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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1100)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good morning, everyone. Welcome to the health committee. We're so happy to see you here today. We have had some very good discussion on post-market surveillance of pharmaceutical products, and the committee is very happy that you have joined us today.

Before we begin hearing from our witnesses today, I'd like to ask for the committee's agreement that at the end of the meeting we set aside 15 minutes to discuss a request from two delegations, from Germany and the Czech Republic, and also to determine the guidelines for the natural health products meetings on May 8. Can I have a show of hands? Is that agreeable, that 15 minutes?

Mr. David Tilson (Dufferin—Caledon, CPC): At the end of the meeting?

The Chair: At the end of the meeting.

Mr. David Tilson: At one o'clock?

The Chair: No, at a quarter to one, before the end of the meeting, the last fifteen minutes.

Mr. David Tilson: Okay.

The Chair: Is it agreed?

Some hon. members: Agreed.

The Chair: Thank you, members.

Now pursuant to Standing Order 108(2), I'd like to welcome our guests, our witnesses today, to our meeting. We have three witnesses today. We have Mr. Andreas Laupacis, and you're a doctor, I believe, are you?

Dr. Andreas Laupacis (Executive Director, Li Ka Shing Knowledge Institute, St. Michael's Hospital): That's correct.

The Chair: Dr. Laupacis, welcome today. I understand you're from St. Michael's Hospital in Toronto. We're very pleased to have you here today.

Dr. Steve Morgan from the University of British Columbia is here as well. Welcome.

And Mr. Patrick Orr, who is a lawyer, I believe—is that correct, Mr. Orr? And you're from Ottawa?

Mr. Patrick Orr (Lawyer, As an Individual): That is correct.

The Chair: Good.

I want to tell you that each of the presenters has 10 minutes to present. Following that, we will be asking the committee members to come forward with their questions.

Could we start with Dr. Laupacis, please?

Dr. Andreas Laupacis: Thank you very much. Good morning, everybody.

Thanks for the opportunity to talk with you about the post-marketing surveillance of pharmaceuticals.

By way of introduction, I'm a patient who consumes drugs, a physician who prescribes them, a researcher who studies their benefits and side effects, and a drug policy advisor. I'm also one of the authors of the proposal to establish a real world safety and effectiveness network, which is currently being considered by Health Canada.

Let me start by saying that Canada and the rest of the world would benefit greatly from a more robust mechanism of post-marketing surveillance of pharmaceuticals, for a number of reasons.

First, some important harms are not detected in the studies that are currently conducted for licensing, either because the harms are so rare that not enough patients are studied in the initial randomized trials to be able to detect them or because the side effects occur after prolonged use.

Second, the benefits and harms of drugs in the real world can be different from the benefits and harms found in the randomized trials conducted for licensing. Those trials tend to enrol patients who are healthier and more likely to take their drugs than the average patient, and the patients are cared for by health care providers who can offer closer follow-up than is usually the case in actual practice. Thus the benefits and harms in the real world may differ from those in the trials done for a licensor.

And third, some drugs are currently licensed on the basis of so-called surrogate markers—for example, a decrease in cholesterol—with no clear evidence about their impact upon the outcomes that matter to patients, such as whether the decrease in cholesterol leads to a decrease in heart attacks or death.

Post-marketing studies have the potential to provide information about the outcomes that matter to all of us. Currently there's no systematic approach to post-marketing surveillance in this country, which is why I enthusiastically support the establishment of the real world safety and effectiveness network, which has been submitted to Health Canada.

This independent network would bring together clinicians who prescribed drugs, patients who benefit from and are harmed by drugs, Health Canada, which approves drugs, the provinces and territories that pay for them, and researchers who can analyse the databases, the forum—that basis of post-marketing surveillance. Such a network would provide important information that is not currently routinely available, particularly if it is well linked with other such networks across the world.

I've been asked to say a few words about Health Canada's proposal for progressive licensing.

As I understand it, the idea is to allow some drugs to reach the market relatively early, on the basis of promising but not conclusive evidence of an attractive benefit-to-harm ratio. This initial licensing would be conditional upon the performance of post-marketing studies to determine if the initial promising results are substantiated when the drug is used in actual practice.

The idea is attractive in one way. It would allow patients who are suffering from a severe disease for which there is no good therapy a chance to try a drug with promise. However, there are also considerable downsides to this approach. There is a reason that randomized trials are the gold standard for the evaluation of new drugs. Because of the process of randomization, in which patients essentially receive the new drug, or standard therapy based upon the flip of a coin, those who receive the new drug are virtually identical to those who receive the current best therapy. This means that one can be quite certain that any differences between the two groups, either in benefits or harms, are likely due to the drug.

Patients are rarely randomized in post-marketing studies, so that those who do and do not get the new drug in the real world are often very different in their underlying characteristics, which can make it very difficult to conclusively determine the drug's benefits and harms.

Although judicious use of progressive licensing in limited circumstances seems reasonable to me, it would be important that post-marketing studies are not used as an excuse not to do the high-quality randomized trials that we need. As well, the legal and political framework must be in place to allow Health Canada to withdraw the drug from the market or limit its prescribing on the basis of negative post-marketing results.

It's important that the committee is aware that post-marketing surveillance will not be a panacea. As I've mentioned, these studies can be difficult to interpret, and there's a relatively small group of researchers in Canada who are skilled in their execution. That is why our network proposal contains a substantial component for the training of young researchers.

● (1105)

I believe that inappropriately withdrawing a drug from the market because of an inaccurate result is just as bad as inappropriately allowing a drug on the market with inadequate information about its benefits and harms. Therefore, the results of post-marketing studies in one jurisdiction should be confirmed by studies in other jurisdictions. That is why the network proposal indicates that our post-marketing network must be well linked with networks around the world.

Because post-marketing studies can be expensive, decisions will need to be made about which studies need to be done and which we can do without. That is why our network proposal suggests a priority-setting committee with representation from numerous stakeholders and a strong scientific director to make the judgment calls about how our limited funds should be spent.

Every beneficial drug causes side effects. Therefore, patients and physicians will always need to weigh the benefits of a drug with its harms. I have an elevated cholesterol level, and although I am otherwise healthy, this morning I took an Aspirin and a statin, a drug to lower my cholesterol, in an attempt to decrease my chance of having a heart attack. By so doing, I realize that I am accepting the small chance of a very severe side effect, such as a major bleeding ulcer caused by the Aspirin.

Another person in precisely my situation and as aware of the same information as I am might decide that the risks of these drugs are not worth the benefit. The important point is that we should both be fully aware of the drug's risks and benefits and should make the decisions that are right for us.

There's an urgent need for all Canadians to have access to the kind of information that I'm lucky enough to have because I'm a physician. Canadians deserve complete and unbiased information about the benefits and harms of drugs, in a form that is understandable to all. Currently, this does not happen.

The information that drug companies provide to the Therapeutic Products Directorate of Health Canada is kept secret, as is Health Canada's assessment of that information. Canadians deserve access to that information, and if legislative change is needed to make that happen, so be it.

There is also a need to produce information about drugs that is written in a language and provided in formats that are accessible to all Canadians. Current warnings from Health Canada about a drug's side effects are long, technical, and difficult to understand for physicians, let alone patients.

Health Canada should borrow from the pharmaceutical industry, which excels at communicating its message clearly and succinctly. The network that we have proposed could also play a role by providing accessible independent information about the benefits and harms of drugs.

In closing, let me thank you for taking the time to consider this important issue. Establishing a more robust post-marketing surveillance system in Canada, although it will not remove all uncertainty, will be a major step forward.

I look forward to your questions, and thanks very much.

● (1110)

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

Could you send your presentation, please, to the clerk when you leave today to make sure it's translated? We'll distribute it to all of the members of the committee.

Thank you for a very insightful presentation.

Dr. Andreas Laupacis: Sure. Thanks.

The Chair: Dr. Morgan, could we hear from you next, please?

Dr. Steve Morgan (Assistant Professor, Centre for Health Services and Policy Research, University of British Columbia): Thank you very much for the invitation to speak on this important matter.

My name is Steve Morgan. I'm an assistant professor at the University of British Columbia's Centre for Health Services and Policy Research. CHSPR, as it's known, is one of Canada's academic repositories for administrative health care data. By tracking the use of medicines, physician services, hospital care, and other services in the health care domain, our research centre is one of the centres in Canada that's able to study the organization and delivery of health care and its impact on the health of populations.

This is an example of what I will refer to as the Canadian advantage in post-market evaluation of the safety and effectiveness of medicines, and I'll return to that Canadian advantage in a minute.

In addition to being a member of the centre's faculty, I am the lead of the program on pharmaceutical policy. Our program is an interdisciplinary collaboration among researchers, trainees, and even policy-makers who are interested in pharmaceutical policy across the entire life course of pharmaceuticals.

The Chair: Dr. Morgan, can I just interrupt you for one moment? Could you slow down just a bit for our interpreters? They can't quite keep up to your interesting dialogue.

Dr. Steve Morgan: For sure.

Our research program spans the life course of pharmaceutical policy, from factors that influence pharmaceutical innovation and research and development, including the location thereof, through to factors that were associated with the coverage of pharmaceuticals, the design of public insurance plans, and, finally, through the analysis of the population's use of medicines, its outcomes both on health status and on the health care system.

I want to thank this committee for its continued investment in the Canadian Institutes of Health Research and other federal granting agencies in health and other scientific domains. I bring this up in this particular forum because some individuals will tie the regulatory policies around medicines to industrial development and innovation policy.

My program at UBC has been studying innovation in pharmaceuticals for several years now. We've learned through this program of research that the way to foster innovation and the way to foster economic development is not through continuing to cut taxes for research investments; it is not to reduce regulatory requirements, which are both factors that will affect profits of industry but not necessarily innovation or the location of their investment. The best thing governments can do to affect innovation and to attract investment is through the direct and strategic investment in scientific personnel, capacity, and networks. This is a conclusion drawn by the C.D. Howe Institute, a reputable research institute in Canada; the Conference Board of Canada; and many others.

To paraphrase Michael Porter, a professor at Harvard who is an expert in what is referred to as industrial clusters, the best policy approach is to be a tough customer for any given sector while at the same time investing strategically in the capacities that would make your research environment a fertile ground for that sector to invest in. Therefore, my group has reached the conclusion that government in Canada is best to invest in organizations like the CIHR to foster research, to foster clinical trials in basic science that lead to innovation, while at the same time being a tough customer, so to speak. And that is, in some sense, the business of this particular committee's hearings today. Being a tough customer at some level also relates to post-market surveillance.

I've been fortunate enough to be collaborating with Mary Wiktorowicz, who will, I understand, be speaking before this committee next week on a cross-national study of post-market surveillance in several countries around the world. One of the key messages, which I am sure Mary will speak to you about at length next week, is that no country has truly succeeded in achieving post-market surveillance by leaving it to the pharmaceutical industry on a voluntary basis.

I don't say this is an accusation of industry. I think it's important to acknowledge that business is business and that pharmaceutical companies are not the agents in this sector whose primary responsibility is to ensure the safety of a population and value for money of the medicines used. The agents for whom that is a primary responsibility are us. It is policy-makers, it is health care professionals, and it is individuals like me, who are academics, who are publicly funded to do research on policy and practice.

You have heard from many individuals who have testified to this committee about gaps in evidence concerning post-market surveillance. I will not repeat this, other than to say it is a natural phenomenon in this sector that there will be evidence gaps at the point a product reaches the market. You've also heard, I think, a variety of conflicting reports around the value of adverse drug reporting.

It is true that few systems in the world attract all adverse drug events that occur, whether they're mandated adverse reporting systems or voluntary reporting systems. It is nevertheless still the case that ADRs, adverse drug reaction reports, are the basis on which roughly half of drugs that are withdrawn from markets around the world are eventually investigated and pulled from market. It is therefore an important signal and not one that should be abandoned because of concerns about the time constraints of practitioners and individuals involved in the reporting.

There are systems in which you can improve ADR reporting. You, as a committee, have heard from Bruce Carleton, who talks about active monitoring and an active system of surveillance for in-hospital reporting. In the hospital setting, it is possible to allocate dedicated personnel to tracking, documenting, and monitoring potential adverse events. Dr. Carleton's network of centres in children's hospitals across Canada is an example of an excellent system for tracking such ADRs. But all the ADR information in the world is going to be of little or no value unless we are tracking who is using medicines, who is not using medicines, and the effects of these phenomena.

● (1115)

Various representatives who have spoken before this committee have made mention of Canada's information systems for tracking drug utilization. Representatives of the pharmacy profession specifically mentioned British Columbia's PharmaNet data system.

PharmaNet is a system in which every prescription written in the province of British Columbia must be entered into a computer system at the point where it is dispensed by a pharmacy. This system tracks safety in a number of ways, the first of which is at the point of retail sale. When a patient fills the prescription, no matter the pharmacy and no matter the doctor who filled the prescription, the pharmacist has access to information that will allow them to identify potential adverse interactions between that drug and the other drugs the patient is receiving.

The second stage of value from systems like this is that every patient who fills a prescription is entered into a database, with the date of the prescription, the type of drug, and an identifying number that allows you to link it to their use of hospital and medical services and to important vital statistics, such as death and the causes thereof.

These kinds of information systems can be used for active and prospective post-market surveillance. Andreas Laupacis, who just spoke, was the former CEO of the Institute for Clinical Evaluative Sciences in Toronto. It is an exemplary institution in terms of the state of science for post-market surveillance using such databases.

The committee has also heard concerns about Canada's lack of an electronic prescription record, and I think this is an important concern. In 2006, the U.S.-based foundation, The Commonwealth Fund, did a survey of general practitioners in eight countries around the world. They found that over 80% of doctors in Australia, the Netherlands, New Zealand, and the U.K. routinely had access to electronic systems that flagged potential problems with drug doses or interactions for the drugs they were about to prescribe to patients.

In Canada, only 10% of doctors report having access to such systems. This is an abysmal failure of our system, given the fact that an investment in it would prevent adverse reactions or poor prescribing well in advance of the actual event. If you can stop a contraindicated drug or an adverse drug reaction before the prescription is written, the patient is more likely to leave the practitioner's office with the right drug in the right dose for their treatment.

There is no panacea, as Andreas has just said. In fact, in order to engage in post-market surveillance appropriately and to have real world drug safety and effectiveness monitored and managed in the way that optimizes our investment in care, we need a variety of approaches. In addition to adverse drug reaction reporting, we also need the prospective and active monitoring of data systems and the development of those data systems. But we will also need to fund new things, such as new head-to-head clinical trials—which manufacturers just don't have an interest in funding, yet are vital to engaging in the gold standard of scientific investigation of which drugs are best for our population.

We may need to do prospective cohort studies, where we collect primary data, possibly including genetic information, such as Bruce Carleton spoke of before this committee. And we may have to do what some refer to as pragmatic trials, or some others refer to as “designed delays”, where we in fact allow some populations of the country to access medicines randomly by choosing postal codes or other mechanisms, while holding the drug back for six months or a year for other populations, to get a form of quasi-randomization in the real world evaluation.

These are complex phenomena. There are many investments that need to be made; therefore, it is important to have sustained and substantial investment in post-market surveillance. Andreas Laupacis has referred to a business case and a proposal for a national network. I would encourage the members of this committee to read the business case and to speak further with the individuals involved with that network.

I want to put the investment into perspective, though. Canadians spend approximately $21 billion on prescription drugs every year. If we were to invest $21 billion as individuals in our retirement savings plans through mutual funds, or whatnot, we could expect to pay the fund managers approximately 2% for managing our return on investment. With all due respect to the managers of the funds, they're just managing financial matters. In the pharmaceutical sector, what we need, in some sense, is a fund manager who is not just managing for return on investment in terms of value for money, but also in terms of the population's health and safety. If you were to translate a 2% investment into monitoring post-market safety, effectiveness, and quality use of medicines in Canada, it would amount to $420 million a year invested in this activity every year, forever.

● (1120)

Now, I don't propose that the government immediately jump from zero to 60 in one moment, but it is quite probable, and I think it is quite important that we seriously consider the fact, that we have under-invested in systems such as electronic health records and such as a coordinating mechanism—which Andreas has talked about—with respect to prioritizing the allocation of scarce human resources toward researching and studying post-market surveillance.

So I would encourage you to carefully consider the investments that could be made, both in increasing the amount of resources available within Health Canada to do due diligence pre-market and outside in the community.

Finally, I want to stress, as you've heard from several members—

The Chair: Dr. Morgan, you've run out of time, so I need you to wrap up your presentation.

Dr. Steve Morgan: This is my last point.

I just want to stress, as you've heard from several witnesses before this committee, that however important—and perhaps essential—post-market surveillance and vigilance is, it is not a substitute for due diligence pre-market. It would not be acceptable to lower the bar before medicines come to market simply because we think we have a safety net in the real world environment.

Thank you.

The Chair: Thank you, Dr. Morgan.

You've given a very insightful presentation, and we'd like copies of it. I understand you're reading from your computer, which I often do. If you could provide the clerk with your presentation, we will ensure that it gets distributed to all committee members. It was a very good presentation, so we value it very much.

Thank you.

Now I'd like to hear from Mr. Patrick Orr.

● (1125)

Mr. Patrick Orr: Thank you very much for the opportunity to speak to the committee today.

I am a legislative lawyer in private practice here in Ottawa. I have been writing legislation for governments in Canada and outside Canada for over 20 years in private practice, and a few years before that with the Government of the Northwest Territories in Yellowknife. I am also consulting counsel on a number of class action lawsuits against Health Canada for regulatory negligence in relation to illegal and harmful medical devices allowed on the market. I should make it quite clear that I am a critic of Health Canada, and that will come clear in my presentation. These court cases also involve serious allegations of negligent post-market surveillance.

After the thalidomide disaster, the role of Health Canada was legislatively strengthened to protect the public from harmful drugs. People think this disaster cannot happen again. Recently, in a CBS report on Trasylol, they reckoned there are 1,000 deaths per month from that drug in the United States. I don't think we are in a position where we've learned many lessons from the past.

There's much I could speak about, but I understand this committee's focus is on post-market surveillance, so I'll restrict my comments to that.

The purpose of post-market surveillance is to protect the public. Health Canada's new commitment to reducing protection of the public through progressive licensing means that more dangerous products will be allowed on the market earlier. This means that post-market surveillance will be even more essential to protect the public.

In my view, post-market surveillance requires four essential things to work. I say this as a lawyer who designs regulatory systems for government. I do it for the Government of Canada, governments in the north, and provinces, as well as foreign governments. The first is that a legislative scheme has to be created to require it. Second, politicians and departmental management have to have the will to actually do it. Third, there has to be adequate staff and budget to do it. Fourth, the involvement of physicians, hospitals, and the public have to be included in the scheme.

In my view, none of these things are present today. Post-market surveillance is an illusion, and unfortunately a very sad illusion, for the public that is relying on it. I make no apology for being a bit gloomy on this, but I will explain my comments one by one.

First, on the legislative scheme, there is no legislative obligation for Health Canada to conduct post-market surveillance. There should be. I understand that a bill has just been introduced, or is about to be introduced today, requiring greater product safety recall powers. We'll have to see what it is, but this could be the beginning of a solution to this problem. I will speak about what I think should be in such legislation for proper post-market surveillance.

At a minimum, the legislation should define an adverse reaction as follows. An adverse reaction occurs when a drug, including its inactive or non-active ingredients, is suspected of causing any of the following: no therapeutic benefit; no diagnostic benefit; no prophylactic benefit; no effect at all; and finally, any injury to the patient. We are hearing about antidepressants that have no effect at all, not even a placebo effect. That should be an adverse report.

There should be mandatory reporting of adverse incidents, both within Canada and outside. There should be mandatory recall of adverse drug products, and mandatory public notice of adverse drug products should be required.

I have spoken with Dr. Ed Napke, who is a physician who was formerly in Health Canada, and he established the original adverse reaction reporting system in Canada. It's one of the first in the world. He insists that drugs must be defined as consisting of both active and inactive ingredients.

There is no obligation to label the inactive ingredients, even though these chemicals will affect the efficacy and safety of the drug product. This committee may not be aware, but Parliament unanimously passed a motion in 1989 asking the government to require complete labelling of all active and inactive ingredients in drugs, but no action has been taken 19 years later.

● (1130)

One example currently in Ottawa is Flomax, a prostate drug. The inactive ingredients in its formulation were changed to allow time release. It now swells up into a hard, glutinous substance about the size of a walnut. If it gets stuck in your esophagus, you can die. And those aren't the active ingredients; they're the “inactive” ingredients.

In my view, the current food and drug regulations are not adequate for post-market surveillance. It's only mandatory for industry to report a serious, unexpected adverse drug reaction, which means a serious adverse drug reaction that is not identified in nature, severity, or frequency in the risk information set out on the label of the drug. If the manufacturer says 5% of the people who take this will be seriously harmed, and in fact 5% of the people are harmed, the industry has no obligation to report that 5%.

There is no mandatory recall of drugs by industry. If a drug starts killing people, the industry is not obliged to recall the product. There is no power for government to order the recall of a drug. It seems very Canadian to just rely on the word "please"—"Please recall the drug. Take it off the market."

There is no mandatory public notice of harmful or ineffective drugs. Instead, we have self-inspection by industry. There is even no need for industry to report any complaints they receive or investigation about drugs to Health Canada. If people are complaining directly to the drug companies, they do not have to report this to Health Canada. They are expected to keep a record of the complaint, but only for one year after the expiry of the drug lot.

Next I'd like to speak about political and management will. Even if there's a good legislative scheme, there must be will, of course, in the government to act to protect the public. In my view, the department has lost its way on this point.

The department is developing a corporate risk profile to identify management challenges, and I'll quote the following from the department:

> The department is developing its corporate risk profile to identify management challenges with respect to the potential corporate risks—e.g. financial, technology, property, etc.—that may impact the realization of its corporate objectives.

So for the department, risk protection is not protection of Canadians from risk, but protection of the department from risk of the public.

The priority of the department is to improve access to drugs and medical devices. Look at their therapeutics access strategy. This is a complete about-face from the original purpose of the department, which was to protect the public.

The 2002 Speech from the Throne advocated speeding up the regulatory process for drug approvals to ensure Canadians have faster access to the safe drugs they need. In my view, this means that more dangerous products will get on the market, requiring even better need for post-market surveillance.

Health Canada refers in its literature to the drug industry as its client. In my own experience with litigation over a temporomandibular joint implant, Health Canada argued in court repeatedly that it owes no duty of care to the public. I repeat, it owes no duty of care to the public. And lawyers for Health Canada argue that if there is gross negligence in the department, even admitted gross negligence, there is no remedy except to vote out the politician. So the only remedy for bureaucratic negligence, lawyers for the department argue, is voting out the minister. I cannot stress too much the profound shift in the philosophy of the department.

I've been working with governments for a long time. I know that no government likes enforcement inspectors who go in and cause trouble, who raise problems with stakeholders. So there's a very strong tendency in government—and it's natural—to reduce inspections because they just cause problems. The inspector goes in, says, "You have this illegal product, take it off the market, or do something about it", the minister or the deputy minister gets a call, and everyone's life is miserable. We have to take steps to deal with that.

In my own TMJ case, the department has resisted for nine years advising the public of a catastrophic medical device allowed on the market by Health Canada. Nine years it's fought us in court, saying it has no obligation to inform the public on this device.

Last week we finally, after repeated motions, got the court to order Health Canada to do a public notice campaign to advise the public that there's a catastrophic.... Now, this is a medical device, but this is the philosophy of the department—they owe no duty to inform the public.

● (1135)

I see that my time—

The Chair: Mr. Orr, your time is up now. Can you just wrap up quickly?

Mr. Patrick Orr: Yes. I was going to speak also about adequacy of budget and staff. It's in my notes, which I have given to committee.

The Chair: I'm sorry, we don't have.... Would you like to just sum up?

Mr. Patrick Orr: Yes. I will not speak to that point.

Thank you very much for the opportunity to speak, and I welcome questions.

The Chair: Thank you.

Now questions are asked of you all. We'll go to our first round; there will seven minutes from each member for the questions and the answers, and we'll start with Monsieur Thibault.

Hon. Robert Thibault (West Nova, Lib.): *Merci, madame la présidente.* Thank you all for being present.

We've been hearing a number of panels, and we hear a lot about the same thing. If you'll excuse me, Mr. Orr, I won't go into the legal matters. I think you're bringing a whole new dimension to this thing as to the regulatory issues. I'd like to stick a little bit with problems and solutions on the post-market question.

I'm glad, Mr. Morgan, that you mentioned Dr. Carleton, because that's a line of questioning I was thinking of when I was listening to Dr. Laupacis. Dr. Carleton was suggesting a network of researchers who would look at specific areas in which you have effects and adverse events, and you try to discover them so that you can predict them in the future and predict how to use....

Then we had a lot of other presenters who were telling us that at the practitioner level, they would use a reporting network if that network had value to them in their practices through two-way interaction with this website. They could get the information they needed to improve their practices or to use these treatments better in the future.

Are you suggesting somewhere between those two, or a marriage of those two types of approaches, in the network you're talking about?

Dr. Andreas Laupacis: I didn't hear Bruce's presentation, but my knowledge is that Bruce is interested in figuring out if he can predict, on the basis of genetic susceptibility, particular people who are particularly at risk of certain adverse drug reactions. My sense is that if we could do that, it would be fantastic.

Hon. Robert Thibault: If I could bring back my question for a minute so that you'll understand, I think the principle he was outlining goes beyond just genetic susceptibility. It's looking at areas of known problems and studying them in detail so that we understand them, and building the knowledge of a few specific cases, rather than taking a holus-bolus approach.

Dr. Andreas Laupacis: Yes. As I said in my remarks, even if this post-marketing surveillance network were to be well funded, one would still need to make decisions about where one is going to concentrate. I would concentrate on areas that, on the basis of initial information from randomized trials, give concern over possible side effects. I think I'd concentrate on diseases for which drugs are used frequently, such as depression or heart failure. I think you really would need a group of practitioners, regulators, researchers, and policy-makers to sit down and prioritize. For sure, it can't be a holus-bolus thing; we wouldn't get anywhere.

Hon. Robert Thibault: I studied a little bit of biology and a little bit of physics, and from my understanding from hearing everybody who comes to this committee, Newton's first law of physics applies to pharmacology also. Unless you have a pharmaceutical product that has zero effect, there has to be an equal and opposite effect. If it has a positive effect, it's also going to have some other effect that probably isn't desirable.

You can't call all side effects catastrophic; I think it's a question of the patient or the practitioner being able to reasonably predict what they will be, and you make a decision on what's right. If I have a terminal disease, I will take a risk that could cause my death if there's a better-than-even chance of having a positive effect at the end.

● (1140)

Dr. Andreas Laupacis: I agree with you 100%. When my patients come in and say they want to take some homeopathic medication that has no side effects, I tell them that if there's a drug that doesn't have any side effects, I don't think it's going to be effective. I think you're absolutely right. The management of people with HIV has been transformed from people who are dead within six months to people who now live a long time—actually, they have a chronic disease. Those drugs all have significant side effects, but I think if you ask almost anybody with HIV if they want to take those drugs, they absolutely do.

Hon. Robert Thibault: I'm using medication now to help me quit smoking. I'm on my sixth week tobacco-free.

Dr. Andreas Laupacis: Good luck.

Hon. Robert Thibault: But it does have significant side effects.

A voice: We see that.

Hon. Robert Thibault: I make my decision as a consumer as to whether I will accept the side effects of that or of tobacco in the long run, and I've chosen the ones from the medication to help me abandon....

A voice: You made the right choice.

Hon. Robert Thibault: As you pointed out on the question of cholesterol, you take that knowing the decision.

On the question of randomized trials—and I turn to Mr. Morgan—as I understand the progressive licensing scheme or suggestion or modifications in looking at the licensing or the enabling legislation, which I understand is supposed to be introduced today.... I'm looking forward to seeing the details. Perhaps we'll have you back at committee on those questions.

I understand it does not represent full clinical trials but maybe the uses permitted for a medication, as we get that knowledge about that medication, so that we can bring it to market faster, but just as safely, is my understanding.

What you're suggesting, though, rather than a randomized trial, is that you go by postal code area, so that some portion of the public may have access to a new treatment and others will be withheld. It sounds good to me, unless I happen to live in the postal code area that won't have access to the scientifically newest or potentially best medication. If I'm in a critical situation, I'll want that. I think that suggestion takes a bit away from the patient.

Dr. Steve Morgan: I think it's important to recognize that these notions of pragmatic trials, or what are called designed delays, are typically applied in cases when we actually don't know if the new drug is in fact superior or if the new drug will cause more harm than good.

They're also designed in such a way that is referred to as a designed delay, and all populations who would be eligible for the treatment will eventually get it. It's just—

Hon. Robert Thibault: But some will only after death.

Dr. Steve Morgan: There's a period during which some people get a medicine and some people don't. It's random. It's basically a pragmatic way of running a randomized trial in the post-market world. It is a new idea. It's been explored for years, but it hasn't been applied very often. But there are provinces now looking into using these pragmatic trials in an environment where we don't know the value and the safety of the medicine.

The Chair: Thank you, Dr. Morgan.

Mr. Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you, Madam Chair. Thank you, gentlemen, for joining us today.

Mr. Orr, I would like to focus on a number of points that you raised in your presentation. From what you are saying, it would seem that no one knows for certain which drugs are on the market or which drugs are been sold to patients. It seems that once drugs are put on the market, it is unclear what they are exactly or what they do. I would just like you to confirm if in fact this is what you were attempting to say and implying.

You also said that once the drugs were on the market, no one was accountable or responsible for potential adverse effects. If I understand correctly, in your opinion, Health Canada washes its hands of the whole situation. Does the industry do likewise, or does it accept some responsibility, since companies need the products they sell to be effective and to meet certain needs, and need as well to keep share values high and maintain their sound reputation?

I will leave you to answer these questions.

[*English*]

The Chair: There is one minute left.

Mr. Patrick Orr: Oh, so I have one minute?

● (1145)

The Chair: I'm sorry. No, it's okay. I misspoke. Go ahead.

I was trying to give you some time.

Mr. Patrick Orr: I apologize for any misapprehension. I believe it is well known what drugs are on the market. I didn't mean to imply that no one knows what drugs are on the market. There could be illegal drugs on the market, but generally speaking, it's well known what drugs are on the market. What isn't necessarily known are the effects of those drugs.

Your second question was on who's responsible for the effects of the drug once it's on the market. Health Canada says it's not responsible; that's its departmental position. Industry has been trying to avoid responsibility. We're getting cases in the States—this doesn't affect Canada directly—where pharmaceutical companies that are mostly based in the States are arguing that once FDA approval is given, they are not responsible for manufacturers' liability. Even if a bad product gets approval, they're scot-free. They have no liability for the product, even for adverse reports. So industry is trying to get out of responsibility.

In my own dealings in litigation with Health Canada, their argument is that the physician and the patient are responsible. So it's *caveat emptor*, buyer beware. The physician is expected to know all the effects of drugs, and if they're bad ones, even unintended ones, the physician is the one at fault.

Thank you.

[*Translation*]

Mr. Luc Malo: How do you feel about the suggestion that an independent agency should be responsible for drug surveillance? Could that be the solution?

[*English*]

Mr. Patrick Orr: That is possibly a solution. It might avoid the problem now, that once Health Canada approves a drug it's very difficult to admit they made a mistake. At least two-thirds of their funding comes from industry, so it's difficult to criticize the people who are paying the budget. So an independent agency might be the solution.

[*Translation*]

Mr. Luc Malo: Professor Morgan, you stated in your presentation that voluntary regulation of the industry does not work and that examples can be cited to prove that fact.

Would you elaborate on that statement? In which countries is a voluntary regulatory scheme working, and why is it not working in others?

My next question is similar to the one I put to Mr. Orr earlier. In your opinion, is it not critically important for the industry to ensure that the products it puts on the market are effective, precisely to ensure long-term profitability?

[*English*]

Dr. Steve Morgan: I think the key point I would like to make is that you have to design a regulatory framework that compels and actually mandates the manufacturer to complete phase four, or post-marketing trials. The penalty would be withdrawal of the product from the market. Several countries, like the United States, France, the United Kingdom, Australia, and New Zealand, have all tried various regulatory frameworks using various forms of suasion other than strict regulation, to encourage firms to engage in these post-market studies. A significant majority of the studies never get completed.

In New Zealand, they created legislation allowing the medical regulatory agency to commission their own studies of post-market safety and effectiveness for medicines. It commissioned those studies to independent academic groups to ensure they were completed in a public and transparent way.

That appears to be New Zealand's solution to the difficulty of compelling a business to complete a study. In some sense, if the regulatory framework says once it's on the market, it's on the market; it's not in the businesses' interest. That's not to blame firms; that's just the nature of business.

We need to change the regulatory framework to either make regulatory requirements subject to withdrawal or to say that the government will engage in the studies and adequately fund the studies to ensure they're completed.

[*Translation*]

Mr. Luc Malo: Earlier on in the consultation process, several witnesses told us that very few adverse effects are reported by doctors.

Why do you think that is the case? In your opinion, what steps could be taken to increase the degree to which adverse effects are reported?

● (1150)

[*English*]

Dr. Steve Morgan: That is a major question. How do we increase the degree to which adverse events are reported? Even when you compel a doctor, a pharmacist, or a hospital to report events, systems tend to report, in the best situations, on average about 10% of adverse events. Mechanisms to increase reporting include possibly compelling and making it legislation, but are more likely to be active about it. The notion of having trained personnel dedicated within institutions to track and monitor ADRs is a mechanism that might work. In Canada we might then have a network of hospitals across the country in which, at least in the emergency room, there was a trained pharmacist whose responsibility was really to look for adverse events. That's one way to dramatically increase the sensitivity with which we collect this information.

Dr. Carleton's network effectively does that within children's hospitals.

There are other mechanisms. Mary Wiktorowicz, who is speaking next week, can tell you about international experience with that.

The Chair: Thank you, Dr. Morgan.

We'll now hear from Madam Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you, Madam Chairperson, and thanks to all of you for your excellent presentations.

Patrick, you are right. The government has just tabled two new pieces of legislation that clearly impact on our deliberations today. One is An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts. The second is An Act respecting the safety of consumer products. It will be important for us to hear your reactions to these bills, because that clearly has an impact on anything to do with post-market surveillance. I'm wondering if I can maybe ask all of you, for the benefit of our study on post-market surveillance, if you would be willing to give us a written critique of these two bills from the point of view of this committee's study so that it might enhance our work and our final report. Would all of you be willing to do that?

I have a couple of copies of each of them with me now, so at the end I could leave them with you.

I am concerned that under the guise of modernization we are actually witnessing a legislative approach that might weaken the capacity of government to ensure drugs, foods, and consumer products are put on the market after all precaution has been taken. I'm worried about that because of the focus on progressive licensing. There are pros and cons, but I'd like to ask you what we should look for in terms of this bill to ensure that any focus on progressive licensing doesn't mean we are lowering the bar—as you, Steve and Patrick, said—in terms of what is acceptable, what can be allowed on the market. What should we look for in that regard?

Second, could you tell me just what this might mean? There is a huge set of "whereases" in this bill:

> Whereas the Parliament of Canada recognizes that a lack of full scientific certainty is not to be used as a reason for postponing measures that prevent adverse effects on human health if those affects could be serious or irreversible

I am wondering if all three of you could give me a bit of a perspective on that end of the question of progressive licensing in this whole context of what we know has been happening in the department.

Does anybody want to start?

Dr. Andreas Laupacis: Sure. I address that a bit in my remarks. I think, again, like anything in life, one is balancing two risks and harms. My view would be that right now the kinds of studies that industry has to come in with to have their drugs licensed are sort of a minimal standard in most times.

Mr. Orr mentioned Trasylol, which is a drug to prevent bleeding in people with bypass surgery. I actually chaired the committee that suggested that the study that looked at Trasylol should stop, because it looked as if it was killing people, compared to the comparative drug. It's a good example, actually, because nobody was saying that Trasylol wasn't effective. There was actually very good evidence that it decreases the risk of bleeding. That's quite clear. The problem was that nobody did the big enough study for long enough to see what its effect upon mortality was, so industry was able to get Trasylol funded because it clearly was....

I slightly disagree with Mr. Orr. I think it's a big exaggerating to give you the sense that we don't know the benefits or the effects of most drugs. I think we do, but often it's these surrogate markers. It's great to know whether it decreases the risk of bleeding, but you sure want to know whether it's increasing the risk of death.

So obviously the down side.... I think I would be looking very carefully to make sure there isn't any marked decrease in the quality of the randomized trials that are required now, which I think is an absolute minimum. There might be some instances of terminal cancer or whatever, where you might be able to make that case, but I'd like to see those specified.

Let me just make one other comment and then I'll stop. That Trasylol study was actually funded by the Canadian Institutes of Health Research, because it was precisely the kind of head-to-head trial that Steve had mentioned drug companies were not interested in doing. They were not interested in comparing their active drug with the competitor's active drug. The Canadian Institutes of Health Research funded a total of seven randomized trials last year—seven. I don't know what they were about, but I'm sure all seven weren't about drugs.

I think one thing this committee should look at is increasing somehow—in our network we were suggesting we would fund more trials—or encouraging or providing the funds to the CIHR to be able to fund more of the kinds of studies you folks and Canadians would want to know about, which would provide the information about the benefits and risks of drugs.

● (1155)

Ms. Judy Wasylycia-Leis: How much time is left? I want to make sure both Steve and Patrick—

The Chair: Two minutes.

Ms. Judy Wasylycia-Leis: Can each of you take a minute at least on this?

Dr. Steve Morgan: Very quickly, I think I would look to ensure that the progressive licences are only used in circumstances that are extremely dire, in which there are compelling and compassionate grounds for making access to a medicine early, on the basis of compassion. Making access to yet another drug to manage cholesterol faster in the name of access to medicines is not necessarily, in my opinion, appropriate. So I would look for that, and I would also look for the double edge of this rapid access, which would be to ensure a greater amount of transparency.

If a manufacturer is going to bring a product to market with little or no evidence of effectiveness, whatever evidence it has, no matter how commercially important it is to the manufacturer, it is asking Canadians to effectively be guinea pigs, and therefore Canadians ought to have access to every piece of trial data that was submitted to Health Canada.

Ms. Judy Wasylycia-Leis: Thank you.

Patrick.

Mr. Patrick Orr: Thank you.

First, the portion of the bill you mentioned, read out, I believe is the precautionary principle, which was developed at the Rio summit on environmental matters, which is that you must take action even in cases of scientific uncertainty. I believe that's what it is, which is a positive thing.

Ms. Judy Wasylycia-Leis: Okay. I think you could read it almost both ways, but that's good to hear.

Mr. Patrick Orr: I'll be optimistic on that interpretation.

Ms. Judy Wasylycia-Leis: Okay.

Mr. Patrick Orr: The other thing the bill should deal with, I believe, is—besides the things I mentioned—basically mandatory compulsory obligations on either officials or industry to do something. So rather than just having everything discretionary—people may do this or may do that—things should actually be required to be done in certain events, and of course the triggering events will be the threshold. Is it very, very high—serious injury or death—or is it a lower threshold?

The Chair: Thank you, Mr. Orr.

Ms. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thank you very much, Madam Chair, and thank you very much to our presenters. We certainly have heard interesting presentations this morning.

I'd like to start with Mr. Orr, if I could, please. I think you said, if I understood you correctly, that we need to have a legislative requirement to do post-market surveillance, that what's in place today is not adequate, and that the legislative requirement should be there to do it properly and to get the best results that we need.

So I've got two or three things I want to ask you. That is one. Then you also talked about a definition of an adverse reaction that I believe is different from the definition we have today, although I'm not so sure there's a very specific definition today that is used by everyone. So maybe you could go over the four or five points that need to be in that definition.

Also, you talked about the medical devices, and you specifically mentioned the TMJ issues. In your opinion, what specific changes to the medical devices regulatory framework would strengthen post-market surveillance in Canada? Could you comment on those three things, please?

● (1200)

Mr. Patrick Orr: Thank you.

The first question was on the legislative requirement. Perhaps it's because I'm a legislative lawyer and I draft legislation, but I believe legislation is generally a good thing, and yes, it's true, I believe for effective post-market surveillance you need legislation. I believe the government has accepted that principle in introducing today a bill on that very subject. I don't believe I have any disagreement with the government on this point.

Your second point was on the definition of an adverse reaction. There is, in the food and drug regulations, a definition of serious adverse drug reaction. I have that in my notes. The definition I gave is what I would call the ideal definition. I did not make this up myself; I got it from Dr. Ed Napke, who designed the first adverse reporting system in Canada. It included everything—devices, drugs, poison. So this is his recommendation that I'm passing along.

The first is that the drug, including its inactive ingredients, or the "incipients", as they're often called, itself causes no therapeutic benefit, or no diagnostic benefit, no prophylactic benefit—no effect at all—or no injury, not just an injury that isn't known to be a side effect. So if bleeding ulcers are expected and people start having bleeding ulcers, that should also be reported. You're deemed to have assumed the risk, but I think most people in their heart don't believe they're going to get the side effect. It will be someone else, not them, who will be among the 10% who get the side effect.

Finally, with regard to the medical device regulations, I actually did prepare for that in case the question came up. These are even worse than for drugs. There's mandatory reporting only if there's death or serious deterioration of health. And that's only inside Canada. If these devices are causing death outside Canada, there's no obligation to report unless someone has started taking corrective action. If the industry is not correcting it, and no one else is aware of it or no one has taken steps, there is no obligation to even report deaths from medical devices outside Canada; it's only inside Canada.

Mrs. Patricia Davidson: Thank you.

Dr. Morgan, I would like to ask you a couple of questions. From your perspective, what is working well within the post-market surveillance system? What should we be focusing on for improvement? Perhaps you can start with that one.

Dr. Steve Morgan: Thanks.

I'm a fan of the line of appreciative inquiry: begin with what you do well and build on that. I think there are a few things. An example would be Isis, a Toronto institute where they're doing excellent evaluation or pharmaco-vigilance work by choosing drugs or drug categories that seem to have a potential risk or a potential benefit that needs to be measured or better determined in the real world environment.

I think we have research centres that are doing excellent work of that nature. I think we are developing databases in Canada. British Columbia has some of the best in the world. I think other provinces are on board in expanding their ability to collect and link data that would be necessary for this kind of research. When Quebec and Ontario are fully developed in that area, it will create the world's largest database for monitoring the safety and effectiveness of medicines.

I also think we've done a lot of work about how to prioritize, how to consult, how to conceive of using our interprovincial network of centres and researchers and policy-makers to create, if you will, a laboratory in Canada. We have a very culturally diverse population, which means that we can actually do research on the effect of medicines on specific populations. We also have effectively 13 different schemes for what's reimbursed and what's not. That creates a natural laboratory to determine what works and what doesn't in terms of policy. It also helps to possibly determine which drugs are effective and which are not, based on differential availability in Canada.

So a few things are done well, as are many more, I'm sure. I think we're off to a good start. What we don't have is this coordinating mechanism and an infrastructure, if you will, to make sure this is done in a way that's deliberate, planned, and sustained, as is necessary to really inform regulatory practice as well as, frankly, a provincial reimbursement policy, which could well be informed by this kind of evidence.

● (1205)

Mrs. Patricia Davidson: There are a lot of different players that take part in the surveillance of health products, and we've heard from a lot of different areas about who should be doing the reporting and who shouldn't and the different roles that different people can play.

What areas do you think Health Canada should be focusing on, what would be the areas that other players could focus on, and who would those other players be?

Dr. Steve Morgan: I think the other players would be provinces that, at the current time, are effectively data stewards as it relates to administrative data records around pharmaceutical use and other health care services. They're going to be a key player in terms of ongoing, active post-market surveillance and what is sometimes referred to as data mining.

Key initiatives to be taken I think are an investment in personnel and infrastructure necessary to engage in this. I think it is also necessary to have a secretariat or advisory council that can actually set priorities and ensure that the research being done is in fact of value to the regulatory frame and these other partners.

The Chair: Thank you, Dr. Morgan.

Dr. Bennett, go ahead.

Hon. Carolyn Bennett (St. Paul's, Lib.): The first thing I'd like is just a clarification from Dr. Morgan about his idea of progressive licence, because I think mine was different. I guess I thought if we were calling for a progressive licence, it meant that what is now a final licence would only be temporary until it had real world experience. So any drug would be on some sort of real world probation.

I didn't see the progressive licence as being something that hurried things up. I thought it was a matter that we would wait and see what happened out in the real world before you get your final papers.

Maybe what I will do is ask the three questions and then you can take whatever time is left.

On the $21 billion, 2% piece—I guess dreaming in Technicolor—what do you think we could do with $500 million if we were going to invest that in addition to what is actually in the process now?

I guess certainly Dr. Laupacis' real world safety network would obviously be a dream come true of part of this, and I want to know whether you see this as part of a separate health protection agency, like the FDA, where it's very clear that its responsibility is for quality and effectiveness, not this murky thing we have right now at Health Canada. Then this network would be like what we now have with the public health network, where all the chief public health officers come together to plan and plot and deal with the safety of the public health.

I guess the third little question was, in B.C.'s PharmaNet right now—in terms of how far behind we are on electronic health records—does the fact that you've got at least the drugs there mean the pharmacists are able to call everybody on Prepulsid and tell them to go and see their doctors if there is a recall?

Those were my three little....

Dr. Steve Morgan: Very quickly, the notion of progressive licensing, which you have articulated—which is to maintain the status quo in terms of pre-market regulation but add a notion that a licence is deemed temporary—is, in my view, the ideal notion of a progressive licence.

According to the front page of today's paper, however, the progressive licensing seems to be pitched as a mechanism for Canadians to get more rapid access to “breakthrough” drugs. I haven't seen the legislation, but if that's the purpose of progressive licensing, it sounds like more rapid access is tantamount to lowering the bar.

There was a fascinating paper recently published in *The New England Journal of Medicine*, I believe it was, suggesting that deadlines in regulatory policy can be harmful to the public health.

Hon. Carolyn Bennett: But in terms of sorting out that little piece, if a drug has been internationally approved—it's in the EU, Japan's got it, everything—is there a process by which stakeholders, patient groups, everybody, could fast-track that drug, based on international evidence, so that we could actually focus on the post-market piece in terms of real world life in Canada? I think Dr. Laupacis, or both of you, had said you want to do it in all jurisdictions.

● (1210)

Dr. Steve Morgan: I think maybe I'll leave this one to Andreas.

Dr. Andreas Laupacis: First of all, around the progressive licensing, I interpreted it the same way that Steven did. So Health Canada might make a drug for cancer available to patients where, before, we might have required studies that showed a benefit in decreasing the risk of death with the cancer, and now it would be approved on the basis of showing a shrinkage of the tumour on an x-ray, for example.

If that's the case, then you can amalgamate all the data you want from around the world, but if you don't have the data that looks at the hard clinical outcome, you're not going to have the ultimate answer you want.

I'm sorry, what was the second part of that question?

Hon. Carolyn Bennett: In terms of the $21 billion, the 2%, if we had $500 million to invest in the dream system, would it be an agency? How would we do that? Would it incorporate your network? How would that be?

Dr. Andreas Laupacis: We were thinking about the network not as taking over the legislative mandate of Health Canada but as an independent and fairly nimble....

I appeared before this committee a while ago as a former chair of the Canadian Expert Drug Advisory Committee, and frankly, one of the reasons I didn't sit for another term was my frustration with getting anything moving that required all 13 provinces and territories and the federal government to agree upon something. So I think you'd need to have a group that's independent but well connected with the policy-makers.

If it were up to me, I would be funding some randomized trials of head-to-head comparisons of the like of Trasylol that I described, which I think would markedly increase the quality of information.

And I'm not sure I'd do what you suggest, which is actually mandate that there has to be post-marketing surveillance for absolutely every single drug that's applied there or that's initially funded. If it's another beta blocker or something, do we really need to do that?

In my view, we don't want to reach the situation where we're doing every study just because the study could be done, because I do worry sometimes that the amount of information we get out there might be so overwhelming that we'll throw out the baby with the bathwater because we can't detect and focus on the things we really need to focus on.

The Chair: I'm sorry, I'm going to have to interrupt. Thank you, Dr. Laupacis.

Mr. Brown.

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

Mr. Morgan, you mentioned something that I found interesting before, about using electronics in, I think you said, New Zealand and Australia to have better real time access when prescribing drugs.

I found that interesting, because previously, when we had the CMA at this committee, one of the things they mentioned was that the real time access to information was an issue. There were some other members, some doctors, who receive updates from fax or mail, who don't get to them as quickly as they could.

Do you have any information on the type of mechanism they use in New Zealand, to have that as a hand-held device like a BlackBerry that a doctor could log onto? Do you have any idea of what the costs associated with such a step would be?

Dr. Steve Morgan: The costs I don't, but I'll give you a Canadian example of an innovative system for bringing electronic prescribing assistance devices into the hands of physicians.

It's from Montreal. Dr. Robyn Tamblyn, at McGill University, runs a project called the Medical Office of the 21st Century, otherwise nicknamed MOXXI. This is a project in which they've enlisted physicians and pharmacists into a system where, at the point of clinical encounter—that is, when the doctor is seeing the patient—they have a BlackBerry-like device, or a Palm Pilot-like device, that provides them with menu-driven information not only about the drugs they are selecting in that encounter for the patient, but also about the drugs that were prescribed by them and other doctors to that patient and whether the patient filled those prescriptions, because that can be an important part of dialogue, to say, “Well, why not fill this?”

So I would encourage this committee perhaps to invite Dr. Tamblyn to speak before you. The results from the Canadian trials of these devices are astounding. The ability with which they have been able to improve quick prescribing is quite impressive.

● (1215)

Mr. Patrick Brown: Are those devices used anywhere?

The Chair: Dr. Morgan, Dr. Tamblyn is coming to the committee next week.

Dr. Steve Morgan: Fantastic. I would direct those questions to her. It's a particularly impressive Canadian success story.

Mr. Patrick Brown: That will be interesting.

In terms of other international examples, do you have any other information you could share with us about where Canada could look for information?

Dr. Steve Morgan: Canada could look south of the border, for instance, to the veterans administration in the United States. The VA runs an electronic system for tracking and monitoring prescription use and for helping physicians make prescribing choices. So do many of the major managed health organizations in the United States. Group Health Cooperative in Seattle has a very well-developed system that is available both to prescribers and to patients, interestingly, so they can see more of their own prescription records.

In the United Kingdom they've invested considerably in electronic health records and electronic prescribing as well, and it is a system to look at. They, like other jurisdictions, have run into some challenges, because it's not inexpensive, and it's a process in which you have to build the trust of the professionals so that they understand that there is, if you will, something in it for them when they engage in electronic prescribing.

As these things roll out.... Group Health Cooperative in Seattle has done a study of this, and they've found that the practitioners don't want to go without it. Take the device away from them and they begin to complain.

Mr. Patrick Brown: I have a question for Andreas.

In your response to Ms. Bennett, you were saying you don't necessarily have to have mandatory reporting in every case. I think you're touching on that a little bit. Could you expand a little bit more on where that line would be, in terms of making it effective?

Dr. Andreas Laupacis: In terms of physicians reporting adverse events, I think you'd want to encourage physicians to do that for all drugs that they think there's an issue with.

My point was around the use of some of these administrative databases, as Steven described, which would allow us to kind of data mine to look for adverse events for every single drug that's approved. Sometimes if you look, you're going to find stuff that looks like it's there, but it may not actually be accurate.

And there's a cost, in terms of both personnel and the cost of doing all these things. So my sense is that if there's a new drug in a class, if there's anything from the initial studies that suggests there's a concern, if someone reports an adverse report, one would want to look at those drugs with the administrative data.

If it were another of a kind, a new statin, as Steven said, to lower cholesterol, and I had a limited budget and time, I'm not sure I'd spend my time looking at that drug. You have to make some kinds of reasonable decisions, it seems to me.

The Chair: Thank you, Dr. Laupacis.

We'll now go to Madam Thaï Thi Lac.

[*Translation*]

Mrs. Ève-Mary Thaï Thi Lac (Saint-Hyacinthe—Bagot, BQ): I want to thank the witnesses for coming here this morning.

My first question is directed to all of you. Today our population is aging. In recent years, the health care system has been under-funded, a situation that has resulted in many accessibility problems. Lack of accessibility to physicians has led people to self-diagnose and self-medicate. Furthermore, the over-the-counter drug market has been growing in the past several years.

In your opinion, is it acceptable that current drug advertising practices can impact people in terms of the treatment they require? When I must use an OTC drug, I always consult with a pharmacist before making a choice. However, not everyone does as I do. Advertising practices can have a major influence on consumers.

I would like to hear your views on this subject.

[*English*]

Dr. Andreas Laupacis: I'm not sure I'm going to be able to answer the question particularly satisfactorily. The number of over-the-counter drugs that are available is relatively small, and I think there is some potential harm. With some of the drugs for arthritis, for example, for acute pain, I think some patients are self-medicating. My own personal bias as a physician is that it isn't a huge issue.

Many patients are on alternative medicines or natural therapies, and I think that's an area where we actually don't know (a) their effectiveness, (b) their safety and what ingredients are there, and (c) how they interact with conventional medicine. So I think that's an area to focus on.

But I would share your concern with the lack of accessibility to family physicians and, in people with chronic diseases like diabetes, to appropriate management. We've talked a lot here about the excess use of medications and their side effects, but I think patients are also being harmed if they don't have access to drugs that have been clearly shown to be effective.

● (1220)

Dr. Steve Morgan: I appreciate your bringing up the question about access because it is an important issue as we discuss prescription drugs. Canada shares the distinction with the United States of being one of the only developed countries not to have universal pharmaceutical insurance coverage. So Canadians in fact face greater financial barriers to filling prescriptions than our comparable populations in many other countries, except for the United States.

I think this is an important issue because it may in fact lead some people to use over-the-counter remedies or other mechanisms that may be less rigorously assessed, or, at least as I think you're asking, that may be below the radar, and this is an important issue. One of the things I think the federal government might do in this domain is to ensure that we are adequately conducting surveys and collecting information about the population's use of these over-the-counter medicines and about their use of natural and homeopathic treatments.

That I think could be done through expanding, for instance, the Canadian community health survey, run by Statistics Canada, or through other mechanisms. So there are possibilities for bringing that information into this research realm so we can better understand it.

Mr. Patrick Orr: I won't be able to comment on the over-the-counter products because I have no expertise in that, but I do want to compliment you on the question itself because it shows that the whole medical system has to be treated as a system in a holistic way. So if you have people with no access to physicians, they might be trying to self-prescribe or self-treat.

I saw in the bus shelter on my walk here this morning someone sewing themselves up; the OMA had an ad about this.

If we want to solve the problem, if people are taking drugs and having adverse events and they have no physician to tell it to, how do we deal with that? Or how do we bring people into the system rather than have them do underground medicine? That's all I can say to people.

The Chair: You only have 10 seconds left.

[*Translation*]

Mrs. Ève-Mary Thaï Thi Lac: Do I have time for one last question?

[*English*]

The Chair: We're running out of time. We have just a few seconds left.

[*Translation*]

Mrs. Ève-Mary Thaï Thi Lac: The briefing notes prepared by the Library of Parliament for the committee contain a section on Health Canada drug notices and warnings. Health Canada has issued warnings about three drugs. I was astounded to read this, because I use one of these drugs and as a consumer, I was unaware that any warning had been issued. Even after the warning had been issued, my doctor renewed my prescription.

Is there not a simple way of advising consumers when they go to the pharmacy that a warning has been issued about a certain drug? We know that...

[*English*]

The Chair: Very briefly now, please.

[*Translation*]

Mrs. Ève-Mary Thaï Thi Lac: When the automobile industry announces a recall or issues a warning, consumers are notified. I would like to be informed in this case as well.

[*English*]

The Chair: I'll go to the next person.

Mr. Fletcher.

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

Today we have talked a lot about post-market surveillance of the consumption of drugs. I want to take a bit of a different angle. Today the *Canadian Medical Association Journal* released a study described as the first to document a wide range of unintended health consequences from a major drug warning.

It describes how Health Canada issued a warning on a variety of antidepressants for children, and as a result, there was a 10% decrease to visits to doctors but a 25% increase in the suicide rate. I read that first in the *Winnipeg Free Press* this morning. I'm looking at the *Leader Post* from Regina.

Could you comment on the unintended consequences? If you're too cautious, you could have unintended consequences the other way, by denying people the drugs they would need. If you deny the drugs or reduce the availability of drugs that people may need, that would be an unintended consequence in itself.

● (1225)

Mr. Patrick Orr: Thank you.

I'm not aware of the study, but I'm aware of the original problem with the drug. I sympathize with the issue. If you alarm people, they'll swing in an opposite direction, and they may do things that are adverse to their health interests.

In my view, the problem is a lack of trust in the system. When the public hears there's this great drug, the advertising hypes it, and then they tell you there are all these unintended consequences; people lose faith in the approval process and the drug company representations. So it's partly an expectation of the public. They're told there's faster access to miracle drugs and so on, but then they get disappointed and might swing in the opposite direction.

We need public awareness that drugs are quite imperfect and they cause lots of problems.

Mr. Steven Fletcher: But this is the problem for government—coming up with a balance.

This is the first study of its kind. I'm concerned. The government is trying to do this progressive licensing to allow people to have access, and we'll keep an eye on the negative consequences and so on, but if we don't do that, there could be a lot more people potentially adversely affected, but it would be a lot more difficult to figure out.

The Chair: Dr. Laupacis, I think you wanted to comment on the other question. Would you like to speak on this as well?

Dr. Andreas Laupacis: Yes. I don't know the details of this study, but I think it's a perfect example of how one needs to balance the benefits and harms of medications in a rational way.

To address your question about whether there are any other downsides to some of the post-marketing surveillance, the fact of the matter is that analyzing these databases that Steven and I have talked about is relatively cheap, because they exist. It's not like a random trial where you have to randomize hundreds of patients.

We need to be careful. There is a tendency, for example, for the pharmaceutical industry to want to mine these databases until they find the result that makes their drug look terrific, publish that, and not tell you that they did 25 studies before they found the one they really wanted. Similarly, some people who might have an axe to grind with the pharmaceutical industry might search these databases 25 times and only report the one that shows harm.

I think it is absolutely crucial that we have a network of these researchers, and that we not make any major decisions such as pulling a drug off the market on the basis of one of these post-marketing studies, but rather on consistent and reproducible evidence from different jurisdictions.

The Chair: Thank you, Doctor.

Ms. Wasylycia-Leis is next. She'll be here momentarily.

We'll go to Mr. Tilson.

Mr. David Tilson: Thank you, Madam Chair.

I have a question for Mr. Orr. You indicated that you've represented people in class action lawsuits. Did I hear you say that?

● (1230)

Mr. Patrick Orr: Yes, that's correct.

Mr. David Tilson: This may contradict a little of what you said, but my understanding is that there is no obligation on health professionals—nurses, doctors, pharmacists, people in hospitals—to report, as you described, the serious problems. I may have misinterpreted what you said. It is my understanding that there is an obligation on the pharmaceutical companies to report serious issues—serious complaints.

If someone gets something as a result of taking a drug, they don't know what's serious and what's not. I don't even know if I know what serious problems are, although I've asked the question of a number of witnesses.

We're probably down to three minutes by this time, but can you give us a short summary of the case law with respect to the liability of professionals who do not have an obligation to make reports to Health Canada, if any?

Mr. Patrick Orr: It's a difficult question for me to answer. It's not an area of my particular expertise.

If you're speaking of the responsibility of physicians to a patient and not industry or Health Canada, my understanding is that their obligation is to take reasonable care to protect the health of their patients. That standard is judged by what's normal in the profession. Reporting by them to industry or Health Canada, I think, is not necessarily part of their standard of care.

Mr. David Tilson: Well, I guess, then, getting to the point, they prescribe something, and it turns out that maybe they shouldn't have, so the patient comes and says, "What in the world is going on here?" and the doc tries to protect himself or herself by saying something.... Well, they may be liable.

I guess I'm getting to the issue of reporting, the obligation to report. Someone has indicated here—at least I thought so, and maybe it was you—that there is no obligation to report, and I don't think there is with these people. But my goodness, if a doc prescribes something and it turns out that there's a serious problem, he'd better report. And if he doesn't, I would suspect he's liable.

Mr. Patrick Orr: That I would perhaps defer to a physician and their code of conduct.

I would speak to mandatory reporting from industry, because there is at least some obligation on industry to report now, although I believe it's only in a very serious event. But I believe the physician should inform the patient that there might be a problem with this drug and deal with it, and they should probably have to report to their professional association, and if it's aware of this drug causing problems, they should report to Health Canada as well.

Mr. David Tilson: Yes. Well, I guess we'll have to watch what's going on.

You made some comments about adverse reactions. Am I to understand you to have said that what are now serious adverse reactions need to be reported? Are you saying that, really, all adverse reactions should be reported?

Mr. Patrick Orr: Yes.

Mr. David Tilson: I'd like others to comment on that.

Dr. Andreas Laupacis: As a physician, if I prescribe a drug thinner like Warfarin, which has a clear risk of major bleeding, and I tell my patient that's the risk and we agree that he or she wants to take the risk and then the patient has a bleed, to my knowledge I don't have an obligation to report it. I have an obligation to discuss it with the patient, and I'll feel terrible that it happened, but that's a well-known side-effect of the drug. Frankly, reporting it to Health Canada, with 30 million people taking drugs, would just paralyze the system.

The Chair: The time is over now, Dr. Laupacis.

Madam Wasylycia-Leis, you have five minutes.

Ms. Judy Wasylycia-Leis: Thank you, Madam Chair, and thank you for your indulgence, since I had to slip out of the room.

I want to try to get back to the essential ingredients of any kind of proper post-market surveillance system. One we've talked about is progressive licensing, as long as it doesn't reduce or move away from any attempt to follow a precautionary principle at the front end. I just want to check that this is what you're saying, and what it means, when the ADM comes to our committee and says they want to implement a lifestyle approach to regulating health products that shifts the focus from a pre-market review to that one that continuously assesses a product's risks and benefits. Is that not a problem?

Secondly, related to that, I know we have to talk about risks and benefits and that there are some drugs that come on the market that have some safety problems but it might be better than dying, etc. Don't we have now an "exceptional circumstances" drug release program to do just that? Why do we need to be less stringent at the front end and put more Canadians at risk in order to accomplish something that's already on the books now?

That's the first question. I'll try to fit in some more if there's time.

● (1235)

Dr. Andreas Laupacis: I guess my short answer would be that I would have preferred wording, not being a lawyer, saying that the post-marketing surveillance would "augment" the information from the initial randomized trials, rather than, as I think you said, "replace", or whatever.

Ms. Judy Wasylycia-Leis: It was to "shift the focus from".

Dr. Andreas Laupacis: "Shift the focus", yes.

Dr. Steve Morgan: I would just reiterate that progressive licensing makes sense if it is to add to the existing rigour that is in pre-market. And you are right: I think Canada does have mechanisms in place to expedite access to medicines for people in dire circumstances.

Ms. Judy Wasylycia-Leis: Do you agree, Patrick?

I'll have another question, then.

Mr. Patrick Orr: Yes. In my view, progressive licensing means reducing the bar.

Ms. Judy Wasylycia-Leis: Okay.

There are two other things we've heard from others about what makes a good post-market surveillance system. One is that we must make sure that Health Canada is completely transparent about the drug approval process. That means trying to find a way to convince Health Canada to put everything on a website about drug approvals and non-approvals.

What do you think of that? I think you've hinted at it already.

The second is establishing an independent board to evaluate prescription drug safety.

Thirdly, there's an issue we haven't touched on much yet: doing everything we can to speak against and stop direct-to-consumer advertising of drugs.

On those three issues, what do you think?

Dr. Andreas Laupacis: Those strike me as reasonable. Also, I would not forget the provinces and physicians as important targets of post-marketing surveillance. In other words, Health Canada has a very blunt instrument, which is taking the drug off the market or not. As a physician, I would benefit a great deal from this kind of post-marketing surveillance because it would help me decide which kinds of patients...and it'll help me to better understand the risks and benefits in the real world.

Ms. Judy Wasylycia-Leis: What you're saying is that the provinces should be integrated into a coordinated national approach across the country.

Dr. Andreas Laupacis: I'm saying that the information from the post-marketing surveillance will be as useful, if not more useful, to the provinces, the practising doctors, and the patients who have much more subtle things to do in their life than saying the drug can or cannot be licensed.

Ms. Judy Wasylycia-Leis: Okay.

Steve.

Dr. Steve Morgan: Perhaps what one needs to do is take the pressure off Health Canada by actually introducing legislation that requires a new degree of transparency with respect to clinical trials that are used to approve or not approve medicines. Right now the onus and the blame seem to lie with the bureaucrats and executives who run the system. Maybe the solution is to take that pressure off them and actually pass some sort of transparency legislation around drug safety.

Ms. Judy Wasylycia-Leis: Patrick.

Mr. Patrick Orr: I agree with that last comment.

Also, an independent board for approvals could be a good idea. There's nothing wrong with a department doing it as long as the department acts independently and in the best interests, perhaps as legislatively required.

Your last question was on direct consumer advertising. I think that's terrible. It's supposed to be prohibited in Canada, but it's not really enforced, and the industry is trying to get around it.

Health Canada is at least trying to protect the standards we have now, but I believe most drug companies are trying to go directly to the consumer to avoid all the necessary approvals and so on.

Ms. Judy Wasylycia-Leis: There is a section in Bill C-51 on clinical trials, which I would like you to look at. It's on pages 19 and 20. It would be helpful to have your written comments on that, along with the other request we made to you today.

● (1240)

The Chair: I think, Judy, due to the time element, we're going to have to ask for those comments in writing. If you submit them to the clerk, we'll ensure that those comments will be distributed.

Could we now have Mr. Temelkovski?

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

Thank you to the presenters.

Mr. Orr, you mentioned that you worked on legislation in several jurisdictions. Are there any models from these jurisdictions that we might learn from?

Mr. Patrick Orr: No, I have not drafted medical device...this is only in the federal sphere in Canada, and I have not done anything in that sphere. Health Canada has not asked me to draft any of its legislation in this area.

There are other jurisdictions. We'd have to look outside of Canada to the United States or Europe. Unfortunately, the United States is not a particularly good model, because that's where many industries are located. I think Canada was a leader in this area but is no longer. Decades have gone by.

Unfortunately, I believe that globally the protection of the public has been reduced. International harmonization means a race to the bottom and lowering the standards. Canada has done that to make it easier to allow drugs on the market.

Mr. Lui Temelkovski: Thank you.

We've heard from other physicians that they are reluctant to fill out reports on adverse reactions. The reason is that they do not receive any material back. It seems to be a one-way street. Do you share that view? Also, what carrots can we use to have physicians and other stakeholders be active in reporting adverse reactions?

Dr. Andreas Laupacis: I personally don't share it. If I were reporting an adverse reaction, I hope I would be doing it out of altruism. The fact that I wouldn't immediately get a response back wouldn't bother me.

I think there are two issues.

To use the example of Vioxx, which everybody now accepts increases the risk of heart attacks, I've had a lot of patients on Vioxx. I'm sure some of my patients on Vioxx had a heart attack, but I never put the two together until the studies were done. A lot of elderly people have heart attacks. When that happens, you don't think about it. I think that's a great example.

If someone had a really weird reaction shortly after starting a drug, most doctors would say maybe the two were connected. But for someone having a heart attack six months after starting Vioxx, it wouldn't have occurred to me. I think it highlights the problems of sort of spontaneous adverse reporting and why you need to look at some of these databases.

Those would be my two comments.

Dr. Steve Morgan: I'd echo that. One of the main issues here is that ADR reporting is one signal. It's a challenge sometimes to detect those rare occurrences and connect the dots. It's the reason why post-market surveillance and post-market drug safety and effectiveness have to be monitored and evaluated by using a variety of tools, not the least of which is ADR reporting, but also administrative data analyses, and running brand-new trials and other mechanisms.

Mr. Lui Temelkovski: What role do you see for pharmaco-surveillance centres of excellence in Canada?

Dr. Andreas Laupacis: I see those centres being linked to the variety of stakeholders we've talked about—the federal government, the provinces, physicians, and patients—identifying areas of research priority. They would do that highly policy-relevant research and feed that information directly back to Health Canada, the provinces, and the policy-makers so they can use that in their policy-making. That's what I see.

Dr. Steve Morgan: I see there also being an advantage in having regional centres of excellence. I think we've thrown the idea out there of having three to five centres in the country. Getting closer to the practitioners—those people who are prescribing and dispensing medicines—is important because it builds relationships so the information can be more readily translated into new practices, let alone regulatory policies.

So there's some value in having a network of centres rather than just a single, more isolated centre in the country.

● (1245)

Mr. Lui Temelkovski: Thank you very much.

The Chair: I want to thank all the witnesses for coming today and giving your insightful comments on the record. We take very seriously all the things you tell us, so taking your time and effort has meant a lot to us.

[*Proceedings continue in camera*]

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