got collected.

NDP-2 would be—

Ms. Libby Davies: Could I ask a question about CPC-2? It's not an amendment; it's just a question.

The Chair: Yes.

Ms. Libby Davies: Now that this has been approved, could Mr. Lee confirm if the minister would be able to disclose information to consumer groups or, for example, to health researchers and guideline developers? Would it actually cover those?

Mr. David Lee: There are two powers here. One is that if there is a risk of injury, the minister can disclose very broadly—so to consumer groups, publicly. There's also an ability in proposed paragraph 3(3)(c) to give it to.... Researchers would fall into proposed paragraph 3(3)(c), a person who carries out functions that relate to the protection or promotion of human health. So there could be a right of access to that proprietary information through that paragraph.

Ms. Libby Davies: Would it include consumer groups as well?

Mr. David Lee: If they were carrying out that function and it was for that function, yes.

Ms. Libby Davies: Okay.

The Chair: Okay. That's good, Ms. Davies.

We're at amendment NDP-2 now.

Ms. Davies.

Ms. Libby Davies: This is amendment NDP-2. I would move that clause 3 be amended (a) by replacing line 27 on page 3 with the following:

may order the holder of a therapeutic product authorization to

and by replacing line 35 on page 3 with the following:require the holder of a therapeutic product authorization to

If you look at the bill, it uses the words, “may order a person who sells”, and then on line 35 it says, “require the person who sells”. In the rest of the bill it talks about a “holder”. I believe the term holder is a broader definition that includes a seller and a holder, so it's a better term to use. I think that's possibly why it's being used in that manner elsewhere in the bill. We think it would be better to use the term “holder” here, so that the minister can be explicitly empowered to issue suspensions and recalls to both types of persons, both sellers and holders of therapeutic authorizations, as it covers the spectrum.

The Chair: That was amendment NDP-2 to clause 3. Is there any other discussion on that?

Mr. Young.

Mr. Terence Young: Chair, we don't support this amendment. In the present language, a person who sells—

The Chair: Sorry, I didn't catch that. Would you not support this amendment?

Mr. Terence Young: We do not. The reason is that in the present language, “a person who sells” captures everyone in the distribution chain, with the exception of the patient, because the definition of “sell” in the Food and Drugs Act includes, “offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration”. So a recall order would do what it's supposed to do, which is to apply to the manufacturer, distributor, wholesaler, retailer, health care practitioners, and pharmacists to get unsafe drugs out of the supply chain.

The language of the proposed motion, “holder of a therapeutic product authorization” would restrict the recall authority to therapeutic product authorization holders only and would narrow the recall powers. So we don't support it because of the apparently unintended consequences.

The Chair: Okay. Were you able to catch all of that, Ms. Davies?

Ms. Libby Davies: I'd like to ask Mr. Lee why the word “holder” is used elsewhere but not here.

Mr. David Lee: We didn't want to narrow it. “A person who sells” does get you that widest group in the chain. As Mr. Young just said, it goes all the way down through the company—which is typically the holder of the authorization—into wholesale and into pharmacy. So the minister would be able to use the order to get everyone in that distribution chain. If it were just “holder” here, it would constrain us to being able to order only a market-authorization holder, which is usually the company. We want to make sure we're getting into all the points of sale.

● (1150)

Ms. Libby Davies: We did hear from a number of witnesses who spoke on this point, and they seemed to say the opposite, that the broader term was “the holder” because it would then capture the seller. These are people who are very expert in drug safety laws, so it's very conflicting.

Mr. David Lee: I have very great respect for all of them, but you need to look at the definition of “sell”. I think what was not raised in that discussion, which is very important to cover, is that “a person who sells”—and that is defined in the act—is somebody who either sells for money or distributes not for money. So it does give you the widest scope under the recall language.

If it were just “authorization holder”, again that phrase is there only to make sure of the powers the minister has over people who have licences to sell.

Ms. Libby Davies: Why do you use “holder” elsewhere in the bill? Shouldn't it be consistent?

Mr. David Lee: It's basically to show who can be ordered to do further tests and studies or label changes, for example. It's usually identifying a group of people who are the regulated parties. That's usually the drug companies or the warehouses that move the product and that hold an establishment licence.

The definition of “a person who sells” is much broader, and it could include a pharmacist. For recall, you really do want to reach through to everybody who's going to be distributing. Pharmacists aren't licensed by Health Canada to do what they do, so you do want to pick up the sale aspect.

The Chair: Okay. I think that was a good explanation.

On the list, I have Mr. Lunney and then Mr. Scarpaleggia.

Mr. Lunney.

Mr. James Lunney: I'll be brief. The point that Ms. Davies is raising came from Elaine Gibson. I thought she made a very credible and very succinct presentation to committee. I believe the explanation that's been provided about the definition of “seller” satisfies the concern Ms. Davies had, so I appreciate the explanation from Mr. Lee and from Mr. Young.

Thank you.

The Chair: We've had a good discussion on this NDP amendment.

Ms. Libby Davies: I think we have a government subamendment.

The Chair: We have a subamendment to the amendment? Okay.

Mr. Dany Morin: I would like to move my subamendment so that paragraph 3 (a) would say, “may order the seller or the holder...”. Similarly, paragraph 3 (b) would say, “requires the seller or the holder of the therapeutic product...”.

That would be my subamendment.

The Chair: All right. That is the subamendment to the amendment, which would involve the seller or the holder.

(Subamendment negatived)

The Chair: I don't see any further discussion on Ms. Davies' amendment NDP-2 . So all those—

Ms. Libby Davies: Excuse me. On a point of order, just as a procedural thing, if somebody moves a subamendment, does the whole floor have to agree to the subamendment or just the mover of the amendment?

If I agree to the subamendment, would that not then be sufficient and we would then just vote on the amendment? No? It has to be two separate votes on every occasion? Okay. That's fine. I just wanted to clarify that .

The Chair: What we'll do is to have our legislative clerk give you the scenario where it wouldn't require a vote and where it would, just so that we're all clear. Okay?

Go ahead, sir.

Mr. Philippe Méla: If you know ahead of time that you may have a subamendment, it would be a good thing to move it at the same time you move your amendment, all at once, and then—

Ms. Libby Davies: But you said I couldn't move a subamendment.

Mr. Philippe Méla: But when you move your amendment, let's say NDP-2, and you know you want to add "the seller or", you can move it at that time. When you say, "I want to move my NDP amendment, but I want to change the wording", you can move it at that point, and we'll consider it a package, if you want. But if you do it at first, as it was, and then you want to add a subamendment afterwards, you can't do it. It's at somebody else, so therefore there are two questions.

● (1155)

Ms. Libby Davies: Clearly it often happens because of the result of what you're hearing from people, right? Then you're trying to mitigate what you've heard. I get it. Thanks.

The Chair: He mentioned it, so I wanted everybody to know.

Ms. Libby Davies: Yes, it's helpful. Thank you.

Mr. Dany Morin: Can you please remind us also of how friendly amendments work? In that situation, could a friendly amendment have worked?

Mr. Philippe Méla: There is really no such thing as a friendly amendment.

Voices: Oh, oh!

Mr. Philippe Méla: It's a fiction, but that's the way it goes. You propose something that's really an amendment. If it's a friendly amendment, everybody would be agreed.

The Chair: Okay. We're still on amendment NDP-2. All in favour?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Ms. Davies, I believe you're up again.

Ms. Libby Davies: This is NDP-2.1. It results from testimony that was given by MEDEC. It seems to me to be a housekeeping thing that's fairly straightforward. What they were saying is that some of these therapeutic products are very big, such as hospital equipment. In terms of withdrawing them from the market, it couldn't necessarily physically happen—or it would be very difficult—that you could move something to a central quarantine. We've proposed this amendment by just saying, after line 28 on page 3 the following, "quarantine the product; or", so that it actually allows something to be quarantined where it is without it having to be moved.

It is based on something that MEDEC raised with us and it seemed to be a logical thing to do to prevent unnecessary damage or storage costs for some of the larger equipment.

The Chair: Is there any discussion on amendment NDP-2.1?

Ms. Eve Adams: Mr. Chair, can we turn to Mr. Lee for a comment?

The Chair: Mr. Lee.

Mr. David Lee: Thank you, Mr. Chair.

In contemplating the difficulty you sometimes see with devices, if you have an MRI in a hospital, for example, to recall it, you don't want to pull it out of the hospital. It would be a great expense, among other things. That's why, in proposed subsection 21.3(2), what's proposed there is a provision for the minister to ask for corrective action to be taken. If there is an issue that they have to correct out in the field—and this is quite usual for devices—it's contemplated within the wording of the order.

The effect would be that if the minister picked up and ordered a corrective action instead of a recall, the assumption is that the medical device would stay where it is and then the company would need to instigate that corrective action. They couldn't sell it or use it while that order is in place, but certainly, the corrective action would be subject to the order. Really, that picks up the point.

I would also point out that, to some extent, proposed paragraph 21.3(1)(b), in sending "to a place", does contemplate quarantine, to the extent we're saying that instead of pulling it all back from the market and bringing it back to the person who put it into the supply chain, which is the usual recall model, we can actually have product directed to a certain place or stay where it is. The minister could use an order to effect that.

The Chair: Is there any other discussion on that?

Ms. Davies.

Ms. Libby Davies: No.

The Chair: All those in favour of Ms. Davies' amendment, which is NDP-2.1? All those opposed?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Ms. Davies.

Ms. Libby Davies: We have NDP-2.2, which is dealing with the same situation, again we're trying to give greater certainty to how this legislation reads. I move that Bill C-17 be amended in clause 3 by adding after 40 on page 3:

> (2.1) For greater certainty, if the Minister makes an order under paragraph (1)(a) in respect of a therapeutic product, that therapeutic product must be withdrawn from the market.

Again, it follows on the same point that was raised by MEDEC in terms of larger equipment. I heard what Mr. Lee says, but I'm still moving this amendment.

● (1200)

The Chair: All right.

Are there any comments or debate on amendment NDP-2.2?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Next up.

Ms. Eve Adams: I would move CPC-3, please.

The Chair: Is there any discussion or dialogue on amendment CPC-3?

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: Next up is Liberal-1.

Mr. Francis Scarpaleggia: Yes, thank you, Chair.

This amendment comes primarily out of the testimony of Mr. Herder. We know that Mr. Young has a similar amendment. However, we believe that our amendment provides for a mandatory process that explicitly lays out in the act a public registry, as opposed to defining this in the regulations, and improves the safety and efficacy of therapeutic products.

Our amendment seeks, first, to ensure that all clinical trials and investigational tests are registered with the minister; second, that therapeutic product authorization would not be issued unless it were registered; and third, that results must be provided to the minister no later than one year after their completion—

The Chair: I don't want to interrupt you, sir, but we could just go right to the discussion if you like, because I'm sure everybody has read your amendment, unless you wanted to provide a commentary on it.

Mr. Francis Scarpaleggia: Just a moment, please.

The Chair: Yes, no problem.

Mr. Francis Scarpaleggia: This actually is our explanation of—

The Chair: Okay, go ahead. Go ahead, then. I'm sorry I interrupted you.

Mr. Francis Scarpaleggia: No problem.

The results must be provided to the minister no later than one year after the completion, with all results being reported for trials or tests that involved human subjects, and that results of clinical trials and tests must be provided to the minister, even if no authorization is issued within six months.

The next part of the amendment deals with publicly disclosing information on Health Canada's website, such as all clinical trials and investigational tests and the results; decisions respecting the issuance or refusal of authorizations and reasons; terms and conditions imposed on an authorization, as well as decisions respecting suspensions and revocations of authorizations and the reasons; the recalls of a therapeutic product and the reasons; and information about any serious adverse drug reactions. There is also a protection that any information cannot be issued to gain an unfair commercial advantage.

This amendments bring transparency to the clinical trial process and the decisions Health Canada makes in regard to issuing authorizations, safety warnings, or recalls, and the reasons for them by ensuring that this information is available on Health Canada's website.

The Chair: Again, I'm sorry for the interruption.

Is there any discussion on the amendment?

Mr. Young.

Mr. Terence Young: Chair, I think we're working towards the same purpose, but the government amendments address these issues and then empower the minister to create regulations. This is an industry that's driven by invention and technology, and I think it's really to the advantage of the regulator and to the government to be able to react quickly to changing conditions and changes that are driven throughout the industry. So we feel this is redundant.

The Chair: Is there any other discussion on the amendment?

Seeing none, all those in favour of Liberal-1?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Next up, we have amendment NDP-3.

Ms. Libby Davies: Thank you.

NDP-3 would amend the bill by adding, after line 3 on page 5, the following:

> 21.61 The Minister must undertake an independent review of all monographs of therapeutic products that the Minister has prepared since the coming into force of this section and must post the results of such reviews on the Department's Internet site.

The purpose of this amendment, Chairperson, is that we want to make sure that independent and objective reviews of Health Canada's approvals of product monographs are available. This requirement would only apply to new drugs.

This was brought forward in testimony by Dr. Meldon Kahan earlier in the spring. We think it's something that should be covered. Basically he said, as people on the committee might remember, that it's very important to ensure that product monographs are objective and are not influenced by pharmaceutical marketing, and that basically there should be an independent review of these monographs.

That is what this amendment deals with.

● (1205)

The Chair: Mr. Young.

Mr. Terence Young: Chair, under Bill C-17 the minister will have all kinds of new powers to direct pharmaceutical companies to issue new documents, new warnings, new safety warnings to clarify things, and to go back and retest a drug, etc.

Currently the Department of Health makes product monographs all publicly available on the Health Canada website. A monograph is a factual statement. It's the statement that the pharmaceutical companies provide to Health Canada to get their first notice of compliance. They're required to update it on occasion. It describes the properties, claims, indications, and conditions of use for a drug and all the other information, including reference to studies. Anyone, any independent researcher anywhere in the world, can have access to that document, just by going on the Internet, to draw their own scientific conclusions.

In fact, under Vanessa's law, the minister has committed to publishing drug reviews. For the first time, drug reviews for drugs that are on the market will be available to any scientist in the world who wants to examine that documentation, as they can in other countries.

This proposed motion would require the minister to actually do an independent review when there's already been a review. Drug monographs are approved by Health Canada in the first place.

In that sense, this would be redundant.

The Chair: Ms. Davies.

Ms. Libby Davies: To go back to the testimony of Dr. Kahan, who I think was a very credible witness, he actually gave us some examples of where these monographs, which Mr. Young says are just factual, were actually inaccurate. He gave us two examples: the product monograph for OxyContin was inaccurate; and the monograph for the Hydromorph Contin is similarly inaccurate, in many ways.

So there are, apparently, serious situations where these monographs, whether they're meant to be factual, are not accurate. I think the need to have an independent review is something that's very important if we're talking about overall drug safety.

The Chair: Are there any further comments on Ms. Davies' amendment, NDP-3?

Seeing none, all those in favour?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Next up is....

Ms. Eve Adams: Mr. Chair, I would move CPC-4.

The Chair: Is there any discussion on the amendment?

Ms. Libby Davies: Yes, I have a subamendment.

The Chair: You have a subamendment to this one here?

Ms. Libby Davies: Yes.

My subamendment also comes from testimony that we heard from Professor Herder. Basically what we're suggesting is that the requirements for disclosure need to be more targeted.

We would change this part of the amendment:

> prescribed information concerning the clinical trial or investigational test is

It would instead read:

> the registration and results, whether positive or negative, from all clinical trials and other investigative tests be

And then it would continue on.

So we would change some of the wording in Mr. Young's amendment, beginning with the word “prescribed”.

I think we have something to hand out.... Oh, sorry; we don't.

● (1210)

The Chair: Okay, so that's in the third line in the amendment after “prescribed”.

We'll read it out again one more time for the committee, and if what I read doesn't sound right, then let me know.

You want it inserted after “prescribed”?

Ms. Libby Davies: Yes, starting with the word “prescribed”, so it would be “that...”.

So proposed paragraph 30(1.2)(c) “shall ensure that” and then it begins “registration...”.

The Chair: Do you want that to be taken out?

Ms. Libby Davies: Yes, so the words “prescribed information concerning the clinical trial or investigational test” would be taken out and replaced with those words in bold.

The Chair: Got that?

Just so that everybody's clear, Ms. Davies's subamendment says to take out where it starts at “prescribed” on the third line, and go all the way down to where it ends with “investigational test”, and then she would like to have inserted, after “that”, “the registration and results, whether positive or negative, from all clinical trials and other investigative tests be...” and then “is made public within the prescribed time and in the prescribed manner.”

So that is the subamendment to Mr. Young's CPC-4.

Is there any discussion on that subamendment?

Mr. Young.

Mr. Terence Young: Chair, the minister will have the powers under the two words “prescribed information” to order the therapeutic product authorization holder to provide any necessary information. Anything, within a prescribed period of time, so this amendment is nothing.

The Chair: Is there any more discussion on the subamendment?

(Subamendment negatived)

The Chair: Any further discussion on CPC-4 amendment?

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: Just bear with me for a moment.

I'd like to point out another amendment that you'll see in your listing here, and I apologize for not mentioning it earlier. CPC-6 is also considered adopted because it is similar to CPC-1 and CPC-2 where it was deemed to be consequential—

Ms. Libby Davies: Can you just hold on while I find it?

The Chair: —to 4, not 1 and 2.

I apologize for that.

All right? I just wanted to make sure that we were clear on that before we went any further.

It looks as if the bells are ringing.

It probably makes a lot of sense to suspend and come back, but I'll just make sure that's what the committee wants to do.

Ms. Eve Adams: We can do another 10 minutes if everyone is amenable to that, just so we try to work through as much as possible.

The Chair: Okay.

Ms. Libby Davies: I don't know what the weather is like but if people are waiting for a bus, it can take forever to come.

The Chair: Yes, that's true. It took me five minutes to get there; I walked there last time.

We'll do NDP-3.1.

Ms. Davies.

Ms. Libby Davies: Did we vote on CPC-4?

The Chair: Yes, it's agreed to.

Ms. Libby Davies: Okay. NDP-3.1 also pertains to adding a clause after line 8 on page 5. We'd like to add a new number 2:

> It is a condition of every authorization that the Minister be provided with all the results of clinical trials and investigational tests involving human subjects within the specified period.

Again, this is based on testimony from Professor Herder, and I think it's to give greater clarity to what the minister is authorized to receive.

So I would move that amendment.

● (1215)

The Chair: Is there any other discussion on NDP-3.1?

I'll give everybody a second to digest it.

Mr. Terence Young: Mr. Chair, I'd like to defer to the legal counsel from Health Canada for their thoughts on this one.

The Chair: Fair enough.

Mr. Lee.

Mr. David Lee: Mr. Chair, the idea that you make the provision of information connect the registration of clinical trials with the validity of a market authorization.... There's a lot to look at there.

A market authorization allows a drug to be given to a patient. These are often very needed. If you're prolonging life with a cancer drug, having technically failed to register and thereby automatically cancelling a licence, or going to the validity of a licence, is a moment of gravity.

There are other measures in this instrument, or at least they're proposed—to go for large fines, and so on—to discipline company behaviour around transparency. It's just as a cautionary note.

The other thing is that in the regulations, as a matter of course as the minister goes along, Health Canada does want to see every study done on the drug and would want to put that in the regulatory requirements. That goes to the drug approval itself. We would suggest that's the appropriate placement of a requirement of this nature.

The Chair: Is there any other discussion on the amendment? We're on Ms. Davies' amendment, NDP-3.1.

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: While we're here, we'll do one quick thing, and then we'll carry on.

I'll ask whether clause 3 should carry as amended.

(Clause 3 as amended agreed to)

The Chair: We're going to suspend. After the vote we'll come back and do it all over again.

● (1215)

(Pause)

● (1300)

The Chair: Welcome back. We're back in session here until 1:45.

Mr. Wilks, I see your hand.

Mr. David Wilks (Kootenay—Columbia, CPC): Thank you, Mr. Chair.

I'd like to move that the health committee extend its current meeting, suspending at 1:45 and resuming at 3:30, for the purpose of clause-by-clause consideration of Bill C-17, and that the committee continue sitting until clause-by-clause consideration of Bill C-17 is complete, or 11:59 p.m., whichever comes first.

The Chair: Okay.

Thank you very much.

Are there any other comments on what Mr. Wilks just said?

Okay, we'll keep carrying on, then.

(Motion agreed to)

The Chair: Just so you know, the clerk has advised me that if we don't get through it by question period, it will be at 253-D in Centre Block.

(On clause 4)

Mr. David Wilks: Also, Mr. Chair, I move CPC-5.

The Chair: Are there any comments for amendment CPC-5?

There is no discussion on amendment CPC-5.

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: There is just one amendment for clause 4, so we've dealt with all the amendments for clause 4. It has been amended.

(Clause 4 as amended agreed to)

(On clause 5)

The Chair: Moving right along....

Mr. Wilks, I see your hand up.

● (1305)

Mr. David Wilks: Just as a clarification, Mr. Chair, CPC-6, as I understand it from earlier, has already been carried, has it?

The Chair: That's correct, and that was earlier.

There isn't anything else I see for clause 5.

A voice: As amended.

The Chair: Yes.

Pardon me. There are a couple.

Mr. Dany Morin: I believe NDP-4 is part of clause 5.

The Chair: All right. So we're going to deal with—

Ms. Libby Davies: NDP-4?

The Chair: No, we have a vote first on clause 5, and then we'll get into 5.1.

So we did CPC-6, the amendment. Now we're going to have a vote on clause 5 as amended.

(Clause 5 as amended agreed to)

The Chair: Now we're on to 5.1, which is a new clause. We're going to deal with that one right now.

Ms. Libby Davies: NDP-4?

The Chair: Correct. They created a new clause, 5.1, and now we're going to deal with NDP-4.

Go ahead.

Ms. Libby Davies: Mr. Chair, this clause 4 was raised by a number of witnesses who expressed a lot of concern that the minister wouldn't necessarily be exempt from liability for lost product sales or other injury to a manufacturer or seller due to decisions that she's exercised under this bill. So we think it's very important that it be explicitly clear that the minister should be free from the threat of liability when making these very important decisions under this bill for the safety of Canadians.

So we've moved an amendment 5.1, that the act be amended by adding the following after section 29.2:

NO LIABILITY

It would continue:

29.3 Despite any other Act of Parliament, no civil or criminal proceedings lie against the Minister or any person acting on behalf of, or under the direction of, the Minister for anything done or omitted to be done in good faith in the exercise or performance of any powers, duties or functions that under this Act are intended or authorized to be exercised or performed.

So again, this was suggested by a whole number of witnesses and was to ensure that the minister does have an exemption from liability.

The Chair: Are there any comments?

Mr. Young.

Mr. Terence Young: Thank you, Mr. Chair.

I saw this recommendation come out of the CMAJ analysis, etc., but the legal precedent for this is that such an exemption is not necessary. The courts would be very reluctant to intercede. They would intercede only in cases in which a future minister exercised his or her power unreasonably, that is, it was not done reasonably and in good faith.

Health Canada has recall powers—for example, for food products, etc.—and to my knowledge have never been sued for doing so. I'd like to defer to our legal counsel Mr. Edwards, please. Thanks.

Mr. David Edwards (Senior Counsel, Legal Services Unit—Health Canada, Department of Justice): The recall powers in the Canada Food Inspection Agency Act—in section 19, for example—have been used without concern in that way for a number of years. I can verify that there have been no cases, but I'm certainly not aware of any successful cases against the crown in that regard.

The Chair: Ms. Davies.

Ms. Libby Davies: I'm sorry. Did you say that there have been cases but they weren't successful?

Mr. David Edwards: No. What I'm saying is that I can verify that there haven't been cases, but I am not aware of any successful cases for sure. I just haven't done the research in detail right now, but I'm quite certain that this is not a major problem for the CFIA.

The Chair: Are there other comments?

Ms. Libby Davies: I have a brief one. We feel pretty strongly about this, which is ironic, because it's about protecting the government minister, which you would think the government side would do.

After hearing what Mr. Young and Mr. Edwards have had to say, I think, as Mr. Young has pointed out on many occasions, we're dealing with some pretty big players here. Maybe under food recall, yes, there are big players there too, but I just think that it is a kind of precautionary measure to be very explicit about this particular bill, because the bill does give extraordinary powers to the minister. Of course, one always assumes that the minister acts in good faith and so on, but I think that to be cautious and to ensure that this is very clear, we should include this in the bill. I think the witnesses were pretty clear on that. They thought it was very important.

● (1310)

The Chair: Are there other comments on this? All right.

I think it's probably appropriate at this time to mention this. If NDP-4 is defeated or adopted, amendment LIB-2 won't proceed, because it's identical to the NDP one. That's just so everybody knows that ahead of time.

Ms. Libby Davies: A recorded vote, please.

The Chair: We've had a request for a recorded vote on amendment NDP-4.

(Amendment negatived: nays 5; yeas 4 [See *Minutes of Proceedings*])

The Chair: The amendment is defeated, and we won't need to deal with amendment LIB-2 either.

Mr. Francis Scarpaleggia: Mr. Chair, before we get to amendment NDP-4.1, I'd like to propose a couple of amendments, if possible, to clause 6. May I go ahead?

The Chair: Do you have a copy?

Mr. Francis Scarpaleggia: Well, it's handwritten.

The Chair: We'll let the legislative clerk make a comment here.

Mr. Philippe Méla: Could I have a copy of it just to make sure it's in order?

Mr. Francis Scarpaleggia: We'll show it to you, and then I'll take it back and I'll read it.

(On clause 6)

The Chair: Okay, Mr. Scarpaleggia, we're in order.

Mr. Francis Scarpaleggia: Great.

The Chair: Yes, Ms. Davies?

Ms. Libby Davies: On a point of order, I know that Mr. Scarpaleggia hasn't actually read it yet, but does it come ahead of line 13?

We have NDP-4. It's ahead of that?

Mr. Philippe Méla: Yes.

Ms. Libby Davies: Thank you.

The Chair: Go ahead, sir.

Mr. Francis Scarpaleggia: I would move to amend proposed paragraph 6(1.2)(a) by including, on line 9, the word “reprocessing” after the word “manufacture.”

In other words, what we're trying to get at here is the testimony of Ms. Abbey, I think. That was pretty powerful testimony. We think we should take the opportunity of this bill to act on this issue.

The Chair: Fair enough.

Are there any comments on the amendment?

Mr. Lunney.

● (1315)

Mr. James Lunney: I'd just say that I did some checking on this. We're not aware of problems other than for.... Certainly it's a big advantage to people marketing new products not to have them cleaned and reused, but we're not aware of any incidents, whether you're using an autoclave or some other way of cleaning things and reprocessing. We do it all the time with other surgical instruments.

Without evidence of a problem there, the cost saving for provinces and hospitals is a big concern today. If it's an economic model we're trying to protect by this inclusion, it's not clear that the companies that provide the one-time use items are in fact providing a service to reprocess their own products.

As it exists now, we have the ability to act through regulations, as far as I understand from our officials. I think we're fine on that particular issue.

The Chair: Are there any other comments or further clarifications?

We have Mr. Scarpaleggia's amendment, and we'll call it Liberal amendment 2.1. It's the portion where he's adding in “reprocessing”.

All those in favour of Mr. Scarpaleggia's amendment?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Ms. Davies.

Ms. Libby Davies: This is NDP-4.1. We're moving that clause 6 be amended by adding, after line 13 on page 6, the following: (a.1) respecting the refusal of issuance of an authorization if the person did not register the clinical trials and investigational tests involving human subjects under paragraph (c.1);

The purpose of this is to ensure that if somebody didn't register for a clinical trial, then they would be refused an authorization for use. We think it's just a clarity in the bill and making it very clear that there's no further authorization if there wasn't a registration.

The Chair: Comments?

Mr. Terence Young: Yes. Thank you, Chair.

With regard to the powers in the act, there are fines and injunctions available if companies refuse to register their clinical trials, and of course the regulator can always refuse to approve a drug without registration of trials.

I would like to defer to legal counsel for a more fulsome answer on that, please.

Mr. David Lee: I would begin with the observation that putting in the refusal criteria when a company applies to get on market is already something that the minister can do, or the GIC can do, under the current act. We can, in regulation, stipulate grounds of refusal without having this as an addition.

Having said that, there is a very important policy discussion here —that is, do you want to tie the refusal of an authorization of an important life-saving drug to a transparency measure, or is it a better discipline to go with fines because patients do need them? Really, it's in making the regulations about why you would refuse a drug submission that the conversation would be held—but in regulations.

The Chair: Ms. Davies.

Ms. Libby Davies: Just briefly I would say it's always better to spell it out in the legislation than to leave it under some regulation. The fact that there would be a refusal of issuance of authorization would of course be a very serious penalty, but I think that's the message we want to get across. There may be fines, but this is partly about transparency. It's transparency related to safety, so it's not just transparency for no good reason. It's there for a reason. So I do think they are linked.

Again, this was brought up by witnesses. The registration of the trials is very important, and if the companies aren't doing that, I think there have to be consequences that say they're not going to go further. I think this is a better way to go than just leaving it as a fine at some later point. It's a lot clearer and a lot tougher.

The Chair: Okay. Are there any other thoughts or comments on that amendment? I see none.

All those in favour of amendment NDP-4.1?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Mr. Wilks.

● (1320)

Mr. David Wilks: Thank you, Chair.

I move amendment CPC-7.

The Chair: Are there any comments on that amendment?

Ms. Davies.

Ms. Libby Davies: We have a subamendment. It would be a subamendment to add paragraph 6(b.2) that would say the following:

The Minister must ensure the status of post-market studies are disclosed to the public on an annual basis.

This is just to ensure that regular disclosure takes place. We think this would be a good addition to the bill, to this particular amendment.

The Chair: Would you happen to have a copy of that?

Ms. Libby Davies: We've been in such a rush to get these amendments in, I don't have it translated, but I do have it for the.... That's why I read it into the record.

The Chair: That's great. Thank you.

Ms. Libby Davies: It's a last-minute thing. Otherwise we would, of course, have had these translated.

The Chair: Okay. I'll read it one more time. It's a proposal is to create paragraph 6(b.2):

The Minister must ensure the status of post-market studies are disclosed to the public on an annual basis.

Are there any thoughts on that subamendment?

Mr. Young.

Mr. Terence Young: Bill C-17 empowers the minister to order the publication of a whole range of things, and one of them is drug reviews. Another one is the initial grant of the NOC powers.

I'd like to ask the counsel to comment on that one as well, please.

Mr. David Lee: Thank you, Mr. Chair.

There is an important principle of transparency around the conditions of an authorization, which is certainly very important in the regulatory cycle.

If a drug is approved and there are conditions to conduct further studies on market, there is an interest by all in knowing what progress has been made. There is an intention to bring that into regulation, but we can do that as a matter of obligation under the regulations without ensuring it through further language here. It's already something the GIC can make a regulation about. The intention to have the element of transparency is very important.

The Chair: Are there any further comments on that? Seeing none, we're on the subamendment. All those in favour of the subamendment proposed by Ms. Davies? All those opposed?

(Subamendment negatived)

The Chair: Now we're back to amendment CPC-7.

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: Ms. Davies.

Ms. Libby Davies: Are we on amendment CPC-8?

The Chair: No, we have it on our list as amendment NDP-5.

Ms. Libby Davies: I must have them in the wrong order. So we're on amendment NDP-5.1?

The Chair: We're on NDP-5.

Ms. Libby Davies: In that case, do you have NDP-5.1?

The Chair: We do. It's further down.

Ms. Libby Davies: All right. I'd like to withdraw NDP-5.

(Amendment withdrawn)

Ms. Libby Davies: I would like to deal with NDP-5.1.

I think that's why we had CPC-8 first.

The Chair: Fair enough.

We'll deal with CPC-8 and then we'll get to NDP-5.1.

Moving right along, CPC-8.

Mr. David Wilks: Thank you, Mr. Chair.

I move CPC-8.

The Chair: Are there any thoughts or comments on CPC-8?

Before we vote on this, I want to make a technical point that the legislative clerk has prepared. If CPC-8 is adopted, the Liberal amendment 3 won't proceed. It's to do with the definition of a clinical trial, which I think is what your amendment is trying to do.

That's just so everybody knows that before we vote.

We're still at CPC-8.

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: We're now back to NDP-5.1.

● (1325)

Ms. Libby Davies: Thank you, and sorry for the mix-up.

In NDP-5.1, we're suggesting that clause 6 be amended by adding after line 30, on page 6, the following:

> (c.l) respecting the registration of clinical trials and investigational tests involving human subjects and specifying the period within which the results of those clinical trials and investigational tests must be provided to the Minister.

Again, this comes out of the testimony that we heard from, I think it was Professor Herder. We believe that this amendment would add the range of clinical trials and observational studies to the mandate of Bill C-17, and give the Governor in Council the power to make regulations about clinical trial registration.

All investigational studies, including not just phase 1 to 4, but also observational studies, should be registered and otherwise subject to transparency. In fact, we did hear from our witnesses that the importance of observational studies is becoming more evident. They are more likely to be used in the future, particularly in the context of rare diseases.

I think this adds a better range, in terms of the clinical trials and observational studies to be added to the mandate of the bill.

The Chair: Are there any comments on NDP-5.1?

Mr. Young.

Mr. Terence Young: Chair, we don't think this clause is necessary, and I'd like to refer to legal counsel.

Mr. David Lee: I should mention that I'm just here as a departmental official, and the legal counsel is beside me. We're both David K.

Mr. David Edwards: I'll let my client speak.

Mr. David Lee: On this, there is a supporting ability to make regulations related to what will be at the legislative level to compel registration of clinical trials. It's the prescribed information in the prescribed time and manner. That would cover all of this.

Your point about observational studies, I think is a very interesting one. That's not yet well defined. It's not as well defined as pre-market studies, so you have the three well-known phases. There are very many different ways to do those.

The value of having the flexibility in the regulations is that as new types of studies come up—and they have in the rare disease area, where we're seeing more study varieties—then we can keep up with that kind of language. The ultimate flexibility is in the regulation-making that's associated with the basic commitment to register trial information.

The Chair: Okay.

Ms. Libby Davies: As I understand it, the way this amendment is written would then provide the ability to deal with the regulations. But unless we spell it out, particularly given that observational studies are used more and more.... I certainly wouldn't want to just leave it to chance.

This has been raised as a very current issue, so I hope we can consider this amendment as giving clarity, so that the regulatory work can then go ahead, including the observational studies.

The Chair: Are there further comments? We're on amendment NDP-5.1. Seeing no further discussion, I'll call the vote. All those in favour of NDP-5.1?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Next up is NDP-6.

Ms. Libby Davies: Again, I think we've moved a step ahead. We had amendment NDP-6. Then, based on further testimony, we rewrote it and did NDP-6.1. Again, I had it after amendment CPC-9. We want to withdraw NDP-6 and go to NDP-6.1. I don't know if that means we go back to CPC-9.

● (1330)

The Chair: I think that's what we'll do. We'll go to amendment CPC-9 and come back to amendment NDP-6.1.

On CPC-9, go ahead.

Mr. David Wilks: Thank you, Mr. Chair.

I move amendment CPC-9.

The Chair: Are there thoughts or comments on CPC-9?

Not seeing any comments for CPC-9, I'll call the vote.

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: On amendment NDP-6.1, Ms. Davies.

Ms. Libby Davies: Thank you very much.

This is a fairly long amendment. I won't read out it in the interests of time. I hope committee members have had an opportunity to read it.

Basically, this would add a new section or clause empowering Health Canada to publish positive and negative regulatory decisions. We think that at a minimum Health Canada should publish rationales for decisions concerning drugs that were approved for sale, drugs refused for reasons of safety or efficacy, and drugs that are suspended or recalled. It's a new section. I think there have been other similar government amendments, but I think this adds more clarity and better definition to the regulations.

The Chair: Are there any thoughts or comments on amendment NDP-6.1?

Mr. Young.

Mr. Terence Young: Thank you, Chair.

Chair, the motions in amendments CPC-3, 4, 5, 6, 7, and 10 require the minister to make publicly available recall, reassessment, label change, and test studies orders; require the minister to make publicly available positive and negative decisions and the reasons for them; and require the therapeutic authorization holder to make prescribed information about clinical trials and investigative tests publicly available. Consequently, the intent of this motion is already covered, with the exception of a section that says “results of clinical trials and investigational tests”.

However, in amendment CPC-10, the minister gets the authority to make regulations respecting the type of information. So it would be a simple matter for the minister to create that authority by regulation through the GIC to get the results of clinical trials and investigative tests, and I'm sure that would be done.

The Chair: Ms. Davies.

Ms. Libby Davies: Well, it does seem that we're leaving an awful lot to regulation. I know there are things that are appropriate to regulation, but I do think that where we can give clarity in this bill, because it is such an important bill in terms of what the minister can do, it should be in the legislation.

Again, this amendment I think offers a sense of clarity and a better definition from which regulations can then flow, particularly in regard to new subparagraph 6(1.2)(d.1)(ii), which Mr. Young has just spoken about, those being the “results of clinic trials and investigational tests”, which aren't mentioned in the earlier government amendments. It's better to go for clarity in definition than not to.

The Chair: Are there any further thoughts or comments on amendment NDP-6.1? All those in favour of NDP-6.1?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Ms. Davies.

Ms. Libby Davies: I'll read this. Amendment NDP-7 is adding after line 8 on page 7, in clause 6, the following:

> (e.1) respecting the establishment of best practices, the promotion of standards of practice and the communication of information relating to the risk, safety, and effectiveness of therapeutic products;

This amendment is really focusing on the need for a federal role in ensuring better communication around drug safety and effectiveness. It enables the Governor in Council to work with other affected parties to implement and publish best practices and evidence-based prescribing standards. It's really about communicating work and making sure that is done. We put that forward as an amendment.

● (1335)

The Chair: Okay.

Mr. Young.

Mr. Terence Young: Chair, the proposed wording does not really make it clear to whom the provision would apply. There are concerns that the provision appears to be outside the federal jurisdiction, so I'd like to defer to our experts from Health Canada, please.

Mr. David Lee: It really matters whether, in making regulations under this section, Health Canada would be enforcing rules on the interchange between companies and physicians, for example, for which there are some rules already governing advertising and promotion. It's a little unclear to us who this rule would apply to.

Perhaps we can seek some clarification on that, Mr. Chair.

Ms. Libby Davies: Just to clarify, our intent with the motion is that it allows the Governor in Council to work with other affected parties. For example, it could be provincial governments, it could be health authorities, it could be research institutes. The focus here is about communicating in terms of best practices and so on.

I don't know if that clarifies it for Mr. Lee.

Mr. David Lee: Thank you for the explanation.

When you're making regulations under this kind of section, because it is up under the criminal head.... Usually the recipe you have to use is that you make a prohibition—make something criminal—and then sort of allow it. Around things like best practices for risk communication, certainly we would encourage that, but touching that area with a criminal pen is a serious movement.

To be honest, we're trying our best to understand how this would work. We understand some of the principles, and we would certainly agree that talking to physicians and our colleagues in the provinces about best practices is something that Health Canada would want to do, but in a regulation it's not something that we would normally envisage doing.

The Chair: Is there any other discussion on amendment NDP-7?

Seeing none, I'll call the question.

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Next up, we have amendment NDP-8.

Ms. Libby Davies: Mr. Chair, this amendment deals with disclosure. It's a subject that's come up quite a few times, both in terms of this bill and in our previous study looking at abuse of prescription drugs and the whole system of disclosure, how decisions get made, and how prescribing practices happen.

This amendment would add, after line 11 on page 7, the following:(f1) respecting the procedures for disclosing gifts or other advantages offered to or accepted from the holder of a therapeutic product authorization or the manufacturer of a drug or device, for limiting the value of such gifts or other advantages and for addressing any conflicts of interest involving the holders of a therapeutic product authorization or the manufacturers of a drug or device.

This amendment, if it were approved, would allow the Governor in Council to submit regulations requiring public disclosure of payments to physicians, medical institutions, colleges, and so on.

This amendment is based on the idea of what already exists in the United States, which is called “sunshine” legislation. In the U.S., manufacturers of drugs, medical devices, and biologicals, working with the U.S. government, actually have to report any payments and items of value over $10 given to physicians, physician associations, medical institutions, etc.

We're not suggesting that this would exactly follow the U.S. legislation, but we think the principle is really, really important. It should be covered in this bill.

So we're not suggesting the specifics of the U.S. legislation, but we do identify that this is an area where further regulations are needed. Possibly Mr. Lee or Mr. Edwards will say that there's a question of jurisdiction here, that it pertains to provincial jurisdiction, but we believe it could be spelled out that if it involves any company or corporation or business that works with the federal government, then it would under federal jurisdiction.

We offer it in that spirit.

● (1340)

The Chair: Mr. Young.

Mr. Terence Young: Mr. Chair, I want to thank Ms. Davies for this initiative.This is a big problem; there is no doubt about that. The debts of gratitude created in our health care professionals by pharmaceutical companies giving them everything from pens to coffee cups to free lunches to free trips, just goes on and on. And it's proven by research to influence prescribing practices.

The Canadian Medical Association should do this voluntarily. They haven't, obviously. My concern is that this isn't related to the safety of a therapeutic product directly, and it could possibly be challengeable because it's not fully under federal jurisdiction, although that's not my primary concern. This bill is about the safety of therapeutic products, and as such is outside the scope of the bill. If the member introduced a private member's bill on this, I'd be happy to support it.

Ms. Libby Davies: I don't know if it is outside of the scope of the bill. I don't believe it is, and I have suspicions as to what Mr. Lee and Mr. Edwards are going to say, but maybe they could respond to that because it relates to any company that works with the federal government, so that jurisdictional question is clear.

And I do think it is related to safety because we heard very clear testimony that this whole chain of events has to do with prescribing practices. When physicians and others get all this free stuff and they get information that's possibly not correct or misleading and they go to these so-called educationals, we heard about it all. When they see ads in the medical journal that are just ads, promotion, and on that basis they're making very important decisions that affect the health of their patients, I believe it is related to the issue of drug safety and it's related to how people are practising.

I'd like to ask Mr. Lee or Mr. Edwards their opinion on whether or not it's within the scope of the act.

Mr. David Lee: Thank you.

I don't want to fulfill your prediction, but we do worry. We walked through this to see what kind of regulations could be made. You would have to have a prohibition on the receipt of a gift of a certain nature, then you'd have to make a rule that says you have to report it in this way. That would be the federal structure, at least that seems to be what this would intend.

The problem with that is then there's a federal rule telling doctors how to behave and when they get a gift, what to do and how to report it. And that's a very difficult ground for federal jurisdiction, so we tried to think this through.

Mr. Chair, when the member says “works with the federal government”, is it regulated by the government or a government corporation?

Ms. Libby Davies: It has some working relationship in that they have to report, there's oversight by the federal government, there's some connection between the companies involved who would be covered by this because they are reporting to, they're under the jurisdiction of, the federal government in terms of regulation.

The Chair: Okay.

Ms. Libby Davies: Could I also ask the legislative clerk his opinion on whether or not this is within the scope of the bill?

The Chair: I've asked him too.

If you go to the part where it talks about conditions. That would be in paragraph (b). Potentially it could be a condition. So it may be a stretch, but we won't rule it out of order.

Is there any other discussion or debate on NDP-8?

Ms. Libby Davies: Can I just be clear? This is about reporting by the manufacturers, not the doctors. The onus would be on the manufacturers.

● (1345)

The Chair: Everybody's clear?

Ms. Libby Davies: May I have a recorded vote, please?

The Chair: We'll have a recorded vote on NDP-8.

(Amendment negatived: nays 5; yeas 4 [See *Minutes of Proceedings*])

The Chair: We had a motion when we came back from votes that clearly indicated we would go until a quarter to 2, and then we would come back at 3 p.m. I think at this point that's what we should stick to.

Ms. Libby Davies: Can I make a suggestion?

The Chair: Yes.

Ms. Libby Davies: I know we passed a motion stating 3:30, but I'm trying to make a flight out. I'd be happy to come back.

If we are going to be in Centre Block, which is a lot closer, I would be happy, if others are agreeable, to make it 3:15, assuming that question period has concluded—I know sometimes it goes a little bit over—just so we have the extra 15 minutes.

The Chair: Mr. Wilks.

Mr. David Wilks: Thank you, Mr. Chair.

Just to bring some clarity to this as well, there are two votes after QP.

Ms. Libby Davies: All right. That's fine.

The Chair: I want to remind everybody, just as Ms. Davies said, that we're going to meet back at Centre Block in room 253-D. Bring your paper with you and bring a sandwich with you, because we're not coming back here.

Ms. Libby Davies: We'll be at amendment CPC-10.

The Chair: Yes. We'll pick up at amendment CPC-10.

I'll suspend the meeting. We'll see you as close to 3:30 as possible.

● (1345)

(Pause)

● (1525)

The Chair: Welcome back.

We're continuing with our examination of Bill C-17. We're working right through.

We left off last time on amendment CPC-10. On that amendment to clause 6, we have Mr. Wilks.

Mr. David Wilks: Thank you, Chair.

I move amendment CPC-10.

The Chair: Is there any discussion or commentary on amendment CPC-10? Seeing none, I'll call the question.

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: I just have a note here. If you go back to amendment CPC-8, you'll see that it affected amendment LIB-3. We'll skip over amendment LIB-3 and carry on with amendment NDP-9.

Go ahead, please.

Ms. Libby Davies: Thank you very much. I won't read the amendment. I'll just give the explanation.

First of all, we should explicitly state that the results of clinical trials are not proprietary and should be publicly disclosed, including things like de-identified patient-level data, post-market studies, and adverse drug reactions reported by drug manufacturers and health care institutions, which are covered under the term "clinical trials and investigational tests". We believe this amendment will actually make sure that those results are not proprietary and are made public.

● (1530)

The Chair: Very good. Are there any comments on amendment NDP-9 on clause 6?

Mr. Young.

Mr. Terence Young: Chair, I'd like to ask the officials from Health Canada to comment on that, please. That would be helpful.

Mr. David Lee: Thank you, Mr. Chair.

I'll point out first that the language "business proprietary information" doesn't quite match up with the definition of "confidential business information". That may be the intent of this wording. Could I get that as a clarification?

Ms. Libby Davies: I'm not sure. Keep going and I'll find out.

Mr. David Lee: Okay.

There is a motion already, a CPC motion, that allows regulations to be made to clarify when something is not confidential business information or ceases to be. With that regulation-making power, it provides the necessary ability for the Governor in Council to make any regulation that this would permit.

The Chair: Mr. Young, do you have something else?

Mr. Terence Young: Chair, we've already passed amendment CPC-9. Amendment CPC-9 allows the Governor in Council to make regulations that would specify under what conditions business information obtained under the Food and Drugs Act is not confidential business information or ceases to be. It's fairly prescriptive and broad, so we see this recommendation as unnecessary.

The Chair: Okay. If there's no further discussion on amendment NDP-9, we'll call the question.

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: Now we're moving on to the clause itself.

Ms. Davies?

Ms. Libby Davies: We'd like to move a deletion in clause 6. Before we vote on the clause overall as amended, we'd like to move a deletion where it says "Subsection 30(3) of the Act is replaced by the following", and then it begins with "(3)". It's at line 11. It's that clause that deals with "Regulations— North American Free Trade Agreement and WTO Agreement".

If the members will recall, we had a witness who came before the committee who was very concerned that these trade agreements would somehow trump this legislation and would then preclude some of the minister's authority. Just on the basis of caution, we'd like to see this clause deleted.

The Chair: Just so we're 100% clear, it's on page 8, and it starts at line 11 and would run until line 22. Is that correct?

Ms. Libby Davies: That's right.

The Chair: So everybody's with us on that? Okay.

Mr. Young.

Mr. Terence Young: Chair, I think it would be helpful if we defer to the Health Canada officials and legal counsel for an explanation of why this is not appropriate.

Mr. David Lee: Mr. Chair, the proposal here was being made because in each of the grants related to the Governor in Council, the language is being modernized and made consistent. So you'll see this in each grant of power to the GIC to make regulations. That's all that was being changed here.

This is in fact a fairly old provision. It was put in so that Canada could implement its commitments under NAFTA and TRIPS. It's really worth mentioning because there is a concern or appears to be a concern that somehow trade would trump safety. Those commitments don't require that. I think some of the observations that Mr. Herder made are very important in this respect.

So what 39 of TRIPS and 1711 of NAFTA require is not that there be non-disclosure of information that's safety related. In fact, it does permit disclosure of safety-related information, but it's in such a way that it prevents unfair competition. The idea is that if a manufacturer has to do clinical studies and invest a lot of money and then hand all of that information, which it wouldn't normally disclose to competitors, to a government, the government can't turn around and give it to a competitor right away so that the competitor gets market access without doing that work.

This section was used in 2006 to implement data protection, which was not designed to prevent disclosure of information by the minister, it just creates a situation where generic companies can't file for a period of six years to copy a brand drug. Again, it would not impede upon the minister's ability to disclose information, it just goes to the unfair competition part.

● (1535)

The Chair: Thank you very much for seeking some clarification. Is there any further discussion on Ms. Davies' amendment?

We'll call the question and it's to do with the deletion of lines 11 through 22 on page 8.

(Amendment negatived [See *Minutes of Proceedings*])

(Clause 6 as amended agreed to)

The Chair: I have a request and I need unanimous consent to do so. From clause 7 to clause 13 there are no amendments, so I'm wondering if I have the permission of the committee to ask the question on all the clauses at one time. Do I have unanimous consent?

Some hon. members: Agreed.

The Chair: Shall clauses 7 to 13 carry?

(Clauses 7 to 13 inclusive agreed to)

The Chair: We have a new clause, 13.1.

Go ahead.

Ms. Libby Davies: Thank you, Mr. Chair, this is NDP-9.1. It's pretty straightforward and the reason we've brought this forward is that there's been an enormous amount of interest in this bill. I think there were more than 45 witnesses who wanted to be heard. We ended up hearing maybe 10 people. It is a significant change in terms of the overall regime, so we think there should be a review within two years, particularly because we've heard there's so much that's going to go into regulation and that's at the discretion of the minister.

I think it would be a very good idea if, in two years, there were a review of this legislation to see how it's operating and whether or not there are any other questions. There are issues around the natural health products. There have been no amendments to include them and we're not including them, but I think it would be a prudent thing to have a review of this legislation after it comes into force.

The Chair: Are there any comments on that amendment?

Mr. Young.

Mr. Terence Young: Bill C-17 represents the biggest change in 20 years, a major, major change, and—

A voice: In fifty years.

Mr. Terence Young: Is it the biggest change in 50 years or 20 years? Fifty years? Thank you. I guess I don't have to say that it was a long time coming, but it has been a long time coming for all of us.

The act, when it becomes law once we get through this process, will be a modernized regulatory act. It will be a world leader, if not the world leader. The concern would be that this section would basically have the people working at Health Canada in constant review mode. In other words, they'd be spending more time on reporting than on administering the act. There's nothing to prevent the committee, the minister, or anyone asking the bureaucrats to produce a report for Parliament at any time. We just don't think it's necessary to put it into the act.

● (1540)

The Chair: Are there other thoughts or comments?

Ms. Davies, do you have any other comments?

Seeing no further debate, I'll call the question on amendment NDP-9.1. All those in favour?

(Amendment negatived [See *Minutes of Proceedings*])

The Chair: That deals with the proposed clause 13.1. We'll move directly to clause 14.

(On clause 14—*Subsections 6(2) and (3)*)

The Chair: Mr. Wilks.

Mr. David Wilks: Thank you, Chair.

I move amendment CPC-11.

The Chair: Mr. Young?

Mr. Terence Young: On a point of order, because there are two separate items on this sheet, I'm wondering.... We voted on the amendment. Did we also vote that it carry? Or is that it? That's all?

The Chair: For clause 13—

Mr. Terence Young: Oh, it was defeated. It's all right. Okay. We're on clause 14. That's my mistake.

The Chair: Yes, my understanding from the legislative clerk was that because amendment 9.1 was defeated that—

A voice: Thirteen was adopted before.

The Chair: I'm sorry. Was your question on clause 13.1 or 13...?

Ms. Libby Davies: No. Did we adopt clause 13 overall? We did? Okay.

The Chair: Yes, when we did the "shall clauses 7 through 13 carry?", we lumped them all together. Okay?

So everybody's good? Thank you.

On clause 14, Mr. Wilks, you moved amendment CPC-11?

Mr. David Wilks: That's correct.

The Chair: Okay. Are there any comments? Is there any debate on amendment CPC-11?

Seeing none, I will call the question.

(Amendment agreed to [See *Minutes of Proceedings*])

The Chair: That's the only amendment for clause 14. Shall clause 14 carry as amended?

(Clause 14 as amended agreed to)

(Clause 15 agreed to)

The Chair: At this point, we're through the bulk of it. We're just going to go through the title, the preamble, the short title, etc. If you have any questions, put your hand up, but it should be pretty straightforward.

Shall the short title carry?

Some hon. members: Agreed.

The Chair: Shall the preamble carry?

Some hon. members: Agreed.

The Chair: Shall the bill as amended carry?

Some hon. members: Agreed.

The Chair: Shall the chair report the bill as amended to the House?

Some hon. members: Agreed.

The Chair: Shall the committee order a reprint of the bill as amended for use of the House at report stage?

Some hon. members: Agreed.

The Chair: That concludes Bill C-17.

Mr. Young, did you have a point?

● (1545)

Mr. Terence Young: Chair, I just want to take half a second to thank the members of the opposition, both Liberal and NDP, for supporting the bill, especially Madam Davies, who has done a lot of work on the bill.

I also want to thank the Health Canada officials who are here today and who have worked on this. One gentleman here today has worked on this concept and bill for 14 years.

Some hon. members: Hear, hear!

The Chair: Mr. Wilks.

Mr. David Wilks: Chair, I believe we have a request for a project budget before us. We should probably deal with that before we adjourn.

The Chair: I agree. We will move in camera for a brief moment to do that.

I would like to thank everybody. This will be our final meeting of the session. There has been a great deal accomplished. With one study started and completed, another almost completed, a piece of government legislation, and a private member's bill, it has been a fairly busy spring session.

We'll now suspend and go in camera to deal with some budget items that we need to deal with.

Thank you.

[*Proceedings continue in camera*]

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