House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 026 • 2nd SESSION • 39th PARLIAMENT

EVIDENCE

Thursday, May 1, 2008

Chair

Mrs. Joy Smith

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● (1105)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Order, please. I'd like to welcome everyone to the 14th meeting of the Standing Committee on Health. Pursuant to Standing Order 108 (2), we are doing a study on post-market surveillance of pharmaceutical products.

Today we have a full complement of presenters, and we have a full complement of questions for all our presenters. We will give each organization 10 minutes to present. Following that, we will go into the questions and answers.

From Health Canada, we have Mr. Michael Vandergrift, Dr. Marc Berthiaume, Dr. David Clapin, and Mr. David Lee; from the Public Health Agency of Canada, Dr. Barbara Law; and from the Ontario Ministry of Health and Long-Term Care, Mr. Brent Fraser. Also on the list we have Dr. Bruce Carleton from the University of British Columbia. Welcome.

I will ask each organization to take 10 minutes. We look forward to hearing from you.

We will begin with Dr. Michael Vandergrift.

Mr. Michael Vandergrift (Director General, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Department of Health): Thank you very much, Madam Chair, for the opportunity to appear in front of this committee again.

We appreciate the opportunity to return to discuss the issue of post-market surveillance. I know this committee has heard from many excellent witnesses, and we're pleased to appear again to provide additional highlights of our work in this area and to respond to any questions you have.

I'd like to turn it over to Dr. Marc Berthiaume to take us through the opening comments. Dr. Berthiaume is director of the marketed pharmaceuticals and medical devices bureau in the marketed health products directorate at Health Canada. As such, he works on the front lines of post-market surveillance of pharmaceuticals and medical devices. In addition to his duties at Health Canada, Dr. Berthiaume is a physician who continues to practise medicine on a part-time basis.

[*Translation*]

Dr. Marc Berthiaume (Director, Marketed Pharmaceuticals and Medical Devices Bureau, Marketed Health Products Directorate, Health Products and Food Branch, Department of Health): Good morning.

All marketed health products have risks associated with their use. Prescription drugs, over-the-counter products, biological, vaccines, medical devices and natural health products all have risks. Some of these risks are known at the time of market authorization, but we also know now that additional information about risks can only become known once the product is more widely used. Regulators around the world, including Health Canada, are now working to build into the system improved capacity to gather and use this information to protect the health and safety of Canadians. This is not a failing of the system and these issues are not unique to Canada.

The strength of our post-market surveillance system, like others, is largely, and quite rightly, determined by how quickly it can identify new risks and how efficiently it can act to mitigate them. Significant improvements have been accomplished in the past few years in these two areas.

The risks of a drug should not be considered in isolation. It is important to always consider the balance between potential risks and potential benefits. This principle applies to the full spectrum of health products from over-the-counter medicines to prescription drugs.

● (1110)

[*English*]

Another important concept when analyzing adverse drug reactions is that they occur as an interaction between a drug, a patient, and the environment, which speaks to the fact that adverse drug reactions have more complex causes than just the drug by itself. For example, a study published in JAMA in 2006 concludes that cases of unintentional overdose or drug misuse account for more than half of drug-related admissions.

Most of the serious adverse events causing hospitalizations are known, well described, and associated with drugs that have been on the market for long periods of time, such as blood thinners, painkillers, insulin, and penicillin-like antibiotics. These potential risks are well known and factored into the decisions of practitioners when they prescribe that specific medication. According to the study mentioned earlier, 16 of the 18 drugs most commonly causing emergency visits for adverse drug reactions have been in clinical use for the past 20 years.

Appropriate prescribing also requires that the risk of a drug be weighed along with its benefits—for example, the number of lives saved or the number of years of increased life expectancy. If a patient has a sustained irregular heart beat, their likelihood of experiencing a stroke is 3% per year, which could lead to death, paralysis, or other serious outcome. To prevent a stroke, a powerful blood thinner called Coumadin is used; it has a known risk of 1% per year for serious gastrointestinal bleeding. The risks of this drug are real, and a significant number of hospitalizations due to life-threatening bleeding caused by Coumadin are documented every year, but this does not that mean that the risk is unacceptable, given the number of strokes prevented. Clearly, good population-level decision requires more than considering drug risks in isolation.

Pharmacovigilance and pharmacoepidemiology are rapidly evolving fields. The changes that Health Canada is proposing to the regulatory system are designed to bring Canada's regulatory system on par with the best in the world. Like other regulators, we are moving to add to the value provided by adverse reaction reports and work towards more systematic receipt and assessment of additional post-market safety studies and other data.

Over the course of this study, concerns have been raised about the need for independent post-market review. Since its creation in 2002, the marketed health products directorate within the health products and food branch has coordinated post-market surveillance and disseminated product safety information. MHPD scientists providing independent scientific evaluation are distinct from scientists who authorize products for market, and the directorate has a budget separate from those parts of Health Canada responsible for pre-market review while at the same time ensuring effective communication throughout the regulatory life cycle of the product.

Since its creation, MHPD has been providing independent assessment and consistency in safety standards, methodologies, and risk messaging to stakeholders; ensuring distinct resource use by dedicated post-market surveillance staff to optimize operational requirements and accountability; enabling patients to take more responsibility for their health product decisions through increased access to reputable and credible risk messages; and putting increased emphasis on post-market monitoring, review, and risk management.

Health Canada made a clear commitment to independent post-market surveillance with the creation of the marketed health products directorate. We have recently issued a five-year post-market surveillance strategy on the MedEffect Canada site on the Health Canada website, and copies have been provided to you today. This five-year plan outlines how Health Canada will continue to evolve post-market surveillance activities in line with new sources of credible safety information and in line with international standards.

The strategy includes a number of key objectives, such as integrating new sources of Canadian and international information, developing international and national partnerships to facilitate work sharing, and implementing a new state-of-the art information management system to improve signal detection and adverse reaction data analysis, including integration of adverse reaction reports throughout the product life cycle.

Within that strategy, one of our objectives is increased use of external expertise to supplement the scientific and medical expertise of Health Canada staff. Health Canada has created an Expert Advisory Committee on the Vigilance of Health Products, which provides advice on post-market policies and programs related to the vigilance of health products. The committee includes a mix of expertise and experience, with members representing patients, consumers, the health and industry sectors, researchers, and academia.

● (1115)

Health Canada also brings together external scientific advisory committees to contribute to the analysis of post-market safety issues on specific products or classes of products. This process was used recently to examine safety issues related to the product Avandia. We want to benefit from and contribute to the broad range of expertise available in Canada for the benefit of Canadians, and we are confident that in doing so the quality of the decisions we make about the risks and benefits of products will be enhanced.

I would like to take the opportunity to highlight three key operating principles that guide our work.

The first is the precautionary principle. This principle is incorporated into our decision-making and grounded in the integrated risk management framework. When we have a significant safety signal, we can and do take action, even in the absence of definitive evidence. A range of actions can be taken, from issuing risk communications to removing market authorization. The choice is determined by the seriousness of the risk identified, the potential for harm in the Canadian population, and the potential ability of the health care system to manage that identified risk if there are also potential lifesaving benefits.

The second operating principle is alignment with the best international practices. There is tremendous value in aligning our terminologies, guidances, and regulations. This facilitates our information sharing and work sharing with other regulators. In support of post-market surveillance, Health Canada has developed information-sharing memorandums of understanding with numerous foreign regulatory agencies and is active in many international initiatives, such as the International Conference on Harmonization, the Council for International Organizations of Medical Sciences, the Global Harmonization Task Force for medical device harmonization, and the WHO, to name a few.

Safety issues that occur in Canada are not typically different from those in other countries, and given the size of the Canadian population, new risks may not be identified in Canada first. Many signals are identified in international studies, as was the case for recent regulatory actions concerning Prexige, Vioxx, and other drugs. Our strong relationships with other regulators allows Canadians to benefit from timely global information sharing and response.

The final key operating principle that governs our work is shared responsibility. Health Canada is only one player in a complex, interdependent, integrated health care system. I would highlight that scientists of the branch are working with various organizations, such as the Canada Health Infoway and others, to leverage advantages in the Canadian health system regarding gaining usable access to the future electronic health record as a source of adverse reaction and other related information, for example.

As you are aware, health care in Canada is delivered by the provinces and territories. Therapeutic choices are made daily by health care providers and Canadian consumers. Health Canada does not regulate the practice of medicine, but strives to provide timely information on the risks associated with marketed products to facilitate the best therapeutic choices, as well as regulate the industry that has a responsibility for selling safe and effective products and informing stakeholders about information concerning the products they sell.

In giving life to these operating principles in our work, our goal is always to better respond to safety issues when they arise, and to fulfill our fundamental role in safeguarding the health and safety of Canadians.

I would like to thank the committee for the work it is doing to support us in this regard. We would be pleased to provide clarification and answers to questions from the committee, and we look forward to the committee's recommendations.

The Chair: Thank you so much, Dr. Berthiaume. I appreciate your insightful comments.

We'll now go to Mr. Brent Fraser.

Mr. Brent Fraser (Director, Drug Program Services Branch, Ontario Ministry of Health and Long-Term Care): I would like to thank the Standing Committee on Health for the opportunity to discuss post-market surveillance in the pharmaceutical sector.

I am the director, Ontario public drug programs, with the Ministry of Health and Long-Term Care, and I assist in managing the Ontario drug benefit program, a drug reimbursement program primarily for seniors, social assistance recipients, and individuals with high drug expenses in relation to income.

I am also the co-chair of the national pharmaceutical strategy working group on real-world drug safety and effectiveness. Part of the mandate of this NPS working group was to look at opportunities to build upon post-marketing surveillance in Canada and the body of evidence that is being done in various research sectors to determine if there are opportunities to coordinate this work and improve collaboration across Canada.

Direction is still being sought from ministers regarding the NPS work. Therefore, the focus of my comments today will be primarily from a provincial drug plan perspective.

As noted in the terms of reference for the standing committee's study on post-market surveillance, there are a number of key issues that are very important with respect to the reimbursement of drug products as benefits under a provincial program, including monitoring a drug product's use, consumer safety, public access to information, and adverse drug reaction reporting.

Products are listed on the Ontario drug benefit formulary based on recommendations from the Canadian Expert Drug Advisory Committee, part of the common drug review; and the Committee to Evaluate Drugs, Ontario's expert advisory committee. Final decisions are made by the executive officer, Ontario public drug programs.

One of the key areas that are raised during a drug product's review by our clinical experts is how the product will be used in a real-world environment, compared to published studies that are often the basis of their recommendations. Drug studies are controlled environments, and there are many restrictions, including when and how the product is administered, patients who are eligible for the trial, and limits on what other medications the patient may receive during treatment.

This environment limits the ability of our experts to make recommendations on what is the appropriate place of therapy for a new drug product or indication. Very few studies do head-to-head trials with other drug products, so we do not have a clear understanding of the overall effectiveness and safety profile compared to other products that may be used to treat similar conditions.

In addition, this does not tell us how the product will be used in the real world. For example, are there higher risks associated with the product in certain patient groups, or is the product more effective for some individuals? Is it better to try other medications first, before moving to other products that have less solid evidence of clinical effect?

Some of the newer products coming to market may rely on surrogate markers as evidence of effectiveness. These markers are often used as a proxy. It may be assumed that a change in a marker is an indicator of clinical effect or outcome. This is particularly challenging because we often do not have the evidence to show the direct linkage between the surrogate marker and the outcome that's presumed.

If there is more reliance on this type of information to support access to new drugs and the drug approval process, post-market evaluation will become increasingly more important. la addition, there will be a need for long-term outcome studies to validate the clinical effects.

Once a product comes to market, manufacturers seem reluctant to complete these types of studies. As a result, we are often caught in a situation where the expert advisers do not have the right information to make recommendations for listing on the formulary, and manufacturers are not encouraged to complete longer-term studies to validate the initial findings upon gaining market approval.

It is imperative that data collected to support post-market research is beneficial for federal and provincial bodies. Although our roles are different, there is often a common link in the type of data that is required to assess drugs post-market. We would encourage manufacturers to continue to work in this area, as this is critical information that will be used by all sectors.

There are many examples of drug therapies that have had unexpected or negative effects when introduced to market. Some of these effects may be seen as a result of persons taking products for prolonged periods of time, well beyond the typical clinical research study period. In addition, these types of experiences will help validate some of the clinical effects that may have been assumed during the review process for new drug products and listing on provincial formularies.

● (1120)

Data collection and analyses are often done individually within different research centres across Canada, and the results of this work may not be communicated broadly. At this time, no organization has been given the mandate to collect and analyze these data. There may also be a lack of individuals who are trained in this area.

Funding to support research programs and linkages among those programs may help to reduce or eliminate duplication of research. It may also help to enrich the data that is collected by including a broader range of participants in the studies. This could be considered as an initial step to funding a larger centre and may help ensure that functions to support these programs and linkages to other national bodies involved in the drug review, funding, and monitoring processes are established with minimal overlap of functions. At this time, some stakeholders are looking at these opportunities to see how some of these networks could be established in Canada.

It is also important for us to clearly understand what information should be collected. Observational data is important for us to understand how broadly products are being used, and they may point to certain risks or concerns. But it may not be specific enough for one to know the actual impact of the drug, and this can create confusion within the marketplace.

The establishment of complex registries to collect data may provide the detailed information required to fully assess a drug post-market, but it will have a significant impact on resources required to collect this information.

The other important factor is timeliness of information. It is not enough to collect this information if the results are not disseminated in a timely manner so previous decisions regarding reimbursement of a drug can be re-evaluated if necessary.

In conclusion, as this work is developed it will be important to consider the impact on all stakeholders, including patients, health care professionals, manufacturers, researchers, governments, and others. A balance needs to be created to ensure that data is collected in a timely and accurate manner but does not overburden the health care sector.

Once again, I would like to thank the standing committee for allowing me to address you on this important issue.

● (1125)

The Chair: Thank you very much, Mr. Fraser, for your presentation.

We will now go to Dr. Carleton.

Dr. Bruce Carleton (Senior Clinician Scientist, Child and Family Research Institute, BC Children's Hospital, University of British Columbia): Good morning, Madam Chair and members of the committee. Thank you again for the opportunity to speak to you.

I would like to reiterate a couple of brief points that I made the last time, but I won't dwell on those. I'm hoping that you read the transcript of comments instead.

The first point is that adverse reactions are a major public health issue, but our regulatory system does in fact prevent most unsafe drugs from being on the market. The difficulty is in heterogeneic responses to drugs, the differences in the variability in response that we all have. I believe last time I presented the example of a skin reaction in which the skin of this young baby fell off as a result of ibuprofen—Motrin, Advil. This is a product that is used repeatedly by people without any particular trouble—I use it myself without problems—but some people do have such a significant reaction. The difficulty in improving safety is that these reactions are not necessarily predictable and they don't occur in large numbers. Finding solutions to these safety problems and allowing drugs to continue to be used when they're effective and they're not unsafe is really the crux of the problem. Addressing this public health issue requires an understanding of response heterogeneity and understanding that we have different responses.

An article published in the *Journal of the American Medical Association* in 1998 suggests that adverse drug reactions not due to error or abuse are in fact the fifth leading cause of death in the United States. This is a very significant problem, and we need ways to address it.

How do we address a problem that occurs in some and not in all? Every drug is different. Some people have reactions to one drug and not another. I believe that a key in this is to understand the role that human genetics play in the difference in response, and that's the context in which I'm speaking to you today.

My work and the work of Dr. Michael Hayden, the geneticist I work with, is about understanding drug response and linking clinical pharmacology and human genetics. When drugs enter the body, there are four basic steps that they go through: they're absorbed, they're distributed, they're metabolized into active or inactive constituents, and they're excreted. Those four steps are controlled by genes. If we understand which biotransformation step results in a toxicity problem—in an adverse effect—we can also understand what genes might be responsible for allowing that particular occurrence. In fact, as I reported last time, Dr. Hayden and I have discovered the genes for three serious and fatal reactions.

We believe this work has tremendous value worldwide. These are drugs that have been used for many years, as my colleagues from Health Canada have stated. The drugs that are currently on the market are also a problem. It's not just the new drugs that are a problem; it's the ones we've been using in cases for 50-some-odd years. What we want to do is to use this new science of pharmacogenomics, combining clinical pharmacology and human genetics, to understand drug response, and then to use that to develop predictive tests to prevent adverse reactions in people who are most likely to experience them—or at least we should know, before we begin therapy, in whom the most serious reactions are likely to occur. If we do this properly, it will happen one drug and one patient at a time.

The technology is rapidly decreasing in cost. The research is building to show this is of value. The Food and Drug Administration in the United States is already recommending genetic testing for at least three drugs and three specific reactions, one of which was our discovery, as part of the network that was funded with Genome Canada money that developed this work, and we're very excited to move this particular area forward.

● (1130)

I'd like to say, finally, that all Canadians, all stakeholders in this process—from pharma, government, and industry to patients, clinicians, and academics—want safer drugs. Everybody wants that. This is an opportunity for us to move forward with a common goal, and we have the national health system to support this. I can't emphasize enough the work that I do internationally with different groups who suggest that in their countries they just can't do what we're doing. We have created an opportunity here. We've embedded our work within the health system in Canada. We've used clinicians to find reactions. By the end of this year we'll have more than 10,000 adverse drug reaction reports and controls that are critical to understanding the differences between people who respond negatively to drugs and those who don't. That work will allow us to move forward on a great many other targets to begin the development of predictive diagnostics to help clinicians make better choices for safer drugs for Canadians in the future.

Thank you very much.

The Chair: Thank you, Dr. Carleton.

We will now proceed to our questions. We will begin with Mr. Thibault.

This is a seven-minute round, Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): Thank you. Please advise me when there are only 10 minutes left.

The Chair: I'll advise you when there are five minutes left, Mr. Thibault.

Hon. Robert Thibault: You've given me a lot to go on and a lot to follow up on. It's very difficult to do it in seven minutes, or even in one session.

I'm pleased to have you with us again, Dr. Carleton. You have brought to the committee one of the few solutions we've seen. A lot of people have shown us what the problems are, and I think we understand them. Some people, including you, have brought us elements of a solution.

I was watching some broadcasts on TV this week that were showing what Ontario is doing in the genetics of cancer. They're trying to be the world leader in getting the cancer genome and are suggesting there's more data in that set than in the whole human genome process. Once they can hold that information and make it available to the world, it might speed up therapies for cures for cancer.

What you're talking about reminds me of something similar that could be done that way. If we could have a proper network, with the work being done internationally and everybody doing bits of it, we could come to a pharmaceutical genome in time. Is the backbone being created internationally?

Dr. Bruce Carleton: The backbone is being created. A number of countries are interested in this in the European Union, of course, and in United States and Canada. International cooperation is important to progress, and we can divide and conquer these particular problems independently as well. There isn't really a need for these large international trials to uncover this.

Hon. Robert Thibault: That's not my suggestion. My suggestion is that if you are doing five classes of drugs and the Swiss are doing three, all of a sudden you have 20 classes of drugs.

Dr. Bruce Carleton: Exactly.

Hon. Robert Thibault: Thank you very much. I look forward to learning more about it and seeing it progress.

I was looking at the document by Health Canada, and it shows signal detection and assessment. I know we have good expertise within the Health Canada organization for this. I've had an opportunity to visit GPHIN at public health, which is similar, but it's working in the area of epidemiology worldwide. Do we have the ability in Canada now to detect and see where the problems are happening in pharmaceuticals generally in Canada—if there is a lack of pharmaceuticals or a lack of supply?

Dr. Marc Berthiaume: So your question is about whether we can identify emerging safety signals in pharmaceuticals.

I think tremendous progress has been accomplished in the past few years in that area, especially very recently with the creation of the Canada Vigilance online database. It is a new database that will enable more efficient collection of spontaneous adverse drug reactions. It will also have a built-in data mining capacity—some kind of software that will help us identify if there are disproportional numbers of certain types of adverse events with certain drugs.

● (1135)

Hon. Robert Thibault: We've heard a lot about the question of the information getting back to practitioners in a reasonable way. The suggestion has been made by practitioners that they would voluntarily inform Health Canada or anybody of adverse events if the information could flow both ways—if they could learn from the same screen as they're informing. Are we moving in that direction? Is this data getting out there in a usable form?

Dr. Marc Berthiaume: I think it's an area in which we're making step-by-step progress. A recent improvement is the ability to submit spontaneous adverse drug reaction information electronically. There is also now the capacity to search the spontaneous adverse drug reaction database online.

Although it's very difficult to have immediate retroactivity for the person who's reporting, they can have more of a population—

Hon. Robert Thibault: I see the potential. I can't imagine that this can't be done. If a client has a certain reaction to heparin and I type that in, it should automatically come back and give the comments, alternatives, and problems. As the database is built, it should feed back quite quickly. The technology seems to be there to do it.

Dr. Marc Berthiaume: The technology to give some estimation of the numbers of adverse events that have been reported to Health Canada for a specific drug and/or a specific adverse event is in place now. There's a delay because the adverse events reports have to be processed, looked at by a specialist, and then entered into the database.

Hon. Robert Thibault: Certainly there will be a delay, but when a practitioner inputs the problem he's having that day, the information known to date could be given to him in usable form. You'd think with Infoway and the work we're doing, that potential would be there. I hope we get there in the future. It's been suggested—

Dr. Marc Berthiaume: We use the *Canadian Adverse Reaction Newsletter* as one way of identifying clusters of cases. It's distributed to all physicians in Canada with the *Canadian Medical Association Journal*. So we have different ways to go back to the physician to—

Hon. Robert Thibault: But I'm sure that newsletter is part of a pile of documentation that goes to a man or woman who's already working long days and doesn't necessarily always have time.... It's not the same as getting the information at the pertinent time.

Mr. Lee.

Mr. David Lee (Director, Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Department of Health): Just to clarify, we've been having a lot of very good discussions with the various practice communities—nurses, doctors, and so on—who really need this information. We're finding that the needs vary depending on the disease they may be treating. Some patients are on quite a few therapies long term, so there are different information needs for them. If you're taking something for a short time, how do we get the best information out there?

To Marc's point, we're really trying to develop what we need there. I think it's a very important discussion for this committee.

Hon. Robert Thibault: Do I have any time left, Madam Chair?

The Chair: Your time is up. Thank you very much, Mr. Thibault.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Good morning, Dr. Berthiaume. In your presentation, you said that you got additional information on risks from drugs, that the risks are becoming known, and that you often check with other agencies elsewhere because they are often tested on a larger scale. That leads me to ask you a question on Gardasil.

When you hear that, in some countries, young girls are dying—there is no proof yet, but even so—that vaccination continues on a massive scale in Canada, and that, above all, tests have not been done on girls for whom the vaccine is intended, that is, young girls from 9 to 12, what is Health Canada's reaction? I know that, at the moment, responsibility lies with the Public Health Agency. Its vaccination program is huge. But at the same time, you are also involved because Gardasil is a marketed product. It is on the market, and it is intended for children younger than those who were used to test it. There are serious complications, that, for some young girls, can mean death.

What is your link with other regulators in the countries where that has happened? What decisions do you need to make to reassure people? What do you tell mothers who give consent for their daughters to get the vaccine? I understand that children need their mother's consent to get it. How do you tell parents that the vaccine poses a risk?

● (1140)

[*English*]

The Chair: Ms. Law.

Dr. Barbara Law (Interim Director, Vaccine Preventable Diseases Prevention and Vaccine Safety, Public Health Agency of Canada): I'm with the Public Health Agency of Canada, and we actually do the post-marketing vigilance for vaccines that are used in humans to prevent disease.

With respect to the deaths in question, I think EMEA put out a press release on January 24, 2008, regarding a couple of deaths. Our action at that time was to contact them the next day, January 25, to ask specifically about their concerns in regard to these deaths. We were reassured by the EMEA officials that they felt that Gardasil was not implicated in the deaths.

Also, through the memorandum of understanding between Health Canada and us, as well as Health Canada and the European Medicines Evaluation Agency (EMEA), we were able to specifically request the reports, which we got by January 28 and distributed to Biologics and Genetic Therapies Directorate counterparts as well as ourselves, to reassure ourselves that there was nothing there that was of concern.

Every death is a concern, but there are actions undertaken. We felt that all the proper actions were taken. We communicated through proper channels with the people who knew about the deaths and we were reassured there was not an issue. Similar things had happened in the U.S., where there were nine deaths.

I think it's important to note that if you looked at the pre-licensure trials that included 10,000 women, not all 9- to 12-year-olds—and I'll come to that in a minute—but among the women who were studied in the 10,000, there was a group that got the vaccine and there was a group that got a placebo, but nobody knew who got which. There were an equal number of deaths in both groups, none of which were thought to be due to either the vaccine or the placebo.

The problem with any product like this that is used in mass programs is that deaths occur spontaneously due to other reasons. At least in a clinical trial, if it does occur, you have an opportunity to show there's no difference between the group that got immunized versus the group that got a placebo, which doesn't contain the active ingredient.

In post-marketing surveillance, you don't have that other group; you just have the report of a death, and you have to try to discern whether this would have happened because of the vaccine or some other reason. So our feeling was, in collaboration and communication with our colleagues both at Health Canada as well as internationally, that these were not due to the vaccine.

I don't know if you want me to address also the question about the children, the younger girls. In the trials that were done for the vaccine itself.... I think it was made evident earlier that any product that comes to market may have been tested, and with Gardasil, it was 10,000-plus individuals who were tested. That's a lot, but that's not enough to detect rare events, and that's why you need to have post-marketing surveillance. In rare events such as death, each one needs to be investigated and looked at.

In the pre-licensure trials that were done, they were unable to include large numbers of younger children, because of the need to do specific tests that were thought to be inappropriate to do on prepubertal girls. So the tests were only done for those 13 years of age and up. But they then tried to test whether the immune response the younger girls would have would be equivalent, and you don't need to have nearly as a big a number as that.

So from the point of view of the effectiveness of the drug, that was clearly studied. For the safety of the drug, you wouldn't have enough numbers even in the 10,000. So the smaller number, a few hundred of the 9- to 12-year-olds, clearly wasn't enough, but that's something that's followed in post-marketing surveillance.

● (1145)

The Chair: You have one minute left, Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: So that would mean that the cause of death of those young girls is known and that you have been able to identify the reasons. You still had to investigate to find out why those girls died. You are telling us that the girls died for some other reason and that no link with the drug can be established.

You are telling us that there were just as many deaths among girls who got the placebo as among those who got the vaccine. So, what was the incidence of that and is the reason for the deaths known?

[*English*]

The Chair: Ms. Law.

Dr. Barbara Law: In some cases, yes; and in some cases, no. Regarding the clinical trials, I can't recall the specific examples right now, but we could certainly forward the results to you, if you would like. It was just that there was no difference between the people who had not received the vaccine and those who had. They were randomized.

In the U.S., where there have been reports of deaths as well, it was quite clear that one was actually due to a fatal case of influenza A. It was just a coincidental thing following immunization. There were two others due to thrombosis complications, thought possibly to be related to the oral contraceptives that were taken in those cases.

As for the deaths in Europe, no specific cause could be found. These deaths would fit the classification of sudden unexpected death syndrome, but there was nothing to pathologically link them in any way to the vaccine per se. These things happen. There are times when it could be an arrhythmia; people can drop dead, and you would like to find a cause and you don't.

All I can say is that in terms of the two deaths you were talking about specifically, the European officials indicate there was no clear cause to which they could ascribe the deaths, either from a vaccine or any other cause.

The Chair: Thank you, Dr. Law.

You mentioned some reports on Gardasil that you had by the end of January. I wonder if you would be so kind as to send those reports to the clerk's office, so they could be distributed to all committee members. These might be useful. Could you do that, please, Dr. Law?

Dr. Barbara Law: Certainly, yes.

The Chair: Thank you so much.

We'll now go to Ms. Wasylycia-Leis.

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

Thanks to all of you.

I want to start by dealing with the issue of reporting of adverse reactions, since it has been a dominant theme here at this committee.

Bill C-51 says that a health care institution “shall” provide the minister with information about adverse reactions. My first question is that in the past, when we've tried to suggest a role for the federal government in coordinating information and strategies across the country, we have been told that the federal government can't do that because of jurisdictional issues. Why or how is this possible now? Has there been a legal interpretation of this? On what basis is this going to be possible?

Mr. David Lee: Certainly the committee will be visiting the discussion at the appropriate time.

We can signal that, as Dr. Berthiaume went through, there has been an evolution in how we look at the post-market. The requirement for adverse drug reaction reporting has been in the regulations for a very long time, so that has been happening. Some of the shifting is a question about who should be doing the reporting, what is the quality, what is the frequency, and which institutions should be involved. That has been the recent policy work.

Ms. Judy Wasylycia-Leis: Fair enough, but we just had the Auditor General here, who remarked on the inadequacy of provincial reporting of wait times to the federal government, and the excuse by you or the government has been that you can't force the government to do that because it's provincial jurisdiction. How can you suddenly do it here?

Mr. David Lee: Again, this is very important architecture to lay in, and we need to be very deliberate about what we're requiring. So we're trying to make sure that we get the burden right, that we get the quality right, and that we get the targets right. That's why we've brought on the discussion.

Ms. Judy Wasylycia-Leis: Well, I hope this is a new approach by the federal government. I hope it means there is a willingness on the part of the federal government to actually play a bigger role in terms of preserving medicare and working to enhance services across this country.

Let me ask you then, why does it say "shall" in this section? Any time it refers to the minister requiring information that has to do with a drug company not being forthcoming and misrepresenting the facts, it is "may". Why is there a discrepancy? Why don't we have the same approach to all levels?

● (1150)

Mr. David Lee: Again, I take it that the committee will entertain a very detailed discussion on these issues as we go—

The Chair: I'm sorry to interrupt you, Mr. Lee. There is a point of order from Ms. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Madam Chair, are we debating Bill C-51 today?

The Chair: No, we are not. We are examining post-market surveillance, and we should stick to that topic.

Thank you.

Ms. Judy Wasylycia-Leis: That is exactly what I am doing. I am asking about adverse drug reactions and mandatory reporting. It so happens that is a topic for this committee to discuss. It's also in the bill. I think we had better be clear about what is happening on all fronts, so we can do our work as a committee.

Mr. David Lee: We like to be helpful to the committee—

The Chair: Continue. That's okay.

Ms. Judy Wasylycia-Leis: I would like to know how you will define adverse reactions.

Mr. David Lee: Adverse reactions, again, have been in the regulations for a very long time, and there is not a proposal to change some of that. Again, it goes to who should be doing it and what other instruments we should be laying in. The very, very good work that Dr. Carleton is doing, for example—

Ms. Judy Wasylycia-Leis: Right. But what will you require health institutions to report on a mandatory basis? You just say it's adverse reactions. Well, how will they know what that is? Is there a definition?

Mr. David Lee: There again, we can leave it to the committee at the appropriate time. The thought, however, is that this discussion—to define—is an important one. There's room to define that in the regulations, so that's a detailed discussion—

Ms. Judy Wasylycia-Leis: Let's hope there's some parliamentary oversight of the regulations, though, because it does not appear to be the case at present.

Mr. Michael Vandergrift: If I may, I believe "adverse reactions" is in fact a defined term in the regulations as they currently exist. Also, there already is a mandatory requirement on industry to submit adverse reaction reports to Health Canada. That already does exist.

Ms. Judy Wasylycia-Leis: It's interesting, because I'm hearing from the Canadian Medical Association that they have tried to get this information and have been told that the word is "serious" adverse reactions. And that hasn't been defined, so they're in a quandary.

On that same issue, then, the biggest question of all on this issue is what are you going to do with all this information? Where are the extra staff and resources? There's nothing in the bill. It just says you're going to collect it. Where is it going to go? What's going to happen to it? Is it all going to go to Mr. Carleton? Or is it going to go to what's his name, the fellow at our committee last week who has a private company?

So to whom is this going?

Dr. Marc Berthiaume: On the first point, about the definitions, there is currently a definition in the food and drug regulations of an adverse drug reaction. There is also a definition of a serious adverse drug reaction. So these definitions do currently exist in the food and drug regulations.

On the question about what will come out of all this information, I think there's been a steady increase in the resources that are dedicated to post-market surveillance in Canada in the past five years. There's a commitment to continue to support that.

If you take, for example, the budget of MHPD, it has increased steadily in the past five years. Our scientific and clinical capacity to process this information has almost tripled in the past five years. There is that capacity now to absorb, process, and evaluate more information related to post-market safety issues at Health Canada.

Mr. David Lee: As to how we bring information back out, there are a number of venues. We'll be exploring that in our discussions as we go forward. But there are changes—obvious things like making changes to labels, but also communicating with the right sector at the right time. Again, this is appropriate to a very detailed discussion, but we believe we're laying in the architecture for that.

Ms. Judy Wasylycia-Leis: We've had quite a negative reaction around this table from people who are part of health care institutions, doctors and other health care professionals, talking about the huge burden that this will mean and how it may not be that helpful because there is no evidence of a coordinated strategy to use this information in a meaningful way and on a timely basis.

Mr. David Lee: Yes, and yet you do hear from the same people the same goal that we're trying to advance, which is to make sure you have good continuous oversight; then you're picking up the really important safety points. It means not overdoing it in therapies that don't require heightened surveillance, but moving it to models where we really do need good, strong surveillance, very active surveillance.

I'm sure Dr. Carleton could talk about that further.

● (1155)

The Chair: Your time is up, Ms. Wasylycia-Leis.

I want to thank you, Mr. Lee.

Now we're going to go to the second round, five minutes each, starting with Dr. Bennett.

Oh, I'm sorry, Mr. Brown, it's your turn. I was going to leave you out.

Mr. Patrick Brown (Barrie, CPC): Thank you, Madam Chair. I appreciate the opposition raising the fact that we didn't get our turn.

I have a question for Health Canada. In the presentation you prepared for us, a reference was made to integrating new international information. I want to know which countries were examined or where we looked for international advice.

I know that in some of the previous presentations, we heard some interesting information from different jurisdictions—New Zealand, for instance, and some states in the U.S. where they've used mobile devices as a means of having more timely access to physicians. I'm wondering if you could shed some information on what jurisdictions you looked at.

Dr. Marc Berthiaume: If I understand your question well, you're wondering how we're going to leverage or how we're going to collaborate more with international agencies to gather more information?

Mr. Patrick Brown: It's not about how you're going to. The strategy includes “key objectives, such as integrating new sources of international...information” and “developing international and national partnerships to facilitate work-sharing”. Are there any countries that have already been contacted or designated to work with you on this?

Dr. Marc Berthiaume: We do have memoranda of understanding with countries such as the United States and the European medicine evaluation agencies, as well as with Australia, Singapore, and Swissmedic. So we do have these types of collaborations; whenever there are emerging safety issues, we can contact them and share information. That's already in place.

It's also interesting to know that the whole life cycle approach, or post-market surveillance, is moving towards what we call risk management planning and pharmacovigilance planning, which is basically a way to gather information in a systematic manner once the drug is on the market. That gathering of information might occur in Canada or it might occur in other jurisdictions, but it will be reported to us by the manufacturers, so we will have access with the life cycle approach to more than what we usually and mostly relied on in the past, which was spontaneous adverse drug reaction, and we will have access to post-market safety studies that the manufacturers with a life cycle approach will now commit to in order to better monitor their products once they are on the market.

This approach is being developed internationally. The FDA and the European agencies are moving to basically develop tools that can support or complement the spontaneous adverse drug reaction systems currently in place in most countries.

Mr. Patrick Brown: This is more of a general question for everyone here today. One figure we've heard frequently, and one I've heard numerous times as we've looked at this topic, is the 10% figure—only 10% of adverse reactions are reported. What are your opinions on that figure? Do you think it's accurate?

I have a follow-up question to that.

Dr. Marc Berthiaume: Based on international references, somewhere between 1% and 10% are reported in Canada. We don't know exactly, because there is no way to exactly estimate the real occurrences.

One concept that is important to understand is that a spontaneous ADR system is not necessarily there to collect all drug reactions; it's there to identify what we call early signals—that is, unpredictable or unknown occurrences of events with drugs that have been recently marketed. Usually people will identify them, especially if they are close to the time the drug was administered and especially if they are serious. Either they are life-threatening or they bring people to a hospital, so these will tend to be reported.

A spontaneous ADR system generates signals that help us identify areas that we need to further investigate. It's not a way to monitor drugs, but a way to identify safety issues that need to be further investigated. Once we identify it and an adverse drug reaction reports an area of concern, then we seek information from other sources, such as medical literature and other regulatory agencies. The manufacturer potentially might have completed some studies that would help us assess the issue. Then we do what we call a single assessment, which is basically a more comprehensive evaluation of the safety issue.

● (1200)

Mr. Patrick Brown: How would mandatory reporting by physicians...? Do you have any estimates on how that would improve the situation?

Dr. Marc Berthiaume: Regarding mandatory reporting by physicians, the current plan is basically to consider—

Mr. Patrick Brown: Hospitals.

Dr. Marc Berthiaume: Hospitals, yes. That will help, because some of the serious adverse drug reactions will bring people to consult in an emergency, so that will enable us to identify, maybe earlier, these signals that need to be further investigated.

Mr. Patrick Brown: There are so many family physicians out there who deal with patients all the time who wouldn't fall under that blanket. Has Health Canada ever given any thought to mandatory reporting for physicians, period, and if they haven't, is it because there hasn't been a positive response to that notion? Has there been any reaction to making it universal?

Dr. Marc Berthiaume: Yes, there has been consultation with numerous stakeholders or representatives of the public and patient interest groups, physicians, and industry. The general consensus was that there was not necessarily a net gain in having all spontaneous adverse drug reactions reported, but more to have a strategic approach to target where it's most likely to make a difference.

There was general agreement that hospitals are where physicians, pharmacists, or other health care professionals are observing these adverse events and are able to report them. As you're aware, hospitals are very structured environments where there are already some mechanisms to basically collect that information. So having hospital-based mandatory reporting by a health care professional is thought to be a very efficient way to identify serious adverse events reports that may make a difference in identifying safety signals earlier on.

The Chair: Thank you so much, Dr. Berthiaume; and thank you, Mr. Brown, for your patience.

We will now go into the second round, starting with Dr. Bennett. It will be five minutes for the question and answer.

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

I want to focus on the national pharmaceutical strategy and how all these issues are obviously both federal and provincial. So I want to know how the NPS is working in terms of the co-chairs' meeting, and working groups and all those things.

I understand that you are co-chair of the working group on real-world safety. Obviously there was a conference in September 2005. There was the invitational workshop on research projects. There was the consultant's report in 2007. Are you ending up in a two-way communication with the federal government in terms of responding to these kinds of things? What recommendations would your working group be making on this issue? Did you comment on progressive licensing? Have you commented on how you would recall a drug?

Some of the people have heard this before, but I used to do a lot of obstetrics and was sometimes up delivering a baby during the nightly news and I would receive a letter from Health Canada three days later to find that a drug had been recalled, but my patients were lined up the next morning worried about it. We seem to have a very old-fashioned way of communicating with physicians about risk.

Also, I want to know if your working group is dealing with any of the stuff around counterfeit medicine. If there has been an adverse drug reaction, how do you know it really was the medicine and not a counterfeit, as we look at the issues around heparin and the real problems coming from the States right now?

So, first of all, how is it going on the NPS? I understand there has not even been a federal co-chair appointed.

● (1205)

Mr. Brent Fraser: With respect to the national pharmaceutical strategy, there are some discussions and some recommendations that are still being considered by ministers, so we are still seeking some direction from them with respect to the next steps. But in the interim, there has been a fair bit of dialogue between the provinces and the federal government. All the working groups represent a number of individual provinces, in addition to representation from the federal government.

Hon. Carolyn Bennett: But were you consulted on Bill C-51, for example?

Mr. Brent Fraser: That hasn't been the mandate of this working group. A lot of the working group itself is focusing more on the fact that there is a lot of research happening out there in the field when you're looking at post-marketing surveillance or post-market studies, so how do you collaborate and form networks of those studies?

On the progressive licensing framework, we've been speaking to Health Canada individually, as jurisdictions, through some of the consultations they've been doing, and that has been through a different vehicle. It has not been through the national pharmaceutical strategy.

Hon. Carolyn Bennett: In a federal-provincial partnership, if it's not your group, who would deal with advice on progressive licensing, advice on counterfeit drugs, and so on? Surely there has to be a forum to have those kinds of conversations with the provinces and territories.

Mr. Brent Fraser: Right. So each province has an intergovernmental affairs section within their ministry. The linkages between the federal government and Ontario would be through the Ministry of Health for Ontario, of which I can speak specifically, and then they will seek out who the correct people are. So for a progressive licensing framework, that would be me and my team of individuals.

Hon. Carolyn Bennett: But all your colleagues from all the provinces and territories don't sit down with the feds and say, “What should we do on progressive licensing?” Is it all done one by one?

Mr. Brent Fraser: We have done it as a group. The directors of the public drug programs typically sit down with Health Canada to understand what the framework is about. We had a meeting within the past six months to understand what the potential approach was going to be.

Hon. Carolyn Bennett: That sounds pretty one way. Were you not asked what you thought it should be?

Mr. Brent Fraser: It was difficult because they were still preparing their regulations, so we couldn't comment. Now that the bill has been introduced, I haven't heard of plans for the directors to provide input as a collective group, but one-way dialogues are happening between the individual jurisdictions and Health Canada if there are concerns.

Hon. Carolyn Bennett: So we have a bill on progressive licensing, but the provinces haven't been asked what they think about progressive licensing.

Mr. Brent Fraser: We have been asked about progressive licensing as a concept, but since the bill was introduced we haven't been asked to comment specifically on the contents of the bill.

The Chair: I'm sorry, Dr. Bennett, your time has run out.

Thank you, Mr. Fraser.

Mrs. Davidson.

Mrs. Patricia Davidson: Thank you very much, Madam Chair.

Thank you very much for being here and presenting.

It's nice to see you again, Dr. Carleton.

I want to ask Dr. Law a couple of questions about vaccines and the surveillance around them. I think we've heard that almost all of the post-marketing surveillance activities lie within Health Canada, but I think your Public Health Agency is responsible for the marketing surveillance of preventative vaccines. What mechanisms are in place for the coordination and ongoing communication between the two departments?

Dr. Barbara Law: It's interesting that historically both drugs and vaccines were with Health Canada when the agency was still with Health Canada as the Laboratory Centre for Disease Control. Then drugs were separated off and vaccines stayed where they were originally, with the Laboratory Centre for Disease Control. That's just some historical perspective.

We do the post-marketing surveillance for preventative human vaccines. The biologics and genetic therapies directorate, which is part of Health Canada, are the pre-market regulators, but they also have post-marketing responsibilities. One thing that's different about vaccines and some biologics versus other drugs is that every new lot of a vaccine has to be studied and given a release for marketing, and BGTD does that.

We interact with BGTD on a number of different committees. They have a committee for risk management, so when an issue comes up related to a vaccine we sit at that table and work with them. We have our National Advisory Committee on Immunization, and they sit at the table there. The committee provides expert recommendations on vaccines and updates vaccine safety information as part of the immunization guide. Different technical documents are produced when a new vaccine comes out—statements on the vaccine.

We run a vaccine vigilance working group. It is a federal-provincial-territorial committee that has members from all the provinces and territories, with a co-chair from the provinces and a co-chair from us. It looks specifically at vaccine vigilance, develops the form we use for reporting, and works on national case definitions and standard national operating procedures for adverse event reporting. We work with the provinces and territories in conjunction with them, and BGTD sits at that table.

We also have an advisory committee on causality assessment. It looks at the serious adverse events, some of which have been mentioned. They include deaths, hospitalizations, anything that prolongs hospitalization, anything that's life threatening, and anything that causes residual damage or potential congenital defects. We pull those reports and, to the extent possible, review them. We can't always get all the information we need for a committee to review them. BGTD sits at that table as well.

So those are all formal interactions. Then we have a number that are informal, ad hoc, as needed, when an event comes up, like the Gardasil deaths that were reported. They weren't Gardasil deaths; they were deaths following. They were temporal associations that were reported to EMEA. When we got that information, we met with our colleagues at BGTD. So we work with them very regularly—not every single day, but several times a week.

● (1210)

Mrs. Patricia Davidson: How are the warnings sent off to the physicians and the people who need them? Is that a cumbersome process, or does it follow the same process as Health Canada's?

Dr. Barbara Law: It's fairly similar, but BGTD would mainly take the lead. As the regulator, they have the mandate to do that, but we work with them when it comes to vaccines.

An example of that is what happened in Alberta recently when there were six allergic reactions—anaphylactic-like reactions. Because of the mumps outbreak, there was a campaign to try to make sure adults had had at least two doses of mumps-containing vaccine. In conjunction with that, several thousand adults were immunized, and there were more possible serious allergic reactions than you would expect to see. That was reported to us. We engaged BGTD and got additional information, but ultimately it was BGTD that decided to quarantine the lot. So that's a fairly major action that doesn't happen very often, but it was taken by them in collaboration with us.

The Chair: Thank you, Dr. Law.

It's now Monsieur Malo.

[*Translation*]

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

Thank you for being here with us.

Dr. Carleton, thank you for being back with us again. Like Mr. Thibault, I find that the approach that you are presenting to committee members is interesting. I would like to go back to the comments you made in your preliminary remarks. As I understand it, the vast majority, if not all, of the medications on our shelves as a result of our pre-market process are safe. If the medications produce adverse reactions, they are, in many cases, because of the presence of genes in some individuals that are not found in others, on whom the medication has no undesirable effects at all.

If that is the case—you can correct me if I am wrong—are we not avoiding the essential if we do not consider the genetic aspects of the entire post-market process?

● (1215)

[*English*]

Dr. Bruce Carleton: Avoiding the essential what...? I'm not sure I understand the last part of your question.

[*Translation*]

Mr. Luc Malo: Are we not overlooking the most important element, that is, the individual who receives the medication and who is different from someone else? If we study medications during their post-market process and overlook all the genetic factors, are we not going round in circles and thinking that everyone is the same?

[*English*]

Dr. Bruce Carleton: Exactly. For the most part, the comments you make are accurate. The issue is what specifically puts individual patients at risk of a serious reaction. If there are genetic variants in certain individuals that put them at risk, they could be responsible for many of the reactions that currently occur with biologics and drugs.

In the example I provided the last time about codeine, there was a duplication of a specific gene responsible for converting codeine into its active form in the body—morphine—and another genetic variation. Instead of converting morphine into an inactive form that was excreted by the body, it converted it into another active form of morphine that increased its effect on the brain, and therefore its effect on bodily function. That is what killed a child in Ontario, as we reported in *The Lancet* medical journal, I believe in 2006.

So human genetics is definitely at play here in terms of response, and how we uncover those genetic differences is important in all of this post-market debate. One of the concerns I have is that just collecting reports on individuals who experience reactions isn't enough; we need a control group. One of the things that research is quite clear about is the need to look at another group of people that don't experience a reaction and understand what makes them different from the people who do experience them.

[*Translation*]

Mr. Luc Malo: I have two more questions about that. First, since it seems so important to move forward in the genetic field, is there support in your program, which seems to be costing $1.5 million, for moving further and faster? Would that put as many drugs as possible under the genetic microscope?

Second, does the government consult you about studying the post-market process when the time comes to draft new legislation?

[*English*]

Dr. Bruce Carleton: We don't have enough funding to do all of the work we could do. We're working in a very small environment now. We're working in children's hospitals across the country on very specific targeted therapies, we're looking at reactions that have been in existence for a long time that cause a lot of morbidity and mortality, and we're trying to solve these problems one patient and one drug at a time. We need more funding and we need to expand the work that we're doing further.

I had a very positive meeting with Health Canada about progressive licensing in the middle of March. We spent three hours together talking a little bit about what opportunity this new framework would present for these kinds of issues, in terms of improving surveillance and improving our ability to produce safer drugs. I think the framework provides an opportunity.

The question now is whether we seize that opportunity and actually make safer drugs for Canadians and the rest of the world. I believe that's what Canada actually can provide.

The Chair: Mr. Cannan was next, but I see he's not available right now. So we'll go to Ms. Wasylycia-Leis first, and then go back to Mr. Cannan.

Ms. Wasylycia-Leis.

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

One of the recommendations we've been receiving from folks during these hearings is that there has to be something to compel pharmaceutical companies to immediately and efficiently give information to the government regarding adverse reactions. I just want to check where that is and how obligatory it is with respect to your proposal.

● (1220)

Mr. David Lee: Again, I would just caution that I can speak to the broader policy discussions we've been having.

What we've identified is that the requirement for adverse drug reaction reporting is certainly down in the regulations right now. It appears in the architecture of the act in several places. It can occur as a term and condition for a standard authorization, and that's through the regulation-making process. As for how you actually bundle those together, I'm sure the committee has heard a lot about periodic safety update reports, which bundle together and summarize those reports to make them useful. That, too, becomes an ongoing requirement, and its frequency can be set out and determined around the therapy.

So as to your earlier point about not burdening health care professionals and others with therapies on which we don't need as much reporting, you can index those. So that's really the concept we're advancing there. So it does occur in a number....

I would point out that you also need to require information in study form, because just having ADRs can't get us where we need to go.

Ms. Judy Wasylycia-Leis: I agree.

Mr. David Lee: And so that also can come down into the licensing.

Ms. Judy Wasylycia-Leis: But I'm wondering where in the legislation is an equivalent requirement to what you now have for health care institutions. Where does it say that pharmaceutical companies “shall” report immediately any adverse reactions?

Mr. David Lee: It doesn't say that as a provision in the act. We would make regulations about that, so that it's a standing term and condition of every authorization.

Ms. Judy Wasylycia-Leis: But why wouldn't it be in the act? Why is this in the act and not drug companies?

Let me ask it this way: how are you going to prevent a Vioxx from happening, either through this legislation or your scheme or plan?

Mr. David Lee: We think we could walk you through that at the appropriate time, should the bill come to committee. It's a very important dialogue. I'd want to really make sure that you can build confidence around that. We think we can do that.

Ms. Judy Wasylycia-Leis: Are you prepared anywhere—in regulation, legislation, or this plan you presented today—to require drug companies like Merck Frosst to immediately get information to you upon learning of any side effects, so that something can be done with it?

Mr. David Lee: Yes, we're putting in a very strong, direct ability to do that. And we can speak—

Ms. Judy Wasylycia-Leis: But if it's that important, why wouldn't you put it in law?

Mr. David Lee: It is. Well, it's proposed, anyway.

Ms. Judy Wasylycia-Leis: Is there a provision in the bill that says that drug companies "shall" present any information that's important to reactions to a drug?

The Chair: On a point of order here, Ms. Wasylycia-Leis, are you talking about Bill C-51 in terms of the "shall"?

Ms. Judy Wasylycia-Leis: I'm talking generally: the plan they presented today—the nice fancy document on post-market surveillance—the bill, anything.

The Chair: I'm just going to tell you the parameters. We can't talk about the wording of the bill, because it hasn't been referred to the committee. We can talk about the subject matter, because it is related to post-market surveillance. I just want to clarify that. So I will give you a couple of extra minutes.

Ms. Judy Wasylycia-Leis: Right, but given the fact, Madam Chair, that we're in the middle of a study that is really redundant.... We have legislation from the government that deals with post-market surveillance. We have a plan before us, the plan for post-market surveillance from 2007 to 2011, I believe it says. So it makes our work pretty frivolous and ridiculous—

The Chair: Ms. Wasylycia-Leis, I'd like to continue, but we cannot talk about the bill until it's referred to the committee. I'm trying to be fair with you, but please continue properly.

Ms. Judy Wasylycia-Leis: All right. Is there somewhere in the government's plans to require that from drug companies—for example, Merck Frosst, which is now under investigation for misrepresenting information or not conveying information on a timely basis, which did lead to hundreds of thousands of people dying? That's a simple, straightforward question for which there should be an answer from government.

Mr. David Lee: There is an answer, that for the last couple of years we've been having very close stakeholder meetings and studying what it is that we need. Yes, absolutely, that has been a topic of discussion; there's no question. We have tried to study what information we need, when in the cycle we need it, and how best to ask for it. That's both domestically and internationally. So we've really studied these things, and—

● (1225)

Ms. Judy Wasylycia-Leis: Okay, but I'm asking, if you studied it a lot, are you prepared to say somewhere that pharmaceutical companies "shall"—just like you say with proposed section 20.7—report adverse reactions?

Mr. David Lee: Yes, we are.

The Chair: Ms. Wasylycia-Leis, your time is up.

Now we'll go to Mr. Temelkovski.

Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.): Thank you very much, Madam Chair.

Thank you to all the presenters. I think I have the same 10 minutes as Robert had.

Let's look at it in this fashion: there are reporting elements on a national basis, and not one but many ways that people can report adverse reactions. There are also international avenues where people report adverse reactions; and there are people, as well as stakeholders, reporting directly to the pharmaceutical companies.

Is all of this information being compiled anywhere, in one unit, or is it reported back in as many facets as it is reported inward?

Dr. Marc Berthiaume: If we take the post-market adverse event report for pharmaceuticals, from any source, whether they come from the manufacturers or consumers or health care professionals, they will all end up in the same area, which is the Canada Vigilance database. This is where the Canadian reports will be collated. It's also in that same area that the international reports are kept in the records. So if we're talking about drugs, it all ends up in the same place.

Mr. Lui Temelkovski: Then Health Canada will report them back to Canadian sources, to the stakeholders, I'm assuming, on a quarterly basis, on a newsletter basis, as you mentioned earlier, right?

Dr. Marc Berthiaume: Yes, there are numerous tools used to report back. This is one of the tools we use to identify emerging safety signals. So in that sense, if we take action, that's some kind of retroaction to the Canadian public and to the reporters. It's indirect, but that's one source of retroaction.

There is the availability of the Canadian adverse drug reaction database, or Canada Vigilance, as it's called now, and that's searchable. So that's another retroaction.

And as I've mentioned before, the *Canadian Adverse Reaction Newsletter* is another way to report back.

Mr. Lui Temelkovski: Are they quarterly, monthly, annual, semi-annual?

Dr. Marc Berthiaume: The *Canadian Adverse Reaction Newsletter* is published every three months, so it's quarterly.

Mr. Lui Temelkovski: It's quarterly. We're familiar with those, because we send something out to the community on a quarterly basis.

Dr. Marc Berthiaume: Maybe I can add some information about its distribution.

That newsletter is distributed to 67,000 physicians in conjunction with the *Canadian Medical Association Journal*. It's also printed and distributed to an additional 26,000 health care professionals, mostly pharmacists. It's also sent to all the professional associations of pharmacists and physicians in Canada so that they can send it back to their members.

There's also the MedEffect e-Notice, which is basically a site where people can register or be subscribers and then be informed of all the emerging safety issues in Canada, which also includes publication of the CARN.

Mr. Lui Temelkovski: Is the EU, the European Union, using a progressive licensing system?

Mr. David Lee: They are certainly using a life cycle oversight model, and that's really what progressive licensing was intended to convey—that you're progressing over time in your knowledge about the therapy. In fact, we've done a lot of studying with the Europeans, because we think they've advanced a lot of this very well. They are a very good model to look to.

Mr. Lui Temelkovski: If we are aggressive in reporting adverse reactions, and the most aggressive we've been is 10% so far—that's what we've heard—should we move away from the current proposed adverse reaction system and put our money or our resources into something like what Dr. Carleton is suggesting, or should they run concurrently with one another?

Dr. Carleton, maybe you could answer.

● (1230)

Dr. Bruce Carleton: At the risk of offending my colleagues to the right—I'm just teasing—of course the work we're doing needs more funding, and there is opportunity to use both a spontaneous reporting system and a targeted surveillance system to identify drug reactions of concern and, most importantly, solutions to these problems.

I feel that we talk a lot about identifying the reactions—identifying reactions, getting reports. It's not enough. We don't report as doctors, as nurses, as pharmacists—even as consumers—because, what is it? At the end of the day, it's a report. It's sent to Health Canada, and no one is quite sure how this is going to be used to improve the safe use of medication for the very next patient who comes to the hospital or into a medical practice environment. We need solutions, and that's what I think needs to be part of this.

I agree with a progressive product life cycle approach for advancing our understanding of drugs over time, but it has to be directed at improving safety. It has to be directed at that. There have to be solutions identified now, a priori, that we will seek to actually embed into the practice of health care so that we'll no longer just be reporting for reporting's sake.

The Chair: Thank you, Dr. Carleton.

Mr. Brown is next.

Mr. Patrick Brown: Thank you, Madam Chair.

I wanted to probe the topic of off-label use in Canada. Could you share with us some information on how frequent it is and whether Health Canada has concerns about it?

We've heard terms like “drug cocktails” in relation to treatments for cancer and AIDS and other new or complex diseases. We've also read information that off-label use is more frequent with rare diseases and also that there's a greater frequency of off-label use when it comes to pediatrics. Could Health Canada share with us a little more description of off-label use and any concerns you may have regarding it?

Dr. Marc Berthiaume: Thank you for your question.

Off-label use of a therapeutic product is basically when a product is used outside of the approved product labelling. It might be a different dosage or different route of administration, or outside of the indication for which the drug was initially approved.

The issue of off-label use is partially under the control of the physician. Sometimes it's the practice of medicine to use drugs outside of their recommended indications. The control or oversight of such off-label practice mostly resides with the provincial colleges of pharmacists and physicians who regulate the activities of their members.

In Canada it does happen sometimes, of course, in the pediatric population. There is some off-label use occurring there due to the fact that often there is a therapeutic need to handle some medical conditions. As well, there is not necessarily a solid body of knowledge that has been routed through the regulatory authorities and approved to basically grant an indication. Off-label use occurs also in certain subpopulations, such as cancer patients and AIDS patients. As I said, it's a reality that basically involves the practice of medicine.

We do, as a regulator, take action when we are aware of an off-label use that generates safety concerns, but we cannot regulate off-label use; it's outside the scope of our authority. As I said, it falls within the competencies of the different professional associations in Canada.

● (1235)

Mr. Patrick Brown: Do you find there's a greater risk for adverse reactions in those scenarios?

Dr. Marc Berthiaume: It's difficult to assess, because there is no evidence. Basically, the challenge around off-label use is that the drug use is not supported by the same thorough evaluation. You are right, yes, that there is a risk of adverse events for off-label use, as there is for approved use. It would be very difficult to assess if there were more.

Mr. Patrick Brown: So the reporting mechanisms are the same for both.

Dr. Marc Berthiaume: Yes, they are. When there is a report for an adverse drug reaction, that report is not related to whether the drug was used within the approved indication or off-label.

It's also interesting that internationally and also in Canada we are moving to a life cycle approach. Basically, the concept is that more and more drug manufacturers will be expected, at the time of approval, to submit information about potential off-label use, whether it's in pediatrics or other subpopulations, and to document or to monitor such off-label use.

In the life cycle approach, the thinking behind it—the same thinking is present also in Europe, for example, where they use the risk management plan—is that whenever you submit a drug, you also have to assess the potential for off-label use, monitor that off-label use, and report that to the regulatory authorities.

Mr. Patrick Brown: When we hear the term “drug cocktail”, such as for complexities like AIDS and cancer, what is meant by that term, and—

The Chair: Mr. Brown, I'm sorry to interrupt you, but you're over your time.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: I have been given some information on Gardasil and I have not had the time to read it. I would have liked to ask you some questions about it.

According to the notes provided by the Parliamentary Information and Research Service, progressive licensing makes sense, but, in the United States, it is less effective than anticipated and that pharmaceutical firms often fail to comply, that is, they do not do, or complete, the required studies. In fact, a number of studies on several products were not even started. Further, the report goes on to say that the FDA does not have the authority to take direct legal action against violators.

What approach could Canada take in order not to find itself in the same situation? What would you do to bring pharmaceutical companies into line more forcefully and to make lawsuits possible? If we adopt the progressive licensing approach, will we have that kind of recourse?

[*English*]

Mr. David Lee: First of all, there are perhaps several misunderstandings around the term “progressive licensing”, which was not intended to mean, in our view, the same thing as moving drugs out earlier.

What we meant by that is that we really want to make sure that as our knowledge about a drug grows over time, we take the best advantage of that information. There is a traditional way of doing pre-market studies, and we didn't want to change that. However, in the United States there are ways by which a handful of drugs can come out “earlier”, meaning earlier in the pre-market study phase. Proportionally, in Canada, we've looked at 32 drugs that way, as compared with the 9,000 generally marketed; and those drugs were for very small populations, where people usually have an unmet medical need, so it's very narrowly confined.

The experience in the United States has really been to make sure that people follow up on studies. We've tried to explore this concept very responsibly, because people in these situations who are taking these therapies need to know the context they're in and that the study can be completed. Europe also has models they're working on in this respect.

So it's how you take responsibility for that handful of drugs—and these are not the general market authorizations that we would see in the life cycle for most drugs. In fact, for the vast majority of drugs there's no change in the pre-market data required. It's just for this very small handful.

Then the question you're going to is that you really want to make sure these commitments are met. So as we've been thinking this through and talking to many groups, there's a very strong insistence that.... For example, the provinces have told us that they want to see most issues resolved, that we have to deal with this responsibly. So again, making sure these commitments are followed up has been a very serious policy that we've looked at extensively.

● (1240)

[*Translation*]

Ms. Christiane Gagnon: A number of witnesses have told us that we need an independent body to do independent testing, both pre-market and during a product's life-cycle.

The Marketed Health Products Directorate, the MHPD, seems to be conducting this kind of testing. They are a branch of the department. According to your presentation, the MHPD is a body that conducts independent tests and ensures that standards and regulations are consistent. But witnesses have told us that there is no independent body and that we need to create one.

How do you respond to that request? What do you think of the testing? Is it really independent?

[*English*]

The Chair: I'm sorry to interrupt you, but we're going to have to get some answers. We only have about 20 seconds left, so could you please—

[*Translation*]

Dr. Marc Berthiaume: The concept of independence comes from the fact that it is a different group doing the follow-up on the medications after they are put on the market. Witnesses have told you that the MHPD was not well known and that people in the directorate should be told to look at medications differently. But there is collaboration and discussion.

Some witnesses have also said that there is room for independent research in Canada. A number of centres in Canada have expertise in this area. There are different ways to conduct independent research.

The MHPD, which was set up in 2002, had, as one of its goals, to allocate resources to the surveillance of drugs after they are put on the market so that they are tested again. This model has been proposed in the United States. I feel that Canada played a leadership role when it set up the MHPD.

[*English*]

The Chair: Thank you, Dr. Berthiaume.

Mrs. Davidson, please.

Mrs. Patricia Davidson: Thank you, Madam Chair.

I have just a couple of quick questions.

When Mr. Brown asked about the off-label use, did I understand correctly that you said the provinces and territories have the responsibility for regulating the practice of health care professionals through the colleges of physicians?

Dr. Marc Berthiaume: Yes. The main responsibility is under the professional associations, which are provincially based.

Mrs. Patricia Davidson: All right. So the practice of the health care professionals plays a part, then, in the off-label use. Is that your inference?

Dr. Marc Berthiaume: When a drug is used off-label, it's because a physician makes a decision in a specific patient when this drug would be, on a population level, contraindicated. Maybe because that patient is allergic to other available therapies or has not tolerated the other available therapies, the physician might make the decision to use that drug in that specific patient, outside the approved indication. That doesn't mean there is no medical rationale behind it, but just that it's outside what has been approved on a population basis.

● (1245)

Mrs. Patricia Davidson: We're talking about the life cycle approach for drugs. If that happens, will the benefits of the off-label uses be recorded? Right now, I think only adverse effects are recorded. Will this help expand the label use?

Mr. David Lee: That would be the intention of the policies we have been trying to develop. You are correct that there is a long-standing obligation on manufacturers to report an adverse drug reaction no matter how it's used, whether it's used, as Marc pointed out, off-label or not. But the intention is to make sure that...all the information you are losing on a population basis. You can use them one by one, but as that adds up in a community of use, you really want to study what's going on there, if you can. That's where the life cycle tools could be introduced, so that you can have varying types of studies, depending on what's really needed either clinically or on the population level.

Mrs. Patricia Davidson: So the intent is to look at the beneficial side of things, as well as the adverse side.

Mr. David Lee: Yes. It's both benefits and risks, and we want to keep those concepts really quite close together.

Mrs. Patricia Davidson: Mr. Fraser, are there things that you can see we should be recommending that would improve recording and information back and forth between the provinces and the federal government?

Mr. Brent Fraser: I think one of the key things that our experts are requesting in terms of information is the timeliness of the information. For example, if a safety event has been reported, whether it's in the press or in another jurisdiction, we often hear very quickly from Health Canada that this event has been reported, but there may be some negotiations or things happening around the labelling of that particular product. I think that is one piece of information it would be very important for us to get access to in a very timely manner, because that puts us in a bit of a black box, and we're not sure what to do with these reports as they come forward. Are they clinically significant, and should we then be changing our practices around reimbursing some of these products as a result of it?

Again, it would really just be the timeliness of the information and really understanding what that information means. Indicating that there is an adverse event with this product doesn't give us enough context around the seriousness of that event and the frequency of those events happening at that time as well.

Mrs. Patricia Davidson: Is your group working towards these things?

Mr. Brent Fraser: Right now we rely on Health Canada, but through some of our listing agreements for some of the products that are on the formulary, if we have concerns around how a product is being used, we may ask the manufacturer directly to conduct some additional observational studies and collect that information for us to help inform our decisions.

Mrs. Patricia Davidson: Thank you very much.

The Chair: Thank you, Mr. Fraser and Mrs. Davidson.

Mr. Cannan.

Mr. Ron Cannan (Kelowna—Lake Country, CPC): Thank you, Madam Chair.

To our witnesses, I'm substituting here today, so I just have a couple of quick comments from observations from your presentation.

With the increased regulation and the regulatory regime that's being proposed, is there a dollar value attached as far as Health Canada is concerned in looking at this five-year window?

Mr. Michael Vandergrift: As you know, budget 2008 provided funding for the food and consumer safety action plan. It was about $113 million over two years. That certainly enables us to begin the work of advancing not only the life cycle approach that's outlined in the proposed legislation but also the associated activities with the overall food and consumer safety action plan the government has put forward.

Mr. Ron Cannan: That's for two years, though. This window we're looking at is 2007 to 2012. Is that going to mean a supplemental increase down the road?

Mr. Michael Vandergrift: Yes. I mean, we continue to be committed to the principle of identifying and costing activities and forming our resource allocation decisions as we move forward. I can speak to what was provided in budget 2008.

Mr. Ron Cannan: How will that money be allocated?

Mr. Michael Vandergrift: Those decisions on how it will be allocated are still being made, so I'm not able to speak any further about that at this point.

Mr. Ron Cannan: Are there implications for the pharmaceutical companies, with the regulatory...? Are there any additional costs?

● (1250)

Mr. Michael Vandergrift: As we move through the proposed bill and other activities, of course there is a requirement to develop regulations. Through developing regulations, we're committed to following the cabinet directive on streamlining regulation, which includes assessing costs and benefits of proposed regulatory approaches and itemizing and presenting those as part of any regulatory packages moving forward.

I'd invite my colleagues to comment further on that if they wish.

Mr. David Lee: We anticipate there will be some elevation in the burdens, but you want to target that to the right place.

A lot of the activities are occurring, as Dr. Berthiaume has mentioned. Pharmacovigilance planning is an example. We're receiving those now, because they're making them for Europe and the United States, so it's really putting in this structure that gives oversight to those activities. To the extent that many of the activities are occurring, we want to make sure we're getting the proper structure, and that will also affect the assessment of burden.

Mr. Ron Cannan: I know that's very important to the constituency I represent. Kelowna—Lake Country in the Okanagan in B.C. has the highest-census metropolitan area of seniors 65 and older. As we're all getting to that age more quickly than some of us would like, obviously additional regulations or additional costs are a concern, so I want to make sure we get the biggest bang for our dollar, as I know each of you does.

I'll follow up on the questions of my colleagues Mr. Brown and Ms. Davidson on the issue of clinical versus non-clinical or off-label drugs, specifically with treatments for cancer, AIDS, and other newer complex diseases. You often have these drug cocktails, as they're known, but there's nothing specific within market authorization. Are you saying you can't compare clinical with non-clinical in terms of adverse reaction?

Mr. David Lee: It might help to reset that a little bit.

When we do a market authorization, we're taking a look at studies in particular types of patients, who will be selected depending on what you want to prove with the drug. If it's for a cancer indication of a certain sort, you'll state that, and then you'll do your study on it, and that'll be the basis of the approval. It may be that the same therapy is effective for other types of cancer or other disease states, but we don't know that, because we haven't seen a study in that kind of population, and that's really what off-label means: it means we just don't have that pre-market authorization.

In a situation of practice, it may be that a therapy is extended beyond what's known and studied, based on other things such as medical literature and so on. This kind of practice is often very well founded, but what we get back is not from a population, so if the drug is being used consistently in this way, we're not getting back that kind of information the way we should be, and that's what we're trying to target.

Is that helpful to you?

Mr. Ron Cannan: Yes.

From a personal perspective, I lost both my parents to AIDS—my mom in 1989, and my dad in 1993. From 1989 to 1993 he was on a cocktail and had to sign off and authorize his physician and Health Canada.

So for 15 years that study on specific sample size has been done. I'm looking at subgroups and at whether you've been able to compare those kinds of effects.

Mr. David Lee: What the term “off-label” can mean there is that, again, when you studied it, you may not have combined those particular drugs. “Cocktail” means you're putting several drugs together in a treatment course; you may not have done a pre-market study or a clinical study on that, but they may be used in conjunction with each other, and that would be called off-label as well.

The Chair: Thank you, Mr. Lee.

Mr. Ron Cannan: Thanks. I know they do that with the children as well.

Thank you very much.

The Chair: Thank you, Mr. Cannan and Mr. Lee.

Go ahead, Ms. Kadis.

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

Thank you for the presentations today. I know we have very little time.

I'm interested in pursuing the reference that was brought up earlier regarding counterfeit drugs and how we are, to the best of your knowledge, checking for counterfeit drugs to ensure that patients are getting the right drug in terms of the relationship to adverse drug reactions.

Mr. Fraser, would you comment?

Mr. Brent Fraser: With respect to counterfeit drugs, they are not really provincial jurisdiction, but I know that the colleges will often have processes and policies in place so that if something is reported to them, they may elevate it through, I suspect, to Health Canada.

Mrs. Susan Kadis: Mr. Lee, what about doing spot checks in pharmacies to find and identify counterfeit drugs?

Mr. David Lee: My colleagues from the inspectorate would best answer that question for you, but I've certainly done enough briefings alongside them to know they are doing a lot of work at the border, and they've been very involved with us in working out the new policies. They also deal with colleagues in the RCMP, for example.

So there has been a lot of good discussion on this topic, but I'm less than qualified to do justice to the question.

● (1255)

Mrs. Susan Kadis: Perhaps you could help to facilitate that information being forwarded to the committee for our report.

Mr. David Lee: Yes, absolutely.

Mrs. Susan Kadis: As well, Mr. Fraser, is your working group going to be providing recommendations for our committee's work, or can you?

Mr. Brent Fraser: The working group has been putting forward some recommendations, but again, those are still being discussed through some of the ministers, so they won't be presented to this committee.

Mrs. Susan Kadis: I think it would be very helpful if we could have that type of information. I know that the FPT ministerial task force on the NPS hasn't submitted a report here since 2006. Are we missing one? Should we be expecting one?

Mr. Brent Fraser: There have been some discussions and recommendations under way, but again, those are still under discussion and we're waiting for direction from ministers on the next steps. So those are still in the formative stage.

Mrs. Susan Kadis: Finally, Madam Chair, I'd like to ask if our witnesses believe that progressive licensing will improve or reduce consumer safety in terms of drugs for Canadians.

Mr. David Lee: That is the absolute intent. It is actually to make sure that not only can we do that at the pre-market stage, but also that we can do it as the therapy goes out. We recognize that it's a complex job, but that's why we're trying to put in very good supervision.

Mrs. Susan Kadis: I'm asking this because the United States has identified difficulties they've had with this process. I think they may not use the same terminology, but they have had difficulties with compliance by industry, I believe.

Mr. David Lee: Yes. Well, they've been making a lot of changes as well. Again, we're not saying that progressive licensing is fast-tracking; rather, progressive licensing describes the way we generally market-authorize a drug, and there's no reduction in standards here.

We're adding to the post-market, because you can only know so much when you first authorize a drug, and then when it moves out into the community of use, you can start to see things that you wouldn't see in a clinical trial. We want to make sure we have really good tools that are very enforceable and effective in communicating, because it's not just enforcement that matters, but also that we're actually communicating well with health care professionals and the consumers and patients who are taking a drug.

The Chair: Mr. Vandergrift, did you want to speak?

Mr. Michael Vandergrift: I would just add that in the American example, they have just obtained new legislative authorities as well. I think these just came into effect in 2007. This also affects their tools vis-à-vis post-market authorities.

Mr. David Lee: We've been talking a lot with our colleagues in the FDA to learn from them, because we want to advance the best model that we can. Similarly, the Europeans have been very helpful to us in showing us what's worked for them as they've modernized.

Mrs. Susan Kadis: So this proposed new approach will not reduce any safety mechanisms at the pre-market stage?

Mr. David Lee: No, no, it will not. It will maintain the very high standard that we have.

Mrs. Susan Kadis: Thank you, Madam Chair.

The Chair: I want to thank the witnesses. We've had a very, very interesting dialogue today and some really good questions and answers. I appreciate this very much.

But I understood that Health Canada was going to bring forward a schematic of post-market activities. Could that perhaps be provided to the clerk so that we could distribute it to all the members? Is it possible to have that?

Mr. Michael Vandergrift: Yes, I think so. We'll go back and check, but I think that should be okay.

The Chair: It would be great if you could do that, and then I'll make sure everyone has it.

I'd like to thank you all for coming today. This concludes our study on post-market surveillance for today. We want to thank you, especially for all your time—and the miles of travel, Dr. Carleton—and for being here today. Thank you.

The meeting is adjourned.

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

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

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