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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1105)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good morning, ladies and gentlemen. It's very good to see everybody here this morning.

Today we are going to be listening to witnesses from the area of pharmaceutical products, prescription and non-prescription, on the post-market surveillance.

We have two orders of business to deal with at the end of the meeting. The first is the motion by Ms. Judy Wasylycia-Leis, and we will deal with that at 12:45. We have another piece of business as well. But seeing as our witnesses are here this morning, we want to make very good use of their expertise and time, and very good use of the time the committee has to ask them questions.

Pursuant to Standing Order 108(2), I'd like to welcome you to the fourth meeting on post-market surveillance of pharmaceutical products, prescription and non-prescription. We have pharmacy professionals who will be taking part in today's panel. We have representatives from the Canadian Society of Hospital Pharmacists, the Canadian Pharmacists Association, Ordre des pharmaciens du Québec, and the National Association of Pharmacy Regulatory Authorities.

I would like to remind the witnesses that you have ten minutes per organization to make your presentations. The committee will hear your presentations first before proceeding to the questions.

Let us begin with Ms. Myrella Roy, executive director of the Canadian Society of Hospital Pharmacists. Welcome.

Ms. Myrella Roy (Executive Director, Canadian Society of Hospital Pharmacists): Madam Chair, honourable members, ladies and gentlemen, thank you for the opportunity to present to you today. *Merci pour l'occasion de présenter à votre comité aujourd'hui.*

My name is Myrella Roy, and I am the executive director of the Canadian Society of Hospital Pharmacists. Before accepting this position, I spent 17 years as a hospital pharmacist and clinical manager with the Ottawa Hospital. The society is the national voice of hospital pharmacists in Canada. We are a not-for-profit organization committed to the advancement of safe, effective medication use and patient care in hospitals and related health care settings.

Today I wish to bring to the committee the perspective of our 3,000 members across the country on the issue of post-market surveillance of pharmaceutical products in Canada, both prescription and non-prescription. In particular, I want to comment on the proposal within Canada's food and consumer safety action plan to introduce hospital-based mandatory reporting of serious adverse reactions to federally regulated health products.

The action plan, as you know, proposes a new approach that helps prevent problems in the first place, targets the highest risks, and responds rapidly to protect the public.These are noble goals indeed, but we are concerned that the move to mandatory reporting of all adverse reactions could make it harder, not easier, to identify the highest risks and respond rapidly to protect the public.

l also want to share with you a proposal for how these goals could be achieved in relation to medication and patient care. Let me begin by making it clear that the Canadian Society of Hospital Pharmacists strongly supports measures to improve patient safety in Canada, and we do recognize the need to increase the percentage of adverse reactions to medications that are reported. We applaud the recent efforts by Health Canada to make online reporting possible, and we welcome the additional local and regional offices that will make it easier for health practitioners and consumers to report.

We are, however, quite concerned that the move to mandatory reporting of all serious adverse reactions will create an avalanche of data, and that searching for and finding the critical information within that data will be more difficult and more time-consuming. The additional time and effort, in the end, may contribute little to the overall body of knowledge on medications and adverse reactions. That's because much of the new data will come from adverse reactions to medication that are in fact well known and anticipated. Pharmacists and physicians know about these serious effects and anticipate them as an extension of the drug's therapeutic effect. We know, for example, that patients who receive warfarin, a commonly used blood thinner, may experience an increased risk of serious bleeding, or that patients undergoing chemotherapy may experience low blood cell counts.

Traditionally, these anticipated adverse reactions and the resulting hospital admissions are not reported, which helps explain why less than 2% of adverse reactions leading to hospital admission are reported to Health Canada. Making it mandatory to report all of these anticipated adverse reactions will not only create an avalanche of new data, it will also place considerable strain on the pharmacists, physicians, nurses, and other health professionals who work in Canada' s hospitals and related care settings. Given the shortage of these professionals and their already high workloads, it comes as no surprise that the workload required to report adverse reactions has been identified as a barrier to reporting in previous surveys. Any requirement to report all serious adverse reactions must consider the reality of shortages and growing workloads among Canadian health care professionals.

● (1110)

The greatest risk in creating so much new data from adverse reactions that we know of and anticipate is that the most valuable information will be lost or diluted by excessive amounts of information we already know. Instead, the society believes the reporting program should specifically target new adverse reactions for existing products and serious adverse reactions for new products. Focusing on these two types of new adverse reactions will provide health care professionals and consumers with quality information they can use and allow us to identify and respond to emerging risks more quickly.

Instead of moving to a new mandatory reporting program, we support enhancing the programs already in place to include reports of new serious adverse reactions. Diagnosing these adverse reactions and their causes will likely be very challenging, since there may be a number of active conditions being treated with a number of medications. It can also be difficult to detect whether symptoms are related to the medication or to the disease being treated. That's why we recommend a multi-disciplinary team approach to assess each case, including pharmacists, physicians, and nurses.

We also strongly support an expanded education and awareness program targeting health care professionals and students, designed to reduce or eliminate many of the motivational barriers to reporting that will not necessarily be addressed by the new action plan. Mandatory reporting does not address the motivational barriers that currently prevent health care professionals from reporting adverse reactions, such as the fear of negative feedback, questioning the purpose and usefulness of reporting, or the desire to publish findings independently. We are confident that an education campaign focused on reporting new serious adverse reactions will prove more effective in the long run than mandatory reporting.

Finally, there's a need to enhance information retrieval from the existing Health Canada adverse reactions database, called the MedEffect database. Consumers and health care professionals need greater access to the information contained in the database. They need this information in a format that allows them to make informed decisions. Currently the database can be searched by drug, but the details of each of the reports can only be accessed by looking at each one individually. This makes it much more difficult to assess any drug reactions.

In short, the Canadian Society of Hospital Pharmacists strongly supports the goals of Canada's food and consumer safety action plan. In many important ways those goals are aligned with the society's own mission and vision. We are concerned, however, that the move to mandatory reporting of all serious adverse drug reactions in Canadian hospitals will make it harder, not easier, to achieve those goals. Instead we call for a more focused approach that concentrates on information we can use: new adverse reactions to existing medications and adverse reactions to new medications. This focused approach will make better use of existing reporting programs and databases, make better use of the valuable time of Canada's hospital pharmacists, and when combined with a multi-disciplinary team approach to assessment, will generate higher-quality information with which we can protect Canadians.

Thank you for the opportunity to present our concerns and solutions. I would be pleased to answer any questions you might have.

● (1115)

[*Translation*]

I invite you to ask your questions in the official language of your choice.

[*English*]

The Chair: Thank you so much. We will save our questions until everybody has made their presentation.

Now we will hear from Mr. Jeff Poston, executive director of the Canadian Pharmacists Association.

Mr. Poston.

Dr. Jeff Poston (Executive Director, Canadian Pharmacists Association): Thank you, Madam Chair.

Good morning to everyone.

I'm the executive director of the Canadian Pharmacists Association, and I'm joined this morning by Denis Villeneuve. Denis is our board member from Quebec, and he's a community pharmacist practising in Quebec City.

I'd like to thank you for this opportunity to present to the standing committee today.

The Canadian Pharmacists Association was established in 1907. We celebrated our centennial last year. We're a voluntary membership association that represents the interests of Canada's 30,000 pharmacists. We do not represent pharmacies or the pharmaceutical industry.

As we know, pharmaceuticals play an increasingly important role in our health care system. For more than 10 years drugs have made up the second largest share of health spending, reaching $26.9 billion last year. But as more and more Canadians benefit from drug therapy, the number of concerns about safety and adverse drug reactions is increasing.

I'm going to hand this over now to my colleague Monsieur Villeneuve.

[*Translation*]

Mr. Denis Villeneuve (Member of the Board, Canadian Pharmacists Association): First of all, thank you for having invited us and for allowing me, as a community pharmacist who has worked in my field for 30 years, to come and share my thoughts with you.

The Canadian Pharmacy Association strongly supports measures to increase patient safety, including increasing capacity for monitoring, surveillance and research; and the reporting of adverse drug reactions. For professionals, for pharmacists and for myself as a community pharmacist, patient safety is a priority. Safety needs to be part of the entire chain of events that begins when the prescriber orders a medication until the results are apparent in the patient.

A strong system must be in place to ensure safe and effective use of medications—one that includes a progressive early warning system for adverse drug reactions, post-market surveillance, and education of health care professionals.

I have prepared a chart in order to explain the complexity of the process to you, which begins from the moment a problem is discovered, whether it be by a health care professional, a doctor, a pharmacist or a patient. You can see that the process is complex and has the potential for an adverse event and potential harm. You must always remember that the patient is at the centre of the process.

We begin by recognizing the problem and beginning treatment, taking into account the analysis that has been done of the case and the patient's situation. Then, we implement was is called the health care plan and the treatment objectives. The information is given to the patient, who is supposed to use the drug according to instructions while watching for signs of improvement and adverse effects. The patient finds himself or herself managing the treatment and informing the professionals of what is happening. It is a cycle that repeats itself: the patient is satisfied or has adverse effects.

Whether or not the medication is prescribed or non-prescribed, there are different actors involved in the process, including the patient.

There are many adverse reactions. According to the statistics, from 37% to 68% of adverse drug events are said to be preventable. But in order to prevent these, the right decisions have to be made at each stage of the process that I have briefly described to you. Moreover, health care professionals are being asked to make rapid decisions, often with limited information or support.

Patients have little support to be involved in the decision-making process, but increasingly, within the context we are discussing here, they are being expected to take on greater responsibility for their care, as well as that of family members.

To help health care professionals and patients make better decisions, we believe education, information and tools must be readily accessible to them.

● (1120)

[*English*]

Dr. Jeff Poston: Thank you, Denis.

Before getting into our recommendations that relate specifically to issues around improving drug safety, I'd like to comment on the concept of mandatory adverse drug reaction reporting, which we believe is being confused with overall steps that need to be taken to improve drug safety.

The Canadian Pharmacists Association is strongly supportive of measures to increase patient safety. We were one of the founding organizations of the Canadian Patient Safety Institute, and we certainly support the need to increase the reporting of adverse drug reactions. However, we believe a multi-pronged approach is needed and are concerned that too much attention is being placed on mandatory ADR reporting as the quick-fix solution.

In terms of making reporting of serious adverse drug reactions mandatory, we question whether all other avenues have in fact been exhausted. Increasing the quality and richness of ADR reports is as important as increasing their number, perhaps even more important, since high-quality reports allow for high-quality analysis.

We feel that mandatory reporting will not improve the quality of ADR reports, it will simply increase their quantity. It may even compromise the system's efficiency and effectiveness by increasing the volume of clinically insignificant reports.

Another concern we have is the issue of enforcement. When you use the word “mandatory”, it often goes with enforcement. We question whether this is feasible and whether Health Canada would be able to devote and maintain sufficient resources for mandatory ADR reporting in terms of compliance or analysis.

We also see the potential for such a development to place significant burdens on already time-pressed health care providers. In fact, we can find no evidence from other jurisdictions that mandatory ADR reporting really supports improved patient safety, and we wonder why mandatory reporting has been singled out for discussion when a more integrated approach to informing Canada's drug safety system is called for. Prior to launching a program whose success is yet to be proven, other viable and perhaps more effective alternatives, we believe, should be examined.

With that in mind, we'd like to make the following recommendations.

We need to establish and aggressively promote education and training programs for health care professionals that focus on better use and better ADR reporting. Health care providers should be encouraged to participate voluntarily in reporting ADRs. An international experience demonstrates meaningful participation when those involved are willing participants. A successful ADR system must be simple to use and must fit into the busy practice of the health care provider. This will also allow for effective expert analysis of the quality data gathered so that we're better able to identify hazards and trends.

We believe that government should invest in innovative research relating to methods of detecting, evaluating, and reporting adverse drug reactions, and support quality decision-making during the prescribing and medication use processes. That's critical to long-term safety and effectiveness. I think a particular focus of the research needs to be the role of the consumer with respect to non-prescription medications and natural health products.

The federal government, through Health Canada, should invest in an electronic ADR reporting system that will integrate reporting forms into the software used by health care professionals at the point of care. These electronic systems should be integrated into prescribers' offices, pharmacies, and hospitals. They essentially should become part of the future developments around the electronic health record.

On another note, we believe that the federal government should fully fund the business plan for the real world safety and effectiveness of medicines in Canada, a project developed as a part of the national pharmaceutical strategy. We need to support the development of the network of centres of excellence proposed in this report.

Pharmacists must also be supported to play a greater role in ensuring the quality use of medications and in reporting adverse drug reactions. Pharmacists are the only health care professionals with a full-time university education devoted entirely to drugs and their use. Better integration of their knowledge and skills into the health care system through collaborative practice arrangements will go a long way to solving many of the problems in medication use in Canada.

Our final recommendation is that we must include the pharmaceutical industry as a partner in establishing programs and processes to ensure the safe and effective use of medications. The pharmaceutical industry possesses considerable data that, when combined with adverse drug reaction data collected by Health Canada, will help decision-makers and health care providers take steps to ensure the safe and effective use of medications. The industry has very effective methods for collecting and disseminating information that can be used to the advantage of Canadians.

● (1125)

On behalf of the Canadian Pharmacists Association, thank you for the opportunity to present our views on this important subject today.

The Chair: We thank you, Mr. Poston.

Mr. Villeneuve, it's very nice of you to share your time.

We'll now hear from our next witnesses from Ordre des pharmaciens du Québec.

Pardon my French. I've been studying it for three years and I still can't speak it properly. I'm hoping some day to be bilingual; it will be about another decade. So pardon my mispronunciation.

Welcome to the president, Mr.Claude Gagnon; and the director general, Madame Manon Lambert.

Mr. Gagnon.

[*Translation*]

Mr. Claude Gagnon (President, Ordre des pharmaciens du Québec): Madam Chair, distinguished members of the House of Commons Standing Committee on Health, allow me to introduce myself. My name is Claude Gagnon, pharmacist, and I'm president of the Ordre des pharmaciens. Ms. Manon Lambert is the director general and secretary of the association.

We wish to thank the members of the Standing Committee on Health for giving us this opportunity to share some of our thoughts on the subject of post-market surveillance.

The mission of the Ordre des pharmaciens du Québec is to protect the public by ensuring the quality of pharmaceutical care and services provided to the public, and by promoting the appropriate use of medication in society. In order to fulfil its mandate of protecting the public and thus fulfil its mission, the Ordre des pharmaciens du Québec delivers licences to practice, guides pharmacists in the exercise of their duties, ensures that the competence of its members is maintained and evaluated, receives complaints from the public and deals with them, controls the illegal exercise of the profession and intervenes publicly on issues related to the use of medication.

The Ordre des pharmaciens du Québec has almost 7,000 members who practice in various work environments, but mainly in the private sector—community pharmacies—and in health care institutions.

As is true of many federal organizations, including Health Canada, the reason for the existence of the Ordre des pharmaciens du Québec is first and foremost the protection of the public.

● (1130)

[*English*]

The Chair: Mr. Gagnon, I'm sorry to interrupt. Could you slow down a little? Our interpreters are having a little bit of difficulty keeping up with you.

Thank you.

[*Translation*]

Mr. Claude Gagnon: Fine.

That's why we would like to take this opportunity here this morning to share our thoughts about federal authorities in the framework of this committee. Although we are aware that we are not directly addressing Health Canada officials, since the result of your work may well influence federal policies and procedures, some of the comments we make here today will therefore be addressed to the federal government in general.

Post-market surveillance and pharmacovigilance in general regarding healthcare products sold with or without a prescription are at the heart of the pharmacy profession in Quebec and in Canada. Since we don't have much time here, we will limit our speaking points to some of the main topics of discussion on this subject, notably pharmacist expertise in post-market surveillance; the need for a surveillance process the integrity and transparency of which are beyond reproach; adequate communication between professionals and organizations; and an effective pre-marketing approval process .

Our health care system is currently confronted with unprecedented challenges both in terms of material resources and organizational and human resources. It is difficult to imagine changes in the way we do things without increasing expenditures. Some of what we will say here today will therefore be based on the assumption that it is necessary to invest funds to improve the system. The result will be Canada's increased capacity to face the challenges of the 21st century in this matter.

The delivery of our health services is provided by professionals who have developed multiple skills over the years, but these are not always utilized in an optimal fashion. This is particularly the case for pharmacists, and we constantly repeat that they are among the most underused health professionals despite their accessibility, availability and unique skills in pharmacotherapy.

In Quebec, the Pharmacy Act lists six activities that are reserved to pharmacists. Among them is the surveillance of medication therapy. This surveillance is not just concerned with the effectiveness of therapy, but also its safety. Indeed, side effects, whether or not they are expected, account for a considerable number of interrupted or modified therapies.

It is a reflex among many health care professionals to wonder whether a certain symptom or health problem could be relieved through medication. However, few such professionals, in fact none except for pharmacists, have the reflex of wondering whether a medication is not the cause of the symptom or medical problem in question. The training and skills of pharmacists in this regard are undeniable. We have to learn to use them better and, in addition, make pharmacists more aware of regulatory bodies. We'll get back to that.

Over the past few years, the pharmaceutical industry has had its share of problem situations which, it must be admitted, undermined its credibility somewhat, or even a great deal. One simply has to think of Vioxx to understand the effects of such a decision on the public. For society, the same issues come to the fore whenever similar situations occur. What did the manufacturers of the product really know? How long did they know it? One could also raise a number of questions regarding the organization responsible for approving the marketing of the product and the agency responsible for post-market surveillance, namely, Health Canada. In a case like that of Vioxx, it is easy to see at the very least an apparent conflict of interest between public safety and corporate profits. In such situations, we must also ensure that the regulatory body responsible for protecting the interests and safety of the public always act quickly and transparently.

Health Canada approves the marketing of a product in good faith, based on the information provided by the manufacturer. In that context, the same organization must constantly face the dilemma of allowing access to innovative new therapies as quickly as possible while respecting the safety of users. Conversely, given the obvious risks for public health, the organization in question must act with the same celerity to demand the withdrawal of a health care product that is too risky for users in spite of the potential benefits.

● (1135)

The federal government must take the necessary means to ensure that its regulatory body acts at all time with full integrity and transparency.

When Health Canada receives information about adverse reactions, it logs it and attempts to determine whether the reaction can be related to the drug in question. In order to do so, Health Canada seeks the manufacturers' cooperation, and this is done not in a confrontational manner, but in the spirit of partnership. This is, after all, the era of partnerships. As a result of this working relationship, a significant number—if not the majority—of communiqués sent to health care professionals are issued by manufacturers and not by Health Canada. This allows manufacturers to demonstrate their apparent willingness to be actively involved in post-marketing surveillance. Such a modus operandi could be indicative of Health Canada not having sufficient resources to do the work itself, or it could be that legal considerations at least partly explain the decision to proceed in this manner.

Whatever the real reason may be, if everything were being done effectively, quickly and in the best interests of public safety, the end could perhaps be said to justify the means. There is evidence to suggest, however, that that is not necessarily the case. In November 2006, Health Canada approved the anti-inflammatory non-steroid drug Prexige (lumiracoxib) for sale for the long and short-term treatment of signs and symptoms of knee osteoarthritis in adults. In July 2007, the indications were broadened to include general osteoarthritis in adults.

It is worth noting that the FDA never authorized the drug for sale in the US. It should also be noted that lumiracoxib is part of the same family as rofecoxib (Vioxx).

In August 2007, Health Canada's Australian counterpart, the Therapeutic Goods Administration, withdrew Prexige from the market due to a number of reports of serious liver adverse events. On August 15, 2007, following the Australian decision, Health Canada published an information update on new safety information regarding Prexige. In this update, Health Canada stated that once it had reviewed the available data, new information would be released to Canadians and Canadian health care professionals, including any resulting recommendations.

Would it not also have been appropriate to advise professionals of this?

On October 3, 2007, Health Canada informed Canadians and the health care professionals that it was stopping sales of the drug following its assessment of safety data provided by Novartis carried out following the Australian government's decision to withdraw the product from the Australian market.

Health Canada stated that decisions issued by other countries can be interpreted as a red flag when dealing with new drugs for which little data is available. In spite of this, a drug which had been deemed dangerous, and which had been withdrawn from the market in at least one other industrialized country, was still available to Canadians for almost two months. Bear in mind that we are talking about a drug that belongs to the same family as Vioxx, withdrawn from the market in probably the most dramatic circumstances we have seen in recent years.

Why does Health Canada have to analyze data for two months before withdrawing market authorization, even temporarily? On the same day, Ms. Meena Ballantyne, an assistant deputy minister at Health Canada, made public project 1540, which proposed the addition of five medicinal ingredients to schedule F of part I of the Food and Drug Regulations. Included amongst these new ingredients to be added to schedule F, as I am sure you will have guessed, was Prexige.

This is what project 1540 had to say about lumiracoxyb:

> Lumiracoxyb is a non-steroidal anti-inflammatory drug that is used to treat pain and swelling in adults, such as osteoarthritis of the knee. Treatment with lumiracoxyb requires individualized instructions or direct supervision by a practitioner, particularly in patients with heart or liver disease. The patient may also require treatment with other drugs and routine laboratory monitoring. Lumiracoxyb may cause undesirable or severe side effects at normal therapeutic dosage levels.

Here in Canada, following an event such as an air crash, it is not for the manufacturer, or indeed even the Department of Transport, to carry out an inquiry. Instead we have the Canadian Transportation Accident Investigation and Safety Board, which is directly accountable to Parliament via the Queen's Privy Council for Canada and is independent from all other departmental and governmental bodies. To foster public confidence in the investigations and inquiries, the investigative body must not only be objective, independent and free from any conflict of interest, but must also be perceived as such.

● (1140)

Is it not about time that the government consider setting up a similar body to ensure transparent post-market surveillance of drugs? A system for ensuring the communication of information concerning adverse drug reactions ought to be clearer, bidirectional, and as effective as positive.

[*English*]

The Chair: Mr. Gagnon, you have gone quite a bit over time. I'd really appreciate it if you could sum it up so the committee has time to ask you questions.

Excuse me, Madame Gagnon, can we continue?

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): But Madam Chair, our witness is making such an interesting presentation!

Mr. Claude Gagnon: Even where the climate is one of direct collaboration and cooperation, and even though there are high-ranking officials working for the various Health Canada entities, it often proves difficult to contact the right person, especially when a specific, personalized response is required, and with some frequency. Pharmacists experience a great deal of difficulty both in giving information to, and getting feedback from, Health Canada.

Many pharmacists have told us that they have reported adverse reactions to Health Canada without having received so much as an acknowledgement in return. As such, it is hardly surprising that some professionals are in no rush to report adverse reactions. There is supposed to be a two-way flow of information and, for example, Health Canada has to advise health care professionals when drugs are withdrawn from the market; however, it would seem that the system has shortcomings on this front as well.

The Ordre des pharmaciens is committed to do what it can to help. Our website contains...

[*English*]

The Chair: Excuse me, Mr. Gagnon. Your presentation is so interesting, but I would ask that you submit it to the clerk. We'll have it translated and distributed to all committee members.

[*Translation*]

Mr. Claude Gagnon: No problem.

[*English*]

The Chair: It's an absolutely fabulous presentation, but we must be fair to all presenters.

It was very good. Thank you, sir.

Our next witness is Ms. Karen Wolfe. She is the executive director of the National Association of Pharmacy Regulatory Authorities.

Thank you.

Ms. Karen Wolfe (Executive Director, National Association of Pharmacy Regulatory Authorities): The National Association of Pharmacy Regulatory Authorities is honoured to appear before this committee today.

Our organization represents most of the provincial and territorial pharmacy regulatory authorities. During this presentation I'll be speaking to the role of the pharmacy regulatory authorities; the regulatory tools that are currently employed, specifically with regard to adverse drug reactions reporting; the challenges posed by mandatory ADR reporting; as well as the opportunity that partnerships could bring.

The Food and Drugs Act and the Controlled Drugs and Substances Act and their associated regulations define how prescription drugs may be manufactured, advertised, labelled, and sold. This legislation informs pharmacists and others of their responsibilities in the procurement, sale, and recording of the sale of prescription drugs.

However, the practice of pharmacy comes under provincial and territorial jurisdiction. The territorial governments retain responsibility for regulating the profession. However, the profession is self-regulating in the provinces, with the authority to regulate delegated through provincial legislation to the members of the profession. The fundamental role is protection of the public.

The Pharmacy Regulatory Authorities regulate people, places, and things. They regulate the practice of pharmacists, the operation of pharmacies, and the conditions of sale of non-prescription drugs. The regulation of pharmacists is accomplished through three core processes defined within legislation: registration or how to become licensed or enter practice, complaints resolution, and continuing competency assessment.

In addition to provincial acts and regulations, other regulatory tools include standards of practice, bylaws, and codes of ethics. These tools combined form a robust system that fully defines the expectations required of pharmacists in order to fulfill their duties. Any deviation from or dereliction of these duties is cause for complaints to be brought against a pharmacist. The complaints are investigated by the regulatory authority, and if sufficient evidence is found, the pharmacist is required to appear before a jury of his peers to answer to the allegations.

The reporting of adverse drug reactions is an expectation of practising pharmacists. In British Columbia, adverse drug reactions reporting is mandatory, as expressed in bylaws, which are approved by provincial government. Bylaw 44(4) states: “Where an adverse drug reaction as defined by the Health Protection Branch, Health Canada, Guidelines for Reporting Adverse Drug Reactions is identified, the pharmacist must notify the patient's practitioner, make an appropriate entry on the patient record and report the reaction to the BC Regional Adverse Drug Reaction (ADR) Reporting Centre.”

In Alberta, standard of practice number 4 states: “If a pharmacist determines that a patient has or is likely to have a drug-related problem, the pharmacist must take appropriate action.” This is further defined under section 4.2, “the appropriate response may include any one or more of the following:” and includes (g) reporting an adverse reaction to the Canadian adverse drug reactions monitoring program.

Ontario's standard of practice number 1.7 states: “The pharmacist documents and reports any unexpected adverse drug reactions to the prescriber and other health care providers as appropriate, and complies with formal adverse drug reactions reporting programs.”

Other provinces have addressed adverse drug reactions reporting within standards of practice, guidelines, and professional practice policies, or alternately, have referenced the *Guidelines for Reporting Adverse Drug Reactions to Marketed Drugs* publication by Health Canada. In short, the regulatory tools to encourage adverse drug reactions reporting by pharmacists already exist.

The reporting of adverse drug reactions is a key component of a robust, comprehensive post-marketing surveillance program on the use of medications in humans. Yet it has been estimated that only a small percentage, less than 10%, of these events are reported. The regulatory tools are already in place to require pharmacists to report adverse drug reactions where appropriate. Yet it seems that neither the presence nor the absence of regulatory tools is the trigger that drives adverse drug reactions reporting. This suggests there are many more challenges that need to be addressed and that mandating adverse drug reactions reporting does not seem to provide a plausible solution.

Many challenges have been identified to adverse drug reactions reporting, many of which have been previously addressed in the 2005 Health Canada discussion paper “Designing a Mandatory System for Reporting Serious Adverse Reactions”. They include lack of training and recognizing adverse reactions, lack of awareness of the existence and benefits of a reporting system, time and effort required to do so, and the lack of familiarity with how to report. I am uncertain that the implementation of a mandatory adverse drug reactions reporting system addresses these challenges.

● (1145)

Another challenge not identified in the discussion paper is the lack of comprehensive, reliable data upon which to assess whether or not an adverse drug reaction has occurred. Great strides have been taken in the development and implementation of a pan-Canadian electronic health record. It is Canada Health Infoway's goal for 50% of Canadians to have their electronic health record available to health professionals by the year 2010. However, until health professionals are able to access the electronic health record for all Canadians, the depth and the quality of information that's required may not provide the results desired with an adverse drug reaction reporting.

Enforceability is yet another issue, and brings forth the question of where the responsibility lies. Pharmacy regulatory authorities have the authority to perform practice audits and site visits to monitor registered pharmacists and licensed pharmacies. However, not all hospital pharmacies are licensed by the pharmacy regulatory authority in each province.

In addition, this is a very resource-intensive activity for the pharmacy regulatory authorities, who rely almost exclusively upon fees collected from licensing and registration of pharmacists and pharmacies as an annual source of revenue.

Finally, should adverse drug reaction reporting be mandated through federal regulation, there is now the question of who should have the responsibility for monitoring and enforcing the regulation.

NAPRA is supportive of adverse drug reaction reporting as part of a comprehensive post-marketing surveillance system that has the ability to look closely at real-world experiences with the goal to identify adverse drug reactions in populations outside a clinical trial setting in order to protect the Canadian public from harm. However, NAPRA does not feel that mandating adverse drug reaction reporting and increasing the regulatory burden will accomplish this goal. It may be more appropriate to adopt a systems approach with other partners and stakeholders contributing to a surveillance and reporting system with a common goal of promoting quality health outcomes.

What is required is a substantive culture change, facilitated through education and communication, to build awareness of the importance of adverse drug reaction reporting as well as the clarity of what is expected. Enhanced development of advanced technological solutions that are easy to use will encourage the reporting of adverse drug reaction to be incorporated into daily practice. Effective data analysis and reporting mechanisms to ensure that informed feedback is available and accessible to health professionals in a timely manner will serve to reinforce the practice of reporting.

We need to think about the role of the federal government, the provincial and territorial governments, professional regulatory authorities, and health professionals, as well as such stakeholders as industry, the Canadian Patient Safety Institute, the Institute for Safe Medication Practices, and academia. If attention can be focused here, and a willingness can be secured from all parties involved to make this issue a priority, it is a certainty that adverse drug reaction reporting events will continue to increase, as they have in the past, without the need to mandate.

Thank you.

● (1150)

The Chair: Thank you very much.

I want to thank everyone for their very insightful presentations today.

We will begin right away with the questions.

Madam Kadis, would you like to lead off?

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

Thank you to the witnesses today. I have a few things to ask.

First, to Mr. Gagnon, I'm wondering if you could clarify whether you received information on adverse drug reactions here in your practice, or within your organization. The concerns, I imagine, were brought to the attention of Health Canada. As I understood you to say, it was not taken off...or the marketing process was not stopped, which is the function of Health Canada, as opposed to pulling a drug off the market.

Had you heard from other sources in other countries that there were adverse drug reactions, and then made that known? Or was it known and the marketing didn't stop? It wasn't clarified exactly: did you receive that information, or did your members receive that, before you brought it to the attention of Health Canada? Or was this something that you had heard about worldwide?

[*Translation*]

Mr. Claude Gagnon: The situations I described are everyday occurrences. For example, we often get information from notices or articles in newspapers, or from patients who have read or heard something about a particular drug. The Internet means that, today, everything happens quickly. I have seen cases where patients say that they were told that a product had been recalled and that they had to return to the pharmacist, yet the pharmacist was completely in the dark. When this happens, we just have to wait, and we cannot even reassure our patients. We are not getting detailed information in time.

It even happens that the Ordre des pharmaciens is sent information after it has been made available to the public—and perhaps Ms. Lambert would like to comment further on this. It is not acceptable that this sort of information is made available to the public without giving health care providers the time to get organized in order to be able to answer Canadians' questions. That is what is so unfortunate about this situation. It generates feelings of insecurity and concern, and there is a lack of transparency. That is what we want to get across to you today.

[*English*]

Mrs. Susan Kadis: Thank you very much, Mr. Gagnon.

Ms. Roy, you said you were concerned that with mandatory reporting of adverse drug reactions, there would be too much information. We've heard that from other witnesses as well; perhaps it's quantity not necessarily enhancing quality. Conversely, would there not also be a problem with not getting enough information to ensure it is adequate to suggest changes should take place, and that there's enough of a sampling of people? Is that also not a challenge, if it's limited?

Ms. Myrella Roy: What I was referring to is that there's typically no need to provide additional information for adverse reactions that we already know enough about. We already know how to deal with these interactions, so just providing more reports on the same reactions will not add to the body of knowledge for health care professionals and consumers on how to deal with these reactions. Then if we have this avalanche of data, it will be difficult to sieve through that data to identify the reactions that are actually very significant—new or poorly documented reactions to existing medications, as well as reactions to new medications.

To answer your question, I'm not sure providing more information on a body of knowledge that is already large will provide any additional—

● (1155)

Mrs. Susan Kadis: Thank you.

In terms of this study, to my mind the question of the frequency of the adverse drug reaction remains. This issue of quantity versus quality, and why both couldn't be considered relevant, has been on my mind since we've started our study. Obviously everyone agrees that we're trying to maximize the knowledge and the reporting in general, and of course the quality, so does it not matter how often it would happen?

Ms. Myrella Roy: In the case of the two examples I provided, we know, for example, that chemotherapy agents can cause a lowering of blood cell counts in probably almost 100% of patients. Will one more report to tell us that it is 100% assist us? Also, serious bleeding from warfarin can occur in a significant number of patients, so is “significant” 45% or 50%? We already know that, so one more report is not going to help us manage patients better.

Mrs. Susan Kadis: Being myself a 16-year breast cancer survivor who experienced chemotherapy at that point, I totally concur with you that it's very typical; I think it's well known that the blood count goes down and treatment is interrupted, etc. But that to me is not necessarily.... I think that's one category; it doesn't necessarily talk about other drugs that are perhaps less expected or not as well known to have almost automatic adverse reactions on a temporary basis due to that particular process in that drug, so would there not be cases in which we would not typically expect to have that?

I think you're making a good point, but I also think there could be cases and drugs that are not known to cause adverse reactions. But if we had a bigger sampling or enhanced knowledge from all health care professionals as well as the patients, we might have a better sampling of what is going on out there. Again there is this issue of frequency; I don't think it's been totally addressed yet. Does it make a difference? Can you say that knowing how frequently a drug has adverse reactions doesn't make a difference in some cases?

Maybe someone else can address it.

Dr. Jeff Poston: I can perhaps jump in and give my view from a practice perspective. I think ideally you want quality and quantity. An observation from the World Health Organization's adverse drug reaction reporting centre recently expressed the need to actually focus on quality. I think one of the challenges in terms of analysis of reports is that if they're missing information and they're incomplete, they don't really contribute.

The quantity argument comes in as one of the challenges that we know in relation to drugs at the clinical trial stage: they only get tested in a very narrowly defined population. I think a critical benefit of post-marketing surveillance is that you are seeing drugs used in a much broader population, so you do want to encourage reporting from a very wide range of people exposed to the drug. That's clearly desirable.

The critical piece—and I think it's the crux of the issue around mandatory reporting—is that if people feel they've just got to send reports in, and there's no attention paid to the quality of those reports, we're no further ahead. The critical piece is that we need to educate people to report better, but also we need to get better quality.

Denis, would you like to comment?

The Chair: Would you also like to make a comment? Go ahead.

[*Translation*]

Mr. Denis Villeneuve: From a practitioner's perspective, it is already very difficult to explain adverse drug reactions to patients. It would be all the more difficult if we had to then say that a given ADR is experienced by one patient in a million. How do you make this sort of information accessible to the patient? It is a real challenge.

[*English*]

The Chair: Madame Lambert, do you want to comment as well?

[*Translation*]

Ms. Manon Lambert (Director General and Secretary, Ordre des pharmaciens du Québec): One of my colleagues pointed out earlier that an integrated system is required. This is because even if we have the best databases available, offering both quality and quantity, we cannot always avoid ADRs if the information does not get—in a timely fashion—to the professional who has a patient standing in front of him. We all know that health care professionals often experience difficulty in getting feedback on the ADRs that they report. Although Health Canada's decision to make the MedEffect's database available on its website constitutes considerable progress, it would seem that health care professionals do not always consult the information that is sent to them and, as such, experience difficulties when using the system.

Our ultimate goal is to provide better treatment for our patients and to have a better understanding of the medications. A lot of emphasis has been placed on mandatory reporting, but I believe that the system as a whole should be addressed. Obviously, mandatory reporting has its role, but patient feedback also has to be considered. In the long run, changes may well be made to change monographs, but that takes time. Amending a monograph involves negotiating with the drug manufacturer, and it really does take a very long time. It is therefore very important to ensure that the link between health care professionals and the body receiving the reports is very strong. It is something that needs to be integrated into pharmacists' daily practice.

● (1200)

[*English*]

The Chair: Thank you, madame.

Now we'll go on to Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: What you are telling us here today is very interesting. For our part, we want to understand how the system works and how the Department of Health is involved.

Mr. Gagnon, you talked about subjects which to me are worrisome. We see that there are medications on the market with known undesirable side effects. You mentioned Vioxx. You said, among other things, that certain products should perhaps be withdrawn from the market, given the data from countries where they have been withdrawn. Gardasil caused the death of five people. I do not know if it was in Belgium, but it was in Europe.

The other day, I asked someone from Health Canada whether, given the five deaths that occurred in Europe, there shouldn't be a moratorium on this product, and whether we could use the data. I was told that this was not up to Health Canada but rather up to the Canada Public Health Agency. Already, this is complicated. Health Canada has told us that this is not the department's responsibility because it is a vaccine that comes under Public Health, and yet, Health Canada approved the marketing of this product.

You are saying the product should be withdrawn, but does this have to be immediate? What kind of tests could be done? I know that in Europe, they are analyzing the effects of the product and the reason why it may have caused deaths.

I am putting the question to Mr. Gagnon, but other witnesses can shed light on this subject for me. For our part, we are going to have to recommend steps with regard to Health Canada, and that is one of the issues at stake.

Mr. Claude Gagnon: Allow me to respond. I omitted part of my speech. That was precisely my point.

I would not want people to lose their trust in the system, be it the professionals or the general public. When we offer a product for sale in our pharmacies, it is because we think it meets the standards for protecting the public. Of course, we know that there are adverse drug reactions, but that they are not major ones; they are supposed to be minor and acceptable. In fact, patients are informed about them.

What is serious is that products that may lead to death among certain people can get through a gate that we can't imagine. We think that the tests done in advance by the manufacturer should be able to detect that kind of thing. Right now, marketing may be accelerated. Post-market surveillance is being demanded in order to detect problems. However, I do not think it is normal that we wait for deaths to occur before we take action, regardless of where they occur on the continent. Whether there are one, two or three deaths, a red light should flash and we should temporarily suspend the sale of that drug until we have the answer. It is up to the company to provide that, and it should not be the public who pays the price. This is where we want to raise public awareness.

Many products are currently at the pre-marketing stage. They have not been licensed and are sold illegally, in theory, since they are accessible to the public. This year, 64 products were withdrawn from the market. Of these, sixty were contaminated by bacteria, contained toxic heavy metal and had not undergone the pre-marketing process. Post-marketing is all very well, but the pre-marketing rules should also be respected. A product should not be sold if it has not received all the authorizations, all the patents necessary to guarantee its quality to the public.

That is the main message we want to convey, and I think it is important for you to take a look at this.

● (1205)

[*English*]

The Chair: Madame Lambert, would you like to comment?

[*Translation*]

Ms. Manon Lambert: As health care professionals, we always have to strike a balance between risks and benefits.

Earlier, this lady said she had received cancer treatment. Usually, when a patient is suffering from a potentially deadly cancer, the health care professionals treating that patient will accept a higher level of adverse reactions and potential risks of mortality, because this is a somewhat desperate situation.

Let's take the example of a nonsteroidal antiinflammatory drug which relieves pain for certain people suffering from rheumatoid arthritis, a very debilitating form of arthritis. We accept somewhat higher levels of ADRs. However, if it is used to cure a tennis elbow, we do not want to have this lead to liver problems and liver transplants down the road. It is in that sense that we have to evaluate the data that is given to us. It is not because a drug has been withdrawn from the market in another country that we should absolutely have it withdrawn here, because the context for its use may not be the same.

As health care professionals, that is the kind of information we like to obtain in terms of feedback. In the final analysis, we are the ones who are faced with the patients, and we have to advise them and inform them of the risks and benefits involved in taking a given drug.

Ms. Christiane Gagnon: Do you think that it is acceptable that the public are aware of only a small percentage of potential ADRs? As I understand it, the public are aware of only 10% of ADRs. People get the impression that everything is being done in secret and that they only find out the real story when it makes the papers. What is Health Canada's role? Could Health Canada be more proactive? There was pressure to get Gardasil onto the market quickly. When an industry is above the law when it comes to certain measures, there is no way of knowing who...

[*English*]

The Chair: Madame Gagnon, time is running out, and you have many questions. Perhaps, Madame Lambert, could you try to sum up some answers for madame.

[*Translation*]

Ms. Manon Lambert: As a general rule, the pre-market review reveals the most common ADRs.

Normally, between 2,000 and 3,000 patients will have tried the drug before it is marketed, although, of course, it all depends on the type of drug. In light of the number of patients who participate in trials, it is clear that we endeavour to strike a balance between getting the drug onto the market and having adequate knowledge of it. Obviously, asking manufacturers to test the drug on a larger number of patients will delay its introduction to the market. Nonetheless, in some cases, I think that is what needs to be done. In spite of pressure brought to bear by manufacturers for financial reasons, in some cases, that is indeed what needs to be done. As I said earlier, however, in other cases, depending on the type of disease, or whether the drug constitutes a therapeutic breakthrough, or whether the patients have no other options available to them, it is sometimes preferable to accept a greater degree of risk. I think that is important to assess the risks and the benefits, and to take stock of what constitutes acceptable risks in a given situation. I do not, therefore, believe that it is appropriate to use the same approach in all cases.

[*English*]

The Chair: Thank you, Madame Lambert. I appreciate your answer.

Ms. Wasylycia-Leis.

[*Translation*]

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

I truly agree with what Mr. Gagnon and Ms. Lambert said about addressing safety issues before drugs are made available on the market.

[*English*]

That's one of the questions we really have to deal with today. The government seems to be fixated on this notion of progressive licensing. Some believe that a part of it's being designed to get drugs on the market faster and thereby minimize the safety precautions at the front end. And that's a big part of what we should be looking at and what the government is out there doing anyway.

We need to get some comments from all of you on this whole new approach to licensing and its impact in terms of drug safety.

Jeff, do you want to start?

● (1210)

Dr. Jeff Poston: Yes, thank you.

The progressive licensing concept is an attractive concept, because I think we know from our experience and the drugs we've talked about—Vioxx, Cisapride, and there's a long list of drugs that we've had over the last 20 years—that we really only truly learn about drug safety through use. Conceptually, there's lots of attraction around just getting the drug into the market as soon as we feel it's reasonably safe, and then monitoring its use in 10,000, 20,000, or 30,0000 patients in order to know whether it's truly safe or not.

So I think the concept of progressive licensing is probably where we need to go. I think the challenges are around actually making sure the systems are in place at a practice level to ensure that we can effectively collect all of the relevant data to make sure we can make a good assessment of safety. And then further, on top of that, there is this need to really better develop systems that support the safe and effective use of drugs.

We've just published a book written by a Canadian who won the Harkness Scholarship this year. It is called *Safe and Effective. The Eight Essential Elements of an Optimal Medication-Use System.* It deals with issues around the evaluation of drugs prior to marketing, but more importantly, it deals with what needs to actually be done in practice to make drug use safe. We can make a copy of this available to committee members.

I think that conceptually, progressive licensing is probably the way we need to go. But a lot of work has to be done in terms of building the systems that would actually support that in the practice environment.

Ms. Judy Wasylycia-Leis: Does anyone here agree or disagree with that notion of progressive licensing?

Ms. Myrella Roy: I would support as well what Jeff has just mentioned, because right now the current system we have focuses only on pre-marketing surveillance, not post-marketing, although there is a little bit of effort there, but not as much, and as Manon mentioned earlier, because there are only a small number of patients who are exposed to the medications pre-marketing, we have limited information.

It seems that progressive licensing will be able to address some of the failures of the current system. We will be able to address issues related to adverse reactions more quickly if we have a system, however that will work. And again, it remains to be determined how exactly we are going to proceed with this progressive licensing, but we will be able to identify reactions sooner and be able to react sooner.

The Chair: You had your hand up. Would you like to make comment?

Then we will have Mr. Villeneuve, following Ms. Wolfe.

Ms. Karen Wolfe: In the same regard, in my experience in attending some of the progressive licensing workshops and getting a better understanding of what it means, from my perspective, it doesn't seem as if this is going to take away anything from the pre-market. However, it's going to add to the post-market and put a greater onus on industry, manufacturers, and albeit health professionals to be more accountable, transparent, and aware of what's happening in the post-marketing system. I don't see it as taking away anything from what currently exists, but enhancing what's already there to make it more robust.

Ms. Judy Wasylycia-Leis: I think there's been a lot of criticism of the pre-market surveillance system, to begin with, in terms of its rigour and ability to really make sure that drugs on the market are safe beyond a reasonable doubt. Even taking into account your qualifying words around risk, I think we have to be careful that we don't lose anything, and in fact try to enhance the pre-market end of things as well.

With respect to adverse drug reactions and mandatory reporting, I've heard you all. I think you make a very strong case about not pushing the envelope on that front, despite the coroner's report in Vanessa Young's case. The coroner recommended a number of other measures. I'm wondering if you think that the recommendations from Vanessa Young's case have actually been acted upon. How are we going to overcome what I see as a deep failing in the system, and that is, when we do get information, how do we make it more transparent and open so that doctors and patients actually make the connections?

In the case of Cisapride, there were adverse reactions, but no one connected the dots. Vanessa shouldn't have died. I don't think mandatory reporting may have helped that. But with regards to getting the information out and getting it connected in people's minds, getting young women to understand, if you're facing bulimia, what this could mean, is there any advice on that front?

● (1215)

Dr. Jeff Poston: Specifically, that was such a tragic case, but I think it illustrates many of the challenges we face. The hard thing there was, apart from Vanessa and her friend, nobody really knew how bad her bulimia was, even her gastroenterologist who was treating her.

There was information. Health care professionals had some of the information, and it was very, very early in terms of our known risks around that. It goes really to the point of the need for patients to be well informed. Certainly when it's children who are involved, parents need to be well informed and there needs to be a much more constructive dialogue between patients and health care providers. It's very much a part of that process we have to build to improve safety.

The Chair: Thank you, Mr. Poston.

Mr. Tilson.

Mr. David Tilson (Dufferin—Caledon, CPC): Thank you, Madam Chair.

This committee made a report in 2004. It's called "Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs". The chair was the honourable Bonnie Brown. I don't think any current members of Parliament were on that committee. I think all you people were. Mr. Poston gave testimony.

Anyway, I'd like to read something from page 6 of that report, which deals with pharmacists, and which I'd like you all to comment on. Only a small portion of this report was on the topic we're on now. There are only several pages of the report that deal with post-market surveillance.

This particular paragraph said:

> ...witnesses called for more fundamental changes. They argued that complete reporting of adverse drug reactions would only take place if it were made mandatory for physicians and pharmacists. They insisted that the pharmaceutical industry should have more extensive mandatory reporting requirements and be required to invest in the post-marketing and adverse reaction reporting process. They suggested the establishment of an independent agency, like the Aviation Safety Board, to investigate drug safety.

I'd like you all to comment. In other words, this report is saying the pharmacy industry should be more active than they've been. Could you all comment on that, starting with Mr. Poston, since he was present at that?

Dr. Jeff Poston: I'm glad you didn't find something that was completely opposite to what I'd said this morning.

We know development happens slowly. I think, from the profession's perspective, we recognize that we actually have to try to change and develop better systems.

One of the things we've done as an association that publishes a lot of information about drugs is actually shift a lot of our material into a digital format. It can be accessed through a web portal and made available online to health care professionals at point of care. So from our specific association's perspective, we've done a lot to improve the delivery of information to health care professionals.

I think the other thing that's happened is that we, and most of the associations represented here, have actually started to build our links with two groups—other health care providers, in our case particularly physicians, and also patient groups—to begin to understand some of the issues that consumers have. We have made some progress in terms of developing more collaborative approaches.

I think the question of an independent agency comes up fairly frequently. I think that's an interesting one that we may have to look at more closely.

Something that we've called for, as an association, is what we've called a national medication management centre that would look at drug safety, effectiveness, and appropriate use, and that would be a stand-alone, independent agency. I think we've made some progress, but obviously there's still more work needed.

● (1220)

Mr. David Tilson: Before we go on to the others, sir, on the independent agency, a lot of professions—medical professions, legal professions, maybe your profession, I don't know—are self-regulatory. Is that what's being suggested here?

You have the drug companies, the manufacturers, producing something. You have doctors prescribing it, and maybe prescribing it inappropriately. You have the pharmacists, of course, who are part of that process. And then you get back to the consumer. They have a rash or they get something funny happening to them and they don't know what to do.

There's another section, which I will, in due course, report to, where they go to the emergency room, and we have problems with our emergency rooms. They line up docs, and we've got a shortage of docs. It's something that's very serious.

My question to you is this. Is that what's being suggested by an independent agency, that there be some sort of self-regulatory body?

Dr. Jeff Poston: No. I think Ms. Wolfe gave a very good description of the regulatory piece that's already in place with respect to the profession of pharmacy at the provincial level that requires some level of reporting. I think what we see the agency's role being is much, if you like, less regulatory. We'll leave the regulatory piece to Health Canada. We get a lot of information in this country about drugs and their use. We have all sorts of bodies that are collecting the information. What there isn't is one place that puts it all together, analyzes it, and synthesizes it into health care policy, and then pushes that information out to health care providers and to health care practitioners. It's really doing a better job around that dissemination of information and education and training and making people aware of the issues around safety and effectiveness.

I think a model that we may need to look at is the Canadian Patient Safety Institute. They've done a lot of work in their three or four years of existence around medication errors and patient safety in hospitals, particularly in general. I think there are some pieces like this that we can look at.

And when I say independent agency, I'm thinking more from an information and education training perspective as opposed to a regulatory one.

Mr. David Tilson: Ms. Wolfe.

The Chair: Forty seconds left.

Mr. Villeneuve.

[*Translation*]

Mr. Denis Villeneuve: Obviously, there would be merit in reporting all adverse reactions, but you have to bear in mind that the feedback would come from patients and would be in their words. How would we, as professionals, manage this additional information that is already known to us?

Firstly, the adverse reaction reported by the patient may already be known to us, it may already have been recorded. Secondly, how are we going to tell patients that if they experience any adverse reactions they should make a list and inform us of them? We are already leery of informing patients of all the adverse reactions listed, for example, in the CPS. How would we manage all of this?

For example, if I meet a patient and tell him that he should inform me of any adverse reaction that I have not mentioned, he is going to want to know what I mean. I would then have to list off the 200 known ADRs and tell him that, should he experience any that I have not mentioned, he should let me know. It would be a real headache to manage. I agree with you. I have been managing information from patients for 30 years, and these are people who are worried about adverse reactions.

[*English*]

The Chair: Thank you so much.

Mr. David Tilson: Madam Chair, I think we've heard all this before. I think they should be witnesses.

The Chair: Thank you, Mr. Tilson.

We'll now go to Dr. Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): As Mr. Tilson pointed out, four years ago the committee suggested that mandatory reporting would be a good idea. I think at that time we heard the reaction from both physicians and pharmacists that they were too busy and it wouldn't really help that much, and it had better be user friendly. Four years later, we're still having 10% of adverse reactions being reported. So I don't think we've done a very good job changing the culture or doing the education or all these things that were supposed to be done in a voluntary way.

I also was a little confused last week by the testimony, on the hospital side, about incident reports, because my experience in hospitals is that the incident report is usually done only if you've been given the wrong drug. It isn't necessarily a predictable reaction. A little rash or something doesn't usually get an incident report.

So if we are going to develop a real learning culture around this, and we only have 10% of the data, what are we going to do? I don't know whether it's in the nice blue book over there or not, but I think in terms of Myrella's testimony, it's just noise if you keep hearing the same things again. And if you're not disaggregating the data.... Is this only women that the noise is about? Is it only women who had grapefruit juice for breakfast? Is it only women taking echinacea? We actually could be learning if we actually report and then find all this out.

So I guess I'm still a bit frustrated that we aren't moving on this at all, even in terms of user friendliness for patients so they are able to get online to do this, or for pharmacies so they can get online to do this. Do I have to give every doctor in the country a BlackBerry in order to do this, with a drop-down menu on which they go “same old rash”?

How are we actually going to design a system in which we have 100% of the data or even 85% of the data, instead of this pathetic 10% with which we cannot, I don't think, learn.

● (1225)

[*Translation*]

Mr. Claude Gagnon: I understand your question and your argument. As health care professionals, even we are not used to this way of working. I have been a pharmacist for 30 years. Personally, I have always thought that a known reaction should not be reported. We report unknown reactions described to us by patients. By unknown reactions, I mean those that are unexpected and not mentioned elsewhere. When such reactions occur, we make a report. Everybody knows that a certain drug might cause a skin reaction.

I have always believed that, in such a situation, my role as a professional is twofold: firstly, to stop dispensing the medication and, secondly, to find a substitute. I know that it happens, but I'm not convinced that all professionals are aware of the need to report known reactions.

Perhaps it is our training that is at fault. We are not taught to make this type of report at university. Perhaps professionals need training on this matter. I am not convinced that everybody fully understands what needs to be reported.

Hon. Carolyn Bennett: What about the frequency with which such reactions occur? That is something which is very important.

Ms. Manon Lambert: We already know the frequency with which reactions to most drugs are experienced. ADRs are detected at the pre-marketing stage precisely because they occur frequently. We therefore have a good idea of the frequency at which they occur. Mandatory post-marketing reporting would not simply reproduce information available at the pre-marketing stage. It is adverse reactions that have not been detected at the pre-marketing stage that have to be reported at the post-marketing stage. These sort of reactions, although rare, are often potentially deadly.

In Quebec, we are 10% short of the number of pharmacists that we require. Some hospitals only have locum pharmacists, people who fill in for a week or so before moving on. If you ask pharmacists to report adverse reactions, or even if you require them to do so, you will be simply wasting your time, as it would do nothing to improve their scientific knowledge or change the way in which they treat their patients.

The focus should be on developing a culture whereby professionals report the more serious ADRs they are not familiar with, and where these reports are met with feedback. Feedback is important, as it allows pharmacists to treat their patients appropriately. At the moment, however, there is no feedback.

● (1230)

Mr. Denis Villeneuve: Could I please add something on frequency?

The question of frequency is an interesting one. Increasingly, we have access to data comparing the frequency of adverse reactions experienced by patients taking a given drug compared to those experienced by patients taking a placebo, a pill with no therapeutic benefit. The data shows that the instance of adverse reactions is very high amongst those taking the placebo. What should we do when faced with the fact that, often, patients who have not even taken a drug experience adverse reactions? It is a question of culture and of the individual patient. It is important to be cautious here. I understand that a 10% shortage in pharmacists is worrying, or even catastrophic, but we have to maintain perspective.

[*English*]

Ms. Myrella Roy: To come back to your example of declaring a rash, currently, as with the definition that's proposed by Health Canada in their MedEffect database, if a rash causes the patient to stay longer in the hospital, this is considered a serious adverse drug reaction and should be reported. That is the type of example I was referring to: this information will not add significant information on how to deal with this intervention, and it will not add significantly to the body of knowledge we already have.

I concur with all of my colleagues in their previous interventions that where we need to act on this—to address your question directly—is with educating health care professionals. We are not doing as much, and that's what I mentioned in my intervention previously. We support greater reporting, but we support greater reporting of quality information.

The Chair: I'm sorry, we've run out of time.

Mr. Brown.

Mr. Patrick Brown (Barrie, CPC): Thank you, Madam Chair.

The first question is for the Canadian Pharmacists Association, for Mr. Poston.

Health Canada contributed funds, from what I understand, to your organization for a web-based communications tool, e-Therapeutics. Could you comment on the outcome of that?

Dr. Jeff Poston: It has gone extremely well. We launched the product into the marketplace two or three years ago. It's a web portal.

As you know, we publish the big blue book, the *Compendium of Pharmaceuticals and Specialties*, which is a collection of Health Canada product monographs. We also publish a book called *Therapeutic Choices*, which is like a set of clinical guidelines to drug use in particular diseases. As for what e-Therapeutics is, we actually integrate the content from those two publications and make them available online.

So the system is working. It's working very well.

For a physician who is treating a particular disease and wants some information, it recommends drugs that could be used, but then the physician can click on that drug and go to the full monograph to get information. The important value of it as well is that we are able to incorporate advisories from Health Canada directly into that system. So in the example we had about the warning from Australia about the risks of serious hepatic adverse drug reactions associated with the non-steroidal anti-inflammatory drug, as soon as Health Canada issued that advisory, we had it on our website being delivered to those physicians, pharmacists, hospitals, and institutions that subscribe to our e-Therapeutics product.

The uptake has actually been slower than what we had anticipated. As you know, the funding was issued on the basis of it being a sustainable business model. We're close to sustainability, but one of the things that are hampering uptake a little bit is the delay that we've seen in the implementation of provincial drug information systems. But the system has been incredibly well received by practitioners.

Mr. Patrick Brown: I have a question for Ms. Roy.

What are your comments on whether pharmacists be remunerated for reporting? Is that something that should be considered as we look at ways to have a greater percentage of adverse drug reactions reported?

Ms. Myrella Roy: Your question is whether or not pharmacists should be remunerated? I don't think I mentioned that at all in my intervention, but I don't think that hospital pharmacists—and I'm pretty sure I can speak for all of my colleagues in community pharmacy as well—consider adverse drug reaction reporting as part of our duty, and we are not expecting to be remunerated for that.

Mr. Patrick Brown: I have a general question that I have asked previous witnesses before this committee. In terms of Health Canada's powers, do you have any comments on whether Health Canada should have the power to recall pharmaceutical products?

Ms. Karen Wolfe: My understanding of the current regulations is that they can strongly suggest to manufacturers that they take their product off the market once serious adverse reactions are reported, yet they do not have the regulatory power at this point in time to mandate it.

I think that would be a step in the right direction for the government agency that oversees the safety of the Canadian public and the use of drugs.

● (1235)

Dr. Jeff Poston: I think I would support that, but it's interesting that the practice recently has been that pharmaceutical companies have pulled their products off the market or made adjustments quite a bit before Health Canada has acted. It's been interesting.

This is, I think, one of the areas that need some studying. It's getting to be quite interesting. Companies will almost react to international reports or will react to the stock market reaction to international reports before they'll actually respond.... They often are acting earlier than Health Canada. The recent incident that comes to my mind is the issue around dosage of cough medicines for children under two, where industry acted very quickly on that.

It's a little bit of a mix, but I think it would be sensible for Health Canada to have the power.

The Chair: There's less than a minute, Mr. Brown.

Go ahead.

Mr. Patrick Brown: Okay, I'll be quick.

What do you think the reason might be for that? Who hears about adverse reactions first? Is it nurses? Is it doctors? Is it pharmacists? Do you have any evidence that would suggest what are the best sources to hear about adverse reactions? How can Health Canada learn about them more quickly?

[*Translation*]

Ms. Manon Lambert: In fact, the best source of information is the person to whom the patient speaks. If a patient experiences a reaction, which he does not necessarily associate with his medication, and he tells his pharmacist, because he sees him on a regular basis, then the pharmacist would be the best source. If, on the other hand, he tells his doctor, the doctor would be the best source. That is how we found out about adverse reactions. Usually, a patient will complain of a reaction, or it will be detected in a hospital by diagnostic tests or lab tests when a functional variation shows up. In such cases, it usually tends to be the doctor who will get the information. But it really is these people—doctors, pharmacists, nurses—who are best placed to report reactions. However, it is not a matter of knowing who is the best placed. I think that the person...

[*English*]

The Chair: Thank you, Madame Lambert. You've kept repeating the answer, and thank you for that.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: It would seem then that there is no register where the various health care professionals, for example, pharmacists, doctors and hospital staff, can record the ADRs that they observe. The various health care professionals seem to be working in silos. How could this data be collated so that it can all be made available to Health Canada? The manufacturers also have a role to play in this process. How could the process be made significantly more proactive? What process would you suggest implementing?

Ms. Myrella Roy: This is something to which I referred in my presentation. Obviously, we already have the MedEffect database; however, it unfortunately has a number of shortcomings. While it facilitates the reporting of new reactions for both health care professionals and consumers, it is difficult to use the information as there is so much of it. If all serious adverse drug reactions are reported, whether they be known or not, the users may wind up having to sift through a thousand individual reports. This makes it difficult to identify significant information. Each report has to be read. I therefore think that there is room for considerable improvement of the database, not only in terms of facilitating access, but also in facilitating use.

Ms. Christiane Gagnon: Indeed.

[*English*]

Dr. Jeff Poston: Perhaps I could just add that one of the things we haven't touched on a lot this morning that I think is important in terms of the work of the committee is looking at non-prescription products and natural health products. That's a very important area that needs some research. We really don't know much about what happens there. It's the other spectrum of the seriously ill patient in hospital who's on all sorts of new drugs. The type of patient that bothers me is the consumer who might be buying products from all sorts of different places and who will mix the products.

I think one of the things we have to look at is perhaps doing more around the role of the consumer in having some awareness around risks associated with drug therapy, and really facilitate reporting and making information available. We know difficult patients who have problems with side effects and that type of thing, but I think that's an important area.

● (1240)

[*Translation*]

Ms. Christiane Gagnon: I was actually just about to ask you a question on non-prescription drugs. Do some of these drugs contain ingredients that could cause problems? I'm thinking, for example, of certain cough medicines. Should these medications not be available as non-prescription products dispensed by a pharmacist? Often, people ask their pharmacist whether they can take a given product. As such, pharmacists are in the best position to inform consumers of the risks associated with a given drug and of how it ought to be taken. Implementing such a system would show greater commitment to tackle the problem. I would remind you again of the person who died after having taken cough medicine.

Mr. Claude Gagnon: If I could make a comment, I would urge caution here. We have to be careful not to blow things out of proportion without good reason. As long as information is provided appropriately, some drugs can be available freely over the counter. Obviously, it is important to educate the public, it is important to have awareness-raising campaigns and to underscore the importance of not exceeding the recommended dose. It is not the product itself that is dangerous, it is the amount that people take. No drug — be it non-prescription, pharmacy-only sale, or prescription — is without risk if the patient does not follow the instructions or fails to take the recommended dose. This is something that the general public has to understand.

We have a message to communicate. We cannot be negligent, it is imperative that the public receive the right information and that they are educated. Adverse effects frighten people. People have to be aware that they exist, they have to be educated, but they must also be reassured. What is important is how we can empower people.

Health Canada gets information after the horse has bolted, but at any rate, I think that there is a general realization that the department has no authority and, hence, no power to act. In what is, I would imagine, an attempt to show good faith, manufacturers withdraw their product from the market even before an official recommendation has been made. That probably explains why the general public is informed ahead of health care professionals. I think that Health Canada should be the first to be informed and should then immediately notify health care professionals.

Professional associations in Quebec, and in other provinces as well, I would imagine, post information on the Internet to facilitate quick access. Furthermore, when a product is considered dangerous, a fax is sent to all Quebec pharmacists. If we have the information in time, it will be delivered in time, but we have to have the information. At the moment, there is no feedback. I think that that is one of the shortcomings.

[*English*]

The Chair: Our time has run out for this particular one, but Ms. Wolfe and Ms. Lambert want to make a quick comment.

Ms. Wolfe, can you take just a few seconds to do that? Then we'll go to Madame Lambert after that.

Ms. Karen Wolfe: To address the issue of non-prescription drugs, our organization has an expert advisory committee that reviews non-prescription drugs and determines conditions of sale, which is a provincial authority. Those different conditions of sale would be a pharmacist-only sale—a pharmacist would need to be interacting with the sale—to be sold in a pharmacy only, a prescription only, or to be sold anywhere. So we do have extra.

The Chair: Thank you.

I am going to have to cut this one off because we're way over and I want to go to Ms. Davidson. We do have to go into committee business at a quarter to one.

Ms. Davidson.

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

I'm just going to go back to the same discussion we were just on—the non-prescription drugs. Whoever wants to answer this is fine.

My concern is about the combination of drugs. Who monitors that? Who gives the advice to the patient?

Monsieur Gagnon, you stated that it wasn't so much the drug, but it was the quantity.

But what about the combination? What if you're taking a prescription drug, but you're also buying something else yourself off the counter? Who knows about that and who advises people?

Whoever.

[*Translation*]

Mr. Denis Villeneuve: I can answer from the point of view of a community pharmacist. We systematically ask patients if they are taking any other medication before we dispense any drug. Once again, it comes down to educating patients.

Moreover, the federal government ran a campaign two years ago seeking to educate patients of the importance of informing their pharmacist of any other medication they were taking. The problem is that, often, patients do not see contraceptives and natural remedies as being medication. In their eyes, medication that you take occasionally is not medication either. That is why we systematically ask the question. As Ms. Gagnon was saying, there are cough syrups that can be highly toxic, and it is not just the combination of drugs that can cause problems. Some over-the-counter drugs are contra-indicated for diabetics and those with high blood pressure. Indeed, in Quebec, we systematically stick labels on drugs that those suffering from high blood pressure or diabetes should avoid.

● (1245)

[*English*]

The Chair: I want to thank our panel of witnesses. Unfortunately, we've run out of time. My apologies.

We're really going to have to get all of you back again. There are so many questions to ask, and there's so much to hear.

I want to wish you a happy Valentine's Day, I want to thank you for your presence here, and I want to ask a special favour of you. We're going into committee business, so I'd be so pleased if you could depart in a very timely manner. If anyone wants to talk, I would wish that you would go out of the room, beyond that door, to do that.

Thank you, panel.

I would like to have the committee go directly to committee business. We have committee business that we need to attend to.

First is the notice of motion put on the table by Mrs. Wasylycia-Leis.

Mrs. Wasylycia-Leis, would you like to read into the record your motion, please? Then we will discuss it.

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

Should I read it all?

Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.): Yes.

Ms. Judy Wasylycia-Leis: I move that the Standing Committee on Health call on the government to strengthen its monitoring and analytical capacity regarding enforcement of the Canada Health Act, in order to better identify challenges facing public health care, including excessive wait times for diagnostics and treatment, the high cost of prescription drugs to individuals and the health care system, and the impacts of increased privatization; and that the Minister of Health appear before the Health Committee within 30 days following the publication of his department's Canada Health Act annual report to indicate what proactive measures his government will be undertaking to ensure that Canadians' rights under the act are fully protected and strongly enforced in light of the current challenges to Canadians' public health care system.

The Chair: Thank you, Mrs. Wasylycia-Leis.

Is there debate or questions or comments on the motion?

Mr. Fletcher.

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

I'd like to thank the member for her motion, but I don't think it is a necessary motion. In fact, I want to assure the member that the government supports the Canada Health Act and the Charter of Rights and Freedoms, and we have made significant progress on this front.

We have put in $1 billion in regard to the patient wait times guarantee. That includes $612 million for the patient wait times guarantee trust, $400 million for Infoway technology, and another $30 million for pilot projects. That's in addition to the $41 billion invested over 10 years to strengthen our health care system. The 2004 health accord included $5.5 billion for wait time reductions.

We have seen significant progress.

Ms. Judy Wasylycia-Leis: I have a point of order. I don't want to interrupt my dear friend Steven Fletcher. I just want to say that what he's discussing isn't really the intent of this motion.

The motion is simply to acknowledge the annual report to Parliament—

The Chair: Mrs. Wasylycia-Leis, this is not a point of order, with all due respect.

Ms. Judy Wasylycia-Leis: Could I explain my motion, then, before—

The Chair: We have to listen to his answer, and then go to Ms. Gagnon. We'll put you third on the list.

Ms. Judy Wasylycia-Leis: Could I not introduce my motion?

The Chair: You just did.

Ms. Judy Wasylycia-Leis: All I did was read it.

The Chair: Mr. Fletcher, would you continue, please?

Ms. Judy Wasylycia-Leis: You did not let me give an explanation.

The Chair: Oh, I see. I'm sorry. I assumed that was the introduction. My apology.

Go ahead.

Ms. Judy Wasylycia-Leis: I didn't really want to read it into the record, but I did want to explain why it's here.

It really isn't to challenge the government on what it has done or not done in the area of health care, but to acknowledge the fact that we have, by law, a health act that requires annual reports to Parliament. That report is a very important tool for monitoring and analyzing the effectiveness of the system. But we've had some difficulties getting that report dealt with—even to this committee. I'm not sure how you've dealt with it in the past few years, but early on, when I was a member of this committee, it was often very hard to get the report on a timely basis and then to get the minister to the committee to talk about the report.

So I'm suggesting the motion because of that, and because of the fact that we've had an Auditor General's report talking about the fact. I just wanted to mention her concerns about the failure to properly monitor the Canada Health Act. That was in 2002 report of the Auditor General. Back then she said, “Health Canada has made only limited progress in addressing the weaknesses we identified in our 1999 audit. As a result, its monitoring still does not allow it to assess and report the extent of provincial and territorial compliance with the Canada Health Act.” Therefore, we don't really have a way to resolve disputes, even if we can identify them.

So I want this to happen, just so the committee can have a mechanism to be involved in a very important process to ensure that the act is being enforced, and so that we can have a good conversation with the minister about any problems identified and whether or not there are enough resources being put towards monitoring the system.

● (1250)

The Chair: Mr. Fletcher, would you continue, please?

Mr. Steven Fletcher: Sure, I'm pleased to be your dear friend. On Valentine's Day, that's very touching.

Ms. Judy Wasylycia-Leis: Would you be my valentine and support this motion?

Mr. Steven Fletcher: I like to leave my options open there.

In regard to the motion itself, the government is making—

Mr. Lui Temelkovski: Don't start all over again!

Mr. Steven Fletcher: The government is making a lot of progress. The Canada Health Act is being fulfilled.

I see that we're short of time, Madam Chair, but let me assure the committee that this government supports the Canada Health Act and that we're making great progress, and I'd be happy to talk about this after the meeting.

Perhaps we should go to a vote, Madam Chair.

The Chair: We certainly could go to a vote.

Are you ready for a vote, or would you like more discussion?

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: The motion on the table calls on the government to strengthen its monitoring and analytical capacity regarding enforcement of the Canada Health Act. The wording is problematic for us. For example, with regard to waiting lists, all provinces try to meet realistic objectives that reflect their particular context. If the Minister of Health wants to give us an overview of what has been happening in the other provinces over the past two years of his mandate, there's no problem with that. I do not, however, want government analytical and monitoring capacity to be strengthened. The Minister of Health says that he is holding discussions with the provinces to gain an idea of the length of waiting lists in the different jurisdictions. Personally, I have no problem with that, but I cannot accept the current wording of the motion.

[*English*]

The Chair: Our next speaker is Ms. Kadis.

Mrs. Susan Kadis: I support the motion, particularly because I'm disappointed that this does not appear to be one of the Conservative government's priorities anymore, specifically the wait times, which are extremely important, as we've heard reference made to them in important documents recently and as they are certainly most important to the Canadian public in having their needs met.

Thank you.

The Chair: If we have exhausted this conversation.... We're running out of time and have one more piece of business.

[*Translation*]

Ms. Christiane Gagnon: I would like to add something, please, Madam Chair.

[*English*]

The Chair: Excuse me one moment. I'm trying to—

[*Translation*]

Ms. Christiane Gagnon: It is all very well to lecture the provinces, but when their budgets have been cut for 10 years...

[*English*]

The Chair: Madame Gagnon, with all due respect, perhaps you could just wait one minute and listen to what I'm trying to finish saying.

We have one more order of business and I know there are three speakers. If we could keep very concisely within this time instead of having a half-hour soliloquy, it would be very nice.

Mr. Temelkovski, you're next. You're on the list, and then it's Madame Gagnon.

● (1255)

Mr. Lui Temelkovski: Thank you very much.

I believe we'd be in favour of the intent of the motion. We'd like to make a friendly amendment to this. If Madam Wasylycia-Leis would like to make a friendly amendment, the friendly amendment is that this motion be reported to the House.

The Chair: Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: I just wanted to point out that it is all very well to set the provinces a challenge or to strengthen the analysis of implementation in order to reduce wait times, but we cannot forget that Quebec has had to reduce the size of its nursing staff because the Liberals slashed the funding provided to the provinces via the Canada Social Transfer during the 10 years that they were in power. Today, we are faced with a shortage of funding available through the Canada Social Transfer, a problem that was created by the Liberals.

I think that all provinces are currently trying to meet targets or objectives. All provinces are cognizant of the shortage of doctors and nurses, and the effect that it is having on lengthening the waiting lists. The Liberals helped create this problem.

I felt that this is something that needed to be said this morning. Thank you.

[*English*]

The Chair: Madam Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you.

I want to reiterate that there is nothing in this motion that detracts from what is now required by Parliament. It is simply a mechanism to follow through on what Parliament has stated, which is that the Canada Health Act, section 23, requires the minister to report to Parliament annually.

So all we're saying is that as the health committee surely we could talk about the report and have a discussion with him. We have a Canada Health Act division at Health Canada that monitors and analyzes provincial and territorial compliance through data and different information. So that's done now. We're saying let's get the information here. We have a provision whereby no resolution can be agreed upon. We have a dispute avoidance and resolution mechanism. So I would think if Steven Fletcher and the government members have nothing to worry about in terms of this area, they aren't going to be upset with following the law and having this come to this committee.

The Chair: Ms. Wasylycia-Leis, the debate is over. Could we now take a vote? Who is in favour of this motion and to have it reported to the House with the friendly amendment?

(Motion negatived)

The Chair: Let's go on to our other order of business.

We have a problem to solve together before we adjourn today. This problem is that the minister would like to join us for the discussion on the organ donor criteria issue. He is available to come on the 11th and the 13th, but we have organized the organ donor criteria for March 4. It is impossible for the minister to be here that day. He is open on March 11 or March 13 to join us as well. I was wondering if I could get the consensus of the committee to move the organ donor criteria to either the 11th or the 13th and switch the post-market surveillance. We're not losing anything; it's just to accommodate the minister. Some of you have said you would like the minister to come, and he has offered to do that.

Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): I'm very pleased the minister wants to join us, and we should accommodate him. This is the way I suggest we do it.

On March 4, we should have our meeting on organ donors exactly as we had planned and we should make an hour available to the minister within that meeting the next time he is available. We'll deal with him alone. He is never going to be part of a panel.

I think this Parliament is a bit stale-dated. There is a great chance there will be an election this spring. There are three non-confidence motions on the books now, and we expect more. I think to put it off for two or three weeks puts it at great risk that we will not deal with it. Some might even suggest it might be the desire of the minister. So we'll make sure he's not confused and we'll deal with it on March 4 and have the minister come later.

● (1300)

The Chair: With all due respect, I don't think that's the objective. We want to get this done.

Mrs. Davidson.

Mrs. Patricia Davidson: I didn't have my hand up.

The Chair: Mr. Fletcher.

Mr. Steven Fletcher: First of all, I'm shocked that Mr. Thibault just called an election.

I think it would be best to have the witnesses there at the same time to get the full flavour of the issue. If there are counter points of view, we'll be able to hear them all at once.

I can assure you that the conspiracy situation Mr. Thibault is suggesting is not the case. It is a genuine conflict on the 4th.

The Chair: Mr. Temelkovski.

Mr. Lui Temelkovski: I'm not clear on this. Do you want the minister to be part of the organ donor panel? Does he have any expertise in this matter? Does he have more organs to donate than anybody else? My understanding of his expertise is that he's closing hospitals rather than anything else.

The Chair: From what I can gather from the clerk's office, I think he wanted to come at the last 45 minutes to answer any questions after the presentations.

We could, at your will, put it on the 11th or the 13th, whatever you wish. It's his offer, and it's strictly the will of the committee. As you know, the minister has really made himself available for everything we've wanted.

Ms. Wasylycia-Leis, please.

Ms. Judy Wasylycia-Leis: Thank you.

I like Mr. Thibault's suggestion. I think we should go ahead with the hearings as scheduled. We have a lot of witnesses ready to go on this issue.

In fact if we can get the Canada Safety Council or whatever—I forget the name of the organization that sets the protocol—we'll be just as far ahead in terms of understanding why this happened. We can deal with the minister at some future date.

The Chair: Ms. Wasylycia-Leis, you want the Standards Council. Is that what you're referring to? Okay. Thank you very much.

Mr. Thibault is next and then Mr. Fletcher.

Hon. Robert Thibault: I reiterate that we're pleased to have the minister if he wants to come on the 11th or the 13th, but I don't see any reason that he has to get the same time as the panel of experts we're asking on the 4th. We've set it up, so let's go ahead with our schedule. On the 4th we'll have the panel of experts, and on the 11th or 13th the minister can respond and make his announcements.

The Chair: Mr. Fletcher.

Mr. Steven Fletcher: It makes sense to have the minister here with the panel so it's all together. Moreover, the election will be in October 2009, Mr. Thibault.

I think the minister is being very accommodating. I think we should have them together on the 11th, 12th, or 13th.

The Chair: If we are going to make the suggestion, I would like a motion to come forward one way or the other.

Mr. Thibault actually suggested it, so Mr. Thibault, please go ahead.

Hon. Robert Thibault: I move that we maintain our schedule on March 4 and that we invite the minister, at his availability, to come to the committee to deal with this matter.

The Chair: Now we are going to take it to a vote.

(Motion agreed to)

● (1305)

The Chair: It is my understanding that we're going to go ahead with the organ donor criteria and all the witnesses. Then we're going to bring the minister in on the 11th or 13th. That is agreed.

The meeting is adjourned.

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