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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), this is a study of the post-market surveillance of pharmaceutical products.

We have a number of witnesses with us today. We have the Auditor General, Sheila Fraser, and Neil Maxwell from the Office of the Auditor General; as well, from the Office of the Privacy Commissioner of Canada, Jennifer Stoddart, the Privacy Commissioner herself, as well as Patricia Kosseim, general counsel. From Canada Health Infoway, we have Richard Alvarez, president and chief executive officer, as well as Mike Sheridan, chief operating officer. Welcome.

I think we all know that each group has 10 minutes to make a statement, and then questioning starts thereafter.

We'll start with Madame Fraser.

Ms. Sheila Fraser (Auditor General of Canada, Office of the Auditor General of Canada): Thank you, Mr. Chair.

We thank you for the invitation to participate in your study on post-market surveillance of pharmaceutical products. As you mentioned, I'm accompanied by Neil Maxwell, assistant auditor general. I believe that some of our past findings on regulatory and post-market surveillance activities at Health Canada would be useful to the committee in its study.

In my presentation, I will highlight some of our findings on the drug products program discussed in our 2006 chapter entitled "Allocating Funds to Regulatory Programs—Health Canada". I am also pleased to talk about two other audits, where we examined programs similar to pharmaceutical products. We reported these findings in our 2004 chapter on regulation of medical devices and our 2000 chapter on the regulatory regime of biologics.

[*Translation*]

I will start with our 2006 Chapter—Allocating Funds to Regulatory Programs. In this audit, we examined issues related to the allocation of financial resources in three regulatory programs.

These programs regulate the safety and use of consumer products, medical devices and, what is of more interest today, pharmaceutical products. It is important to note that the audit was on the allocation of financial resources and how this affected that Department's ability to carry out its regulatory responsibilities.

We did not examine other aspects of pharmaceutical products, such as post-market activities. We concluded that Health Canada did not know if it was fully meeting its regulatory responsibilities for the Drug Products program.

First, Health Canada needed to determine the activities that must be carried out in order to meet the Department's regulatory responsibilities. Program managers for Drug Products indicated that they considered the level of post-market compliance and enforcement activities to be insufficient. This could have consequences for the health and safety of Canadians, such as exposure to unsafe, ineffective or dangerous products.

Second, we found that Health Canada needed to determine performance targets for the activities.

Third, Health Canada needed to determine the level of financial resources required to carry out the activities necessary to meet is regulatory responsibilities. We found that the demands on regulatory programs were increasing while the funding remained constant, making it difficult for program managers to fully meet the Department's regulatory responsibilities. Although the funding remained constant, the core funding for the Drug Products program had decreased 32% over three years, if all sources are considered.

Furthermore, most of the additional funding that Health Canada received had been allocated to pre-market activities, and funds that were meant for the Drugs Product program were reallocated to other programs. For more details about funding, please refer to the table we distributed.

● (1115)

[*English*]

In its responses to our recommendations, Health Canada stated that it planned, among other things, to improve the operational planning process; review the funding, including core funding allocated to regulatory programs; work on a cost recovery strategy and regime, including the establishment of a full costing model; introduce a budget management framework with guidelines on resource allocation and monitoring of Treasury Board decisions; and improve performance measurement.

Health Canada also promised to conduct comprehensive reviews that would serve to establish program baselines by defining the required level of activities that the program must carry out, identify the targeted performance for these activities, and identify the resources needed to carry out these activities.

Health Canada promised to make these changes by March 31, 2008, or earlier. The department's next progress report is scheduled for the end of April, and your committee might wish to examine what progress has been made, especially concerning the baseline study for pharmaceuticals.

The two other audits were about programs similar to pharmaceuticals. We found similarities in the findings related to post-market activities. We would ask you to note that these audits are dated, and we have not conducted recent audits to see if our concerns have been resolved.

[*Translation*]

Post-market activities were a concern in our 2004 audit on the regulation of medical devices. We found that health Canada did not carry out any inspection activity at the post-market phase and did not know the extent to which the regulations were being respected.

The Department had made it mandatory for the manufacturers to report serious adverse events, but had done little work to increase the number and quality of reports received from health care professionals. The rate of reporting on adverse events was significantly less for Canada compared with the US and the UK. In addition, there were weaknesses in the analysis and interpretation of adverse events, and there was no proactive system to identify patterns that could signal a serious safety concern.

We also noted that Health Canada had never developed a communications plan or strategy for medical devices to ensure that Canadians were fully aware of risks.

In addition to recommending that Health Canada address these weaknesses in post-market activities, we also recommended, due to the weaknesses also found in pre-market activities, that Health Canada make a choice: either provide adequate human and financial resources to deliver the program as designed, or redesign the Medical Devices program and the Regulations to manage risks in a way that requires fewer resources.

[*English*]

Finally, in our 2000 audit on the regulatory regime for biologics, we found that Health Canada had difficulty managing the workload of pre-market and post-market activities. Officials told us they had trouble staffing positions. We recommended that sufficient databases be implemented to adequately process, analyze, and disseminate information on adverse reactions and events for biologics.

As you can see from these three chapters, we have had concerns about resource allocation and post-market surveillance for several years now. It seems that the emphasis has been on pre-market activities, to the detriment of post-market activities.

As you know, I cannot comment on the policy approach, but I am encouraged to see that some of the issues raised in our reports, such as problems with post-market surveillance and under-reporting of adverse events, are included in the government's *Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food*.

I would like to take this opportunity to update the committee on other work we are conducting. We have a chapter on infectious disease surveillance in our report to be tabled on May 6. We would be pleased to meet with you again after tabling to discuss that.

We are also beginning an audit on electronic health records, and we plan to provide this report to Parliament in fall 2009. Several provincial auditors general will concurrently carry out audits on the same subject matter, leading to a comprehensive look at the implementation of electronic health records in Canada.

Lastly, we will soon begin developing a plan identifying the audits we will conduct over the next five years. We would be pleased to discuss our plan with you at a future date.

I hope our comments today will help your study on post-market surveillance of pharmaceutical products. I look forward to reading your report and the government's subsequent answer to it.

Mr. Chair, that concludes our opening statement. We would be pleased to answer any questions the committee members may have.

Thank you.

● (1120)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, and thank you for staying within the time. It sounds like you've done this before.

We'll continue with Madame Stoddart.

Ms. Jennifer Stoddart (Privacy Commissioner, Office of the Privacy Commissioner of Canada): Thank you very much, Mr. Chair.

[*Translation*]

I am very pleased to speak to the committee about the privacy implications of the post-market surveillance of pharmaceutical products. With me today is Patricia Kosseim, General Counsel and an expert in health law.

You have received a fairly comprehensive document prepared by our Office which starts out by saying that while Canadians regard the health care they receive as a top priority, they also consider ongoing privacy protection to be very important.

This morning, I will begin by briefly discussing some issues that are addressed at greater length in my submission, a copy of which has been circulated to members. These include the potential re-identifiability of data, the privacy implications of electronic health records, data breach notification requirements and finally, the concept of “work product” information.

The Privacy Act applies to federal government institutions, agencies and Crown corporations. As such, it applies to government health surveillance programs such as Health Canada's Canadian Adverse Drug Reaction Information System or CADRIS, and other government initiatives, such as the Federal Health Care Partnership's plans to develop electronic health records.

[*English*]

I'll start with the issue of re-identification of data as a privacy issue in post-surveillance of medications.

From a privacy point of view, one of the key issues we grapple with is the concept of re-identifiability, particularly in the era of increased digitization of health data and surveillance programs, proliferation of publicly available information through the Internet, and sophisticated technological capacity to link up information across different databases. Personal information is critically defined in both the public and private sector law as "information about an identifiable individual". Exactly what is identifiable or potentially identifiable is a relevant issue for your present study.

Re-identification was at the heart of a recent decision in January of this year by the Federal Court in the matter of Gordon and Health Canada and the Privacy Commissioner of Canada. We were interveners. I bring to the attention of this committee four points.

First, in a situation involving personal information about an individual, the right to privacy is paramount over the right of access to information. That was the first major conclusion of this recent finding, which is not being appealed.

Second, the Federal Court adopted the legal test that was proposed by my office, and I quote: "Information will be about an identifiable individual where there is a serious possibility that an individual could be identified through the use of that information, alone or in combination with other available information."

Third, the court concluded that disclosure of some information, in particular factual circumstances, where it is combined with personal information, is to be scrutinized for its effect on personal information.

Finally, the Federal Court emphasized the importance of ministerial discretion in deciding whether or not to exceptionally release this personal information in the public interest.

On privacy considerations in electronic health records, major initiatives under way to develop electronic health records promise great things for Canada's health care system: improved quality, efficiency, productivity of health care services, enhanced patient safety, more evidence-based decision-making, facilitated knowledge transfer, and greater accessibility to services and treatment.

So as health information structures proliferate across the country, the traditional lines between health care, surveillance, quality assurance, and research will become increasingly blurred. This is not necessarily a bad thing; however, the notion of purpose, which is such a critical concept in data protection laws, and the ones individuals actively turn their minds to when they provide informed consent in any meaningful way—we all ask what you want this information for, and what's going to be done with it—is increasingly being challenged by this approach.

As the concept of purpose becomes stretched, other purposes can begin to creep in. Beyond health-related purposes are other more worrisome purposes to which personal health information may eventually be put, particularly as external pressures for such information continue to rise. Marketing, employment, insurance considerations, law enforcement, and national security are just some purposes that loom on the horizon. These are clearly not part of the deal that Canadians think they are getting themselves into when they think of the development of electronic health records.

Another critical concept that is increasingly being challenged in the context of EHRs and electronic clinical trials is the central concept of accountability, particularly as more and more entities join up through interoperable systems, as public-private partnerships develop to leverage resources and achieve commercialization objects, and as data flows across provincial and national borders in a global economy. So I guess that's where I join up with my colleague the Auditor General.

In order to help work through some of these challenges, our office is participating in the recently created Canada Health Infoway privacy forum that brings together representatives of the health ministries and privacy oversight offices across Canada. We're very pleased to be part of this critical discussion that is starting to address issues of informed consent, secondary purposes, and accountability as they relate to the implementation of interoperable pan-Canadian electronic health record systems.

● (1125)

[*Translation*]

The third issue is data breach notification requirements as they relate to privacy.

With the growing digitalization of health data also comes increased scope and impact of potential breaches. A number of recent cases which I highlight in my submission have brought this problem to light. Not a day goes by in Canada without a report of someone finding identifiable personal health records in a trash cash behind a clinic, hospital or doctor's office.

Industry Canada is currently looking at how to incorporate into the Personal Information Protection and Electronic Documents Act, or PIPEDA, mandatory breach notification requirements. This is a welcome development which we hope will serve as an incentive for organizations to put proper security safeguards in place and to be open and transparent when something goes wrong.

In the meantime, our Office has issued guidelines to support organizations through critical actions steps, including assessing the risk and extent of potential harm, and deciding when, how, who and whether to notify individuals. When dealing with highly sensitive personal health information, special considerations should be taken into account, such as psychological risk of harm.

I would now like to turn to the section of my submission on work product, an issue that was discussed at length when other parliamentary studies were conducted on personal information protection. I am available to answer all of your questions about how concerns over protecting information apply to this area.

[*English*]

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

We'll continue now with Mr. Richard Alvarez.

● (1130)

Mr. Richard Alvarez (President and Chief Executive Officer, Canada Health Infoway): *Bonjour*, Mr. Chair and members of Parliament. With me today is Mike Sheridan, our chief operating officer. On behalf of Canada Health Infoway, I want to thank you for the opportunity to contribute to your study on post-market drug surveillance.

Since we don't have too many opportunities to appear before you, I'd really like to take the liberty of telling you about some of the important work we're engaged in, work that I believe will transform the delivery of health care in Canada.

Created in 2001 by Canada's first ministers, Infoway's mandate is to accelerate the development and adoption of electronic health records—or EHRs, as we call them—across the country. Infoway is an independent not-for-profit corporation whose members are Canada's 14 deputy ministers of health. We are funded by the federal government and operate as a strategic investor with all 13 provinces and territories, jointly investing in core systems across the country. I will explain in a moment what these core systems are.

First I will say that the collaboration has been unique and a remarkable success story. By working together, provinces and territories are sharing best-practice designs and systems, which have dramatically reduced the cost, the time, and the risk.

Having read some of the testimonies before the committee, I note that previous presenters suggested our emerging EHR infrastructure could be part of the solution of effective post-market surveillance of drugs. Infoway certainly agrees that the potential exists, but as I will outline, there are some challenges.

The good news is that while our solutions have not been specifically designed for surveillance, they are already contributing to reduce adverse drug events.

I have a simple example, if you will allow me to share it with you. In Ottawa one evening a senior enters an emergency ward, confused and disoriented. Physicians need to stabilize his condition with drugs, but first they need to know which other medications the senior may be taking. Fortunately, today every emergency room in Ontario now has access to the drug profile viewer, which enables authorized physicians to view the medication profile of every recipient on the Ontario drug benefit plan, thus preventing dangerous interactions and adverse drug events before prescribing or dispensing.

I would like to explain some of the core systems that Infoway and its partners are introducing, but first, as a precursor to everything else I say, we recognized from the start that the success would depend on privacy and security being fundamental to all the plans we develop, to all the technology we design, and to all the systems implemented by the provinces and territories.

Our chief privacy strategist works closely with her counterparts at the federal level and with the territories and provinces. We have a team of senior engineers dedicated to designing privacy and security best practice into our core architectures, which are the basis of specifications that jurisdictions will use with their vendors.

Each project must carry out a privacy impact assessment that examines the solutions against the privacy requirements of that applicable province or territory.

To support the data needs of public health officials, researchers, and policy-makers, the systems are being designed to accommodate the identification. This would allow data to be accessed and studied anonymously, providing a wealth of health indicators.

So where are we today? Each province and territory has established a detailed three- to five-year road map to build the foundation of the electronic systems they need. Almost 260 projects are under way, representing an investment by Infoway of approximately $1.5 billion, or 95% of our total funding.

Jurisdictions' contributions, I should add, for development, deployment, adoption, and ongoing maintenance often represent multiples of this amount.

The bedrock of electronic health records are five complementary clinical information programs, or the core programs, which we jointly invest in. Each program on its own is delivering important benefits to Canadians and our health care system. Together, they capture a patient's comprehensive medical history. This is where we ultimately need to be, where all clinicians have all the right information at the right time to deliver safe, efficient care.

The first program is our registries programs, basically a sophisticated electronic directory that unambiguously identifies patients, health care providers, and in some jurisdictions health institutions.

Our next program is the diagnostic imaging program, focused on digital storage, retrieval, and sharing of a patient's X-rays, ultrasounds, MRIs, and CT scans. Going digital eliminates the cost and the inconvenience of handling film. It allows radiologists in urban centres to service remote or under-serviced locations. It has increased diagnostic speed and integrity, while improving the productivity of our radiologists—and they are pretty scarce.

Our next program is the lab information system, which allows clinicians to electronically capture and view lab results and reports from hospitals and community and public health laboratories. This reduces the time for diagnosis and eliminates duplicate tests.

● (1135)

The drug information system represents Infoway's fourth clinical program. Drug systems allow prescriptions to be sent, viewed, dispensed, and confirmed electronically. When they are fully implemented, they will automatically flag to the prescribing physician and dispensing pharmacist the potential dangerous drug-to-drug interactions and allergic reactions associated with a particular drug.

When Infoway began its drug investment program, very few provinces and territories had plans for a system that would provide all these capabilities. Over the last year, however, the strategies of collaboration, development, and shared cost have spurred most jurisdictions to undertake drug information systems that will cover all drugs for all people, which is a very important development.

Our last, and in many ways most important, program is the interoperable EHR, or the glue that hangs some of these other programs together. It consolidates an individual's health information from a variety of sources, including the ones I've outlined, into a single secure and integrated health record. Depending upon funding considerations and jurisdictional readiness by 2010, we're very hopeful that the interoperable EHR will be available for 50% of Canadians.

Let me close with specific issues on post-market surveillance. As you well know, the complexity of drug monitoring is exacerbated by the explosion of new products and by the aging population living with multiple chronic diseases and taking several different drugs. Drug trials typically target a limited population over relatively short durations. Often they lack real-world exposure. Analyzing de-identified data sources from EHRs that contain prescription information, examination findings, lab reports, diagnostic test results, and other patient outcome information at the population level would allow benefits and risks to be more rapidly and effectively assessed. Subject to privacy considerations, technically de-identified data could be loaded into an aggregated database in a format that allows analysis using various reporting tools.

In the future, it may be possible early in the drug life cycle, or at any point, to track efficacy and patient safety across a wide population.

Now comes the bad news, because having said this, I must caution the committee that, first, our current plans and funding do not include the tools or the required analysis systems to do post-market surveillance studies. Second and more immediate, although completion of our current goal in 2010 represents a significant milestone, it represents less than half of the EHR solution.

To finish what we've started takes commitment, and unfortunately it takes money. Two recent studies estimate that a total of EHRs for all Canadians in all settings would be about $350 a Canadian, or about $10 billion spread over 10 years. The promising news is that these same studies confirmed that once fully implemented, electronic health records will deliver savings estimated at between $6 billion and $7 billion each year, money that can more productively be reinvested in other priorities, whether they be health care, education, innovation, or infrastructure.

In conclusion, Canada is implementing a powerful health information platform whose driving force has been better health care for individual Canadians. Once in place, it may present opportunities for building secondary applications such as post-market surveillance for drugs.

Mr. Chair, that concludes my opening remarks. I would be delighted to answer your questions.

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

We will now start the seven-minute question and answer period with Dr. Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thank you all very much.

My concern has always been that the technology is there to actually help us do this right away. If we look to the veterans administration in the United States, from the worst care in the country to the best care in the country, most of that was transformed because of their insistence on an electronic health record in a hurry.

I have huge concerns that even though the technology is prepared and able to encrypt the data, the examples that keep being used around privacy are ones where the data was not encrypted, and that privacy bogeyman keeps getting in the way of our getting on with what we need to do.

If we remind ourselves of Judith Maxwell's very important work during the Romanow commission on what patients and Canadians think about privacy, where they are more than willing to let their family doctor let the consultant know what's going on, we have been hindered sometimes by various health professions not wanting their prescribing practices tracked, as opposed to the patients, who actually do want to know whether their information being shared without the identifiers on it could make a safer system. I think most Canadians would want to be part of that.

If we go forward—and we heard in this committee last week that it's the written prescription that means the diagnosis can't be put on it, because it's a scrappy piece of paper that can fly anywhere and have the diagnosis and the prescription on it—I would want to know, first from the Privacy Commissioner but also from Infoway, can we and could we, if we had the resources, go immediately to electronic prescribing that included the diagnosis, which would actually help us with off-label prescribing and would help us with everything from recalling a drug to all the things that we are worried about in this real-world safety, of what we're talking about in post-market surveillance?

● (1140)

Ms. Jennifer Stoddart: Honourable member, that is a very specialized question about the role of diagnostic information. I would say that it probably could be done if you took the appropriate privacy precautions. The issue would be, is this information personally identified? If it's not personally identified, if it's de-identified, is it identifiable? How easily would it be identifiable, and who is it being shared with? What are the security considerations around it: the encryption, the safety procedures, the security procedures, and so on?

Properly done, this might be possible. Not properly done—and that's why we are working closely with Canada Health Infoway and the provincial commissioners—this could be very injurious to Canadians if their various personal diagnoses are found in trash cans in alleys, as is now happening with health information.

So you understand that it's a severely qualified answer.

Hon. Carolyn Bennett: Yes.

Given the investments that we are prepared to make with Infoway and with the provinces and territories around encryption and around using the technology possible—two key systems, whatever it is—with due respect, I'm concerned that this is now being discussed between privacy commissioners and technical advisers of Infoway, and that the citizens of Canada are not actually being involved in a meaningful way in a citizen engagement process by which they could determine what risk they are prepared or not prepared to have in order to get the best care for themselves possible, as well as the safest possible system, including post-market surveillance.

Is there a citizen engagement process to deal with this issue of privacy and health records?

Ms. Jennifer Stoddart: We do polling on an annual basis. That is the extent of our direct consultation on this area. Perhaps Canada Health Infoway and the provincial commissioners, who are not here today—

Hon. Carolyn Bennett: With due respect, I don't think polling has any relevance on this, because it just depends on what kind of question is asked. A proper process involving deliberative dialogue, in terms of the risks and the positives, is the only way that something as sensitive as this can be determined. I would like to know whether Infoway has the resources.

How do privacy commissioners determine what is the value system of Canadians without talking to Canadians in a deliberative fashion?

Ms. Jennifer Stoddart: On that answer, honourable member, we rely on the laws that I have to administer, and their interpretations. Regarding the complaints that come before us, I remind you that we have many complaints. We've intervened, and I just gave the example of the very important complaint dealing with the release of a field of information—which was the province—in the CADRIS database, and our role in intervening on that. So we do this indirectly. For the moment, my office is not equipped to run general personal consultations on something that, with due respect to the question you asked me, is a very specific question about diagnostic information.

What we know from documents, from being active in this field, from talking to our partners, is that Canadians value both. They value their health. They value their health system. They also value their privacy. They're willing to make arrangements—even, one might say, compromises—between the two, as we all do in balancing our privacy values with the other things we may want to achieve in this society.

● (1145)

Hon. Carolyn Bennett: I can remember that one of the realities of being a family doctor was that I happened to be up all night delivering a baby when a drug was recalled, so I didn't see the news that night. The patient who came in first the next morning had seen on the news that a drug that they were on had been recalled. At that point, I had no way of sorting out in my office which other patients were also on that drug, other than by memory.

We know that it would be possible with a proper system to involve the patients. And certainly, the heart-rending testimony of one of the witnesses whose daughter was still on the drug months after it had been recalled....

So in terms of patients and Canadians being polled on this information, they need to hear the stories that would inform perhaps a broader understanding of what privacy really means.

Maybe, Dick, you can tell us how far you are on being able to get all the doctors hooked up so that we can recall a product in an effective way. Or do you think that will be done through the pharmacies?

The Vice-Chair (Mr. Lui Temelkovski): In 30 seconds or less.

Mr. Richard Alvarez: You've asked a lot of questions. Let me just stop and say, look, we're trying to run a 21st century health care system with 19th century paper. And there is absolutely no security in the paper world. Papers are used on movie sets and they fly all over Toronto—actual medical records. We've had those types of examples.

So yes, we have done discussions and polling with Canadians. Ninety percent of Canadians want the electronic health record as long as their privacy considerations are looked after, and they look to the people they put in place to make sure those are looked after. When they're told there be will an audit trail, that if there's unauthorized access they will be informed about it, the comfort levels certainly go a lot higher.

So from a privacy perspective, we are putting in a whole host of things—user identities, user authentication, access control, and a whole bunch of things. But the way the systems have been designed, you have a client registry that has demographic information; it's not a lot of use to most people. With the labs, the drugs, etc., not only is the data encrypted in there, but it has a code that has to get hooked up to the client registry before you can find out whose information it is. So even if you hack into those systems, you're not going to be able to find out whose information it is.

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

We've gone a minute or so over.

Monsieur Malo.

[*Translation*]

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

Thank you for joining us today.

Mr. Alvarez, I would like to come back to something you said in your conclusion. You quoted some figures that are sure to please the Auditor General, and perhaps she will be tempted, during the course of her study on electronic health care, to take a closer look at them. However, I'd like you to elaborate further on your comments.

You told us that while it would cost $1 billion a year over ten years to implement an effective system, the resulting savings would be in the order of $6 to $7 billion a year. In addition, this would put an end to adverse events in relation to prescription drugs and post-market surveillance.

I would simply like to know how you came up with these figures. If they are conclusive, how is it that everyone who hears them is not proclaiming this as the solution for the future? For an outlay of $1 billion a year over 10 years, we can save $7 billion a year. It seems to me that if these figures were accurate, we would already have opted for this course of action.

Could you elaborate further on this scenario.

[*English*]

Mr. Richard Alvarez: *Veuillez m'excuser*. I'm going to answer in English, but my colleague over here might want to add something.

First, these numbers haven't been pulled out of the air. The numbers have basically been derived from two major studies, one by Booz Allen, one by McKinsey & Company. Also, we have similar sorts of numbers when studies have been taken in the U.S., certainly when projects like this have been rolled out in the NHS system in England, and certainly in the Scandinavian countries, etc., and in Australia when they've done the numbers.

The simple fact is this. For years we haven't invested in these systems, because it's very difficult at times to sell these infrastructure systems to the public. It's much easier to sell another doctor, another nurse, another MRI machine, another piece of equipment. If you're really going to transform the system, then you have to have some evidence-based medicine in which to work, and this is the way it brings you evidence-based medicine, by having these technologies.

Look at the financial industry. It would not be able to perform today without the kind of computerization it put in. Let me tell you, that in itself took 20 years and a lot of money. When they transformed that industry, they were spending anywhere up to 12% of all their revenues. Today they're spending probably about 6%, because the systems, the ATMs, are there.

In Canada we're spending anywhere between 1.5% and 2% on information technology, and that's right across the country. We can't make these kinds of changes unless we get it up to about 4%, but it's a very tough sell to be able to do that.

In terms of the benefits, I don't think treasury's going to take out that $6 billion and $7 billion. I can tell you that with the tsunami of our aging population and chronic disease, they really are going to be in a position where we can expand the capacity, improve the access, if we put these systems in place.

Mike.

● (1150)

[*Translation*]

Mr. Mike Sheridan (Chief Operating Officer, Canada Health Infoway): As Mr. Alvarez said, EHR systems have not been implemented everywhere in Canada. Nevertheless, to give you some idea of the benefits to be had, I would just mention diagnostic imaging. According to the follow-up studies that have been, the productivity of radiologists has increased by 20%.

These studies weigh other possible program benefits, and the potential for using funds. When we look at everything, at amalgamating drug systems, diagnostic imaging systems and laboratory systems on a Canada-wide basis, the potential for substantial savings is clear.

Mr. Luc Malo: Would you care to comment on that statement, Madam Auditor General? Can we in fact do this kind of cost-benefit analysis using the information currently available to us?

Ms. Sheila Fraser: Obviously, I cannot comment on this particular matter because we are just beginning our audit.

Given the scope of the project, we would expect a cost-benefit analysis to be done, because we are talking after all about several hundreds of millions of dollars.

As Mr. Alvarez mentioned, we can draw on the experiences of other countries and adapt these to the Canadian reality.

Mr. Luc Malo: Will you be focusing on this area in your audit?

Ms. Sheila Fraser: I would assume so. Perhaps my team would not want me to commit to doing something that wasn't planned, but this is certainly the kind of information we would include, whether the organization did a study and assessed potential. However, we would not be verifying these studies or giving them any credibility. It would be more a matter of making a passing reference to them and nothing more.

Mr. Luc Malo: May I ask the Privacy Commissioner one small question?

Some of the witnesses who testified before the committee talked about doing more work with the human genome in an effort to establish a causal link with respect to drug adverse events.

Could the use of the human genome in studies of this nature have privacy implications?

Ms. Jennifer Stoddart: Yes, it could. Our Office is following very closely the issue of genome studies and genetic studies. In fact, this is one of the four research and action priorities that we have identified for the next few years, given the implications for privacy and other areas ranging from medicine to crime prevention legislation, national security considerations and so forth.

● (1155)

Mr. Luc Malo: In spite of everything, could the human genome be used in post-market studies to advance science, and at the same time, could people's privacy still be respected in the process?

Ms. Jennifer Stoddart: That is a very touchy question. In theory, I see no reason... There may be certain ethical, medical or scientific considerations of which I am not aware. In theory, if personal information protection laws are well crafted, they do not stand in the way of scientific advances.

It is important to distinguish between information that is truly personal, that is provided in a medical context, and other information that may be provided under other circumstances, for example, to Revenue Canada. Where privacy is concerned, it is important to look at the context.

Nevertheless, in theory, there is no reason why science could not benefit from human genome studies or why personal information could not still be protected at the same time.

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

Thank you, Mr. Malo.

Go ahead, Ms. Wasylycia-Leis.

[*English*]

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

Thanks to all of you for your presentations.

I want to start with the Auditor General.

Madam Fraser, you focus on some of the deficiencies in the system with respect to post-market surveillance. And you express hope that the new safety plan and the legislation that was just tabled this week will help in that regard. I want to get to that. But I first want to ask if you have evidence to suggest that we've actually done a proper job in terms of pre-market surveillance.

You say that without post-market surveillance there are consequences for the health and safety of Canadians because of exposure to unsafe drugs and products. If there are unsafe products getting to market, then maybe we haven't done a proper job in terms of actual pre-market surveillance.

You mentioned money. One indicator is that more of the money available has gone to pre-market than post-market. But has that produced any better results? Are we producing any safer products? Are there fewer incidents in terms of drugs on the market with respect to reactions and so on?

Ms. Sheila Fraser: Thank you, Chair.

The last time we actually looked at that question was in 2004, when we looked at the regulation of medical devices. We looked at the whole licensing activity there and at the pre-market evaluation process. We found that Health Canada was following their process rigorously. The issue there seemed more to be delays, but they did have a process.

That doesn't mean that because you have a good process to license a product problems won't surface after it's on the market. That's because of the limited trials and a number of reasons. So when we looked at medical devices, we found that the pre-market was fine. For post-market, though, there were a lot of issues—very few inspections of manufacturers, the whole question of reporting of adverse reactions, and the list goes on and on.

The more recent audit we did was on the department's ability to assure Parliament and Canadians that they were carrying out their regulatory activities appropriately. We expected, for a regulatory program, that the department would know what activities it should carry out, at what level—for example, the number of inspections it should do—what resources would be required, and what funding would be needed. We found, quite honestly, none of that. They would have inspections, but they would not be able to tell us how they had arrived at the number, what an appropriate number of inspections they should be doing was, or what resources would be required.

So there was the whole question of how the department itself knew that what it was doing was appropriate and sufficient.

On the whole question of funding, it started, actually, in our audit on medical devices. Some of the regulatory programs effectively have no base funding, and funds are being reallocated. Even funding that's been given for special initiatives—it could be for pre- or post-market activities—is being reallocated to other programs within the department.

So unless there's a clear baseline, a clear analysis of what activities should be carried out—what the baseline is, what the results of all that are, and what resources are required for the regulatory programs—it's difficult, I think, for Parliament to have assurance that these regulatory programs are being managed well.

● (1200)

Ms. Judy Wasylycia-Leis: In other words, what you're saying is that we must get the department to come to this committee with information that was promised by March 31 of this year, in order to assess?

Ms. Sheila Fraser: That's right. There's a report that is to be tabled shortly. It is to be ready within this month, and I would certainly encourage the committee to ask the department to provide that report and perhaps to have a discussion with them on where they are in addressing those recommendations.

I think Mr. Maxwell would like to add a comment.

Mr. Neil Maxwell (Assistant Auditor General, Office of the Auditor General of Canada): Thank you, Chair.

I have just a short comment, which is to say again that it is worthwhile to follow up on that baseline report or, as they were calling it, comprehensive review. And it has been promised already to Parliament. The public accounts committee has been promised a copy of that, so I would think it would be available.

Ms. Judy Wasylycia-Leis: Is there an obligation on the department to table it in Parliament?

Ms. Sheila Fraser: They have committed to tabling it with the public accounts committee.

Ms. Judy Wasylycia-Leis: Okay. I'd love to spend more time on this, but I should get on to post-market surveillance and the question of adverse reactions, since that's our study.

I'd like to ask both of you, Madam Fraser and Mr. Alvarez, since both of you talked about the responsibility right now of manufacturers to report adverse reactions to government. I think you, Madam Fraser, have indicated that, at least in the past, that has not been done adequately. I haven't seen evidence to suggest that it's been done any more effectively recently. In fact, who should get the information and who's responsible are contentious points around these committee hearings. In the new legislation that just came down, there is an attempt to make mandatory reporting from health institutions, and lots of the witnesses here have big concerns about that.

What would be your advice on adverse reporting? Do you see that it's actually happening, that manufacturers are doing their job? Are we getting complete reports? How do we make it happen?

Ms. Sheila Fraser: Again, Chair, I'll refer to the audit we did in 2004 on the regulation of medical devices. I caution, again, that this is dated information.

At that time, we noted that there were several weaknesses in the analysis and the interpretation of data. While the manufacturers and importers were required to report adverse events, Health Canada had done very little work to increase the number and the quality of reports that were received from health care professionals, who are, of course, the first ones to see this. We compared in that report the rates of reporting among Canada, the U.S. and the U.K. In 2002—I'll just provide the information—the rate of reporting of adverse events per million of population was 510 in the U.S., 148 in the U.K., and 33 in Canada, which obviously would lead one to believe that the reporting of adverse events is not complete and is not adequate in this country.

Ms. Judy Wasylycia-Leis: Mr. Alvarez, do you have any reason to believe that's changed? How would you address the legislation on adverse mandatory reporting?

Mr. Richard Alvarez: Mr. Chair, I'm not in a position to address the legislation, but I am in a position to tell the committee that for the first time in Canada, we are now setting up databases on drugs and on other products that will have all people and all drugs. So even if you wanted to do true post-market surveillance prior, you didn't have the information to do that type of work. You had to rely on the pre-marketing through clinical trials.

We're now in a position to move in that direction, obviously depending upon privacy considerations, etc., which I know can in fact be incorporated, and these studies can in fact be done. I think, as we're moving into the system—and it's basically there in British Columbia and Alberta, and it's moving very quickly in Saskatchewan and in P.E.I—over the next 18 months to two years we will see these systems in place. It's going to take some will to increase our post-marketing surveillance, because the data will in fact be there.

● (1205)

The Vice-Chair (Mr. Lui Temelkovski): Just wrap up.

Mr. Richard Alvarez: In terms of reporting, there are many pilot studies that we invest in to look at the feasibility of things that have never occurred before, and one of them is adverse events reporting. We are investing in a study with British Columbia right now in a neonatal unit.

Since the process started, the adverse reporting has tripled in terms of the reports that they were filing earlier on, and the follow-up has been substantial as well. Obviously if there's a will, there is a way of doing this.

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

We'll move on to Mr. Fletcher.

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

I would also like to welcome Rob Clarke, the new member from Saskatchewan. I think Rob would be pleased to see that this committee is well behaved and is doing important work.

I won't comment on who's here and who's not here at present, but just on the Auditor General's report. Health Canada did respond to that report by tabling an action plan in February 2007. The action plan included commitments, I understand, by the department to put in place measures to improve resource allocation and operational planning, processes, performance measurement, and costing programs.

I believe the department also committed to conducting comprehensive reviews of its regulatory programs, and there are progress reports being provided every six months to the public accounts committee dealing with your report. I understand that report will be tabled here at health committee as well.

Madame Fraser, I wonder if you could comment on the impact of these follow-ups. I believe Health Canada accepted all of your recommendations.

I am just going to get all my questions out off the top.

In regard to Infoway, it seems that Infoway is going to be key in any post-market surveillance program. I wonder if you could explain to us the challenges of dealing with 14 different jurisdictions, private sector physicians, and all the other stakeholders, and what your approach is in dealing with those challenges? What is your vision regarding the health records of the surveillance tool?

If there's time, I'd ask the privacy people to comment on the previous two witnesses' comments.

Ms. Sheila Fraser: Thank you, Chair.

I would just respond that, yes, the department agreed with all the recommendations in that audit on the allocation of funds for the regulatory program. It did provide an action plan. In fact, it did begin even to take action on some issues we could see toward the end of our audit and even during the course of the audit. So we are cautiously optimistic that the issues will be addressed, but we will only make a final judgment when we go back to actually re-audit the issue and see if the department has put in place the actions it has committed to do.

Mr. Richard Alvarez: Mr. Chair, let me speak first to the approach. I've been in health care for nearly 25 to 30 years, both at the provincial and at the national level, and I've never seen as high a level of cooperation between the federal government, the provinces, and the territories as around this initiative.

The example I gave is that at one point in time, and not so long ago, with the exception of PharmaNet in B.C., where they were collecting information on all drugs and all people and giving it to the pharmacists to do the kind of work we're talking about on adverse drug events.... That was a 10-year-old project, and it never ever took off anywhere else in Canada. Today, it's now going to be right across Canada, adopting very much the same designs. And it's the same for the labs and the diagnostic imaging. It's the same for the architecture. All of the provinces and territories are coming together. And we've been using federal dollars to leverage their dollars, as well.

So in this arena, we don't have a program that goes into health surveillance. So there could well be a program started around post-surveillance that will have a common design, because you're going to need to be able to get a critical mass of as much data as you can; you're going to be looking at trends across the country. So there is a way, from a leadership perspective, to build this on a national basis, where the jurisdictions do collaborate with the federal government and others.

In terms of the EHR as a surveillance tool, as I said in my remarks, there is enormous potential, as long as it's done right from a privacy perspective.

● (1210)

Mr. Steven Fletcher: By the way, the federal government did invest an additional $400 million into Infoway, in addition to the $1.2 billion that was in the fund originally.

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

Ms. Jennifer Stoddart: Thank you, Mr. Chair.

In response to the honourable member's question, I'm going to comment on the Auditor General's report. We too audit, but we audit for the protection of personal information. We think it's a very useful way to encourage compliance.

Last month, I tabled my reports on plans and priorities for the coming exercise before this House. In that you will find that we plan to audit electronic health information in its relation to personal information management, both in Infoway Canada and in Health Canada. But to do that we are going to wait until the fiscal exercise in 2009-10, after the Auditor General's report and then the follow-up has been tabled, from not only the reports that she just talked about, but her coming Infoway report, so we don't duplicate anything her office has done.

Mr. Chair, may I ask our general counsel to talk about the challenges of coordinating privacy among 14 jurisdictions?

The Vice-Chair (Mr. Lui Temelkovski): Absolutely, please.

Ms. Patricia Kosseim (General Counsel, Office of the Privacy Commissioner of Canada): Thank you, Mr. Chair.

Certainly the challenge of dealing with federal, provincial, and territorial realities is a real one, and we commend the leadership of Infoway for the great work they do in that area.

From a regulatory perspective, juggling those different regulatory frameworks is also quite challenging. Not only are there 14 jurisdictions and laws, but within each jurisdiction there are different laws, some dealing with the private sector, some with health information, and some with general personal information.

One example of where leadership can come to bear on these sorts of challenges is how, over time, the regulatory frameworks have either adapted or evolved or have been amended to enable the reality of electronic health records to work with the Canadian public to an acceptable and agreeable solution for implied consent within a circle of care, so that when individuals go to see their physicians, they understand that the information in the electronic health care arena can be shared with other health professionals engaged in their circle of care or their treatment without necessarily having to go back to get their informed consent every time. That concept has grown to be acceptable and workable.

However, there are other concepts that remain very distinct in each jurisdiction, that have yet to be resolved and harmonized. For instance, the rules for using personal health information to support research or surveillance or other secondary purposes outside that circle of care are not harmonized around a certain agreeable standard.

There is still work to be done. We're pleased to work with Canada Health Infoway and the privacy forum to begin to address those challenges. As well, Infoway senior officials have come to our FPT privacy commissioners meetings in recent years to give us regular updates.

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

Now we'll move to the second round, a five-minute round, with Mr. Thibault.

● (1215)

[*Translation*]

Hon. Robert Thibault (West Nova, Lib.): Thank you very much, Mr. Chairman.

[*English*]

Thank you all for your presentations.

I understand the complexities of privacy issues and provincial legislation and regulations and of trying to work your way around those, but it seems to me, as a simple citizen, that if the Canada Health Infoway or the health providers out there are using the information about me for the purposes it was gathered, then it's being done on my behalf to improve my outcomes. So it would seem to me that for most of the users of this information, if you could separate their data from their personality, then I wouldn't have any problem with it. It wouldn't matter to me if anybody in this country, any researcher, etc., knows there is a Canadian of a certain weight with certain medical conditions, and of a certain age. I don't want my insurance people to know that; I don't necessarily want all this information out there, but as far as the medical practitioners are concerned, they can know there's such an individual.

I want the people who will have to work with me to have my identity and all of that information immediately. I'm willing to take a little bit of a risk for that; I'm taking a little bit of a risk that maybe somebody would get some information I'd rather they not have, provided that the people who do need it will have it. I don't know if that's the same risk as my medical records flying off a movie set.

So I hope that we will be able to find such an accommodation and that the provinces are working with the federal government in modifying their regulations and legislation in a way that we can get that one day.

Are you seeing any progress in that area, Madam Stoddart?

Ms. Jennifer Stoddart: Yes, we are. We're seeing continuous progress.

Everybody, I think, is trying very much, in good faith, to work through concepts that predate the electronic health records and the possibilities these have for improving the health of Canadians. They are working through a lot of these complex legal, organizational, and societal issues, because you mentioned that it's not just about me and my doctor, me and my nurse, me and my family; there is the whole industry, there's the infrastructure, there's the increasing blurring of the public and the private sectors, there's the cost of developing effective specialized drugs, there's the pharmaceutical industry, and there are international considerations as well.

So we are all working intently at trying to move definitions forward in a way that preserves values while making the definitions workable to all, and I think everybody is cooperating in this very intense discussion quite well.

Hon. Robert Thibault: Thank you.

Mr. Alvarez, pretty well every practitioner who has appeared at the committee, when they talked about the reporting of adverse drug events—and I think we're generally hearing that 10% of serious adverse events are being reported now—they told us that they'd be willing to report every, or pretty well every, adverse event if there were a simple, efficient method that fed back to them. I don't know how you would define that, but it should tell them: this is what you should have expected; what you got is reasonable, and you should have expected it; or these are the alternatives you can use. So it would require participation by the practitioner, by Health Canada, but also by the industry, by the manufacturers of these pharmaceuticals and the people who have experience with them.

I'm very pleased to hear of the advances you're making, but will they get us there? Will they result in a two-way dialogue with practitioners?

Mr. Richard Alvarez: Mr. Chair, before I answer your question directly, I should say that we have a primary role, and the primary role is basically to provide better care at the point of service. The primary role includes the prevention of adverse drug events.

Earlier on, we had a comment about the cost. There have been studies done in Canada that show that between 9,000 and 24,000 Canadians are killed or suffer serious injury every year. Many of these are preventable, and 70% of them are because of fluids and drugs, adverse effects from drugs. Seniors are generally on a minimum of 12 medications, so—in terms of preventing—the systems that we're funding are systems that, at the time of prescribing, will enable you to see medication histories and to see what you're prescribing, and whether it will in fact have a likely adverse event with what the individual is on already. So that's the prevention side.

In terms of adverse events occurring—or in some cases, unexpected results where you're trying to kill one ailment and it increases cardiovascular risk, etc.—that's certainly possible to do on a population basis. When you start to look at people who are on a particular drug, and what their outcomes have been all the time, and why their outcomes have...or how their lab tests have spiked, that is certainly possible in terms of the secondary uses of data.

We've really just dipped our toe in, in terms of the reporting aspects in B.C., where I believe four out of the six health regions are reporting adverse events from neonatal units. From my understanding—and certainly that of the clinician who's running it—it is relatively easy to do, and it does really increase the numbers that are reported and the feedback mechanism that steps in to stop that from occurring.

● (1220)

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

Hon. Robert Thibault: Mr. Chair, I have 20 minutes left.

The Vice-Chair (Mr. Lui Temelkovski): I'll let you know the next time you have 20 minutes.

Some hon. members: Oh, oh!

The Vice-Chair (Mr. Lui Temelkovski): Mr. Tilson, please proceed.

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

My questions or comments are directed towards Commissioner Stoddart.

I always enjoy your comments because there are many challenging issues with respect to privacy. I'm looking forward to reading this decision that you have given in your comments—this Federal Court decision—particularly the comment where it says that privacy is paramount over the access to information, which we've heard before. I'm always amused by that, particularly coming from a small community, as many of us do, because in small communities there are no secrets. It's impossible to keep secrets in small communities. However, I understand that.

I want to canvass this, though, because we're told that for Health Canada to look at serious adverse reactions, we need to look at a whole slew of things. There may have been a practitioner who goofed in his or her prescription. Someone may have said, “Oh well, instead of taking four pills, I'll take eight pills.” There may be some genetic issues. There may be all kinds of things that deal directly with the individual. We know that when doctors discover that someone has a communicable disease, they have an obligation to tell the spouse. We know that when a teacher, for example, finds that some child may have been abused or may be bruised, they have the law and they have to go and report that.

I guess I get to the question: how can the government properly study serious adverse reactions if they don't know the identity of the individual?

Ms. Jennifer Stoddart: Mr. Chair, perhaps I could tell the committee a bit more about the facts of the case I was talking about in which this came up. As a general principle, privacy trumps access.

The case had to do with a request to the Information Commissioner. It was my colleague's case, in fact, a request from a CBC producer who was interested in accessing the results of this CADRIS database about adverse drug reactions. I can ask Ms. Kosseim to supplement my remarks, because she actually worked on this case.

As I understand it, Health Canada had all the personal information. The issue was not that Health Canada didn't have many fields; I think there were 60 or 80 fields, and most of these fields could be released to the journalist. The issue was with the fields the Information Commissioner did not release. The debate was about the province field. “Province” is not generally thought of as being personal information, but Health Canada's position—with which we concurred—was that if you released the province field, in certain cases that field, coupled with obituary notices, would allow journalists to understand who exactly had died and just release their information.

I don't think, Mr. Chairman, that any of this hampers Health Canada or the scientific study of adverse drug reaction in any way. In fact, they did have the name.

● (1225)

Mr. David Tilson: Except, of course, as someone said, we're now into talking about events beyond the borders of this country, which are aspects we probably should be studying. Drugs are coming from other countries. For Health Canada to adequately study something, to adequately discover whether there's a problem with a specific drug, I believe there may be circumstances in which Health Canada may at least want to know the identity of that person to properly determine whether or not it's safe.

We all have Canada Revenue Agency problems in our offices, so we stick a consent form in front of them, and they have to sign it. What if the person doesn't want to sign the consent? I assume that would happen with drugs. If they come in with a reaction and see the pharmacist or the doctor or whoever, and they say they'll report it, then I assume they'll stick a consent in front of them. I don't know whether they will or not. What if they don't, and what if they don't want anybody to know they had this reaction? If Health Canada doesn't know what that is, then how is it a benefit to the general public?

Ms. Jennifer Stoddart: Mr. Chair, the honourable member raises a very good question about public interest as compared to individual privacy interests. There's no one answer that does it for all. I think in those kinds of contexts you would have to set up the legislation framework. If you're trying to monitor something as important as adverse drug reactions to drugs being administered to a large population, it would be necessary for the regulatory agency to have as much personal information as it needs to adequately monitor the drug; otherwise, there are going to be unsafe drugs on the market.

Mr. David Tilson: Do I have time?

The Vice-Chair (Mr. Lui Temelkovski): You have to say thank you.

Mr. David Tilson: Thank you.

The Vice-Chair (Mr. Lui Temelkovski): We have to move on to Madame Thi Lac.

[*Translation*]

Mrs. Ève-Mary Thaï Thi Lac (Saint-Hyacinthe—Bagot, BQ): Good morning. I want to start be telling you that I am not a permanent member of this committee. I am standing in today for my colleague Ms. Gagnon. I will likely be sharing my time with Mr. Malo. I also stood in for a colleague at last Tuesday's meeting.

No one is disputing that Health Canada's current warning or advisory system has shortcomings. Let me give you an example. I was floored to learn last August that a warning had been issued about a prescription drug that I use. In November, I went to have the prescription renewed, but I was not informed of this drug advisory. Obviously, if the advisory warned people not to go out in the sun while on the medication, then the adverse effects I might be facing would not be as serious as, say, cardiovascular problems.

It is important for the consumer to be alerted. Protecting people's privacy should be the overriding consideration. Right now, users of certain prescription drugs are unaware that warnings or advisories have been issued by Health Canada.

Here is another simple example. If your automobile is singled out by a manufacturer's recall, you will be notified by mail to bring your vehicle to the dealer or to a mechanic to have the necessary repairs done. However, in this case, if people are not even informed that taking a certain drug may pose a health risk, it is clear that there is something wrong with the warning and advisory system, that it fails to protect consumers.

Ms. Sheila Fraser: Mr. Chairman, as I already noted, we looked into the regulation of medical devices in 2004 as well as the overall communications plan and strategy for warning consumers. In its report, the Medical Devices Review Committee noted that in the early years of this decade, the communications strategy left a lot to be desired. It was also noted that Health Canada had neither a communications plan nor a strategy in place to assess the situation. Of course, the department had various ways and means of communicating with consumers, but no way of verifying if these means were effective.

At the time, we conducted interviews in 19 hospitals and asked people to share with us their thoughts on Health Canada's communications strategies. We were told that with respect to issues of some concern, Health Canada was not people's main source of information, that HC warnings were often issued much too late to be of use.

I found your example of automobile recalls quite interesting. We also used it as an example of a process that could be put in place. Other possibilities are also mentioned in the report.

● (1230)

Mrs. Ève-Mary Thaï Thi Lac: Thank you.

Mr. Luc Malo: Do I have any time left?

The Vice-Chair (Mr. Lui Temelkovski): You have one minute.

Mr. Luc Malo: Madam Auditor General, how much would it cost to put in place an effective post-market surveillance program?

Ms. Sheila Fraser: Well, I think that is a question for the department to answer. As I said, it would first need to determine which activities are required.

Mr. Luc Malo: But in terms of meeting the program's objectives?

Ms. Sheila Fraser: It depends on how these objectives are defined.

Mr. Luc Malo: You have not examined these objectives?

Ms. Sheila Fraser: No. However, we did say that this is something the department should do.

In 2004, we observed that departmental officials had analysed one part of the program. They estimated that approximately 75 people were needed to handle the prescription drug component, whereas in fact they were working with a staff of 37 people.

In short, the department did analyze human resource requirements for post-market activities.

Mr. Luc Malo: Thank you.

[*English*]

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

Now we will move to Mr. Brown. You're on.

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

I appreciate the testimony so far.

I looked at this for a while before this committee, and I would like you to touch a bit further on the specific issues of the Privacy Act regarding the Government of Canada's use of electronic health records, and any other patient data, for post-market surveillance use. Are there any issues that you see with personal information protection of electronic documents?

Ms. Jennifer Stoddart: Yes, with the use of personal information by the Canadian government, particularly sensitive information like health information, there are issues. I think the issue is not so much the information that Health Canada has in its databases to study this—it obviously needs extensive information, and I mentioned the number of fields of information that were in this existing database—but who else would have access to this database and what fields of information would be shared. I gave the example of the recent court case in which we were involved: what examples of this database would be shared with researchers doing work, university hospitals, the pharmaceutical company, and so on?

So as Health Canada goes forward to increase its efforts in this area of post-prescription surveillance and adverse reaction, this is something I think it will consider carefully. It will probably do what's called a privacy impact assessment and send it to our office, as required under Treasury Board guidelines. We would comment on it then.

● (1235)

Mr. Patrick Brown: I understand there's a lot of data mining of the administrative databases by government to look at health risks. What standards should be applied to protect privacy in utilizing our own administrative databases?

Ms. Jennifer Stoddart: We have been questioning government departments recently about their use of data mining. From the answers we've been getting, it's perhaps not as extensive as some urban legends would lead us to believe. Under the Privacy Act there is quite a bit of discretion for the Government of Canada to use information given in one context for another context, as long as the use can be labelled consistent.

Mr. Patrick Brown: One question I've asked a lot of the witnesses as we've studied this topic is about enhancing the use of electronics as prescriptions are made. Originally concerns were raised by the CMA that they didn't have real-time access to information. Do you have any concerns about handheld devices being used to access patients' information or to get immediate updates from Health Canada on health risks? Are there any new issues there that we should be cautious about in regard to privacy?

Ms. Jennifer Stoddart: That's an interesting question that goes back to the whole issue of security and confidentiality around electronic health records. While they may be more efficient, they are ironically far more vulnerable if they're not done properly. This is a huge challenge for all of us.

One of the early studies my office commissioned about four years ago went into the privacy risks of being able to capture personal information from handheld devices being used by doctors in hospitals across Canada and where the patient records were. We know about the increasingly recognized dangers of the Wi-Fi communication network—the problem of trying to constantly update your encryption levels to protect yourself against smarter and smarter hackers.

So given the sensitivity of a lot of this information, coupled with possibly specific personal information in some cases, this is a huge concern. I think organizations like Infoway are constantly struggling with that in their investment in security, which is increasingly demanding.

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

We will move on with Madam Wasylycia-Leis.

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

Madam Stoddart, on this whole question of privacy, it seems to me that this is often used as an excuse by industry for not giving open, frank, transparent information about adverse reactions, about problems with drugs, about safety issues. How do we prevent that? How do we separate out the legitimate concerns around privacy from the need for an open, transparent system?

Ms. Jennifer Stoddart: Mr. Chair, could I ask the honourable member if she's talking about people's access to their own personal information in the hands of companies or third party access?

Ms. Judy Wasylycia-Leis: I'm thinking about information pertaining to individuals, and reactions of drugs, and the fact that industry has a poor record for getting government and consumers the information they need to make proper choices. And they sometimes hide behind privacy. But is there any reason for that to be the case? Is there not a simple, straightforward way of providing information that doesn't link it to individuals? And isn't it just as legitimate?

Ms. Jennifer Stoddart: Thank you for the question, Mr. Chair.

PIPEDA, the private sector law, governs many organizations in Canada. In the other provinces where it isn't extant, there is substantially similar legislation. We are very concerned about an interpretation of the law—remember, a law can be interpreted in many ways—by organizations so that individuals don't have access to their own personal information. In fact, in January we took a case to the Federal Court on this very issue of whether or not a person could have access to their personal information, held in this case not by a pharmaceutical company but by an insurance company.

Could I ask Ms. Kosseim, who actually pled that case, to tell you about it? We're very engaged in this.

● (1240)

Ms. Judy Wasylycia-Leis: Sure, although my concern isn't so much with access to my own records, although that is a legitimate concern. My concern is that companies will, under the guise of needing to protect information, say that they can't be forthcoming with information on adverse reactions and problems with drugs on the market and will use that as an excuse not to actually get.... We have to find a way to account for the failure of industry to fulfill its obligations and report. It's not doing it. I want to make sure we're not putting up the privacy issue as a roadblock.

Ms. Jennifer Stoddart: This committee is looking at legislation that would seek to address this issue. There are many ways of making scientific information available to the public and more transparent, in which personal identities can be de-identified or blurred. I just gave you the example.

In the other court case we're involved in, there's a case-by-case very sensitive analysis, but you do it in such a way that the overall results are given and personal identities are taken out of that information.

Ms. Judy Wasylycia-Leis: Madam Fraser, you've done a lot of work and spoken and written a lot about regulatory frameworks. Going back to 2000, you mentioned the growing influence of the industry over the regulatory process, and also the international globalization and standardizing across the board. There are a lot of concerns, and they have led some people to suggest that the only way we can be sure of a fair and objective analysis of drugs on the market is to have an independent board that has no connections to industry, that is separate from the department, which doesn't seem to be trusted anymore, as the only way to keep government accountable on this front.

Do you have any thoughts on that?

Ms. Sheila Fraser: Mr. Chair, I'm sure as Ms. Wasylycia-Leis can appreciate, this is really getting into policy, and we do not comment on policy.

The Vice-Chair (Mr. Lui Temelkovski): You are hands-off.

Ms. Judy Wasylycia-Leis: I appreciate that, and I understand.

But from an objective point of view, separate from any of the specifics of Health Canada, there is the question, in this area of drug safety, of having within the regulatory framework an independent advisory board or an independent evaluation board as part of the whole mix to ensure safety.

Ms. Sheila Fraser: All I can say, as I mentioned earlier, is that in 2004 when we looked at medical devices, we did look at the activities for licensing, and we found that the department was carrying out all of the procedures in accordance with their own policies. Now, should they decide to have an independent committee, that would certainly supplement, perhaps, the rigour with which this is done. But we did not see any indication of difficulties in their following through on their own process. The concern at the time seemed to be more the time that it took something to get to market actually, and the delays in that process.

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

We'll continue with Madam Davidson.

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

Thanks very much to our presenters.

Mr. Alvarez, you spoke about a pilot project regarding collecting adverse events or keeping track of adverse events at a neonatal unit in British Columbia. You indicated you were having some success, or you thought you were having some success, with this project as it was being piloted. Can you talk a bit more about how it's being done? Whose responsibility is it to report and to whom are they reporting? One of the things we've heard from different areas is that there may need to be remuneration involved because of time and so on. Perhaps you could touch on that.

And how is the information that's being collected dispersed in a wider sense? How wide is the network that's being attached?

Mr. Richard Alvarez: Mr. Chair, I will ask Mr. Sheridan to address that since he's intimately involved in the project.

Mr. Mike Sheridan: I'm not sure I'm intimately involved with the project, but certainly it is a pilot project. It was intended to show some innovation and adoption techniques.

The innovation was to change the way reporting was being done, in this case in a neonatal unit, with the assumption that once deployed and in place, this certainly could be used in other care settings, in other institutions, in other types of wards and care facilities.

The notion was that prior to the implementation of this particular system, the majority of the reporting was done on paper, and as Mr. Alvarez has always indicated, our health system on paper doesn't always look that good. So the system that was put in place was very standardized, computer-usable, a web-based application. That all sounds very complicated, but the reality is that it was click and point, enter the information, and then that went to another base.

Who was involved? Part of the process of getting electronic health records to work is adoption of these things by the actual users in the care community. The three hospitals that were involved in this particular project had a great approach. They created a team, and ostensibly, in the neonatal units, everybody became a part of the team—the doctors, the nurses, and the staff. In fact, when we had a presentation at our last board, they had created these little buttons that said “I am part of the team”. And of course everybody was trying to do that.

In terms of the actual adoption, the process was a team effort within the hospitals per se. The result, in terms of the reporting, was a web-based reporting tool that was much easier to use and much more accessible than the paper products that had been in place before.

The final piece was that this was aggregated into a centralized database, where the information could be used by “the team” in terms of giving better care and better follow-up.

● (1245)

Mrs. Patricia Davidson: Did this information go to Health Canada, or was it used internally by the team?

Mr. Mike Sheridan: This was a clinical application within three hospitals in Vancouver.

Mrs. Patricia Davidson: As far as adverse reporting goes, could it be applied to Health Canada?

Mr. Mike Sheridan: It's early days in this particular piece, but certainly the evaluation of the benefits and the actual implementation, use, etc., haven't been fully completed. We would want to see the results of that analysis.

We also have a very similar project that's being put in place in Newfoundland.

I think it's early days in terms of the application of this to any particular pan-Canadian reporting system.

Mrs. Patricia Davidson: Were there privacy issues, since it was closed-circuit reporting?

Mr. Mike Sheridan: A privacy impact assessment was done prior to the investments by Infoway. The results of that didn't indicate anything particularly negative or problematic with respect to privacy.

Mrs. Patricia Davidson: Thank you.

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

That concludes our session this morning. We will go in camera. We'll take a short break.

I'd like to thank the witnesses for—

Hon. Robert Thibault: Is it an in camera motion? I don't think it's in camera.

The Vice-Chair (Mr. Lui Temelkovski): No problem. Thank you.

Thank you very much to the witnesses.

We will have the motion passed around so everyone has a copy.

On a point of order, yes, sir.

Mr. Steven Fletcher: On a point of order, it says in camera on the agenda.

The Vice-Chair (Mr. Lui Temelkovski): Let's give it a second until they clear out. We'll deal with that.

Can we have the room cleared, please? Thank you.

Mr. Fletcher, you mentioned you want—

● (1250)

Mr. Steven Fletcher: Yes. I had a point of order, that the schedule indicates we are discussing committee business and that it's in camera.

The Vice-Chair (Mr. Lui Temelkovski): It is an option of the committee, and since the mover wants to have it in public, we'll have it in public.

Mr. Steven Fletcher: Well—

Mr. David Tilson: I want to speak on that, Mr. Chair, on a point of order.

The Vice-Chair (Mr. Lui Temelkovski): You can speak on it if you want it—

Mr. David Tilson: I want to speak on a point of order.

The Vice-Chair (Mr. Lui Temelkovski): What's your point of order, Mr. Tilson?

Mr. David Tilson: Are we in session, Mr. Chair? There are still people in the room.

The Vice-Chair (Mr. Lui Temelkovski): Yes, we are in session.

Mr. David Tilson: Okay, Mr. Chairman, I appreciate this notice of motion that has been presented by Mr. Thibault. We've had a number of sessions on organ donor matters. We've had at least four hours. Is it four hours, I think, Madam Clerk? I think the motion may be in order, but I think the issue is that this is another way of asking for a report.

Madam Wasylycia-Leis raised this issue—

The Vice-Chair (Mr. Lui Temelkovski): Mr. Tilson, that's not a point of order.

Mr. David Tilson: Well, it is, Mr. Chair.

The Vice-Chair (Mr. Lui Temelkovski): That's debate.

Mr. David Tilson: Mr. Chair, I'd like to finish what my point of order is.

Madam Wasylycia-Leis raised this issue as to whether we were going to make a report and this—

The Vice-Chair (Mr. Lui Temelkovski): Mr. Tilson, this is debate on the motion.

Mr. David Tilson: No, it's not, Mr. Chair. With respect—

The Vice-Chair (Mr. Lui Temelkovski): Also, the member has not introduced his motion yet.

Mr. David Tilson: Then you'll give me an opportunity to speak on a point of order after he's made his motion. I'm going to say the same thing.

The Vice-Chair (Mr. Lui Temelkovski): That's debate. It's not a point of order; that's debate.

Mr. David Tilson: Mr. Chair, I'm suggesting that this matter be referred to in camera proceedings because, in effect, it's another way of dealing with debating what is going to be the contents of a report, and normally when you talk about a report, that is done during in camera proceedings. I don't recall ever being in a committee, Mr. Chairman, where you discuss what's going to be in a report in public session.

The Vice-Chair (Mr. Lui Temelkovski): Okay, I hear you. What you're saying is that you want it to be in camera.

Mr. David Tilson: That's what my point of order is.

The Vice-Chair (Mr. Lui Temelkovski): That's good. That's a long way to get to the point of order. Thank you.

Mr. David Tilson: I'm sorry. I have that way about me.

The Vice-Chair (Mr. Lui Temelkovski): That's what I like about you.

I think we can—

Mr. Steven Fletcher: On a separate point—

The Vice-Chair (Mr. Lui Temelkovski): Excuse me. Can we have a show of hands on whether we go in—

Mr. David Tilson: Mr. Chair, I know you're going to ask for a vote on this. I'm saying that normally the process is that when you discuss a report, you don't need a motion. That matter is dealt with during in camera proceedings. Can you tell me a committee—

An hon. member: Well, Mr. Chair—

Mr. David Tilson: Excuse me.

Mr. Chair, can you tell me of a committee that has ever discussed —

An hon. member: I'm trying to help you, David.

Mr. David Tilson: —the contents of a report in open session? I can't.

The Vice-Chair (Mr. Lui Temelkovski): We're not discussing a report right now, Mr. Tilson.

Mr. David Tilson: Well, that's what this says, Mr. Chair.

The Vice-Chair (Mr. Lui Temelkovski): We're discussing a motion to go in camera or not.

Hon. Robert Thibault: On a point of order, to be of assistance to the committee, if will make it easier for everybody, I'm willing to discuss this in camera, to go in camera immediately and discuss it.

The Vice-Chair (Mr. Lui Temelkovski): That was my question.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo: Mr. Chairman, Mr. Thibault's question is most relevant. However, the two members of our caucus who looked into this were Réal Ménard and Christiane Gagnon, neither of whom is here today.

There was nothing in the agenda to indicate that this motion would be debated today. Therefore, I did not examine this notice of motion with the two interested individuals. I would ask Mr. Thibault and the rest of the committee to postpone this discussion until next week, basically because I want my party's position on this matter to be clear.

● (1255)

[*English*]

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

[*Translation*]

Hon. Robert Thibault: The clock is ticking, Mr. Chairman and there will certainly be some discussions and points of order that could put us over our allotted time. I agree with my colleague.

However, I want to let him know that we did give notice of motion within the prescribed 48 hours. The motion was brought before the committee and members received a copy of it. They had an opportunity to discuss it in caucus. Nevertheless, as a gesture of good faith, and if there are no objectives, I will consent to postponing this discussion until next Tuesday's public meeting.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): We will adjourn for today, and we will have this put on the agenda for the next meeting.

Madam Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: I'll do this in writing, but I'd like to make a motion that could be considered on Tuesday as well. It is that the Standing Committee on Health prepare a report based on the hearings conducted with respect to organ donor criteria, specifically the issue of gay men being excluded from being organ donors, and that the report be tabled with the House of Commons.

The Vice-Chair (Mr. Lui Temelkovski): Madam Wasylycia-Leis, if this is a new motion, I suggest you send it to the clerk, and we will look at it within the required time for notice of motion.

Ms. Judy Wasylycia-Leis: What I'm saying, Mr. Chairperson, is that I'm giving notice now. I've read out the motion. I can put it in writing to make it easier, but the 48 hours starts as of now.

The Vice-Chair (Mr. Lui Temelkovski): Please do. That's fine.

The next meeting will be in camera.

Mr. Steven Fletcher: I have two points, Mr. Chair. I would like to know from the clerk what action has been taken to correct the record on the erroneous information that was provided to the committee in the first meeting, provided in a letter last week.

I'd also like to point out something about the basis of these motions. We've heard many times that the legislation does not exclude gay men from donating organs, so it seems that the committee is ignoring the testimony that was given by the people who have to enforce the law.

The Vice-Chair (Mr. Lui Temelkovski): What was the second item?

Mr. Steven Fletcher: That is the second item.

The first item is correcting the erroneous information that was provided by the witnesses in the first meeting, as per a letter that was pointed out to the chair and the clerk at the last meeting.

The second is that men who are gay are able to donate their organs. I don't know why we would suggest that they're not.

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

I think we can take that into consideration in our next meeting under committee business. I would suggest that we take half an hour at our next meeting to deal with the motion and other committee business. And that will be in public, because Monsieur Thibeault wanted it that way.

The meeting is adjourned.

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