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Chair

Mrs. Joy Smith

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● (1110)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good morning, ladies and gentlemen. If we can all take our places so we could get started, I would really appreciate it. It is about seven minutes after 11 o'clock. I was a few minutes late because I was speaking in the House, so my apologies.

Having said that, I am pleased to announce that pursuant to Standing Order 108(2) and the motion adopted on Tuesday, December 11, 2007, the committee is beginning its study on post-market surveillance of pharmaceutical products, prescription and non-prescription.

I would like to welcome the officials from Health Canada who are here with us today. Welcome. We're so glad you could join us.

I would ask the assistant deputy minister, Ms. Meena Ballantyne, to introduce her colleagues before she begins her presentation.

Ms. Meena Ballantyne (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Thank you, Madam Chair.

I'll start with the introductions. We have Diana Dowthwaite, who's our director general of the health products and food branch inspectorate; Dr. Chris Turner, who's the director general of marketed health products; Mr. David Lee, who is the director of the office of patented medicines and liaison in the therapeutic products directorate of the health products and food branch; and Mr. Michael Vandergrift, who's the director general of the policy, planning and international affairs directorate in HPFB.

The Chair: Thank you for those introductions.

I would remind members that the first round is seven minutes, in the following order: first of all the Liberal members, the Bloc Québécois, the NDP, and then the Conservative Party. For the subsequent rounds, members are given five minutes for questions, alternating between the opposition and government members.

Ms. Ballantyne, if you would like to give your presentation, then we will start with the questions directly following that. I will recognize the people before they speak, because that keeps order—hopefully.

Ms. Meena Ballantyne: Thank you very much, Madam Chair.

It's a pleasure to be here today before this committee to provide an overview of Canada's post-market activities for pharmaceuticals. In my opening remarks I will provide an overview of the main components of our program, the measures the department has recently implemented to enhance it, and the new strategies being considered to strengthen our safety system.

[*Translation*]

As the federal authority responsible for regulating health products and food, Health Canada plays a key role in protecting and improving the health and safety of Canadians.

Let me provide you with an overview of how we are regulating pharmaceutical products, which is the focus of the committee study.

[*English*]

I'll begin with the federal-provincial-territorial roles in pharmaceuticals.

As you know, all levels of government have a clear mutual interest in ensuring the safe and effective use of pharmaceutical products. The federal government is responsible for the regulatory oversight of the safety of pharmaceutical products made available to Canadians, and all governments also provide drug plan benefits to Canadians. In the case of the federal government, it's through the first nations and Inuit health branch for our first nations communities.

Before a pharmaceutical product is authorized for sale in Canada, the manufacturer must provide the department with scientific evidence of its safety, efficacy, and quality. Scientists then review the evidence to determine whether the risks associated with the product are acceptable in light of its potential benefits.

When the product is approved for sale, Health Canada conducts a number of important post-market activities, which this committee has identified in the terms of reference for the study. These include post-market surveillance and compliance and enforcement, as well as risk management activities and risk communication.

Post-market surveillance is the process of tracking pharmaceutical and other health products already approved on the market to access signals and safety trends once these products are in use by a wider population. It is the responsibility of the manufacturer to report serious adverse reactions.

Health Canada also encourages reporting from health care professionals and patients. Health Canada assesses the data and takes appropriate action if a serious health risk is identified or if the risks associated with the product outweigh its benefits. Such actions can range from issuing warnings to the public and the health care community to cancelling the market authorization of a product.

Regulators worldwide face new challenges in the regulation of health products, driven by changing trade patterns, increased globalization of the industry, rapidly evolving science, increased complexity of regulated products, and greater expectations from the public. Steps have been taken over the past several years to address some of the pressures and challenges facing our regulatory system. Through investments in the past, the efficiency and responsiveness of the drug review system has been substantially improved. Health Canada has cleared its submission backlogs and is now meeting internationally benchmarked performance targets for review of new drug submissions for pharmaceutical and biologic products without compromising its high standards of safety.

Following the high-profile safety issues related to COX-2 drugs and building on the recommendations made by the Standing Committee on Health in 2004, targeted measures have been implemented to strengthen the safety of pharmaceuticals and other health products through significantly enhanced funding.

I would like to thank the Standing Committee on Health for its past work on issues related to health products, particularly the 2004 “Opening the Medicine Cabinet” report, which helped guide our most recent work on strengthening and modernizing Canada's safety system for pharmaceuticals.

For your information, we've provided a kit with all the various reports that built on the work of the Standing Committee on Health over the past few years, which has more details about some of the information we're going to talk about this morning.

Improvements made in the past few years to strengthen post-market surveillance, which is of most interest to this committee, include enhanced clinical trial oversight, strengthened assessment and surveillance of marketed products, and strengthened compliance and enforcement.

We have increased our capacity to collect more and better information about the safety of products currently on the market, as well as our capacity to assess the information and to communicate the risk. For example, we have launched the MedEffect Canada website as a single window for timely safety information about health products. There are 17,000 subscribers to the MedEffect e-notice at this point. We are also distributing the *Canadian Adverse Reaction Newsletter* to approximately 67,000 physicians through the *Canadian Medical Association Journal* and to 25,000 pharmacists across Canada.

We have also opened two new regional adverse reaction offices, for a total of seven across the country, and have seen a 50% increase in the number of adverse reaction reports submitted to Health Canada since 2006.

● (1115)

While these investments were necessary to address immediate gaps in Canada's current safety system, the view was that Health Canada needed to fundamentally change the way it regulates health products, which is widely shared by stakeholders.

[*Translation*]

In the fall of 2006, Health Canada launched a broad review of its legislative regulatory and policy frameworks for health products, known as Blueprint for renewal. It articulates a number of orientations to modernize the regulatory system, including proposed strategies to strengthen the safety of pharmaceutical products throughout their life cycle.

[*English*]

We held national consultations with over 150 stakeholders on the blueprint document that you have in your kit. Strong support was expressed during these consultations for the proposed approaches to modernizing our system.

The blueprint outlines a number of gaps in the regulatory system. For example, we have legislation, the current Food and Drugs Act, that is outdated and was designed to address the realities of the 1950s, as opposed to the year 2007. The system is reactive, not always focused on the greatest risks, and uses blunt instruments that often result in a one-size-fits-all approach to regulating products. It focuses on pre-market and point-in-time approaches to assessing the safety of products, rather than looking at risks and benefits continuously across the product life cycle. The experience with COX-2 drugs has demonstrated the need to address these gaps, particularly in post-market authorities and capacity, to help prevent similar incidents from happening in the future.

The proposed food and consumer safety action plan that was announced by the Prime Minister in December 2007 and the related discussion paper that was released and posted on our website in mid-January, a couple of weeks ago, would fundamentally change the regulatory system for regulating pharmaceuticals and other health products so that it can be more responsive to rapid changes in the regulatory environment and better protect the health and safety of Canadians. This shift would be achieved through the implementation of a life cycle approach, an approach that is consistent with other leading regulators, such as the U.S. Food and Drug Administration and the European Medicines Agency.

With the proposed life cycle approach, a number of actions could be taken more proactively to prevent safety incidents, strengthen targeted oversight activities, and respond rapidly to incidents when they do occur, which sets the international standard for vigilance activities.

The successful implementation of the action plan would require legislative amendments to the Food and Drugs Act. Specifically, authority would be required to implement life cycle approaches to regulating health products, thus shifting the focus from pre-market review to one that continuously assesses a product's risks and benefits, both before and after it reaches the market, by putting conditions on the licence. It would provide a more modern and effective compliance and enforcement regime, including modern fines and penalties and the power to remove unsafe health products from the market. It would enable the department, in cooperation with the provinces and territories, to make it mandatory for hospitals to report on serious adverse drug reactions. And it would enhance the openness and transparency of Health Canada's regulatory activities to support greater public involvement in regulatory decision-making.

The implementation of a life cycle approach to regulating health products will provide information about the risk-benefit profile of a drug, based on its use in the real world. It will allow Health Canada to better respond to safety issues when they arise, therefore reducing negative consequences on the health of Canadians related to the use of unsafe products.

This concludes my opening remarks. I have colleagues with me who can provide details on some of the issues we've talked about. I leave it up to you to ask questions, or we can provide the details now, as you like.

● (1120)

The Chair: Before we go into the question period, is there anybody else, from the presenters here today, who would like to make comment? I will give you that opportunity now, if you'd like to briefly do that.

Ms. Meena Ballantyne: No, I think we're fine. We'll just respond to the questions.

Thank you.

The Chair: Very good.

We'll begin with Dr. Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thank you very much.

Thank you for coming and thank you for the good beginning in changing this. I think most of us at this committee have felt that post-market surveillance could be Canada's gift to the world. With the single-payer system, there's no real reason why we couldn't be the best at this in the world.

Unless people know about it, we're not going to be very effective at it. I think your opening remarks say that there's still some disappointment in terms of the take-up on this and the actual reporting of adverse affects, both from stakeholders and from citizens.

This would be my first question. There was a very popular website where all Canadians went for their information, called the Canadian Health Network. It was a place where Canadians could look for information on things. Why would you shut that down rather than use it to attain the goals that are in your blueprint here, where it talks about developing mechanisms to encourage participation...? I think, from the performance report the committee saw, this is a website that almost doubled its site visits in the previous year. Yet the minister had the audacity to tell us that it had outlived its usefulness.

So I just don't understand why you're rebuilding and starting from scratch again when there was something very useful there that could have been used. I don't understand.

Ms. Meena Ballantyne: I would like to emphasize, Dr. Bennett, that you're absolutely right that we are increasing our efforts, making concerted efforts to get communications out to the public using a variety of sources. We have put into place mechanisms such as the MedEffect website that I talked about, and a lot of other risk communications that we target through the CMA, for example, to all the doctors in this country, and through direct mailings to all the doctors and pharmacists as well. So there's no question that we're trying to make sure we can get the information out as fast as possible, and the more information the better.

I'm not aware at this point...and I'll invite my colleagues to speak about this Canadian Health Network. But we do have the MedEffect website, which has been in place for the past five years.

Hon. Carolyn Bennett: Meena, maybe you could ask the department to give us a full report on why. In every consultation we have done, stickiness in traffic was found to be the most important thing to a website—how you get people to come, to see that they trust it, and then build the traffic. To start a new website is very difficult for people. So the decision of Health Canada to start myriad new websites when there was one that was already working just seems to fly in the face of what any communication consultant would ask you to do.

Mr. David Lee (Director, Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Department of Health): Maybe I can give you some information, at least about the effectiveness of the MedEffect website.

We know that since it was implemented in 2005, as a result of therapeutics access strategy resourcing, there were over two million page views and web traffic of approximately 860,000 visits to that website in 2006. So we know from that statistic alone that there is significant interest in that website.

We also note from a survey we did in 2006, a public consultation on the MedEffect website and the online use of it, that there was significant awareness and trust in it, and that Canadians had faith in that vehicle to communicate.

I think part of our problem is that.... I don't want to say no two Canadians are alike, but obviously people have different preferences as to what site they would like to use in terms of the way it's configured. So probably a one-all solution isn't the best. We recognize, for example, that as Ms. Ballantyne said, the Canadian Medical Association and its daily infoPOEMs.... I am a physician and I get those daily, directly in my e-mail box, and I use them. Those are one method of communicating risk information. Other Canadians may prefer the MedEffect website, while others may prefer the Public Health Agency of Canada or other vehicles. We recognize that.

What I can tell you is that we have consulted with Canadians, and the majority of those consulted did have confidence in the MedEffect website as a reliable source of information.

● (1125)

Hon. Carolyn Bennett: Can you tell me how many went to the MedEffect website, and were sent there, and where they were sent from, using links from other websites such as the Canadian Health Network?

Dr. Chris Turner (Director General, Marketed Health Products Directorate, Department of Health): I doubt it. I am not the expert in IM/IT, but we can look into that for you and get back to you.

Hon. Carolyn Bennett: I think the fight between the Canadian Health Portal and the Canadian Health Network is legendary. I would like to know how we could be more coherent, between the Public Health Agency and Health Canada, on communication strategies with Canadians.

Seeing as the current legislation is outdated in design, I want to know what you are doing now to get the legislation modernized in terms of real world experience. We know we are approving drugs with which we have had no experience in the real world, and we don't know if they'll fight with echinacea or grapefruit juice or other medications when we put them on the market.

Ms. Meena Ballantyne: I'll invite my colleague Mr. Lee to respond to that.

Mr. David Lee: There are a number of things we're actually doing to study, in very practical terms, how we need to modernize. We recognize there's a big gap sitting there. A lot of the machinery we work with now in the regulations is 40 years old.

What's missing, the big gap, is really in the post-market. So as you mentioned, when we look at something pre-market, we're really looking in very ideal conditions at how the drug is behaving in very selected patients. It's when it gets out into the market that people might have other diseases that will affect taking the drug. They might be taking other drugs. That's where a lot of our new scientists are actually gathering. We need to pay attention to what other regulators in the world are doing. There are a lot of very good instruments we're studying there and trying to pull into the Canadian discussion.

We're also learning from Canadian patients. The people who use drugs chronically need a lot more information because they're with the drugs everyday. We need to understand their information needs when there's a risk with a product we might all take for a week and no more.

It's really an important study to us. We're trying to bring in as much as we can from the communities that use drugs, and make as few assumptions as possible. We've been conducting consultations for the last couple of years and really bringing people in at a very early stage to get a good solid evidence-based framework.

Hon. Carolyn Bennett: Could you table the consultation—

The Chair: Madam Bennett, I'm sorry—

Hon. Carolyn Bennett: No, I just need him to table the consultations that have been done to date.

The Chair: I'm sorry. We'll have to go on to the next person.

Madam Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Thank you for being with us today.

We are beginning our information sessions on the post-market surveillance of pharmaceutical products. We made this subject a priority because we read the newspapers and because quite a few citizens are expressing their concerns. There are products on the market that affect the lives and health of the population. Many people are wondering wether they should go on consuming certain pharmaceutical products or using certain cosmetics.

On page 2 of your presentation, Ms. Ballantyne, you say: "Through increased investments, the efficiency and responsiveness of the drug review system has been substantially improved [...]" And then you say that in 2004 "[...] targeted measures have been implemented to strengthen the safety of pharmaceuticals and other health products through funds provided by the 2005 Budget."

If I remember correctly, the Auditor General had noted that the funding of the regulatory program supervised by Health Canada was on the increase, but that the basic funding, for medication, had decreased by 32% over three years, which means $7.1 million in 2003-2004 and $4.8 million in 2005-2006.

How come you did not mention this gap? You seem to be saying that the budget you have available will enable you to achieve the objectives of your reform. How do you explain that you did not mention anything about a lack of funding and resources? It seems that Health Canada, with the various branches in charge of drug safety, is unable to meet its obligations by supervising the entirety of the process up to the post-market stage of the products.

These are my first questions.

● (1130)

Ms. Meena Ballantyne: I will begin my answer in French, but with your permission—

Ms. Christiane Gagnon: You could answer in English, we have interpretation. It will be easier for you.

Ms. Meena Ballantyne: All right. It is because I would like to give you an accurate answer.

[*English*]

We are presently looking at our resource base, further to the AG's report and further to the investments that have been made in the past. We're considering what resources we need to carry out our regulatory responsibilities in an effective and modernized way. That work and those discussions are ongoing at this moment.

There is no question that there is an issue of resources. We're looking at a variety of mechanisms to address that, because it is important for us to make sure we can carry out our work in a way that meets the expectations and needs of Canadians. So we're hoping in the next few weeks to come forward with a response to the public accounts committee. We've done a comprehensive review of our programs and services further to the AG's report. We have some consultations that have been under way on our cost recovery regime, which has also been outdated since the mid-1990s.

What we're suggesting is that there is a need to transform the way we regulate health products in this country, so that we can meet the needs of Canadians now and in the future and keep up with our international partners, because we are lagging behind our international partners. We need to do that in a responsible way and make sure there's sufficient attention focused not just on the pre-market but on the post-market.

In my view, this life cycle approach we're talking about is really transformative in terms of our taking a drug and not just being reactive and looking at it at one point in time, and then just putting it on the market and letting market forces, in this case Canadians, actually experience these adverse effects and bear the consequences of our decisions. So what we're saying is that with the life cycle approach we will be monitoring these drugs and health products throughout their life cycles, so that when these get out into the real world, they are past the clinical trial stage and there are people using them who are very young, very old, with a number of other health conditions, whom we can monitor, and so that we have the regulatory foresight. The latter is not a blunt instrument. Yes, we can always recall a product.... Actually, in this case, we can't, as we don't have the legislative authority to recall a health product in this country, which I personally find absolutely appalling.

So what we're saying at least is that instead of just using that, can we just calibrate what we need to do.

[*Translation*]

Ms. Christiane Gagnon: I know, but it is what you told us and that is what is written in your action plan. However, we know that the current mechanism for approving drugs does not enable us to detect most of the adverse side effects of the drugs. However, your plan and your strategy for the post-market analysis for 2007-2012, provides that Health Canada new plan is intended to modernize the system, as you said, of regulations in Canada. At the same time, you will be guided by, and you will even apply the standards set by the international conference on harmonization of technical requirements. We know very well that this plan, that you used as a model, will shorten the drug approval process by bringing the protection standards down to the lowest common denominator. Thus, you want to develop, as they did, a unique set of regulations for all clinical trials.

I was alarmed by the fact that the current drug approval mechanism does not enable us to detect most of the adverse side effects. However, if you want to take the ICH as a model, you will, just as it did and shorten the approval process for certain drugs. You know that the pharmaceutical companies would like to do all the marketing of certain drugs because it is more profitable for them. I do not think, therefore, that you are going in the right direction, if you use the ICH as a model.

● (1135)

[*English*]

The Chair: Madame Gagnon, your time has run out, but I will let the witness answer your question.

Would you please be so kind as to answer madame's question?

Mr. David Lee: Picking up on the ICH implementation, I think we need to state very categorically and strongly that there is no intention in the modernization to decrease the amount of science that you need to get approved to make sure that there is a favourable benefit and risk for the product when it goes onto the market. That's very important to state. So there is no compromise or shortening on that at all.

The idea is that as you go from the pre-market, which is really an experimenting with the drug, there are still quite a few things you don't know when it gets out into the real population. That's where the science is really starting to grow. It is fairly new. We probably don't have enough pharmacoepidemiologists in the country.

There is a lot of hope, though, that we can work with our decision-making partners in the provinces and so on to really get the best interventions when they make sense. So you really want to keep your surveillance of those risks that are plausible risks that make sense.

And there is a lot of planning element now, so pre-market, a lot of what's in the international environment is making sure that before a drug company is allowed to sell a drug, even in the pre-market situation, they have a really good plan for how they're going to track risks out on the market. And there is a lot more commitment to that planning.

And that starts to appear in regulations. That's not about decreasing the standard for getting on; it's really about governing, and looking, and planning well. Planning doesn't get you everything, so you still need interventions if something is going wrong with a drug, but the idea of planning is fundamentally a good one, we think, and it will improve the oversight.

The Chair: Thank you, Mr. Lee.

Madam Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you, Madam Chairperson.

And thanks to all of you for your presentation. It's very timely, actually, that we've started these hearings at the same time as, I understand, your department has started hearings on what I think would probably be considered the fourth attempt in the last decade to overhaul the Food and Drugs Act, always under the premise that it's outdated and needs to be modernized, and always based on moving our system from a precautionary model to the risk management model.

Everything you've told me today sends up all kinds of alarm bells that you're simply trying to do what we have defeated four times over at this committee or in the House for the last decade. Everything you've suggested to me today and to us says that in fact you're advancing the agenda for minimal pre-market precautions and beefing up the post-market end without necessarily ensuring that this government and this department have done their utmost to ensure that the products put on the market are safe beyond a reasonable doubt.

My first question is, why do you think the risk management model, which is to let the buyer beware and take their chances, is better than the do-no-harm principle? And how is that good for Canadians?

Mr. David Lee: This is a question that really does go down to the heart of the whole model. Frankly, if we were advancing a model that was lessening the standard upfront, then you would be right to be concerned, but we're not doing that. We need to be very clear here that we want to keep the science uniform upfront. There are some good advances going on in science—new modelling, new statistics—and we can take a look at those good evolutions.

But what we're proposing here is really the merger of science and common sense, because science can say that you could take a long time to resolve certain uncertainties with a drug, and it could take generations for some of it. But you've got to use common sense, because people on therapies need to know things from time to time—caution, don't take with another drug; warning, if you're in this population and you're vulnerable, don't take the drug. So there is this interaction you have to have with the market, and we're trying to do that responsibly. That's what the debate is for us.

● (1140)

Ms. Judy Wasylycia-Leis: It may be that you're not, right now, reducing requirements at the pre-market end. I would argue, in fact, that the department and consecutive governments, not just the present but also the past government, have done all the damage they needed to do to change the pre-market surveillance to a risk management model already.

As soon as I was elected in 1997, the first thing that happened was that the Liberal health minister got rid of the one independent drug research bureau that was left to test for—get it—post-market impact. In other words, implications when a drug and a food reacted in a negative way, or a drug to a drug, or a drug and a natural health product—gone.

Scientists have had to leave the department because they stood firm and said, “We aren't going to be bullied by the government, which has been bullied by corporations, to minimize our standards and our scientific data.” So we're now at a point where all those stringent controls at the pre-market level are basically reduced to industry regulating itself.

Now you're going the next step and giving us this fancy language about either progressive licensing or life cycle stuff. I mean, as far as I can tell, these are just nice, fancy words to in fact allow government to take one more step to get rid of the Food and Drugs Act, which is founded on the precautionary principle and “do no harm”, to bring it in line with regulatory, trade, and WTO standards.

The pressures on the international front, in terms of trade, seem to be driving this. Let me give you the example, and you answer. If we have this precautionary model, how was it that we had a situation with rancid baby food on the market, where no one felt compelled to report that to Health Canada, because they were going to wait to see if someone got sick? Then when someone gets sick, they'll report it to you, and you might do something.

Now, that is a perfect example of what the government over the last 10 years has done and what your department is doing now. I would want to know where, in all of this, is the provision to ensure that we have a much more proactive response when dangerous products hit the market.

First, I don't imagine that with food we can do it all, but with drugs, at least, ensure that you have drugs that are safe before they hit the market. You've moved to self-regulation, or “let the industry regulate itself”. Vioxx is a good example. Let it on the market. It's better for the drug companies to go through all the testing and do the regulatory stuff, but let it on the market, and then pay off when someone dies, because it's cheaper for them.

You need to explain to us how this is going to be better for Canadians.

Mr. David Lee: The really good opportunity for you here is to talk about how we're going to responsibly lay in these instruments. These are based on science. Frankly, you would find reasons to be very proud of the rigour our scientists bring to their exercise. We actually spend a lot of time talking to them, because we need to know what the data gaps are for them, what they need to know, so they build confidence in a drug before it goes on. There's a lot that goes on in that.

I think you would have reason to feel very good about that rigour. We don't want to displace that; that's not the idea. We want to bring really good science, and that's hard to do with rules that are 40 years old and straining to keep up with the modern science, actually.

The Chair: I just have to let you know we have a little bit less than a minute left.

Ms. Judy Wasylycia-Leis: Okay, then I have one final question. What's the purpose of progressive licensing or life cycle...whatever... when in fact it appears that you're really trying to move new drugs more quickly to the market, and then give Canadians the confidence that something will be in place to help them once they get sick? You haven't demonstrated to us how you're in fact dealing with concerns raised previously about drugs that get on the market and aren't safe, never mind how progressive licensing is going to help that.

● (1145)

Mr. David Lee: Progressive licensing, as a premise, stands for the fact that we progress over time in our knowledge about the drug and we're seeking the best regulatory oversight and intervention as we go along. We can walk through the instruments, internationally and domestically, to get the best presence there.

As a population regulator, you get to see how drugs are behaving. Really, the premise is to use our science wisely and then support that through the architecture of regulations and framework, and that's what we're trying to achieve.

The Chair: Thank you, Mr. Lee.

Mr. Brown.

Mr. Patrick Brown (Barrie, CPC): Thank you, Ms. Chairman.

The first question, could you provide the definitions of the terms used in the post-market surveillance, so we can have that on the record for the committee—terms such as "drug medical device", "drug review process". Obviously the words we use are important, so it would be helpful to get your definitions.

Ms. Meena Ballantyne: So you're seeking the definition of post-market surveillance?

Mr. Patrick Brown: Yes, if you could, and how you would define adverse reactions, natural health products, therapeutic products, pharmaceuticals.

Ms. Meena Ballantyne: I'll invite Dr. Turner to respond with regard to the definition of post-market surveillance.

Mr. Patrick Brown: And the associated terms.

Ms. Meena Ballantyne: Yes.

Dr. Chris Turner: The definition of adverse reaction is actually found in the Food and Drugs Act, in the associated regulations. I don't have the definition in front of me, but it's a serious, unexpected, or expected reaction or response to a product that's been taken.

There is exact wording, and we can provide that to you.

Ms. Meena Ballantyne: Maybe I'll tell you how I look at it in terms of post-market surveillance.

Basically, when a drug or health product is out on the market, we use a variety of means to collect information on that drug's use out in the market. Through MedEffect, through our Canadian adverse drug reaction newsletter, through any of the information we get through our compliance and enforcement activities, we gather the information, we assess it to look for signal checks in terms of what the data is telling us, and we liaise with our international counterparts as well as with our provincial and territorial counterparts within Canada. From that signal detection, we decide if any action is warranted, and we act upon it.

So post-market surveillance is basically the activities that do that, which is what we do in the marketed health products directorate that Dr. Turner is responsible for.

Dr. Chris Turner: I'm not sure, do you want the technical terms or do you want the plain-language definitions?

Mr. Patrick Brown: The plain-language definitions.

Dr. Chris Turner: If you want the plain-language definitions, they're in the glossary to *Access to Therapeutic Products*, which I think was provided to you. It's an oversight document.

For example, an adverse reaction in here is stated as the following: "Any undesirable effect of a health product. This can range from a minor effect such as a skin rash to a life-threatening one such as liver damage." Again, that's not the technical term that's used in the regulations, where it's a "noxious and unintended response". So it sort of depends on what you want.

The glossary also includes definitions of pharmaceuticals. For example, post-market surveillance is defined as such: "The process of tracking drugs and other therapeutic products, already approved and on the market, to assess signals and safety trends once these products are in use among a wider population."

That's sort of what you want, right?

Mr. Patrick Brown: Yes, that's helpful. And we do have copies of that.

I also wanted to touch on your revised blueprint, which was produced in early 2007. I notice that one thing that was mentioned with respect to post-market surveillance was the lack of regulatory authority in this area; inadequate collection, analysis, and dissemination of safety and effectiveness information; as well as the need to establish stronger partnerships, nationally and internationally.

Could you expand upon that a little bit in terms of what partnerships you're talking about nationally and internationally that we need to improve upon to enhance our research capacity?

Ms. Meena Ballantyne: We have a variety of partnerships in this country, with health care professionals; with provincial and territorial governments; with our partners such as the Canadian Institute for Health Information and the health technology body CADAS; and with international regulatory agencies as well, such as the USFDA, the EMEA, the Australian Therapeutic Goods Administration, and others. We have regularly established contacts with all these partners at a variety of levels and in a variety of fora.

The scientists, for example, go to the ICH, as was mentioned, for the harmonizing of standards. I go to Heads of Medicines Agencies meetings, where we talk about top-of-mind issues at the level of heads of agencies. I met with Andy von Eschenbach, my counterpart from the U.S., as well as the EMEA and the U.K. and 14 other countries in early December to make sure that we're all going in the right direction on whatever issue we need to work on together.

As we've said, the science across this world is the same science, and we're all facing the same problems in terms of keeping up with evolving science and technology and being able to adopt standards so that we can all do our regulatory work in a smart way. And then we retain our right, as of course each country does, in terms of the regulatory decisions we need to make based on our history, our context, our tolerance for risk.

● (1150)

Mr. Patrick Brown: The blueprint speaks of the challenge to strengthen it. What ways are we looking at improving our current policy?

Ms. Meena Ballantyne: We're doing a lot more of it, at a variety of levels.

Mr. Patrick Brown: Just more actively?

Ms. Meena Ballantyne: Yes, we are much more proactive in trying to seek opportunities to share work with them and to share reports of post-market surveillance. If they're picking up any signals in those countries, then we would have this rapid sharing of information.

Mr. Patrick Brown: Was that not done before?

Ms. Meena Ballantyne: It was done before, but we've recognized that it needs to be done much, much more proactively than ever before.

Dr. Chris Turner: I would add that one of the interesting aspects of the developing science around post-market surveillance is that it is evolving. You asked whether some of this work done before. It wasn't, because the tool to do it was not there.

I have a three-page report, which we could leave with the committee, that talks about what our regulatory partners are able to do in their jurisdictions. We in Canada, as Dr. Bennett mentioned, have an opportunity to lead, using tools like the National Prescription Drug Utilization Information Service, NPDUIS, and COMPUS, the Canadian Optimal Medication Prescribing and Utilization Service. These are resources that we can bring to the table.

With others—for example, in New Zealand, France, and Norway—there are pharmacovigilance centres connected to health care facilities. In the U.K., there's the general practice research database, which resources a group of physicians to keep track of their patients and enables that information to be mined. Data mining, which wasn't as available before, is a tool we use in some partnerships with the U. K. and HRA, our equivalent. We leverage the general practice research database.

But on our side, we also have these opportunities we can bring to the table. We have discussions, as Ms. Ballantyne said, with our foreign regulatory partners so we're able to leverage the worldwide surveillance experience.

The reality is that rare adverse reactions, especially if they are in a subpopulation, are less likely to be identified in Canada than they are when you can data-mine the worldwide experience. If we want to address the needs of a subpopulation, we may have to go to that part of the world to get it. For example, with some of the products, like traditional Chinese medicines and ayurvedic medicines from India, it's much more likely that Canadians are going to be able to mine that information from those parts of the world where there is a larger population.

Those are some examples of our foreign partnerships. We recognize that we don't have to do it all ourselves, but we have to be integrated with our foreign regulatory partners to be able to leverage the expertise.

The Chair: Thank you, Dr. Turner.

Ms. Kadis.

Mrs. Susan Kadis (Thornhill, Lib.): Thank you for coming today to help us study such a critical area, to ensure that Canadians can be confident that the drugs they are taking are safe.

That's what I would like to ask you. Can Canadians feel a sense of security regarding our current post-market surveillance, particularly in relation to adverse drug reactions?

I know about some fairly recent experiences where there were very serious and potentially serious adverse reactions. I know from the literature we have received that it is not mandatory for health professionals to report. I'm sure many do, but based on what I'm seeing, perhaps many don't. I find it surprising and perhaps somewhat shocking that it is on a voluntary basis. I understand that industry does it on a mandatory basis, but for health professionals it seems to be optional. Perhaps you could illuminate us as to how many physicians in hospitals and in private practice are now routinely providing that information.

On this whole notion of voluntary, you mentioned rare adverse reactions, but how do we know they're rare? Someone could have a serious reaction and may be led to think it is very rare. In fact, if it hasn't been reported adequately, for whatever reason, maybe it isn't so rare. I think this is a critical area in terms of ensuring that confidence.

It sounds as if there is a need to improve. Are we going to make changes that will significantly improve that confidence level, or are we going to leave out this piece regarding information? It's the information that is going to lead us to the best possible decisions for Canadians' health and safety regarding pharmaceuticals.

● (1155)

Ms. Meena Ballantyne: You're absolutely right that it is mandatory for manufacturers to report adverse events, but not so for health care professionals or, obviously, Canadians.

In the reporting of adverse events, there is a lot of underreporting, for a variety of reasons, going on in terms of barriers to reporting and communications channels. We've been looking at this issue actively, because that's a fundamental part of any kind of post-market surveillance activity. There's no question that, using a multi-pronged approach, we need to try to increase the reporting on these, because that's going to add to our information base in this progressive licensing or life cycle approach.

I'll let my colleagues who've been working on these issues much longer than I have speak to this, but in all our consultations in terms of looking at the international practices, looking across this country and talking to a variety of people, what was felt was that at this point in time there are many folks who are starting to work on putting systems in place to report these incidents. For example, a couple of the provinces—I think Manitoba and Saskatchewan—are putting into their hospitals or regional health authorities critical reporting systems. We have the Canadian Patient Safety Institute, as we know, trying to encourage that, so that it's not an individual who's held responsible and it's a system issue that we can all learn from.

During our consultations with all these folks, what came up was that at this point in time maybe the best place to start could be focusing on mandatory reporting by hospitals of serious drug adverse reactions to their regulated products, because we know that at some stage people will have to be, unfortunately, hospitalized if they've suffered a serious adverse event. What we're saying is that maybe as a first step we will try to have mandatory reporting within health care institutions. We're actively working with our colleagues in the provinces and territories, and there are a number of issues to be worked out, but I think the mood worldwide is to go in that direction, because we know we have to increase the reporting of these things using a variety of means.

Mrs. Susan Kadis: Thank you.

Along those lines, internationally, are other countries having health professionals provide that information currently on a mandatory basis? How do we compare, in general, with post-market surveillance?

Dr. Chris Turner: As part of the workup for this issue—and this again is something that was discussed with the previous Standing Committee on Health—we have done an international survey of foreign regulatory action, and what we've found is that there are a certain number of countries that do have mandatory reporting requirements for health professionals, but what we've also been told by them and what the evidence shows is that those requirements for mandatory reporting by individual health professionals have increased neither the quality nor quantity of adverse reaction reports. As a result, we have, again, through consultations with our provincial and territorial partners, and as well, by looking at some of their critical incident reporting systems, found that groups and teams of individuals provide more and better-quality reports.

In addition to the numerous other initiatives we've put in place since the creation of the marketed health products directorate in 2002, in the last year there was a 17% increase in the number of domestic adverse reaction reports. That's significant. We have seen a continual increase in those reports since 2002, as another element.

So there isn't just one solution. We recognize that the best place to get...I don't want to call it the best bang for the buck, but the most likely place to get the serious adverse reactions, which are the ones we're most concerned about, is from health care institutions. As a result, working with our provincial and territorial partners, hopefully they will be able to leverage the information, because we know that hospitalizations from adverse reactions are a significant drain on the health care system, in addition to individuals.

● (1200)

Mrs. Susan Kadis: Thank you, Dr. Turner.

The Chair: Madam Kadis, I'm sorry, you have just 30 seconds.

Mrs. Susan Kadis: Thank you, Madam Chair.

I wholeheartedly agree with going in that direction, but of course you have to consider the fact that at that point, when they go to the hospital, it may be fatal, whereas if we can get the information earlier we may avert that fatality.

I would encourage also that you table the study that you referenced before regarding MedEffect. We know that with the Canada Health Network there were three million viewers, so it far exceeded the MedEffect and was another important tool for information.

The Chair: Thank you, Ms. Kadis.

Dr. Turner, when you were answering questions from Mr. Brown, you referred to a three-page document on international partnerships. I was wondering if you would be so kind as to table that with the clerk so that members of the committee could have that information.

Dr. Chris Turner: Sure.

The Chair: Thank you so much.

Ms. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thank you, Madam Chair.

I'd like to thank each of the presenters who are here today to answer our questions.

I just want to carry on a little bit along the same line as Ms. Kadis did.

On page 2 of your presentation, Ms. Ballantyne, you talk about Health Canada encouraging reporting from health care professionals, and you say that it's only the manufacturer that is responsible for reporting serious adverse reactions. I have a few questions along this same line.

First of all, what is the definition of “adverse reaction” versus “serious adverse reaction”? Is anything mandatory at all right now for health care professionals?

When I go back to page 5 of your presentation, you talk about the legislative amendments to the Food and Drugs Act and about the authority to make it mandatory for hospitals to report. We're again back to the definition of adverse reaction and serious adverse reaction. Your definition will probably answer this question, but are serious adverse reactions the ones that require hospitalization? How would we know that if health care professionals don't have to report anything? How do we know whether or not there are adverse reactions out there? If it is only the manufacturers that have to do this, isn't there a huge gap? How would the manufacturer even know if there had been a reaction? Isn't it the doctor or the patient who would know whether or not there had been a reaction? If I had one, I wouldn't be contacting the manufacturer of the drug; I'd be contacting my doctor—

Mr. David Tilson (Dufferin—Caledon, CPC): Or your lawyer.

Mrs. Patricia Davidson: I'd start with my doctor.

If you start making it a mandatory requirement for physicians and health care professionals to report everything, how are you going to balance the increased red tape and bureaucracy, and everything else that's required, with the fact that our physicians and health care professionals are overloaded today with that type of requirement from governments? We hear every day that government requires too many reports to be filled out; this has to be done, and that has to be done, and we don't have time to do our nursing care or doctoring care.

Could you answer those questions, please?

● (1205)

The Chair: Dr. Turner, go ahead.

Dr. Chris Turner: The definitions of adverse reaction and serious adverse reaction are in the regulations. A serious adverse reaction does involve hospitalization, but it involves several other things as well: if there is a life-threatening reaction; a death, obviously; a disability; or a congenital anomaly. Those are internationally harmonized definitions of serious adverse reactions. They're not Canadian only.

As was discussed previously, we are attempting wherever possible to harmonize this internationally, because we need to be able to merge the data. If someone has coded something in their database as serious, based on a different definition, and we're not using the same definition, it makes it impossible to come up with a summary to know what its significance is and to use numeric comparators—what we call proportional representation index numbers—to be able to say that one report makes any difference in the context of all the other reports in that class of drugs, or all of the drugs reported.

I hope that addresses your issue about what is serious.

As for how we would know there were other things going on, in addition to working with our foreign partners to be able to identify trends.... That is what adverse reaction reports are; they are not individual. They're not like *CSI* or a coroner's report—and some of them may be coroners' reports—but are used for trending, which is studied more intensively and may involve a study—

Mrs. Patricia Davidson: But the trending must come from individual reports.

Dr. Chris Turner: By accumulating them.

We have other approaches. For example, we're working with groups such as the Canadian Medical Association and the Canadian Institute for Health Information in terms of hopefully, in the nearer future, being able to leverage reports without relying on, or waiting for there to be, a voluntary report.

In terms of your point about manufacturers' reports, although 66% of the reports that we get actually come from manufacturers, they get them from health professionals or consumers. So, for example, if there's a 1-800 number on a label and a consumer calls the manufacturer, then the manufacturer has to report it. In other words, the mandatory component is that anything the manufacturer is aware of they have to tell us, no matter where they get it. If they hear about it themselves, or if a physician, a nurse, a dentist, a naturopath or a consumer tells them, they have to make a report.

The problem is that the level of quality may be extensively different, depending on how close they were to the situation. If one were a salesperson in a doctor's office who got a full case report from that physician and then sent it to us, obviously that may be more useful than if we just know that somebody had a rash, but didn't give you a dose, and there's no temporal relationship to when the drug was taken. That's less useful. We would get the full range of that in the approximately 17,000 domestic reports we get per year and 350,000 foreign reports per year. So it becomes a trending exercise.

Then once we've identified what we call a signal, and they're potential signals, then those are further investigated. That may involve actually doing a post-market study. That may involve talking to foreign regulatory bodies. That may involve including academia or provinces and territories looking at utilization information. That may involve purchasing utilization data from groups like IMS, or Brogan Inc., and others who have that kind of information, to be able to put the full picture together.

Ms. Meena Ballantyne: I would just add that the beauty of the new approach we're proposing is that you could attach the studies that Chris is talking about to the licence, so that you would be saying that based on the science and the sound science in the best interests of Canadians, we will issue a licence for a drug. But we want to make sure that we monitor it closely, for whatever reason. If there's something in the science that's telling us that we don't have all the information at this point, but we've made this assessment—and it's always going to be based on science—that the benefits outweigh the risks at this time, but we want to monitor it very closely as it moves forward, right now we can't do that. We would just give it a licence, wait for an adverse event to happen, and then just pull the licence, which is a very blunt instrument.

With this progressive licensing, we could say to the company that they have to carry out this post-market surveillance, they have to submit the studies, they have to reassess the product, and we will be monitoring it very closely. So we would be able to use something that isn't taking the drug off the market, because it does benefit. As long as the profile always remains that the benefit outweighs the risk, then you would continue to have it out in the market.

● (1210)

The Chair: Thank you, Ms. Ballantyne.

Mr. Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you, Madam Chair.

Good afternoon. With your permission, I will take a specific case to find out how you deal with the information you receive. This morning, many women must have felt somewhat afraid when they read *La Presse*. This might even be the case for my colleague from Quebec, but I would not want to get into her more intimate secrets. In *La Presse*, this morning, we read that anti-ageing cream contains DMAE which affects cell division and can cause serious skin problems. Dr François Marceau drew this conclusion which was published in the *British Journal of Dermatology*.

What do you do when you receive or read this kind of information and when you are notified of a study?

Ms. Meena Ballantyne: I will ask Dr Turner to answer your question.

[*English*]

Dr. Chris Turner: I think what you're raising is that information can come to us from a variety of sources. For example, today there is a report of a Quebec citizen who had a fatal reaction to taking excessive doses of cold medications.

We don't limit the investigation or the creation of a report to someone actually sending us a report by fax—and we have toll-free fax and phone lines—by the online electronic reporting, etc. If there's a publication in a scientific journal, especially related to a Canadian, and we become aware of it, that can become a case.

So it depends, first of all, on whether it is a regulated product or not. If it's one of our products, for example, if it's a cosmetic, is it a cosmetic that's regulated by another part of Health Canada? It would depend then into which monitoring system it would go, and there are numerous monitoring systems—veterinary drugs, cosmetics, pesticides, etc.

But if it comes into our awareness and it's a regulated drug or product, then we will follow it and examine for trends. So if there is a concern such as was raised, then we would do a search of the database. And some of the fields of that database are public, so if you wanted to search it yourself, you would be able to. That's unique to Canada, actually, that we have that. Then it would be further investigated based on the trend.

[*Translation*]

Mr. Luc Malo: Is there a process for changing the category of products? Currently, it is a cosmetic product, therefore it should be classified as a cosmetic. However, we have learned that this product penetrates the skin and that it can affect the cells. Therefore, it might be some other kind of product and not a cosmetic.

Is there a process to change product categories rapidly? As I listen to you, the process seems to me to be too long, given the fact that we are studying something that could very quickly change a person's whole life. Some women who read this in the morning newspaper may well panick.

[*English*]

Mr. David Lee: The department's interests clearly are to cover risk, no matter what the product line is. What we need to be stable about is how valid the risk is, because you don't want overreaction. So you want to really have the focus on what it should be to make sure that the risk is well managed, if there is one. So that's the study you want.

Dr. Turner was pointing to the kind of very complex analysis that has to go along, but what he's not getting now are the instruments to be able to do something effective once it's on the market, because the blunt instrument Ms. Ballantyne keeps pointing to is that we have to threaten to take it off to get more information; and it's a very old instrument.

Here you would be able to say, okay, we've identified a risk, we want to see more information, we want to see more studying to validate it. If we need quick intervention, because it's a very difficult risk to manage, then you get more direct ability to do that, including communicating well about the risk.

So what we're looking for is really being able, through the licence, to manage these various activities and make sure that you heighten the controls when you need to, and that's the life cycle governance. Once it's out there, you get the oversight that you need.

● (1215)

Ms. Meena Ballantyne: Can I just add something to answer your question? We're constantly scanning the media and other reports to see what's out there. As you can well imagine, a number of events and reports come to us.

We have people on the ground. For example, we have seven regional offices in the marketed health products. They're people out there in the provinces and territories working with those communities, trying to get Canadians and health care professionals to report more, encouraging everybody to report more.

The minute we get this data, we're looking at it quickly, making an assessment: is this an issue or not? If it's something that is a really huge issue or something we need to communicate to Canadians, we have a variety of risk communications. We have some criteria to trigger the appropriate risk communications, without, as Mr. Lee said, panicking the population.

Sometimes we will do an information update. If this is one of those cases, we would provide information, put it on our website, put it on our MedEffect website, if needed. Then the second stage would be getting out information to the physicians. We have a health care professionals advisory that goes out through the CMA, through direct mailings, to all doctors in this country. It goes out to pharmacists in this country. We work with the associations.

We use the media as well to get this information out. We recognize that in a crisis situation we would have to get this information out as quickly as possible. For example, there was the counterfeit toothpaste issue last summer. We thought there might have been something in it. Through our inspection programs, we found reports and confiscated this toothpaste based on, I think, a complaint that came up. We analyzed it in our labs. We had to act within a 24-hour period. We erred on the side of having people ask us why we reacted so soon as opposed to why we waited so long.

This branch does a balancing act on a constant basis. We're trying to do this in a much more effective, responsive way. We have to target our resources to the areas of greatest risk. This is what the action plan is talking about, active prevention, because it's in all our best interests to make sure health and safety is protected.

The Chair: Thank you, Ms. Ballantyne.

Mr. Tilson.

Mr. David Tilson: Thank you.

I'd like to return to an issue that was raised by Ms. Kadis and Ms. Davidson, and that has to do with reporting by health care professionals.

Your paper—I appreciate your giving it to us in writing, incidentally, it's been helpful—uses the word, as Ms. Davidson says, “encourages”. I don't understand that. Whether you're talking about the topic we were just dealing with, counterfeit toothpaste, or some genuine reaction, if citizens have a problem, they go to their doctor or dentist or health care professional or whoever you're talking about and ask why they have this rash after taking this drug. You're telling me they don't have an obligation to report it to Health Canada.

I don't understand that. Is there a jurisdictional issue? Why is that?

Ms. Meena Ballantyne: I'm going to ask Dr. Turner to respond to you, but I just wanted to say there are a number of issues related to mandatory reporting by health care professionals. In reporting adverse reactions, and particularly serious adverse reactions, it's more of an issue of quality rather than quantity, because you want to focus on the very serious areas. This is what I'm talking about in terms of targeting oversight on areas of greatest risk.

Which one would you rather be focusing on, the rash, which is painful for the person who's going through it—there's no question about it, and they're seeing their health care professional—or something you need to know about, as we talked about, under the criteria for a serious adverse event where it's a life and death situation? This is the philosophy we're talking about.

In terms of the health care professionals, you asked the question about enforcing it. It would create another burden on these doctors and health care professionals who are on the ground. We don't have enough of them in this country and worldwide. How do you encourage that, to report without—

● (1220)

Mr. David Tilson: If they prescribe the drug, I would think they'd be concerned about who told them to prescribe the drug, which gets to the issue of whether Health Canada.... Health Canada approves the drug, presumably.

Ms. Meena Ballantyne: Yes.

Mr. David Tilson: Then I don't know whether they have a guide or whatever you use that goes to the docs or the manufacturers. I assume you do.

Ms. Meena Ballantyne: Yes.

Mr. David Tilson: So they're tied into it already. I made the smart remark when Ms. Davidson was talking that if you have a problem that's serious enough, you call your lawyer. So what actions should a medical practitioner take? Surely they have an obligation. If there's a reaction.... It may not be the drug. It may be just that the particular person can't deal with that issue, but it may not be. Otherwise nobody will ever know if they don't do it, if they don't feel like it, you know, because it's a cloudy day out.

I just don't understand that.

Ms. Meena Ballantyne: You're right, there is a jurisdictional issue. As we all know, this is the practice of medicine, which is under provincial and territorial jurisdiction. I think the movement is that we're all trying to work together. The health care professional community, the industry, all levels of government, in terms of saying let's work together, collect as much information as we can; let's start somewhere where we can see how it works. As I said, there is a movement afoot in some of the provinces and territories to try to collect this information, get everybody to report this without assigning individual blame, taking a systems approach to health care.

Mr. David Tilson: I'd like to move to another area, and that has to do with cross-border shopping and other jurisdictions. It's been briefly mentioned in some of the issues that have been raised here. I am thinking particularly about the United States and the number of drugs that come across the border that people have access to.

Can you talk about that? It was mentioned already, but I would like you to elaborate on it.

Ms. Meena Ballantyne: In terms of the volume?

Mr. David Tilson: I don't know, someone gets on the Internet and calls Michigan and says send me such and such drug, and then it gets over here and there's a problem.

Ms. Meena Ballantyne: I don't think we have anybody here who can talk about the cross-border drug issue.

Mr. David Tilson: I assume that a health professional has recommended a particular drug and said that they can get it down in New York State. I don't know. I just know there is a certain exchange, and there has been an issue in the past number of years about people acquiring drugs on the Internet. I wonder whether that's another problem that Health Canada has had to deal with.

Mr. David Lee: There are probably a number of legal issues travelling through that conversation, and we would want to be very accurate with you.

Mr. David Tilson: So we're not going to talk about that.

Ms. Meena Ballantyne: We could provide you with some information, if you wish, at a later date.

Mr. David Tilson: No, that's all right. If you think of something, send it to the committee.

Ms. Meena Ballantyne: Okay.

Mr. David Tilson: In your presentation you talk about two new regional adverse reaction offices. Can you tell us where they are?

Ms. Meena Ballantyne: Alberta and Manitoba is where they are. So we have one in every province. I think there's one for all of the Atlantic.

Mr. David Tilson: So they are right across the country?

Ms. Meena Ballantyne: Yes, there are seven of them now.

Mr. David Tilson: What happens at those offices?

Dr. Chris Turner: They're primarily responsible for two big jobs. The first is to collect and process the initial adverse reaction report from their local area. Second is to promote and encourage reporting in the area.

A third one is perhaps encouraging appropriate use of adverse reaction information, because people tend to abuse it, for example the media, which tends to sensationalize it and scare Canadians away from using products that may actually be beneficial to them. There may be an issue with the subpopulation, etc., but they don't adequately explain it and put things into context.

So they have a huge job in working with their local constituencies to submit those reports to the national database.

● (1225)

The Chair: Thank you, Dr. Turner.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you, Madam Chairperson.

I want to try to zero in on what specifically the government is proposing with respect to this new approach around post-market surveillance, because I don't get those specifics from the paper, other than some talk about a life cycle approach.

I'm wondering what mechanism is in place or is being contemplated that will provide independent assessment of a drug, or any product, once it is on the market. Or is it all industry based? Is there any proposal for an independent post-market surveillance body?

Ms. Meena Ballantyne: We currently have an expert advisory committee on the vigilance of health products, which has just been struck a few months ago, which includes patient-consumer groups and health care professionals. They're there to provide advice to me in terms of post-market surveillance issues related to health products. This is a new expert advisory committee.

Ms. Judy Wasylycia-Leis: Yes, but that's a body that's not going to look at the actual drugs or the products and provide independent advice. I am asking, in terms of this whole scheme you've given us of the life cycle approach, where the independent analysis is. Once a product reaches market and there are problems identified, what do you do? Who is doing it?

Ms. Meena Ballantyne: I'll let David answer in a minute, but I was going to say that what we've said, and encouraged, and put on our website in terms of inviting public input into policy-making, into decision-making, is one way of doing this. We have a whole marketed health products directorate, which Dr. Turner heads up, which is designed specifically to make sure we monitor the situation, we strike expert advisory committees as needed when we hear of signals—

Ms. Judy Wasylycia-Leis: Okay, but you're not getting my question, which is this. For consumer safety, there has to be a body that is independent of drug companies. Anyone with a stakeholder interest, who actually has a role in assessing the adverse reactions of drugs or whether or not this drug should stay on the market, should be pulled. I don't see that anywhere in this scheme of things, anywhere.

We used to have an independent drug research bureau. We don't have that. We were told, oh, we're going to give this to third parties, universities. I remember that coming from the Minister of Health. I've never seen any evidence of a body being set up.

You've now presented us with this new framework and this new plan around a life cycle approach. Where is the independent analysis, pre- and post-market?

Mr. David Lee: Could I start with the first part of your question, which is, what are the precise instruments we're actually talking about?

What we've been proposing over the last years is an array of tools, and they include, for example, an ability to get companies to do studies, but others to do studies too. In terms of requiring changes on label, making sure that we have nice clear powers...and that's really the information about how to use the drug.

Reassessment. Reassessment is a really important component. In Europe, for example, they require reassessment every five years for every product. It's hard to know, after five years, what you now know about a drug right across the board. So what we're trying to do is study that tool, for example, and figure out how from a data point of view, how from a safety point of view, it is valuable to do a reassessment.

Those are the kinds of tools that we're studying, how they work in other jurisdictions, and then coming back and talking to Canadians —patient groups, academics, and others—about how those tools could work. So once they're hooked into the licensing situation, and you can make them obligations on market and then bring them back into our analysis, that's really where we have this conversation going on. So there are precise tools that you can lay in to do that.

I mentioned pharmacovigilance plans and risk management plans, which are commitments you make—

● (1230)

Ms. Judy Wasylycia-Leis: That's great, but you're not looking at an independent body at all, free of any market, free of any drug company influence.

Go ahead.

Mr. Michael Vandergrift (Director General, Policy, Planning and International Affairs Directorate, Department of Health): The federal government has been working with provincial and territorial colleagues, as well as networks of academic centres, in developing what's been called a real world drug safety and effectiveness network, which will be used to collect data about real world impacts, tapping into administrative databases and the like. There has been a business case developed on that. That's under continuing discussion between governments, with hopes to advance that. That would also form another source of data that can be used and tapped into by the regulator in terms of looking at real world impacts of pharmaceuticals.

Ms. Judy Wasylycia-Leis: To help us, then, is it—

The Chair: Thank you, Mr. Vandergrift.

I'm sorry your time is up, Ms. Wasylycia-Leis. My apologies.

Mr. Fletcher.

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

I'd like to thank the guests for coming. I'm going to try to rapid-fire my questions so that I can get them all in.

What I'm hearing from my colleagues is really the balance between risk and benefit. If you have an approval process that's too long, there would be an adverse event in not providing access to drugs to the people who need it. That's a bad thing in itself, but you don't want it to be so fast that you're putting the population at risk. That's a tough thing to do.

The Standing Committee on Health just completed a study on the common drug review, as I'm sure you all know. What role, if any, would you expect the common drug review to have in relation to the life cycle of any particular drug, and what effect will Health Canada's proposal with the life cycle approach to drug safety have on the common drug review?

As well, how do you propose to deal with different indicators? Once a drug is in the market and it's found to help another ailment, how does that work? And how do you propose to deal with those types of situations?

Ms. Meena Ballantyne: In terms of your first point, about balancing the benefits and risks of any health product, you're absolutely right that it's a call we make in terms of providing timely access to innovative products but also assuring health and safety first and foremost.

That leads into the CDR. We are currently in the process of reviewing the standing committee's report on CDR. We are taking a very serious look at that, looking at the linkages between your recommendations and this new approach that is being proposed, because there are some linkages. We will be tabling that before the April deadline.

In terms of the CDR, absolutely, the access and timely access to products is what CDR is most concerned with. We look at safety, quality, and efficacy. CDR basically takes that information and puts in another criterion, which is, as you know, the cost-effectiveness. We need to look at that very closely in terms of how we build that into the life cycle approach as we move forward. At this time, I am not able to provide you with a precise answer on that.

Your third point asked what we do once a drug is on the market and is used for another purpose. I'll invite my colleagues to speak to that, but my understanding is that it would have to come back in, because if it's being used for another purpose then that really is off-label use. The company would have to resubmit it through the regulatory process because it is being used for another purpose.

I know that off-label use, particularly in the case of children, where this is.... We know that the clinical trials are often done on adults. Sometimes some of these medications are provided to children without adequate testing being done. That is off-label use, which poses its own challenges. We need to look at that.

I'd like my colleagues to add to that, if they wish.

● (1235)

Mr. David Lee: I would just add that in advancing the large framework, we've been trying to be very mindful about how the rest of the system works. This has been urged on us by many participants. We have been in close conversation with CDR about just what data they use and what we need to look at to make sure that there are no slippages in the system and that we all understand at least our own roles and the extent to which we can be efficient together as decision-makers or as people who recommend decisions.

We've been trying to do this very close analysis together. I think that was one of the things the committee urged us to do. We're trying to understand how to have earlier conversations to make sure we get a lot of efficiencies built into the system.

Mr. Steven Fletcher: Do I have time for another question, Madam Chair?

The Chair: I'm sorry, Mr. Fletcher, there are only about three seconds left.

Mr. Steven Fletcher: In three second or less, since the last report of the standing committee on “Opening the Medicine Cabinet”, what has Health Canada done?

The Chair: I'll let you briefly answer that.

Ms. Meena Ballantyne: The documents we've tabled today have really benefited from the Standing Committee on Health's report, in a number of areas. So in that 30 seconds I would say that the blueprint for renewal, the new action plan that is being tabled and proposed, has benefited from the work of this committee, and we're very grateful for that.

The Chair: Thank you, Ms. Ballantyne.

Mr. Temelkovski.

Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.): Thank you very much, Madam Chair, and thank you to the presenters.

Crime Stoppers has a number to call; Neighbourhood Watch has a number to call; whistle-blowers and Pizza Pizza have numbers to call. Is there a number to call regarding adverse reactions?

Dr. Chris Turner: There is a toll-free phone and fax line, and soon there will be postage-free mail-ins. If they are Internet savvy, there is also an online reporting form.

Mr. Lui Temelkovski: Is it advertised outside of the regular partners, which are hospitals, doctors, pharmacists?

Dr. Chris Turner: It's widely advertised. MedEffect promotes it. MedEffect is linked through some 400 other sources, so there are those sorts of electronic outreaches. As well, it's advertised in various professional journals. And a lot of our consumer group partners also promote the access with their patient groups in their publications. So it's widely disseminated.

Ms. Meena Ballantyne: Part of our proposed action plan is to get more and better information out to Canadians. We've been doing a lot of work with health care professionals and with the communities, but we're trying now to reach out to Canadians much, much more.

Mr. Lui Temelkovski: Doctors report adverse reactions to Health Canada directly, and they also report them to manufacturers. Dr. Lee mentioned that doctors are nudged to report them and that pharmaceutical companies have a pre- as well as post-plan for reporting of adverse reactions. Is that the best way to have adverse reactions reported, to the drug companies, which vet the information and then send it to you? Or is there a better model, maybe going to you directly?

Ms. Meena Ballantyne: We're looking at the best way to get information about adverse events. For example, the manufacturers must report them—absolutely. That's mandatory. We're encouraging health care professionals and Canadians to report them. We're working with all our sources across the world to get data. With this new approach, we would try to get as much information as possible and attach it to the conditions of the licence so we could act if we needed to.

● (1240)

Mr. Lui Temelkovski: Can it be added to the doctors' licensing that they must report these? It becomes part of their training and part of their everyday job, that they have to. Some of the pharmacy people are telling me that due to privacy reasons, one Shoppers Drug Mart does not release information to the Shoppers Drug Mart next door, let alone to Health Canada or anybody else. I was also informed that one hospital does not even release information to another hospital unless they're comingled in one way or another.

Ms. Meena Ballantyne: That's absolutely right. There are jurisdictional issues with attaching anything to the licences of health care professionals such as doctors or pharmacists. This is a practice of medicine and pharmacy that is under provincial and territorial jurisdiction. We've been having discussions with them, because I think everybody recognizes that we need to do something. What's the best approach? Where do we start? What's practical, given privacy concerns, given the state of information technology in terms of being able to share these? These are all barriers to moving forward fast on this issue.

Mr. Lui Temelkovski: I have one other question.

All provinces have a health card, and our seniors have a health card, which is a federal card, I believe. Their medication is being paid for through federal funds, I'm assuming, through the seniors' medical program.

Ms. Meena Ballantyne: It's provincial.

The Chair: Mr. Temelkovski's time is up.

Is that your answer, Ms. Ballantyne? Is there anything else you would like to say?

Mr. Lui Temelkovski: That's fine.

The Chair: Thank you so much.

For just a moment, I would like to ask Ms. Dowthwaite a question. I know you've been listening very carefully, and there's just something I would like to ask.

Does Health Canada rely on HPFB inspectors only for post-market surveillance investigations, or are provincial or other inspectors used as well?

Ms. Diana Dowthwaite (Director General, Health Products and Food Branch Inspectorate, Department of Health): We primarily use our own inspectors, but we also have alliances, and we rely on information we get from coroners' offices, from the colleges of pharmacy that were talked about, and through our linkages with the RCMP and other regulatory authorities. We have 100 of our own inspectors across the country, and we rely on information we get to conduct those investigations and inspections.

The Chair: Could I ask what role the inspectorate plays with respect to improved post-market surveillance?

Ms. Diana Dowthwaite: As we talked about, as part of our inspection program, we go into different companies and verify that they have a system in place to do the adverse reaction reporting that's required. We also work with Chris's group. Remember we talked about signals? If a signal comes in and requires an investigation or an inspection, it moves to this side of the house, and then we come in, and we'll investigate or inspect the information and then decide if there's any compliance and enforcement action required as a result of that information.

The Chair: Thank you. You've been very helpful.

Ms. Davidson.

Mrs. Patricia Davidson: Thank you.

I want to go back to what powers the ministry has and what they don't. On page 5 of your presentation, you talk about the power to remove unsafe health products from the market, which is part of the legislative amendments you're looking at.

We've all heard about the warnings about drugs: you don't buy them; if you have any left in your cupboard, you take them back to the pharmacy or the doctor, and all these things. What happens to the product that might be remaining on the shelves? Who checks into that? Doesn't the Minister of Health now have the ability to recall a product?

Ms. Meena Ballantyne: Surprisingly no, the Minister of Health does not have any legislative authority to recall a health product at this point in time. What has worked in the past is that it's usually been in a company's best interest to recall a health product when something goes wrong. We've had very good success in terms of having, for example, a compliant pharmaceutical industry that is able to pull its products off the market.

But we need to be able to act quickly. The Minister of Health should have the authority. Every other country has it. On the food side we have it, but on the health products side we do not. With the proposed amendments to the Food and Drugs Act that we're talking about, which would represent the first time in over 40 years that we would be proposing to move forward, we would seek the legislative authority to be able to do that.

In terms of answering your question about who goes and checks whether these things are still on the shelves, it is the job of the inspectorate to make sure that any action we've taken is carried out. They would go out and make sure that's done.

We've been very proactive on the inspectorate side. For instance, we just did a customs blitz in a variety of centres across the country to see what was coming in. Maybe Diana could expand on that a bit.

● (1245)

Ms. Diana Dowthwaite: We did a customs blitz on the mail centres, just so we could have some statistical data on what kinds of parcels and drugs are coming across the border, and we're calculating that data right now, so I can't give you any information on that. But to follow up on Meena's point, it is a voluntary compliance, and the majority of the time the companies are complying. It's in their best interest to comply, and we do it as a compliance verification to make sure they've done the recall properly and that the product has been taken off the shelves.

Mrs. Patricia Davidson: Thank you.

The Chair: We have four speakers, and Mr. Thibault would also like to ask a question. We're going to run out of time, because we only have about 14 more minutes left, so I'm just going to make members aware of that. We'll go on to Madame Gagnon right now. So perhaps you could be considerate of each other, to allow Mr. Thibault time to intervene.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: Let me tell you about a rather worrisome case. I would like to know what kind of decisions you make when you learn, for instance, that some people have died after taking a drug or a vaccine.

In Europe, two people died after taking a vaccine against cancer of the cervix. Now we had a sizeable vaccination campaign here. Many people reacted because apparently, certain stages of the process had been skipped because they were in a hurry to put this drug on the market. In Europe, young adolescents died after being injected with this drug.

Your answers lead me to believe that you are never proactive and that you wait for serious or extremely serious situations to come up before reacting. In the example I cited, the stages preceding the marketing of the product were followed too hastily. In certain provinces, the stages which consist in detecting the undesirable side effects of the drug had not been completed. And then, two people died. Was that the cause? It raises some questions.

When people die and when, within a very short period of time, we succeed in connecting the deaths to the injection of the vaccine, don't you think that we should impose a moratorium? Right now, we are running a huge vaccination campaign with this vaccine, and it has been widely criticized. People feared the very things that happened.

How do you analyze the situation?

[*English*]

Ms. Meena Ballantyne: It's quite true we are reactive. We are trying to move toward a much more proactive approach. There's no question about it. So if we did get an indication of two deaths due to this vaccine, we would have to make sure we knew the cause and effect in this case, because—

● (1250)

[*Translation*]

Ms. Christiane Gagnon: Are you aware of that?

[*English*]

Ms. Meena Ballantyne: We would hope so.

[*Translation*]

Ms. Christiane Gagnon: Are you aware of that?

[*English*]

Dr. Chris Turner: Vaccine surveillance is done by the Public Health Agency of Canada, but they then liaise, in this situation, with the biologics and genetic therapies directorate in our branch, so they're—

[*Translation*]

Ms. Christiane Gagnon: Are you aware of the fact that two cases of mortality were reported by the European Agency for the Evaluation of Medicinal Products? It was on January 25.

[*English*]

Dr. Chris Turner: No, as I said, the monitoring activity my directorate does is not responsible for vaccines. That's monitored by the Public Health Agency. So I can't speak to whether or not they're aware of this at this point, but I would suggest—

[*Translation*]

Ms. Christiane Gagnon: It is really unbelievable that you are not in touch with... I was opposed to the Public Health Agency of Canada precisely because that makes two entities that do not seem to be communicating. Each one is working in isolation from the other. You are involved in post-market surveillance, and it is a public health issue. I can hardly imagine why there is no contact. I was opposed to this separation between Health Canada and the Public Health Agency of Canada.

[*English*]

Ms. Meena Ballantyne: I'd like to say that we might not be aware here, but we have a whole team of people who are scanning this, who are probably aware of this, and we can check into whether we know about it.

[*Translation*]

Ms. Christiane Gagnon: Many of the mothers who read the newspapers must be worried about this now. Some tests on young women aged from 15 to 25 had not been carried out.

[*English*]

Ms. Meena Ballantyne: But as you can.... If I may, Madam Chair—

The Chair: You were trying to answer.

Dr. Chris Turner: One of my directors from our area who is monitoring pharmaceuticals has just advised me the EMEA in Europe has issued a risk communication on this issue, so there is an awareness of it. But as I said, we're not primarily responsible for the monitoring of adverse effects for vaccines, so we wouldn't be responsible for that. But just as an aside, we are aware of it, if that gives you any confidence.

The Chair: Thank you, Dr. Turner.

Thank you, Madam Gagnon.

Mr. Tilson, go ahead.

Mr. David Tilson: Madam Clerk, is the Canadian Medical Association coming as a witness in the future on this topic? I'm going to talk about them.

The Chair: The clerk informs me that they are on the witness list.

Mr. David Tilson: A representative from the Canadian Medical Association sent me—I don't know what it is—a paper, purportedly by them, in which they talk about a number of topics, one of them being strengthening post-marketing surveillance. I have no idea the date of this. It was faxed to me on January 23, 2008. This is what they say:

> Currently post-marketing surveillance of drugs in Canada is inadequate, relying on reporting which is often erratic and inconsistent, and for which reporters are not compensated. Canada needs a coordinated post-marketing surveillance system to monitor the ongoing safety of marketed drugs. Surveillance should include medication incidents and adverse drug reactions, and should document and consider the effect of the "systems factors" contributing to these events.

Of course, I don't want you to repeat what you've spent the last two hours talking about, but have you got anything to add to this? I assume they're going to come. I assume this is a reliable piece of paper I have and that it's accurate, so if they're going to come, they're going to say this.

The Chair: Mr. Tilson, they are invited for February 26. They have not confirmed yet, but that invitation is there.

Mr. David Tilson: Well, if this is correct, if this is their statement, could one of you comment on that? It's like an opposition statement.

The Chair: Yes, go ahead.

Mr. Michael Vandergrift: I'd say that's precisely what we're striving to do, to have a more coordinated approach to post-market surveillance activity, and as Dr. Turner was mentioning, that's a combination of increasing reporting of serious adverse drug reactions, but also doing things like working with data sets that exist at provincial and territorial levels, data sets that the Canadian Patient Safety Institute is developing, and data sets that CADTH, the drug and health technology assessment agency, has. So it's a combination of recording and data coming in, but also proactively mining data sources that exist. That's how you can get a better and more complete picture of what's taking place out there.

● (1255)

Mr. David Tilson: The answer that was just passed to you there, what does that say?

Mr. David Lee: I'd just add that ongoing surveillance of this nature is really very key to our life cycle management. I mean, this is why we're asking for these tools, to be able to coordinate.

Mr. David Tilson: Yes. In other words, you're acknowledging some of these things and you're saying you're trying to improve on them.

Mr. David Lee: Absolutely.

Mr. David Tilson: I have one more question. What do they mean by "reporters are not compensated"? What does that mean? Do you know what that means?

Ms. Meena Ballantyne: I don't know if that means the health care professionals who might be reporting it. I'm not sure. I think that's what they mean.

Mr. David Tilson: Okay. Well, they're going to come—if they're going to say this and elaborate on this, some day I'd like the ministry people to respond to this. I don't know how we do that.

Thank you.

The Chair: Perhaps, Ms. Ballantyne, we could put that question aside and see if we can get an answer to that to clarify. That's a very good question, Mr. Tilson. I'm sure the committee would like to have some...perhaps, Mr. Tilson, if you could write that up, we could pass it on and share it.

Mr. David Tilson: What?

The Chair: Your question.

Mr. David Tilson: Well, it's on the record. They can read it.

The Chair: All right, there you go.

Do you have anything else? You have one more minute, Mr. Tilson.

Mr. David Tilson: Really?

The Chair: You do.

Some hon. members: Oh! Oh!

Mr. David Tilson: No, I'm going to pass and give my time to Mr. Thibault.

The Chair: Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you very much.

I have a couple of questions. I still want to allow Mr. Thibault—

The Chair: We have two more people.

Ms. Judy Wasylycia-Leis: Maybe we could go 10 minutes after the hour?

The Chair: If we do it quickly, we can have you, Mr. Fletcher, and Mr. Thibault.

Ms. Judy Wasylycia-Leis: At the same time as the committee is dealing with this process, the government is fast at work putting in place draft legislation to revamp the entire the Food and Drugs Act. In fact, at a briefing on January 24, just a couple of days ago, Ms. Ballantyne actually said that the government is pushing this through as quickly as possible.

One of the premises of that legislation, as you presented it at that briefing and as we've seen in previous attempts, is to remove the legal basis that now underlies the Food and Drugs Act, which is now a criminal law, whereby the Government of Canada has the absolute obligation to ensure that drugs and food and water and products that are on the market are safe beyond a reasonable doubt.

I'm wondering if you could tell us your timeline so we could fit that into our work. Secondly, could you give us a draft of that legislation—you obviously have one now—or some framework we could look at, so we'll know as you're proceeding with this what's on your agenda and how we can fit that into our work? We assume that is something that will be considered by the government and not used as wrapping paper.

Ms. Meena Ballantyne: Madam Chair, I'd like to just clarify that regarding the timelines for this, as we've talked about, this committee had a report. We've had a blueprint for renewal. We've had consultations over the last few years that have led us to the point we're at now, which is that this government has tabled the action plan to amend the Food and Drugs Act.

So it hasn't been a rapid evolution. This has been coming over the past few years. There's been consensus built up in this country, from every source, that this is the right direction to go in and that we need to modernize and strengthen our health and safety regime in this country.

We are currently in a 30-day consultation phase in which we're seeking input from everybody. As we all know, the legislation will make its way through the system, and I'm sure we'll be back here talking about the legislation.

Ms. Judy Wasylycia-Leis: Are we being included in your 30-day consultation period? Are you presenting us with your plan and asking us for advice?

Ms. Meena Ballantyne: The plan is the discussion paper that's on our website. We've talked today about the actual—

Ms. Judy Wasylycia-Leis: But I think there needs to be a different relationship and a different request when you're dealing with the health committee. I think we should have formally been informed of your plans at the outset, and we should have made provision for some way to actually give a submission as the health committee, if that's possible, to your plans.

In fact, Madam Chairperson, you should know that this is legislation that has been before the committee before, five years ago, ten years ago. We had a copy of it. It was Bill C-80. It was vetted, people reacted, and as a result, the government buried it. Now they're trying it again. I think we have to avoid having this sort of snuck onto the agenda, and we have to have a full clarification of what the government's plans are with respect to revamping the Food and Drugs Act.

● (1300)

The Chair: Thank you.

Can we go to Mr. Fletcher now?

Mr. Steven Fletcher: Yes.

You're more than welcome to tailor your private members' bills if you have any on this. I'd like to assure the member that the Government of Canada doesn't use wrapping paper. It's very wasteful.

The fact that this committee is looking at this issue is going to be very helpful for the government in developing whatever's being developed. The member will be very well aware that there is a parliamentary process when it comes to legislation. It's introduced to Parliament, and in the second reading there's a vote, and then there's a review, and then a third reading. That is how it's been done since Confederation. I'm sure the member doesn't want to disrupt tradition.

I think those are all my comments, Madam Chair. I'll pass it on to Mr. Thibault.

The Chair: Time is really up, but is it the will of the committee...? Could we please give Mr. Thibault a minute to ask a quick question?

Will you be brief?

Hon. Robert Thibault (West Nova, Lib.): Yes, I will be very brief.

The Chair: All right, if you can do that, we'll do it very quickly. We ask our presenters to answer as briefly as they can, because we have other duties we have to get to.

Mr. Thibault.

Hon. Robert Thibault: Thank you.

If you can't fully answer, then perhaps you could submit....

Building on Mr. Fletcher's point, I'm pleased about the progressive licensing, where we can get out breakthrough drugs as quickly as possible to benefit...and then we continue. But this brings about the problem of off-label use, which could be of great benefit to patients and to the medical community. Because of its use, it doesn't lend itself to adverse event reporting.

I hope you can find a way to marry the two proposals, permitting off-label use and doing the progressive licensing so they can be brought in.

Mr. David Lee: Thank you.

We're very sensitive to this discussion. We want to make sure we have the most responsible treatment there.

One of the problems with off-label is that you lose the information once it's on market. So you want to do your best by the drug whether it's on- or off-label, frankly. We need to work a lot with the prescribing and dispensing professions to do that. Again, we want to bring a lot of responsibility to that issue.

The Chair: Thank you so much.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: On a quick point of order, Madam Chair, given the fact that the revamping of the Food and Drugs Act is so intertwined with what we're studying in terms of post-market surveillance, what assurances can you give us that what we're doing has any meaning if in fact the government is on a deadline and a schedule of a 30-day consultation period and is bringing forward legislation? How can we have a meaningful role in that when in fact our schedule goes much beyond 30 days?

The Chair: Mr. Fletcher.

Mr. Steven Fletcher: On the same point of order, I think this is for the steering committee and the members engaging in debate. So perhaps we could leave it up to the steering committee and the chair's discretion.

The Chair: I have to say that it really is not a point of order, but I thank you for your comments.

I want to thank our presenters for coming today. We very much appreciated your presentations.

The meeting is adjourned.

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