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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1105)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Order, please.

I would like to welcome the witnesses who are here today.

What we're going to do is listen to the witnesses, but before we actually hear from the witnesses, I want to remind members that we will be discussing committee business in camera, beginning at 12:30. We will go in camera at that time for discussions.

The witnesses have heard this as well. At 12:30 we will ask you to leave the room so we can go into our business.

We really want to welcome you. We feel very privileged to have you in front of the committee today, and pursuant to Standing Order 108, I'd like to welcome you to the eighth meeting on post-market surveillance of pharmaceutical products.

You know, members, that our panel today consists of representatives from the Anemia Institute for Research and Education, the Consumers' Association of Canada, and PharmaWatch.

Just to get started, I would like to remind the witnesses that witnesses have 10 minutes per organization to make their presentation. What will happen is that the committee will hear all presentations first before proceeding to the members.

Let us begin with Ms. Durhane Wong-Rieger.

Dr. Durhane Wong-Rieger (President and Chief Executive Officer, Anemia Institute for Research and Education): Thank you very much. I really appreciate the opportunity to be here.

I am here as the president of the Anemia Institute for Research and Education. I will also speak, though, in my role as president of the Canadian Organization for Rare Disorders.

Let me just put into the context, in terms of post-market surveillance, that for us this really means all the collection, analysis, and utilization of data on the impact of health technology. Certainly we're very pleased to see the health committee moving forward on this. At the moment, I think our major concern is that we believe the way it's being done currently is really not very useful to patient decision-making, and in fact, in some respects it may actually be quite harmful. As patients, we're well aware of the need to balance safety and efficacy, the risks and benefits, costs and affordability, but at the end of the day, patients really have one bottom line, and that is to be able to have access to medicines, and certainly to the most appropriate medicines, as soon as possible.

The second need for us is really making sure that, at the end of the day, the therapies we're getting are perceived to be working. Currently I would say that most of the system around post-market surveillance is really not very helpful to what we would call patients being able to make the trade-offs between risk and benefits, partly because in many respects we just aren't given that information. We're not given it usually from the physician, who may prescribe a medicine and not necessarily talk about it in terms of risk and benefits, and certainly we're not given it from the point of view of the government or from the manufacturers in truly understanding what the trade-offs are in those decisions around trade-offs.

We expect that post-market surveillance, though, is not only going to answer the question, is this drug safe and does it continue to be perceived as safe, but also, is the drug effective? So what we're directing back is to say, in terms of post-market surveillance, that the information, the collection of data, needs to be as much geared towards assuring that drugs are effective, and certainly effective for the specific patient populations for which they're being used, as well as whether they are continuing to be safe. That, to me, is one of the first challenges.

Let me briefly give a couple of scenarios that help drive our thinking.

Certainly the Anemia Institute has been very much concerned, in moving out of an area that the institute grew out of, about the issues around tainted blood. I think what we were keenly aware of, of course, is that at that time, even when the post-market data were very clear that we had a problem with the blood system, there was no uptake in terms of that information. There was no decision-making that actually took advantage of that information as it came down.

I was very pleased, as we went through the reforms of that system, to be named to the first board of directors of the Canadian Blood Services. However, I walked off that board two years later, in part because it was my sense that in setting up the new board of directors and the new Canadian Blood Services, we had certainly abandoned science and logic as a reaction to what had happened and, in fact, became hypersensitive to the issues around the post-market “safety”, to a point where it became very detrimental.

I'll give you two examples. One was the whole issue around banning donors who had accumulated more than six months of stay in England. At that time, the reason for the ban was because of the concerns around BSE among cattle. There was a concern that people who had been in England over a period of time might in fact actually have been exposed to contaminated beef and may be at risk for CJD, and there was a theoretical risk that CJD could be transmitted through blood.

At the end of the day, we made a fairly draconian decision to ban donors who accumulated more than six months of stay. I won't go through all the details of what was wrong with that decision, but I will say that decision was made fully in the face of no science, and actually a lack of common sense. Even today, some 15 years later, when it is very clear that there is in fact no such risk and there has been maybe one potential case of transmission of CJD, and we have in our own country now evidence of BSE in the cattle and we have evidence of it in the U.S., we continue to keep this ban. That, for me, makes no sense.

So we're doing something as a post-market reaction to an incident that happened, but we're unable to actually correct that once we're into it.

● (1110)

The second one I will give is continuing to ban donors who are men who have sex with men. Sure, in the early 1980s that was a problem, but now, some 25 years later, we are overreacting. It's not only a case of shutting the barn door after the horses have left; we're actually not even opening them up again when the horses are desperately needed. We have to be able to set up a system that works on the basis of science and logic and doesn't just become reactionary.

My other concern, as I say, from Anemia Institute, is that one of the recommendations coming out of the blood system was to be able to use alternatives to blood whenever possible, and we've had a real problem now with the erythropoiesis-stimulating agents. Yes, there are really very important issues that post-market surveillance has actually been able to find, and we give full credit to all of the agencies that have been examining that and understanding some of the risks that have been exposed.

Our problem right now is the way in which the process is being done, and certainly the U.S. FDA is a very poor example, in how they're reacting to it. I think it's a reactionary response to what happened with some issues like Vioxx. It does not help patients, and certainly I don't think it helps clinicians, when you have ongoing rolling reviews, ongoing restrictions that are taking place without full evidence. We think there needs to be a systematic approach towards this, understanding how much new information to gather—at what point do you come up with a decision, at what point do you put that out—and not constantly putting out little red flags and sending out DHCPL letters every time you have a new piece of information. It doesn't help us. We have to do this much more systematically.

We have developed some fairly good systems in terms of pre-market clinical trials and how to assess them. We have to apply that to post-market.

Finally, I'll go back to my issues around rare disorders. I think this is a very important opportunity for us to take advantage of what we see as a very positive happening in Health Canada with the progressive licensing framework—the ability to begin to provide some approval around drugs even as the evidence is continuing to be developed. We think the progressive licensing route is a very progressive way of working, and we have been very pleased to see some of the opportunities.

We're hoping that with this progressive licensing framework, as we bring in drugs—especially for the rare disorders, which continue to pose a great deal of difficulty in meeting the kinds of standards that your normal clinical trials would have—we'll be able to set up a very robust post-market system for these drugs, as they're coming in with much earlier evidence.

Certainly we see patient registries as being a very powerful tool to that. Again, I would argue very strongly that we need to have some systematic rules around how we're going to set up those patient registries. I really urge that those patient registries be internationally based, not just for rare disorders but for all—whatever we're doing in post-market surveillance has to be international—and that we also need to fully engage the patients. I think this is where the system has failed the patients. We still do not have a system in which patients are fully aware of where they can report adverse events. They don't get any feedback even if they do report them, and they certainly are not part of the whole post-system of communication and dissemination. Patients need to have information at a post-market stage that is patient friendly and fully understandable.

We applaud Health Canada for the patient-friendly monographs that are coming out with the new drug licensing. We think this is a very positive move. We think that the same thing needs to apply in post-market.

I also applaud very much what Health Canada's doing in terms of allowing people to have direct access to adverse reaction reporting as it's coming out. So as a patient, I can sign up. I can get the warnings. I get a very quick synopsis of it. I can decide whether it's useful to me. I urge, too, that this information also be patient friendly, because what we get is sort of just standard; it's not necessarily fully intelligible to a patient.

In conclusion, I will say that we don't easily praise what is happening in government, so when we do, it means a lot to us. We think that Health Canada has done some very significant things over the past few years, including setting up the post-market, engaging patients fully, and developing the progressive licensing framework that sets up an ongoing opportunity to no longer call it just post-market surveillance, but to have ongoing input.

We do think the patient registries could be a very important part of it, and I would really urge that we more fully engage patients in the reporting of adverse events, in terms of receiving that information, having direct lines into the government, and certainly direct access to that feedback and information.

● (1115)

I would also encourage Canada to do something that we think they're very remiss in, and that is to support patients and patient groups to help disseminate that information. We're one of the few countries I know of in the developed world that does not directly support patient organizations, and it makes it daunting for us to do our work. It's no good casting aspersions on the patient groups for taking industry funding when there are no other sources of funding. I really encourage the government to take a look at that.

Thank you very much for the opportunity. We're very pleased to see the Standing Committee on Health take up this issue. We encourage very robust scientific methodologies for linking post-market surveillance to the pre-market data, but we also urge that the information be considered in a very systematic way, certainly considering the patients at the end of it.

Thank you.

The Chair: Thank you very much for your presentation.

We'll go now to Mr. Fruitman.

Mr. Mel Fruitman (Vice-President, Consumers' Association of Canada): Thank you, Madam Chair.

We at the Consumers' Association are very pleased to have this opportunity to appear here today.

By way of background, for over 60 years the Consumers' Association of Canada has represented the interests of ordinary Canadians in their role as consumers of goods and services as provided by both the public and private sectors. We are not a professional medical advocacy association, nor do we represent persons with specific medical interests or illnesses. Our mandate is to inform and educate consumers on marketplace issues, advocate for consumers with government and industry, and work to solve marketplace problems in beneficial ways.

I am one of those 33 million Joes and Janes—to be politically correct—on the sidewalk mentioned by a committee member. And in fact, I am a volunteer. Since I am a layman, I will speak in those terms and not in medical jargon, in which I am not well versed.

Canadian consumers expect that the goods and services of which they avail themselves will be safe. This particularly applies in the medical arena. We at CAC recognize that the term “safe” is an absolute that can rarely, if ever, be guaranteed, and that a more appropriate term would be “to do no harm”. Consumers instinctively recognize this distinction, since they are aware that overdosing on even relatively benign products can have harmful effects and that many medications have potential side effects or contraindications, to use the technical term, I believe, even though they may not be familiar with the specific details.

We are extremely concerned that apparently an increasing number of pharmaceutical products that have been deemed safe, in that they were available for purchase, have subsequently been found to be anything but. Additionally, consumers are confused by the frequent media reports purportedly based on sound information that tell us that pharmaceuticals that had been promoted yesterday as life-saving are now seen as likely to harm or kill us. All of this raises the question: who, if anybody, is minding the store?

It is our understanding that the current system for approving pharmaceuticals is analogous to the way drivers used to be licensed. After a specified test or tests, the privilege to drive, or in this case to sell, is bestowed and is not revoked except for egregious circumstances. There is no attempt to determine if the capability to perform as required or expected still exists. Unfortunately, the analogy breaks down because there is no capability to revoke the right to sell pharmaceuticals.

Health Canada is proposing the introduction of a progressive licensing regime. To continue the driver analogy, this is similar to the graded drivers' licences that have been introduced over the years, whereby a young driver, after passing a test, is allowed to drive under limited circumstances. As time passes and additional tests indicate enhanced performance, the limitations are reduced until they are completely removed. But again, there does not appear to be a mechanism for following up over time or for revoking the privilege to sell.

Instead of a progressive licensing system—and part of the problem, I think, is interpretation of what that system is—we would prefer to see a continuous one. This would be one in which it is clearly recognized that an authorization to sell pharmaceuticals to Canadians is not an absolute, but that Health Canada can revoke that privilege if at any time it has cause to believe that the health and welfare of Canadians would be better served by removing that product. This means that there has to be an ongoing surveillance of the products. This would include the regulatory authority to require new or additional studies if clinical trials or data gathered either domestically or internationally suggest that there are safety risks for Canadian patients.

We do feel there is merit in allowing some products, as alluded to by Durhane, to be used in limited circumstances during the early stages of evaluation, and maybe evolution. These are cases in which the need for a drug is critical and the risks can be well documented by the manufacturer sufficient for the patient and doctor to make an individual risk assessment and decision.

We have noted during the course of these hearings numerous objections to the establishing of a post-authorization or post-market surveillance system, with reasons ranging from the idea that it would impose too great a burden on the reporters to the idea that the mechanism doesn't exist, how would Health Canada cope with and be able to sort through a multitude of reports, and how is it to be funded. There seems to be surprisingly little thought given to going beyond the excuses to how this can actually be made to work. The starting point has to be a positive one.

● (1120)

We think the Canadian Medical Association has got the right approach, which I think is worth repeating:

> ...to effectively monitor the safety and effectiveness of the country's drug supply, ...a strong post-market surveillance system should include an effective process for gathering drug safety data coupled with a simple, comprehensive, and user-friendly reporting system; a rigorous process for analyzing this data to identify significant threats to drug safety; and a communications system that produces useful information distributed to health care providers and the public in a timely and easily understood manner.

We need to look at the establishment of a simple, cost-effective reporting system for reactions to pharmaceuticals that may be indicative of potential harm. We are not medically qualified to suggest what the cutoff point for reporting should be; however, much of the discussion seems to have been revolving around whether reporting only severe adverse drug reactions should take place. We understand that a working definition of an adverse drug reaction is “a noxious or unintended response to a drug occurring at doses normally used or tested for the diagnosis, treatment, or prevention of a disease or modification of an organic function”. In some cases we understand that this is qualified by some practitioners who add “significant morbidity or injury to patient, but did not directly cause death”.

We feel that in the interest of patient safety, the lower threshold should apply. We would even express some concerns about the limitation of doses normally used. There will be instances in which patients frequently exceed the specified dose either because they feel that an increase will help them get better faster and/or they were not made sufficiently aware of the dangers of doing so.

The system has to be able to track patterns of behaviour as well as low levels of unintended responses, which may be indicators of a widespread or imminent problem. In some cases, solutions may be as simple as including more, better, or more understandable information with the drug. Of course, if there are indications of a pending serious problem, appropriate stronger action would have to be taken.

We also note that there have been many comments about international harmonization of testing requirements and suggestions that Canada should not proceed on its own but should work only within that environment. It is our fear that this approach would most likely result in extreme delays in moving forward. The work of international bodies' attempts to achieve common ground or consensus usually moves at a glacial pace and with a great deal of politics involved—usually.

One last comment that doesn't appear to directly relate to the topic at hand is that we are adamantly opposed to consumer advertising of pharmaceuticals. In fact, in the context of this current discussion, we think that such advertising has an extremely detrimental effect on the efficacy of the medical system. It can lead to increases in misuse and inappropriate use, leading to overloading any reporting system that may be devised and diverting attention from more substantial concerns.

Thank you very much. I'd be pleased to try to answer any questions you might have for me.

● (1125)

The Chair: Thank you very much, Mr. Fruitman.

We'll now go to Ms. Fuller.

Ms. Colleen Fuller (President, PharmaWatch): Thank you.

I'm representing PharmaWatch. My name is Colleen Fuller, and my colleague Carol Kushner and I are both going to present.

First of all, thank you very much for inviting PharmaWatch. We're really pleased that the standing committee is looking at post-market surveillance. Of course, we have been following the work of the committee for many years and we are looking forward to your report.

PharmaWatch is a consumer advocacy group. We were founded in 2001, like a lot of other consumer groups, to begin pushing Health Canada to do a stepped-up ADR monitoring. We are focused on adverse drug reaction collection, although we obviously recognize that post-market surveillance has a much broader lens than that. We would take the position that the rest of the responsibility within the marketed health products directorate isn't going to get done if there is no data collection. So we do focus on adverse drug reaction reporting, and we are specifically focused on consumer reporting of adverse drug reactions.

Consumer reporting is a relatively recent development both in Canada and internationally. In Canada it wasn't really until the year 2000 that there was a focus on consumer reporting. Consumers began to be identified as a category or a source of report in 1998. That was the first time there was any ability to know how many reports were actually coming from that source. In 1998 it was estimated that 7.1% of reports were contributed directly by consumers, and by 2006 that had increased to 24.2%. So there has been a significant increase in the number of reports coming directly from consumers.

However, the contribution of consumers to the overall collection of data is very, very low, and what we are mostly focused on is increasing the contribution of consumers to the database. One of the reasons is that both our information and an increasing number of international papers that have been published in the last five years indicate that consumers are really able to make a significant contribution to our knowledge about the safety of medicines that are being prescribed. They are often overlooked as a source of information, or the information they contribute is often downplayed because they're not health professionals and physicians and so forth, but they actually are able to make a significant contribution.

Although the level of consumer reporting has increased in the last four to six years, overall, as I said, the number of consumer reports is quite low. We have conducted in the last three to four years a number of focus groups across the country. What we know is that awareness about Health Canada's ADR program is very, very low in Canada amongst consumers. In fact, if you say the term “adverse drug reaction” to most consumers in Canada, they won't know what you're talking about.

We think this situation really needs to be addressed with dedicated resources and funding by the marketed health products directorate. I concur with Durhane that patient groups, consumer groups, really have to be utilized by Health Canada in a much more significant way than they have done so far. We also believe that the priorities within the health products and food branch are focused on approval of drugs and expedited approvals within 300 days and so on, and that this focus needs to be shifted, obviously not entirely, but there has to be a reorientation and a greater allocation of resources and staffing to the marketed health products directorate.

In the summary I have provided a table comparing the resources and staffing that are allocated between the two directorates, the therapeutic products directorate and the marketed health products directorate. In terms of funding, TPD gets triple the funding that the marketed health products directorate gets and almost four times the staff.

We feel there needs to be a rethinking within the health products and food branch about where their resources and funding are being dedicated.

● (1130)

Finally, in our report I've listed our recommendations. I'm just going to finish by highlighting a few of them.

We make two types of recommendations. One is to increase consumer awareness about ADR reporting, and the other is about the actual collection of consumer ADR reports.

On the awareness side, we think there has to be dedicated funding for community-based promotion of consumer reporting and that there has to be a lot more investment in educational materials and promotion through television, radio, and through the media. We think the toll-free number that consumers can use to report ADRs should be listed on every package insert and every prescription label; that there needs to be a source of government-approved, unbiased information about drug safety and adverse side effects; that there has to be material published and geared towards different literacy skills, because this is a major problem in trying to communicate not only information about the reporting system, but about the risks that are detected in the collection of the ADRs. We also need to think about establishing a national clearing house for patient and consumer information on drug safety that is independent of the pharmaceutical industry.

On the collection side, it's obvious that people need to be trained. When we were first set up, we collected adverse drug reaction reports, and believe me, this is not an easy task for anybody. You have to be trained; you have to be educated.

The Chair: Ms. Fuller, I just want to say that we have reached seven minutes.

Ms. Colleen Fuller: Okay. I'll finish by saying that the marketed health products directorate needs a greater investment in direct consumer reporting.

Thank you.

The Chair: Thank you.

Ms. Kushner.

Ms. Carol Kushner (Director, PharmaWatch): Thank you.

I'm here to support a proposal that has been made to the federal, provincial, and territorial ministers of health. It comes out of a need to make clear how to improve post-market surveillance. There are recent news stories about Vioxx, hormone replacement therapy, and SSRIs—the selective serotonin re-uptake inhibitors—which don't seem to work better than a placebo. There are news reports that lowering cholesterol may not be all that it's cracked up to be for large numbers of patients taking certain medications. Apparently it's not helpful to the elderly, and it has never been demonstrated to be helpful to women. Yet large numbers of people in these groups are taking these products and exposing themselves to serious risk.

Canadians desperately need unbiased information about how well drug products work in the real world—information from outside the clinical testing environment. We need to know if they live up to their early promise. We're getting indications that some of these products are not living up to their early promise, that they're not safe when taken as directed. We need clarity about the risk-to-benefit profile of each product as it's approved. We just don't know at this point, and what we don't know can hurt us.

This proposal that I'm urging you to support—PharmaWatch supports it and has been involved in its development—is to create a five-year program of post-market surveillance that could, if approved by these federal, provincial and territorial ministers, fill some important knowledge gaps.

It's being supported by a broad-based coalition of researchers, medical providers, consumer groups, and other health providers. It would be a pan-Canadian project. It would build on existing structures, so there would be no need to invest heavily in new infrastructure. You could use bodies like ICES, the Institute for Clinical and Evaluative Sciences, in Ontario, which already has built-in expertise in this arena. Of course, we need approval from the ministers of health in all the provinces and the federal government.

I see Carolyn Bennett smiling, because she knows how easy that is to achieve, right?

All I'm suggesting is that endorsement of this proposal from this group would be helpful in opening that door.

There are specific advantages to be had from this proposal.

First, there would be a broad-based committee made up of consumers, professional pharmacists, regulatory agencies, research centres, industry, and government, all working together to set the strategic direction and to identify the first drugs that would be part of the investigation.

Another advantage is that it could produce much more timely results. We waited four years to find out about Vioxx, 15 to 20 years to find out about HRT. We're waiting too long to find out what we don't know and what we need to know.

The results could also help provincial drug plans figure out which products they should include in their formularies. We need to know that we're getting our money's worth when we put out those government dollars.

The program would also provide a concrete demonstration of the usefulness of the national pharmaceuticals strategy. It has been around for four or five years, and I don't know that it's produced much.

● (1135)

The Chair: I know that we're anxious to answer questions, and you're a bit over time. Would you wrap up, please.

Ms. Carol Kushner: I have one sentence left. My last sentence is that the proposed budget for this project, which I think is around $20 million a year, $21 million for the first year, is a tiny fraction of the $26 billion we now spend on drugs.

Thank you.

The Chair: Thank you.

We'll now go to questions. Dr. Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thank you all very much. It's great to see you continuing your role as knowledgeable citizens who are paying attention.

A lot of people are thinking that it's pretty hard to do all this in the bureaucracy of Health Canada. There have been calls numerous times for a separate FDA North or a drug agency that would be a little bit more fleet of foot, with professional leadership, but that might be in a better position to deal with counterparts provincially and would be able to deal with data collection and being on the ground and receiving things.

In terms of a real public health network for Canada, do you have any feelings about the proposal for a drug agency—it would probably be half the staff of Health Canada—off on its own, in terms what we were able to do with the Public Health Agency, with David Butler-Jones dealing with his counterparts?

Dr. Durhane Wong-Rieger: If you had asked me this five years ago, I would have said definitely. Many of us have been very pleased with the kind of progress Health Canada has been able to make. Certainly they've demonstrated it, as we look at something like the progressive licensing framework, as we look at some of the post-market surveillance. I sit on the vigilance of health products committee. Health Canada has demonstrated in lots of ways in which it can be fleet of foot.

I will raise one caution about these stand-alone agencies—and this is not to reject the idea, because I think there's some merit in it as well. I go back to groups like CADTH, which are supposedly independent but at the end of the day are accountable to nobody. They're not accountable to the public, but they sit off...and that's not the same as the Public Health Agency of Canada. I have some real concerns about that. They have an independence that was in theory supposed to be good but at the end of the day also becomes counterproductive.

I don't think there's any such thing as being unbiased. Whether it's government, industry, or patients, we all have our biases. To presume there's any way to set up something that is going to be more unbiased because it's outside any particular group....

I think what Colleen and the others have suggested makes great sense. We need multi-stakeholders. We can talk about how we can achieve that, whether it's with an independent agency or whether it's within Health Canada. I would say that probably doesn't matter as much as how it's working.

● (1140)

Hon. Carolyn Bennett: I would see an agency that would be accountable to the minister, that would give transparent advice to the minister such that citizens would know what the agency said. If the minister, politically, couldn't do it, then the minister would have to account for that.

Mr. Mel Fruitman: Dr. Bennett, I can't answer that question directly. But I would take it back several steps and say I think it would be very appropriate at this time for the federal government to take a look at consumer protection in its entirety, which has fallen underneath the floorboards ever since the disbandment of the consumer agency approximately 20 years ago, and start at the top, looking at what needs to be done in terms of consumer protection across all areas. Then it could step it down from there and look at what would be the most efficient delivery system for each area. It may involve splitting off the various elements into the different departments, and into departments that do not have a conflict of interest, such as the Canadian Food Inspection Agency.

Hon. Carolyn Bennett: Thank you.

Ms. Carol Kushner: At PharmaWatch, we don't have a specific position on creating a separate agency, but we do have a specific position on creating an arm's-length from government research arm through this proposal we've been supporting to collect post-marketing information about specific products.

What's really important is to put the post-marketing and the pre-approval pieces of the current Health Canada regime on more of an equal footing. We've got a terrible imbalance. All the energy is going into getting those approvals. We want more energy going into protecting public safety and looking for those early signals of problems with either efficacy or safety.

The Chair: We only have one more minute.

Mr. Temelkovski, you still have a minute to ask a question, if you'd like to.

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

There are numerous agencies that collect data right now. How do you see that data being collected in one place, or do you see it in one place? As far as the funding formula on that goes, should it be funded through the provincial-territorial agencies, or should it be funded directly by the federal government?

Dr. Durhane Wong-Rieger: That's a loaded question, as you know.

We believe that it is in fact a national issue, recognizing again that health is funded at both levels. Carol made a comment about FPTs, and we do know how difficult it is for FPTs to work. We know that even the simplest FPT agreement takes many years to work out.

I would turn it back to Health Canada, turn it back to the federal government, to be honest with you. I think we do need, as you've indicated, some kind of coordinated data compository. That doesn't mean that there can't be multiple channels and multiple collections, but there needs to be a coordinated system. Certainly from an analysis point of view, there needs to be one coordinated analysis, so you don't end up with these reports that come out on a rolling basis, where you get a report here and a report there and a report elsewhere. I think it has to come back together to one spot.

So whether it is an FPT or whether it's federal, I think it's pretty much an open question. If you ask me personally, I would say I'd like to see the federal government take the lead on it. And if we're talking about a five-year program, let the federal government step forward and put together a five-year pilot project and fund it. That will make it work. If we wait until everybody agrees that they're going to fund it together, it won't work. It'll take us years to get to that point.

Take the leadership and fund it. Do a pilot.

● (1145)

Ms. Carol Kushner: I would add that there are already provincially funded agencies. There's a provincial contribution already built into the proposal I was speaking of, in that the Manitoba Centre for Health Policy or ISIS or some other agencies have indicated a willingness and an expertise in this arena to jump in and collect new data on the real world efficacy and safety of drugs. That is a provincial contribution. So it would be always Health Canada working in partnership with the provinces.

The Chair: Thank you so much.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Thank you for being here today.

Ms. Fuller, I would like to come back to your earlier comments. You said that Health Canada is speeding up some of its processes and that the target should be the safety and efficacy of drugs. You were talking about expediting approvals within 300 days. I would like to raise the issue of a drug that has been put on the market, Gardasil. Were the clinical trials really focussed on ensuring the safety of that drug?

When we hear about deaths in Europe and the United States, isn't it risky for the Public Health Agency of Canada to pursue a mass vaccination program for girls from the age of 15? How might Health Canada react towards a product that has been marketed elsewhere but which has caused harm and even deaths?

[*English*]

Ms. Colleen Fuller: From our perspective, the biggest problem with the vaccine is its promotion. This is a new vaccine. The clinical trial history could have been more complete and longer, from our perspective. But there is no clinical trial that will ever be able to detect all of the potential risks associated with a drug or a vaccine or a medical device. It's just not possible.

Our concern with this particular vaccine was that it was being promoted for a mass vaccination, that all girls were being targeted for a vaccination with Gardasil. We felt that was just inappropriate because the deaths due to cervical cancer in Canada are quite low, and because there has been significant progress as a result of the Pap smear screening program. There wasn't the need for this type of mass vaccination program.

That may be different with different population groups as well. People who are not in large urban centres don't have access to regular cervical cancer screening, and so on. So there are these differences even among the Canadian people. And internationally, that's even more so.

With this particular vaccine, I haven't seen a plan for the post-market monitoring of the use of the vaccine and I'm not even sure if there is one. Perhaps there is and I haven't seen it. I don't know. But with this type of heavy promotion and what we already know about the adverse side effects, which have been reported internationally, I think Health Canada should be proposing some very systematic collection of data and monitoring of adverse side effects. And I haven't seen that.

Ms. Carol Kushner: I would only add that I think fewer than a hundred girls in the 12- to 13-year-old age category were actually subjected to clinical trials.

There have been some assumptions made in the clinical testing: first of all, that younger girls would be similar to older girls and young women; and secondly, that it was important they vaccinate girls who had not yet become sexually active because their risk of having been infected already with HPV was so high, and that would have rendered the vaccine absolutely useless. So it was important to demonstrate efficacy by testing it on girls who were not yet exposed.

The other thing is that the groups that are most at risk tend to be immigrants, Innu women, and people in remote locations. Apparently, at least for some subpopulations, the virus causing HPV among some of those populations is not the one targeted by Gardasil, so we have a problem there as well.

I think this program was just launched a little too hastily.

● (1150)

Dr. Durhane Wong-Rieger: Can I make one additional comment on that? I think it's a perfect question and it's a perfect example of the disconnect between what happens in terms of Health Canada and their approval for marketing and what actually happens in terms of the availability and marketing.

It goes back to the federal-provincial divide. At the federal level they approve it for safety, approve it for efficacy. I think when Health Canada does that approval it means something, and it means something significant. The problem is that then when we talk about making it available, that information is not necessarily carried over in the right way, but as other people have said, the availability becomes totally disconnected. And it's almost impossible to call it post-market surveillance anymore, because as we're talking about progressive licensing and continuous licensing renewals, we have to be talking about ongoing surveillance.

So this is a perfect opportunity to ask, based on the uncertainty of the information—there is always some uncertainty—based on, as you say, the patient populations it's been tested on, what else do we need to do in order to be assured that if we're going to roll out the program, we're going to collect, in a continuous way, the information that is going to feed back into that decision?

And again, Health Canada, in their progressive licensing framework, has set it up perfectly to say that as we get more information, we can re-evaluate where we are. So as this program rolls out, as we collect not only safety information but efficacy information, we should be able to feed it back into the approval process to ask, where are we, and do we agree? And that should also feed back into the accessibility or the marketing process to ask, is it still being marketed in the right populations?

So it's an ideal opportunity to set up that integrated framework, and this is really where we do have to have that close cooperation between all of the stakeholders, including the patients and the clinicians, but also between the various levels of government.

As we're looking at it, it's an example where we can really take advantage of what we're trying to do in terms of setting up a much more robust, continuing surveillance of both efficacy and safety, but also the appropriate patient populations. And I would agree that I don't think it has been done.

The Chair: Thank you, Ms. Wong-Rieger.

Ms. Wasylycia-Leis is next.

[*Translation*]

Ms. Christiane Gagnon: I just would like to make a comment.

[*English*]

The Chair: Madame Gagnon, your time is up.

Please go ahead, Ms. Wasylycia-Leis.

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

And thanks to all of you for being here today.

I want to start by asking each of you if you have any money for your organizations from pharmaceutical companies. Do you, Durhane?

Dr. Durhane Wong-Rieger: Yes, we do.

Ms. Judy Wasylycia-Leis: Can you give us more detail? For example, which companies are involved?

Dr. Durhane Wong-Rieger: We have it in terms of any time there's a conflict of interest.... We work with a number of organizations, including organizations that deal with us on anemia. We deal with organizations that deal with us in terms of blood. I also get some funding from—

Ms. Judy Wasylycia-Leis: But do you get some money from pharmaceutical companies?

Dr. Durhane Wong-Rieger: I get money from pharmaceutical companies.

Ms. Judy Wasylycia-Leis: Mel?

Mr. Mel Fruitman: No. We get no money at all, actually.

Ms. Judy Wasylycia-Leis: Does PharmaWatch get any money from big pharma?

Ms. Colleen Fuller: No, we don't get any money from big or small pharma.

Ms. Judy Wasylycia-Leis: I ask that question because we've had a number of presentations over the course of the study, and we're not always informed about what's behind some of the groups' recommendations. I always get a bit suspicious when I hear a very unequivocal support for the government's present system by those groups that don't seem to have connections to big pharma. It seems to be very worrisome.

To start with, Colleen and Carol, you've clearly raised some concerns and you have no funding from big pharma. What is your sense of the government's plans with respect to post-market surveillance?

Even though we're involved in the study, a parallel approach is being carried out by the government. According to the department officials themselves, it will shift the focus from pre-market review to this continuous assessment of risks and benefits. This has been tried before by previous administrations. It's always been defeated because of concerns about products getting onto the market without necessarily being safe, without the precautionary principle having been practised.

I want to know what you think about that plan, because in fact it gets at the heart of our discussions.

● (1155)

Ms. Colleen Fuller: We are a critical voice. We criticize Health Canada. We criticize the pharmaceutical industry for policies that result in harm. That's what our role is. We have been, and continue to be, critical of Health Canada because we feel that their orientation is focused on creating a friendly business environment for the pharmaceutical industry and ensuring pharmaceutical investments in Canada.

We think that approach often subordinates the public interest. I'll tell you, as somebody who has been involved in this area because of a very serious adverse drug reaction, that my impression of Health Canada was that they wanted to convince me, and I think they want to convince the public, that the industry is doing the right thing. They want the public to have confidence in the industry and believe that the industry is able to place the public's interests above the interests of their own investors, and I don't believe.... I think Health Canada does think that they are charged with that responsibility—to balance the public interest with the interests of pharmaceutical investors—and I don't agree with that, so I'm concerned about the direction.

My concern about post-market surveillance right now involves a number of things. One is that there's discussion about applying a cost-recovery model to post-market surveillance, which we are completely opposed to. We also feel that post-market surveillance should not take the place of a rigorous system that is put in place before drugs ever get to the market. That is the most important thing: post-market surveillance is obviously very crucial, but nothing can take the place of a good system to ensure we are getting safe and effective drugs on the market in Canada.

Ms. Judy Wasylycia-Leis: Carol, I'd like you to comment in that context. We already have, as you know, an imperfect system in terms of pre-market approvals. It must worry you, then, to hear department officials say they're going to shift the emphasis from that to post-market. Talk about some of the problems.

Ms. Carol Kushner: It's very worrying. We've already seen Canadians suffering significant harm from drugs that went through the old system—even the old, old system, before we speeded up approvals to the point where they are today, because approval times have come down significantly. One of the problems is that the department itself, the directorate, is penalized if they take longer with a drug. So there's a cost to their budget if they're slower.

The idea that we should actually speed up approvals even more, to my mind, would only expose Canadians to further potential harms and, in a sense, deceive the public into thinking this was perfectly safe, just as it was before. It's not.

We have to take a step back and look at these issues again. We have to be sure that when we approve a new drug, we're as sure as we can be that it's safe and efficacious. And even then, because of the nature of clinical trial evidence, we still have to do good post-market follow-up to make sure that when it's exposed...because a drug that is tested on a thousand people may be used by a million people or more.

Ms. Judy Wasylycia-Leis: Carol, could you talk a bit about some of the problems we need to watch out for as we go through these hearings? You're an expert, I think, from reading in the media, on astroturf groups—

Ms. Carol Kushner: Yes.

Ms. Judy Wasylycia-Leis: I'd like to know what we should watch for as people come before us with connections to drug companies, how we can identify them, and what we're likely to hear from them and how we should treat the evidence from these groups.

While you're at it, could both of you address the fact that there are a number of expert advisory committees to Health Canada with representatives of industry on them? What does this do to the work of these committees?

● (1200)

The Chair: We're just about out of time, Ms. Kushner, and that's a big question. So I'd just ask you to summarize it, because you'll have other questions coming at you as well.

Ms. Carol Kushner: Okay, I'll be very brief.

The issue around industry-funded groups is that in general—and this is a generalization—they tend to emphasize faster access to new products and they under-emphasize safety concerns. Almost always they are talking about needing access. That seems partly to be a defence of a patient group that might need access to that drug, but it also reflects what is very much in the pharmaceutical company's interests.

The Chair: Thank you, Ms. Kushner.

Mr. Brown.

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

Thank you for your presentations here today.

Certainly this committee has been fortunate to have heard many distinguished presenters as we've studied post-market surveillance, and one thing I heard suggested early on in the testimony thus far was mobile devices, electronic devices, as a way to have real-time exchanges of Health Canada updates. I heard from the Canadian Medical Association that sometimes their notices to physicians are mailed out or faxed out, and that there is a block of time involved there that could be hazardous when prescriptions are made.

Secondly, we heard from Terence Young on behalf of some victims, including his own daughter, who suffered, unfortunately, from an adverse drug reaction. One thing he suggested, which I wanted to get your comments on, was better pooling of international information. He said there was a timeline—and I forget what it was, but I think he said it was six or eight months—within which studies by a pharmaceutical company had to be shared if their products were being used in Canada. He thought that if study results were found, they should be shared within 48 hours with Health Canada.

I wanted to get your impressions, one, on how mobile devices would be useful, and two, what we could do to better exchange internationally the studies done on pharmaceutical products. They may be sold in Canada, and the study may have been done outside of Canada, but there should be a requirement on that pharmaceutical company to share that information in Canada.

Dr. Durhane Wong-Rieger: For the most part, we see that a lot of the studies are in fact international. I go back also to some of our work with new and innovative therapies for rare disorders. Certainly for many of our patients, having no access to medicine is a much greater harm than not. And many patients do recognize that there are risks and benefits and trade-offs. I think what's important is to inform patients of that so they can make good, informed decisions.

Obviously the data have to be, as you say, internationally pooled. In many cases, you're only going to be able to pick up an adverse event, for instance, if you have access to the international database.

What I caution against, though, is what we consider to be some of these knee-jerk reactions. Every study can come out with a different set of outcomes. You have to have in place, the same as you have for an application for approval, a continuous-surveillance or post-market scientific framework. If in fact a physician were to receive a new alert every single time a new study came out and we had these rolling alerts coming out.... We're seeing that happening in some cases, in part because governments have tended to become very reactionary. So people are much more concerned about accusations of not being proactive or accusations of not being up to date with the information, and they end up with these rolling comments. I think that becomes as dangerous, in fact, as not providing the information.

What we need is a systematic framework: how much information, how do we collect it, when should it be made available, how is it analyzed, how is it communicated? Right now, all we're doing is working within very much an ad hoc kind of framework. I don't think we have a framework that really has been put together.

Mr. Patrick Brown: Could we get a comment from PharmaWatch as well?

Ms. Carol Kushner: The important thing here is transparency and access. Right now, an awful lot of data that comes forward to Health Canada the public never sees and the doctors never see. Negative trials are usually not published. One of the issues related to finding out that, for example, SSRIs don't work better than placebos is that the negative trial data was never published. The trial data that said this product wasn't helping never made it into a publication. Now, that might have been because it was actively suppressed or because the study wasn't of high enough quality to merit inclusion, but for whatever reason.... Also, a good proportion of those negative studies were reinterpreted as positive. This is the sleight of hand in science known as creative writing.

● (1205)

Mr. Patrick Brown: I know my time is limited, so I have a quick question for Durhane Wong-Rieger.

You said in your presentation that we need to avoid politically biased reporting in the use of post-market data. Could you expand upon that a little bit? Is there currently politically biased reporting on post-market surveillance?

Dr. Durhane Wong-Rieger: I go back to saying that everybody has a bias. When we look at Health Canada, at the government, at the drug review agencies, at the provincial governments, and at industry, everybody comes with a bias. I think the challenge is to put that bias out there and to be very clear. Unfortunately, there is no such thing as an unbiased report. What you need is a combination of all the stakeholders and to go back to the opportunity for all stakeholders to have access to information. But there's no such thing as being totally unbiased.

I go back to my example of the government reaction to tainted blood. All the decisions can be looked at in terms of the political biases that went into them, both before the inquiry and after the inquiry. None of them were based on pure science. None of them, one can say, carry no bias of the agency, whether it be reactionary or whether it be protective.

Mr. Patrick Brown: Mr. Fruitman, do you have any comments?

Mr. Mel Fruitman: Yes. I'm certainly in favour of having more information sooner rather than less. I'm not familiar with the exact process, but if they wait until it's published somewhere to have the information, I think that's too long. There should be some mechanism by which the appropriate agencies internationally exchange this information, perhaps even at the early stages. Unfortunately, if they wait until it is published, even if it's in professional publications, then it takes a long time. Then, too, we run into the situation of the media picking up on these things and incorrectly reporting so much of this information, because they aren't equipped to interpret it or they don't read through to the end, where it says something quite different from what the heading seemed to say. None of that serves the public well at all.

Also, perhaps there should be some requirement for researchers, if they stumble across something that should be known.... I think of the Nancy Olivieri case several years ago, in which she basically broke the terms of her contract but felt that she had to do so in the public interest. There needs to be some mechanism by which somebody like that would in fact be required to submit that information and not be penalized or vilified for it. She was subsequently, at least, exonerated.

The Chair: Thank you, Mr. Fruitman. I appreciate your insightful comments.

We'll now go into the second round, which is five minutes.

Mr. Temelkovski.

Mr. Lui Temelkovski: Thank you very much. I'll share my time with my colleague Susan.

Consumer reporting is the law. I think we all agree on that. What would make the consumer report? And how would that happen? How do you see that happening—from the consumer to the stakeholder, such as the pharmacist? Right now one pharmacist working for the same company—Shoppers Drug Mart—on this corner does not communicate with the pharmacist down the street on the other corner. Communication is very important.

On Tuesday, we heard from one panellist. He said that if the report is larger than one screen on the computer, it's too big for any professional to fill out. So how would we encourage somebody to report? What are some of the carrots and sticks that we should use?

Dr. Durhane Wong-Rieger: I think one has to talk about the different patient populations. When we're talking about very small patient populations—hemophiliacs, or people who have other kinds of conditions—patient registries become really important. Again, you're dealing with very small databases, you're dealing with a lot of uncertainty in terms of outcomes. You get down to, in many cases, very individualized responses to drugs and treatments.

So having a comprehensive patient registry in which ongoing information is collected.... For instance, every month hemophiliacs load their information, talk on electronic mikes, and send it off to the clinic, the database. So all that information is constantly collected.

That's different from, as you say, a large-scale public drug in which people may be taking it who are not necessarily part of a specific patient population.

I think the most important thing in order to encourage people to report is actually to give them good feedback. If in fact I get feedback in terms of what my report is relative to what others have done, if I get examples in terms of what other kinds of reactions or what evidence of efficacy there is, and if we get the good information back that can summarize this, that is probably the best encouragement in terms of reporting.

I'm really willing to do some very onerous reporting. Especially, I will go back to some of our rare disease patient populations, where there are a lot of adverse reactions that we have no clue to.

● (1210)

Mr. Lui Temelkovski: So what you're saying is that we really don't know which came first, the chicken or the egg. Do we tell professionals that we will give them reports and outline the kinds of reports that we'll give them before we ask them to report? We have to ask them to report first, before we tell them how we're going to report it.

Maybe we can hear from the other panellists.

The Chair: Ms. Fuller seems to want in on this. I just want you to keep in mind, if you're sharing your time with Ms. Kadis, that she's going to have to have an opportunity. We're just about out of time.

Ms. Fuller.

Ms. Colleen Fuller: We have enough information to have an idea about who is reporting amongst consumers. For example, both in Canada and internationally, it's known that women are more likely to report than men. They report on their own behalf and they report on behalf of family members and so on.

An obvious strategy would be to focus on women—where women get information, organizations that women belong to and so on—to raise awareness about ADR reporting and about their opportunity to do so.

We also think that community health centres are a venue through which information about ADR reporting should be placed and that patients who walk into a community health centre should basically be approached about adverse side effects.

The MedEffect website that Health Canada established is very, very good for people who are able to use the Internet, but the reporting form is atrocious. It's horrible. It is not consumer friendly. Even if people are prepared to report online, they are so unlikely to use that reporting form.

Most people, in fact, will not use the Internet to report. They're more likely to report on the telephone.

The last thing I want to say is that PharmaWatch has adverse drug reaction reports from consumers that we are unable to give to Health Canada because of the privacy legislation. If we're collecting information from consumers, this is where it stops. It's because Health Canada will not accept information that is anonymous. They have to have a patient identifier. This is a discouragement to a lot of consumers who don't want their personal information known.

The Chair: I'm sorry, Ms. Fuller, but we're way over time.

My apologies, Ms. Kadis. We have to go to Mrs. Davidson.

Mrs. Davidson.

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

I want to continue on the same line. Right now when we're looking at reporting, it's not mandatory. The onus, though, is on the manufacturer to do the reporting.

To whoever wants to answer, who do you think should be doing the reporting? And should it be mandatory?

I'll start with you, Mr. Fruitman, because I think you had some other comments to make.

Mr. Mel Fruitman: I think we get ourselves into a bit of a bind here when we talk about professional reporting systems. Of course, it is a different situation when you have specified groups who are involved with the medical profession in a much more active way than, say, 98% or 99% of the population out there. I think the reaction of most people, when they take a drug that does something they don't expect it to, is to either call their pharmacist and say, "Hey, this happened, do I need to worry about it?", or call their doctor, whichever one they can get hold of.

I think that needs to be the starting point. I don't think you need to stimulate that. People do that naturally. It becomes a means, then, of how to set up a simple reporting system—for pharmacists, for doctors, or for anybody else who may be the appropriate point of contact there—that allows them to determine, simply, is that report significant? Should it be carried out? Should I fill out a form and forward it to whoever the appropriate body is to collect and analyze that data? You have to have a reporting mechanism right down at that level.

In effect, it becomes mandatory. I don't think you have to legislate —i.e., if you don't report, we'll take away your licence. Instead, set up a system that allows it to be done simply, so that all this data can be collected. Indeed, sometimes it can be refined over time if it turns out you're getting a lot of reports, or maybe these things are inconsequential, or maybe they indeed do indicate something that needs to be made much clearer and apparent to all the practitioners and the general public.

● (1215)

Ms. Carol Kushner: I think we ought to actually spend a little bit of time looking at the research in this area, because it suggests that patient or consumer reporting directly is a far richer resource than when the report is reduced, through coding, to a few words. I think there will be a real loss if we do anything that would discourage consumers from reporting directly.

Mrs. Patricia Davidson: Do you mean directly to Health Canada?

Ms. Carol Kushner: Yes, I do.

Now, at the moment we don't have a formal position on our board about mandatory reporting. Our board is somewhat divided. Some people, especially physicians, are saying, "I would spend all of my time making these reports. You have no idea how many people are experiencing these adverse side effects. I wouldn't have time to see patients. All I'd be doing is filling out reports."

On the other hand, when a patient reports to a doctor or a pharmacist that they're experiencing a problem, maybe it should be mandatory for the doctor or the pharmacist to say, "Aha, here's a way for you to report"—either to PharmaWatch or to Health Canada.

Mrs. Patricia Davidson: Mr. Fruitman, you disagree with that?

Mr. Mel Fruitman: I think it just won't happen. By putting that kind of obligation on the consumer.... We're all so time-pressed as it is, we don't get to do the things we want to do now. I think the natural reaction is to query, should this be happening, and is it of concern to me? Once they get an answer to that question, they're not going to go beyond that. Even if they're told that perhaps they'd better stop taking something right away because it has a very harmful side effect, they're not going to go back, sit down at their computer, and report to somebody. It's over and done with, as far as they're concerned.

Dr. Durhane Wong-Rieger: I think part of it, though, comes back to the level of uncertainty. The more uncertain the data, the more innovative the product, the more you have to put in a robust surveillance system. In some cases, as a condition to having that drug approved, you have to set up a very robust surveillance system. The only way the clinicians are actually going to be able to prescribe that medication is in fact if they agree to do the monitoring and the surveillance. On the other hand, if you have something that has in fact been around for a long time, I think that requires a lesser level of surveillance.

So it really depends, I think, on the product we're talking about. As we've said before, when you're talking about very specific patient populations, in many cases you want to put in a very rigorous ongoing monitoring system in order to make sure you have a product that works and is also safe.

The Chair: Thank you, Ms. Rieger.

Monsieur Malo.

[*Translation*]

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

We all share the same common interest, the participation of patients in adverse side effects reporting. I only would like to know if patients should also play a role in the reporting of positive effects of drugs. I am thinking of cases where a medication would result in more benefits than expected.

[*English*]

Ms. Colleen Fuller: When patients contact us, they tell us about the positive effects of.... Most of the patients we talk to are taking more than one drug. They have both positive and negative experiences; it's not only negative experiences.

Yes, patients do have a role in communicating the effectiveness of the drugs they're using. When patients are talking about medicine, there are a number of different things that they want to tell you, and there is also information that they want to get. Reporting adverse drug reactions or reporting about the effectiveness of a drug also is part and parcel of a quest for information about other people's experiences and so on. It's all of a piece, if you want to put it that way.

So yes, patients have a role in communicating information about the effectiveness and efficacy of drugs as well as about adverse side effects.

● (1220)

[*Translation*]

Mr. Luc Malo: In our meetings with witnesses like yourselves, we realize that there is a lot of information available. Several organizations are collecting that information. I think that the problem is more on the level of communicating, processing and storing that information. I am talking about the process by which, after analysis, the information is communicated to physicians and pharmacists. I wonder if we will improve the efficiency of the system by adding the patient to the list of persons who collect data. I think that we already have a lot of information, but that we don't really know what to do with it.

[*English*]

Ms. Carol Kushner: I think you're quite right that there is a huge responsibility on Health Canada to become more effective as communicators of this information. Right now, the ways in which doctors are advised about problems with drugs don't appear to be that effective, necessarily. They are probably more likely, frankly, to react to a front page news story than to an official report from Health Canada. That's a problem.

One thing that will happen, I can assure you, is that when patients read that the drug they are taking is on the front page of their newspaper, they will then inquire about what else they could be taking, what the alternatives are, whether this bad thing is likely to happen to them too.

So I take issue a little bit with the gentleman from the Consumers' Association of Canada, with all respect, because I think that no one has a greater interest in the safety of drug products than the person who is taking them. Especially if it can be easy for them to make a phoned-in report, they have a perfect interest to do so.

The question is, what then is the response? Is it going into a black hole, or is there going to be some reporting back of how their information was used? I think there needs to be more of a quid pro quo.

In other words, if I tell you my story, you have to tell me how it helped fill in the history of this particular product; you have to tell me what steps are going to be taken to advise the larger community about this problem.

Or if my story is a one-off and really wasn't very relevant, I'd like to know that too. I don't mind negative results, but I'd like to know something was done with that report.

[*Translation*]

Mr. Luc Malo: How can we judge if the information reported by the patient is relevant an d needed?

[*English*]

The Chair: I just want to say that we have somebody else, Mr. Fruitman, who also wants to say something, and we only have 50 seconds.

Mr. Fruitman.

Mr. Mel Fruitman: Quickly, in terms of individuals, they're not interested in reporting; they're interested in finding out what it means to them.

Going back to the question about reporting positive results, I'd be quite concerned about that. If you're reporting negative results, it indicates that further testing is required. Reporting of positive results becomes anecdotal type of information, and I see potential for great misuse of that anecdotal type of information. I'd approach that extremely cautiously.

The Chair: Thank you very much.

Mr. Tilson, it's your turn, and we just have five minutes. Thank you.

Mr. David Tilson (Dufferin—Caledon, CPC): I'm going to refer to a report of this committee in 2004, in which all of your organizations participated. In fact, I think Mr. Fruitman gave testimony. Page 5 of that report was on post-market surveillance. The report dealt with a number of things, advertising as well, and that may have been why you were there.

It says this: “In 2002, the department received more than 8,500 domestic adverse reaction reports and more than 106,600 foreign adverse reaction reports. There were 169 recalls of drugs for human use for the same year.” And this is the sentence I'm concerned with: “Health Canada estimated that half of newly approved therapeutic health products have serious side effects identified only after approval and marketing, due to exposure with the larger population.”

My question is this. We're looking at post-market surveillance, but what about the approval system? I find that sentence rather shocking, actually. This is after approval. Have any of you put your thoughts to whether we're looking at the wrong thing, whether the approval system should be improved? I don't even know how that could be.

● (1225)

Ms. Carol Kushner: Yes, we should be using comparators other than placebo, in addition to placebo. We should be using the best drug to treat a given condition against a new drug to see whether in fact the new drug that's coming out actually performs as well.

Dr. Durhane Wong-Rieger: That's not going to tell you. I think the heart of your question is that most studies are not powered to find adverse events, because they're very, very rare in the grand scheme of things. Most studies are powered to find out whether or not they work and whether or not there are some known side effects. I think that's a good question.

I would suggest that it is in fact the right role for post-market and not the role for pre-market. We are looking for a balance. I go back to many of our patients who have severe, life-threatening diseases, who are looking for some treatments here, and they will make those trade-offs between saying they don't know what all the risks are, they do know what some of the benefits are, and they are willing to move into this. We need to continue to collect that information post-market. Having a robust and early-warning kind of post-market system would help address what you need.

The question is this. If we have continual surveillance and we think about it as I think Health Canada has now, where do we draw the line in terms of saying it can now be made available and we'll continue to collect that information? It is a bit of a moving target, and I don't think that's wrong. Most of us are now looking internationally at life cycle of products, and it means ongoing collection.

I hear what you're saying, but I think it becomes a matter, then, of those kinds of judgments. I don't think we have it wrong yet, right now, in terms of where we give the approvals. I don't think we have it right in terms of how much ongoing surveillance we do and what we do with that information.

Mr. David Tilson: I think you were the one who said a lot depends on how great the risk is. Before you proceed, you try to minimize the risk as much as possible. There's always going to be risk; I think that's what you're saying.

Dr. Durhane Wong-Rieger: That's right.

Mr. David Tilson: Madam Chair, I have a quick question with respect to cost. All of you have ideas as to where we're going to go on this, who's going to do it, how long it is going to take, and how much it is going to cost. I don't know whether anyone's ever estimated what the costs of some of your theories are.

The population's getting older. We have a shortage of doctors. We have increased medical education. We have problems in emergency departments. Everybody wants more money.

In Ontario, at least, 46¢ on the tax dollar was for health care. I assume now it's close to 50¢. I don't know. All of us have to watch that; otherwise we won't be able to spend any money on roads. I hate to put it like that.

Dr. Durhane Wong-Rieger: I'll make a quick comment.

Mr. David Tilson: So does someone have a comment on the issue of costs for all of your theories?

Dr. Durhane Wong-Rieger: If I go with Carol's proposal of, say, $20 million—and I don't know what it is because we haven't costed it out—I will say we allocated $2 billion in compensation for people infected with hepatitis C. I think the cost of not investing up front is going to be much greater, and there's also the costs of the patients who are involved. So I say put the money up front.

Mr. David Tilson: The problem is that everybody uses that argument. The doctors say, if you don't put in some more doctors, we're going to have more problems in emergency departments.

The Chair: Thank you.

Mr. David Tilson: They all use that argument.

The Chair: Thank you, Mrs. Rieger and Mr. Tilson.

Ms. Wasylycia-Leis, very quickly. Thank you.

Ms. Judy Wasylycia-Leis: I have two quick questions to Carol and Colleen.

What would be your opinion of Canadians when it comes to drug safety? Do you think they accept Durhane's proposal, which is, having checked for safety precautions as much as possible, letting products on even if they're not safe? Or do you think Canadians expect to see products on the market that are safe beyond a reasonable doubt, as much as it's possible given the science and our whole approach?

Secondly, with respect to progressive licensing, could you tell us what we've learned from Vioxx that raises concerns about progressive licensing and how it might lead to a focus on approval of already approved drugs for new medications?

● (1230)

The Chair: We need to do this quickly, I'd just remind you, because we are adjourning at 12:30.

Ms. Carol Kushner: With respect to Vioxx first, the information about Vioxx only came to light because the manufacturer was trying to expand the indications for which it was approved. They thought it would help to prevent colon cancer. The researchers had to twist themselves into knots to hide the fact that this drug in fact was more dangerous, not safer. They had to suggest that naproxen was protective for heart attacks, not the opposite.

In effect, by allowing drugs on even faster, we are really risking not just one more Vioxx story, but many Vioxx stories, and we're going to repeat them again and again. So I would say let's err on the side of safety, let's use the precautionary principle, let's use good science, and let's beef up both pre-approval and post-marketing.

Ms. Colleen Fuller: I would just add that most Canadians have an expectation that when a drug is approved and sold on the market in Canada, it has been shown to be safe. That is the precautionary principle, that during clinical trials a drug is shown to be safe. The risk management approach is that if the drug shows no harm during clinical trials, it's approved, rather than demanding that it be proven to be safe. It sounds like a subtle difference, but it's not that subtle. Canadians have a right to expect that the drugs that are proven on the market are safe.

The Chair: Thank you very much, Ms. Fuller.

It's too bad that we do have time constraints. We have to be fair and equitable amongst all of us so everybody can ask their questions. As much as I think my questions are more important than anybody else's, I don't think anybody else around this table agrees with that.

You've given some very insightful answers and I would thank you very much. I would ask now that you leave the room in a very timely manner, because we have to get to some business. If anybody wants to speak with you and doesn't want to attend to the business here, then conversations can happen outside.

Mr. Fletcher.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): I have a point of order.

Mr. Savage, have you changed your name? It's spelt incorrectly. Is that maritime education?

Mr. Michael Savage (Dartmouth—Cole Harbour, Lib.): I fixed it on this side to make it more readable. “Right honourable”. Thank you for noticing.

Mr. Steven Fletcher: No problem.

The Chair: Thank you for that very insightful observation.

Thank you to the witnesses for coming. It's been a pleasure.

As I said, if you have any conversations, could you please take them outside, Ms. Wasylycia-Leis and Ms. Kushner? Thank you very much.

We'll go right into our business.

[*Proceedings continue in camera*]

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