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Chair

Mrs. Joy Smith

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● (1105)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good morning, ladies and gentlemen.

I would especially like to welcome our medical professionals today. We have people from the Canadian Medical Association, the Federation of Medical Regulatory Authorities of Canada, the Ontario Ministry of Community Safety and Correctional Services, and the Canadian Men in Nursing Group.

We welcome you. We're very happy you could make it to our committee this morning. We will have your presentations very shortly.

Before we do that, I would like to remind members that we should leave approximately 15 minutes at the end of the meeting to deal with the motion from Ms. Wasylycia-Leis. We also have a budget to consider for future witnesses. Some of our witnesses are coming from quite far away, so we really have to deal with that today.

Pursuant to Standing Order 108(2), I would like to welcome you all to the fifth meeting on post-market surveillance of pharmaceutical products, prescription and non-prescription.

I would like to remind the witnesses that you have 10 minutes per organization to make your presentations. Keep your eyes on me, because I will cut you off and I don't like to do that. I just want to make sure everybody gets a chance to speak, and that all members around the table get a chance to ask you questions. We will hear all your presentations before proceeding to questions.

Let us begin with Dr. John Haggie, chair of the Canadian Medical Association.

Dr. John Haggie (Chair, Board Working Group on Pharmaceutical Issues, Canadian Medical Association): Thank you very much.

Good morning, ladies and gentlemen. On behalf of the Canadian Medical Association and our more than 67,000 physician members across Canada, I welcome the opportunity to participate in your committee's study on post-market surveillance of prescription drugs.

In addition to being the chair of the CMA board's committee on pharmaceutical issues, I'm also a practising physician from Appleton, Newfoundland, so I can also speak to the clinical aspects of this issue.

To effectively monitor the safety and effectiveness of the country's drug supply, the CMA believes a strong post-market surveillance system should include an effective process for gathering drug safety data coupled with a simple, comprehensive, and user-friendly reporting system; a rigorous process for analyzing this data to identify significant threats to drug safety; and a communications system that produces useful information distributed to health care providers and the public in a timely and easily understood manner.

Canada's current post-market surveillance system requires considerable development if this is to be accomplished. In our more detailed submission before you, the Canadian Medical Association presents recommendations that will support optimal patient health and safety and meet the information needs of health professionals and the public.

The CMA recommends Health Canada be given the tools, including regulatory authority, to require post-market studies of newly approved drugs if clinical trials identify possible safety risks that require manufacturers to disclose information if Health Canada deems it germane to making a decision in the interest of patients' safety, and to take action if post-market research uncovers new safety concerns. This could mean ordering changes to product labels, or even pulling a product off the market.

However, this enhanced authority will be useless unless Health Canada is given more resources to analyze and evaluate the information it receives. Without additional resources, merely increasing the number of ADR reports will only add to the backlog in the in-boxes of analysts.

In 2007, a coalition of Canadian research centres prepared a document, a business plan, for a drug effectiveness and safety network that proposed an integrated and comprehensive network of centres of excellence to support evaluation of drug safety and effectiveness in Canada. The committee should consider this concept and recommend moving forward.

On the reporting of adverse drug reactions, it's important to emphasize that this is only one possible way of gathering drug safety information. More structured post-market studies should also be considered as a way of augmenting spontaneous reports. The CMA acknowledges that ADRs are under-reported both in Canada and worldwide. We support measures that would strengthen Canadians' capacity to report these reactions.

Such measures could include a user-friendly reporting system, improved follow-up capacity, linkages to international post-approval surveillance systems, active solicitation of ADR reports from all health providers, and limits on what should be reported. There's no reason to require reports of side effects that are already known to be associated with given drugs. The reactions Health Canada most needs to know about are those that are unexpected or occur in newly approved drugs. There should also be incorporation of the ADR reporting process directly into the electronic medical records.

Our list does not include mandatory reporting of adverse drug reactions. If you build a comprehensive, efficient, and effective post-market surveillance system, physicians will participate actively in it. Forcing them to participate before the system has been built will result in failure and alienation. Moreover, we strongly remind the committee that provider reporting by itself does not constitute a rigorous system of surveillance.

Post-marketing surveillance doesn't exist in a vacuum. We believe that government should take other measures as well to promote the safety and effectiveness of prescription drugs. Real-time information is essential for effective surveillance. CMA strongly recommends that governments invest in supportive information technologies that will greatly increase physicians' capacity to report adverse drug reactions.

● (1110)

New prescription drugs, especially those that represent a therapeutic breakthrough, must be made available as quickly as possible to those who could benefit from them. However, improvements to post-market surveillance should not be used as a justification to lower the standards for a pre-approval review.

The CMA supports a risk-based approach to product safety assessment, with regulatory requirements that are greater for products with greater risk and lower for those with less risk. Health professionals and the public must have access to all information, both positive and negative, about new products. Health Canada should make the results of all clinical trials available to health professionals and the public. However, physicians believe that direct-to-consumer advertising, or DTCA, of prescription drugs inflates the market for potentially risky drugs and does not provide the public with enough information to make appropriate choices. We recommend that brand-specific DTCA not be permitted in Canada and that the loopholes permitting a limited amount of brand-name promotion be closed.

Canadians do have the right to accurate, unbiased information on prescription drugs and other therapies to help them make informed health decisions. The federal government should develop and fund a comprehensive program to provide accurate, unbiased, and independent prescription drug information for use both by patients and health professionals. The CMA is prepared to work with other stakeholders through a comprehensive program to promote optimal prescribing and drug therapy monitoring by health professionals. Such a program should be founded not on sanctions but on education, including objective academic detailing to ensure that information is accurate and impartial; the use of information technology and practice tools; be organized and implemented with the participation of professional and patient organizations; and include strategies to improve patients' knowledge of, and adherence to, drug regimens.

The Canadian Medical Association will develop a vision for an optimal prescribing program and implement portions of it over the coming year. The CMA commends both the standing committee and Health Canada for their intent to reform Canada's post-market surveillance system. Canada's physicians are prepared to work with governments, health professionals, and the public in strengthening this system to ensure that the prescription drugs Canadians receive are safe and effective.

Thank you.

● (1115)

The Chair: Thank you, Dr. Haggie.

We'll now hear from Mr. Douglas Anderson from the Federation of Medical Regulatory Authorities of Canada.

Are you a medical doctor as well, Mr. Anderson?

Mr. Douglas Anderson (President Elect, Federation of Medical Regulatory Authorities of Canada): No, I am not.

The Chair: Thank you.

I always like to call medical doctors “doctor”. I want to make sure I have the proper introduction.

So thank you, Mr. Anderson. Please carry on.

Mr. Douglas Anderson: Madam Chair and committee members, I thank you for the opportunity speak to you today on this important issue of post-market surveillance. My name is Douglas Anderson, and I am the president-elect of the Federation of Medical Regulatory Authorities of Canada, or FMRAC. I'm also the associate registrar of the College of Physicians and Surgeons of Ontario.

I'm addressing you today on behalf of FMRAC and its 13 members, the provincial and territorial medical regulatory authorities. These are more commonly known as the colleges of physicians and surgeons in each province. They are statutory bodies established by provincial or territorial legislation to do the following: serve the public interest, establish and maintain the standards and honour of the profession, establish rules for the proper professional conduct of its members, determine qualification for registration and licensure, and determine and evaluate the competency and conduct necessary to maintain registration and licensure.

I will address two issues regarding post-market surveillance: first, respective roles of Health Canada and our member medical regulatory authorities; and second, the responsibilities of practising physicians.

Monitoring the safety and the efficacy and quality of prescription and non-prescription drug products after they have reached the marketplace is a complex process. It includes surveillance and inspection, adverse reaction reporting with subsequent reports, communication of health risk to professionals and the public, and compliance verifications and investigations. The medical regulatory authorities have a number of policies dealing with drugs and prescribing issues. For example, the College of Physicians and Surgeons of Ontario, where I work, has specific policies. I won't bother to read these, considering the time.

These policies for the most part focus on clinical, administrative, or prescribing issues: for example, appropriate clinical indication for some drugs, appropriate office procedures for managing drugs, and avoiding medical errors, etc.

Another member, the College of Physicians and Surgeons of British Columbia, has a review program to evaluate prescribing by physicians of mood-altering drugs and narcotics, identify multi-doctoring for the purpose of obtaining addictive drugs, oversee and ensure the appropriate prescribing of methadone in addiction treatment, and evaluate the treatment of chronic non-malignant pain through the appropriate use of narcotics. The College of Physicians and Surgeons of British Columbia has access to detailed data on physician prescribing that is not available in other jurisdictions. B.C. PharmaNet is a province-wide network that links all B.C. pharmacies to a central set of data systems. PharmaNet supports drug dispensing, drug monitoring, and claims processing.

Endeavours by the federal government to work with the provincial and territorial governments to expand this kind of initiative across the country would be greatly supported by FMRAC and its members.

It is important to note that these policies and programs do not directly address the safety, efficacy, and quality of prescription drugs and non-prescription drugs after they have reached the marketplace. We agree it is important for physicians to report adverse drug reactions. It is the opinion of FMRAC and its members that the coordination of this activity is best handled by Health Canada. I'll address this later.

The role of the medical regulatory authorities can be a facilitative one, in the form of transmitting information through their respective publications or websites. There are several examples of this across the country. Even this role presents a challenge to our members. The medical regulatory authorities frequently receive bulletins from Health Canada describing drug recalls, adverse drug reaction problems, cautions with respect to specific agents, and so on.

● (1120)

It is not clear to the medical regulatory authorities what Health Canada expects them to do with this information. Information can be posted on the websites with links to Health Canada, or it can be highlighted in a newsletter. However, information sent by Health Canada to the 13 provincial and territorial medical regulatory authorities is not necessarily passed on to all practising physicians, for several reasons, including the cost consideration, legislative mandates, and timeliness of our publications. We cannot assume responsibility for confirming that practising physicians have had access to and have read and understood the materials produced by Health Canada.

As I stated before, FMRAC and its members believe in the importance of reporting adverse drug reactions. Several have promoted this issue to practising physicians through various means, including publications—for example, newsletters, and websites.

A reporting system that encourages reporting rather than one that potentially penalizes non-reporting would be more fruitful in the longer term. Technically a mandatory reporting system should be accompanied by means to monitor and enforce this compliance. FMRAC is of the opinion that in the current federal-provincial-territory structure for health care, this is not possible. The medical regulatory authorities have no means of detecting lack of compliance, other than by the established complaints process. If a provincial or territorial medical regulatory authority receives a complaint about a physician who has not reported a serious adverse drug reaction, it will deal with it, as with all other complaints, through our due processes.

We would support a simple reporting system for physicians, possibly linked to the electronic medical record. At this pre-implementation stage of the EMR and the electronic health record, EHR, it would be useful to create a field for quickly reporting an adverse drug reaction directly to Health Canada. If the tool is intuitive, timely, and easy to use, this reporting could be done as part of the regular patient-physician encounter.

Any reporting mechanism is only as good as the ultimate use that is made of the information provided. It will be important to include credible, timely monitoring of this information. This role should be within Health Canada's mandate.

Here's an example. A physician reports a mild to moderate adverse drug reaction through the EMR. Health Canada has been monitoring all the reports, and it notices that this represents the one hundredth such report across the country within the last year. The surveillance is raised a level and a request for more information goes out to the 100 physicians. As this activity now requires a significant time commitment on the part of the physician, it would be helpful for Health Canada to have worked with its provincial and territorial counterparts on appropriate remuneration for this activity.

From a medical regulatory perspective, a system for reporting adverse drug reactions should also be a learning tool for the providers, physicians, and others. Once a report has been filed with Health Canada, it would be useful if there was an electronic exchange of information between Health Canada and the health care professional. An example of meaningful educational information from Health Canada would be data on trends, numbers of reports received on a particular drug and the nature of the reports, and suggested courses of action. Providers are more likely to make the effort to produce and submit a report if they know they will receive valuable, timely information in return that will help them provide optimal care to their patients.

It would also be very useful and educational for the physician who has filed a report to receive information on the end result: were the modifications made to the drug profile, to the recommended dosage? In addition, an acknowledgement to the physician for their valuable input is always welcome.

Once a simple and timely system based on sound educational principles is in place, FMRAC and its member medical regulatory authorities would gladly promote its use to practising physicians across Canada.

I would like to thank you for your attention, and I would be pleased to answer any questions.

● (1125)

The Chair: Thank you, Mr. Anderson. As I said at the beginning, we'll wait until all the presentations have been heard.

The next witness is from the Office of the Chief Coroner for Ontario, Dr. Andrew McCallum.

Could you please give us your presentation, Dr. McCallum.

Dr. Andrew McCallum (Regional Supervising Coroner for Eastern Ontario, Office of the Chief Coroner, Ontario Ministry of Community Safety and Correctional Services): Good morning, Madam Chair and members. I'm here representing Dr. Bonita Porter, the Chief Coroner for Ontario, who unfortunately couldn't be here and sends her regrets.

What I'd like to do this morning is give the members a brief overview of death investigation in Canada and in Ontario in particular—which is what I know best—speak about our role in adverse drug event reporting, and perhaps offer some suggestions to the committee for their consideration.

In Canada we have a mixture of death investigation systems. We have medical coroners, as in Ontario; lay coroners, as in provinces like British Columbia; and medical examiner systems, as in Newfoundland, Alberta, and others. Dr. Haggie represents one such system. In the Northwest Territories, Nunavut, and the Yukon, there are lay coroners. That's simply related to the lack of resources and people in those areas, and the vast distances.

All coroners and medical examiner systems, however, have the same goal in mind. There are mandatory questions that must be answered about deaths that are investigated, there is a need to support the criminal justice system, and finally, there is the goal of advancing public safety.

In our office in Ontario we investigate about 20,000 of the 80,000 or so deaths that occur per annum in the province. Those investigations are conducted by approximately 300 coroners, all of whom are practising physicians in Ontario and all of whom have full-time jobs doing something else, except for people like me; I represent one of the nine regional coroners who report to the chief coroner for the province.

Of the 20,000 deaths we investigate per annum, approximately 15,000 are determined to be natural, and it is in that category of death that we find most of the adverse drug events. Over the years we have not had, in my view, the majority of cases reported, and I think this parallels reporting in other jurisdictions and other systems. A variety of factors relate to that, many of them common to the difficulties faced by physicians in practice in general.

For your information, over the last five years there were 176 adverse events reported that were associated with death but did not directly cause the death. Those are “involvements”, or what we term to be “significant contributors”, but not the actual cause of death. Over those five years we had 18 cases reported in which it was felt that the adverse drug reaction itself caused the death. My strong suspicion is that this number under-represents the total significantly. I think the committee should be aware of that, and it does speak to the need to enhance the reporting mechanisms available in Canada to report these kinds of events.

In our work as coroners we make liaison with organizations such as yours, obviously, in the Parliament of Canada, and also with ministries in Ontario, such as the Ministry of Health and Long-Term Care and the Ministry of Labour. We've recently had dialogue with Health Canada and had a visit from Ms. Pepper, who represented the Canada Vigilance program and spoke to us about the need for us to liaise with them. We certainly support that need and initiative and want to increase and enhance our involvement with Health Canada in this regard.

Since 2001 there has been a formal request directed at coroners on behalf of the chief coroner to ensure that adverse drug events are reported. We have recently revamped our investigation information system, which is comprehensive and computer based, to allow us to capture more accurately the type of drug adverse reaction that has occurred, so now we capture the adverse drug reaction, which we define as a “noxious or unintended response to a drug that is used at therapeutic, prophylactic or diagnostic doses” and “directly leads to death”. That's a situation in which we would call it the death factor or the prime cause of death.

We also track, however, what are termed as “involvements”. An involvement, to us, is a serious adverse drug event that contributes to the death, but doesn't cause it directly. This is our definition; it differs from the Health Canada definition. Perhaps it is most germane to think of those as the iceberg and the small number of cases in which death actually occurs as the tip. Nonetheless, both are very important.

We do a number of things in response to situations in which an adverse drug reaction has caused a death. We may call an inquest. An inquest in Ontario is a relatively uncommon event now, for a variety of reasons. There used to be hundreds; there are now perhaps 50 to 70 per year, and of those the vast majority are mandatory.

● (1130)

We may call what's called a regional coroners review, which is a formal review in a committee-like setting with the health care provider or institution to discuss the event that occurred and hopefully generate findings and recommendations aimed at the common goal of advancing public safety and preventing a similar death in the future.

We may refer the case to one of our expert committees, and one of those committees is the patient safety review committee, which I chair. That committee is comprised of a multidisciplinary group. The Institute for Safe Medication Practices is represented by Mr. David U. There are various specialists in medicine, nursing, systems safety, and we will review cases in a paper manner and produce a report, which is then distributed to the concerned parties, including the providers and, of course, the next of kin.

That information is often disseminated through other media—one such example would be the *Dialogue* of the College of Physicians and Surgeons of Ontario, or the *Canadian Medical Association Journal*, and so on—to try to increase the knowledge of practitioners and people who ought to be aware of the problem.

We find at that committee that about a third of the cases we see have some involvement with medication. It is a very prevalent and prominent issue for us, and we think it is for you as well.

I would just say in closing that we are most prepared to participate in reporting and liaison with Health Canada to try to advance the common goal of improving the safety of the public in Canada.

The Chair: Thank you very much, Dr. McCallum.

Our final witness is Mr. James D'Astolfo.

Could we please hear from you? You are part of the Canadian Men in Nursing Group.

Mr. James D'Astolfo (President and Founder, Canadian Men in Nursing Group): Good morning, honourable members of the committee. It is with great pleasure and honour that I speak to you today about post-market surveillance of pharmaceutical products.

My name is James D'Astolfo, the founder and president of the Canadian Men in Nursing Group.

Our organization represents men in the nursing profession and is made up of registered nurses, practical nurses, and nursing students. Our organization's mission is to provide a voice for men in nursing, in the hope of supporting and strengthening the image of nursing. We intend to pursue our mission by collaborating with governments, organizations, and other health care professionals and by showing leadership in our communities and internationally. Additionally, it is our organization's mandate to ensure that health issues are being heard both by governments and within other organizations.

I'm sharing my time today with Mr. Irfan Aslam, vice-president and director of finance for the Canadian Men in Nursing Group.

Nurses play an active role in the safety, efficacy, and handling of prescription and non-prescription drugs and provide administration, education, and support to patients and their families, both in their communities and in acute and non-acute health organizations. We have outlined a number of recommendations, which we hope the committee will adopt as part of its blueprint for renewal.

Here are our recommendations on consumer safety. Consumer safety is an important aspect in the handling of both prescription and non-prescription drugs and plays an important role in ensuring that the safety of Canadians is of high priority.

Recommendation one is to provide front-line health care workers, like nurses, with information on changes to pharmaceutical products.

Recommendation two is to ensure that nurses are equipped with resources and ongoing educational training to prevent medication errors in both acute and non-acute health organizations. The California Institute for Health Systems Performance stated in its report in 2001 that in improved work environments, promoting ongoing education was of importance.

Bar coding medication systems, other assistive devices, and educational workshops and in-services also play a critical role in reducing medication errors. The bar code system has been used to prevent medication errors. The bar code proposal would create a system in which patients receive a bar-coded identification bracelet that is linked to their medical history. Scanners linked to computerized medical records would verify that the proper medication is used. It was estimated through the FDA that the bar code system would reduce medication errors by 50%, making a significant financial saving.

Recommendation three is to ensure that medication labels are required to have both the generic and trade names on their products, that medication instructions are included and given to both the consumer and the health professional, that these instructions be translated into different ethnic languages to ensure effective compliance, and that they be made available through pharmacies in Canada.

Medication guidelines have been used by the U.S. Food and Drug Administration to help patients avoid serious adverse effects, inform patients of side effects of their products, and enhance the directions for the use of the product for its effectiveness.

Recommendation four. Canada being a very multicultural country, many ethic groups do not use only prescription and non-prescription drugs, but herbal and natural remedies as well. Some people believe that herbal products are harmless, but it is estimated that about one-third of drugs, including digitalis, morphine, and several chemotherapeutic agents, were developed from plants. So indeed, herbs are potent products.

Herbs can affect body functioning, and therefore, when herbs are taken concurrently with drugs, interactions are possible. This is why it is important that the committee look at including interactions between herbal remedies and pharmaceuticals as part of the Canadian adverse drug reaction monitoring program.

● (1135)

Mr. Irfan Aslam (Vice President and Director of Finance, Canadian Men in Nursing Group): My name is Irfan Aslam, and I will go on with another recommendation.

Recommendation five is to ensure that Canadians are informed of any pharmaceutical product approval and non-approval in an open-access system that includes a summary of the rationale for approval or non-approval and supportive data. The consumer can then make an informed choice, along with their health care providers, as to future use.

As a member from the Canadian Medical Association suggested, the clinical trial data should be available to researchers who are conducting the research and also to Health Canada. Once we have all the available information in one place, it would make it easier to see what additional information is needed. Then action can be taken as to the safety of the drug.

Recommendation six is to provide evidence-based information in an efficient manner. We are living in an age of information technology, and I think the best way to perform this task is by having an e-learning tool for pharmaceutical education. The tool would be web-based e-learning for patients and health care professionals. It would include the correct way of taking medication, some dos and don'ts, and links to government web pages and different community supports so patients and health care professionals could learn more about the medications.

The next recommendation is about adverse event reporting. Currently, health care professionals are not obliged to report any adverse event. This can be changed. However, it should only be changed once the other pieces of the post-market surveillance system are in place. When we have all the other systems there to support the health care professional, you might want to consider making it mandatory, but it should not be done at this time.

The next recommendation is about the capacity for monitoring, surveillance, and research. We feel that more can be done in the area of monitoring non-prescription drugs, or what are called over-the-counter medications. One way to address this problem would be event monitoring. According to the *British Medical Journal*, many health professionals and researchers in England have found that prescription event monitoring provides a valuable addition to pharmacovigilance of prescription products in England. Many pharmacies have put in place the electronic linkage of computerized patient drug records and point-of-sale systems. This linkage could allow the systematic collection of data on the use of non-prescription medications, which might be a useful tool for monitoring over-the-counter medications.

Now, with all these recommendations and the recommendations that have been put forward by other colleagues, you might be able to come up with the best post-market surveillance program for pharmaceutical products. However, such a program will be useless unless you have enough personnel to implement the program. So our last recommendation is to recruit more health care professionals—doctors, nurses and people in Health Canada—to analyze the reported information. That would ensure that the proper implementation of any post-market surveillance of our pharmaceutical product program would be possible.

We would like to thank you for your time in hearing us today, and we hope you find some of our recommendations useful as part of your blueprint for renewal. We look forward to answering any questions today and in future.

Again, many thanks to the committee. Thank you.

● (1140)

The Chair: Thank you very much, both to Mr. D'Astolfo and to you, Mr. Aslam, for your presentations.

We'll begin with Dr. Bennett and Ms. Kadis. They are going to be sharing their time. Thank you.

Go ahead, Dr. Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thank you, Madam Chair. I'm just going to ask a bit of a question, and then Susan will finish. If you would answer them together, that would be helpful.

To begin with, I wanted to hear whether you believe that in order to do your jobs better, in order to ensure patient safety, a diagnosis should be part of the prescription pad or that hopefully one day we will be e-prescribing.

Speaking to Mr. Anderson's concern about whether doctors have actually read something, in the electronic age it is quite possible to send something out and have it marked as read, at least. Should we not have the capacity in this country for Health Canada or somebody to speak directly to doctors? I know that during SARS we would have thought that it was a good thing.

Should there not be also, if it looks as though there's a cluster of trouble, an alert going out saying, remember, Vioxx is only for patients who have gastric problems; it is not recommended broadly. We could maybe have avoided something.

I guess that's just where I'm coming from in terms of using the technology to actually do what we need to do for Canadians.

Go ahead, Susan.

Mrs. Susan Kadis (Thornhill, Lib.): Thank you. Yes, it's along another line actually.

Mr. McCallum, you mentioned there was a discrepancy in the definition of "adverse drug reaction" between Health Canada and you, and you also broke it down that there was "involvement", as you called it, or "contributing factor" and also "cause of death".

I think we'd like to hear a little more elaboration on that, because that would seem to be very significant in terms of maximizing the information to prevent deaths due to adverse reaction.

If we have time, to the Canadian Men in Nursing Group, considering that the reporting is not mandatory now but rather optional, when as health care professionals do you feel it's necessary to voluntarily report? In other words, is there a common standard or criterion?

As well, if we have time, do the physicians discuss this issue with you? What is your role essentially, and are you relying on the physicians to report it? What is that relationship in terms of adverse drug reactions?

Dr. Andrew McCallum: Thank you.

I'm glad you asked the question because I think I've left you with a mis-impression. There isn't a significant difference between the definitions as we put them versus Health Canada's. The wording might be slightly different, but the intent is very similar.

Let me just read to you the definition we use versus theirs, just to reassure you. The food and drug regulation definition of an adverse drug reaction is this: "A noxious or unintended response to a drug occurring at doses normally used or tested for the diagnosis, treatment or prevention of a disease or modification of an organic function." That's Health Canada's definition.

Our definition is this: "Noxious, unintended response to drug when used at therapeutic, prophylactic or diagnostic doses. Significant morbidity/injury to patient, but did not directly cause death". This is the involvement code.

We track involvements as well as death factors because it's important to have a three-dimensional picture of what happened to a person who died. So the involvement is a sublethal, if you like, or not lethal involvement of a drug, whereas if it's a death factor it is thought that the drug actually caused the death.

So our definitions are not significantly different, but we do have a different end point. Obviously Health Canada is interested in all drug reactions. We're interested in our population.

● (1145)

Mrs. Susan Kadis: So along that line, just briefly, are you trying to get those slightly different definitions in line with one other?

Dr. Andrew McCallum: We have not had that discussion, no.

Mrs. Susan Kadis: Okay, thank you.

The Chair: Does anyone else want to make a comment?

Dr. Andrew McCallum: I'm sorry, Dr. Bennett had a question, if I might answer, Madam Chair, on whether we rely on the physicians who are coroners to report.

The answer is yes. However, the regional coroner reviews every case, and if we see a case where it is thought that an event should have been reported, we will question the physician, ask them to report it, and/or report it ourselves. That's a change. We've only been doing that for about the last 18 months. We didn't review every single coroner's case in the case of natural death in the past.

The Chair: Mr. Anderson, you wanted to make a comment.

Mr. Douglas Anderson: Yes, I wanted to address Dr. Bennett's comments directly.

The concern there is that a doctor has a number of e-mails coming through from various sources. Our concern is, is that one highlighted appropriately? I agree entirely with Dr. Bennett's comments related to SARS. The OMA, for example, and our organization did an excellent job in getting the information out on a timely basis to the physicians in the field, and so we would be very supportive of that direction, Dr. Bennett.

Hon. Carolyn Bennett: If the diagnosis were on the prescription, would that help you do your job?

Ms. Fleur-Ange Lefebvre (Executive Director and Chief Executive Officer, Federation of Medical Regulatory Authorities of Canada):

Several of the jurisdictions have addressed that, and there's some privacy legislation that right now can be seen as an impediment. We are strong supporters of e-prescribing and we are working really hard in that area. Now, we have some jurisdictions that are moving ahead with the pharmacists and the physicians, jointly trying to address that and trying to work with the preliminary standards through Canada Health Infoway to see how far we can push that. But there are some privacy concerns about the diagnosis on a piece of paper that contains a prescription. That has been voiced by some of the legal counsel and our members.

Hon. Carolyn Bennett: Would that be avoided by its being encrypted and electronic?

Ms. Fleur-Ange Lefebvre: Yes, it would, so that would provide a lot of advantages.

I'm just going to comment briefly, if I may, on the alerts. One of the things we're also working on, as you know, is emergencies and disasters. One thing that's really important is that when physicians receive an alert they have to be reassured that it is in fact an alert. There's a lot of work we can do together on this, with the Public Health Agency of Canada and Health Canada, to make sure that alerts—adverse drug reactions and emergencies—can be handled in a way that is comprehensible and immediately identifiable by the physician at the receiving end. We're not there yet, unfortunately.

The Chair: You have a couple of more minutes.

Mrs. Susan Kadis: I have another question for the Canadian Men in Nursing Group.

The Chair: All right. Please go ahead.

Mrs. Susan Kadis: The question was, given that we don't have mandatory reporting but that it is optional, when, as health care professionals, do you feel it's necessary to voluntarily report? Are there common criteria or standards that guide that? Do the physicians discuss this issue and what the role of nurses is, and how is that taking place in terms of adverse drug reactions?

Mr. Irfan Aslam: My other colleagues here from CMA have also commented on that.

Right now, under the reporting system, there is no obligation on health care professionals to report. However, in my experience and according to the last literature search I've done, most of the physicians and other health care professionals would report if they found some kind of adverse effect of a medication. It's not mandatory at this time, and we don't want it to be mandatory at this time, because we do not have the rest of the pieces that are needed to support the health care professional. If you are going to make it mandatory at this time, I don't think it would be helpful in bringing more information from the professionals.

Mrs. Susan Kadis: Thank you.

Has there ever been a time when you've been in a position where you've felt it should be reported and the physician did not, for some reason, report it, and you wanted to?

Hon. Carolyn Bennett: You mean that the nurse reported it because the doctor hadn't?

Mr. Irfan Aslam: In my own experience, I have not actually seen this happening. Usually it is done in the form of a group, so if a nurse or doctor noticed an adverse effect, they would discuss it with each other. After that, it would be reported.

If you were taking a scenario in which one person had not reported, I've seen that the other person would report. For example, if a doctor missed an adverse effect event, then the nurse would report it, or vice versa.

● (1150)

Mrs. Susan Kadis: How often do you see adverse drug reactions?

Mr. Irfan Aslam: Minor adverse drug reactions are quite common. In my practice I see maybe once a week a minor reaction. But if you're talking about something that is really serious, that is very rare, Andrew was talking about 176. So you can see that in all of Canada there were only 176 events that actually resulted in that, and only 18 of them were reported because—

Mrs. Susan Kadis: That goes to one of my first questions, Madam Chair, if we have just a moment.

When would you feel it necessary to report? Is there a criterion or a standard?

Mr. Irfan Aslam: There is no particular criterion. However, when we see that this drug is not acting in a way that it is supposed to act.... We can get the information. Right now we are getting other professionals—doctors and pharmacists—to get that information. There are side effects attached to each and every drug. If there's something outside of the side effects that have been written there or that are well known, then we do report.

The Chair: Thank you very much.

Dr. Haggie, I think you indicated.... You have only about 50 seconds.

Dr. John Haggie: I think Dr. Bennett's comments and her colleague's questions speak to communication.

One of the difficulties we have is the number and volume of communications. I can get up to about 80 communications a month on drug- and product-related issues. They're opened, but whether they're read to a large extent depends on context, because they tend to send everything to everyone. It's actually very difficult for me to sift the signal from the background noise. It's well nigh impossible.

If I have only 50 seconds, I'll stop there.

The Chair: Thank you, Dr. Haggie.

Madame Gagnon.

[*Translation*]

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

They say that 50% of adverse drug reactions can be attributed to an ineffective or inappropriate prescription. Health Canada has noted that a number of physicians are acting outside of federal regulations.

In your opinion, what could prompt a physician to prescribe a product that has not been tested for purposes other than those for which it is normally used? What responsibilities does a physician or Health Canada have in relation to that practice? For example, opiates, which are medications prescribed for chronic pain in patients with a terminal illness, are often prescribed for acute fractures, which is an off-label use.

What is the purpose of such a practice? Who authorizes it? Given that a determination has already been made as to the uses of the medication, and that it has already been tested for such uses, physicians who do this are actually operating outside the Drug Act.

[*English*]

The Chair: Ms. Lefebvre.

Ms. Fleur-Ange Lefebvre: Because my colleagues seem to be catching up with the translation, I'll have a go at this.

I'm assuming that you're talking about off-label use of prescription drugs.

[*Translation*]

You are essentially talking about off-label use of drugs.

Several weeks ago, at a Health Canada meeting, I was surprised to discover that, for certain drugs in certain populations, such as the pediatric population, off-label use is more extensive than on-label use. The figures are really quite astonishing. You are right to say that this is not consistent with the regulations, but the fact is that medicine is constantly evolving, and off-label use of drugs can have some fairly significant beneficial effects.

I believe this brings us back to the previous question, which has to do with communication. There has to be a means of communicating quickly with the people writing prescriptions, the people using them and Health Canada, so that we can bring all those results together and arrive at a system that offers maximum benefits to patients.

That is a little outside of parameters of your question, but it is a very difficult issue.

● (1155)

Ms. Christiane Gagnon: Some people who comply with the regulations are critical of that kind of behaviour, saying that there is tremendous pressure from the industry to promote the use of certain drugs. Do you share that concern or apprehension?

Ms. Fleur-Ange Lefebvre: I will let my colleagues from the Canadian Medical Association answer that question.

Ms. Christiane Gagnon: The reason I'm asking the question is that there can be terrible consequences. This results in deaths, is very costly for the health care system because of the number of hospitalizations, and the figures are alarming. In the United States, they result in 106,000 deaths every year, and more than two million adverse drug reactions require a patient to be hospitalized. We can compare that to what is happening in Canada and Québec.

[*English*]

The Chair: Who would like to address that?

Dr. Haggie.

Dr. John Haggie: I think everyone's looking at me.

I think there are a couple of very important points here. One is medication error. Medication issues have been highlighted in other jurisdictions, and in the Baker and Norton report, as a major issue.

I think I will just put that point to the side and concentrate on Madame Gagnon's initial point, which is about off-label use.

I think there are several factors that need to be recognized. One is that the label is related to the licence that's issued for that product. Often these licences are actually very narrow. For example, there currently are anti-arthritic or anti-inflammatory agents on the market that are indicated or labelled for use for arthritis in the knee only. If you write that prescription for somebody with a hip problem, you're using it off-label. From a pharmacological point of view, it's very difficult to justify scientifically why a drug will work on the knee rather than the hip. To be honest, I personally believe this is a marketing ploy, because it allows them to change the label later on, with the patent continuing to run from the date of the new label. That's one factor in terms of what's on the label in the first place.

The second thing is that there is an art to medicine as well as a science. In the negotiation on a case-by-case basis between a physician and a patient, it may be appropriate to use a drug in situation A that you wouldn't use in situation B. Technically that is outside the label. With time a lot of these things become established practice.

I think one of the reasons that pediatric practice makes bigger use of off-label indications is that when drugs are initially released on the market, they are labelled for adult use only; there are no comparable medications for children. Therefore, under those circumstances, do you treat or do you not? You have to say, well, this is technically off-label, but as an experienced pediatrician or pediatric surgeon, I have no reason to believe the pharmacology in the children in this situation is any different; therefore, this offers me an option that doesn't otherwise exist. If you look at some drugs on the market now, they were originally marketed as anti-tumour agents and are now used in children for rheumatoid arthritis, for example. That was started by experts in the field using the drugs on a case-by-case basis for off-label purposes.

So I think you have to allow the clinician a certain amount of leeway. And some of the issues with labelling may actually relate more to the label rather than the use.

The Chair: Would anyone else like to make a comment on that?

Dr. McCallum.

Dr. Andrew McCallum: Madam Chair, I completely agree with Dr. Haggie's comments. I would say it's important that the committee recognize the temporal difference between peer-reviewed literature—expert use of drugs, which emerges very quickly—and regulatory response. There will be a gap at times.

I think the committee ought to use the term "inappropriate" off-label prescribing as its major interest as opposed to just off-label prescribing, because there certainly is appropriate off-label prescribing as well.

● (1200)

The Chair: Madame, you have two minutes.

[*Translation*]

Ms. Christiane Gagnon: You must admit, however, that it is a concern. I would like to get an answer from you. How can we be more vigilant? What kind of action is required to monitor both marketing and regulations? There appears to be a vacuum at this time, which means that labelling may pave the way to other types of uses. What kind of action is required? Would it not be appropriate to test these drugs on more people, including children? Children are often administered drugs that were not developed for use in children.

[*English*]

Dr. John Haggie: You're right, there is a huge knowledge gap. The bulk of the information about pharmaceutical agents that the average practitioner receives comes from the pharmaceutical industry directly just because of ease and convenience. That's what the drug companies do. That's how they operate.

Our proposal incorporates moving away from that, to provide unbiased, impartial, peer-reviewed material available to a physician when he or she has a clinical problem in front of them and wishes to write a prescription. We provide excellent training for undergraduates in pharmacology and for residents in internal medicine and a whole variety of specialities in pharmacology. Those resources, with a little adaptation, could be made available to physicians who have been in practice for 20 years and haven't crossed the threshold of a medical school in that period.

So the work is there; it is how you deliver this. You can do it on an educational basis. Whilst we don't have a mandate as an association to do that, continuing education for our members is a vital interest. Dr. Shortt here is our new director and assistant secretary general of knowledge transfer, and that's going to be his mandate over the coming years.

In terms of actually writing a prescription in day-to-day office work, you need real-time electronic database access to something as simple in the electronic record as an Agilent. If you write a particular medication electronically for a patient who is, say, under three years old or over 80, and that is not appropriate...and there are such things as the Beers list. The list itemizes and updates the drugs that are inappropriate for the elderly, for example.

So by just incorporating that simple list, if you wrote a prescription for a patient over the age of 80 for a medication on that list, it would stop you at that point and say, "This is worth reconsidering. Is there a better drug you can use?" Perhaps it would even list some better drugs.

These are decision support tools. The pharmaceutical industry, or rather the pharmacists, have gone a long way to providing that network for their members at the dispensing stage, which is really a very appropriate and very easy point to do that. But a vast majority of clinicians in this country still use a paper and pen. Until you get around that and move to a system akin to the pharmacists', and that will speak to the pharmacists, you're kind of stuck with—

The Chair: Thank you, Dr. Haggie, very much.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you, Madam Chairperson. Thanks to all of you for very informative presentations.

Of course I'm tempted to ask especially the doctors and nurses what their reaction is to the federal budget, which didn't mention the shortage of doctors and nurses in our country today, but I won't.

I will, though, start my questioning—and if you want to skip it , feel free. I will reference the federal budget in this context of post-market surveillance. We saw in the budget what I would consider a rather piddling amount for health product and food safety, $113 million. I'm not even sure if that includes pharmaceuticals at all. I raise that in the context of the adequacy of our system now to ensure safety of products.

I reference the CMA's brief, where you make a very excellent point about...and I'll just quote from you because I think it is well worth putting on the record time and time again: "A strengthened post-market surveillance system should not be used as justification for lowering approval standards".

I also reference the Men in Nursing brief, which says that "Ensuring that Canadians are informed of any pharmaceutical product approval and non-approval in an open–access system..." is absolutely critical.

I want to get at two big issues. One is to get your comments about the present system with respect to pre-market approvals and what's needed, from the CMA's point of view, to ensure we aren't condoning any attempt by the government to fast-track drugs by participating in this and making recommendations, follow what it would call the business transformation program, and do everything on the basis of pressure from the big brand-name pharmaceutical companies to get drugs through quickly without adequate testing. I want to know your reaction to that, what needs to be done.

Secondly, what mechanism would you put in place to ensure accountability and transparency in terms of drug information? Both of you and the others have mentioned this as well.

We've had a number of different suggestions. One is for the government being required to put everything on its web page in terms of all the studies and adverse effects that researchers and others have identified for every drug approved or not approved, and as well, to have an independent advisory board to offer advice and evaluate prescription drug safety.

I raise those two issues. I think you're all right in terms of suggesting that too much emphasis on mandatory adverse drug reporting leads us down a path where we will ignore the big issues. I'd like some advice around both the pre-market approval process and the transparent and accountable system you have in mind.

Does anybody want to start?

● (1205)

The Chair: Mr. Aslam.

Mr. Irfan Aslam: I can comment about the findings you mentioned about information we have available.

It is true we have a lot of information available over the Internet about different drugs, but sadly, most of that information is not evidence based. A lot of patients in my practice go to the Internet and look at different medications. They are obviously concerned about their health and the health of their loved ones, so they read this information and ask questions about one website saying one thing and another website saying the total opposite, and they're wondering which one they should believe.

I think government can do a lot about that. We can have just one system; we can have information available on web pages, some kind of e-learning tool that we proposed in our recommendations. It would have comprehensive information about the drugs. The patients don't have to look around for information that is not evidence based.

In this age of information technology, information is everywhere, but we need to try to promote the right kind of information that will be helpful to our patients and will help solve their concerns and current medical status. If they get that information, then they know the right questions to ask or who to approach for that information.

Ms. Judy Wasylycia-Leis: Okay, I appreciate—

The Chair: Mr. Shortt, would you like to comment on this for Ms. Wasylycia-Leis as well?

Dr. Samuel Shortt (Director, Knowledge Transfer and Practice Policy, Canadian Medical Association): Yes, thank you, Madam Chair.

We've seen nothing in the materials provided by Health Canada to suggest that the barrier is in any way going to be lowered for access to market for new drugs by adding a post-surveillance component. Health Canada has consulted as recently as February 15 with the health professions and has overtly stated that the current regulatory regime for market approval will not be changed.

Ms. Judy Wasylycia-Leis: Let me ask you, the CMA, and others a question. I'm still searching for answers around the proper process to ensure the access to information and transparency of information that you've all espoused, especially from the drug companies, which are a problem by all accounts. I'm sure you're not going to disagree with that. Some of the recommendations include an open-access website that would have all drug approvals and non-approvals on it, as well as a summary of and the rationale behind the decision; a complete review of all clinical trial data used to reach a decision made available to the academic community; and finally, an independent board to provide oversight of the regulatory process and keep it accountable.

Are there any objections to any of those three suggestions?

● (1210)

The Chair: Dr. Haggie, you have about three minutes. Go ahead.

Dr. John Haggie: No. We as an association think that is a nice outline of the system. We see the post-marketing surveillance very much as part of a process that begins with initial clinical trials and evaluation and the licensing of drugs, and then moves through the product cycle to keep an eye on what happens once these things are out there. And more importantly, or equally importantly, we see it as a feedback loop so that the physicians who use these drugs have access to what is going on with them in the real world as it happens, in a way that they can use.

The difficulty we've had with some of the current mechanisms, again, as far as post-market surveillance and adverse reporting are concerned, is that they are concentrated simply on adverse reporting. There isn't really anything else that we've seen. The clinicians who use these drugs are baffled by the process. The definitions of what they're supposed to report on aren't clear always. The process by which they are reported has been improved of late but still is something of a black box. Once you send the form in, you don't really know what happens afterwards. There is the great fear that in some way they are, by reporting these adverse reactions, either wasting someone's time with something that's trivial or potentially putting themselves in a situation where a torrent of paperwork is going to be unleashed on them, in addition to whatever else is going on at the time.

The current process really needs a lot of attention to make it into the sort of Cadillac version that we've suggested, and it needs attention from all directions.

Ms. Judy Wasylycia-Leis: Let me just follow up with two things, then. One is—

The Chair: Excuse me. You have just one minute, Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Okay, very quickly then, many physicians...and I'm sure members of your association have talked about the problems with the present approval system for drugs. In fact, Dr. James Wright says, "At present, the system for reviewing and monitoring prescription drugs in Canada has serious deficiencies and often fails to consider patients as the primary focus."

Others have reported on how drug regulations in Canada are shrouded in secrecy. Even the names of the drugs in the approval process are not disclosed. Any information that industry submits, including clinical trial data on safety and effectiveness, is deemed confidential and can only be released under access to information requests.

We have numerous problems, whether we're talking about pre- or post-approval surveillance. We have serious problems in terms of drug safety. Now, we can go into reams of information about side effects and adverse reactions. We can talk about Propulsid and the Ontario coroner's inquest. Surely you can't sit here today and say that the system, as it is, is effective.

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

Could we have Mr. Tilson, please.

Mr. David Tilson (Dufferin—Caledon, CPC): Thank you very much.

Thank you all very much for coming and providing your expertise.

I was listening to Madame Gagnon asking a question on the number of deaths in the United States. I expect it's not as high, but it's pretty bad in Canada as well. That's why we're holding these hearings as to how this can be improved.

I look at the issues, most of which you've addressed, which are whether reporting should be mandatory or voluntary, reporting serious reactions versus all reactions, and who's to do the reporting. Should everybody be involved: medical practitioners, nurses, pharmacists? I think the only mandatory reporting is with the pharmaceutical companies. I think we're talking about hospitals now.

And you get to the question where someone dies or has a very serious reaction, and there's a lawsuit. Everybody gets sued. Health Canada, the pharmaceutical company, the doctor that prescribed it. They don't know; no one knows. I think you gave an example of a drug that may have been prescribed for a hip and someone took it for a knee. So you don't know these things.

It would be useful if the committee had statistics as to the amount of litigation in this country on all these issues. Does anybody have any statistics? If there are only some for Ontario, that would be useful.

There are all kinds of causes. There are errors in prescriptions or that the drug should or should not have been approved. There's a patient who takes increased medication, or not enough; in other words, they broke the rules that the practitioner was recommending. There are genetic issues, the issue that Dr. Haggie raised about something that is good for one part of the body but not for another part. Are there statistics out there that could help us?.

● (1215)

The Chair: Who would like to take on that question?

Dr. Shortt, would you like to start?

Dr. Samuel Shortt: Sure.

The statistics would at best be impressionistic. I would suggest that probably the best source to consult would be the Canadian Medical Protective Association, which is aware of litigation involving physicians.

However, I would caution you that the American literature is quite informative. If you look at litigation for malpractice generally, and not specifically focused on drug reactions, you'll find that the vast majority of these cases are not because there was an issue of negligence or inappropriate practice, but because of the outcome that the patient didn't particularly like. Malpractice litigation is a bad reflector of bad medical practice. Turning that around, and this is important, the vast majority of people who do experience negligent care never bring suit. So the American system is not a good indicator.

Mr. David Tilson: I understand that.

You all have similar backgrounds, but from different angles. I think the figure Madame Gagnon gave was 200,000 in the United States a year. Does anyone know what it is in Canada? It's pretty high, I'll bet. Does anyone know?

The Chair: Dr. Haggie, go ahead.

Dr. John Haggie: The answer is that at the moment, the data doesn't exist in any usable way for this country.

One of the things our proposal might do is to address that in terms of getting proper prevalence data. We would see the post-market surveillance system with reporting from physicians as a trigger, which would then be taken by centres of excellence to do proper epidemiological studies. If you rely on a reporting system, whether it's voluntary or mandatory, your figures are going to be inaccurate.

Mr. David Tilson: I understand that. You could have some senior person go into a hospital and have the wrong drug, but they're old and they're going to die anyway. I hate to be so crass about it, but there could be all kinds of reasons that have absolutely nothing to do with errors by doctors or drug people or whoever. I'm just saying that to properly assess this issue it would be most useful if we had some stats. I gather that all of you are saying there really aren't any stats, and if there are, be cautious on how you look at them.

Is that your message?

Dr. John Haggie: Yes, essentially.

The Chair: Madame Lefebvre, you wanted to make a comment on this. Would you please go ahead.

Ms. Fleur-Ange Lefebvre: Thank you.

When my mother was discharged from the hospital in early January, she was discharged with a piece of paper that contained the names of over 25 medications. Some she was to continue, some she was to stop, and some she was to start. There was a mistake, which I picked up. The pharmacist didn't know; it was on the piece of paper. Once they had plugged all the information into the pharmacist's computer, a drug interaction showed up.

We have the tools to do this; we're just not communicating. My mother has more than one physician—she has five physicians. Connecting this information is going to be very key to what we can do from now on.

Concerning your comment on the seriousness of the adverse drug reaction, the example we proposed was for a mild to moderate drug reaction. If somebody at the other end, at Health Canada, is monitoring the reports coming in through the electronic medical record, they have predetermined a number: if the severity is this, one is enough to get some feedback; if it's not, 100 may be enough.

Somebody has to be doing this work at the receiving end of the reports. Then we'll have a system in place that will be useful, educational, and used. That's where the “mandatory” may not be so important.

● (1220)

Mr. David Tilson: Dr. Haggie, you mentioned that Canada needs to provide a user-friendly reporting system. You talked somewhat about that. Can you add to your comments about what you mean by that?

Dr. John Haggie: The issue of reporting an adverse event has been very cumbersome until lately. It has improved with Health Canada's MedEffect. Having said that, I would suggest that probably 60% of my colleagues aren't actually aware of its existence, even though it's been up and running for a while.

The difficulty with it is that the vast majority of primary care physicians, who probably write the vast majority of prescriptions in this country, aren't clear on what it is they're supposed to be reporting.

The side effects profile of a drug is documented in a thing called the *Compendium of Pharmaceuticals and Specialties*, which is a huge book and which has an arcane indexing system based on both the trade name and generic name. It takes probably four or five minutes to find the right page simply because of that. When you do, the information there, which is in very small print—and as you get a little bit older, that becomes an issue—is in a very logical and ordered fashion, but it's not usable. It doesn't tell me anything more about how that patient is likely to behave with that drug than I could have had, probably, without reading it, if it were a drug with which I'm familiar. Really and honestly, when you look in there for side effects....

I had a patient a few months ago who had what I thought was a significant reaction to an antibiotic I'd prescribed. They were jaundiced and they got worse, and I wondered if it might be the medication. I went to the CPS, and after 20 minutes of rummaging through there found that jaundice was a side effect of this particular medication. I stopped the medication, and the patient got better—and I did know more about it.

It was a significant adverse reaction, and it lengthened the length of stay with the patient. But the reason I stopped was that it was well known, well documented, and there was a percentage figure there in the book. Was my report going to add anything to the body of knowledge, based on what I understood of the system? I said to myself, no.

If you were dotting the *i*s and crossing the *t*s there, then perhaps I was in some way culpable for not doing a report, but this is just a reflection of the utter lack of clarity about the current system. I didn't know whether it was a valuable thing to do, whether I was going to have problems with doing it, and whether it was indeed going to add anything. If it wasn't, then quite honestly I wasn't even going to spend the five minutes that would be required to log in on the Internet and do it, because I had other things to do.

The Chair: Thank you, Dr. Haggie.

I'm sorry, Mr. Tilson, we're out of time.

Monsieur Thibault.

[*Translation*]

Ms. Christiane Gagnon: Madam Chair, I just want to make one clarification. I did not refer to two million deaths, but rather, two million serious hospitalizations due to adverse drug reactions. However, there were some 106,000 deaths.

Two million relates more to the situation in the U.S.

[*English*]

The Chair: Thank you, Ms. Gagnon.

Monsieur Thibault.

Hon. Robert Thibault (West Nova, Lib.): Thank you, Madam Chair.

Welcome to all of you, and thank you for the most useful presentation. I particularly welcome Dr. Haggie, from the east coast, from Newfoundland. Being an east-coaster myself, it's wonderful to hear that beautiful Newfoundland accent here in Ottawa.

Dr. John Haggie: We all have Newfoundland accents.

Hon. Robert Thibault: I appreciated the comments you made.

I've been struggling with some of the testimony we've had. We know that we don't want our family practitioners to be burdened with more paperwork that doesn't have value. We know that we ask them now, if we need CPP, if we need insurance claims, to do a lot of paperwork that doesn't necessarily contribute to our health and that wastes our time. And that's very difficult in a time when we know that we have a lack of medical professionals.

But you made a point, I think, that if we structure this properly, this could be a very useful tool on both ends. You could have an electronic system that helps you in prescribing, as it did the pharmacist in Madame Lefebvre's mother's case. It could help you in prescribing and also make it very easy for you to report incidents without having to worry about whether they're significant or not significant. In the case of the jaundice situation you were talking about, you could have reported that case. It would have been two keystrokes rather than you having to spend an hour typing out a report. I think that would be useful, with the proper analysis.

It seems to me that with the initiatives we're taking on the Canada Health Infoway and with those investments being made—we already have a digital data transmittal system for billing for family practitioners—those things could be achieved, and I hope they will be.

Before I come back to it, I had a couple of questions for clarification for Dr. McCallum. You're saying that in the case of Ontario, you had 20,000 deaths that involved the coroner and that 15,000 of them were seen as natural deaths but involved a coroner. And a number of those were drug related. Some of them, you said, had a death effect and others were involvement. What were the numbers in each of those two categories?

● (1225)

Dr. Andrew McCallum: You're correct. Just to give you a breakdown of that, of the 176 in which there was involvement—in other words, an adverse drug event occurred but it didn't cause the death—141 were natural. That is 141 out of 176. Twenty-eight were considered accidental. And I don't have the breakdown of what "accident" means. We consider an accident to be the death of someone due to an unforeseen occurrence, and that would include certain drug reactions. Of the small number, the 18 I referred to, 14 were natural and four were accidents.

Hon. Robert Thibault: So it comes down to a very small number in our most populous province.

In those 176 cases, would you include drugs like morphine, in the case of palliative care, that could have an involvement but would not be an unexpected...?

Dr. Andrew McCallum: Yes, that's a possibility.

Hon. Robert Thibault: So morphine in palliative care would be included.

Dr. Andrew McCallum: Not necessarily. It would only be included if it caused an adverse drug event. For example, if a patient who is being palliated were to suffer respiratory failure because of an inadvertent overdose of narcotic and then died of the cancer the palliation was required for, that would be a natural death with an adverse drug event included as an involvement.

Hon. Robert Thibault: So it would be included in those 176.

Dr. Andrew McCallum: Yes.

Hon. Robert Thibault: How many, within those 176, would you suggest are that type of thing—not necessarily morphine, but that type of palliative care or chronic care—that would be, I would say, unavoidable?

Dr. Andrew McCallum: I would say that the majority would be, and I think the key word used there is "unavoidable", but not in the sense that the death was unavoidable.

Hon. Robert Thibault: Right.

Dr. Andrew McCallum: The event could have been avoided, but it didn't cause the death.

Hon. Robert Thibault: Yes, but in normal medical practice, when my turn comes and I'm dying and in excruciating pain from cancer, I hope you're not going to withhold morphine because it might have a negative health effect.

Dr. Andrew McCallum: Thank you for the question. And if I might just comment, it's very important that the committee understand that key fact. We do not want to have a chilling effect on physicians, particularly in end-of-life care, so they're afraid to prescribe appropriate palliative medication because of fear of death investigators coming along and saying, "Oh, you gave a lot of morphine there and we're concerned about your practice." We certainly don't want that. So we're very careful about that.

Hon. Robert Thibault: I have one last, broad question. We've heard here—and I don't want to go either way on this question, I'm trying to learn—that only 10% of serious adverse effects are currently reported. But we know that if we poll the Canadian population on political matters, we are content with polling 1,000 Canadians, and it gives us a significant picture. Is the 10% we're having reported now representative of the population and not the practice? Would that give us the picture of what's happening in the pharmaceutical/medical world?

● (1230)

Dr. Andrew McCallum: It might, Madam Chair, but if I could, I'll quickly turn this over to the other members.

The reason I say that it might is that there's a bias introduced by the method of reporting. In other words, if the difficulty of reporting leads to under-reporting, it might introduce a bias that skews the result—we don't know. When you talk about polling, you're using a scientific method of enrolling a certain proportion of the population and you can statistically predict the likelihood and generalize to the rest of the population. We're doing this retrospectively, and I don't think we can say that.

The Chair: Would anybody else like to make comment on this?

Dr. Haggie.

Dr. John Haggie: I think Dr. McCallum's points are well made. I think the reporting bias would work in favour perhaps of over-reporting of severe problems, but at the other end, you'd get very much an under-reporting of minor side effects.

One of the issues for a practising physician is how to find out what a side effect is. Again, you go to this massive tome; but it's not incredibly useful, which leads me to another point. I have a printout here on a very common stomach drug given for indigestion. It says here that the side effects may include abdominal pain, nausea, vomiting and flatulence, diarrhea or constipation. It can cause somnolence or insomnia. It can cause agitation and aggression or depression and hallucinations.

Hon. Robert Thibault: It sounds like one of my speeches.

Some hon. members: Oh, oh!

Dr. John Haggie: I wouldn't dream of saying such a thing, sir.

But you see what I mean about context and utility? It's practically a waste of the 20 minutes to look it up. If you have someone who's ill, then you will use any source you can.

Quite honestly, as a little bit of an older physician, I would say my practice has changed dramatically in the last five years; I've stopped using this book. Our website under the aegis of CMA has a very active online resource for things like this, and I use it instead. But the traditional sources of information are useless. But again, it's not something I can use when I write the prescription; it's something I have to go looking for afterwards, and that's my problem.

The Chair: You have a minute and a half, Mr. Thibault.

Hon. Robert Thibault: I don't know who would best answer this question. Perhaps it's Madame Lefebvre. It's a question about off-label use.

I don't want to discourage off-label use. I think Dr. Haggie gave a perfect example of how it evolves and why in some instances it's good. But then we see extreme cases where there may be very good off-label use, but you wonder how fast that information can be made available or the research be done so that it can become a regular treatment.

I read the piece in *Maclean's* magazine a short time ago about a cancer drug that had been used for macular degeneration, and was quite successful, but that thing is gone. The clinical research hadn't been done for wide distribution or wide use.

Will the changes at Health Canada to progressive licensing have a positive effect on being able to integrate different uses for drugs that are labelled for one reason now?

The Chair: Madame Lefebvre, did you want to make comment on that?

Ms. Fleur-Ange Lefebvre: Yes, I think that's exactly it. We're quite excited about this progressive licensing, and we think it should be accompanied by progressive reporting. That's what we're talking about.

Report what you have to report. Then somebody at the other end will say, okay, this is the point where the flag goes up; we have to do something. So link that to progressive licensing, especially for use in children. You have to remember, children are in our system from age zero to 18. Well, the six-month-old doesn't need the same thing as the 13-year-old; and regarding the 17-and-a-half-year-old, where are you? So you have to be careful with that.

For off-label use for certain populations that have not been tested, or for certain uses that were never envisaged to begin with, physicians are smart; they will try something if they think it might have a beneficial effect for their patient. If they can feed that in quickly and usefully to a system that is monitoring all of that, we're quite in support of the progressive licensing.

The Chair: Thank you very much, madame.

Mr. Brown.

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

I want to talk a little bit about electronic measures, and I have a question for both the Canadian Medical Association and the male nurses group.

What types of electronic measures are utilized right now in terms of electronic access for physicians to a patient's current prescriptions, and what measures might be suggested to enhance that? Would a portable device be something that could help avoid post-market medical errors by having timely access to a patient's current prescriptions?

In terms of the nurses group, is there any form of electronic access that you currently have?

But I'd start off with the Canadian Medical Association first.

● (1235)

Dr. John Haggie: Thank you.

My electronic access to a patient's drug record is the telephone and the fax machine, if I cannot find what I need from the patient, and sometimes you can't because the patient will be in a condition that renders them not able to give a good account of themselves and there may not be any caregiver who's aware of their current situation.

The most reliable source of what they have is a phone call to the local pharmacy. I practise in a fairly rural area, and I only have to make, potentially, seven phone calls to access the one that may have dispensed it. The catch is that if they've used more than one pharmacy then I still don't know, but their pharmacy is usually linked with the other ones.

That's a slightly facetious answer, but basically I have no online rapid way of doing that at all.

Mr. Patrick Brown: How beneficial would it be if you had access to something like that?

Dr. John Haggie: It would be a huge quantum leap in safety for the patient—there is absolutely no doubt about it—once you have that mechanism in place simply to tell me what they're on and what they're taking. They don't always take their medication, but if I know that they've not had a refill on one particular medication for six months, I can probably assume they may not have been taking it.

Again, it would be a huge leap and it would be a skeleton, a backbone, onto which you could plug decision support tools, as I've alluded to before, about age-sensitive prescriptions or drug interactions, as Fleur-Ange has mentioned. It would be the backbone, but I don't have that at the moment.

Mr. Patrick Brown: Do you know of any evidence that there are rates of medical errors caused by not having this information in a timely way? Is there anything the committee could look at further that might speak to where this deficiency exists?

Dr. John Haggie: If you look at primary care in the United Kingdom, you'll find that a vast majority of family practitioners, certainly in urban areas, have e-prescribing and electronic medical records. In some jurisdictions they don't actually give a written prescription. The patient has their pharmacy on record, the button's pressed, and the prescription goes directly there, so it's being filled while they're still leaving the surgery or making their way out.

I think there is data in publications from the U.K. that show very clearly that you can reduce the number of drug interactions, particularly in the elderly, with a mechanism like this. Certainly in hospitals—a lot of my practice is hospital based—we have medication error reduction protocols, and we also have checklists for prescriptions, to try to reduce the chances of writing the wrong drug up.

With medication errors, there are lots of holes in the cheese to line up. So you can get the diagnosis wrong and prescribe the right drug for the wrong diagnosis or vice versa. Then you can get the right drug but the wrong dose. Then you can have interactions with others. In hospitals there are already a lot of fail-safe mechanisms that will reduce that happening, but they're not necessarily electronic.

Mr. Patrick Brown: How long does it take for a government alert on drug safety to actually get out to a physician? If there were an electronic mechanism or you had a handheld portable device, maybe there'd be a way to speed that up. What are the current timelines if there's a government alert issued?

Dr. John Haggie: Mostly, I get them by fax or snail mail, as my daughter calls it. Occasionally our college will promulgate an alert it has received, but it's very variable.

The other problem I have is that when the alert arrives it doesn't mean anything to me, necessarily. Take, for example, the tragic case of that young lady, Vanessa, who had cisapride. That's a drug I used quite a lot. I can vividly remember getting a report from Health Canada that said it was associated with EKG abnormalities. That's all it said. What that meant to me is that if you had a girl of her age who had EKG abnormalities like that, you'd go look to see if she was on the medication, not that if you leave this girl on medication like that she's going to die, or if you have a girl of this age on this medication, make sure they have an EKG. That never happened.

I'm sorry, I went on a bit.

● (1240)

The Chair: Thank you.

Mr. Malo.

[*Translation*]

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

I want to thank all of you for being with us today.

Having heard the comments that were made this morning, I am realizing that health care professionals may not have all the information they need in order to correctly use the pharmacology available to them. I also note that this is not only a problem in Canada; many other Western countries are struggling with that issue. Would you care to comment?

As a solution, you are advocating that the legislation be beefed up, in order to give it more teeth and force the industry to carry out more post-market studies and disclose all available information, whether it is positive or negative. However, the industry could object, saying that this might result in trade secrets being disclosed. What is your response to that concern?

[*English*]

The Chair: Who would like to answer that?

Mr. Anderson, would you like to make a comment on that?

Mr. Douglas Anderson: Not having any direct access to the pharmaceutical industry, I think this is mainly directed towards their bailiwick. I don't mean to be evasive on this, but I think this would be better directed towards the pharmaceutical industry per se, sir.

[*Translation*]

Mr. Luc Malo: Perhaps Dr. Haggie, from the Canadian Medical Association, could respond, since he addressed that in his presentation.

[*English*]

Dr. John Haggie: I think it's a balance, as with most things. If you look at the pharmaceutical industry and the licensing requirements for Health Canada, that negotiation could take place with protections for trade secrets and these sorts of things, provided the experts at that level were fully informed.

The catch comes later when it's released on the market and you have some concerns over the safety of a product. There was an issue with a drug used in open heart surgery, where it transpired that there may have been a body of research that the pharmaceutical company had omitted to give, certainly to the public domain, even though Health Canada may have seen it. It's a balance you need to strike somehow between protecting the individual and the practitioners who use these drugs in good faith, and yet balancing the commercial interests of the pharmaceutical industry.

As a physician and a patient advocate, I would have to say you need to tip that balance in favour of the patient.

[*Translation*]

Mr. Luc Malo: Thank you.

You also said that both physicians and nurses are prepared to participate in the process. All professionals want to contribute to the creation of a rigourous system that works the way it should. You even went so far as to suggest that adequate compensation should be given to professionals who prepare these reports, as a means of confirming available information.

Are professionals who do report compensated for it? And, what do you think would be adequate compensation, so that all the information to be collated effectively?

[*English*]

The Chair: Dr. Haggie.

Dr. John Haggie: Currently under the system in the province in which I practise, which is Newfoundland and Labrador, it only compensates you for face-to-face patient contact at a provincial level under the care plan. It is not unreasonable, I don't think, to adopt a graduated approach. If you have to spend a lot of time and effort providing copies of your charts, perhaps even looking up blood work and these sorts of things to provide information, that time and effort should be recognized.

At the other end, if you have a user-friendly reporting system that literally takes two seconds to do, which will then trigger, say, an audit or an assessment by a centre of excellence somewhere to look at prevalence, that's a different thing. You can make a case that this doesn't warrant anything like that level of remuneration.

As a general principle, it would be unfair to my colleagues in practice if I didn't say that any effort they put in should have some kind of compensation.

● (1245)

The Chair: Thank you very much.

I think we're running out of time now. It's a quarter to the hour and we have to go to the two pieces of business we agreed to when the committee started. But I want to say a special thank you to all the witnesses who came today. Your presentations were very insightful. We went a little long on some of the answers because you brought such great new information.

We will now go to committee business.

I will ask Ms. Wasylycia-Leis to please move her motion before we proceed with the debate.

Ms. Judy Wasylycia-Leis: I so move my motion as presented.

I don't need to speak at length about this. It's similar to the motion I presented at an earlier meeting. It has been pared down to simply refer to the annual report and to request that the Minister of Health appear before this committee as soon as possible in order to deal with this report, and then to report back to the House.

The Chair: Can we have it opened for discussion?

Mr. Fletcher.

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

I think we know how this is going to turn out, but just for the record I'd like to say that the minister has appeared in front of the committee several times already, or has offered to do so. He will be appearing presumably for estimates. Beyond what has already been committed.... Just for the committee's information, he's extraordinarily busy. So if this motion does go through, it may be some time before he is actually able to come forward on this topic.

If the committee wishes to pass the motion, it's certainly the committee's prerogative. But we already discussed a similar motion at the last meeting. It was defeated and should stay like that. Therefore the Conservative members will be voting against the motion simply to keep things consistent with what has already been agreed upon.

The Chair: Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: Madam Chair, I wish to express our concern in this regard. Where health care is concerned, we have the Quebec clause as to how the motion should be interpreted. This may suggest that the Minister of Health should get directly involved in health care matters in the provinces. I want this to be included in the motion because it is consistent with the position taken by the Quebec Minister of Health—namely, that nothing is to be interpreted in a way that would interfere with Quebec's jurisdiction. That is the intent and the will of the Government of Quebec.

I don't know whether this would result in the provinces being given directives. If it only refers to exchanges of information, I have no problem with that. In any case, I think we could take advantage of the Minister's visit to ask broader questions, rather than limiting ourselves to the Canada Health Act alone. We could ask him about rare diseases, for example, or ask him to give us his impressions of our report. However, as regards the health care or drug insurance schemes, Quebec retains exclusively responsibility for planning, organizing and managing health care services in its area of jurisdiction.

This motion was moved by a member of the New Democratic Party whom I respect for her values and her contribution to discussions of the health care system and other policies. However, her propensity for excessive centralization is tantamount, as far as we are concerned, to non-respect of provincial jurisdiction, particularly as regards health care services.

I just want to make that point so that, if we do pass this this morning, that can be done based on the direction I have just laid out. Thank you.

● (1250)

[*English*]

The Chair: Madame Gagnon, just to clarify everything, you want that amendment put right into this motion? Is that what I'm hearing you say?

[*Translation*]

Ms. Christiane Gagnon: Yes.

[*English*]

The Chair: Okay, is there any discussion on this particular amendment that you'd like to engage in at this time?

I'm going to give it to the clerk because her French is far better than mine.

Ms. Christiane Gagnon: Try it. It's funny.

The Chair: That would give you some amusement today, I'm afraid.

Okay, go ahead.

[*Translation*]

The Clerk of the Committee (Mrs. Carmen DePape): It reads as follows:

> We are in favour of the motion tabled by Ms. Wasylycia-Leis, insofar as the traditional interpretation of the Canada Health Act prevails — namely, that where health care matters are concerned, Quebec is accountable only to its citizens; nothing should be interpreted in such a way as to derogate from Quebec's jurisdiction; Quebec has clearly expressed its determination to exercise its own responsibilities; the Government of Quebec considers the health care system and the Quebec health care scheme to fall within its exclusive jurisdiction. Thus it has sole responsibility for planning, organizing and managing health care services in its area of jurisdiction, based on Quebec's legislative and regulatory framework.

[*English*]

The Chair: Mr. Fletcher.

Mr. Steven Fletcher: We all understand what the separatists' agenda is and—

[*Translation*]

Ms. Christiane Gagnon: I'm sorry, Mr. Fletcher, but they are not separatists. That is the will of the Government of Quebec, represented by a federalist Liberal Party. I don't like…

[*English*]

The Chair: Excuse me, Madame Gagnon.

Mr. Fletcher.

Mr. Steven Fletcher: I don't think any federalist party could support that motion outright. I think if you're going to do what the NDP member wants to do, you have to accept the motion, but with that amendment, I think any federalist party should be very concerned about it and should vote against it.

The Chair: Mr. Thibault.

Hon. Robert Thibault: Well, I fail to see when the amendment begins in those paragraphs. I fail to see how it changes or how it relates to the motion by Madam Wasylycia-Leis. Therefore, I can't support it.

As far as the principles she's enunciating go, some sides of those I agree with, and some I have some trouble with. That's a whole other matter of debate. But as it has no relationship to the original motion, I can't support it.

● (1255)

The Chair: That being said, then I have to rule that it's inadmissible, because it doesn't relate. Your arguments are well taken at this time, Mr. Thibault.

Having said that, we're back to the motion. Let's take a vote on whether or not we're going to accept—

Hon. Robert Thibault: I haven't spoken on the main motion.

The Chair: If you would like to do that, please speak on the main motion.

Hon. Robert Thibault: First of all, I'd like to thank Madam Wasylycia-Leis for bringing this forward. I think this is quite appropriate. The Canada Health Act is the foundation of the cost-sharing mechanism between the Government of Canada and the provinces on matters of health in Canada, and it sets out the five principles on social medicine in Canada.

The report that's been presented to Parliament points out some problems in the administration of that act. Some provinces are not respecting it. Some are being fined retribution for that, as they should be, under the Canada Health Act, and have had some financial support withdrawn by the federal government, and we see a case of one that is not. I think the minister should be able to respond to that.

Further, we have the recent Castonguay report, some areas of which, it has been suggested, are an affront to the Canada Health Act. I agree, and I think it would be worthwhile to have the minister answer significant questions at this time.

The Chair: We have had discussion, and we do have another item of business. With your permission, is it the will of the committee to just take this to a vote now?

(Motion negatived)

The Chair: We'll now go on to the budget. We have a budget we have to pass in order for the witnesses to come.

Order, please, or we're going to be here a little longer.

We have to work with a budget because we do have people coming in from B.C. on the donor seminar. We have two witnesses coming from Edmonton, two witnesses from Toronto, one from Quebec, and one from Montreal, so we do have to have a budget of $15,900.

Can someone put forth a motion to pass this budget?

Mr. David Tilson: Yes, I move it.

The Chair: Thank you. You moved that it be passed.

Are we all agreed, or is that a question? Could I have a show of hands?

Hon. Robert Thibault: Is that for the budget?

The Chair: Yes, we are trying to get agreement to pass the budget of $15,900 today.

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

The Chair: Thank you.

Go ahead, Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: Madam Chair, Mr. Tremblay, who is Chairman of the Canadian Organ Donors Association, would like to appear before the Committee. I think there is a problem with the witness list. Is there an appropriate balance there?

[*English*]

The Chair: All right, I'll ask the clerk to speak to this, Madame Gagnon.

[*Translation*]

The Clerk: Ms. Gagnon, six organizations have confirmed that they will appear, which represents 15 witnesses. They include the Canadian Council for Donation and Transplantation, the Canadian Society of Transplantation and the Canadian Association of Transplantation.

[*English*]

The Chair: It is going to be a very busy day with everybody, so thank you. I think this is definitely all we can do on that day, but perhaps we can look at it at yet another time. We'll leave that open to another meeting.

Ms. Judy Wasylycia-Leis: On a point of information, since my motion was defeated—which means the minister won't be coming to the committee on this particular issue of the Canada Health Act—and given the fact that Parliament automatically defers the annual report of the Canada Health Act to us, which means we'll be discussing it without the minister, could I ask when that will be scheduled and how soon we could actually fit it into our schedule?

● (1300)

The Chair: Could we put that on the agenda for the next day? We would have to find out when that would be scheduled. Is that agreed?

All right, I am going to dismiss the committee now. Thank you.

The meeting is adjourned.

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