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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1110)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good morning, ladies and gentlemen. I would like to welcome you all to the committee this morning.

This morning I want to welcome to our committee Gerald Dal Pan. We're going into a video conference. Can you hear me, Doctor Pan?

Dr. Gerald Dal Pan (Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration): Yes, I can hear you.

The Chair: Good. I want to welcome you to our video conference.

Dr. Gerald Dal Pan: Good morning. It's a pleasure to be with you this morning.

The Chair: We're having trouble hearing you. The sound people are working on it right now.

Gerald, tell us who you are and your role at the U.S. Food and Drug Administration.

Dr. Gerald Dal Pan: I'm Dr. Gerald Dal Pan. I'm a physician and an epidemiologist, and I'm the director of the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration.

The Chair: Great. Welcome to our committee today.

We have Mr. Dal Pan here because we want to hear, on a more international level, how post-market surveillance is being done.

Gerald, would you go ahead and give us your presentation? Thank you.

Dr. Gerald Dal Pan: Good morning, honourable members.

The Office of Surveillance and Epidemiology focuses on monitoring post-marketing safety of human drugs and therapeutic biologics, on the development and evaluation of risk management programs, and on the prevention of medication errors. The monitoring of post-approval safety of the blood supply, vaccines, tissues and other biologic products, medical devices, and dietary supplements is located in other FDA units.

I am pleased and honoured to appear before you today to describe our post-marketing drug safety surveillance system and to answer any questions you may have.

FDA's mission is to ensure that safe and effective new drugs are available as quickly as possible and that drugs already marketed remain safe and of the highest quality. The monitoring and understanding of the safety of drug and therapeutic biologic products is a process that proceeds throughout the product's life cycle, spanning the period prior to first administration to humans, through the entire marketing life of the product.

In each stage of drug development, important drug safety information is obtained. At the time a drug is approved, there is a substantial amount of data regarding its safety profile. In the pre-approval review process, FDA reviews these data, along with data on the product's efficacy, to determine if the potential benefits of the drug exceed the potential risks for its intended use. The risks of a product are presented in a product's approved labelling, a document that can be updated throughout the product's post-marketing life.

Although the pre-approval testing of a drug is very rigorous—and the review of the data is very thorough—there are still some uncertainties about the complete safety profile of a drug when it is brought to market. Even the most extensive pre-market testing cannot anticipate all the potential adverse reactions that might occur. This is because clinical trials include a limited number of patients, a relatively short duration of treatment, relatively narrow patient populations, and often do not include special groups such as the elderly, children, pregnant women, or different ethnicities.

The goal of the post-marketing safety program is to identify adverse events that were not identified prior to approval and to understand better the spectrum of adverse events associated with a drug, including adverse events recognized prior to approval.

A core aspect of the post-marketing drug safety system in the United States is the reporting of adverse events to FDA. In the U.S., suspected adverse events in individual patients are generally identified at the point of care. Patients, physicians, nurses, pharmacists, or anyone else at the point of care who suspects there may be an association between an adverse event and a drug or a therapeutic biologic product can, but is not generally required to, report the adverse event to either the manufacturer or to the FDA.

The public can send reports directly to FDA via the MedWatch program, which was established in 1993 to allow health care providers and consumers to send a report about serious problems that they suspect or associate with any medical product—be it a drug, biologic, or medical device—directly to FDA. Members of the public can also voluntarily report suspected adverse events to a product's manufacturer, which is then subject to regulations regarding the submission of these reports to FDA.

For certain serious adverse events, manufacturers must report them to FDA in an expedited fashion, within 15 days. These requirements vary according to the marketing authorization status of the drug. For other adverse events, manufacturers report on a periodic basis, either quarterly or annually, depending on how long the drug has been on the market.

● (1115)

The adverse event reports that FDA receives from the public and from manufacturers are entered into a database known as the Adverse Event Reporting System, or AERS for short. FDA receives more than 450,000 reports a year. About 94% of them are from manufacturers. The remaining 6% are directly from the public via the MedWatch program. This database currently contains over four million reports of adverse events.

FDA safety evaluators review these individual case safety reports to determine if new safety information needs to be added to the products label. The review of adverse event reports is a complex process and cannot be covered here in detail. The analysis of these reports has been a cornerstone of our post-marketing safety system for over four decades, and will continue to be an important part of our drug safety system. However, the science of drug safety has evolved over the past two decades. New sources of data and other methodological approaches are being developed and implemented to complement the information we obtain from the reports we receive from patients and practitioners.

Today there are available to us certain large databases containing administrative medical data as well as electronic medical records. With increasing staffing and access, we anticipate much greater availability of these resources in the future. These are rich sources of information on the potential side effects of medications. Observational epidemiological studies, which include case control studies and cohort studies, are approaches that can confirm an association between a drug and an adverse event and can also provide a quantitative measure of that association. Observational epidemiological studies are time-consuming and costly. FDA uses them to examine important drug safety questions that cannot be answered with data from spontaneous report systems.

Clinical trials also provide another approach to examining drug safety questions. Many clinical trials are designed primarily to examine a drug's efficacy; nonetheless, they collect important safety information. Clinical trials for new doses and new uses of drugs often continue after a drug is approved. In some cases, clinical trials are designed primarily to examine a specific safety question. I would like to emphasize that many recent important drug safety actions in the U.S. have been on the basis of observational studies or clinical trials, and not on the basis of individual case safety reports.

Active surveillance systems are also being explored to identify and examine drug safety issues. Active drug safety surveillance systems, which take advantage of large repositories of automated health data, are now being developed and tested by multiple organizations. The commonality of these systems is that they do not rely on individual health care providers or patients to recognize and report adverse events that may be related to medication use. Rather, these systems often use sophisticated statistical methods to actively search for patterns in databases that link prescription use, outpatient medical care, and in-patient medical care in a way that might suggest the occurrence of an adverse event related to drug therapy.

While there is much interest in developing these systems, there is also much work to be done in the validation of these systems. In any case, one system is unlikely to address all drug safety problems for all patient populations. Thus, while the spontaneous reporting system has been the cornerstone of post-approval drug safety in the United States for several decades, new approaches based on large population-based databases are being used and are being explored, and will likely play an increasingly important role in this system.

In addition to our activities related to the monitoring of drug safety, we are interested in the safe use of drugs. Toward that end, we have implemented risk management plans for certain drugs whose benefits exceed their risks only when there is careful adherence to certain conditions of use. Many of our current efforts are directed at assessing the public health benefits of these plans, which involve all sectors of the health care system.

New legislation passed in the United States in September of 2007, the Food and Drug Administration Amendments Act, recognizes the importance of post-marketing drug safety by explicitly granting FDA the authority to require companies, under certain conditions, to make post-marketing safety-related labelling changes; to perform post-marketing studies and clinical trials to answer drug safety questions; and to implement risk evaluation and mitigation strategies for prescription products.

● (1120)

In addition, this legislation directs FDA to evaluate formally the safety of new drugs 18 months after they have been on the market, or after 10,000 patients have been treated. We are currently in the process of implementing these and other drug-safety-related provisions of this law.

To ensure that the public is aware of our safety findings, we have embarked on many efforts to enhance our public communications of safety-related findings. These include labelling information specifically directed toward patients, communication of new safety findings before the product label has been changed, and the publication of a quarterly drug safety newsletter. The Food and Drug Administration Amendments Act also includes provisions for providing information to the public.

Finally, but not least importantly, drug safety is a global activity. At FDA, our relations with our international counterparts are very important to us. We have especially close and productive relations with our colleagues at Health Canada in a multitude of settings, including at World Health Organization meetings, other international meetings, bilateral meetings, and routine information exchanges.

I'm happy to answer any questions you may have. Thank you.

● (1125)

The Chair: Thank you, Dr. Dal Pan. It's been very interesting to hear what you had to say.

I should have introduced myself. I'm Joy Smith, the chair of this committee, and we have members from all sides of the House who are very anxious to ask you questions.

In the first round we have seven minutes per person for them to ask the question and for you to answer it. I want to thank you, before we get into the questions, particularly for all your insightful comments to the committee, which are very helpful to us. Thank you.

We will start off with Dr. Bennett.

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

Even before we get to post-market, I was interested in what the FDA had, because I understood that in the case of drugs for which most of the research and approvals were done in other countries, such as the EU or Japan or other places, there'd be a committee of stakeholders that could fast-track a drug into the market, and then you would watch it in a post-market way. Is that true, or was that an experiment? How did that go?

Dr. Gerald Dal Pan: I'm not responsible for the pre-market review of drugs. We can certainly get an answer to that question for you.

We do, however, in broad terms, review all drug applications, regardless of whether they've been approved in another country first or if the United States is the first approval. We often take the data that form the basis of approval to a public advisory committee, and that can happen whether the drug has been previously approved in another country and approved in the United States, or whether the first approval is in the United States.

With regard to your specific question, I'm not familiar with the program you're talking about, but I can certainly have my colleagues here look into that, and we can forward an answer to the clerk.

Hon. Carolyn Bennett: Thank you very much.

In terms of the life-cycle approach and real-world safety, would you consider what you have in the United States to be progressive licensing?

Dr. Gerald Dal Pan: “Progressive licensing” is not a term we use here. I believe it is a term that's used in Canada, and I've heard that term presented at meetings before. When we license a product, it can be marketed, but we continue to watch it closely. Our new legislation puts in a formal requirement for a review 18 months after a drug is on the market, or after 10,000 patients have used it. But once the product comes to market, it's marketed. It's a licensed product.

Hon. Carolyn Bennett: We're wondering if it's like a learner's permit for a driver's licence, and whether you don't get your learner's permit until you have the 10,000 patients or whatever.

On the issue of post-market surveillance in watching for counterfeit drugs, I understand that last year at a conference the FDA was quite concerned about the resources it had, and that it was only able to inspect about 1% of the drugs coming into the United States. Are you doing things like spot checks and using other ways to determine counterfeit drugs in the pharmacies in the United States?

Dr. Gerald Dal Pan: We have a large field organization here at FDA that's present at many borders. We also have an office of compliance in the Center for Drugs. My office works closely with them. We can get an answer to you on that question as well. Counterfeit drugs are of great importance to us, and we can get specific information about those programs to you. They do not fall under my office's purview.

● (1130)

Hon. Carolyn Bennett: If you had an adverse reaction, how would you know if this was a counterfeit drug or the real thing? We have had some deaths here in Canada, specifically one in British Columbia, where someone bought from an Internet pharmacy. We also have a problem with Internet pharmacies with Canadian flags all over them that aren't from Canada. They sell drugs and say they're from Canada, but they may well be counterfeit. How would you suggest that you check an adverse reaction for whether it was the real thing or counterfeit?

Dr. Gerald Dal Pan: That's an important question; it's often difficult. You are probably aware that we have been experiencing a problem with the drug called heparin in the United States. Heparin is a drug that's been available for decades. It's one of the oldest drugs we have, and its safety profile is relatively well known because it has been around so long and has been so widely used. Last November and December there were clusters of outbreaks in dialysis centres around the United States. Multiple patients were getting allergic reactions. Although in rare cases patients receiving heparin can get an allergic reaction, these clusters were particularly unusual.

Our Centers for Disease Control and Prevention, another government health agency, did an outbreak investigation and determined that it was the heparin from one particular manufacturer that was responsible for the outbreak. The heparin was put through very complicated testing and it turned out to be contaminated, even though it came from the manufacturer. In these cases, we're not really dealing with a counterfeit product but with a contaminant. Since this was a relatively widespread problem, we were able to identify both the cause, which was this particular manufacturer's heparin, and the contaminant.

It may not always be easy to determine that an adverse reaction is caused by counterfeit drug rather than a properly manufactured one. If the drug safety profile is well known and the drug has been around a long time and you start seeing adverse reactions that don't fit the pattern, you might suspect the counterfeit, but it would be difficult. If you don't have the actual medication to test, it would be even more difficult.

Hon. Carolyn Bennett: Does that apply for natural health products as well?

Dr. Gerald Dal Pan: Natural health products such as dietary supplements fall under different regulations. They are regulated by our Centers for Food, which could provide you with some information on this. We could ask them to send a response to that question.

The Chair: Thank you, Dr. Dal Pan.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Good morning, Doctor Dal Pan.

How do you determine whether a drug is safe for the public? We read in the newspapers that a number of drugs have been pulled off the market, and that there should have been a much more proactive approach to avoid deaths and detrimental effects, which have a measurable impact on the public.

There were a few deaths reported among girls who had been given the Gardasil vaccine. But no country has called for a moratorium on the mass vaccinations carried out by various public health authorities.

Under your drug safety oversight system, how is a moratorium issued regarding a given drug? What are your parameters? It seems difficult to initiate a drug recall. There have to be a lot of cases in order for a drug to be pulled off the market. In the case of Gardasil, it seems that the clinical trials were improperly done or carried out hastily so that the drug could get to market more quickly.

● (1135)

[*English*]

Dr. Gerald Dal Pan: Gardasil is a vaccine, and vaccines are regulated somewhere else in FDA. But let me answer the question about drugs, because I think your comments about gardasil are relevant to many drugs as well.

First of all, when a drug comes to market, we know there are still certain things we will be learning about the drug safety profile. As I mentioned in my opening remarks, it's really impossible to know everything about a drug once it comes on the market. We approve drugs because we believe the potential benefits exceed the potential risks, and our monitoring of drugs throughout their life cycle is aimed at ensuring that the potential benefits exceed the risks. We do much more monitoring in the post-approval period to monitor potential risks than we do to monitor potential benefits or new benefits.

That balance is often difficult to determine, the balance between the benefit and the risk, and in some cases we bring this to public advisory committees. Our new program in the last eight or ten years to have risk management programs is really designed to ensure that certain drugs whose benefits exceed the risks in certain narrowly defined conditions adhere to those conditions so the benefits do exceed the risks. But learning about the safety of drugs once they're on the market is a complex process. One of the complexities is to determine if the adverse reactions we're seeing are actually due to the drug or if they're due to patients' underlying diseases or to other factors. So it's never a particularly easy question.

[*Translation*]

Ms. Christiane Gagnon: We were hearing earlier about the issue of speeding up the drug approval process. The United States is taking part in the international conference to harmonize the technical requirements. I would like your comments on the objectives of that conference, which is to accelerate the drug approval process.

What impact would that have on drug safety? Would you like to see the United States approve shortcuts in the drug evaluation process?

[*English*]

Dr. Gerald Dal Pan: Again, I'm not in the unit that approves drugs. In the United States our goal is to approve most drugs in a ten-month timeline. For certain drugs that are for serious or life-threatening diseases, we can do it on an accelerated pace in a six-month timeline. But we always ensure that the review of safety is completed before we make a decision to approve a drug. If we need to ask the company for more information, we will.

I'm not aware of the particular conference you're discussing, but we can try to get some information on that for you.

[*Translation*]

Ms. Christiane Gagnon: I would appreciate that, since we are studying this issue. We would like to know about more effective approaches to ensure drug safety, both before and after they are put on the market.

If the approval process is shortened in order to get a drug to market, there may be impacts, and we will have to react after the fact. That might mean that people will die or suffer irreversible health consequences, such as blood clots, aneurysms or other serious effects.

Could shortening the approval process have a direct impact on people's health?

● (1140)

[*English*]

Dr. Gerald Dal Pan: I think a few things are involved in the adequate testing of a drug. One is the numbers of patients tested and another is the length of time to which they're exposed to the drug during the testing process. My colleagues who do the pre-approval testing can work with me to get information on this for you. We use standards for drugs that are going to be marketed for chronic use, and we can get those to you. I think it's important to understand, though, that many of the serious adverse events are also relatively rare, and even large clinical trials won't pick up all of them. So it's a balance we have here.

The Chair: Thank you, Dr. Dal Pan.

We'll now go to another member of our committee, Ms. Wasylycia-Leis.

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

Thank you, Mr. Dal Pan. I appreciate your input today.

I would like to go back to your comments about heparin and pursue the idea of inspection and proper surveillance of drugs that are produced overseas. In the case of heparin, I believe it was a factory in China that resulted in a batch of heparin being contaminated. What does the United States do now, in terms of inspection overseas, to ensure that drugs are safe and free of contaminants?

Dr. Gerald Dal Pan: This is obviously a very big topic here in the States right now. It's a topic of many congressional inquiries, including one this morning as we speak. As I said before, my office doesn't deal with the inspection of drugs coming into the country, so we can get you some detailed information on that. I wouldn't be the appropriate person to answer that question.

Ms. Judy Wasylycia-Leis: Would you be able to tell us if it's a general policy of the government in your country to have overseas inspection capabilities? Is it all done at the border, or is it done only in reaction to problems arising?

Dr. Gerald Dal Pan: We'd have to get you an answer from the people who really implement those policies.

Ms. Judy Wasylycia-Leis: Thank you. I may keep asking you questions that you may not be able to answer, but I'll try anyway.

A news story today suggests that in both Canada and the United States we have regulatory rules that allow companies to conduct secret science that tends to jeopardize the lives and health of hundreds of people who take part in clinical trials. What safety precautions do you have in place to deal with this development? What do you do to ensure that information that's considered proprietary is shared with your government and released for surveillance purposes?

Dr. Gerald Dal Pan: On the post-marketing side, we have regulations that require companies to report basically all the safety information they have on their drug, but not all of it in an expedited or timely way. So individual case safety reports of events that are both serious—and we have a regulatory definition of that—and not on the product's label have to come to us within 15 days. But most other things—like individual case safety reports that don't meet those serious, unexpected criteria, and reports of other kinds of studies that companies are doing—are only reported to us on a periodic basis, either quarterly for the first three years after approval, or annually thereafter.

We had an incident in the United States where we had an advisory committee meeting about a drug, and we were considering whether that drug had some serious adverse effects on the kidneys. We convened a public advisory committee, and it concluded that there were some effects on the kidneys, but the drug should remain on the market and we would change the label. A week after that advisory committee met, we learned that the company had embarked on a large observational study using these databases I described in my opening statements. It showed that not only were there problems with the kidneys, but there was excess mortality with this drug, which was a new finding. That caused quite a big stir here.

While the company is required to report it, it's only required to report it on an annual basis. So we are in the process of rewriting some of our safety rules. We put out a draft a few years ago on post-marketing safety, and we'd like to address some of these kinds of issues.

But our expedited reporting has largely been based on these individual case safety reports, and it's clear that drug safety is moving much beyond that.

● (1145)

Ms. Judy Wasylycia-Leis: Thank you.

Can I pursue a bit of this whole agenda item? Take Vioxx as an example. It has been in the news recently in terms of the possibility of Merck Frosst not disclosing information that would have prevented some of these thousands of deaths as a result of using Vioxx.

What have you learned from that situation? What are you doing about drug companies that may not be either disclosing certain information that would be important for health and well-being or misrepresentation by drug companies of a risk and benefit profile of a particular drug?

Dr. Gerald Dal Pan: We learned quite a lot from Vioxx here at FDA. One of the things we learned is that the public wants to know when we know about something. As you may recall with Vioxx, there was a delay of over a year in adding information about heart attacks to the label.

We've started a program here in the last year or two through which.... When we are working on an important safety issue but before we've brought it to resolution, before it has been added to the product's label, we are issuing what we call "early communications of safety findings", so the public can know this is something of concern to us, that we're working on it, or that we've concluded this and we will be adding it to the product's label. The way it was communicated to the public before was through the product's label. Now we are being proactive in communicating that earlier.

In addition, the legislation that was passed in September of 2007, the Food and Drug Administration Amendments Act, has provisions for us to work on a timeline with companies to get information about important new safety findings in a way that should preclude this long period before the information gets on the label.

So there are two things: the legislation that allows us to get this information to the label in a more timely fashion, and our own proactive public communications.

The Chair: Thank you, Dr. Dal Pan.

We'll now go to our next committee member, Mrs. Pat Davidson.

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

Thank you, Dr. Dal Pan, for your presentation this morning and for being with us to answer our questions.

I want to go back for a moment, please, to the life-cycle approach. I think you said that in the United States—and it's true in Canada too—you balance the benefit and the risk of a drug before it's licensed, and that's some of the determination that goes into it. You also said, I think, that you learn about the drug during its life cycle.

I'm sure you're aware that there's legislation before our Parliament to introduce a life-cycle approach to the regulation of these products. Health Canada has said much the same thing. They indicate that the concept of this life-cycle approach is that over time there's a progression of knowledge in and about the drug.

Could you outline the difference between what you do and what we're proposing here with this new legislation?

Dr. Gerald Dal Pan: I have to be fully frank and say that I'm not aware of the details of the proposed legislation, so I couldn't make that kind of comparison for you.

Mrs. Patricia Davidson: And as far as the life-cycle approach goes? I think you made the comment that you learn about a drug during its life cycle. Do you in fact take that into account in your process?

● (1150)

Dr. Gerald Dal Pan: Yes, we do. One of the things we have is risk management for drugs. This starts before the drug is approved. We look at what it is about this drug that may cause problems when the drug is on the market and whether there are certain things, based on the drug's chemistry, biology, or certain findings in clinical trials, that we may want to keep a close eye on after the drug is approved.

We have a group in my office that works on risk management. We work with the parts of FDA that are responsible primarily for the pre-market review. And for certain drugs—not the majority, but for certain of them—we can institute risk management plans that will keep an eye on these things after a drug is approved and see if the risks and benefits are changing, post-approval. This is in addition to all our normal safety monitoring that goes on as part of a routine.

Mrs. Patricia Davidson: Thank you.

You mentioned, I think, in your presentation cooperation and collaboration with different countries. You talked about the World Health Organization. I'm wondering if there are specific mechanisms or structures that either are in place or that could be put in place to help regulation between Canada and the United States, since we're such close neighbours.

I live in a border community, and it's certainly very commonplace for people to drive across the border to get some drugs that are available there and that maybe are not available here, even across-the-counter drugs. Could you comment on putting mechanisms in place that would help coordinate between the two countries?

Dr. Gerald Dal Pan: We have a memorandum of understanding with Canada. It allows us and Health Canada to share information. We've found that very useful.

In the end, I think it's important to understand that each society may have its own different idea about risk and benefit. This may vary from one country to another, although I think Canada and the United States are probably pretty similar in these ideas.

In terms of risk management and other things, these involve many aspects of the health care system. They depend on the health care system structure as well as individual scientific determinations about risk and benefit. There are some harmonization procedures we have with Europe and Japan, such as the International Conference on Harmonisation, but those are in terms of clinical trial data, which is largely about format, number of patients, and things like that.

I don't know if that answers your question.

Mrs. Patricia Davidson: Yes, it does.

I'm interested to know what some of the largest challenges are for you in the United States when it comes to post-market surveillance. We've heard from a tremendous number of witnesses that it's not mandatory for the medical profession; it's not mandatory for the public. We've heard a lot of different testimony about who should be doing it, how they should be doing it. Are those some of the challenges you face? How are you dealing with them?

Dr. Gerald Dal Pan: We face all these challenges. I think our challenges are very similar.

In terms of reporting adverse events, we do not have a requirement in the United States for physicians, nurses, pharmacists, patients, or anyone else at the point of care to report an adverse event related to a drug to either the manufacturer or to the FDA. We understand that only a fraction of the adverse events that are really happening are reported. It's often quoted to be 1% to 10%. The real percentage is probably not known, but probably varies from drug to drug.

What's most important about these systems, though, isn't the number of reports you get, but the quality of reports you get. We get over 450,000 reports a year, but a lot of them are lacking the kind of critical information we'd need or want to make an accurate determination of what role, if any, the drug played in the adverse event. We can go back and get follow-up information. We can do that. That's very time-consuming and resource-intensive, and we don't have the resources for that.

With regard to other kinds of surveillance systems—these systems that rely on large databases of health care information and electronic medical records—FDA doesn't own them. The drug companies don't own them. These are owned by independent parties. In the United States, with a private health insurance system, they're often owned by health insurers or health plans. One of the challenges we're going to have is how to get everybody together: the FDA, other government agencies, the companies, the people who hold the data—health systems, hospital systems, practitioners, and academics who have the skill to look into these data. How do we bring all these people together—and handle important issues of patient privacy and confidentiality and things like that—to look at this data to see what's happening?

So FDA is just starting some initiatives.

● (1155)

The Chair: Thank you, Dr. Dal Pan. Your presentation today has been very helpful to our committee. I want to especially thank you for taking the time to come via video conference. I think this collaboration between our two countries is extremely important. As I said, we as a committee all want to thank you for your time. I would bid you good day, and I look forward to some more contact on the same issue in the future.

Thank you, Dr. Dal Pan.

Dr. Gerald Dal Pan: Thank you for having me here today. We'd be happy to answer any other questions you have in the future.

Thank you.

The Chair: Thank you so much.

Committee, we will take a two-minute break.

We have some food for you if you'd like to take this opportunity to get it, and we will resume in two minutes.

● _____ (Pause) _____ ●

● (1200)

The Chair: We will resume our committee meeting now.

I would like to particularly welcome our witnesses. We have Jean-Pierre Ménard, attorney and specialist in medical law. We have Tom Brogan here as well. He's president and chief executive officer. And Julie-Kim Godin is here joining us, and I understand she is part of Mr. Ménard's group.

Welcome to all of you.

We give each organization ten minutes to speak, after which we go into committee questions, starting with seven-minute rounds.

Mr. Jean-Pierre Ménard, would you like to start?

[*Translation*]

Mr. Jean-Pierre Ménard (Attorney and Specialist in Medical Law, Ménard, Martin, Avocats, As an Individual): Good afternoon. I will be giving my presentation in French.

I will begin by introducing myself. I am a lawyer specializing in health law. I am first and foremost a practitioner. My practice is a bit special because it deals with approximately half of all health care-related legal cases in Quebec. We basically defend the rights of users and patients in all areas of the health care system. Today I will be presenting from the point of view of patients and patients' rights, since this is a very important factor when we are talking about oversight of drugs after they come on the market. It is an important issue for patient safety.

I would first say that my practice is not an ordinary one; it is not an American-style approach either. We promote certain values such as quality, safety and accessibility, in particular. My comments today will focus primarily on our commitment to safety.

I am very pleased to be here and I thank the committee for giving us this opportunity to express our views. It is important that the whole process be reviewed because, if we look at the current regulations, it is clear that they are extremely weak and limited from the standpoint of the public, consumers, and those taking these drugs. The regulations are based mainly on self-regulation by the pharmaceutical companies as to the undesirable effects of drugs put on the market. The only control is the obligation that companies have under section 16 of the regulations to indicate to Health Canada any cases where the drug is found to have had an undesirable effect.

Under the act, Health Canada can ask for analyses, etc., but the public has no concept of how the companies interpret the rules. In other words, are they using a restrictive interpretation, which would result in too few cases being reported? Moreover, the public has no idea whether Health Canada checks or validates how the companies interpret the information. And people do not really know what Health Canada does with all the reports. The department is empowered to do additional analysis and testing, but I personally have not seen any reports or documentation or anything else to show that those rules are actually implemented.

There is also the possibility of clinical trials being carried out in phase 4 as well. There are a lot of rules governing clinical testing in phases 1, 2 and 3, but practically none for phase 4 testing. So there is a problem. That aspect should be looked at in the legislation.

There is also a system of voluntary reporting by health professionals and the general public. This is a voluntary, administrative system that does not have any process set out for it. Likewise, there is no follow-up mechanism for these reports. So an ordinary citizen or a professional might report a problem, but what happens to that report? Nothing is known about what the process might be. I think that this is an important precaution, since it is a major issue for health safety, as I have said.

As one possible approach, I would mention the Quebec Health Safety Act passed in 2002. In Quebec, the legislation did get changed. It resulted from a case that was dealt with by my office. Steps were taken to amend the legislation, to change the rules governing the safety of care. The premise was that a certain number of health care accidents occur in our health system. Similarly, there are certain undesirable effects of drugs as well. Up to that point, they were often considered to be anecdotal incidents that were talked about and reported but there was never any follow-up. In 2002, the legislation was changed to make the reporting of health care incidents and accidents mandatory.

Under the Quebec act, drug side-effects are considered to be health care accidents. The legislation requires that they be reported within each health care institution. Incidents must be reported to an internal body called the Risk Management and Health Care Quality Committee, which the law requires to be set up. So disclosure must be made to patients whenever they suffer complications, and they must be given support or told what action will be taken if such a thing happens. The committee is required to investigate all incidents to determine what occurred, prepare reports and recommendations, and keep a registry.

● (1205)

So Quebec's health system already has a very structured legal framework. This legal framework would be extremely useful in this case for reporting the adverse effects of drugs, or for reporting any unexpected results linked to taking prescription medication.

If we generally consider what might be more useful for Health Canada, it might be a good idea to take into account Quebec's system without creating any overlap. I believe that the legislation in Quebec and Manitoba is fairly similar. These two provinces are ahead of the others in this regard. Whatever the case may be, what is important is that we now have an organized and accountable system that allows people to report accidents. These cases are handled by an organization that investigates and makes recommendations to improve the situation.

Today, the voluntary disclosure system is purely administrative. There has been a significant increase in the number of disclosures made. This system, which is not very well known by the public, involves a lot of red tape. Despite this fact, it received thousands of disclosures. It's unbelievable. Further, I believe this is only the tip of the iceberg. My impression is that in reality, if the system were better known, more user-friendly, tighter and more accountable, we would receive many more complaints. And if that was the case, we would certainly be in a better position to improve the safety of the public.

As I said, these statements are often perceived by doctors as being nothing more than more bloody paperwork. Even if they see things which should be reported, most of the time doctors don't do so because they can choose between making a report to the federal government, which is a lengthy process, or to treat the patient. That's often their dilemma. Further, people have no idea what happens after they send in their statement. Under a post-market surveillance system of pharmaceutical products, perhaps disclosure should be mandatory for health care professionals. But even under a mandatory system, people usually under-report any incidents. If they are not forced to do so, the under-reporting will be even greater.

I know that this information is not relevant to the committee's mandate, but it is estimated that only between 4% and 5% of post-vaccination accidents or complications are reported, despite the fact that there is a mandatory reporting process in place for post-vaccination incidents. So just imagine the very low number of cases which would be reported under a system where that is not mandatory. However, I think this is one solution that we should consider.

Perhaps we should also force manufacturers to do a bit more. The packaging of drugs provides information and medical terms. It also contains a package insert describing the risks and effects of the medication, and so on. Why should we not force manufacturers to also include a telephone number or an Internet address which people could access to report any adverse reaction or complication? That way, manufacturers would be more accountable to the people who take their drugs. They also could indicate what to do in case of an adverse effect. I think this would be the very least that should be done.

I also believe that the regulations, or even the act, should outline the disclosure process, so that people realize it is important. For now, it's a purely administrative issue. People might think that the information ends up somewhere, but they don't really know where. There should be some kind of organization within Health Canada to conduct follow-ups and people should know what the process involves, rather than hearing that there were 30, 40 or 50 other complaints without being able to in any way appreciate the significance of what has happened.

Regarding the management of risks and the safety of these medications, we should benefit from provincial experience. It's clear that from a marketing point of view, we can benefit from provincial health care systems, at least in the case of Quebec, where there is a system for managing health care accidents which is structured, regulated and organized. In order to avoid overlap and wasting time, it would be important to benefit from that experience.

It is all the more imperative to do this because there is growing pressure to shorten the time it takes to licence drugs. The same applies to the access to medication under the Special Access Programme, for example. There is the risk that we will see more drugs ending up on the market for which the trials during phases 1, 2 and 3 will not have been extensive enough. It therefore becomes all the more important to strengthen monitoring during phase 4, to implement a legal framework, and to create ethics oversight committees under phase 4.

● (1210)

At present, ethics committees get almost no legal supervision. Their makeup and operation varies. With regard to the object of the research, we know that these practices are not very reassuring. Clearly, this needs thinking about. Unfortunately, a number of these aspects also fall under provincial jurisdiction.

[*English*]

The Chair: Mr. Ménard, we're a little over time here. You will have lots of time to answer questions, and I thank you for your very insightful presentation.

Mr. Brogan.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Madam Chair, perhaps I could just make a comment. I'm impressed with the interpreters on that. They were very good. That was a lot of information given very quickly.

The Chair: We were absolutely amazed.

I was concerned about you. You're awesome. Thank you.

Give them a hand, everybody.

Some hon. members: Hear, hear!

The Chair: Okay, Mr. Brogan, please proceed.

Mr. Tom Brogan (President and Chief Executive Officer, Brogan Inc.): Thank you very much. I'm honoured to be able to present to this committee, and I thank you for inviting us.

l was employed by the federal government between 1974 and 1989, and l was the chief policy analyst on the 1987 Patent Act amendments. Those created the Patented Medicine Prices Review Board and curtailed the use of compulsory licensing. l was acting director at the Patented Medicine Prices Review Board between 1987 and mid-1989, when I left to create a private company, Brogan Incorporated. The idea was to bridge the gap between government and the private sector. I saw when I was in government that there was not a lot of communication of much substance. So we've tried to create an empirical base on which both parties could communicate on equal grounds.

It was not planned at that time, but we now have the largest prescription database in the country. We have somewhere around 1.5 billion prescriptions in our database, coming from a very large number of sources. We have140 dedicated professionals analysing and reporting on these data. These data obviously permit very extensive and complete analysis on a large range of issues, and they do so without jeopardizing patient privacy, since we don't have a patient ID. There's a scrambled code put in place of any direct patient identifier. These are the kinds of data that Dr. Dal Pan was talking about...owned by the private sector in the U.S.

Over this period of time, we've pioneered the analysis of administrative drug data, including beating the Americans to the punch, which I'm proud to say. We've already done many of the current and proposed new proposals that you heard about from previous witnesses. These analyses have been used by government, academia, and industry to inform decisions about drug coverage and utilization. We've conducted a number of studies measuring drug cost by age groups, regional variations, and a detailed analysis of high-cost claimants. By the way, some of that is provided in a briefing document I provided earlier.

Recently we completed an analysis of the Alberta seniors drug plan, a project we worked on in conjunction with the Alberta Ministry of Health. Another study looked at drug use by 1.2 million Canadian children. This is the largest study on pediatrics ever done anywhere from an administrative database. You've probably heard about NPDUIS. That's a simple re-creation of what we have already created. It's been under way at an exorbitant cost. The government could have bought something right off the shelf.

l think the committee will see there is a direct relevance to our activities and the questions it quite astutely has put forward for examination. Specifically, l would like to speak to just a few points: capacity for monitoring; surveillance and research; public access to information; and adverse reaction reporting.

We've developed a significant database and expertise in handling these complicated and large data sets. There is no risk to patient privacy. However, the government does not make adequate use of this capacity for monitoring, for surveillance, or for research. I think too much effort is put into replicating what already exists.

While the knowledge derived from our existing database is powerful and can be used for the better management of health systems, we're hampered by limited access to data. While we have the largest prescription database, we don't have data from every provincial government. Some government officials have been resistant to making these kinds of data available, and there's no clear reason for their position. This means valuable information for the management and improvement of the health care system is not being used.

I will give you a specific example to explain. We've discussed a data-sharing arrangement with all the cancer agencies in the country, and the participants are very interested in creating a central repository. However, it's not an unwillingness but a lot of effort is required for them to extract the data to send to us. While we have one province on board now, and we're looking for several others, it's a very slow and tedious project. This means that there is no comparative information on the use of cancer therapies across the country, little data on the effectiveness of treatments, and of course little data on adverse events rates in real life.

● (1215)

I don't want to dismiss the value of clinical trials; this is an add-on to clinical trial information.

The most powerful information will come from an integrated database where you're putting together all aspects of a patient's health resource use—again, without knowing who the patient is—and that would be lab tests, doctor visits, hospital visits, drug use. This is not difficult to do, but it is a very large project. Everything is there to have it done, but there has to be a willing spirit to make it happen.

We hope this committee would encourage Health Canada, for one, to make more use of the private sector in monitoring surveillance and research in all areas of health care. There is a capacity among private sector participants to dramatically expand what government agencies are trying to accomplish.

We would also suggest that this committee encourage governments that hold data to share this with the private sector. A more broadly based data set would allow us to extend our analysis significantly, and the more eyes examining the data, the more insights that will be developed. Of course, this will be done under the privacy and confidentiality rules that prevail now. I believe that all of this information can play a pivotal role in managing many aspects of the health care system.

Thank you, Madam Chairman.

The Chair: Thank you so much. We appreciate your presentation this morning.

We're going to go into the first round, and we will begin with seven minutes per person, for the question and the answer.

We'll go to Ms. Kadis first.

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

Welcome to our guests.

To Mr. Ménard, are you familiar with the new proposed government legislation, Bill C-51, regarding life-cycle approach and progressive licensing? What is your position on this? Do you feel it will increase or decrease product safety for Canadians?

[*Translation*]

Mr. Jean-Pierre Ménard: The life cycle approach offers interesting perspectives. To date, we have worked with drugs until they get to the market after which we play a very minimal role. Conceptually, this is a good approach, but in concrete terms, what will we really monitor and look at? What kind of information will we require from pharmaceutical companies? I think it's important to look at these matters. The overall idea is a good one, but we'll have to implement mechanisms to increase transparency and accountability, and provide better information in order to protect the public. Clearly, we will now obtain more information from the government. Consequently, we'll be able to go further. However, we'll have to see how this will benefit the public.

● (1220)

[*English*]

Mrs. Susan Kadis: Thank you.

I have another question.

From your perspective and experience, would you say part of the reluctance of medical professionals in reporting is due to fear of being sued? How prevalent are lawsuits in Canada regarding medical malpractice specifically due to adverse effects from medication?

[*Translation*]

Mr. Jean-Pierre Ménard: Drug-related lawsuits that can be filed against doctors are often due to a failure to advise patients of known complications, which might have influenced the latter's choice. It may also be the failure of the doctor to prescribe the right medication, or he may be sued for prescribing the wrong one.

In the case of prescription drugs or drugs being marketed with specific indications, it is not unusual for doctors to develop what are called off-label uses, meaning for other reasons than the reasons for which the drug was originally designed. There is some risk associated with this, but that is not the reason why doctors are not reporting complications. In general, doctors are saying that they are not reporting them due to a lack of time. They wonder whether they should treat the patient or fill out a form. Furthermore, numerous doctors know little about the post-approval drug monitoring system. Under Quebec legislation, they are now required to report complications to the government. Even if this is a statutory requirement, it is still difficult.

[*English*]

The Chair: Thank you, Mr. Ménard.

Ms. Kadis, I understand that you and Dr. Bennett wanted to share time.

Mrs. Susan Kadis: Mr. Thibault would like to share some of the time.

The Chair: Thank you.

Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): Thank you, Mr. Brogan.

You're talking about administrative data. Could you quickly define that? Is that data you're getting from secondary sources—for example, from insurance companies?

Mr. Tom Brogan: I don't want to quote the number of sources, but it would be a source like insurance company payments or payments made by a private drug plan or a government drug plan—we receive both—or from a hospital database.

Hon. Robert Thibault: Would the data include any information on the effectiveness of the pharmaceuticals in question?

Mr. Tom Brogan: Not directly. This is a supplementary use of the data, a supplement to adverse reactions or effectiveness. In quite a large number of cases, not all, you can look at the full range of drugs the patients have been on, how soon they stopped the medication, and other things that might raise a flag that there's something going on.

Hon. Robert Thibault: But you would only know how long when they stopped billing for the pharmaceutical, not necessarily when they stopped taking it. If they took it at double the rate for half the time, that type of use, you wouldn't know.

Mr. Tom Brogan: We do know how many pills they acquired over a period of time. We purchase pharmacy data, and when you look at it, you see that Canadians are good at using—

Hon. Robert Thibault: I'd like to get into the question of off-label use. That's one of the areas we found interesting, especially when we came to children, because very few clinical trials are done on minors. In looking at the off-label use of drugs, did you differentiate with respect to minors, children?

Mr. Tom Brogan: Yes, we did. In that study, we looked at it.

Hon. Robert Thibault: What percentage of the use was off-label?

Mr. Tom Brogan: In the case of Viagra, 100%. For other drugs, I can't tell you.

Hon. Robert Thibault: That prompts a whole lot of questions.

Mr. Tom Brogan: There is quite a legitimate use for it.

Hon. Robert Thibault: With Bill C-51, with the progressive licensing, do you see an opportunity to improve the off-label situation? I don't want to stop off-label use. I understand that it's a necessity, but it seems that it has become almost systematic—most of the new pharmaceutical products used for children haven't been tested for children. They all end up being off-label, and you wonder if the proper information is getting around. Do you see some possibilities for improvement?

Mr. Tom Brogan: Yes, there could be dramatic improvement in monitoring off-label use. The administrative data can lead you to some pretty sound conclusions, which need follow-up.

Hon. Robert Thibault: Beyond the monitoring, you'd have to impose some clinical trials on that population.

Mr. Tom Brogan: That's right. One option is to look at what's been done in other countries. Have Health Canada negotiate with the drug companies to encourage them to do trials in children. I believe in the U.S.—it's been a while since I've studied their law—that for pediatric use a company will get a certain period of market exclusivity if they conduct the research for that use in children. So there are incentives available.

Hon. Robert Thibault: We've heard from witnesses that only about 10% of serious adverse events get reported. We've seen the actual incidence of events in the population. In your study on pediatric pharmaceutical use, are the negative adverse events higher?

● (1225)

Mr. Tom Brogan: We didn't measure adverse events.

The Chair: Monsieur Malo.

[*Translation*]

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

Ladies and gentlemen, thank you for being here with us.

Mr. Ménard, in your presentation, you said that there should be a legal framework for everything related to pharmaceutical vigilance. More specifically, how should this be done?

Mr. Jean-Pierre Ménard: First, the main principles of the legislation and details can be specified in the regulations. However, the legislation should be amended to include the possibility, even the duty, for everyone to act—depending on whether we want to make it an obligation for certain groups within the population such as health care professionals or others—and set out in the regulations a formal mechanism in order to report all adverse effects. We should also create a mechanism for the government to receive such information and assess its merits, so that individuals reporting such cases can get input and we can be certain that all these reports are being put to good use.

Currently, it is possible to know whether a certain number of cases regarding a particular medication have been reported and the effects, but is this a reality? Scientifically, is there a recognized link between the drug and the complication? How important is it? At present, there's nothing to validate the results or follow up on reported cases in a structured way. I think it would be useful to have a structure or an organization—a little bit like the risk-management committees mandated under Quebec law—to study this and to make recommendations or to provide a follow-up to these questions.

It would also be appropriate to consider the possibility of simplifying the administrative process, for example, with the assistance of the health care system. People have been designated for these purposes. Some people have difficulty reporting problems. In the case of seniors who have difficulty reading and writing or who suffer from adverse reactions to drugs, it can be extremely difficult to get them to report this via the web.

So, I think that we need mechanisms or processes in the health care system to help people do these kinds of things too. This should be done through the health care system, because it's more difficult for people to deal directly with Health Canada. People don't know where to begin to do this.

Mr. Luc Malo: You say that you have no opinion on whether or not these reports should be mandatory or voluntary?

Mr. Jean-Pierre Ménard: The issue of mandatory reporting is something that could be discussed at great length. In the Quebec legislation, there are a number of procedures that relate to mandatory reporting. For example, any accidents that occur with vaccines must be reported. There is also widespread under-reporting. It is estimated that only 5, 6 or 7% of cases are reported.

The problem surrounding any implementation of a mandatory reporting process relates to the sanctions that will apply if reporting does not occur. The College of Physicians refuses to apply any type of penalty. Therefore, I think that the provinces and the professional bodies should take a close look at this issue. It is a matter of educating the professionals.

Moreover, having it included in the act makes it a tool, an instrument that cannot be overlooked. We must not say that since people are ignoring the requirement, it should not be included. I don't think it would be useless to include it, because it could eventually be used for education, training, planning of programs and procedures. We are only seeing the very tip of the iceberg, when it comes to the number of reports that are being made at this time. I have a feeling that in the field, this is something that is more apparent because the pharmaceutical component represents an important aspect of our practice. Drug-related accidents are constant and frequent. This is also an important part of our professional practice.

It has become quite clear that there is not enough public monitoring taking place at this time. Very little is known about the effectiveness of this monitoring. What we do have is limited to informal checks. It is clear that we will have to strengthen that side of the equation as well.

● (1230)

Mr. Luc Malo: Madam Chair, if I may, I would like to give the rest of my time to my colleague Ms. Gagnon.

[*English*]

The Chair: Absolutely.

You have about two minutes, Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: I will be very brief, Madam Chair.

I would like to come back to a drug, the Gardasil vaccine, which was linked to the death of young girls in other countries. There were apparently 11 deaths. When a drug is taken off the market, under what circumstances—and I know that you are a legal professional and that you provide help in similar cases—there be agreement to continue the vaccination campaign? We know that Quebec has started an intensive campaign to vaccinate adolescent girls, even though some people have died elsewhere. What is the relationship between the drug and the cause of the illness?

Mr. Jean-Pierre Ménard: With respect to public authorities, the main concern is the safety of the population with regard to this type of occurrence. In general, if information leads one to believe that a product might be dangerous, I think that it is within the powers of the public authorities to immediately stop vaccinating people. Quebec law currently allows for an immediate stop to any vaccination program, for example. However, the power to withdraw a drug from the market rests with the federal government. The law also provides for other types of authority. In my opinion, it depends upon the will or lack of will to exercise these powers. From my understanding of the law, I will say that the current powers are adequate. But do we or do we not want to use them? It is a matter that relates more closely to politics than it does to law.

[*English*]

The Chair: Is that the end of your questioning, Madame Gagnon?

[*Translation*]

Ms. Christiane Gagnon: Not enough care was taken with respect to Gardasil, because the vaccination campaign is continuing. Quebec started vaccinating two or three weeks ago. You are a legal expert, can you tell us who would be responsible if a young girl in Quebec were to die after being vaccinated with Gardasil?

Mr. Jean-Pierre Ménard: Vaccinations come under public health, and the federal government is also involved in that area. There is a very high degree of vigilance regarding all those problems.

Ms. Christiane Gagnon: What is their legal responsibility?

Mr. Jean-Pierre Ménard: If we are told about a risk or a known association and if the government or the institution that carried out the vaccination does not report it, there is clearly a responsibility. The government is also accountable. It could be taken to court in such a case. We would obviously look into all those issues.

[*English*]

The Chair: Thank you very much.

Ms. Christiane Gagnon: Thank you.

The Chair: We now have Mrs. Wasylycia-Leis.

[*Translation*]

Ms. Judy Wasylycia-Leis: Thank you.

Mr. Ménard, you said that if a provision was introduced into our legislation concerning mandatory reporting—

Mr. Jean-Pierre Ménard: Yes, mandatory reporting.

Ms. Judy Wasylycia-Leis: The provisions in our bill are inadequate, on the one hand because there is no effort being made to strengthen them, and on the other, because there is no indication as to how this information is being used.

What reservations do you have about the provisions in this bill?

Mr. Jean-Pierre Ménard: If a mandatory reporting process is introduced, it must be effective. However, if there are no consequences as a result of non-reporting, we are not much further ahead.

Voluntary reporting has drawn very little attention because it is governed only by an administrative process. There is no legal process involved. There are no parameters for it. I think that it would be important to put it into the legislation so that it is more formal and better understood. That way, people would also be aware of it. Right now, you have to go on Health Canada's Internet site, which contains a lot of information. Lawyers are used to doing that, but it is not easy for the general public to find what they are looking for.

Mandatory reporting is something to look at. It is important to note that some provincial laws, like the Quebec legislation, already contain that kind of obligation. When something happens in a health care facility, it has to be reported. Do you introduce something that may be redundant, or is it better to try to cooperate to obtain the information from the provincial system? Those aspects need to be considered as well. There is no point creating two structures if there is already one that is working and can provide information through agreements or otherwise.

There is no magic formula. Even if the legislation calls for mandatory reporting, doctors and nurses have to be made aware of the requirements. Nurses need to be involved because they are often the ones who see the reactions. Doctors are paid on a fee-for-service basis. Generally speaking, there is no fee for this sort of thing, and many doctors therefore do not report them. It might be easier for nurses to do so. I do not have any magical answer, but it would be important to put in place a better structure for these processes.

● (1235)

Ms. Judy Wasylycia-Leis: Do we have things to learn from Quebec and Manitoba regarding implementation at the national level?

Mr. Jean-Pierre Ménard: There are two issues that are significant. The notion of the right to medical safety is beginning to surface in all western health care systems. Ten years ago, this issue wasn't even discussed. We've only begun to talk about this in recent years, and it is becoming a major concern for the French, English, European and Canadian health care systems. Health care must not only be efficient and ethical, but also safe.

Quebec was the first province in Canada to legislate on this matter, and Manitoba followed suit in 2005. There is a current trend to begin acknowledging this principle. The principle must be part and parcel of a framework, something similar to section 3 of the Health and Social Services Act. In all decisions regarding the management and delivery of health care, safety must be guaranteed, among other things. A patient's right to drug safety must be exercised in several ways, such as quality control, advisories, or interruption of drug distribution. To my mind, a patient's right to drug safety must be provided for in the legislation proper, and not in the preamble. This strikes me as a significant step forward.

[*English*]

Ms. Judy Wasylycia-Leis: Merci.

Mr. Brogan, I'd like to ask you a couple of questions. First of all, where do you get your funding? Whom are you connected to? How do you make a living?

Mr. Tom Brogan: We make our revenue by selling reports to drug companies, government, small clients, insurers.

Ms. Judy Wasylycia-Leis: Are you funded at all by drug companies in terms of your operations?

Mr. Tom Brogan: If they need reports of some description, we produce those reports. It's not funding per se. It's earned income.

Ms. Judy Wasylycia-Leis: Drug companies haven't invested in your company and...?

Mr. Tom Brogan: No.

Ms. Judy Wasylycia-Leis: So you wouldn't have any conflict of interest in this, other than providing the services to drug companies and getting remuneration for that?

Mr. Tom Brogan: We have the same rule that I had in government: the data show what the data show. If the client doesn't like it, the only thing that's certain is that they'll pay the bill. That's it.

Ms. Judy Wasylycia-Leis: What is the difference between your database and the national prescription drug utilization information system?

Mr. Tom Brogan: Ours is larger.

Ms. Judy Wasylycia-Leis: Is it your recommendation here that government should rely on your database in future?

Mr. Tom Brogan: Well, I think there's an opportunity for us to work together, which I've offered up more than once. It doesn't make sense to me to have two independent data sources that are doing the same thing.

Ms. Judy Wasylycia-Leis: You don't think this is something that should be fundamental to government, and part of the role of government?

Mr. Tom Brogan: Oh, I think the government absolutely should have a database. My point is that they've gone out on their own and built something that we already had. If we had worked together, we would have had a bigger and better database much quicker.

Ms. Judy Wasylycia-Leis: Where do you see your proposal fitting in with regard to this broad study of post-market surveillance?

Mr. Tom Brogan: Right now, if I understand the role of CIHI and others, they're not really into a patient-level analysis. That's the kind of work we've done, and I think there are probably some other private sector companies out there.

I don't think government can do all of the work that's necessary. I don't worry about competitors. There is so much to do in this area. The number of questions is just endless, so—

● (1240)

The Chair: I'm sorry, Mr. Brogan, we're way over time. Thank you for your answer.

Mr. Brown.

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

Mr. Brogan, you mention in your brief, on the third page, that "only a minority of adverse events is reported". Could you comment on that a little bit? How do you draw that information, and what percentage would that minority be? Are there any estimates?

Mr. Tom Brogan: I've seen the estimate of around 10%. That's been pretty consistent. When I was in government, we used to look at figures like that. I think that figure has been around forever. And in talking to physicians and people in hospital...it's more impressionistic; no empirical analysis that I know of has ever measured that.

It's a very difficult figure to get a handle on, partly because what constitutes an adverse event? Is it the minor headache or is it the...? I mean, obviously a death would be a serious adverse event, but there's such a range in between. So getting a definition of that is quite....

Mr. Patrick Brown: I guess the 10% figure is more the conventional wisdom.

Mr. Tom Brogan: Yes, it is, absolutely. Every time we ask that kind of question of physicians, the answers range from "I never report them" to "The really bad ones I'll call in".

Mr. Patrick Brown: One thing I read is that it will be a challenge if we have expectations that regulations can change to require physicians to take a different approach.

What approaches are realistic? One thing I heard from the CMA when they were here previously was that real-time access to health warnings is an issue. If they are sent by fax or mail there is a real-time difference in the sense that information doesn't get to physicians as fast as it could. We've heard that in some areas, such as in New Zealand, they utilize mobile devices to provide information and databases directly to physicians in an immediate manner. What are your thoughts on that? What could we do to enable physicians more efficiently?

Mr. Tom Brogan: How do we communicate adverse events to the physician?

Mr. Patrick Brown: That's one angle, but it is also about tying them to a database so they can see a patient's history.

Mr. Tom Brogan: Let me deal with informing doctors. It's quite possible to know which doctors are prescribing which medications, so Health Canada wouldn't be beyond the pale. This might fall under provincial jurisdiction, so I want to be careful here. If a doctor is prescribing a fair amount of a drug that is found to be causing a lot of adverse events, those doctors could be targeted with messages. I believe that Health Canada and some private companies actually do that. How effectively they do it, I don't know.

As for information coming in the other direction, I think Mr. Ménard said it quite well. The choice for a doctor is either treating the patient or reporting the adverse event. From talking to doctors, given the work they have to do, it's very difficult for me to see how we could encourage them to report more frequently. It takes time away from their very busy practices and away from the patients, and it's not crystal clear. There is a fairly good website, if I understand correctly. There's the telephone.

One way that might be more practical would be to have the provincial agency or Health Canada, whichever has jurisdiction, contact doctors who are writing a lot of prescriptions for drugs at risk. That would be a relatively inexpensive way to do it. Ask them if they're getting adverse reactions.

● (1245)

Mr. Patrick Brown: Ms. Wasylycia-Leis was commenting before about the nature of your database. I think you said that it was pretty significant in size, bigger than the NPDUIS database. I think it was mentioned on your website that this was data collected from nine or ten provinces and over 17 major drug program administrators. Could you maybe tell us about the size of your database and whether it's based on Canadian data only, or does it have some foreign data incorporated into it as well?

Mr. Tom Brogan: Our data comes from Canadian sources only. There are multiple levels of data. We get expenditure data from every province except Prince Edward Island, so we know how much a province has paid for each drug under the public drug benefit plan. That data's fine for looking at trends and spending on each individual drug and so on, but that's not really where the power of the research is.

The next level is where you have an anonymized patient code. They scramble the patient codes so no one can identify who the patient is. Every time they send us data, which is usually daily or weekly, it has the same patient code on it, so we can track people over time. You can see the dosage people are taking, which drugs they are taking, whether they are on more than one medication, and whether they have quit taking a medication. We get the same kind of information from about 5,000 or 6,000 pharmacies in Canada. That's the difference in the data.

We get those data for our analysis from two provinces, one federal organization, and just about every insurer in the country, and that's what the reports have been built upon.

Mr. Patrick Brown: Previously today we heard some comments from Gerald Dal Pan from the U.S. Food and Drug Administration, and my colleague Ms. Davidson,asked about the life-cycle approach.

This is a general question to you and Mr. Ménard. What are your comments on the life-cycle approach? Is that a step in the right direction?

Mr. Tom Brogan: I believe that is the right track, yes, very definitely.

The Chair: Thank you, Mr. Brogan.

We're now going to go into our second round of five minutes each. We are very close on time, so we will start off with Mr. Temelkovski.

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

Mr. Ménard, you mention in your presentation that when drugs are introduced into the marketplace, the drugs should be accompanied by a pouch with a phone number so people can call in adverse reactions. Did I hear you right, first and foremost?

[*Translation*]

Mr. Jean-Pierre Ménard: Yes. There's a package insert with each drug. It contains a description of the drug, specifies the risks involved, and provides certain indications. It is clear that under the statute and regulations, the manufacturer should be obliged to indicate to the user where to report any adverse effect. This would allow users to provide greater feedback. Therefore, those who believed, rightly or wrongly, that they experienced adverse effects could draw the attention of public authorities to this problem.

[*English*]

Mr. Lui Temelkovski: This phone number where it should be reported, would you be in agreement to have it reported to Health Canada, or should it be reported to the manufacturer of the drug?

[*Translation*]

Mr. Jean-Pierre Ménard: I think it must be reported to public authorities. Currently, under-reporting is said to be prevalent. The problem regarding post-market regulation is that expectations concerning self-regulation by pharmaceutical companies are much too high. Yet, through experience, we know that this mechanism works to a certain extent, but is very limited. In order to gain public trust, and guarantee accountability within the process, a neutral public authority must be responsible for regulation.

[*English*]

Mr. Lui Temelkovski: We agree so far. Once it is reported then to the public authority—to Health Canada—how do we engage the shareholders, the doctors, the pharmacists, the health professionals? How do we engage them to increase the reporting, or is it not necessary as long as it is quality reporting rather than quantitative reporting?

● (1250)

[*Translation*]

Mr. Jean-Pierre Ménard: I believe that quantity is just as important. With respect to reporting adverse drug reactions, we could opt for a highly elaborate formula that only a professional would be able to understand easily, but it would be preferable to adopt a rather simple process. If we are serious about prevention, we absolutely need a critical mass. In other words, out of 10 adverse drug reaction reports, two or three will be significant. Nonetheless, we cannot focus exclusively on the good, the strongest and the best. I think we need to invite ordinary people, especially professionals, to get involved in the process. Among other things, we have to dedicate ourselves to educating the public and professionals.

Even if this matter falls under provincial jurisdiction, professional associations also have a role in educating their members. In my opinion, people are receptive if they know that there's a purpose, and that things will be studied and analyzed. It is much easier to convince people when that is the case.

As we speak, some doctors who have filled out and sent in their reports say that they do not have the slightest idea of what happened next. We must make sense out of all this. It would be important for the message to be conveyed by the relevant public authority.

[*English*]

Mr. Lui Temelkovski: Public reporting is done on a small number; we've heard about 10%. Should we look at public reporting in other jurisdictions, such as other countries, and do you think that pharmaceutical companies that have that data should be obliged to share that information—that international experience—with local authorities?

[*Translation*]

Mr. Jean-Pierre Ménard: We did not identify any countries where adverse reactions were reported 100% of the time. The number of reports varies according to country, but rates never reach 90% or 95%. Rates are always lower. There are two schools of thought. Some say that even if we make reports mandatory, if there are no sanctions or consequences, this will mean that nothing will happen and people will not comply. It is tantamount to legislation being enacted and nothing being done to make sure that it is respected. Conversely, if an obligation is built into the law, this means that the issue is considered important, and by extension makes people's responsibility just as important. The person who holds such information and does not report it...

[*English*]

The Chair: Could you just sum up, Mr. Ménard?

[*Translation*]

Mr. Jean-Pierre Ménard: I believe that a public message can be sent through making such reports mandatory.

[*English*]

The Chair: Thank you, Mr. Ménard.

We'll go to Mr. Tilson.

Mr. David Tilson (Dufferin—Caledon, CPC): Monsieur Ménard, there is no statutory obligation for a doctor to report an adverse reaction. From your experience as counsel, what does case law say? What are the courts saying? In other words, there are lots of malpractice actions. I would expect that if a patient comes to see the doctor and says that he or she has had a reaction, and the doctor thinks that maybe it is genetics or maybe the person didn't follow a prescription or maybe it's all kinds of things, then maybe it's malpractice. My question to you is whether the courts have said that the doctor should have reported this and that this is part of a malpractice action. In turn, would that cause doctors to report all cases of adverse reactions?

[*Translation*]

Mr. Jean-Pierre Ménard: Firstly, there are laws that oblige doctors to indicate other things. For example, we have a law on youth protection, as well as a law on mandatory reporting. In Quebec, under the Health and Social Services Act, there's an obligation to declare all accidents or incidents. They are broader, but they are obligations nonetheless.

Legally speaking, we have, indeed, yet to find a ruling in case law that sanctions a doctor for not having made a report. Why? Because in civil litigation, it must be proven that a doctor made a mistake and that this mistake was harmful to the patient. Yet, when patients consult their doctor because they believe that they are having a bad reaction to a drug, the act of reporting or not reporting this incident —even if that in itself could constitute a breach in civil law—is not the cause of the patient reacting adversely to a drug. Generally speaking, this is not the type of offence that would lead to a malpractice suit. This is why we do not have any case law of this nature.

The only way of making doctors more accountable for their actions is by broadening these obligations through professional ethical codes, or statutory law. Nonetheless, with respect to case law, the courts are not sanctioning this type of offence in civil litigation because the offence in and of itself did not result in the consequences suffered by a patient. It may have consequences on other patients if a report is not made however, there could consequences for other patients. Perhaps other patients who were aware of the fact that a doctor did not declare information that he or she held could take legal action. It is a rather long and arduous road.

● (1255)

[*English*]

Mr. David Tilson: On the obligation to report by pharmaceutical companies, Mr. Brogan, can you tell me what that is? Do they have to tell Health Canada? Can they just say that it is a minor thing and that they are not going to report it?

Mr. Tom Brogan: This is a bit outside our area, and I don't know the answer.

Mr. David Tilson: Okay, you'll pass on that.

Does anyone else have any knowledge about the obligation of the drug companies?

[*Translation*]

Mr. Jean-Pierre Ménard: Currently, the obligation is contained in the regulations. We do not know how it is verified or applied by the government. It is in section 16 of the regulations.

[*English*]

Mr. David Tilson: Yes.

On the issue of regulations in other jurisdictions, we have drugs coming from the United States, back and forth, and from Europe, back and forth. Does anyone have any philosophies or statements about what links should be made with these other jurisdictions? In some areas they have higher requirements and in some areas they are not as high.

Does anyone or everyone want to respond?

Mr. Tom Brogan: In my experience, Health Canada is very well informed of what's going on in other jurisdictions regarding drugs.

Mr. David Tilson: I'm sure they are. My question is whether there should be some formal links, agreements with other jurisdictions—with the European Union, with the United States, the provinces.

Mr. Tom Brogan: I have no comment.

[*Translation*]

Mr. Jean-Pierre Ménard: Obviously, I believe that these types of agreements are needed. In other countries, there are a certain number of agreements that acknowledge drug certification, for instance. Certain processes are approved in Australia, Japan, and countries of the European Union, for example. It is clear that with respect to regulation, we could very well assess what is being done with respect to some of the activities of pharmaceutical companies in the European Union, Japan, Australia and the United States. In certain respects, we could draw inspiration from foreign regulation and even look into sharing information and expertise with respect to the implementation of certain programs and regulatory processes, in the interest of uniformity and enhancing quality control. Companies may tend to seek certification in countries where requirements are not as stringent. There are benefits in seeking to standardize and align requirements, and in implementing comparable processes and regulations. That would also prevent companies from pitting governments against one another.

[*English*]

The Chair: Thank you very much.

I'd like to thank the witnesses.

I believe, Mr. Ménard, that Madame Gagnon has a question. We've run out of time, so she can ask it to you after committee. It is one o'clock, and another committee is coming in.

I would like to thank you very much for joining us in committee. You've given us some very good insights.

● (1300)

Mr. Jean-Pierre Ménard: I will send Mrs. Gagnon a copy of my notes.

The Chair: Oh, that's wonderful. Thank you.

Mr. Jean-Pierre Ménard: I apologize not to have brought....

The Chair: That's all right.

Madame Gagnon, Mr. Ménard will send you the notes.

The meeting is adjourned.

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