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Chair

Mrs. Joy Smith

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● (1110)

[*English*]

The Vice-Chair (Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.)): Ladies and gentlemen, I call the meeting to order. We can take our seats and get started.

Today we have with us three groups of witnesses. From the Best Medicines Coalition we have Linda Wilhelm, vice-chair, and Gail Attara, member. We also have Terence Young from Drug Safety Canada and Michèle Brill-Edwards from the Canadian Health Coalition.

Could we start with Linda Wilhelm, please.

Ms. Linda Wilhelm (Vice-Chair, Operations Committee, Best Medicines Coalition): I want to thank you for giving me the opportunity to come here today on this very important issue that's critical to patients living in this country.

The Best Medicines Coalition is a national alliance of organizations and individuals representing those living with or affected by chronic disease or illness. We have a core mandate of ensuring access to the best evidence-based medicines for Canadians.

BMC's patient representatives are actively involved in discussions about drug review reform, patient safety, and general health policy development. Improvement of post-market pharmaceutical surveillance in Canada is one of our key goals.

This coalition encourages implementation of a robust system of comprehensive reporting, monitoring, analyzing, disclosing, and communicating a prescription drug's adverse effects throughout its use over time. Even though drugs are studied extensively before being approved for sale in Canada, an adverse event might not emerge until it's been widely available in a real-world setting.

Identifying adverse events is critical, but we caution against knee-jerk responses that cut off medications from an entire population when only a particular subset are affected. We seek a national system whereby patients have full, timely access to medications and full disclosure of each medicine's known risks and benefits profile.

I am just going to speak to a few initiatives we've been involved with. One is the progressive licensing framework. We fully support the work of Health Canada's progressive licensing framework and the proposed life cycle concept. Ongoing work in modernizing the regulatory framework while working towards harmonizing Canada with international regulatory standards is imperative.

We recognize that the current outdated regulations are insufficient to address the current and future need for the complex and sophisticated treatment approaches needed by Canadian patients. We support the life cycle approach because we believe it will improve health outcomes while enhancing collective, ongoing knowledge of how each medication works, good and bad, in the real world.

We believe that adherence to the progressive licensing framework will enhance ongoing drug safety in Canada by better reflecting the safety, quality, and efficacy mandate of Health Canada. This approach will allow for a more comprehensive range of responses to drug safety issues, rather than necessitating a full retraction from the market, as prompted by current legislation.

Further, BMC applauds the Health Canada team, under the direction of David Lee of the therapeutic products directorate, for the inclusive, consultative, and, I would say, comprehensive approach to this policy development, and particularly for welcoming and inviting patient input throughout the whole process.

We also believe that you need multistakeholder involvement in any solutions moving forward. To move towards effective post-market surveillance, the system requires major advances and comprehensive adverse event reporting. The current statistics provided to the Expert Advisory Committee on Vigilance in Health Products at a recent meeting show that only 1% to 10% of current adverse events are reported.

It is incumbent on Health Canada to increase this reporting quickly and drastically. We recommended broadening the base of sources for adverse event reporting. All players in the health care system—patients, caregivers, professionals, institutions, industry, and government—have a role in ensuring comprehensive reporting of adverse events. Reforms must move forward that will balance responsibilities in the reporting of adverse events, which currently lie primarily within the pharmaceutical industry. Although controversial, we recommend exploring some measure of mandatory reporting.

Here are some suggestions for improving reporting within various sectors.

I'll begin with patients. Currently most patients are not aware that they can even report an adverse event directly. This warrants a major public education campaign. Through such a campaign, those taking medications and some over-the-counter products could learn to provide necessary feedback regarding their negative experiences. A newly developed, consumer-friendly form is in the final stages of development. Ideally, this could be handed out to patients when a prescription is filled.

In addition to being the conduit for information transfer to the patient, pharmacies could display reporting information notices and MedEffect banners to direct patients on how to report an adverse event.

● (1115)

Currently health professionals only report the most serious adverse events, and there is little evidence that reporting goes beyond this. Attitudes and practices regarding reporting must be addressed within the community, with a goal to increasing reporting rates. Medical education curricula, as well as those of all health professionals, should include a module on adverse reporting and the importance. Continuing education on this topic for practising professionals, as well as awareness campaigns aimed at these audiences, could be beneficial.

On hospitals, despite many obstacles and resourcing considerations, mandatory hospital reporting is integral to a comprehensive system.

I'll finish with resourcing and infrastructure. In any meaningful discussion about the future of post-market surveillance, resources must be addressed. This includes human and financial resources, in addition to infrastructure development. We encourage the Government of Canada to provide Health Canada with the authority and adequate funding for all components necessary to ensure a viable program. In addition, the Government of Canada must allocate resources so that other players in the system, including patients, professionals, and hospitals, can serve a meaningful role.

Post-market surveillance is uniquely complex and involves all stakeholders, and to date there have been some successful improvements in contributions to extending trying to improve the rates, and we hope these will continue.

● (1120)

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

Mr. Young, I believe you're next.

Mr. Terence Young (Chair, Drug Safety Canada): Good morning.

My name is Terence Young. I'm the founding chair of Drug Safety Canada, a former Ontario MPP, and the author of the book, *Death by Prescription*, which will be published by Key Porter this coming September.

Drug Safety Canada promotes the safe use of prescription drugs. We accept no money from any corporations. As chair of Drug Safety Canada, I am party to the CanWest MediaWorks Inc. lawsuit in the Ontario Superior Court of Justice in support of Health Canada's continued ban on direct-to-consumer advertising of prescription drugs.

We focus on serious adverse drug reactions, those that are fatal, life threatening, disabling, incapacitating, or result in prolonged hospitalization, the ones that the pharmaceutical industry, which we call big pharma, want you to believe almost never happen. The term "big pharma" refers to the world's largest international drug companies as a group.

This morning I'll briefly summarize the results of six years of research begun after we lost our 15-year-old daughter Vanessa to the Johnson & Johnson prescription drug Prepulsid in March 2000.

We believe prescription drug safety will be enhanced with proposed mandatory adverse drug reaction reporting. A previous Minister of Health, Ujjal Dosanjh, went as far as announcing he would do it, and nothing followed.

About 1% of adverse drug reactions are currently reported, and yet the big pharma companies frequently publish the 1% on their drug labels as if that's all that occur. Big pharma tracks worldwide drug deaths centrally but generally does not report adverse drug deaths to Health Canada that occur in 192 other countries. They normally blame those deaths and serious reactions on overdose, contra-indicated drugs, and conditions the patients might have, and change the fine print on the label that no one ever reads. They almost never admit their drug caused deaths, even after it has been pulled off the market, because the insurance they buy against drug crashes would therefore not pay.

First, we recommend that the new legislation empower and require Health Canada to demand all studies done on prescription drugs and all adverse drug reaction reports from the world market to be delivered immediately or within 48 hours, and not be held up, as they are now, from six months to a year.

We congratulate Minister Clement for introducing legislative change to implement this measure in hospitals, and we hope it will lead to a robust reporting system to which all health care professionals contribute. It will provide an early warning system for dangerous drugs and a living database from which to identify dangerous drugs and no doubt save lives.

Every decision to take a prescription drug should be based on an informed and objective appraisal of one thing: will the benefits outweigh the risk for this patient?

Here is the scope of our current problem. All drugs cause adverse reactions—not some, all—and many are deadly. The president and founder of Eli Lilly once said, "Any drug without toxic effects is not a drug at all." "Rare" means between one out of one thousand and one out of ten thousand, so take no comfort with rare side effects. Three million Canadians are currently taking SSRI antidepressants, so between 300 and 3,000 will suffer any rare reaction.

To quote Dr. Andrew Weil, "The only difference between a drug and a poison is dosage." So every drug has a potential to harm patients. For example, 16,000 to 17,000 people die every year in the U.S. alone from ordinary over-the-counter aspirin, ibuprofen, and naproxen.

Prescription drugs are the fourth leading cause of death in the U.S. and Canada, behind only cancer, heart disease, and strokes. Most of these deaths are covered up, which is why you will not find them recorded by StatsCanada. But three University of Toronto professors did a very comprehensive mega-study in 1998, in the United States, that showed 104,000 deaths in U.S. hospitals caused by prescription drugs administered as prescribed—not in error, but as prescribed. Many observers believe there could be as high as another 100,000 deaths caused by prescription drugs outside hospitals. That would be the equivalent of about 20,000 deaths a year in Canada.

One out of five new drugs in the U.S. is taken off the market for harming or killing patients or will have the highest level of warning placed on their label, and half of new drug withdrawals occur in the first two years.

One out of four adult hospital admissions to medical wards in Canadian hospitals is drug related, mostly adverse reactions, improper drug selection, or non-compliance.

So the human cost is staggering. What is the financial cost?

According to the Canadian Pharmacists Association, approximately $2 billion to $9 billion a year in Canada is wasted on inappropriately prescribed drugs. Inappropriate prescribed drugs injure hundreds of thousands of patients every year in Canada. Some estimates put the cost to our medical system at $10 billion a year.

Adverse drug reactions are really like an epidemic. How did it get to be that way? How high is our current standard for approving prescription drugs?

● (1125)

They have to be effective. What does that mean? Effective means slightly more effective than nothing. There is no regulatory requirement to show that any new drug is more effective than the current top-selling drug on the market for the same condition. All they have to do is prove that the drug works 1% better than nothing, which is a placebo. Even that is a major challenge for many of the drugs the big pharma companies have unloaded on trusting patients.

For example, in the U.S., it's shown that the drug Vytorin simply doesn't work. The drug companies that produce the two drugs that combine to make it covered that up for 18 months while they sold another $7 billion worth to unsuspecting American patients.

Dr. Allen Roses, the worldwide vice-president of GlaxoSmithKline, has said that the vast majority of drugs—more than 90%—only work in 30% or 50% of the people. He said that cancer drugs work 25% of the time, Alzheimer's drugs work 30% of the time, and many others only 50%. It's because of the powerful placebo effect that patients are often unable to determine when a drug is working. Millions of patients are put at risk of nasty or dangerous side-effects with no benefit, and billions are wasted.

Recommendation number two is, because governments are the largest customers for pharmaceuticals—about $8 billion a year—we believe new drugs should be tested for effectiveness against not just placebos but existing proven drugs. Governments should not pay for new drugs, which are always more expensive and offer new risks to patients, unless they are proven more effective for patients in the same condition.

Safe. What does safe mean? Safe does not mean safe as most patients think. Safe is relative to the drug and condition it is treating. Safe often means just less harmful than the current drug. If a new drug is approved, the one you are currently taking may no longer be safe.

Off-label prescribing. Three out of four doctors prescribe drugs off-label, a practice widely promoted by stealth in the industry. This means prescribing a drug for a condition for which it is has not ever been proven safe and effective. It is illegal for drug companies to promote it, but they do it in a myriad of ways anyway, using financial relationships and debts of gratitude to our doctors who do it for them.

A good example is Vioxx. It was originally approved around 2000 for arthritis and short-term pain. Merck promoted it off-label for many other kinds of pain and drove its use up to $2.4 billion before it was pulled off the market in 2004. Between 55,000 and 65,000 people died of heart attacks and strokes after taking Vioxx, about as many Americans as were killed in the Vietnam War.

Phase four of testing. We test drugs on the public without telling them. Phase four of testing is selling them on the open market. Any patient taking a new drug becomes a guinea pig in a giant drug trial. Doctors have no legal obligation to tell patients this, and most don't.

Our third recommendation is that doctors should be required to obtain truly informed consent for prescriptions and explain to patients that, by taking a new drug, they are in a trial, and that when they take a drug off-label the true risks are not known. This is currently done, by the way, for the acne drug Accutane.

Misleading communications. Patients are not informed of the risks they are taking. Big pharma risk communications are written by lawyers for lawyers in tiny print and cryptic euphemisms to encourage sales and confuse the reader. Drug labels, which patients never see and doctors rarely check, are up to 60 pages long, with safety information often on the last page, making sure few people ever read them.

Patient information leaflets handed out in drug stores are dangerous because they create a false sense of security, almost never mentioning serious adverse reactions. For example, the 29-page drug label for Viagra mentions side effects of vision loss, permanent damage to your penis, hearing loss, heart attack, stroke, and death on page 28. The truth is that hundreds of men have died within five hours after taking Viagra. Viagra, by the way, is also dangerous with grapefruit juice.

Recommendation number four is that patients should be getting independently written patient information leaflets—like the U.S. MedGuide—with each prescription that states up front, in plain language, all serious adverse reactions, all contraindications, the true safety record of the drug, and possible alternative therapies.

In 1997, Health Canada was directed to partner with big pharma, the pharmaceutical industry, but 41 drugs had been pulled off the market in Canada from 1963 to 2004 for safety reasons, often—like Prepulsid—for injuring and killing patients. In 1997 Health Canada's testing labs were closed in the budget to save $10 million. Let's look at what Health Canada has been doing since then. They did not even keep a list of drugs that had been withdrawn from the Canadian market or why. They did not routinely try to assign causality when evaluating adverse drug reaction reports; so they take the report and they don't try to find out what caused the patient's death. We could find only one occasion when Health Canada actually ordered a drug off the market, and that was Prepulsid, the drug that killed my daughter.

● (1130)

Post-market studies, which are promised in order to get drugs approved, are routinely left undone by big pharma. No one at Health Canada ever follows up.

Recommendation five is that new legislation should ensure that Health Canada officials collect important safety information and use it to order post-market studies and get dangerous drugs off the market. Health Canada will need the budget to hire and train more drug reviewers and safety officers to do that.

Big pharma view Health Canada as a client. By 2002, 82% of the therapeutic products directorate budget was being paid by international drug companies in exchange for faster drug approvals. This makes drug reviewers' jobs dependent on the industry.

No regulator should partner with those they police. The pharmaceutical companies are there to make money; Health Canada's mandate is to protect patients. We believe there should be no relation whatsoever between the jobs and investment in the pharmaceutical industry and what drugs we allow to be given to vulnerable patients. Health Canada should have no mandate to assist the pharmaceutical industry to make money, which is a clear conflict of interest for a regulator. Aircraft tire inspectors should not be worried about jobs at Michelin or Goodyear.

This ongoing problem could be resolved by establishing an arm's-length independent drug agency to handle all regulatory matters. This idea was germinated in 1964 by Justice Emmett Hall's Royal Commission on Health Services, expanded in 1992 in the Gagnon report, and recommended in 2002 by the Romanow commission.

Faster drug approvals can only be justified for 5% of new drugs.

The Vice-Chair (Mr. Lui Temelkovski): Mr. Young, could you please go through the recommendations, as opposed to the text as well, due to the time? Thank you.

Mr. Terence Young: Yes.

Dr. Michèle Brill-Edwards (Board Member, Canadian Health Coalition): Mr. Chair, I would be very pleased to give two minutes of my time to Mr. Young.

Mr. Terence Young: Thank you very much.

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

Mr. Terence Young: The big pharma companies call themselves "research based" and push to get their "cures" and "breakthrough" drugs on the market faster. Less than 5% of drugs introduced in Canada are considered to be breakthrough or substantial improvements over existing therapies. In 2006 only one drug out of the 89 approved would fit that category.

The truth is that Health Canada already prioritizes drugs identified as breakthroughs and assigns reviewers accordingly, having shortened the time for approvals by 2002 to 215 days. There is no justification for lowering the safety bar for the other 95% with conditional or fast-tracked approvals.

The recommendation proposed is that conditional drug approvals should never lead to faster approvals where benefits will not outweigh the risks by the evidence. Drug reviewers are like the air traffic controllers of drug safety. No one tells air traffic controllers to get those jets in faster.

Clinical drug trials are biased in many ways, the most common being burying those that show the drugs don't work. In January an entire class of drugs that three million Canadians take, SSRI antidepressants like Paxil and Effexor, was shown not to work for the vast majority of patients who take them. The drug companies had convinced our doctors that they do work for this large group by making sure that 88% of their clinical trials that showed the drugs didn't work were never published. Doctors believe that the drugs are 11% to 69% more effective than they are. Since 1988, SSRIs have caused thousands of excess Canadian suicides.

The recommendation is that we support the proposal for compulsory registration of every clinical trial at its start, and we add that it must include complete transparency. All data and results are to be published on the Internet, even if the trial is not completed. We recommend that the new legislation include an offence of "misleading the regulator".

The precautionary principle. Risk management is the industry standard for conducting business responsibly. What it means in reality is that they're managing their risk of being sued successfully when their drugs harm patients. It is a practice that puts human lives on the same continuum as money, a key reason prescription drugs are the fourth leading cause of death. We are concerned that the paper's proposal for monitoring corporate risk management plans could be construed as Health Canada adopting corporate risk management.

The precautionary principle does not appear anywhere in Health Canada's documents. In its essence, the precautionary principle means better safe than sorry. It recognizes that in a complex system it's impossible to fully predict outcomes. It assumes that errors occur, and the higher the magnitude of the error, the greater the level of precaution required. It shifts the burden of proof to those who are favouring a risky course of action. With big pharma's dismal safety record, it is crucial to insist they provide evidence that their products are safe and effective before the products get into the bloodstreams and organs of our loved ones. The best way to do this is using the precautionary principle.

The Canadian Environmental Protection Act states that under the constitutional laws of Canada, the government must apply the precautionary principle where there are threats of serious or irreversible damage. Surely we must set the same high standard of managing risk to our loved ones as we do for waterways in our new legislation using the precautionary principle.

One final recommendation. "Cause and effect" is an extremely high standard. In fact, it's an inappropriate standard for regulating prescription drugs. Deadly adverse drug reactions are almost impossible to prove—for example, the hundreds of heart deaths after people took Viagra—because our regulators and courts often buy into the industry standard of proof, which is a higher standard than any court in the world. By cause and effect, cigarettes do not cause lung cancer.

We recommend that new legislation should authorize the whole range of regulatory activity to be triggered by the association of an adverse drug reaction with a drug based on worldwide epidemiological evidence. This will save hundreds and thousands of lives.

I have two additional recommendations, Chair, but I want to give the rest of the time to my colleague.

● (1135)

The Vice-Chair (Mr. Lui Temelkovski): Yes. We've heard for 16 minutes.

Mr. Terence Young: Thank you very much.

The Vice-Chair (Mr. Lui Temelkovski): We do have your recommendations, but only in English. We will have them translated and distributed to every member in the next few days.

Now we will hear from Michèle Brill-Edwards.

Dr. Michèle Brill-Edwards: Thank you, Mr. Chair.

I am Dr. Michèle Brill-Edwards. Today I'm representing the Canadian Health Coalition. I'm a member of the board of the coalition. I'm replacing Mr. McBain, who could not attend today.

The Health Coalition has a mission to preserve and strengthen public medicare, and also to advocate for the protection of the health of Canadians. It is a not-for-profit, non-partisan organization dedicated to protecting and expanding Canada's public health system for the benefit of all Canadians. The CHC was founded in 1979 at the Canadian Labour Congress-sponsored SOS Medicare conference attended by Tommy Douglas, Justice Emmett Hall, and Monique Bégin, the leaders of public interest in health care in Canada.

I'll make some brief remarks.

Much of the view of the Canadian Health Coalition is already expressed in the presentation of Drug Safety Canada. I would like, however, to speak briefly to the scope of the problem, the nature of pharmacosurveillance in Canada currently and some of the problems, and then make a very few recommendations.

In essence, the scope of the problem is huge. As mentioned, the number of deaths due to the proper use of medications in Canada and the United States has been studied and is pegged at somewhere between the fourth and the sixth leading cause of death North America-wide. That tells us that we are not dealing with something rare and unusual. We're not dealing with a system that may help save the odd life here and there. We are dealing with a very major cause of mortality for Canadians.

The current system of pharmacosurveillance is in essence a passive system. In other words, input reports from health care professionals, doctors, pharmacists, nurses, and so on come into the system in a very haphazard manner, without any knowledge on the part of Health Canada as to the true number of serious adverse reactions that are really out there. The analysis that is then undertaken by Health Canada is problematic, partly because of the inherent difficulty of ascertaining a true signal of serious problem from the noise of adverse events that may or may not be related to the drug in question but may be related to the disease of the patient or other extraneous factors.

A second issue, however, is that the analysis within Health Canada of the reports received is, in essence, opaque. It is not transparent. So the messages go in, and there's no understanding on the part of physicians and pharmacists and people who need to know what analysis is done or how it's done or how valid it could be. The output of the system is often very belated and rather cryptic, and there are examples we could discuss regarding SSRIs, for example, and suicidality. SSRIs are antidepressants and have been now demonstrated, after many long years of tortured analysis, to be related to suicidality in both adults and children, but in children particularly. Recently we've learned that these drugs have no efficacy in the treatment of depression.

The belated and rather cryptic output doesn't tell doctors and other health care professionals how the drug safety analysis was really done and what supports the guidance. These outputs are largely ignored by the profession. So we have a real problem of trust in Canada with regard to the Health Canada drug safety system.

As a result of that lack of trust, there's very little reporting. Doctors and pharmacists feel there is no point in reporting to a system that doesn't give them back useful information. Another result is that heed is not taken of important messages that are put out by Health Canada, because of the perception that they are not well founded. The problem is compounded as we look to the future and ask how we could improve the system. The issue of trust comes up immediately.

● (1140)

It is very simple, in an academic way, to say that passive surveillance is not adequate. It certainly is not adequate. It is very easy to say we need active surveillance, better systems, targeted, focused adverse reaction reporting, and mandatory reporting, as Terence Young has discussed. It is very easy to say those things, but if we want those measures to work, we have to have trust on the part of health care workers that there's a thinking, concerned, committed Health Canada as the intermediary that acts in the public interest to reduce this burden of unnecessary deaths due to medicines.

I would like to add that in addition to active surveillance, meaning not only mandatory reporting but also focused studies that would ascertain epidemiologically the cause and effect likelihood, we also need a system for the investigation of what have been termed catastrophic drug safety failures. In lay terms, these are drug crashes, or drugs that arrive on the market and are on the market for many years, and unbeknownst to patients and their professional caregivers, there are very serious problems and many resulting deaths. Vioxx is probably the most famous example, with tens of thousands of deaths demonstrated through studies done by the FDA before the drug was removed.

My last recommendation is for an independent investigative drug safety board that is separate from the regulator and separate from the industry, and that can investigate problems arising after the industry and the regulator have made the decision to bring the drug to market. It is not acceptable for the industry and the regulator to investigate themselves behind closed doors when thousands of lives are at stake.

If the committee needs a model for such an independent board, it was proposed about a decade ago in *The New England Journal of Medicine* by two very prominent clinical pharmacologists with an interest in drug safety. The very handy analogy they used is that if the federal aviation authority sets the regulatory standards for flying, we automatically know we will need a separate air safety board to investigate plane crashes. That is just common sense; we don't want a conflict of interest there. Why do we not then have a similar situation where the FDA or the health products and food branch of Health Canada are the people who set the regulations, but then also have an independent, separate safety board that immediately investigates when a serious drug failure comes to light?

I would like to add on behalf of the coalition that many of the recommendations that have already been stated by Drug Safety Canada are recommendations we concur with.

Thank you.

● (1145)

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

We will start questions now with Madam Kadis.

Mrs. Susan Kadis (Thornhill, Lib.): Thank you, Mr. Chair, and welcome to all our witnesses today. I must say that you gave us information in great depth and answered many questions. I'm sure there are many more questions on this very important and vital area.

You referred to having an independent drug board, which seems to be something that is needed and was advocated for today, from what I'm hearing. We heard from Health Canada that adverse drug reactions are voluntarily reported, primarily by health professionals, but that patients can also report them directly through a toll-free phone line at several regional vigilance offices or via the MedEffect website.

So I want to ask you today, have you or your organizations or advocacy groups reported any adverse drug events, and to what degree, if that is so? Do these different reporting avenues provide sufficient access, in your opinion, to the Canadian public? I think you're saying that it's not necessarily so, but perhaps you could elaborate on this particular component, which I think is very important. Also, do you access any of the adverse reaction information available on Health Canada websites for information and/or analysis?

Ms. Linda Wilhelm: The question is directed at me, I guess.

I have. I do know of the MedEffect website. Unfortunately, I would say most Canadians do not know about it.

A couple of years ago the Canadian Arthritis Patient Alliance, an organization I am involved with, met with Health Canada and went over the consumer reporting. Our feedback to them was that the current form they were using was not consumer friendly. It was not written in language that patients could understand, and the whole process was very difficult for a patient to navigate.

The other issue was—and as a patient myself I've experienced it—when I experienced an adverse reaction. When I went to my specialist and mentioned that I was experiencing this reaction, he challenged me and said, “How do you know that's not just the progression of the disease?” So in effect, I was shut down. And it wasn't up to me to decide that. It was to be reported and then for all the patients to be able to report it, and for them to find out what the reaction was.

That's why we feel there needs to be far more education, and we're really happy to see Health Canada coming out with a consumer-friendly form, because we've spent two years trying to tell them it was needed. And now it's soon to be released and it is just being tested now.

And we need to be more aware. As for the pharmacists, there needs to be an education campaign about the fact that people can report, that they can self-report. Canadians don't know that. They rely on their doctors and pharmacists. Pharmacists do the majority of reporting, but it really isn't enough.

Ms. Gail Attara (Member, Steering Committee, Best Medicines Coalition): I'd like to comment on that too.

I am the executive director of the Canadian Society of Intestinal Research as well as being a member of the Best Medicines Coalition.

In our organization a few years ago, when the MedEffect website was really launched, we put a big announcement in our newsletter and we let people know via our website with regard to that ability for people to report.

I think this is really an untapped area that can be used by Health Canada, by partnering with charities and saying.... The patient groups who are out there would be happy to get this information out too, and in our case, we're not asking you to give us money to do that. We're just saying this is awesome and we're really happy to see it. Let's partner with you. Give us the script that needs to be sent out to everyone and we'll be happy to put it through the vehicles of our newsletters and our websites.

Our website gets 500,000 hits a month, so certainly this is going to be a good way for people to communicate messages. So please don't underestimate the power of collaboration. And it doesn't necessarily mean it's going to cost money in this particular way.

● (1150)

Mr. Terence Young: Thank you.

The only death I ever reported was my own daughter's death, which was the day after she died, because I never felt anything useful was being done with the reports. We focused at the time on research.

We know the doctors don't generally report adverse drug reactions for a range of reasons. In fact, there's a form in the back of that big blue book that they all have in their office, the *Compendium of Pharmaceuticals and Specialties*. Most doctors have never used it or don't even know it's there.

One reason is that they're afraid of being sued. In fairness, sometimes it's difficult to identify adverse drug reactions, because they haven't been trained to do so. Sometimes they have 40 patients waiting in the waiting room and they don't want to take the time to fill out paperwork to the government, although with modern technology it's pretty easy to log on and fill out a form that says "suspected adverse reaction".

So we support the initiative starting in the hospitals. We would also support patients reporting adverse drug reactions, if it's a robust system, because patients can provide more detailed information on what they experience. But there have to be people on the other end who are taking that information and doing something with it.

Another reason doctors don't report is that they haven't felt, for years, that anyone was doing anything with that information.

I looked up recently the most popular drug. The highest-selling drug in the world is a cholesterol-lowering drug—Lipitor. There are 2,000 adverse drug reaction reports on the Health Canada website. In our view that means there have been 200,000 adverse drug reactions that were so significant that the doctor, the health care professional, or the patients themselves had logged on and ordered....

By the way, the reporting of adverse drug reactions on the Health Canada website is the only significant change that we have seen in the eight years since Vanessa died. It's the only thing that has been carried out to improve the situation.

There was an inquest into Vanessa's death a year after she died. There were 59 recommendations made by the jury, and it's the only significant change we've seen.

So change is due. This is a great opportunity to make positive change.

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

Dr. Michèle Brill-Edwards: As a practising physician, I have reported adverse drug reactions. It is equivalent to putting a note in a bottle and sending it into the ocean. There's no feedback at all.

The second thing is that in the time that I was a senior officer with Health Canada and involved in adverse reaction reporting evaluation and action, in a regulatory sense, I was aware that we in essence had no systems to carefully evaluate adverse drug reactions. A good example would be the case of Prepulsid. When the file was looked at—after I left government and through access to information—to see what had been done at Health Canada regarding reported deaths with Prepulsid, the drug that killed Vanessa Young, the earliest memos were one from the drug company's adverse reaction reporting officer saying, "I think I have five deaths", and one from Health Canada saying, "I thought there were seven." And neither of them had looked into any of the deaths.

This is a system where reporting is not the issue. People would report if there were something competent and timely in the way of useful information from Health Canada as a result.

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

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Thank you for joining us this morning. You have made a number of fairly specific recommendations.

I would like to talk about Gardasil. A number of people who took this drug in Europe and in the United States, but not here in Canada, later died. Here in Canada, a major campaign is underway to have young girls between the ages of 15 and 25 vaccinated. Of course, it is difficult to establish a link between the deaths and the use of this drug. I understand that a company is currently conducting an investigation in Germany and in Switzerland. For now, no one is able to establish a cause-effect relationship. Eight young girls have died in the United States.

I contacted officials at Health Canada because they are the ones who initially approve a drug for use and grant a patent. They told me that vaccinations were the responsibility of the Public Health Agency. It was the agency that had opted to go ahead with the vaccination program. In your opinion, is there not a breakdown of some sort in the chain between the moment a patent is issued and a drug is administered to patients? The chain is rather hard to follow.

Young girls continue to receive the vaccination despite the known risks involved. In light of the situation, I'm wondering if perhaps a moratorium could be imposed for a few months, depending on the type of investigation that we may wish to conduct. Were you aware that Gardisil could have serious side effects? How can patients be made aware of these possible side effects? Perhaps in the case of a young girl of 15, the parents should be notified as well. So then, I ask you, how could we be more vigilant under the circumstances? We feel completely powerless.

● (1155)

[*English*]

Mr. Terence Young: Can I go ahead, Chair?

The Vice-Chair (Mr. Lui Temelkovski): We'll start with Dr. Brill-Edwards.

Dr. Michèle Brill-Edwards: Yes, I think that your question is very pertinent, and it demonstrates the limitations of post-marketing surveillance.

On the early part of your question about how we establish a link, a causal link, between a marketed product, a vaccine or a drug, and the adverse events that we see, the answer is that it is with extreme difficulty and a great deal of time and effort. Once the drug or vaccine is out on the market, it becomes almost impossible to do the randomized control trials that are done prior to marketing and that should be done in a manner that is sufficient to identify problems. Once the drug or vaccine is on the market, randomized trials are not really an option, so the ability to demonstrate a causal link is lost. You can demonstrate an association. This is a scientific term that means on a balance of probabilities this is a causal problem.

The second issue is that once a drug becomes politicized, the science behind the drug and the surveillance done on the drug or vaccine becomes secondary. There is evidence both in Canada and in the U.S. that this particular product became the subject of tremendous political pressure, to the point that the company's own top researcher for the clinical trials spoke out publicly to say that both the company and the regulator were taking action to provide the vaccine to very young girls—as young as nine, 10, and 12 years old—when in fact none of the studies was done in that population and there is no evidence that the drug will be helpful or what harms might arise.

Lastly, your point about informed consent is crucial. As a parent, I've had my daughter announce in grade school that she was getting a vaccine the next day. When I asked, what have they told you? She gave me a little pamphlet that had nothing about the vaccine, just a public health message that it was to be given, and she, at the age of 12 or 13, was going to sign for her own vaccination. It was a vaccine that I did not particularly feel confident about.

You're absolutely right that we are taking tremendous liberties with people's health in a manner that would be offensive to the average citizen if they understood what is really going on.

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

Mr. Terence Young: Thank you, Chairman.

Gardasil is three painful needles over a period of time. It costs $450, is effective on 70% of the viruses that can be cancer causing, and may only last five years. Would you buy a television or an automobile that works 70% of the time and only lasted five years?

It's an unproven drug that was only tested on less than a hundred 12-year-old girls, which is the market they're selling it to. Remember I said before, are we sure that the benefit outweighs the risk? There's no way to tell at this point.

I just conclude by saying that Gardasil is brought to us by the same people who brought the world Vioxx.

● (1200)

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

[*Translation*]

Ms. Christiane Gagnon: Another undesirable side effect, aside from death, is spontaneous abortions. The drug can also cause blot clots and vascular bleeding. How should Health Canada react to this serious news?

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Please make a half-minute response.

Mr. Terence Young: Health Canada should respond by saying exactly what Dr. Michèle Brill-Edwards just said to you. They should post it on their website. They should make Canadians aware.

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

We will now move on to Madam Wasylycia-Leis.

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

Thanks to all of you for your presentations.

I'm going to start with Best Medicines Coalition. I always get a little curious when I see a brief that presents unequivocal support for a present government policy without any equivocation and any kind of concerns, especially given what we've heard from Terence Young and Michèle Brill-Edwards, and especially what we've heard from so many individuals out there who have been hurt, and hurt badly, as a result of lack of vigilance in our system.

So when I see this kind of unequivocal support for the progressive licensing framework, I either think you're a mouthpiece for the government or you're a mouthpiece for big pharma. I looked back and I realized you had been asked to declare your funding sources in a previous health committee meeting, and you did not do so again today. So I want to clarify that, according to the last record, you get half your money at least from big pharma, brand name drug companies.

Ms. Linda Wilhelm: That is correct, and I believe I thought where we get our funding was included with this submission—

Ms. Gail Attara: It's in our brief.

Ms. Linda Wilhelm: —and we are trying to balance that funding. Nonetheless, all our members are volunteers, and we don't receive any money for what we do. In fact, many times it costs me money to do what I do.

To support the progressive licensing framework is a process that's been ongoing for—

Ms. Judy Wasylycia-Leis: You've answered my question.

Thank you.

In your brief you say something about getting support from the drug industry. I'm looking for it right now: "The pharmaceutical industry is a major supporter." You didn't declare your financial support, so I think that's important for everyone to know. As Terence Young said at the beginning, none of his money for the coalition comes from the corporate sector.

I think what we're finding is that there are some legitimate concerns that people are having a difficult time raising because there's been such a hold over this agenda from the brand name drug companies. We saw it with many of the presenters, and we're very concerned.

In fact, the importance of this meeting here today is not to focus simply on adverse drug reactions, although that's an important part of it. The point of this meeting actually should be to understand what the government is really about, and Michèle Brill-Edwards will have a sense of this. So will Terence Young, because we've been through this many times before, and this is a government bent on totally revamping the Food and Drugs Act in the name of modernization.

What we're seeing is a move away from the precautionary principle, which most Canadians actually support, the "do no harm" principle, to the risk management model, which is to let the drugs on the market and then worry about the impact. If there's a reaction, then let's just allow people to sue the drug companies, because that's a lot better and a lot cheaper than having to really make sure our products are safe beyond a reasonable doubt.

So I want to ask Michèle Brill-Edwards—I know you've been active on this file for over 10 years—how many times you've seen this agenda item come to the fore, how you and the coalition have helped stop it in the past, and what we can do now to bring some light to this whole issue.

Terence, you identified Vioxx as a good example of what's wrong with the progressive licensing system, and other concerns around transparency and accountability, which I think we need to hear about as much as we need to hear from you about mandatory adverse drug reporting.

So Michèle and then Terence.

● (1205)

Dr. Michèle Brill-Edwards: Regarding the history of Health Canada's attempts at what is loosely termed "legislative renewal" for the Food and Drugs Act, you're correct that there have been numerous attempts in the past. For example, in the late 1990s there was an intention to roll the Food and Drugs Act into an omnibus act with 10 other acts of Parliament, which failed miserably, but only because of the actions of non-profit groups in bringing to the attention of Canadians the abysmal destruction of regulatory powers that was about to occur.

So the track record is not good. The issue here, in historic perspective, is that we have been through roughly 30 years of deregulation, beginning with the deprofessionalization of the agency in the 1970s and 1980s, removing people with expertise who could challenge drug companies. At the same time, we had regulatory indifference publicly. It was politically voiced as red tape—safety and so forth are nothing but red tape to regulators.

In the more final phases, we've had the dismantling of the actual department, the destruction of the drug research labs, the half-destruction of the food research labs, and the farming off of environmental health to a different department.

Now we are in the true final phase, fourth phase, of deregulation, which is dismantling the very legislation that creates the power to do such things as create a moratorium. We have that ability at the moment. It would be quite possible to do, but Health Canada not only does not enforce the regulatory authority it has, it now seeks to actually dispel itself, to dismiss the regulatory authority so it can no longer be held accountable when things go wrong.

Ms. Judy Wasylycia-Leis: Terence.

Mr. Terence Young: Thank you.

About a month after Vanessa died, I had a call from a pharmacist at an Ontario hospital. She told me she did a report on the cancer ward in her own hospital and that seven out of nine patients who had been given Prepulsid had died. They were very sick patients. They were cancer patients. Many of them, if not most, were going to die anyway. But they died after taking Prepulsid, when it was contraindicated.

She sent that report to Health Canada. Health Canada covered it up for a year and a half. This is a result of the partnering direction they had with the industry.

We did an FOI for a CBC film. We discovered a memo from a senior Janssen-Ortho executive, directing Health Canada officials how to answer questions on this drug, Prepulsid. It was telling them what to say after a CBC *Marketplace* show—coaching, working together.

At the inquest into Vanessa's death, the vice-president of regulatory affairs and linguistics was giving testimony. She said, "We view Health Canada as a key customer." In another quote, she said, "Health Canada doesn't warn Canadians about drugs; it helps them take them." This is a vice-president of Janssen-Ortho, which is a Johnson & Johnson company.

I believe it's not what the drug companies tell us that harms patients; it's what they don't. They also withhold a great deal of information they classify as “commercial” in the summary basis of decision. It's humorous, because they get the same drugs approved in the States, and the FDA will publish the same information on the Internet. So Health Canada is hiding it, saying they can't talk about it, they can't tell us.

I'm optimistic this new act will provide all that transparency, including the clinical trials, as I mentioned to you as well. In researching my book, I found probably 40 or 50 different ways clinical trials are biased. The most obvious is publication bias. They bury the bad ones and get the good ones published. They omit washouts, people who start the drug trial and then stop because the drugs affected them badly. They pretend they were never in the trial. Another is what they call non-responders, people who say they didn't feel any difference with the drug. So they take them out of the trial as well.

When trials are going badly, they shut them down and pretend they never existed. They test drugs on homeless people who have a range of illnesses like liver damage, etc. And they test drugs, in some cases, in uncontrolled conditions. In some cases, to get better results, they test a drug and compare it with another drug in a higher dosage than they're going to be selling.

I haven't lost my sense of humour in all this. You have to see them to believe them.

● (1210)

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

Mr. Brown.

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

I've got a few questions for Mr. Young.

Thank you for your testimony here today. Certainly you were able to share a very powerful story with us. I appreciate your doing that.

I was interested in a few things you mentioned. You mentioned that big pharma has information from 192 countries around the world and that some of that is not shared with Health Canada. Could you elaborate a little bit on that?

I'd also like you to elaborate on this. You mentioned that Mr. Dosanjh, when he was health minister, announced some policies, but they weren't implemented. What were those policies? I missed that.

Mr. Terence Young: In doing the investigation into Vanessa's death, I found out the regulators in each country. Janssen-Ortho, for example—their head office is in Belgium, Janssen Research Foundation—would only communicate with each regulator in each jurisdiction individually and talk about the deaths or injuries within their jurisdiction. And so at the inquest into Vanessa's death, our counsel asked how many deaths there had been worldwide. The vice-president could not answer because it was not routinely part of her job to investigate and find out how many people worldwide had died from a drug.

These companies have more money than many countries—I'm not exaggerating—with capital values of over $100 billion. There are more than 100 countries in the world that have nowhere near that kind of money. They deal with the regulators on a one-to-one basis.

In 1998, Prepulsid had a black box warning on it, the highest level of warning, coordinated with the FDA, but they didn't put that warning on the drug in Canada because no one told them they had to.

These are the games the pharmaceutical companies play. If they're ordered to do something, they do it. If they aren't, they maintain the drug is safe and keep selling it.

Minister Dosanjh announced he was going to move forward with compulsory adverse drug reaction reporting for doctors, but nothing ever happened. I can only assume he received huge lobbying pressure from the Canadian Medical Association and the pharmaceutical industry to not bring it forward.

Mr. Patrick Brown: Another interesting statistic you raised was that adverse reaction deaths were the fourth leading cause of death in Canada. What information is that comment based on? Was there a study done?

Mr. Terence Young: The primary study was done by Lazarou et al., three professors from the University of Toronto, in 1998. It was a macro study of hospitals. I don't remember the number of hospitals, but I have a reference for you in the printed material. They determined that 104,000 people die from adverse drug reactions in the United States, in hospitals alone, from prescription drugs taken as prescribed—not in error, but as they were prescribed. Others have extrapolated that figure and asked about the deaths that occur outside hospitals. They think that may be as high as another 100,000, although it's very difficult to prove.

So using the population ratio, that would be 10,000 in Canadian hospitals and then potentially another 10,000 outside Canadian hospitals.

Mr. Patrick Brown: It is certainly a chilling statistic.

One thing we had talked about in this committee was electronic devices and how they might equip doctors more effectively. As a general comment, how much would it help if warnings were communicated by Health Canada in real time to those in the medical profession who are prescribing drugs?

Dr. Michèle Brill-Edwards: Again, the problem is not the reporting process; the problem is the very delayed analysis of reports at Health Canada. Real-time reporting already exists. When you go to the website and fill out the adverse reaction reporting form, it's transmitted almost instantly to Health Canada. When does Health Canada get around to analyzing the collection of reports? That's the problem.

You have to understand that a single report does not tell Health Canada anything. It's just a report. The adverse event could be due to the drug, or it could be due to something else. The only way you can begin to separate a true red-flag report from the noise that's coming in from many reports is when you start to see a pattern. You have to take reports that are similar and start searching and sifting and looking for a pattern, and that is what Health Canada is not doing promptly in a timely fashion.

Having real-time reporting is already there, but it's not enough.

● (1215)

Mr. Patrick Brown: The reason I raise that is that one of the comments, when I asked the Canadian Medical Association the same question, was that when there's a new warning, sometimes it comes in by fax and sometimes it's mailed. So that real-time reporting is not there. It could be a span of weeks.

Dr. Michèle Brill-Edwards: I'm sorry. I misunderstood your question.

Mr. Patrick Brown: Yes, I meant communication from Health Canada to doctors.

Dr. Michèle Brill-Edwards: You're talking about what goes out to doctors.

Mr. Patrick Brown: Yes.

Dr. Michèle Brill-Edwards: Yes, there is a huge deficit on Health Canada's part in the manner in which they communicate with physicians. There has been a long-standing attitude within the department that the system doesn't work because the doctors don't send them reports, so what obligation does Health Canada have to speak to them?

Mr. Patrick Brown: What is your recommended solution?

Dr. Michèle Brill-Edwards: The recommended solution is to have transparency in the system. It is to demand that the ways in which the department is assessing the information and the reasons behind their communications are transparent, so doctors can judge whether they agree with what's been done and said within the department and can evaluate the validity of the advice that's coming out.

The second thing that could easily be done today is to have every physician who is linked to the Internet—and that is, in today's world, in the practising world, about 95%—aware that they have the opportunity to have immediate e-mail alerts from Health Canada. That is as real time as you can get.

It demonstrates the passivity of Health Canada. They have this system operating, but they don't make any effort or have any outreach to the physician and pharmacy community to say, “Please help us. Please give us your e-mail address. Let us send you these reports.”

Mr. Patrick Brown: Another comment you made that I was interested in, Mr. Young, was that international studies should be shared with Health Canada within 48 hours, not within the current six to twelve months. What are those timelines based on?

Mr. Terence Young: The medical community calls them signals. A patient falls dead, and they think it might be due to a prescription drug. That could be in the U.K., South America, the United States, or somewhere else. The medical community calls that a signal. They start counting them, and when they get enough of them, they call it noise. When they get enough noise, somebody actually starts to look into it.

If the signals—the information the drug company got when it was reported to them that it was potentially a cause—were immediately sent to the regulators, the regulators could start to open their own files and start to investigate the drug themselves. You could have patients doing their own adverse reaction reports too. So they would get information earlier, and they could act sooner, instead of it taking months and months and months, while the body count rises.

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

Now we're moving to the second round. In the second round we'll keep it to three minutes, so we can finish. It is the same for everyone.

Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): I can't burp in three minutes.

The Vice-Chair (Mr. Lui Temelkovski): We'll help you.

Hon. Robert Thibault: I want to thank you all for your discussion and for bringing that forward. It's a very difficult area. I want to see drugs available. If there's a chance of somebody being saved by a pharmaceutical or product, I want them to have access to it. At the same time, I agree that they should have all the information.

We had one practitioner telling us that when you read that compendium everything that could possibly be in there is included. You really don't know what is significant and what isn't, so that's one of the reasons it gets to be in disuse.

The other thing we heard from Dr. Brill-Edwards, and that we have heard from others, is about interaction between practitioners and the system on adverse drug reaction so you could have that benefit. Technology gives us that chance. As we do the Drug InfoNet and health InfoAid, hopefully that will be part of it.

We see that the pharmacists have quite a good system, and our MDs and practitioners don't.

A voice: The vets and the dentists have it.

Mr. Robert Thibault: The vets and the dentists do, and the pharmacists, so that possibility is there.

As for health care contacting practitioners, I don't know about every province, but every practitioner in Nova Scotia does his or her billing by way of technology. With the MSI system, they are online, so why couldn't that system feed the health advisory or an advisory on drugs?

I do want to be careful, and I'll give you as much as I can to answer, but in your consideration I'd want to be careful. I like the idea of progressive licensing. I understand why off-label use is done with drugs. I understand these things are necessary.

But I'm also scared when I hear Mr. Young talk about Gardasil. Until I heard you say that, I saw it as something that held great promise. If I'm the father of a young daughter, I would be very happy that it's available for her and it's is going to protect her. But then you raise these points that there is a lot of risk. That scares me, frankly. You're telling me something could be prescribed to all young women in Canada that would be licensed and encouraged by our government, that would even make it into a budget speech; it would make it through our system, and it carries that risk.

Could you elaborate?

● (1220)

Mr. Terence Young: I think Gardasil does hold promise, but when they don't know whether it will last beyond five years and it hasn't been tested with other vaccines.... The most important word in drug safety is contraindication. If it hasn't been tested with these 16 other vaccines, say, that little girls might have had before, they could run into contraindications. I'm saying it's unproven. I'm saying there are too many unknowns about it to ask every little 9- or 10-year-old girl to take these three painful needles.

There's another one coming out, by the way, following Gardasil, which will apparently protect against the other 30% of cancer-causing HPV. Who knows how they will react?

There are always questions, and you want the questions answered. You want to monitor patients very closely. You don't want a million little girls taking something when it's brand new. It's better to start it slowly with patients who are more willing, in this case—I was going to say patients who have the condition, but there is no condition yet—and build it up slowly, so that if it has a deadly side effect you can catch it before a million patients are exposed to it.

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

We'll move on to Mr. Tilson, for three minutes, question and answer.

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

All of your testimony is most compelling. In fact I find it alarming. It makes me never want to take a drug again.

I'm not going to summarize what you said. I made notes, as we all have. We all have that information. It's most useful for the committee to consider as to what recommendations we'll make to Parliament.

I'm still not clear on this. As I understand it, the only people who can make a report to Health Canada are the pharmaceutical companies. That's what I understand, although I think now we're talking about hospitals.

My question is for anyone. If an individual has a reaction and they're not too sure whether it's serious or not, because you only report serious reactions, what happens? What does that person do? They don't know where the drug company is. You talked about a friendly form. You talked about doctors trying to talk you out of filling it out. I think you mentioned that. You said a lot of alarming things.

So I've had a reaction. I think it's a serious reaction. What do I do today?

Ms. Linda Wilhelm: That's why we need to empower the Canadian patient to be able to report. It's not up to the patient to decide what is serious. I actually think all adverse reactions should be reported, and let Health Canada figure out what's serious and what's not serious, what's significant and what's not significant.

Drugs have helped a lot of people, and I'm walking testimony. I wouldn't be here today if it wasn't for a biologic to treat the rheumatoid arthritis that I've lived with for 25 years. There is always a risk-benefit. But there has to be more of a dialogue, and Canadian patients have to realize that just because a drug is there doesn't mean it's safe. There always has to be a dialogue with their position: is the benefit of this drug going to outweigh the risks of this medication?

Natural health products, over-the-counter medication, everything you do has a risk to it. It's up to patients to be informed and educated, and we're not doing a good job of that.

Mr. David Tilson: Let's assume it's a serious reaction. My question is to anyone.

What do I do? I clearly have a serious reaction and I'm almost dying. I'm trying to think of a serious reaction, and I don't even know what one is—I think I do. Let's say I'm convinced I have one. What do I do? I go and fill out a form somewhere, but who gives me the form?

● (1225)

Ms. Gail Attara: Presumably you would go to the hospital if you had a really serious problem, and then the hospital would take care of that.

But I think you raised a really important thing in that we don't know what to do. The public doesn't know what to do.

There are many times that things are going on that we don't even know about. All of you here have probably taken ibuprofen. Do you know that after one dose of ibuprofen your stomach bleeds? One dose. You don't see that, so you don't even know that it's going on. Some people think, "I can just get this medicine over the counter, therefore I can take a couple more, and I'll give it to my kids." We're not even aware of things that are going on inside of us, what it's doing to our cardiovascular system and all those things.

We don't know when we take a medicine whether it's taking it or whether it's interaction. If we had a public education awareness campaign to tell people what they can do and the infrastructure to manage that, I think that's the biggest challenge that we have here and this committee has. Where is the infrastructure going to come from that's going to manage all those reports?

Mr. David Tilson: I'm finished.

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

Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Good day and thank you for joining us. I have a few questions that I will put to you in quick succession, after which you can respond.

Earlier, you stated that several drugs were administered to people who were not members of the group targeted by these studies. I was wondering how many people taking this drug fell into this category and how serious the problem actually was?

You also suggested that an independent evaluation bureau be set up. What type of funding should this bureau receive and what advantage would this present over the system currently in place?

Thank you.

[*English*]

Dr. Michèle Brill-Edwards: Regarding the first question on off-label usage, Health Canada and other regulatory bodies—not Health Canada alone—leave practitioners in the lurch, because we have a system in which the manufacturer asks for the drug to go to market for particular uses, the so-called indications, for which evidence has to be produced. And when evidence is available, the drug goes to market for that use in that general population—let's say adults—but if the same drug is useful for other purposes, and research has been done on it by universities or medical groups and has been published in the literature, and it is well accepted that the drug has a bona fide other use, that is not then reflected in the approval of use by Health Canada. So this forces doctors to use drugs in an off-label fashion, with the result that the industry can always say, oh well, it was used for a non-approved use. It gives them an out; it reduces their liability. But in fact it's a very dangerous process that forces doctors to use drugs for indications where there isn't any official authority saying yes, this is how the drug should be used.

I'm a pediatrician, as well as a clinical pharmacologist, with extensive regulatory experience in years past. I am now working part-time in the emergency department at CHEO, the Children's Hospital of Eastern Ontario in Ottawa. We see patients day in and day out, and we are using drugs that do not have a pediatric indication but are used worldwide and accepted as appropriate for use in those indications.

So this whole notion of off-label is very misleading in that it allows the drug companies to get off the hook by saying, oh, it was an unapproved use. And it leaves doctors and patients with no federal body having said yes, this is appropriate.

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

I'd like to thank the witnesses for all of their testimony and information.

We will be breaking—

● (1230)

Ms. Judy Wasylycia-Leis: On a point of order, Mr. Chairperson, could we have five more minutes to hear the witnesses? I'm sure we could get our business done within 20 to 25 minutes.

The Vice-Chair (Mr. Lui Temelkovski): We have lots on the agenda already.

Ms. Judy Wasylycia-Leis: Maybe she could just answer the second question.

Dr. Michèle Brill-Edwards: Very quickly, such an agency would not require much in the way of resources but the commitment of the industry, the government politically, and the regulators to accept an independent agency that functions in a quasi-judicial fashion and cannot be influenced by the money of the industry.

I would say that it would cost approximately—I'm guessing here—maybe $20 million annually. It's not a big sum, when you consider the billions of dollars of profit that are at stake and the thousands and thousands of lives that are being lost without such a board.

Mr. Terence Young: If I could comment too, the figures that I gave the committee from the Canadian Pharmacists Association—$2 billion to $9 billion in savings if drugs were only prescribed appropriately, and another $10 billion for care from adverse drug reactions—mean that $19 billion would be on the table in savings if drugs were only prescribed when appropriate.

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

Now we'll move to an in camera session. I will allow the witnesses to take a moment to—

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): If we are to go in camera, I have point of order first.

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

Mr. Steven Fletcher: The point of order deals with testimony from the last meeting; it's just a clarification of the record. There was some testimony given by the Canadian Society of Transplantation that I think is incorrect.

The Vice-Chair (Mr. Lui Temelkovski): We will look at the testimony. It's there on record, and unless they've written to us to tell us that it's different—

Mr. Steven Fletcher: No, no. I'm suggesting that they misspoke, and I just want to clarify the record.

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

Mr. Steven Fletcher: It's not a point of order?

The Vice-Chair (Mr. Lui Temelkovski): No, it's more a point of debate.

Mr. Steven Fletcher: No, no, it's not a point of debate.

The Vice-Chair (Mr. Lui Temelkovski): Our analysts are capable enough of figuring out what has been misspoken—and you can tell us about this afterwards.

Mr. Steven Fletcher: Okay.

On another point of order, it turns out that the Canadian Society of Transplantation was in fact consulted by Health Canada during the consultations we had. The president recognizes this in a newsletter that he printed out. It says:

> Our community also finds itself in the midst of a large number of changes with implementation of the CSA Standards, Health Canada developing regulations for Transplant Programs and CCDT developing consensus papers for donation and transplantation practice. CST is working with Health Canada and CCDT to ensure that the community is well represented during these initiatives.

I also have three or four decks from Health Canada.

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

Mr. Fletcher, thanks for putting that on the record, but you're aware that's not a point of order.

I think we'll have a break and then go in camera

Thank you.

[*Proceedings continue in camera*]

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