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Chair

Mr. Ben Lobb

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● (0850)

[*English*]

The Chair (Mr. Ben Lobb (Huron—Bruce, CPC)): Good morning, ladies and gentlemen. Welcome and thank you for coming to the committee meeting this morning.

We're studying Bill C-17. We have the minister and officials with us. The minister will be with us for the first hour and then we'll continue on with the officials. If we have 15 minutes for committee business at the end, we'll do that.

Welcome, Minister. Welcome, officials. We'll allow you to start. You have 10 minutes or thereabouts for your opening remarks and then we'll go into our rounds of questions.

Hon. Rona Ambrose (Minister of Health): Thank you, Mr. Chair.

It's great to be here. I'm going to ask Anne, David, and Supriya to introduce themselves quickly.

Mrs. Anne Lamar (Acting Assistant Deputy Minister, Health Products and Food Branch, Department of Health): How do you do. I'm Anne Lamar. I'm the acting assistant deputy minister of health products and food branch at Health Canada.

Mr. David Lee (Director, Office of Legislative and Regulatory Modernization, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Department of Health): Good morning, I'm David Lee. I'm the director of the office of legislative and regulatory modernization within the branch.

Dr. Supriya Sharma (Acting Associate Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Good morning. I think I have the longest title of anyone here. I'm the acting associate assistant deputy minister of the health products and food branch and also the senior medical adviser for the branch.

Hon. Rona Ambrose: Thank you, again, Mr. Chair and committee members.

I'm pleased to be here today to speak to the protecting Canadians from unsafe drugs act, or Vanessa's law.

This important legislation will make a difference in the health and safety of all Canadians. I commend the committee for studying it. I know you will ensure that it receives the focus it deserves.

I would like to state at the outset that I'm appearing before you with an open mind. I know there are many parties interested in making this piece of legislation better. I look forward to the recommendations from the committee.

I am the minister responsible for this bill, but I do believe that all political parties and all members of Parliament have an interest in ensuring the safety of the drugs that we rely on for our health. I look forward to the study by the committee and potential amendments to this legislation.

As you know, this bill is actually named after Vanessa Young, who tragically died of a heart attack while on a prescription drug that was later deemed not safe and actually was removed from the market.

Stories like this remind us all of the very serious consequences pharmaceutical drugs can have, and of course of the need for all governments to ensure we have the strongest possible safety systems in place in order to prevent other families and patients having to suffer such a terrible loss.

I'm also pleased that Terence Young is here not only as a committee member but also very much as a subject-matter expert on this issue. I appreciate all the work he has done to get us to this place.

Colleagues, what it comes down to is this. Canadian families expect when they go to a pharmacy or a hospital that the drugs they receive are safe, that they're of high quality, and that they're effective in treating their condition. They expect that government will ensure that unsafe products are quickly identified and appropriate action is taken, including, if necessary, their removal from the marketplace.

Canada does have one of the most rigorous drug approval systems in the world for pharmaceuticals and medical devices. This system ensures, as far as possible, the safety of these products before they are marketed.

However, once these products are on the market, my department has very limited ability to gather information about these products and to take action when a problem arises. This is largely because the laws in this area have not been substantially updated in over half a century to reflect the post-market realities of drugs and medical devices.

Because of the problems with the current legislation, as Minister of Health I use the example that I have the authority to recall a bag of Doritos, but I don't have the authority to recall an unsafe drug from the market.

When there is a safety concern and a drug should not be on the market, we have no option other than to negotiate with the manufacturer in the hope that it will voluntarily come to the right decision. I find this unacceptable.

Vanessa's law will enable us to order a manufacturer to take immediate action to recall a product if it poses a serious or imminent risk to human health. Health care institutions are also not currently required to report adverse drug reactions. There exists no authority to order label changes on packaging if we feel additional information or studies are required.

In this bill's development, we spoke with representatives from patient safety organizations, the provinces and territories, and industry. All of their input was invaluable in developing this bill. There was an overwhelming consensus that stronger drug and medical device safety tools are absolutely necessary.

Vanessa's law will give our government the tools needed to ensure that drugs are safe and that strong measures are taken when concerns are raised. It will require health care institutions to report serious adverse drug reactions and medical device incidents. It includes tougher penalties to better reflect the serious nature of violations.

The measures included in Vanessa's law will provide the power to order drug or medical device manufacturers to make changes to the label or package of a drug or medical device. This will speed up the communication of important safety information and prevent harm to Canadians and their families who rely on these products.

When a consumer buys a drug at the pharmacy, the drug is accompanied by the manufacturer's label on which there is information on the safe use of the drug and warnings about the negative effects. Sometimes the information and warnings are not sufficient or clear enough.

When the labels are not clear, the patient's health may be in danger. Currently, when my department becomes aware of a safety problem that requires a new warning on a label, we contact and try to convince the manufacturer to add this new warning to the label.

This process can take a long time, since we have to rely on the manufacturer to take action to change it. Meanwhile, the patient's health continues to be in danger. Again, this situation is unacceptable and it must change.

Vanessa's law will provide the power to compel information and require companies to perform additional tests and studies on products. For example, I would be able to compel further studies on a drug that was designed for adults but was routinely causing adverse reactions in children.

Vanessa's law also introduces tough new fines for those who do not comply with these measures. It allows for significant penalties, including jail time, on companies that sell unsafe drugs in Canada.

The current fines and penalties simply do not reflect the severity and the nature of offences that can occur. Previously, the fine was $5,000 per day. To put this into perspective, this is the same amount that a person can be fined for littering under some municipal bylaws. That will now change to $5 million per day. For any company that intentionally misleads Health Canada, or recklessly harms a Canadian, the law will also provide the courts with the discretion to impose even higher fines and jail terms where they find it justified.

Before concluding, I would like to state once again that I am open to amendments to this bill. I've listened to the debates in the Commons, media commentaries, and heard directly from doctors and patients, and of course patient safety experts, since we introduced the bill.

I think it's clear that improvements can be made that address elements including transparency in clinical trials, disclosure of regulatory actions, and confidential business information. I think the committee is in a good place to put forward well-informed amendments that will make this bill even better. I have consulted widely, and feel these amendments will be very helpful.

In closing, let me again state that our government has listened to the experts. We agree with health care professionals that we need a strengthened drug safety system. Drug safety is not an issue that should become, in any way, a victim of partisan games and rhetoric. I thank the committee for approaching it in this fashion. I know that Canadians expect this issue will be taken very seriously as this committee studies Vanessa's law.

Thank you, Mr. Chair.

● (0855)

The Chair: Thank you, Minister.

That concludes the opening remarks. We'll open it up for our first round of questioning, starting with Ms. Davies.

Ms. Libby Davies (Vancouver East, NDP): Thank you very much, Chairperson.

Thank you to the minister for appearing here today.

It's good to hear your comments about the bill. I know that you've put a lot of work into the bill. It's a very important bill. As you noted, there's been support in principle from all the parties in the House, because I think we all recognize that drug safety and the provisions in the bill are long overdue. In fact, I would remind us that it was as far back as 2011 that the Auditor General, in his report, flagged this issue as something that needed attention.

Minister, I have been a bit perplexed about the process here. Recently we had charges made, allegations, that this bill was being held up, when in actual fact it just had a very few hours of debate in the House at second reading. Of course, second reading, looking at the bill in principle, is very important. Members wanted to speak in the House. The government basically sat on the bill for six months.

I wonder if you could tell us why the government didn't move on this bill for six months and is now apparently trying to create a political crisis around this bill, that it has to be rushed through at the last minute, when really it's been sitting there for six months and not being called for debate. We could have debated it, have it go through committee, send it back to the House and it probably would have been passed by now if the government had moved on it. Could you respond to that please?

Hon. Rona Ambrose: When Vanessa's law was introduced, I did have high hopes for its quick passage, given the support that it received by all parties in the Commons. I know you yourself said that it was a step in the right direction. I also received correspondence from several members, from all parties, who believe that this is a very important bill and urged me to secure passage of Bill C-17, which is Vanessa's law, as quickly as possible.

We did work in that direction. I will simply say that sometimes the work we do is caught up by.... The House leaders do the work that they do. I will just say at this point that, yes, there were exchanges between House leaders as to when this bill should move forward. I'll just leave it at the fact that I'm glad that we have now seen the bill unanimously supported by all parties to move to committee. I'm glad to see that happen.

Ms. Libby Davies: Thank you.

I guess we can take it that the government House leader, who controls the House agenda, for whatever reason made a decision to wait on this bill for six months. I'm glad we are dealing with it now, and I'm sure the committee will go through the bill very carefully. We have witnesses to hear and I think they're going to be pretty good witnesses. We'll go through the bill clause by clause.

If I have some more time I would like to ask a couple of general questions.

As you've noted, you are open to amendments, which we very much appreciate. One of them has to do with the issue of overall transparency and the question of drug safety. We have to begin at the beginning and go right through the process.

There's the question of transparency in clinical trials, for example, the need to publish both positive and negative regulatory decisions, the need for Health Canada to publish the rationale for decisions they make concerning whether drugs are approved for sale or refused for safety reasons. I think the whole issue of transparency and people needing to know, whether it's the general public or whether it's researchers or clinicians in the field, is being raised about whether or not the bill could do a better job, and also including the results of clinical trials, including post-market studies and adverse drug reactions reported by drug manufacturers.

There are some elements of that in the bill, but we wonder whether it could go further. I wonder if you could give us a general response as to whether or not that's an area that could be looked at in ensuring greater transparency and greater reporting so we have the full spectrum from beginning to end.

● (0900)

Hon. Rona Ambrose: Sure, I'd be happy to.

I've made transparency in our regulatory decisions a priority at Health Canada. Quite a bit of work has already been undertaken in our transparency framework that we launched a few months ago. I'm proud we're moving in that direction, but as I said, I'm open to amendments. On regulatory transparency, in particular, I think that properly written amendments to Vanessa's law to require public disclosure of safety decisions would provide clarity to Canadians on how and why Health Canada takes certain actions.

I know some drug safety experts have considered the importance of transparency for both negative and positive decisions made by drug regulators. The committee may also want to consider that element, should it have thoughts on how best to improve Health Canada's transparency for decision-making. Again, I think this is a good opportunity to put forward amendments in that respect and around clinical trials, obviously. I've commented on that. I think this bill already takes us in the right direction and puts us ahead of some jurisdictions, but I'd like us to work on a bill that puts us ahead of all jurisdictions when it comes to transparency of drug safety.

Again, I'm open to amendments, both on the clinical trials and on the transparency of regulatory decisions.

Ms. Libby Davies: Thank you very much. I appreciate that response.

There's one other area of the bill. A number of people have written in, and maybe you won't have time to address this, but we'll certainly ask your officials in the next round, regarding what's in and what's out in the bill in terms of the new definition of a therapeutic product.

Some of us, and maybe all of us, have received a very graphic picture of over-the-counter products, some of which would be in the definitions in the bill and some of which would not be. I think we're going to have to...or maybe it's just a better explanation, but on the face of it, there are certainly some questions about what the definition means and what's included and what's excluded.

That's going to be another area that we obviously need to look at and clarify.

Hon. Rona Ambrose: Sure.

I could go into the definition in the bill, but it sounds as if you're more interested in what's in and what's out. I'll ask David, who did a great deal of the work drafting the legislation, to speak to what's in and what's out.

Mr. David Lee: Mr. Chair, technically what's in is both drugs and devices and what's excluded is natural health products as it's defined in those regulations. We are certainly looking at some products that would apply under the drug definition, like disinfectants, and so on. Again, that's also part of our regulatory road map as we work on regulations under the act as well, so we can speak to that.

The Chair: Okay, thank you very much.

That concludes your round, Ms. Davies.

Next up for seven minutes is Ms. Adams.

Ms. Eve Adams (Mississauga—Brampton South, CPC): Thank you very much, Minister, for appearing before us today. I know you have been extremely diligent and have shown great leadership in advancing this file.

All Canadians feel vulnerable going to their doctor or to their hospital when they're ill or their children are ill. We rely on the expertise of medical professionals to prescribe the best possible medicine for ourselves and for our family members.

What is tragic is to eventually find out that information that would have, perhaps, provided for a better outcome could have been available and made available to families and individuals.

I genuinely want to commend the minister for coming forward and for showing great openness in advancing this legislation, in coming to our committee and saying that she's extremely open to listening to amendments that would make for more transparent legislation. We share your desire to become global leaders when it comes to patient safety.

Minister, currently hospitals and health care institutions are not required to report serious adverse reactions. I know that doctors are certainly very busy when they're in the hospital, and so on. Could you explain to us what this legislation would bring about, how we would strengthen patient safety in requiring hospitals and health care institutions to report on adverse drug effects?

● (0905)

Hon. Rona Ambrose: Thank you very much for that question.

You've raised an important point. It is the case that reports on adverse drug reactions are essential pieces of information for drug regulators. It's essential that Health Canada receive that information, that it be high-quality information, that it be clear, and that it be comprehensive so we can ensure that we have the appropriate knowledge to take action.

We are all aware that drugs are powerful chemical and biological substances. They can have both positive and negative effects, but also unwanted side effects, so the issue of adverse drug reactions is an important one. Currently, only drug companies and sponsors of clinical trials must report serious adverse reactions to Health Canada. That obviously is important information for us to have because it allows us to take action with the aim of preventing such effects from recurring.

We know that a significant number of Canadians who are admitted to hospital each year suffer from very serious adverse drug reactions. However, reports of these drug reactions are not always shared with Health Canada. As the regulator, that seems like a gap we need to close, which is what we want to do with Vanessa's law.

Indeed, while adverse drug reaction reporting to Health Canada has been on the rise over the last five years, it's still estimated that less than 10% of all incidents are reported. So you can see the need for closing this gap. This under-reporting of critical drug safety information is a very serious concern. It limits our ability to identify potential safety issues at an early stage and then, of course, to take quick action to prevent further harm to patients.

Of course, we see hospitals as being the unique entities and institutions to identify and report these incidents. Although most drugs are prescribed by family doctors and used outside of a hospital setting, the truth is that when there's a really serious interaction, people usually go to the hospital or take their children to the hospital. It makes sense to us that this would be where we would focus our efforts.

We already know that adverse drug reactions are under-reported. Vanessa's law would give us the tools needed to improve the collection of this information. Although some tools, such as electronic reporting, have already been developed to encourage health care institutions to provide this information, it's still not enough. This is why we've introduced these measures to require certain health care institutions to report serious adverse drug reactions and serious medical incidents directly to Health Canada.

Better reporting by health care institutions will ultimately lead to a reduction in preventable harm to patients. We know that many emergency room visits are related to serious adverse drug reactions and that many of these are actually preventable. If we have the information and the ability to take action to prevent harms from occurring in the first place, not only will this lead to the safer use of drugs, but it will also free up valuable hospital resources.

We understand that all of us rely on the health care system. This is why we've increased transfers to health care. We also recognize, and we are acutely aware, how busy health care institutions are. We believe that Vanessa's law does not impose any unnecessary burdens on our health care system. I mention this because it was one of the issues raised with me by the provinces and territories.

I have to tell you that the provinces and territories are very supportive of this legislation, very supportive. They are looking forward to working with us on the implementation, more so on an institutional basis, to make sure hospitals understand what their requirements and obligations are. We look forward to working on that.

We will obviously be developing the regulations in consultation with the provinces and territories. Those will then set out exactly for them what information they are required to report, which health care institutions will have to report, and how that information will be reported and in what timeframe. We've made a lot of progress with them already to date.

● (0910)

Ms. Eve Adams: Thanks, Minister.

I know you've been working collaboratively with not only the provinces and territories but also with the leading minds, the experts and the patient groups, on this file. Can you give me a sense of the feedback you've been receiving from those patient groups?

Hon. Rona Ambrose: We've received very positive feedback, particularly in the area of adverse drug reactions. We're essentially building a new system across the country of reporting. It's one that is obviously much more thorough, much more comprehensive, and much more consistent. I do believe that all of those who are involved in the health care system feel strongly that this needs to be done and are supportive.

After the bill passes, then we move to the regulations, which will impact the institutions themselves. We'll work with them on how they'll report and we'll make sure that hopefully we have the most consistent type of reporting across the country.

At the end of the day, the important thing here is that we have a huge gap. As I said, we think we're collecting at this point only around 10% of adverse drug reactions across the country. That's not nearly enough. If the regulator doesn't have that kind of information, how can we make the appropriate decisions on the safety of drugs? On that issue alone, the issue of adverse drug reaction reporting, this piece of legislation will make a huge difference for the safety of Canadians. I'm very excited that we're moving forward with this, as are the many, many stakeholders who care about patient safety and as are the provinces and territories. They know that this is a way we can collaborate. We're the regulator. They have the information. We look forward to closing that gap so that we can provide better safety information to patients and to physicians.

Ms. Eve Adams: You must be very proud. This is critical legislation, and you've done outstanding work.

Hon. Rona Ambrose: Thank you.

The Chair: Thank you very much.

Ms. Bennett, you're up for seven minutes, please.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thank you for coming, Minister.

I have three questions. The first is with regard to the issue you raised around prevention. When we did the post-market surveillance study at this committee, it was very clear that in future, with personalized medicine, we can sort out that certain people have genetic predispositions to a certain drug interaction or to an adverse reaction. In the science around the definition of serious risk or injury or harm, how will the department determine whether it's a number of people with a serious predisposition to a problem or whether it's a general problem for which the drug must be recalled for the public good?

Second, as my colleague was asking, could you explain your thinking on why toilet bowl cleaners are included in this because it's a disinfectant, but natural health products are not?

Third, I think we know, whether it's trying to talk to physicians about SARS or whether it's trying to talk to physicians about recalls, that the time that elapses before Health Canada makes a decision and it actually gets out to the doctors is.... From the time when you make your decision, I may have in my office been prescribing this drug for three weeks before I get the letter from Health Canada. In 2014 do you think Health Canada has the resources or the systems in place to actually communicate with the front-line providers to tell them they have to stop prescribing this today, and not when...?

I can remember one situation when I was up all night delivering a baby, and it was on the news that a drug had been recalled. One of my patients, who'd been watching the news, came in and asked me the next morning what I thought about that drug being removed from the market. I wouldn't have known about it if my astute patient hadn't filled me in.

Those are the three things that I would like to know about in terms of whether those are areas for amendments.

Hon. Rona Ambrose: On the question of prevention and how Health Canada will assess whether or not it's a predisposition or a general harm, I'll ask Dr. Sharma if she would answer that for you.

● (0915)

Dr. Supriya Sharma: Absolutely. In terms of the definition of serious, it is dependent on the situation. As you know, for an individual patient an adverse reaction can be quite serious...for a group of patients, because they are predisposed to that. The bill actually allows us to collect that type of information.

It's really important to understand when a product goes on the market it can be used for a variety of different purposes in a variety of different populations. Right now we do rely on the companies to come in with that information.

In terms of the new provisions, the bill allows us to ask for specific studies, specific analysis, specific information to come in. That helps us look at that analysis and then decide whether or not changes need to be made.

The changes can run the gamut of communicating to help practitioners and patients, making warnings more prominent on the label, adding warnings to the label, or it could go all the way to requiring that product to come off the market.

Now if you have a serious adverse event that affects a small group of people, you don't want to limit that access for everyone. Based on what the adverse reaction is and what we're seeing, we need to have the tools, the flexibility, to make the appropriate risk decisions.

Hon. Rona Ambrose: Thank you, Supriya.

To your question, Dr. Bennett, on the low-risk products, on natural health products, to be frank, I struggled with this one because I thought everyone should be under the legislation, but the reality is and the case was made from the natural health products community that their products are low risk.

My discussion with them was....

Hon. Carolyn Bennett: May I just say that on the study of natural health products, it's one thing to be a natural health product from a reputable company, but I think what we were worried about is if you find out that Sleepytime Tea has Valium in it, or if echinacea actually has ephedrine in it, you have the ability—

Hon. Rona Ambrose: Yes.

Hon. Carolyn Bennett: —to remove that in terms of it not being accurately labelled. But if something has a contaminant in it or.... I think there is some concern about....

Do you believe you already have that power?

Hon. Rona Ambrose: We are regulating natural health products now, as you know. In terms of capturing them under Vanessa's law in adverse drug reactions, their belief is they are low risk, and so they shouldn't be treated as pharmaceutical products.

What I will say is if someone goes to the hospital with an adverse drug reaction, the reality is it doesn't matter what they have used. They are going to tell the physician what it was, and it will be captured.

Hon. Carolyn Bennett: You don't even have to say how much sugar is in it. That pink water that actually is full of sugar, a diabetic may not even know they shouldn't be drinking that.

Hon. Rona Ambrose: On labelling, that's not.... Vanessa's law is about adverse drug reactions and about patient safety. Obviously, natural health products are regulated, and we are able to change labels on them, and we deal with health claims made by naturopathic or natural health product manufacturers.

Again, I think you should ask the experts that question when they come to committee. Ask them if there is an adverse reaction from a natural health product whether this legislation is enough to cover that.

Hon. Carolyn Bennett: In terms of how you will communicate with physicians....

Hon. Rona Ambrose: Diane-35 is an example. We had 40% off-label prescribing with Diane-35. Not only had we sent numerous Health Canada warnings to physicians, we also did a checklist to....

Hon. Carolyn Bennett: Do you have an ability to do that other than through the—

The Chair: Ms. Bennett.

Hon. Carolyn Bennett: —College of Physicians and Surgeons?

Hon. Rona Ambrose: We have a number of ways we communicate. I can ask Anne to give you a list of all of the different ways in which we communicate through associations beyond just the College of Physicians and Surgeons. We can communicate directly, but, yes, we have a number of ways.

Anne, if you want to expand on it....

The Chair: Thank you very much.

Moving right along, we have Mr. Wilks, for seven minutes, please.

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

Before I ask my question, I've heard from time to time that sometimes those of us in the back seats of the House of Commons can't make a difference. I believe my colleague, Mr. Young, has proven that wrong, and that he will make a significant difference in the lives of millions of Canadians in years to come. So thank you for that.

Minister, I appreciate your being here today.

You made mention of the competence and transparency in regard to the health care system. Can you provide the committee with some additional details on what Health Canada is doing to provide Canadians with the information they need to make informed health decisions? How will Vanessa's law give Canadians the information they need to make informed decisions about the use of therapeutic drugs and medical devices? Would you be able to provide the committee with some examples of these transparent measures?

● (0920)

Hon. Rona Ambrose: Sure. Thanks so much.

The fact is that Canadians do expect more information from Health Canada when it comes to patient safety issues. This legislation is incredibly important, but the current legal framework that we have is outdated. Just like every Canadian, I expect more. We expect to have that kind of information at our fingertips, and we expect the regulator to be able to make decisions when they're confronted with clear information that a drug is negatively impacting Canadians.

We know that 83% of Canadians are online now. They expect access to accurate information. They want it quickly and they want it easily. This is especially true when it comes to health and safety information. In most cases we will purchase over-the-counter medications or pay a visit to the doctor to receive prescribed medication. Along the way, we will read the label or receive information from a pharmacist about the proper dosage, when to take the medicine, and how to take it. We may also read or receive information about any side effects or other health warnings of which we should be aware. But the reality is that we sometimes do not get all of the information that we should, and the information can be confusing for people to follow.

Last year, as you know, we took important steps to help Canadians better understand medicine. As a result, our plain language labelling initiative is set to make prescription and over-the-counter labels and safety information easier to read and understand. Through the introduction of a standardized format for information on drug labels, this includes what's called a drug facts table.

In addition, the plain language labelling regulations will advance key safeguards, such as requiring labels to be in plain language, requiring that companies include contact information on labels so that users can report problems and adverse drug reactions, requirements for manufacturers to provide mock-ups of labels and packages for our review, and requirements for manufacturers to provide evidence that drug names will not be confused with other authorized products.

Canadians are already familiar with the nutrition facts table on food. Many report using this information to make informed decisions when choosing healthier foods. It makes sense then that we would have a similar tool to help Canadians make equally informed decisions when it comes to choosing the right medications and over-the-counter drugs.

Vanessa's law will build on the successes of the plain language labelling initiative by enabling new ways for our government to collect more information to provide to Canadians.

First, it will require a mandatory reporting of serious adverse drug reactions and medical device incidents by health care institutions. The knowledge gained by Health Canada through this reporting will help us to inform Canadian patients about any safety concerns or risks more quickly and more transparently.

Second, it will authorize Health Canada to compel manufacturers to make a label or packaging change when it's needed to alert patients and prescribers about a potential side effect or other health risk that only becomes known after the product is on the market. This will also expedite the communication of important safety information by Health Canada to prevent harm to Canadians who rely on these products.

Third, Vanessa's law will authorize Health Canada to compel manufacturers, when necessary, to provide more post-market information about their products. Companies may be required to gather ongoing evidence of the product's benefits and risks, to conduct new tests and studies, perhaps on specific populations, or to undergo a product reassessment. For example, as I mentioned, I would be able to compel further studies on a drug for adults that was routinely causing side effects in children.

Of course, information is power, and we are committed to gathering the information that Health Canada needs to ensure that Canadian patients and caregivers are empowered to make the most informed choices about their drug and medical device decisions. The measures in Vanessa's law will build on other efforts that we've undertaken to make more data and information available to Canadians than ever before.

For example, the department's Healthy Canadians website and social media channels give Canadians important up-to-date health and safety information, written in plain language. More than five million Canadians have visited these online sources. Canadians also have access to Health Canada's online databases, including a drug product database that provides information about all approved drugs. Our recalls and safety alerts database is another critical resource to learn more about the possible risks associated with health, consumer, and food products. Vanessa's law will help us to add valuable information to these trusted sources.

● (0925)

Canadians also need to understand that when they are using therapeutic drugs and medical devices, they need to know how to use them. They need clear, plain language information on the drug label to make the right choices for themselves and their families, and they need access to it transparently and in a timely way. They also need assurance that the regulator of therapeutic products has the ability to gather information throughout the life cycle of these products.

The plain language labelling initiative and our commitment to regulatory transparency and openness are important steps forward to meet the information expectations of Canadians. Vanessa's law will provide the necessary legal authorities for us to ensure that labels and information contain the most accurate information for Canadians to use to make informed decisions for themselves and their families.

Mr. David Wilks: Thank you very much.

The Chair: You are right on seven minutes. Congratulations.

Mr. David Wilks: Thank you.

The Chair: Next up is Mr. Morin. He has five minutes. I'm pretty sure everybody can speak both official languages, but if you can't, this would be a good time to put in your earpiece.

Go ahead, sir.

Mr. Dany Morin (Chicoutimi—Le Fjord, NDP): I will start with English.

Minister, good morning.

Hon. Rona Ambrose: Good morning.

Mr. Dany Morin You just mentioned all the different consequences of this law. Would you estimate that there will be a great deal of burden on the companies producing therapeutic products if they have safe products? What kind of burden do you think this will have on those companies?

Hon. Rona Ambrose: What kind of burden...?

Mr. Dany Morin: Do you think it will put a lot of burden on those companies that say that they produce safe therapeutic products?

Hon. Rona Ambrose: First of all, I would say that I am sure those who are in the health care business take safety very seriously as a community. It's not just their own product. They should, I hope, support ongoing efforts to make the regulatory framework and the legal framework for patient safety legislation stronger. I hope that all companies do.

We believe, in terms of red tape, if that is your question, that the proposed changes will have a limited impact on the day-to-day business of industry, as companies are already responsible for meeting similar requirements in other countries.

As I indicated before, what I believe we're doing is closing a gap that needs to be closed. We see this approach in other jurisdictions. Many of these companies operate internationally, and so they are familiar with this kind of regulatory environment.

Mr. Dany Morin: Thank you, Minister. I agree with you. That is why I believe, if I can go back to natural health products, that this law would not put any new heavy administrative burden on the natural health product manufacturers.

Are you still insisting that even those low-risk products should not be included in this law? As you said, the burden of this law will not be cumbersome for companies that say they produce safe products.

Hon. Rona Ambrose: I'll leave it up to you to question the experts on that. The recommendation to me was that those are considered to be low risk. The pharmaceutical industry and the pharmaceutical and prescription products are what this law applies to. Again, I'll leave it up to the committee to ask those questions further and probe on that issue.

● (0930)

Mr. Dany Morin: Okay.

Hon. Rona Ambrose: I think Anne wants to say something. I can tell she is—

Mr. Dany Morin: Perhaps she can do so in the second hour.

Hon. Rona Ambrose: Sure.

Mr. Dany Morin: Before moving to the second question, I would say again that the administrative burden will be quite low, so I believe that the natural health product companies could also be under this law.

Minister, my other question is, how will you ensure that there are enough resources to report adverse drug reactions and to coordinate the information once it has been received?

Hon. Rona Ambrose: This is a priority for the government. We will ensure that we have the resources available to implement the legislation.

Mr. Dany Morin: Can you expand a little more on that? As Dr. Bennett has said, the ramifications are nationwide. It is, needless to say, a complex system. You said that you seem to be prepared. Can you expand more?

Mrs. Anne Lamar: Yes, there are a couple of points that I would make in terms of our resources. The short answer is yes, we have the resources to implement the new authorities.

In terms of the reporting, the department has been continuing to invest in really updated IT infrastructure and platforms that enable us to do more efficient reporting, a sort of e-reporting, which also lessens the burden to industry in that regard.

We will also be using new technologies to mine data more efficiently and be able to access the information more rapidly. We think, in fact, we'll be moving to a more efficient system. In addition to that, we'll be working very closely with the provinces and the territories to ensure that we are leveraging the systems they currently have in place as well, so not to duplicate those over again.

Mr. Dany Morin: Thank you.

The Chair: Thank you, Mr. Morin.

Next up we have Mr. Young for five minutes.

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

Minister, when the safety of patients is at stake, Canadians expect strong measures in place to ensure appropriate action taken by regulators. Currently in Canada the penalties that can be levied against wealthy companies that put Canadians at risk are the equivalent of a slap on the wrist.

Existing levels of fines and penalties in the Food and Drugs Act reflect the age of the legislation and not the multi-billion dollar pharmaceutical industry that Health Canada regulates. If I can just give some examples from my own research, I have a list here of the who's who of the pharmaceutical industry, what we call big pharma, the biggest companies.

These are companies that parents trust, that have safe drugs for their children, themselves, and aging seniors, and that have, in fact, committed criminal offences in the United States and paid fines. No one ever seems to go to jail. I've never heard of anyone going to jail. I'll just give you some examples.

GlaxoSmithKline, in July 2012, paid a $3-billion fine for illegally promoting packs of Wellbutrin and Avandia. Now illegal promotion is not just that they put up too many billboards. Illegal promotion means they told the doctors, or they somehow made the doctors believe, that the drug was safer or more effective than it was, or that it was appropriate to prescribe it off label for uses for which it hadn't been proven safe. When drug companies promote off label and illegally, people die. A lot of people die. GlaxoSmithKline paid $3 billion in 2012 for illegal promotion of Paxil, Wellbutrin, and Avandia.

Merck paid $1.6 billion from 2008 to 2012 for giving kickbacks to health care providers to get them to prescribe their drugs.

Eli Lilly paid $1.3 billion in 2009 for illegally promoting Zyprexa, so that doctors thought it was effective for Alzheimer's with zero evidence that it helped Alzheimer's patients. In fact, it increased their risk of death by 200% to 300%.

Novartis paid $422.5 million in 2010 for off-label promotion of Trileptal.

Forest Labs paid $313 million in 2010 for off-label promotion of Levothroid and Celexa.

The list goes on: Allergan, Elan, Johnson & Johnson—$81 million in 2010. AstraZeneca, Abbott, Sanofi-Aventis.... This is just back to 2008. This has been going on since the late 1990s.

Can you please provide the committee with some additional details on how Vanessa's law addresses this reality with regard to fines and penalties? Do you feel that these new fines and penalties alone will serve to deter wrongdoing in the world of profit-driven big pharma companies?

Hon. Rona Ambrose: First, let me thank you for all the great work you've done to advance this issue and for being such an amazing patient safety advocate. We're really thankful to have you on committee as this bill goes through. Thank you very much to MP Young.

Obviously, you know full well the consequences of adverse drug reactions and I do think it is so critical that Vanessa's law provides for much higher penalties and even jail time, because we do have to recognize, as you say, the serious impact of adverse drug reactions on our communities.

The bill does introduce new fines for those who do not comply with important safety measures. It allows for significant fines and penalties for companies that sell unsafe drugs in Canada. As you point out, right now the fine for companies who put Canadians at risk is simply not reflective of the realities of the harms that they cause. A fine of $5,000 per violation is a drop in the bucket for many companies that can generate profits of literally hundreds of millions of dollars. With this amendment the fine will change to up to $5 million per violation. In addition to this, the proposed law will also give the court discretion to impose even steeper fines, with no limitations imposed through legislation, and up to two years of jail time if companies break the law intentionally.

I do think that Canadians will support this legislation. They expect that the drugs they purchase from the pharmacy or from store shelves should be safe for the use of their families. I do think by introducing these tough new fines for companies who put Canadian families at risk, we will ensure that companies that break the law will pay the price for compromising this trust and putting the health of Canadians at risk.

It is an unfortunate reality that there are always a few who choose to engage in unethical behaviours, suppressing negative research and withholding vital safety information in order to increase their profit margins, but if these companies were to be convicted today, the punishment for their crimes would fall woefully short of meeting the severity of the risks.

Through Vanessa's law, a company that intentionally provides Health Canada with false information, fails to adhere to conditions of sale, fails to recall a product when ordered, or fails to revise a label as requested, will be in violation of the law and will face very stiff new penalties. The increased fines and penalties are also consistent with those found in our other consumer-based legislation, such as the Canadian Consumer Product Safety Act and the Safe Food for Canadians Act.

Vanessa's law also proposes an injunction power to permit the minister to apply to the court to order a person to stop doing an action related to an offence. This new authority will prove helpful in preventing future contraventions and in dealing with cases where ongoing non-compliance creates a risk to health. If an injunction is not complied with, the regulated party would be in contempt of the court and the court could then impose a fine or imprisonment. These measures will allow the government to take more effective action against those who jeopardize the safety of Canadians.

I think the updated powers go a great distance further than what we have today to protect Canadians from unsafe drugs.

● (0935)

The Chair: Thank you very much.

Ms. Davies.

Ms. Libby Davies: Minister, I'd like to come back to a question that my colleague, Dr. Morin, raised.

Although one could say that there's a measure of responsibility for the pharmaceutical companies that are producing these drugs, and that's very important, at the end of the day, as I see the legislation, it's actually Health Canada, your department, that has to do the heavy lifting in terms of seeing this process through. For example, it gives you the power to call for more studies. It gives you the power to actually make a recall, to require labelling, to do follow-up.

You're not going to do that on your own. You have to have experts who are helping you do that. I do want to say that nothing would be worse than passing this law only to find that we actually don't have the resources within the department to undertake the levels of work and the further research that might be required to actually put this law into effect.

There have been cuts at Health Canada, so I think it would be very helpful for the committee to know, for example, what additional resources your department will be able to draw on in order to actually implement and enforce this bill, assuming that it is passed by the House.

Hon. Rona Ambrose: Let's remember that Health Canada is doing a lot of this work today in terms of assessing the safety of drugs, going through the drug approval process. We have many hundreds of experts, researchers, physicians, who work on our staff, who are doing these assessments. What we're talking about in terms of the drug approval process is making those assessments more transparent, easier to understand, more available to Canadians. Obviously, that takes some resources, but it's about doing our work differently.

In terms of collecting the information from institutions and then ensuring that we can assess that information, again, we do those assessments on an ongoing basis.

I don't know, Dr. Sharma, but maybe you want to explain how it is we do a drug safety assessment. We do these things today. What we want is more information—

● (0940)

Dr. Supriya Sharma: Yes.

Hon. Rona Ambrose: —and more information will help us do our work and make sure that we have more comprehensive information about any particular drug when we're looking at the post-market analysis.

Ms. Libby Davies: The reason it's very important is that the Auditor General's report in 2011 clearly referred to the time lag for people actually getting information. In fact, he said that two years is too long, so already we have a problem.

I don't know whether or not now, since 2011, the time lag has improved, but to me it's a really serious question. If the information isn't getting back to people about the adverse reactions, about what the problems are in terms of drug safety review, then really the bill is not doing the job it should do.

I think we need some very specific markers on this to demonstrate to us that the recommendations from the Auditor General are being met, and that there will be serious improvements in terms of drug safety review and the timeline that it takes.

Hon. Rona Ambrose: Sure, and Anne wanted to make a comment about the timeliness.

Mrs. Anne Lamar: In reference to the AG report from 2011, obviously, Health Canada took those recommendations very seriously. We've completed, actually, the majority of the action items that were recommended. We can certainly provide more follow-up details to the committee on that.

I think that what is being proposed in Bill C-17 is actually completely in line with the OAG report. In fact, we have already started, as the minister alluded to, to move some of our priorities, change the way we are doing our business. I referred to some of the efficiencies that we find around electronic reporting, with large IT systems that help us to manage that information.

You also referenced a time lag in terms of information coming in and being able to provide a signal assessment. Again, that will be enabled and be even stronger with new systems. I think as well with the fact that we won't need to be negotiating on some of the authorities like recall, for example, where it does take more time for us to get information out to the public, we will see ourselves saving time in that regard. Our capacity to communicate, to take that information and communicate it externally to Canadians, to pharmacists, to practitioners who need it, I think will clearly be enabled.

Ms. Libby Davies: You mentioned that you could provide the committee with information about what steps have been taken to meet the recommendations of the Auditor General from 2011. I'd like to take you up on your offer and ask that you provide that information to the committee, Ms. Lamar. Could you do that?

Mrs. Anne Lamar: Yes.

Ms. Libby Davies: Thank you.

The Chair: Thank you, Ms. Davies.

Mr. Lunney.

Mr. James Lunney (Nanaimo—Alberni, CPC): Thank you, Minister and officials, for being with us today.

Minister, I think a lot of people would be surprised to learn from your earlier remarks that it's been nearly 50 years since patient safety legislation has been significantly updated. This seems to be a worldwide phenomenon that there are great gaps in the information on safety and effectiveness of drugs used in real-world settings. More information is needed on the safety and effectiveness of pharmaceuticals when used by the diverse patient populations, and outside the controlled, experimental environment of clinical trials.

I was wondering if you would be able to elaborate for the committee on how Health Canada currently undertakes post-market surveillance activities. What kind of improvements are here in Bill C-17, in Vanessa's law?

Hon. Rona Ambrose: I'd be happy to outline the current approach. It does demonstrate a contrast with what Vanessa's law hopes to deliver.

As I mentioned in my opening remarks, we do need to recognize, and I fully believe, that Canada does have one of the most rigorous drug approval systems in the world for drugs and medical devices.

This system does ensure, as far as possible, the safety of these products before they're marketed. Before a pharmaceutical product reaches the market it must satisfy strict safety, efficacy, and quality evidence requirements.

Health Canada's team of scientists thoroughly review and evaluate all of the evidence that is provided. Once they've determined that the benefits of the pharmaceutical product outweigh the risks, the department will issue an authorization allowing the pharmaceutical product to be legally available for Canadians to use under specific conditions.

However, and that's where Vanessa's law comes in, once these products are on the market, we currently have limited ability to gather information about these products and to take action when a problem arises.

When Health Canada does issue a market authorization to allow a pharmaceutical product to reach the Canadian market, the department monitors these products to detect any new risks.

This work includes the collection and evaluation of adverse drug reaction reports submitted by industry, patients, caregivers, and health care professionals. We also have a review of periodic safety updates that are submitted by manufacturers, an analysis of information gathered from various sources such as medical and scientific literature, other regulatory agencies internationally, and manufacturers.

You can see that we're doing the best we can possibly do with the powers we have, and that does go quite far, but as many members of the committee know, in the bill before you today there is room for improvement. The scientists and those who work on this issue relish the thought of having more authority and more powers to be able to act in this area.

It was only recently that I announced that Health Canada would start posting summaries of after-market drug safety reviews on its website, which was a great initiative. These reviews provide a plain language description to Canadians with respect to what was assessed, what Health Canada discovered, and what action it took.

This new approach allows the department to share information gathered from the scientific literature, health care professionals, the manufacturers, and other international regulators. These drug safety summary reviews make Health Canada an international leader in the transparent posting of this kind of information, now ahead of both the United States and the European Union.

However, as I've said, Canada's overall safety system for drugs is based on legislation that is over 50 years old now, and lags behind many international regulatory counterparts.

While we've taken action to strengthen post-market drug safety, we still do not have key legislative authorities or tools needed to efficiently further protect the health and safety of Canadians. Vanessa's law will provide us with that. It will provide us with the legal weight to help better protect the health of families.

For example, as we already discussed, adverse drug reactions to pharmaceutical products are estimated to account for one quarter of emergency room visits in our hospitals, and most adverse drug reactions are vastly under-reported.

This is why, as I've said, Vanessa's law includes measures that will require mandatory adverse drug reaction reporting from health care institutions. It will also give our government the tools needed to recall a drug or require a label change.

I will use the example of Diane-35. People ask why this takes so long. Journalists are asking why it is taking so long for us to come out with the action we promised on Diane-35. A lot of it was because we had to negotiate with the manufacturer and that took months.

In this instance, now that we have these authorities, we don't have to negotiate. We were able to take the action we wanted to take on Diane-35. We had a checklist and worked with the associations that were involved with the drug to disseminate very good information to physicians to make sure they were not prescribing Diane-35 off label, and the manufacturer did cooperate with us. It did take us a number of weeks, even months, to be able to reach that point.

That's just one example of why it's important that we have these authorities, so that Health Canada not only has the information but they have the weight, then, to act on it as quickly as possible.

● (0945)

I do think this legislation will make a great deal of difference in the lives of Canadians, but also for the department. They look forward to having these extra tools to do their jobs.

The Chair: Thank you very much.

That concludes this portion of the meeting. It's over an hour that we've had with the minister this morning.

Thank you very much, Minister, for your time.

Hon. Rona Ambrose: Thank you.

The Chair: We're going to suspend for a minute to allow the minister to leave and to also allow any other departmental officials who are going to join us to come to the table.

● (0950)

Hon. Rona Ambrose: Good luck with your deliberations on the bill. I appreciate it.

● _____ (Pause) _____ ●

The Chair: We'll get back at it. We're going to continue with our questions.

To lead off this round, we have Ms. Davies for five minutes. As we know, in the meeting today we're going to go until 10:30, and then we have some committee business.

You don't have any prepared comments; you're just going to take questions. Is that right?

A voice: That's right.

The Chair: Okay.

Go ahead, Ms. Davies, for five minutes.

Ms. Libby Davies: I'm trying to focus the questions on material that started coming to us in anticipation of witnesses being heard, in order to get your reaction, at least in general, to what we might be hearing at committee. I think the committee is of a mind that should it be required, we could call you back later, based on what we've heard from witnesses, because there might be some clarification needed.

I have a couple of questions. First, it's very clear that the minister can recall something. What about suspension? It seems to me that the bill doesn't really address the issue of suspension. Was there consideration made of the need to have suspensions as well? Also, how would you see it differently from a recall? That's one question.

On the other question, we did get some information just very recently from MEDEC, which is the medical technology association. I haven't read all of the info that they put out, because we just got it yesterday, but they are concerned about the fact that the bill doesn't address single-use medical devices, which they say is quite a problem. Devices are manufactured and are intended for one use, but apparently what really happens out there is that they are reused and reused, including by hospitals. There's that issue as well. I wonder if you had contemplated that being covered in the bill in terms of single-use medical devices.

Those are the two questions right now.

● (0955)

Mr. David Lee: Mr. Chair, on the first issue about suspension, when putting in measures at either the legislative or regulatory level, you need to look at what the instrument does. Recall is introduced at the act level. Suspension is something that Health Canada can do under the current regulations. It really has to do with how the authorization works. As Health Canada approves a product out on the market, it does so with a threshold. It looks at the product and it says that the benefits outweigh the risks and the chemistry is okay.

If we see something that gives us concern, then we can reach for a suspension, and that will still be effective under this current set of proposals. You're really looking for.... If we start to see that there's a serious risk introduced and the drug shouldn't be sold anymore, then we can invoke suspension. Recall, though, is also where you need to reach into the market and pull the product back from the market or correct it.

Ms. Libby Davies: Just to be clear, then, a suspension doesn't necessarily mean that the product can no longer be sold?

Mr. David Lee: No. Suspension does mean that it can't be sold anymore. The authorization allows you to sell. There's a prohibition in law that says that you don't sell unless you have an authorization.

Ms. Libby Davies: A suspension would be that you can in effect take it off the market for a period of time while there is further clarification and testing, whereas with a recall it's just gone. You take it off presumably for good, or...?

Mr. David Lee: Yes. Recall is usually when we need to reach into the market and say something is so dangerous right now we need to remove it from supply. It usually comes back to the manufacturer usually from pharmacy and from retail. That's different from suspension. Suspension just says don't sell any more into the system.

Ms. Libby Davies: But there might still be product out there that's being sold.

Mr. David Lee: Usually when there's a suspension we will advise the whole drug system and people will appreciate that there is a stop. Sale includes distribution, so technically speaking, you shouldn't see more of the drug going out to any one particular patient when we suspend.

Having said that, sometimes it is so dangerous you really need to remove it from pharmacy shelves and that would be recall.

Ms. Libby Davies: No, I get that. It was just more the suspension element that I wasn't quite so clear on.

What about in terms of the single-use medical device?

Dr. Supriya Sharma: We are talking about the reuse of single-use devices. If it sounds like an oxymoron it's because it is.

The idea from our perspective is that if a product is for single use there should be good reasons that it's for single use and it should be labelled as such. We do have symbols on medical devices and wording on medical devices for products that are for single use.

Sometimes those products that are for single use are then reused, reprocessed, and refurbished. Some of those are legitimate. For example, in a hospital if you have surgery that's taking place and you have a number of total knee replacements and you open up different sizes. If you don't use them they can be re-sterilized and used again.

The concerns that are coming now is if you actually send it off to a facility and they somehow change that device, so it's not longer that same device, or there might be new risks that are introduced.

From Health Canada's perspective, if a product can be safely reused and reprocessed, then the company that manufactures it is in that unique position to know all about that product and to be able to tell us this is how it should be reused or reprocessed and that should be on the label.

Ms. Libby Davies: They're not under the bill. These devices are not within the definition of these therapeutic products. Is that correct?

Dr. Supriya Sharma: They are.

Ms. Libby Davies: They are?

Dr. Supriya Sharma: They are. The concerns that we have right now are.... For example, let's say we have a product that's for single use and it's going out and it's being reused and there are concerns about that. We don't have a way to then compel the manufacturer to study that or to change the label to reflect that. That would be included in the bill.

The concerns that we have, though, are that the product should be used based on the label and we should have information that we can see in Health Canada to assess how they should be used, whether it's for single use or for reprocessed devices.

● (1000)

The Chair: Okay, Ms. Davies, we're over time. Thank you, though.

Ms. Adams, go ahead.

Ms. Eve Adams: Mr. Chair, I'd like to split my time with Mr. Lunney.

I have a question regarding the birth control pills that made headlines recently, both Alesse and Diane-35. Do you feel that the legislation and the definitions within the current proposed legislation go far enough to enable Health Canada to recall products like Alesse or Diane-35?

The issue with Diane-35 was that it was off-label use and people were taking it for far too long. With Alesse the issue was that there were really ineffective medications in the pack, so basically placebos. People thought they were taking a prophylactic and there was no use in taking it and some unwanted pregnancies ensued.

Do you feel this legislation would allow you to circumvent that type of problem or to act speedily should something like that happen again?

Dr. Supriya Sharma: There are a number of parts of the legislation that would have helped in both those situations.

The first part is really what we talked about in terms of the recall. Again, for the vast majority of companies when Health Canada said they would like a recall, they do recall. The issue is if we don't get that consent, if they don't want to recall. Again, down to the patient level.... This gives us the authority to say they must recall. That's one part of it.

The other part of it really speaks to getting information around off-label use. Again, off-label use certainly is within the purview of practitioners. They need to be able to make decisions for their individual patients. What the legislation does is it gives Health Canada the authority to get information on off-label use.

If there is an off-label use out there that's potentially introducing risks, then we have the ability to ask a company to study it, to get information and then to use that information to make changes to the label or to communicate to people so that when they're actually making decisions about their health they are doing that with the benefit of all the information that they need.

Ms. Eve Adams: Some have raised the concern that currently this legislation would only allow Health Canada the power to recall a therapeutic product if it presents a serious or imminent risk of injury to health. In the case of Alesse, for instance, where the drug was simply ineffective or a placebo, that was not how Health Canada interpreted it. They didn't consider that a serious adverse health consequence. They deemed that a lifestyle impact.

I go back to my question. Do you feel as though this legislation gives you broad enough powers to act in the interests of Canadian patients and consumer safety?

Mr. David Lee: We've taken this question up and really searched carefully through the language, the threshold that you need to use for recall, and we absolutely think that, looking at Alesse, we would be able to effect recall on the language that we've proposed. A failure to work in that case would also constitute grounds for a recall. We have run that through our assessment.

Ms. Eve Adams: Perfect. I think Canadians want to know that we're not going to get bogged down in definitions, but that we have the ability to act immediately for the benefit of Canadian consumers.

Mr. David Lee: That's what we would do.

Ms. Eve Adams: Thank you.

Mr. Lunney.

The Chair: You have 40 seconds.

Mr. James Lunney: Nearly 10 years ago I raised an issue about deaths in the hospital. Currently there are an estimated 1,400 deaths per year with C. difficile in the hospitals...common classes of medications, proton-pump inhibitors, acid suppressants.... I was told then that CNISP, the nosocomial infection surveillance program, would get to the bottom of it, but amazingly, they did not collect the data on the meds they were on at admission. I understand we're working now to get that corrected, and they're going to actually collect the data. That would be very helpful.

I have a question that maybe you can answer, and I'll direct this to Dr. Sharma.

Labels...there are warning devices out there. There's a fact sheet on C. difficile. In 2004 when I raised it the first time, there was a great two or three paragraphs at least explaining the biological plausibility and why taking people off these meds might be an important way to reduce the risk, 40% to 270% we now know, of contracting an infection that could take your life. The warnings got weaker. After the DSEN, the drug safety and effectiveness network, reported just a short time ago confirming the concerns I've been raising for 10 years, amazingly, PHAC moved to take the warning, even the one liner, off the three-page fact sheet on C. difficile.

Can you explain how that's possible?

Dr. Supriya Sharma: In terms of the Public Health Agency of Canada report or the fact sheet, I think you would probably have to direct that to them. If there's a question for Health Canada, I'd happily be able to take that.

Mr. James Lunney: I would assume you would sort of talk to each other and I thought one of you perhaps was involved with PHAC.

However, the warnings were weaker. We need strong regulatory response on that. I understand we're going to have much better tools now, but I'm talking about the tools that were available to communicate to doctors that were a little more cumbersome. It seems to many that the fact that tools were missing meant that people were actually not collecting data or they were looking the other way to avoid problems.

● (1005)

Dr. Supriya Sharma: Certainly the provisions in the bill, as we mentioned, give us more flexibility in terms of collecting data. It really comes down to two parts of it. One is that there are powers in the bill that actually ask companies to do reassessments. You can have a situation that's going on for a period of time; you can have one look at the data, but that may not be sufficient. It's really looking at that body of data, being able to drill down, and being very specific to look for specific issues.

The other part of it is to then ask for new data, whether it's studies or whether it's new information that needs to come to bear to make those decisions. I think when you have more information, then we can do the analysis and we can make sure, as we do and endeavour to do, that the labels reflect exactly the state of information that—

Mr. James Lunney: I've been putting information for 10 years in front of Health Canada, and there's no action.

The Chair: Mr. Lunney, your time is up, sir.

Mr. Young, you're up for five minutes.

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

In October 2013 Marit McKenzie of Calgary died of a blood clot in her lungs after taking Diane-35, which is one of the newer generations of birth control pills, for acne. She was preparing for her school formal. This use was not proven safe and effective; it was off-label use prescribed by her doctor. Tragically, because she bought it at Shoppers Drug Mart, she had no safety warning of blood clots and so she died. Shoppers Drug Mart is recorded in the *Toronto Star* as saying they didn't issue a warning because they didn't want to frighten consumers about rare adverse effects, so they robbed her of the opportunity to make an informed decision.

By law in Alberta, the maximum damages Shoppers or the drug company would have to pay for such a loss is $85,000. So in normal risk management practices why would they warn patients? It hurt sales, and if something terrible happens, they only have to pay $85,000 anyway.

I joined the minister recently to announce the transparency framework, and the media took a mixed approach. They gave credit that it was a good idea, for example, in the *Toronto Star*, but then they criticized it because all drug reviews weren't going to be published right away, which I thought was very unfair. This is a huge change. If drug reviews for Diane-35 had been published and open, I suspect Marit Mackenzie would have had a proper safety warning and might have decided to not take Diane-35 at all.

Could you please comment on the transparency framework, on the change of publishing drug reviews, and why it makes sense to publish the ones for which there is not an established safety profile, the newer drugs, or one that appeared to have a risk, rather than go to the trouble of printing all of them now? A drug review can be up to 10,000 pages, and then it has to go for translation. There's a tremendous cost and timeframe to do that. Would you comment on the fact that—I hope you agree with me—it makes sense to publish the ones where there's an apparent risk first and then go to the others?

Mrs. Anne Lamar: Thank you for the question.

As you are aware, the minister has made her intention known that we will be publishing drug summaries moving forward, as well as making the full reports available upon request. We are trying to provide information that is meaningful to the people who are requesting and looking for that information. The drug summaries, for example—because as you've noted, the reports themselves are very, very dense and technical—will provide very, very plain language information that will be available to everyone, and particularly consumers, so they have a very good understanding of what the implications of using that drug may be, and of course they will then be able to discuss that with their practitioner.

On the other hand, in the consultations we've been doing with all of our stakeholders, we do know there are other groups, academics, for example, that are very, very interested in seeing the more fulsome reports of our safety assessments. We are committed to making those public. Of course we have to be mindful of potential information that we may need to redact, but really our goal is to make those as public as possible, with minimal oversight in terms of what would be removed from those reports.

Mr. Terence Young: I assume you have the resources to make that happen.

Mrs. Anne Lamar: We do.

Mr. Terence Young: Ms. Lamar, could you please describe how Vanessa's law will make drugs safer for children in Canada?

● (1010)

Mrs. Anne Lamar: I'm going to ask Mr. Lee to take that on, given his familiarity with the bill.

Mr. Terence Young: Of course.

Mr. David Lee: This is where a number of clauses in the bill can really work together very valuably.

You can start with approval. There is a section in the proposals that would allow us to put conditions on authorizations, so to plan out what to look for as a drug goes out. If it's not approved for kids initially, we can put in some measures that we want to see if we think it's going to be used in that population.

If we start to see something, we will also be able to ask for further tests and studies, which could include monitoring who's being prescribed the drugs. It would be a utilization study. Again, if we see anything of concern, we can ask for signals to be confirmed. They can come in and do a reassessment—

Mr. Terence Young: Could you explain to the committee what a signal is?

Mr. David Lee: Oh, sorry.

If we start to see adverse events occurring and we see that kids are being harmed, then we can pick that up and try to understand it and figure out if it's the drug and if we need to do something, and we can use these powers to very immediately get at that analysis and do a reassessment. Then we can either go to suspension or indicate to the community of practice not to use it in that community, which we call a contraindication, and we can really make sure that message gets out there to change prescribing behaviour.

The Chair: Thank you very much.

Mr. Easter, go ahead, sir.

Hon. Wayne Easter (Malpeque, Lib.): Thank you, Mr. Chair.

I have two questions, and I see the bells are ringing.

Dr. Bennett asked a question earlier on the ability of Health Canada to communicate with physicians in a rapid and effective way. The process, as I understand it, is very slow at the moment now in case of emergency. I think, Ms. Lamar, she felt that you didn't have enough time to respond or that you didn't get to respond when she was here.

Second, in the interest of time, Mr. Chair, this question is for Mr. Lee.

I've had experiences with family members who are on a fairly extensive drug regime. When there are new drugs added, general practitioners will say, “Okay, we'll go with a new drug.” I can tell you about one experience in which a person was on 28 pills—I don't know how many drugs—and after a near-death experience and after review, that dropped to 12 pills a day, and the person was a changed person. There was an adverse reaction to one drug with another which created severe problems.

Is there anything in this bill that will deal with that situation? Sometimes it's not just a certain drug, but it is the application of that drug in conjunction with other remedies that are being taken by the individual.

Those are my two questions, with the first one for Ms. Lamar.

Mrs. Anne Lamar: Thank you for the question.

Coming back to some of my earlier comments, I think one of the things that we have working in our favour now is that we work in an environment that has an enormous number of venues for communication. There are many platforms to communicate, and social media is very helpful and instrumental in getting our communication messages out.

In terms of when we do have health and safety information that we need to pass along, we really take a system-wide approach. We are not only communicating with physicians. Of course, practitioners are our key target audience for us, but we also use the College of Physicians network, for example, and pharmacists and retailers as well. We try to reach out to organizations that are also having face-to-face interaction where products are sold. In the case of a recall for example, we also work with retailers and pharmacists who are actually distributing that product so they are also aware.

We actually do fairly regular evaluations, if I can call it that, of our risk communications processes to ensure that they are effective, that they're timely and that we are meeting the needs of those we provide them to. We have numerous ways of communicating electronically. We use old-fashioned technology, networks and phones, as well. We also do a lot of direct interaction with health care practitioners.

Mr. David Lee: On the second question about a new drug coming in and a person taking many drugs, that can happen. Clinical trials don't always tell us how the therapies will react together.

I think one of the big promises from the proposals is the institutional reporting, because as patients go in and they're taking a number of medications, seeing that very early is very important, so if there is a reaction between a new drug coming out and other drugs that are already out there, we can try to pick that up. The quality of reporting could increase in that environment.

Right now, if you get an adverse reaction and then you look at it, the patient could be on four or five drugs, and have a number of medical conditions. It's hard, looking at that, to tell what happened. These new powers of being able to follow up and really study and verify and to do it in a disciplined way is really what we're trying to move through in Vanessa's law.

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Hon. Wayne Easter: To come back to Ms. Lamar, there is no question there are all kinds of platforms out there to communicate now, but in an emergency situation, one needs to ensure the message gets through. If I can use even MPs as an example, we have so many platforms now for people to communicate with us, we sometimes miss them. Somebody thought they'd get to you on Facebook, or somebody else thought they'd get to you on Twitter, while somebody else thought they would get to you through your website or by e-mail. With all these different channels of communications, what we find in our racket—and it's not to be critical of the health area—is sometimes the messages can be missed.

Is there any emergency line or tool of communication that is being looked at or could there be improvements that you can think of?

Mrs. Anne Lamar: I'm going to ask Dr. Sharma to provide you with some more details.

Dr. Supriya Sharma: To start, I think you're absolutely right. When the bill first came in, there was no Twitter; there was no Facebook. People got information in very different ways. It's still that way, I think. When we're talking with practitioners and physicians out in the community, people want to get information in different ways. We've now gotten to the point where there are so many different platforms and different places where you can get that information. That's why at Health Canada what we're doing around the drug products is we're really trying to consolidate all that information.

One of the initiatives as part of the transparency initiative is something we're calling the drug product register. It actually will take all that information and put it in one place. When we have emergency information that we need to get out to practitioners, we have an e-mail push. People subscribe to that, if that's the way that they want to get the information. We have the Healthy Canadians website now and things get tweeted out.

Also, if we really need to reach all practitioners, we do have resources that we can go to that actually keep repositories of information for all practitioners across Canada. In that emergency setting, if we need to do that, we can do that.

The issue for us, though, is what is the most effective way to communicate. It may be through existing channels. We're doing a lot of work on the effectiveness of risk communications, going out to end users to ask how they want to get information and what's useful to them. Then we'll package it accordingly.

The Chair: Thank you very much.

That's going to conclude this portion of our meeting.

I'd like to thank all our witnesses here and guests. We're going to suspend for a minute. We're going to come back in camera. I would ask all those that shouldn't be here for an in camera meeting to leave as quickly as they can and we'll get into the portion of our in camera meeting.

Thank you.

[*Proceedings continue in camera*]