House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 023 • 2nd SESSION • 39th PARLIAMENT

EVIDENCE

Tuesday, April 15, 2008

Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1110)

[*English*]

The Vice-Chair (Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.)): I call the meeting to order.

Pursuant to Standing Order 108(2), we are continuing our study on post-market surveillance of pharmaceutical products.

Today we have with us Alan Cassels, a pharmaceutical policy researcher, School of Health Information Sciences, University of Victoria; Mary Wiktorowicz, chair and associate professor, School of Health Policy and Management, York University; and have Robyn Tamblyn, science director, McGill Clinical and Health Informatics, Department of Medicine, McGill University.

We will start with ten-minute opening remarks from each presenter, and then we will go into our question and answer session.

I thank you for coming here and bringing all of your good information. We will start with Mr. Cassels.

Mr. Alan Cassels (Pharmaceutical Policy Researcher, School of Health Information Sciences, University of Victoria): Thank you very much for having me here. I'm surprised there's no snow here. Usually when I come to Ottawa, I like to gloat about how difficult it is back in Victoria, where we're wading through the cherry blossoms and the daffodils.

My name is Alan Cassels. When I told my family last week that I was coming to Ottawa, my 11-year-old daughter, a budding environmentalist, said to me, “Dad, are you going to be increasing greenhouse gases to travel all the way to Ottawa for a ten-minute speech?” I had to explain to her that every day in our country people are being harmed or die because they are taking perfectly legal prescribed drugs. I told her that I didn't want her or her brother, or anyone, for that matter, to die because they or their doctors didn't learn of the potential dangers of prescription drugs. I told her the story of Terence Young, who lost his own daughter when she took a drug they thought would help her. So my daughter said to me, “Okay, Dad, you can go to Ottawa.”

I've been doing drug policy research in British Columbia for 14 years. My research at the University of Victoria is funded by the Canadian taxpayer, mostly through grants from the Canadian Institutes of Health Research and the Ministry of Health. I've never held any stocks or shares in pharmaceutical companies, nor have I ever done any work for the pharmaceutical industry. I mention this specifically because I think it's important. As a researcher, I like to base my assertions on data, and my reading of the data tells me that most of the time, when patient groups—many of those groups, by the way, do vital and important work—have ties to the pharmaceutical industry, they will push for policies to improve the profits of the companies that fund them.

My reading of the data also tells me that the people you've heard from before who demand better transparency of drug information, better regulation, more careful safety screening of drugs, and better warnings are not receiving funding by corporations whose interests are in profits. Those who have gone before me, specifically Michelle Brille-Edwards, Terence Young, and those from the Canadian Women's Health Network, have made some very good suggestions. I support those suggestions, and I hope this committee acts on them.

I also want to tell you that I went to school not too far from here, in Kingston. I went to the Royal Military College of Canada. As an officer in the Canadian Forces, I was a parachutist, a military diver, and a ship's watch-keeping officer. I have two United Nations missions under my belt. I've faced the business end of an AK-47 assault rifle. I've faced minefields in Cambodia, and other sorts of near-death experiences on the high seas. I have two medals for my peacekeeping and one medal for 12 years of service in the Canadian Forces.

I only mention my military experience for one reason. It's because I've come to understand fear and how it tends to motivate people. Let me explain.

This drug that I hold up right now is the most prescribed drug in the history of the world. It's a drug to lower cholesterol, called atorvastatin. It also goes by the trade name Lipitor. Globally, the manufacturer sold $14 billion worth of this drug last year, and in Canada about 14 million scrips for atorvastatin were written for Canadians. In total, more than 20 million prescriptions for cholesterol-lowering drugs, or statins, get consumed in Canada every year, at a cost of over $1.5 billion. That's an awful lot of money for one class of drugs.

Let me tell you three things about high cholesterol.

First of all, high cholesterol is not a disease. It is a risk factor for a disease, but it is treated as a disease in and of itself.

Secondly, taking a drug to lower your cholesterol may save your life. If you are a man and have had a heart attack, it can help prevent another one. The benefit of the drug in these high-risk men is about 3%, which is to say that even in high-risk men, over 90% of the men who swallow these drugs every day for five years will see no benefit in terms of living longer. There's evidence that the drug will not provide any benefits for women, and these drugs provide no benefit for the elderly.

The third thing I want to tell you is that taking a drug to lower your cholesterol could kill you. I don't want to be dramatic about this, because many people who take these drugs don't have any problem with them, but some people who do will experience terrible, severe, and sometimes intolerable adverse effects. The most well-known adverse effect is a disease called rhabdomyolysis. It's a muscle-weakening disease that can cause kidney failure and death.

● (1115)

Cerivastatin, a drug that went under the name Baycol, was very, very good at lowering cholesterol, but it also killed people. It was removed from the Canadian market on August 8, 2001.

Five years after Baycol went off the market, Health Canada issued a public advisory about the risks of rhabdomyolysis. That was on July 12, 2006. Did Canadian doctors read the warning? Did they even see it? Did consumers become concerned and stop taking their statin drugs? Not the way I read it; Canadians swallowed 22 million scrips for statins last year, and the number has risen steadily over the last decade.

Yesterday I searched the Canada Vigilance online database and found 1,173 adverse reports for this drug, atorvastatin. How many people are actually being hurt by this and other statins? The simple answer is that we don't know. Those 1,173 reports could represent between 1% and 10% of people injured by atorvastatin, which means to say that there could be between 11,000 and 111,000 Canadians injured by that one drug alone. There are seven statin drugs on the market in Canada right now.

The pharmaceutical industry spokespeople will tell you that they should be involved in the education of consumers about drugs, but let me show you how they choose to educate consumers. This “toe tag” ad appeared in many magazines and major newspapers across Canada. This one came from the *National Post* of February 20, 2004. It shows a toe tag hanging off a corpse with the headline, “What would you rather have, a cholesterol test or a final exam?” Here's another example, from *Maclean's* magazine, of the same ad.

These ads are probably the most egregious example of disease-mongering that this country has ever seen. The ads, which ran in both France and Canada, were the subject of a letter from the World Health Organization to the medical journal *The Lancet*, complaining that this kind of advertising is undoubtedly driving the inappropriate use of cholesterol-lowering drugs around the world.

How many of the 22 millions scrips for statins in Canada this year are prescribed for men at high risk? Probably three-quarters of those drugs are taken by women, the elderly, and low-risk men who would see no benefit.

The point I want to make is that in Canada we don't control the advertising and promotion of diseases, we don't control the definitions of disease, and we don't provide adequate impartial health or drug information to Canadians or to our physicians. We allow conflicted experts to sit on committees that decide the definitions of disease, and we allow our physicians to be educated by the pharmaceutical industry. This is an industry that spends in excess of $3 billion a year marketing their products directly to Canadian physicians.

So where does the poor patient end up in all of this? In my estimation, Canadians are naked in the pharmaceutical marketplace.

My recommendations for post-market surveillance revolve around stopping bad and misleading information from getting to patients and physicians, and ensuring that we have adequate data before drugs are released in the wider population. I have four recommendations.

First, I think we need a policy on disease-mongering. We need to maintain our current ban on the direct-to-consumer advertising of pharmaceuticals, but we need to go a bit further than that. We actually need more strict control of the advertising of diseases. I call it “disease-mongering” and the industry calls it “disease awareness”.

One place to start is to ask Health Canada some hard questions: What is your policy around disease-mongering? Can you collect data to see if disease-mongering is driving the inappropriate use of pharmaceuticals? What research into disease-mongering have you commissioned? What other steps is Health Canada taking to control it? Instead of trying to deal with patients who may be dying from prescription drugs, how can we stop people from taking drugs they don't need in the first place?

Secondly, we need better information for patients. After all, it's the patients who put drugs like this in their mouths every day. There's a dire need for Canadians to receive approved and regulated information about diseases and drugs provided by an independent, objective source that's free from profit-driven industries.

The Government of Canada recently showed its interest in objective consumer health information by killing funding for the Canadian Health Network, one source of quality, publicly funded information on the Internet. In terms of medical treatments, the Cochrane Database of Systematic Reviews is one of the best sources of independent research behind common health treatment.

● (1120)

A site licence for the Cochrane database, which the Canadian government currently won't fund, would cost about $500,000 per year, so that all Canadians—and not just people like me who work at universities—could access these reviews.

Other groups, like the Common Drug Review and the Canadian Agency for Drugs and Technologies in Health, need our full support and stable, long-term public funding.

The third thing is that we need better objective information and education for physicians. It's not just the patients who need independent information. It's time we recognize that leaving the education of our physicians to the pharmaceutical industry has some downsides. We need better education on prescribing, education that comes from an objective source, preferably one with public funding.

Australia has a national organization called the National Prescribing Service that does probably one of the best jobs in the world of providing physicians with useful, up-to-date, and unbiased information about drugs. Why can't we replicate that here on a national level and with input from the provinces? It would make a great first step in moving towards a national pharmacare plan in Canada.

The last thing is a point about progressive licensing. My suggestion would be that we should learn about drug safety from looking at how other industries operate. I personally think that post-market surveillance needs to be done and it needs to be done better. But to me, it's largely a sad, after-the-fact proposition. We have to do post-market surveillance because we do all the pre-market stuff so poorly.

Could you imagine another industry, say the nuclear industry or the airline industry, where we allow the manufacturer to rely on post-market surveillance for the safety of their airplanes or their nuclear plants? No one would accept the proposition of having the job of the regulator be to count the bodies afterwards and then decide if this is a good technology to expose to a wider population. We would never accept allowing the airline manufacturers to use people as test subjects in terms of the safety and effectiveness of its planes. We demand the nuclear and airline industries to take a zero-risk approach to their products, so why do we accept a lesser standard for products that people consume every day?

In terms of progressive licensing—and this is connected to Bill C-51—I have no idea where this will lead. But I'm left with one question about these current attempts to “modernize” the regulatory environment around drugs. How would a more modern drug licensing regime prevent another Vioxx, another Propulsid—the drug that killed Vanessa Young—or otherwise stop the thousands of Canadians who may be suffering adverse effects of cholesterol-lowering drugs?

Thank you.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Mr. Cassels.

Now we'll move to Dr. Mary Wiktorowicz.

Dr. Mary Wiktorowicz (Chair and Associate Professor, School of Health Policy and Management, York University): I thank the committee for inviting me here today to engage in this dialogue.

Let me begin by saying that although pharmaceuticals are assessed for safety and efficacy at the pre-market stage, current pre-market evaluation is really recognized as incomplete. While the strength of randomized clinical trials, which is the primary evidence on which drugs are approved to be on the market, is the determination of short-term efficacy, safety is often unresolved within the limited controlled context of these pre-market randomized control trials. Their small size and short duration don't allow them to detect late-onset or less frequent adverse drug reactions. Patients with comorbid diseases are frequently excluded from such trials, and pregnant women and children. So pre-market randomized controlled trials really have limited generalizability. At the same time, these pre-market trials are essential to establish efficacy from an initial assessment perspective for safety before widespread population exposure. So we can think of pre-market randomized trials as necessary but woefully insufficient.

Canada's lack of systematic monitoring of marketed drugs means that adverse drug reactions are often not evident until years after a drug is on the market. As a result, many drugs with unacceptable harm-benefit ratios remain on the market for prolonged periods of time, thereby leaving Canadians exposed to unanticipated risks.

As representatives from the FDA noted in a publication—I believe it was *The New England Journal of Medicine*—the immense biological subtlety of human pharmaceuticals often cannot practically or adequately be detected in formal clinical studies. In the conclusion of that particular article they advised against taking a new medicine in the first two years in which it's marketed. I think that's a huge statement.

Researchers who have taken a look at the effect of adverse drug reactions have found that they are between the fourth and sixth leading cause of death in the U.S., contributing to more than 100,000 deaths and 1.5 million hospitalizations yearly. Since we have basically the same drugs in the Canadian market as in the U.S., we can extrapolate that in Canada the figure would be about 10,000 deaths annually due to adverse effects, or about 150,000 hospitalizations yearly. That means our current passive system of adverse event reporting—we do have a system in place, and it's after the fact—captures less than 5% of all of these adverse drug reactions. We're really only capturing the tip of the iceberg and not the whole picture.

The medicine digoxin offers a very good example. While the FDA received only 82 reports of adverse drug reactions annually, a post-market study that involved data-mining of hospital records found that it was associated with over 200,000 hospitalizations in seven years. So there were 82 reports from patients through their doctors, but 200,000 by taking a look at hospital records and seeing what hospitalizations were linked to that particular drug.

I find it very counterintuitive that just as a new drug enters the market and its use increases exponentially, its effects and patterns of use are no longer actively monitored. This is an oversight that could be ameliorated through a system of post-market surveillance.

I would like to share some insights with you from a comparative analysis that colleagues and I have done on how the U.S., Britain, France, New Zealand, Australia, Norway, and the European Medicines Agency approach pharmacosurveillance. I'm going to highlight the role that research networks can play, and how the knowledge they produce can be used by drug regulators to inform their regulatory decisions.

In these countries, two main approaches are used to look at the safety and efficacy of drugs after they're in the market. The first involves risk management plans. How these risk management plans work is that when a drug sponsor, a manufacturer, is about to have a product approved for the market, they negotiate the terms of the marketing and how they will assess risk on the market. The second involves developing a national network of research centres that can be commissioned or can submit proposals to conduct independent research. That could include observational studies that incorporate electronic health care databases.

● (1125)

Let me begin with the risk management plans. These currently are used by the European Medicines Agency, EMEA, in which the regulator requests drug sponsors to develop and implement a risk management plan to monitor each new drug's safety once it's on the market.

What we found is that the EMEA's risk management plans really lack transparency. What we can find about the plans is just a very brief summary on the Internet. More seriously, though, they don't involve the systematic approach to developing a study protocol. Instead, these protocols are developed on a case-by-case, ad hoc basis and they often don't entail any rigorous scientific method.

For example, they can involve developing a registry of patients who are taking a particular medication without any control group. The importance of having a control group is so you can monitor patients, but how will you know their level of adverse effects is higher than that of someone who is not taking it if you're just observing them? So you really need a control group, and that would be a far more rigorous approach. Alternatively, they can involve educational initiatives to physicians for patients, but as we all know, when industry is involved in promoting their medications, you don't necessarily get the full story on the risks and the benefits.

If we were to go that route in Canada, risk management plans should be informed by a process of risk assessment that precedes risk management, in which the magnitude of the harm is modelled by incorporating all pre-market data that's been generated and anticipating population exposure levels, so a far more rigorous approach. Unless Health Canada adopts a more systematic, rigorous approach to the risk management plans than the European Medicines Agency, including defined standards for research methods similar to the pre-market phase one, two, and three trials, and sets conditions regarding blinded assessments, alternate methods should be used to assess post-market safety and effectiveness. Such a study is developed and conducted by independent pharmaco-epidemiologic research centres.

In our study, we concluded the EMEA risk management plans are of limited value, even though they lend the impression of systematic surveillance. Just as a point of emphasis, they put something in place so the public is under the impression their drugs are being monitored, when often what is being done is not an effective approach to surveillance at all.

Reliance on drug company studies can also be imprudent, given the inherent conflict of interest, even when safeguards are incorporated. For example, in France, where they take a look at some of these risk management plans, they have an oversight committee to ensure industry adopts a scientific approach, but even those studies have weaknesses, because in the end, industry analyzes the data and interprets what they mean.

Getting industry to conduct these studies through the marketing process is an inadequate process. But at the same time, industry could still fund the research, as in the case of Italy, in which manufacturers contribute the equivalent of about 5% of their promotional budget to the Italian Medicines Agency to fund post-market research by university and clinical researchers. It would also allow studies of an entire drug class. And what I mean by that is often a pharmaceutical company will study a particular drug, and even though there are competing drugs on the market that address the same problem, they refuse to do a head-to-head comparison of one with another. So as a drug benefit plan, you're trying to decide which drugs to fund; as a physician you're trying to decide which drug to prescribe to your patient. If you don't have information on how the benefits of one drug compared to another are in an overall study framework, it's very difficult to know which one to choose.

Pharmaceutical companies have also been shown to report their research selectively, by either publishing studies with only positive results or finding a way to convey a positive outcome for those that have negative results. Recently, Turner et al. reported in 2008 that it would appear that 94% of trials for selective serotonin re-uptake inhibitors, SSRIs, were positive. In contrast, they conducted a separate analysis of the entire range of trial data submitted to the FDA and found that only half of those studies showed positive results. So again, industry can find a way to lend a positive approach even to studies that are negative.

● (1130)

These issues highlight the need for public oversight to ensure post-market studies address key research questions, that they are designed to produce valid results, and that they are reported accurately.

Minimizing study duplication is also likely to foster continued cooperation from doctors. A lot of these studies—these randomized controlled trials—involve working with physicians who prescribe the medication to their patients and then monitor how the patients are doing. If you're going to do separate little studies all over the place.... They found in France, where they're starting to do some of these observational studies, that physicians are starting to say they've done enough and that their patients are tired. The physicians just won't engage.

So if you're going to develop some kind of a strategy, you should use your resources, including physician time and patient time, in the best possible way.

The second approach to post-market surveillance that I would like to propose is an independent research network that creates a framework to allow oversight of study design, ensures validity, facilitates independence from commercial interests, and makes comparisons of drugs in the same class possible. Research would also be publicly available instead of being proprietary. Often we have a problem where the drug benefit plans in the provinces would like more information on the safety and efficacy of a particular product and Health Canada tells them it can't share that information because it's proprietary. So there's a problem with transparency in terms of getting the information to the drug plans and ultimately the physicians and patients who will be using that information. If we have research that's conducted in a public forum, then we will allow that data to be publicly accessible.

Several national regulators commission post-market studies from several centres. The U.S. has a research network called DEcIDE. New Zealand has a national pharmaco-vigilance centre. And in the European Union they are developing an EU-wide approach to commission international pharmaco-surveillance research from over 60 research centres across Europe. This is in the early stages of development.

Canada is well positioned to realize the potential for a national network of research centres. Our provincial health care plans have electronic health care records and pharmacy dispensing records that could be used to conduct observational research that would augment an activity already underway in Canada.

But a commitment and a will to support cooperation among provincial health care systems and Health Canada is essential to develop the infrastructure needed for pharmaco-vigilance and public health impact studies.

● (1135)

The Vice-Chair (Mr. Lui Temelkovski): If you could wrap it up, please, I would appreciate it.

Dr. Mary Wiktorowicz: Sure.

So while national approaches are emerging, international coordination could also hold the potential to extend global resources and to address this policy challenge.

In order to be a global participant in this kind of international cooperation, it's in Canada's interest to explore the models of research networks that are emerging internationally and to develop an approach that optimizes our innovative research capacity to address public health concerns.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Dr. Wiktorowicz.

We'll continue with Dr. Robyn Tamblyn, from McGill University.

Dr. Robyn Tamblyn (Scientific Director, Clinical and Health Informatics Research, Department of Medicine, McGill University): Thank you very much.

I'm delighted to be here, and I'm really delighted that our government is taking this initiative to examine progressive licensing and pharmaco-surveillance. I think it is such a low-hanging fruit, a sure-win proposition, that I'm just thrilled to be here.

I don't think I need to convince anybody here that this is a good thing to do, because drugs are like surgery—they can cure you and they can kill you. Surgeons get controlled by hospitals. They have to have privileges. They do morbidity-mortality reviews, that kind of thing. But drugs...well, drugs get to be prescribed by everybody. Actually, there are 50,000 physicians—25,000 of them are primary care physicians—and they prescribe basically 80% of all the drugs. So there aren't the same natural controls here. So I think pharmaco-surveillance is definitely going to be an exciting initiative and one that's surely overdue.

Not only that, but what I would like to talk to you about is how you're going to do it, because we have some unique advantages in Canada that no one else in the world has. That has to do with the fact that we have a socialized health care system, that we actually provide services—come one, come all—for every Canadian. By virtue of having to administer a system like that across the board, we are like a series of health maintenance organizations—one in each province—that provide complete population coverage. If you get bankrupted by your health, you're not tossed out and no longer visible to the system. We count every one and all.

I would say that the only other countries that have the kinds of administrative systems that keep track of what everybody is doing are Denmark and Iceland. Those are the only other groups that have that kind of deep, detailed information on what's happening.

Now, what's exciting about this is that you're doing that anyway, so you can leverage that in. In fact, Canadian researchers have leveraged that. They have become leaders in the world in terms of how they actually assess the risks and benefits of drugs, using these detailed health services records that are maintained in each and every province.

What Mary referred to, and what Dr. Laupacis referred to earlier, is a proposition that was put together by a group of regulators, drug benefit managers, and researchers to say, “We can build a network across this country that will allow the timely observation and surveillance of who is using the drugs, how much they are using, and what the outcome is of that information on a daily basis”. That's possible, on a daily basis, with the information we have.

We haven't leveraged this opportunity. The data sit there in large servers and computers. Why don't we do that? I really don't know.

We've put together a proposition, during the first time that people such as myself have collaborated in such a broad scale with everyone, to actually link together these data repositories in each and every province. We will be the envy of the world.

Iceland actually sold its data. Saskatchewan has actually, I would say, more or less sold its data to the industry to have this kind of information.

We can have this information as Canadians. A proposition has been put forward; it's on the Health Canada website. I think we should be excited about that as Canadians, because I think we could become world leaders. This will be the place where people should come to actually assess the risks and benefits of drugs, using this data.

The second investment that we have made, which is also exciting and actually provides us with the complementary tools, is essentially the investment that we've started to make in the electronic health record in Canada. Some $1.4 billion has been put aside for upgrading the electronic health record in Canada. As part of that investment, about $34 million was put aside to create a repository of all drugs, all people, in each and every province. That information flows when the drug is dispensed into a repository. All electronic prescriptions would flow to those repositories.

Why is that information critical? The information is critical because in fact by putting in place essentially electronic prescribing, computerized, drug management systems for each and every provider in this country, we have certain huge assets. Number one, you have information on each drug dispensed for every Canadian. Number two, you have the potential to say, if you make this a mandatory requirement, “Why was that drug prescribed?” So you begin to be able to monitor why drugs are being prescribed. Are they being prescribed for people on whom the drug was tested or not?

● (1140)

I think that is a critical question, because in various studies I looked at, anywhere between 30% and 90% of some drugs are being used in people who have not been tested. That is a risk management thing we can actually address by essentially collecting that information through what we've already invested, which is an electronic drug repository, drug management system.

The second thing that is important about that is that should we achieve the objective of widespread adoption that is present, let's say, in Denmark, the United Kingdom, and Scotland, we would see almost 100% of physicians using electronic health records to deliver care. The advantage we have is that this would mean that with the repositories that have been built through Canada Health Infoway, that information on all labs, all diagnostic images, and all drugs would be available, irrespective of who prescribed them.

That means that for the first time ever a physician will have a complete drug history when they're prescribing. What drugs have you taken? What drugs have been stopped because you've had adverse effects from them or you've been allergic to them? What drugs should not be prescribed because there is another drug that another physician has prescribed that you don't remember, because you're calling it the purple pill? It actually is a magenta colour and is long and oblong, and there are 400 pills that shape and size that you'll have to figure out on your own, thank you very much.

We have this opportunity of leveraging this incredible investment that has been made to build these repositories, to say to each and every physician in this country and each and every pharmacist in this country that they shouldn't be prescribing or dispensing unless they have information on all of the drugs a person is currently taking or has taken in their medical history. We will have that information. That is the most exciting piece.

The second piece is when problems are identified. As Mary and Alan have pointed out, when problems are identified a piece of information is sent, essentially, to a physician to join the other 900 pieces of information that arrive daily on his or her desktop. That piece of information, instead of being sent by paper, essentially could be linked to the drug in the repository, and every time that drug is prescribed an alert fires to say that drug has just killed 300 people. An advisory is on this drug: “For this treatment, the indication that is this is not a good thing to do.”

This is possible in this day and age. We've already made this investment, and what it requires now is really a strategic decision about how we are actually going to leverage our investment so that we have the tools to actually do daily day-to-day monitoring for all Canadians through these two very exciting opportunities, where we've already made deep investments in Canada.

On a final note, while information technology is probably going to revolutionize the way we deliver care, one area where I'd have to say we're weak—in fact, we're at the bottom of the pile—is that we've built fabulous state-of-the-art resources where information resides and can be identified very effectively and accurately as being your information, but we have not addressed what other countries have done in terms of how to get the practitioners in our country to use that information.

We have some strategic decisions we need to make in order to actually have all 50,000 physicians, 150,000 nurses, and 60,000 pharmacists in this country using that information, so that we no longer have deaths because someone actually got three anti-coagulants because they didn't recall taking the first two, or an excessive dose of digoxin, which happened because two physicians were prescribing for them. This happens every day in our country, and it simply is not necessary.

Once we have this information, it can be a mandatory requirement that all stop orders on drugs get attached for a reason. Adverse effects and treatment ineffectiveness account for 66% of all stop orders in this country. Secondly, you can actually make it a mandatory field to have treatment indications so you know when people are getting drugs that are what I call the grand social experiment: they're getting drugs for which they weren't tested.

● (1145)

I would beg you to consider some of the strategic policies that were put in place in other countries, which have succeeded in achieving an almost 100% uptake of computerized prescribing electronic health records: a policy for paying for quality; support for training and transformation of practitioners in adopting electronic health records; and most importantly, the delivery of value-added benefits to those practitioners who work daily against all odds with a very archaic information system and need these value-added tools at the bedside.

Thank you very much.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Dr. Tamblyn.

Now we will continue with questions and answers, for seven minutes per questioner. We'll start with Madam Kadis.

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

Welcome to all our guests today for our continuing study of post-market surveillance.

Recently, as you probably heard, there was an announcement by the government, a consumer protection announcement. We do need a balance between protecting patients against harm and helping them to get life-saving drugs and medication as quickly as possible.

It would seem, based on the government's latest announcement, that we are going to rely more than ever on post-market surveillance, because the government appears to be fast-tracking drug approvals. Do you believe that this change is effective and will be beneficial for Canadians' health and well-being, or will this put patients and Canadians at more risk? We have heard some testimony concerned about risks. Will potentially harmful drugs, such as Vioxx, be prescribed to patients more quickly through that process? Also, they are proposing that hospitals and industry will, on a mandatory basis, report adverse drug reactions, but pharmacists or doctors will not.

I am interested in hearing your comments on the new announcement—if you think it will actually enhance the safety, health, and well-being of Canadians, or if there are concerns associated with that.

Here we are trying to strengthen, I believe, post-market surveillance and doing a very in-depth study. By the same token, I am concerned—and others have raised the issue—that we will have less rigorous standards for safety at the earlier stage of the pre-market trials.

Dr. Mary Wiktorowicz: I think the post-market aspect of this bill is important, because you need that capacity to be able to do the research, as my colleagues and I have pointed out. But when it comes to the pre-market portion of the bill, I get afraid. For example, as you mentioned with Vioxx, would Vioxx have been prevented if we lowered the standard for getting it on the market quicker? I don't think so. I think you're going to have more Vioxxes. Certainly we'll have post-market surveillance in place, but how that post-market surveillance will be done is very ambiguous right now. We don't know, actually.

It is great to set up a system of post-market surveillance, but right now there are a lot of questions as to how it will be done and the role that industry will play. So I would not lower the pre-market framework of phase one, two, and three trials. My sense is that there are consumer groups who step forward and say that patients want drugs at an earlier time, but I still think that there's a problem with getting them. They are not aware of the risks that are also associated with these drugs. The risk-benefit profile of these drugs is not completely clear. You're taking a much greater risk than I think is warranted.

Health Canada does take a longer time than other countries in reviewing drugs currently, and I think that is one of the pushes, but the fact is we have had a lower record of withdrawals than the United States and other countries have had. One of the reasons is that drugs are on the market in the U.S. and we get to see them, and when there's a Vioxx out there, we're not even going to approve it. We're not letting it out of the gate. Actually, I think that's a good thing. I'd rather be protected than take risks.

If you're talking about drugs that address life-threatening conditions like AIDS and cancer, we have a fast-track system already within Health Canada that allows those drugs to get on the market after only phase two trials, as far as I know. The drug companies are responsible for doing the post-market studies after the fact.

The problem with leaving industry in charge of the phase four trials, which are the post-market trials, is that there is no obligation for them to complete those trials. In the U.S. they found that less than half of the post-market studies that industry had agreed to conduct were ever begun. There is recent legislation, from the fall of 2007, that will give the FDA the power to compel industry to complete those phase four studies, but even in our current system, where we allow some fast-tracking, those studies are not necessarily completed, and there are no repercussions for industry; they just go on and market.

Just to summarize, I think I would not reduce the standards in the pre-market phase. We definitely need greater surveillance out there. So I laud the post-market portion of the bill, but the pre-market portion I would amend to strengthen it and not lower the standards.

● (1150)

Dr. Robyn Tamblyn: There are two issues there. One is what you ideally want if you are going to pay for a drug. If you're a drug benefits manager in a province, you want to know whether it's worth it for you to pay for the drug. You essentially want to know whether that drug is going to reduce your costs—your hospitalization costs, your emergency-visit costs, your treatment costs.

Unfortunately, many of the phase three trials have end points that don't allow that to be determined. For example, this is the reason British Columbia is running its own trial for the Alzheimer's drugs: to determine whether or not they delay nursing home admission, because that's their big cost, right? Whether the person does one point better on Mini-Mental status isn't really that helpful, because that's not really the end point that you care about.

That's one issue, and Canada can't really take that step alone. We're 2% of the drug market, so do we want to take that step alone? I think we should take it internationally and say that in phase three pre-market standards, we want to have disease end points and not intermediate proxy end points. That means the trials are going to be longer. They're going to be more expensive, and—let's not kid ourselves—the cost of those trials will be downloaded onto the price of the drug, so I think there's not just a simple answer to your question.

The second issue is that at the moment you cannot control off-label prescribing. Once a drug is out in the market, you can't say, “Don't prescribe it for kids and don't prescribe it for people who are taking more than three other drugs”, which is the group on which it was tested. The group on which it was tested is not necessarily the group in which the drug is going to be used.

That can again be a pre-market requirement. You can say you want the target population on which you test that drug to be just like the target population in which you're going to use that drug. A granny who is on 16 drugs and who has three other health problems is going to be pretty unpredictable, as you can imagine, and you're going to need a very large sample of people on which to test that new drug.

The third thing you really care about is whether this drug is any better than the other drugs on the market. That's what Mary was talking about. If you want to know that, you make it a pre-regulatory requirement that the trials get compared to current comparators on the market for treating the same treatment indication. Again, can Canada go it alone? I doubt it. I think we are a small portion of the drug market and I think that there would have to be an international agreement to do so.

In the end, you're still going to have some unknowns—the rare events that are going to happen, the off-label prescribing that's going to happen—and there you're going to get some unexpected outcomes for which you have to have a post-market surveillance. There's no other way of doing it.

So either you get international collaboration on getting the right end points before notice of compliance or you actually put in a robust system after the fact to say that it's conditional upon your meeting the following requirements in the first two years the drug is on the market, and you've got that information system behind you to say you can actually measure it—not on the people that you select to be in your study, but on each and every person who's on that drug.

● (1155)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Madam Kadis.

Please go ahead, Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Thank you for your presentations, they are very informative and provide additional information on drug monitoring.

Mr. Cassels, you've addressed a number of interesting points. If others would like to answer my question, it might broaden the debate on prescription drug advertising. I don't really watch any advertising, because I do not take any specific drugs; I do not suffer from any illness requiring me to take drugs.

Let's take the example of Viagra. We get the impression that it is a harmless drug. However, in actual fact that is not the case. How could we amend the legislation to ban this type of advertising? You said there is no control over the definition of the illness and that marketing is inadequate. The individuals concerned who have erectile difficulties want to solve those problems. But this type of advertising is completely false when it comes to the effect the drug may have on health and the adverse events which could occur.

Mr. Alan Cassels: I'm sorry, but my military college French is not very good.

Ms. Christiane Gagnon: You may answer in English: I can hear the interpretation.

Mr. Alan Cassels: Then I will speak in English.

[*English*]

I have a couple of points.

When you said that some drugs are harmless and some drugs are dangerous, I think I would want to correct that to say that there's no such thing as a dangerous drug.

[*Translation*]

Ms. Christiane Gagnon: No, I referred to advertising.

[*English*]

Mr. Alan Cassels: Sure, there's the advertising, but the drugs themselves are inert in the sense that it's how they're used that influences whether they're being used wisely and safely or incorrectly and dangerously.

In terms of drug advertising, such as erectile dysfunction drugs and so on, what some manufacturers would say is that advertising the drugs provides information to consumers. The style of ad we see in the U.S. gives you information about the drug and provides some information about the side effects. That's a regime that's currently not allowed in Canada.

I forget the second part of your question.

[*Translation*]

Ms. Christiane Gagnon: How should we amend the legislation to ban all advertising? There is a great deal of drug advertising. We always get the impression when watching it, that the drugs are harmless and that they will solve our problems. Patients are seen to be happy. Earlier on you referred to cholesterol. I took the example of Viagra.

What should we do to prevent this type of advertising from appearing in newspapers or various advertising-driven media?

[*English*]

Mr. Alan Cassels: If I understand the question correctly, it is about what can be done so that these advertisements don't pop up in other media.

Currently we receive a lot of direct-to-consumer advertising of pharmaceuticals from the United States in magazines and so on. We have the ability to block ads from the U.S. if we want to. It seems that Health Canada or the regulatory environment is not that interested in blocking ads from the U.S. But we could do it if we wanted to.

The ad I referred to was not a drug ad; it was a disease ad. It's an advertisement for a condition. That's, I think, what companies are using in Canada to drive people to their doctors to seek the drug they're selling. In fact, they're selling the condition, not necessarily the drug.

The main point I was trying to make is whether we can at least try to curb the excesses of disease advertising. Of the many people who see those ads, perhaps some might go to their doctors and open up a conversation, and that might be a good thing. But many of those people are going to get worried. You're going to create a certain psychological anxiety in the population, and you'll drive those people to their doctors to ask for tests and drugs that they probably don't need.

I hope that answers your question.

● (1200)

[*Translation*]

Ms. Christiane Gagnon: Yes, you did answer my question. I was wondering what type of advertising or whom your comments were targeted to. You mentioned disease ads creating anxiety and a need for people to visit their health care professional to ask for a drug. It remains drug advertising. The end result of this process would be to get a drug.

Dr. Mary Wiktorowicz: I think the problem is, as Mr. Cassels mentioned, that the advertising comes from the United States. In Canada, companies are not allowed to do this. If you want to draw up new legislation, perhaps you should prohibit Canadian broadcasters carrying American programs from broadcasting such advertising here, in Canada. It is true that it is prohibited in Canada.

Ms. Christiane Gagnon: There still is advertising, though. They do circumvent the law. It is one way of circumventing the law.

Dr. Mary Wiktorowicz: Yes, that is what Alan showed. Companies are not allowed to associate a product to a condition, but they manage to do certain things without associating the drugs to the condition.

Ms. Christiane Gagnon: On a completely different note, according to public health authorities, Gardasil is a vaccine for young girls from 9 to 15. It was announced in Quebec and everyone seems happy.

However, I was reading that young girls have died abroad, if I'm not mistaken; eight have died in the United States and in Germany. When we hear that, we can't help but wonder whether the drug might not be at fault. I realize we must be cautious. We cannot withdraw all drugs from the market. However, there have been eight deaths, and in Canada we continue to carry out massive inoculations. Apparently, this vaccine would counter the HPV strains responsible for cervical cancer.

Why do we continue to do this? Why isn't there a moratorium, why do we not stop this massive inoculation?

As a consumer, if I had a 9- or 11-year-old girl, I would be very concerned. Very few people know about this. We do because we sit on the Standing Committee on Health, we read more and try to be informed.

What type of information should there be? Does this raise a flag? A red flag? Nine-year-old girls cannot be concerned about developing cervical cancer 10 years from now. However, it is up to parents to make these decisions.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): A short answer from one of the witnesses, please.

Dr. Robyn Tamblyn: I think it was an exciting new opportunity to prevent cervical cancer in kids, young girls. I think we lost sight a little bit of the fact that we didn't have a post-vaccine surveillance program in place. I think that was a terrible shame, that in fact the medication was funded without any follow-up, especially in young girls. Who knows what's going to happen?

Fortunately, vaccines by and large tend to be safe, although we've just been through this whole issue of vaccines and autism, as being a potential trigger for autism, and we really don't know the answer to the question.

The Vice-Chair (Mr. Lui Temelkovski): Thank you.

Madame Wasylycia-Leis.

● (1205)

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

Thanks to all of you for being here. It's a very informative panel.

I want to start with you, Alan Cassels. I've just been skimming through your book, *Selling Sickness*, and you make an observation that I think we've heard supported at other testimony, that the pharmaceutical industry is working very hard behind the scenes to define and design the latest disorders and dysfunctions in order to create and expand markets. You talk about that with the words "disease-mongering".

I know we don't have time to get into that whole issue here today, but I would like you to relate that to what we're dealing with in terms of post-market surveillance and with respect to Bill C-51, which is actually about post-market surveillance, supposedly.

The fact that the drug companies that you refer to have been very supportive of Bill C-51 raises all kinds of alarm bells for me, but I don't want to just be subjective about it. I want to know if in fact there is some legitimacy to the argument we have made that the progressive licensing framework will in effect facilitate speedier approval of drugs into the market, and hence cause more safety concerns down the road, as opposed to being a neutral scheme, as the government claims it is.

Mr. Alan Cassels: It's a very good question. That goes back to Ms. Kadis's point: how interested are we in speed?

I would ask all the committee members to imagine themselves undergoing surgery where someone is taking out a tumour, or a uterus, and so on, and the surgeon is standing in the operating room and has people, bureaucrats, standing behind him and telling him, "Go faster, go faster, you need to do this procedure quicker and quicker." Most people would say that's completely irrational. You want your surgeon to do a proper job. You want him to take his time and be careful.

Why would we expect a different standard when it comes to evaluating or reviewing the safety of drugs? We have the manufacturers and the industry-funded patient groups saying "Faster, faster." So I try to ask, is there any legitimacy to the need for speed? My answer would be, show me the conditions in which we are being slow in approving drugs. Is it in the high cholesterol? Is it cancer treatments?

We already have a number of programs in Canada where people with rare diseases can get pre-market access to drugs under clinical trial conditions. There are already those ways to get speedy drugs if you're facing life-threatening conditions. I can tell you, if I were facing a rare, life-threatening condition, I would want faster access to those treatments too. But they're so rare and so beside the point.

Most drugs are not treating rare and life-threatening conditions; they're treating high cholesterol, high blood pressure, gastroesophageal reflux, and the pain of arthritis—long-term, chronic treatments on which we can afford to take the time to make sure those drugs are causing more benefit than harm.

I hope that answers your question.

Ms. Judy Wasylycia-Leis: I wouldn't be so worried about this notion of progressive licensing if I felt confident that all caution was taken at the pre-market level, yet we keep hearing all kinds of horror stories in terms of the drug approval process.

We know that the licensing framework allows for the industry to basically pay for its drug approvals. We know that there are many drugs like Vioxx out there, and it doesn't seem that the post-marketing surveillance, a big centrepiece of progressive licensing, is going to do much on that front.

The government says nothing's changed, and yet we have a deputy minister or an ADM who comes to the committee and says, "We're implementing a shift in the focus from pre-market to this life cycle approach". And we've got, of course, groups out there—and I think about the Best Medicines Coalition, with which I'm under some criticism for suggesting that it's supported by big drug companies—saying this bill and the progressive licensing system is great because it will get drugs that they want faster to market.

So is it not a worry? And what do we do in terms of our work as a committee to counter that possibility? This question is to all of you.

● (1210)

Dr. Mary Wiktorowicz: I think you're identifying a huge problem. Right now what I'm seeing, especially in the U.S., is that lawsuits are now taking the place of the regulatory role.

If you take a look at, for example, antipsychotic medications, one I'm familiar with is Zyprexa. A very significant side effect is weight gain. Patients put on about ten pounds, and then they get diabetes. Maybe ten pounds is too little. They put on a lot of weight right after going on the drug, and they get diabetes. Diabetes, as you may well know, is very serious. It leads to hardening of the arteries and all of the cardiac conditions and limb and eye problems. It sets you up for lifelong physical degeneration. This is for treating perhaps schizophrenia or perhaps depression. I have even heard of off-label prescribing of these drugs for children.

One of the reasons they say these side effects were not picked up is that the pre-market clinical trials were maybe three months. Maybe they were six months. I don't know what it is in this case. Thousands of patients in Canada and the U.S. now suffer from diabetes as a result of taking Zyprexa. There was a class action lawsuit in the U.S. settled out of court. Patients have now received a lot of money because now they're saddled with diabetes.

If you're telling me that we're not getting the drugs out there fast enough so patients can take them fast enough, I'm saying you're trying to get them up faster so that patients can acquire these illnesses or side effects that are far more deleterious sometimes than the conditions they're trying to treat. If you're telling me that is a better system, I don't see the logic.

Ms. Judy Wasylycia-Leis: It's been hypothesized that in fact it might be, from the drug companies' points of view, cheaper for them to pay off big lawsuits than it is to put the investment in at the front end to make sure that the drugs are safe beyond a reasonable doubt.

Dr. Mary Wiktorowicz: That's right, and you want to put patients' lives in the balance. As Robyn had pointed out earlier, you are experimenting on people. The administrators in the FDA have admitted, in a published journal, that in the first two years they don't recommend taking a new drug because we just don't have the experience.

We do have the systems in place for some of the life-threatening conditions now, and there are certain provisions in the bill that I would support for the post-marketing. I mean, you do need to allow Health Canada to share its information with committees that might be involved in setting up post-market surveillance studies and so on, taking advantage of the electronic databases. We need that post-market component, absolutely.

But on the pre-market, there is a clause in the bill that I noticed. Right now our Food and Drugs Act is very vague, saying simply that the minister will ensure that sufficient studies are conducted to ensure that the drugs are safe and effective, and it's similarly vague in the current proposed legislation.

Maybe we need more detail around that. Maybe we need more detail as to the kinds of studies, that the three phases of clinical trials need to be conducted, except for certain conditions, life-threatening conditions.

As Alan pointed out, it's not the majority of drugs that need to be fast-tracked; it's perhaps those that address the life-threatening conditions.

Ms. Judy Wasylycia-Leis: Do we perhaps...? Oh, sorry, Dr. Tamblyn.

Dr. Robyn Tamblyn: On the speed issue, I just want to say that you're either dragging your feet just to drag your feet because you want other countries to actually try it on their populations first and experiment, or you're going to say that you want to have something in the pre-market trials that will tell us, really, what the benefits and risks are on real diseases, not on intermediate end points. It seems to me that we should be pretty clear about what we really want. I don't think that's an excuse for saying we won't do post-market assessment of the drugs. You have to do post-market assessment of the drugs. I think it's a huge problem that you license it and then say, "Okay, you're good to go, and I don't want to see you again."

The progressive licensing component, to me, was to say that there is a need—there has to be a need—to actually assess this drug, even if you were able to actually get international collaboration to look at end points, such as diseases, and not at intermediate proxies. Even if you could do that, is it still going to be used in populations of people on which it wasn't tested, and will there be rare outcomes that could never be identified in the pre-trial studies? You have to have both, in a sense. I would hope that we don't toss out the idea of progressive licensure just because we're worried that it's going to be fast-tracked.

Ms. Judy Wasylycia-Leis: I just worry that it might be, under this present government, a progressive term that is used to actually make a very bad public move in terms of drug safety. So I'm trying to make sure that we have the right precautions to prevent that in the bill and in this report we'll end up doing.

● (1215)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Madam Wasylycia-Leis.

We'll go on to Mr. Brown.

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

Thank you for the comments so far.

I was actually looking forward to your testimony, Dr. Tamblyn. One of the previous speakers before this committee said that you were an authoritative source on technology and how to bridge the divide in getting knowledge to physicians a lot sooner. So I've been anticipating your comments.

One question I've asked previously, as this committee has heard, is about using mobile devices and how we can use technology better. I started asking that question because the CMA said that real-time access was an issue. When they came before us they said that doctors routinely get updates in the mail or even sometimes electronically. But by the time they get them, they're not as time-sensitive as they should be.

I heard one comment a few weeks ago that they've tried mobile devices—I think it was in New Zealand—and I wanted to get your comments on that. All of us around Parliament walk around with BlackBerries. Could we use that type of vehicle to have that real-time access so it isn't a matter of weeks or months or days to get immediate updates to physicians as they prescribe?

Also, that repository of information you spoke of, would that be something feasible that we could link to on an instant electronic level?

Dr. Robyn Tamblyn: My take on this is that there is a very elegant way of doing this, which is that you connect the warning to the drug at the time it's prescribed. Every drug actually has a unique identifier in Canada. It's nationwide. We're in a delightful situation when it comes to drugs—low-hanging fruit, for sure. Actually, if you link it within the context of an electronic prescribing system, that means you actually set it up so that any time that drug is prescribed, that alert comes up to say that this drug has this warning attached to it. That means that you can actually change that at midnight tonight and it will be online, in real time, for everybody who's prescribing that drug tomorrow.

It's just like the parking meters in Montreal. They change the tariffs overnight from $4 to $6 an hour. I mean, bingo, they're really in good shape. That's what you can do. That's what technology can do. It means that you have to get every physician prescribing electronically, and that's where we have lots of very valuable lessons to learn from Europe, where, effectively, they've accomplished that.

The thing I worry about, if I carry around a portable book, is that it will become like this e-mail nightmare we're in right now. Everybody's e-mailing you, and now it takes your entire day to work through all your e-mail. It would just be another morsel of information arriving on your BlackBerry. It's not integrated—I have ten warnings already on my BlackBerry, but now I'm prescribing to so-and-so, and I'm trying to remember what that warning was. There's a more elegant way of doing this.

Mr. Patrick Brown: It's almost like you need a device so you can just put the patient's name in it and then link into what dangers might exist based on the prescription.

You mentioned that there have been some accomplishments in Europe. Where could we learn about them? Which countries have had successes we could potentially research a bit more?

Dr. Robyn Tamblyn: This is what's interesting about it. What we've done in Canada is we've had a very technology-driven solution, which has put together the vaults of repositories. We're state of the art when it comes to that, but what we haven't dealt with is asking what the user wants. So the countries that basically said okay, what are we going to do here, went from the grassroots up.

Now, it's interesting that in England and Scotland they said the thing that's really inefficient for them is doing all those refills, especially with those older people who are on eight or ten medications. They've got diabetes, they've got hypertension, then they've got COPD, and then they're good to go on twelve medications. That was what was taking them time, and they were doing it wrong. The pharmacist couldn't read it and therefore they called them back. So what they did is they actually made refill medications easier to do, and that's what actually allowed them to integrate electronic prescribing into their system in both Scotland and the United Kingdom.

When it comes to Denmark, they did a different value-added, again growing out of sort of the grassroots experience. The value added in Denmark was to be able to communicate effectively with the specialists, primary care physicians and their patients, and actually to consolidate that. So that's what got people up to delivering care, a part of their care, using computerized platforms, and that's where you integrate these messages. You integrate it right in there at the time you're prescribing.

So this is the message: that you have a value added that is essentially defined by the professionals themselves. They can tell you, and then you deliver that at the front end, through your computerized interface. That's number one. Number two, you have to help them get trained up and ready to go.

When we first tried to do this—and I'll be very short—it was in 1990, and we hooked up 150 primary care physicians to the government's database and said, “Look, you can have access to the information on each and every patient, what the drugs are that they're being prescribed.” Well, they were horrified. They were horrified because they didn't realize all the medications their patients were taking and all the other physicians that were involved in their care. They didn't realize that.

But the other thing that we realized—to our horror—is that they had rudimentary understanding of computers. They would say “Come fix my computer. It's not working.” And you'd arrive, and the computer was all in bits and pieces all over the desk and they'd say, “Well, I was trying to figure out how it worked, so I just took it apart.”

They would have their grandsons come in and help them prescribe for their patients, and actually use the computer, because those are the kids who knew how to do it, right? They would just fiddle with the dials and say, “Grandpa, use this. This is how you have to do it.”

So we learned a lot of lessons from that, and the lesson we continue to learn is that our health professionals are way back in the 1930s and 1940s in terms of the way they do work. In fact, we do not have an industry that's robust here—neither do they really have it in the States—to essentially understand the complexities of care and build solutions that will solve some problems.

We've got huge problems. When it comes to the drug management process, we have huge problems that can kind of be lightly fixed without going deeper in terms of the investment technology, deeper than the heavy investment we've already made to build these repositories, so we can leverage those with now more policies—strategic investments—and not technology investments.

● (1220)

Mr. Patrick Brown: Well, let's hope that 2008 is different from 1990 in terms of compatibility with computers. Governments have sort of thrown money towards the goal of making health records electronic, but the reality is that we're still a fair way away from that.

What challenge would that present, in terms of having this repository of accurate information? Would it at this point be incomplete, or would it still be at a state where it would be extremely beneficial?

Dr. Robyn Tamblyn: The repositories...right now, by and large, the pharmacies are all electronic. They're all computerized. It's good for their business. They do online adjudication of drugs—what am I going to pay for it, yada yada yada. So they're pretty much computerized. So now it's just a matter of saying okay, how are we going to get the physicians computerized? And we don't have a plan.

Mr. Patrick Brown: What could be helpful with the federal government in terms of moving that yardstick forward? What recommendations would you have for us, if we did develop that goal to have this dream?

Dr. Robyn Tamblyn: That's a tough one. I'll just take a few things I think we've learned from other countries.

The one thing that for sure seems to be driving rapid adoption is that you're somehow paying for quality. And then you need to ask, well, where are my diabetics? Have I actually done their annual foot check, ophthalmology check, their biannual glycosylated hemoglobin check? Where are they? And you need a computerized system to find them. Right now, you can't find them very readily without it.

The physicians we have in this fairly large prototype we run tell us, “Can you give me my list of diabetics? Can you give me my list of asthmatics?” So you need a computer to get the work done.

The second thing they did, and you could think of a kazillion creative ways to do this, is they put in place, either through the professional coalitions or through the government itself—so in Denmark, the professional coalitions, in the U.K., the government—deep investment to support the training and transformation of practice. So the computers, the network, the Internet and that kind of thing, paying for my staff to migrate to a new.... That's all on the providers' end. That's their business. They have to do that. So that isn't a solution that's going to work, for sure.

The third thing is this issue of value added. What problems are you trying to solve for me, the practitioner? What we realized is that they have fragmented information, so that's where our repositories will help. They actually want to have decision support, they want to have alerts on the 33,000 drug interactions that are available. They want to have that information. So there are some strategic value-adds, which I've added in my handout. If we build solutions along that line, in collaboration with the professional groups, I think we would be in better shape than we are now.

● (1225)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Dr. Tamblyn.

Now we'll move into our second round. It will be a shorter round in order for us to finish our committee business—three minutes each party.

Mr. Regan.

Hon. Geoff Regan (Halifax West, Lib.): Thank you, Mr. Chair.

I'll be very brief, and then if there's time my colleague Mr. Thibault may have a question.

I want to ask the witnesses about the notion that Health Canada seems to be proposing to do not only what it already does in terms of the pre-market approval of drugs, but also to do the post-market surveillance of drugs. To what degree do you see a conflict of interest in doing that? What problems do you foresee because of it? Do you think this process of post-market surveillance should be at arm's length, and how would you achieve that?

Mr. Cassels is keen to answer.

Mr. Alan Cassels: Yes, it's an easy answer.

I would say, absolutely, they need to be two separate functions. The group that approves and regulates the airline industry is not the same group that goes and inspects the crash sites and looks for the black boxes after they crash. We set that up for a reason, and that reason is very sound. To have one agency doing both activities I think is not the way you want to go. I would agree with what previous speakers in other sessions have said, that the best way to go about it would be to have an independent drug safety agency, funded at arm's length, separate from Health Canada.

The Vice-Chair (Mr. Lui Temelkovski): Mr. Thibault, do you want to ask a question?

Hon. Robert Thibault (West Nova, Lib.): I think Madam....

Dr. Mary Wiktorowicz: Yes, I think the group that does the studies has to be independent. Usually when Health Canada is involved, they work with industry, and the necessary arm's-length independence for the studies is missing.

I think Alan's suggestion is a good one. You need an arm's-length industry, but you also need independent research centres to conduct those studies, to analyze those results. As I mentioned, a researcher recently re-analyzed the data that were submitted to the FDA by drug companies for 12 different SSRIs, anti-depressant drugs, to treat depression, and they found that the results were positive for only half of them, whereas industry found positive results for 95% of them. There's a problem there. Those data are not being analyzed in the right way. So you really need the studies to be independently done.

Just because industry has manufactured those products doesn't mean they should be running those studies. Let the researchers do their work, independent researchers. So you'd need a system of accrediting research centres that they follow the appropriate protocols, that they have the appropriate expertise. Europe is currently going in that direction. They're going to set up a network of 60 research centres. Individual centres will determine whether they meet the accreditation standards, and then they'll determine which centres will conduct which studies.

I think that's a far better way than the risk management plan, which means negotiating with industry as to what will be done, without standards in place, and then millions and millions being spent on research that doesn't really get you to where you want to be anyway. It doesn't produce the results that you really need—those independent, rigorously designed and conducted studies.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

We'll now move on to Mr. Lunney.

Mr. James Lunney (Nanaimo—Alberni, CPC): It's been a fascinating discussion, and now we're down to the three minutes. Time is really limited, so I'm going to fire three questions out here as quickly as I can and hope that I can retrieve three answers.

We're discussing the effects of drugs on adolescents, and surveillance. Somebody mentioned SSRIs. The effect on adolescents can be very dramatically different, as I understand it, from what we expect in adults. Maybe somebody could comment on that.

I believe it was Mary who commented on the fourth to sixth leading cause of death in the U.S., about 100,000, with 1.5 million hospitalizations. In Canada it would be about 10% of those numbers—10,000 and 150,000, respectively. The Ross Baker study—University of Toronto—suggested 24,000 deaths a year in Canada, conservatively. That's just hospital-based. On the difference between the 10,000 and 24,000, are you referring in one instance just to drug-related, inappropriately, or even appropriately?

The third one is coming off Susan Kadis's comment about the new bill, and will it help. The new bill really eliminates the food and drug context of the Food and Drugs Act. It puts natural health products and drugs in the same category. My question really is this. As therapeutic products, should low-cost, low-risk, non-patentable, orthomolecular remedies—vitamins and minerals—be subjected to the same level of pre- and post-market surveillance as pharmaceutical drugs, which are obviously altered from a natural form?

● (1230)

Dr. Mary Wiktorowicz: Let me begin with the point you mentioned about the discrepancy between the 10,000 and the 24,000 of hospitalizations. I raised the 10% just as one-tenth of the U.S. But my figure is a little different from what Ross Baker would suggest, because his figure also combines misprescribing. That means when there are actual errors, when the nurse doesn't deliver the appropriate medication that could easily double the number of problems there. I'm just looking strictly at if you take the drug as prescribed, what might happen.

Mr. James Lunney: Thank you.

Dr. Robyn Tamblyn: Adverse drug-related events were estimated to be about the sixth leading cause of mortality. It's vastly underestimated by chart review studies because you're only picking up the ones you recognize and you're only doing it within the hospital. I think that's a big thing. It's like drugs and surgeries. They cure and they kill, so they're potent things.

Teens.... I have two teenagers. We now know that their brains are different. Drugs aren't tested in teens and drugs aren't tested in kids, by and large. So they are social experiments. That's why I am so supportive of progressive licensing and ongoing pharmaco-surveillance for those reasons alone.

I don't think I remember your last question.

Mr. James Lunney: It was about orthomolecular versus xenobiotic—

Dr. Robyn Tamblyn: Absolutely.

One of the most interesting studies was on L-tryptophan, which was a natural food product. The ingredients it was made with, by one manufacturer, actually produced a very rare condition called eosinophilia-myalgia syndrome. In fact, a Japanese company made that product and a number of people died from that.

So, absolutely, I think that's essential.

Mr. James Lunney: So a broad-spectrum vitamin D, any vitamin, should be put to the same scrutiny?

Dr. Robyn Tamblyn: I think so.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you for your presence here today.

In earlier testimony, we heard that there are very few adverse reactions reported and that the figure varied somewhere between 5 and 10%.

I am simply wondering whether the proposed clause 20.7 in Bill C-51, compelling health establishments to advise the minister of adverse reactions to drugs, may have a positive effect on the fact that few events are reported.

At the end of the day, will this provision make the process more effective and will the drugs that are available on the market have less of a chance of causing adverse reactions?

[*English*]

Dr. Robyn Tamblyn: It's not a good idea, mainly because there will be a false security from thinking you'll get more. You probably will get more, but we've learned something from public health. There are declarable, mandatory reportable diseases, such as tuberculosis, diphtheria, and malaria. There's a list of 16 or so. The problem of under-reporting them is so huge that public health officials have worked out fairly complicated methodological approaches to assess and inflate the under-reported figure. That's number one.

Number two, courtesy of bioterrorism in the United States they're moving to a whole new way of attempting to detect emerging epidemics. It's probably not as good as you might hope it will be. If in a declarable disease like diphtheria we can't get our act together to declare it, just imagine how it's going to be for adverse events for drugs.

I would rather put the investment in something else, like a systematic surveillance system.

● (1235)

Dr. Mary Wiktorowicz: They have found that where they imposed mandatory reporting, even for health professionals like physicians in France, they didn't get any higher rates of reporting of adverse effects. As I said, it might be wasted energy.

Mr. Alan Cassels: The reality is that physicians have information overload. People want them to have electronic devices, and patient records at the press of a button. Putting something on top of that like mandatory reporting, in the experience in other countries, is simply not going to happen. So you need a better way.

[*Translation*]

Mr. Luc Malo: I have a small question for you, Dr. Cassels. You told us early on that cholesterol levels were over-medicated and that you carried out studies which will tend to show that.

Why would it be then that so many drugs continue to be prescribed for a problem which, in your opinion does not exist, or, if it does exist, has few long term effects on health?

[*English*]

Mr. Alan Cassels: First let me clarify that we don't study cholesterol-lowering drugs at the University of Victoria. There have been 14 major studies of the major cholesterol-lowering drugs. Why are they still being used? The answer is complex, but you might want to read the first chapter of my book about cholesterol.

The main thing is that the power of the market is so intense that it overrides anyone who raises concerns, anyone who points out lack of data, and anyone who essentially looks closely at the data and finds that those drugs aren't as effective as the manufacturers say they are.

[*Translation*]

Mr. Luc Malo: Are you saying that physicians are being manipulated?

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Monsieur Malo, I think—

Mr. Alan Cassels: By all means, they're being manipulated.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

Now we'll move on to Mr. Fletcher for a three-minute round.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): I'd like to thank all the members of the panel for what has been a very interesting discussion indeed.

Mr. Cassels, you talked about disease-mongering, and that's an interesting way of putting things. I've looked at the adverts, and there are some credible organizations on the advert you passed around, like the Canadian Diabetes Association and others. So I wonder if you could comment on the relation between what you call disease-mongering and the fact that very credible organizations have put their names on that advert.

To those who discussed the issue of the pharmaceuticals' ability to advertise, I can't get into the specifics of the cases, but there are two cases where the federal government is in court trying to keep the prohibition on advertising of pharmaceutical products. I'll throw that out to Mr. Cassels.

I would also like to hear Robyn's comments on post-market surveillance and the life-cycle approach, because that is really key to the legislation the minister has brought forward.

Mr. Alan Cassels: That's a very good question. So the question is about the logos of the various patient organizations on this ad.

Have you ever heard of Making the Connection? Does anyone know what that is? How about the Canadian Lipid Nurse Network?

Mr. Steven Fletcher: What about the Canadian Diabetes Association, though?

● (1240)

Mr. Alan Cassels: Okay, but let's take those two first. They are what we would call astroturf organizations. There's a clear strategy by the public relations companies working for the manufacturers to create patient groups to give their imprimatur of respectability to this kind of thing.

In terms of the Canadian Diabetes Association, the question I would ask is, how much money is the Canadian Diabetes Association receiving to lend their good name to this kind of advertising? I look at the guidelines produced by that organization and I ask, are these guidelines evidence-based? On some things they are very good; on others, it's as if the guidelines were written by somebody who works for a company selling those drugs.

Mr. Steven Fletcher: I would like to point out that about a year ago there was an organization that came to the committee, I think it was the Best Medicines Coalition, that maybe did not disclose as much as it should have.

I'm running out of time, so could I hear your views on the life-cycle approach to products.

Dr. Robyn Tamblyn: On progressive licensing?.

Mr. Steven Fletcher: No, the life cycle.

Dr. Robyn Tamblyn: The bottom line is that the provinces are paying both for the benefits and the consequences of not doing such a great job at evaluating things. They either do the foot-dragging approach of gee, this is pretty expensive and I don't really know, and I can't control it, and whatever else.... It's preciously important to actually get real-time information on who the drug is being used on and what the experience has been. Quite frankly, we have the capacity, if we keep it at a steady state—and, ideally, grow it a little bit—to actually answer these questions.

For example, one of the most notable studies that looked at how well a drug worked in practice in fact discovered that inhaled corticosteroids actually reduced the risk of asthma death, or near asthma death. That study was done by a group of researchers from McGill—not to be proud of my university or anything, but that group was from McGill—who used Saskatchewan data to try to address a problem that had been identified in Australia. Because we have such unique data here, we could actually answer that question.

It turns out that with one of the drugs that was producing a 55-fold death increase, a fast-acting rescue medication, the problem was essentially that it was very potent. What they discovered serendipitously through this was essentially a drug that is incredibly protective, just as we discovered that Aspirin is incredibly or wonderfully protective as time goes on.

It's these lessons learned that are going to come from ongoing pharmaco-surveillance of medications. It's expensive; we spend a lot of money on it, and increasing amounts of money on it, so we should do it right and actually monitor it, just as surgeons are monitored.

The Vice-Chair (Mr. Lui Temelkovski): Thank you, Dr. Tamblyn.

We'll now go to Madam Wasylycia-Leis.

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

I don't have much time, but I would like to come back to the Bloc's question about direct-to-consumer advertising, as I think it is a problem in terms of both costs to our drug system and problems in terms of drug safety. It's about pushing drugs onto people and accelerating demand.

I believe this present legislation will open the door wider to direct-to-consumer advertising, so I would like to know what you think about it, if you have had a chance to look at it. But if you haven't, could you comment on the fact that the minister says there is no change with respect to DTCA? In other words, the status quo will continue, and all the ads that you've shown today, Alan Cassels, will be permitted and be allowed to multiply, because they don't tie the specific condition to the name of the drug.

Can you comment on the advisability of closing that loophole in the drug regulations and what we should do about any opening of the door on this issue with respect to the broader DTCA matter?

Mr. Alan Cassels: I think that opening the door to DTCA is a very bad idea. You can take the experience in the U.S. with Vioxx, for example, one of the most widely prescribed drugs in the history of the world. The uptake of that drug was huge, and the impact on the population, as we've seen, was deaths in the tens of thousands.

I'm not sure whether the current legislation before the committee is really going to open the door to direct-to-consumer advertising. But if it does, they're going in the exact opposite direction they should be. What we need to be doing is enforcing the current laws that we have. There's good evidence that our laws around direct-to-consumer advertising are not being well enforced. We could actually reduce the effects of advertising from the U.S.

Someone might ask, well, what are you going to do about the Internet? I would say that one of the best things to do is to counter marketing with quality, objective drug information. That's what Canadians expect, and I think that information has to be provided by the public purse.

● (1245)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Madam Wasylycia-Leis.

I'd like to thank the witnesses for your presentations and for answering all the questions. Thank you very much. You may be excused now.

We'll continue with our meeting.

Mr. Thibault, would you like to introduce your motion?

Hon. Robert Thibault: The motion has been circulated.

The principle of the motion is quite simple. And it's not prescriptive; I'm not writing the legislation in this motion. I'm asking the minister to redo the legislation in a way that doesn't target any specific group, but that looks at the risks—where you would have risk from donors because of specific lifestyle issues, not whether you're part of a same-sex group or not.

It's making sure that we protect the supply of organs. With the current regulations, people are refusing to consider potential donation because they are on the list of who should not be donors. The practitioners have the ability to use those organs, with the proper signatures and all that, but the problem is that people will not become donors with those regulations in place.

This seeks to repair that. It's a request to the minister to modify the regulations. Therefore, I would move the motion.

The Vice-Chair (Mr. Lui Temelkovski): Thank you.

Mr. Fletcher.

Mr. Steven Fletcher: Thank you, Mr. Chair. I have several comments about this motion.

First of all, it's wrong; it says things that are simply not true. Nowhere in the regulations, for example, does it exclude gay men from donating organs. The current regulations are based on science; they're only based on science.

I want to reiterate that contrary to what has been reported in certain media, the regulations do not ban homosexual men and others with identified risk factors from donating organs. No Canadian will be prevented from becoming an organ donor based on gender, race, age, or sexual orientation. The primary focus of these regulations is safety, with the recipients in mind.

We have moved a long way since the lessons of the tragic tainted blood scandal, and those lessons must never be forgotten. The prevention of transmission of disease to transplant recipients is the primary focus of these regulations. Sound, scientifically based risk management is at the centre of the regulatory framework, and it's consistent with international standards and best practices.

I'd like to remind you that in 1999 the Standing Committee on Health, in a report entitled "Organ and Tissue Donation and Transplantation: A Canadian Approach", recommended that cells, tissues, and organs—CTOs—safety standards be made mandatory through incorporation into regulations under the Food and Drugs Act.

The CTO regulations came into force on December 7, 2007, following extensive consultations over 11 years with the transplant community and Canadians. That includes most of the time during the previous Liberal regime. During these consultations, not a single comment objecting to the current wording of the applicable risk factors for infectious diseases was received—not a single comment.

The technical context of these regulations is based on standards developed by working groups of independent experts appointed by Health Canada, which included representatives from the transplant community, provincial and territorial governments, transplant recipients, and the ethics community. These standards were first published in 2003, under the previous government.

These regulations enshrine into law the best practices that have been ongoing in Canada in the field of transplantation since the mid-1990s so that transplantation will remain safe for Canadian patients. The same risk criteria are used in the screening of donors in the United States, Europe, and the United Kingdom.

All risk factors in annex E are based strictly on scientific evidence. They are used in assessments that evaluate behaviour and medical circumstances and do not target specific groups. For example, gay men are not singled out, or even referenced—

● (1250)

The Vice-Chair (Mr. Lui Temelkovski): Mr. Fletcher, are you reading your letter to us?

Mr. Steven Fletcher: No. These are just some comments I'd like to share.

The Vice-Chair (Mr. Lui Temelkovski): Where's annex E?

Mr. Steven Fletcher: Annex E is in the regulations or the CTO material. Annex E explains who can and who cannot donate.

The Vice-Chair (Mr. Lui Temelkovski): Could you wrap up, please?

Mr. Steven Fletcher: I would be happy to.

For example, the "men who have had sex with men" category includes men who would not consider themselves homosexual.

If a donor falls into a high-risk category it is a decision between the recipient and his or her physician as to whether a transplant is appropriate. No eligible organs are wasted or discarded.

Testing alone is not adequate to eliminate risk. Testing of potential organ donors is performed at the hospital level and uses less sensitive tests than those used for blood donors.

It is important, Mr. Chair, that I get this in, so please bear with me for another minute.

It is important to note that the Canadian Standards Association is an independent, not-for-profit association that functions as a neutral third party providing a forum for committees of experts to work on standard development. It is one of four organizations accredited by the Government of Canada to develop national standards.

The CSA is responsible for more than 3,000 standards, codes, and information products in the areas of health care, the environment, and public safety. Moreover, Canada is perceived as a regulatory leader in the field of transplantation safety. The WHO has recognized Canada's leadership in this area, and recently Australia has requested permission to use our standards in the development of their regulations.

The CTO regulations are sound. They're based on science and in line with international practices and don't need to be changed. The CSA technical committee is currently reviewing the risk factors contained in the standards to assess whether new scientific data has arisen that would point to a need to adjust the risk factors.

The Minister of Health will report on the results of the review when the work is complete, in about three months' time.

This motion is not necessary. It contains false and misleading information, and the committee should focus on the work that is before it.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

We have a number of other speakers: Mr. Thibault and then Madame Gagnon.

Hon. Robert Thibault: I'll be very brief, because I would hope this comes to a vote today. I would only say that the problem is with annex E, which has exclusionary criteria. Included in the exclusionary criteria are men having sex with men, whether or not it's safe sex, unsafe sex, whether or not it's one man having sex with multiple partners or in a monogamous, safe relationship. So that is the problem.

It is true—and we've heard that here—that transplant physicians can use organs from people who are on the exclusionary list with the proper permissions and all those things. That is fine. The problem arises that because we have these standards, based on CSA annex E, that exclude specific groups, those groups are not signing their cards to become donors. So this reduces the pool of available donors, and that is the problem.

The motion does nothing to reduce the safety. There are safety aspects, but the motion calls on the minister to draft regulations that are based on risk and not on sexual orientation.

One final poin: What we have to ensure is that our regulations will also survive. These regulations as currently stated might not survive the test of law. We saw in the work of the Library of Parliament that it was derogated powers to the second degree, where the law now gives the cabinet the potential to make regulations. Here cabinet again gives CSA the possibility of making recommendations, because it's CSA that does annex E. So cabinet is no longer making regulations, but a third-party organization.

But time is running short. I hope we are able to vote before we leave.

● (1255)

The Vice-Chair (Mr. Lui Temelkovski): Thank you.

Go ahead, Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: It is true that Mr. Fletcher is partly right in referring to regulations and standards. However, we could ask for regulations not to be based on a standard. The standard is restrictive and not respectful of the population as a whole. Reference is made to men having had sexual relations five years before an organ donation. I think that is absolutely unacceptable. Why not mention high-risk behaviour?

For instance, if a woman has had sexual relations with a gay man or bisexual man who engaged in a high-risk behaviour, she may not necessarily be inconvenienced, but she would probably also be high-risk. That would be discriminating against a significant section of the population.

You have to have a moral conscience when you want to donate an organ, for instance. It would be up to individuals, men and women alike, to comply with the conditions required of organ donors. I am in favour of this amendment because this standard sends out the wrong message to society. As you have stated, there are tests that are offered. Tests are done on all organs, and they are very reliable. It was mentioned by scientists who came to see us at the last two meetings.

It is very self-righteous to introduce such an exclusive standard. We maybe voting on this soon; as far as I am concerned, my mind is made up.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

Would you like to comment, Madam Wasylycia-Leis?

Ms. Judy Wasylycia-Leis: Thank you, Mr. Chair.

If I speak just briefly, may I have your assurance that we'll still be able to have the vote before the clock runs out? Will we be able to extend the time briefly?

The Vice-Chair (Mr. Lui Temelkovski): The extension of the meeting is at the will of the committee, but we still have a number of speakers.

Ms. Judy Wasylycia-Leis: Okay.

I want to support the motion. I had also a motion on the books that I do not need to proceed with; it was only there as a way to advance the work of this committee on the two sessions we held with respect to organ donations.

I hear what the parliamentary secretary is saying. While this whole issue may not be about deliberate discrimination, by implication it sends the wrong message for the wrong reasons. We know that annex E of the document is in fact exclusionary, and it is in regulations.

The U.S. model would be a far more appropriate model to follow if Mr. Fletcher is concerned about that being the example. These are guidelines; they are not exclusionary and they are not in the regulations.

I think the motion makes sense in terms of sending appropriate messages to our community and to Canadians everywhere that we want to see people sign their donor cards without restriction, knowing that there is a good process in place. We don't in any way have to practise anything that would appear to be discriminatory by any stretch of the imagination and send the wrong message to the gay community.

● (1300)

The Vice-Chair (Mr. Lui Temelkovski): Go ahead, Mr. Tilson.

Mr. David Tilson (Dufferin—Caledon, CPC): Mr. Chairman, the time ends soon. I can start to speak, but I can tell you that I have another meeting to go to, and I can't consent to going past one o'clock, so I don't know.... It's up to you, Mr. Chairman. I can speak—

The Vice-Chair (Mr. Lui Temelkovski): We could put the vote.

Mr. David Tilson: Well, no, Mr. Chairman, I'm not agreeing to that. I have the floor; I'll speak—for 30 seconds, if I have to. That's what we've got.

I'm just telling you that this is a very serious motion. The Liberals are talking as if this were something brand-new. They started this whole process. Do you think this thing started overnight? These are very serious matters, and I spent a lot of time at the last—

Hon. Robert Thibault: Point of order, Mr. Chairman.

The Vice-Chair (Mr. Lui Temelkovski): Go ahead, Mr. Thibault.

Hon. Robert Thibault: I recognize that this is not going to come to a vote today. Last time, because some members wanted to give it further personal study, I agreed that it could be delayed until today. Today you won't have an opportunity to put it to a vote, but I would request that it be the first item on the agenda at the next regular meeting of the committee.

The Vice-Chair (Mr. Lui Temelkovski): Are you ready to take a vote?

Mr. David Tilson: No. I'm in the middle of speaking, Mr. Chair, and I have a lot to say on this.

Hon. Robert Thibault: The time has gone, so I suggest that it be the first item at the next meeting, because it has to be disposed of. It is a matter for the committee. The government side is not agreeing that we vote on it today, so it will still be the committee's business when the committee meets next time.

The Vice-Chair (Mr. Lui Temelkovski): Monsieur Thibault, on Thursday we have the ten-year plan review meeting, and I think if the committee is willing to use the beginning of that meeting.... Or should it be another meeting, a subsequent meeting?

Hon. Robert Thibault: This is the point I'm raising, or the question of privilege, or whatever. I'm on a point of order.

My item is on the floor.

The Vice-Chair (Mr. Lui Temelkovski): I hear “Let's vote”.

Hon. Robert Thibault: Are you ready to vote? Okay.

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

The Vice-Chair (Mr. Lui Temelkovski): Thank you.

The meeting is adjourned.

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

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

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