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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)): Welcome, everybody. I would like to bring the meeting to order.

Welcome to our guests who are here today. We have with us the Cancer Advocacy Coalition of Canada, the Expert Advisory Committee on the Vigilance of Health Products, the Institute for Safe Medication Practices Canada, and representation from the University of Montreal.

Pursuant to Standing Order 108(2), I'd like to welcome you all to the seventh meeting of the post-market surveillance of pharmaceutical products, prescriptions, and non-prescriptions.

I'm going to ask the witnesses to give a 10-minute presentation. After all the presentations are finished, we'll get the questions from the committee.

We're very grateful that you took the time to join us this morning, and we're eagerly listening to all the insightful information that each one of you will tell us. Could we please begin with the Cancer Advocacy Coalition of Canada?

Dr. James Gowing (Chair of the Board, Cancer Advocacy Coalition of Canada): Thank you for recognizing the importance of post-market surveillance and for providing the opportunity to many groups like ours to present suggestions for improvements.

We are very gratified that you've seen fit to act on one of our previous recommendations, made when we presented our views to you during your hearings on the common drug review last year. Please accept our congratulations on your December 2007 report regarding CDR. In our view, your recommendations, if implemented, will substantially improve the cancer drug approval process in Canada.

The Cancer Advocacy Coalition of Canada is a full-time registered non-profit group, comprised of physicians, patients, and business executives from across the country, who are all unpaid volunteers. We publish the annual *Report Card on Cancer in Canada*, the only independent evaluation of cancer system performance in the country. In the just-released 2007 report card—which you should have in a day or two, as it's in the mail—we examined the allocation of research funds, the needs of young adults with cancer, the clinical trial research process, health human resources, access to diagnostics and drugs, and the role of nurses in supportive care. We publish these reports to identify barriers to better cancer control and to offer constructive solutions that are also realistic and implementable.

For the past three years, the articles about access to cancer drugs have recommended phase four, or post-approval, trials to confirm treatment results in the cancer population at large; and for two years in a row we have recommended increased translational research to identify the subsets of patients that benefit from these new drugs. Post-market surveillance is an appropriate portal to initiate these proposals, and it could encompass a more comprehensive system of information that is analyzed, shared, and disseminated to benefit patients.

When a new cancer drug is approved, the only obligation at present is the reporting of unexpected adverse events—and even this is not done comprehensively. From the physician's perspective, lack of effectiveness is an adverse event, when the treatment has added toxicities and other health risks to the patients, with no good result.

The information available to physicians about a new cancer drug is often not very helpful in the real world. Patients in preapproval clinical trials represent, at best, 3% of the wider population; and when patients at late stages of disease are treated in these trials, they generally achieve a response rate of 20% or less. Evidence suggests that response rates in the real world can drop to 10%. But for responders, the outcome could be a cure.

There are notable exceptions, such as Herceptin, where a tumour marker has been identified to improve patient selection. In such cases, the response rate is impressive and can include cure. However, most drugs do not have biomarkers, and for the majority of patients who do not respond, we are subjecting them to a drug with potential severe adverse effects with no hope of benefit. The objective, then, is to use every means at our disposal to identify the patients who will benefit and to spare those who will not benefit from the wasted time and avoidable adverse effects.

If post-market surveillance were formalized to capture information on positive results, as well as adverse events, then the characteristics of responders and non-responders could be captured for analysis. The immediate benefits would be remarkable. Better patient selection for the use of these expensive new drugs would save a huge amount of money that is otherwise fruitlessly spent. To accomplish that goal, post-market surveillance must collect additional reporting, and much of this must come from physicians, who can offer the important clinical detail necessary for further analysis. Reports ought to be submitted on every patient treated with a newly approved cancer drug within 12 weeks of initiating the treatment to ensure the accuracy of the information.

● (1110)

Physicians and others will not cooperate with an onerous paperwork exercise that produces nothing useful for their knowledge or their patients' well-being. The reporting we envisage could be done on a single computer screen; indeed, the proposal is undermined by anything more time-consuming. The information system required has to be linked to appropriate research by qualified entities, such as the National Cancer Institute of Canada, and have some assurance of timely outputs that are readily available online. Then the effort is worthwhile.

The data gathered should be readily available online and be presented in a manner that offers greater meaning than mere compilations of reported events. Indeed, if this undertaking is to serve its intended purpose, physicians and health administrators would find many other valuable uses for the data, including guideline writing and biomarker research.

In the final analysis, as this new knowledge becomes available, the true potential of each cancer drug would be realized, patient access would be increased, and treatment results improved.

A three-month increase in average survival translates into years for the 15% or so who respond to a drug. Three patients are alive well beyond three years after taking one of these new drugs and have reported their stories in our report card this year. Their written reports are very compelling stories. I would encourage you, when you get this report in a few days, to look at their proposals.

The Cancer Advocacy Coalition encourages you to focus on what is possible and needed, rather than what is already done. A robust post-market surveillance system could be an integral system providing valuable information and education, benefiting all Canadians and saving money.

I want thank you for your time and interest.

The Chair: Thank you so much for your presentation, Mr. Gowing.

We're now going to hear from Ms. Diane Brideau-Laughlin, chair of the Expert Advisory Committee on the Vigilance of Health Products.

Ms. Diane Brideau-Laughlin (Chair, Expert Advisory Committee on the Vigilance of Health Products): *Bonjour, madame*. Thank you very much. My presentation will not be very long.

Thank you for the opportunity to participate in the proceedings of this committee.

[*Translation*]

My name is Diane Brideau-Laughlin and I am the Chair of the Expert Advisory Committee on the Vigilance of Health Products. I would like to take a few moments to discuss the mandate of the Committee, as well as its current composition.

[*English*]

The Expert Advisory Committee on the Vigilance of Health Products constitutes an integral part of the health product and food branch's post-market surveillance strategy. Its mandate is to provide the branch with ongoing external expert advice on broad strategic policy in regard to the safety and therapeutic effectiveness of marketed health products for human use. It also provides a mechanism to involve the public, providing them with a forum to have their views heard by experts, who can discuss their input and incorporate the discussions into the recommendations provided. In other words, it consists of real people who work in the real world and who have the opportunity to speak to real people about real issues regarding their health.

The committee was established in November 2007 and has met twice so far. The inaugural meeting was an orientation session on the branch's various post-market strategies. The second meeting, held recently in February, in Longueuil, Quebec, discussed issues relating to adverse reaction reporting primarily.

The current membership is composed of eight women and nine men from across the country. We have representation from the Atlantic region, Quebec, Ontario, and the western provinces. We also have an individual with aboriginal expertise on reserve and in rural settings. The membership includes health professionals, patient and consumer advocates, and researchers in academia as well as in industry. It has individuals with interests in ethics, epidemiology, biological sciences, human medicine, health product vigilance, public health, social sciences, risk assessment, as well as communication and risk management.

It's a privilege to be the chair of this committee, and thank you.

● (1115)

The Chair: Thank you so much for your presentation, Ms. Laughlin.

Our next witness is Ms. Sylvia Hyland, vice-president of the Institute for Safe Medication Practices Canada.

Please, go ahead.

Ms. Sylvia Hyland (Vice-President, Institute for Safe Medication Practices Canada): Thank you.

Carmen, do you have the handouts?

The Chair: Everyone has a copy of them. Thank you.

Ms. Sylvia Hyland: Thank you, Madam Chair.

On behalf of the Institute for Safe Medication Practices Canada, I would like to thank you for inviting us to be part of your study on post-market surveillance. ISMP Canada is an independent national not-for-profit organization established for the analysis of medication error or incident reports. Our purpose is to identify underlying contributing factors or causes and to make system-based recommendations for enhanced patient safety.

We are working together with the Canadian Institute for Health Information and Health Canada to develop the Canadian medication incident reporting and prevention system. We also work closely with the Canadian Patient Safety Institute and other organizations and associations working to advance medication safety and patient safety at a provincial, national, and international level.

Our area of expertise is analysis of the preventable subset of adverse drug events. We know from a number of studies, including the Canadian adverse events study and two studies in the U.K., that a large proportion of adverse drug events are in fact preventable.

Through the shared learning from reports of medication incidents that we have received, we've made approximately 195 recommendations for consideration by hospitals as safeguards in their medication use systems. Of those, approximately 50 have now been adopted by CCHSA, the Canadian Council on Health Services Accreditation, as required practices.

The Chair: You have a very insightful presentation, but you're going a little bit too fast for the translators.

Ms. Sylvia Hyland: Oh, I'm so sorry.

The Chair: Could you slow down just a little bit? Thank you.

Ms. Sylvia Hyland: Thank you. I will.

Having 50 of our recommendations adopted by the accrediting body influences 3,700 health care sites and exemplifies how learning from reports and their analysis can lead to knowledge translation and proactive system enhancements.

I would like to take this opportunity to provide you with some examples relevant to Health Canada's regulatory mandate.

The first photograph I have for you is a picture of a transdermal patch introduced into the market. Because the patch was almost invisible, practitioners in emergency departments reported not knowing that patients were receiving a highly potent narcotic; the patches were being missed. The manufacturer responded very quickly and added both the name and colour to the patch, as seen on the next page. Medication patches are relatively new, and these incidents inform the need to include regulatory guidelines for labelling of patches.

On the next page you'll see two bags. The bag on the right, which is intended for pharmacy use only, was inadvertently infused intravenously instead of the IV solution on the left. We received three reports, one of an incident leading to serious harm, and we knew that in the U.S. there had been a fatality reported due to a similar error. We worked with the manufacturer, and they changed their label, as seen on the next page. This is a significant improvement.

There is still opportunity to improve the packaging of the bag. Until we make it impossible to connect a product not for IV use to an IV line, such dangers continue to exist.

On the next page you'll see two ampoules that were mixed up and reported as a near miss. The risk for harm is high. We have worked with individual manufacturers to improve such labelling, and we've provided an example of how the labelling can be improved on the next page, where you see the upper ampoule with print on glass and the lower ampoule.

We think printing critical information directly on glass should not be permitted. Ultimately this learning needs to be incorporated into regulations or guidelines so that the knowledge is translated into current and future manufacturing practices.

The next example is interesting because the label meets regulatory requirements for display of concentration. However, the product is not prescribed in millimoles; it is ordered by the physician in grams, and the conversion is not an easy calculation. We acted after only one report. The manufacturer quickly changed its label and thanked us for not just identifying the problem, but for providing recommendations for improvement. Note that this company took the extraordinary step of removing their logo from the label in order to give prominence to critical information.

In the last example we show five neuromuscular blocking agents. Neuromuscular blocking agents have been identified as high-alert drugs, which means that the drugs, when involved in an error, have a high incidence of causing harm. Three of the manufacturers voluntarily chose to follow our advice to place a warning on the top of the vial and two did not. This is a good example of a situation in which we could evaluate the recommendation together and, if it is reasonable, make it a requirement, again so that the learning is not lost on future products.

The key message is that underlying practice errors are opportunities for system enhancements to help prevent recurrence. Unless underlying risks are mitigated, it could be predicted that the errors will repeat again and again.

A key component of reporting programs is the follow-up and analysis and being responsive. For medication incidents, this includes identifying whether there are preventive strategies. It is also important to demonstrate to reporters that they have made a difference through their efforts to report, and this will in turn increase reporting.

ISMP Canada is aware of Health Canada's plans and initiatives to strengthen post-marketing surveillance, such as additional regulatory authorities post-market with labelling, and we would like to offer our assistance where possible.

Thank you.

● (1120)

The Chair: Thank you so much.

Our final witness is Dr. Yola Moride, associate professor in the Faculty of Pharmacy, University of Montreal.

Welcome, Doctor.

Dr. Yola Moride (Associate Professor, Faculty of Pharmacy, Université de Montréal): Thank you very much for providing me with this opportunity to present my views. I would also like to mention that I'm the current president of the International Society for Pharmacoepidemiology, and for several years I have been an expert consultant for regulatory authorities such as Health Canada as well as the European Medicines Agency, EMEA, as well as for the pharmaceutical industry. It's important also that I say that my presentation presents my views and not those of the organizations I'm affiliated with.

At present in the post-marketing setting, safety surveillance is mainly conducted through spontaneous reporting. While it is recognized that spontaneous reporting is the best method to detect a previously unknown safety issue at the level of the entire population, it is not suitable to quantify a risk. Spontaneous reporting is highly efficient to generate a signal, but not to evaluate the risk. Therefore, at the present time drug safety data originate mainly from randomized controlled clinical trials at the time of approval and spontaneous reporting thereafter as the main safety net to monitor drug harms.

What we have observed under this model is that over the past 30 years in Canada there have been 121 drug withdrawals due to safety issues. This represents extreme, if not catastrophic, regulatory decisions that should be avoided because of the major negative impacts at many levels, such as drug companies, regulatory agencies, and eventually loss of confidence by the public.

In other jurisdictions, such as the U.S. and the E.U., it has been recognized that the current model is insufficient to properly monitor the benefits and harms of medicines. Hence, there has been a major shift in paradigm for drug safety surveillance. Instead of relying entirely on randomized clinical trial data to assess the benefit-risk of a drug and afterwards on the spontaneous reporting system, authorities have introduced in their regulations risk management in all phases of drug development.

Since 2005, a pharmaceutical product is authorized on the basis that in the specified indication at the time of authorization, the benefit-risk is judged positive for the target population. However, it is recognized that not all actual or potential risks will have been identified when an initial authorization is sought. In addition, there may be subsets of patients for whom the risk is greater than that for the target population as a whole, or there may be subsets of patients for whom we are willing to accept greater risks because the condition for which they are treated is serious and they do not respond to any other available therapy.

Furthermore, there may be potential risks that need to be addressed, and to conduct additional randomized trials prior to the submissions will probably not bring the answers that are needed because some of those adverse events are extremely rare. Instead, an active surveillance system from the time of marketing would allow us to properly monitor these potential risks.

Finally, the benefits of a drug must also be monitored in the post-marketing setting, because even though a drug has been judged efficacious according to clinical trial results, the benefits may be much lower in the real-life setting. This is the case, for example, with anti-depressants, whereby more than 50% of patients discontinue their treatment before the minimum recommended duration of six months. Hence, patients are exposed to the risks that occur early in the treatment and to very little benefit since the drug must be taken for an extended period of time. Again, this would not have been reported in clinical trials.

Tools are available, such as observational epidemiological studies, to bridge this information gap and ensure that the benefit risk of a new drug is maintained. Should problems be identified in the usage of these drugs, or at-risk patients be identified, then interventions can be rapidly implemented to maintain the benefit-risk within the acceptable range. Such interventions are referred to as risk minimization action plans.

So the current risk management model involves various phases that can be summarized into detection, evaluation, minimization, and communication.

● (1125)

In the EU, all new drug applications must be accompanied by risk management plans. In the U.S., although not mandatory, such plans are expected by the FDA. In fact, drug approval may be delayed if the plan is judged not satisfactory.

Pharmaceutical companies are now realizing the huge economic consequences of not taking full responsibility for properly managing the risk. We are moving away from a reactive process to a much more proactive approach involving a broader evidence base and a widening of expertise, resources, and methodologies. Studies are conducted in the context of conditional approvals, and denial of marketing occurs if commitments are not met.

For many years Canada has been a leader in the area of pharmaco-epidemiological research, with one of the highest concentrations of experts in the world and access to invaluable resources, such as prescription and medical services databases that are available through our public health care system. Yet studies conducted in Canada are mainly investigator-driven. In the absence of legislation, those studies are not being implemented right at the time of marketing to ensure that real-life data on drug safety is generated as soon as possible and fed back to the regulators, who can then reassess the benefits and risks of a drug. In the absence of such legislation, regulatory authorities such Health Canada have very little leverage to request these studies.

Finally, an important element of risk management is risk communication. In addition to the package inserts, the evidence being generated must be fed back to the health care professionals and patients as soon as possible. The process by which the risk is being managed must be transparent and no longer a top-down approach.

In conclusion, the current model, such as the one used in Canada, is deemed insufficient to appropriately optimize the benefits and risks of medicines in the post-marketing setting. Risk management is the new paradigm that will use complementary sources of data and methods. Although the methods and expertise have been available in Canada for many years, they have not yet been packaged to be part of the drug regulatory process.

There are many resources in Canada that remain underutilized, such as claims databases, that could be useful in improving the analysis of spontaneous reporting of data and in evaluating the risk in the post-marketing setting.

Thank you.

● (1130)

The Chair: Thank you very much.

Obviously this panel of witnesses today is extremely good, and we have appreciated the comments you've made.

We'll now go to questioning, starting with Monsieur Thibault.

Hon. Robert Thibault (West Nova, Lib.): *Merci, madame la présidente*.

Thank you all for your presentations. They were very informative.

There seem to be recurring themes in the presentations on this subject. As I think Dr. Moride pointed out, it's not necessarily that we have a lack of information in the country; it's how we use it and how it's interlinked. We also have the question put forward on whether practitioners would willingly provide information on adverse effects—or even the larger question of post-market surveillance, I presume—if there were feedback, if valuable information came back to them that helped them in their practices. It's a shame that we haven't got to that point yet.

We are wrestling with whether there should be legislation. Should mandatory reporting be necessary? Would that assist us? It's a difficult question. I think it's made a little more complicated by Dr. Gowing, because his definition of adverse effects is a little different from what we've been dealing with so far. It's beyond somebody being rushed to the hospital; it includes somebody not receiving the effect you would expect from a therapy.

I want to open the question to all of you. We've heard of two possible elements here of change, aside from the technological aspect. One is progressive licensing, where medication would come on the market at different levels and be progressively licensed as information was available. The second one that we heard a lot about is off-label use. We've heard of the necessity for off-label use because of the way we license our drugs and the therapies they eventually become useful for.

It appears to me that both of those instances would be a great way to get a lot of the data you were talking about, Dr. Moride, because the uses wouldn't necessarily be the ones they were licensed for. So you could expect the community to feed back more at that time if the health treatment community was getting useful information from it.

I open it to all of you to comment.

Dr. Yola Moride: The issue of off-label use has been recognized as extremely important. In the current setting, spontaneous reporting would address the issue of off-label use, because it's all adverse events that should be reported, regardless of the indication.

Hon. Robert Thibault: But if we're hearing that only 10% of adverse events are reported and about the wide use of off-label therapies, then we can presume that it's not efficient.

Dr. Yola Moride: Do you mean spontaneous reporting? It's extremely efficient because it does what it intends to do, which is generate a signal. You don't want the system to be swamped with the common and not serious events.

This component, I find, is working efficiently. It covers the entire population, but it doesn't address the other issues related to drug safety. We need data on the risks and on the at-risk populations.

The issue of off-label use actually is included in risk management planning. There need to be provisions and specific actions planned right from phase two with regard to what will be done regarding the potential for off-label use.

Dr. James Gowing: Off-label use is a very good thing, I think. In the case of one of the drugs we use to control pain, gabapentin, 90% is used off label. The label is for epilepsy, but in terms of controlling cancer pain, patients receiving gabapentin often need only about 10% of the amount of morphine and other drugs because they use it.

We should be collecting that information, though. This is why I think, for our proposal on new cancer drugs coming out, whether they're used on label or off label, I wouldn't want to interfere with that. But we should be collecting that data, and we're not. So we're not learning anything from it. Some of the uses of off label are actually a whole lot better than what they're labelled for.

● (1135)

Hon. Robert Thibault: That's the point I want to make. We've heard examples of drugs licensed for adults being very useful for children, but they are not licensed. Almost all of that therapeutic use is off label because of the clinical trial problems and all those things.

I'm just wondering if the exchange of information across the medical practice community on these off-label uses is very good. Are people learning of the potential of these drugs?

We know that the pharmaceutical manufacturers will promote the label use, but it's more difficult to promote the off-label use.

Dr. James Gowing: Well, they're not allowed to promote the off-label use. Certainly in the oncology community there aren't that many of us across the country, and we soon learn what works and what doesn't. We should be collecting that knowledge and disseminating it more widely, and we're not.

Hon. Robert Thibault: We heard.... Sorry.

Dr. William Hryniuk (Past Chair, Cancer Advocacy Coalition of Canada): The additional consideration is that there's some reticence to publish the use of drugs off label, so in fact the communication between professionals about off-label use and effectiveness is inhibited. But if this mechanism were introduced, that would automatically overcome that impediment.

Hon. Robert Thibault: That would provide that information.

We had one presenter here last week who suggested that a lot of the drugs that were on the market now had low efficacy; they are of value to a small percentage of the population. There is 15% efficacy in some cases, and you'd be led to think that for 85% of the people taking the drug it has no value or it only increases the positive results by 15%.

Could you explain this matter in terms of your oncology practice? How do you see this?

Dr. James Gowing: In my oncology practice, when a drug is administered to a patient, if it's not working, we stop. I think that's only good medicine. I think any other physician here would say the very same thing.

Why I think I've come to this committee is because we should learn from those experiences, and we're not. I'm recording that in my patient notes on computers. That information is being recorded, but nothing is being done with it. That's a terrible waste.

We could learn what works and what doesn't work. We could learn more about side effects and everything if we collected that data. That's why we're here.

Dr. William Hryniuk: A 15% improvement in survival is a statistical number; it doesn't relate to what really happens. It may be that 85 of the patients didn't respond and 15 responded beautifully and are living disease-free for many years; in fact, that is the rule.

The use of 15% improvement in median or average survival is meaningless in human terms. What we need to do is identify the 15 patients who respond and go on to live healthy lives and not treat the other 85. That's the real problem. It's not the 15% improvement in average survival.

Hon. Robert Thibault: Thank you for that, because the information we've been provided was a little dire, in the way I have received it: that some of these drugs would be of very little use and yet were still on the market.

Ms. Diane Brideau-Laughlin: I think part of the problem in how we're evaluating the literature and evaluating the outcomes is with the outcome that's actually being looked at within the clinical trials. That may be what misleads the population.

We're not looking at hard end evidence; we're looking at what we refer to as surrogate markers. We look at a decrease in blood pressure as being an efficacy, with a blood pressure medication, for instance. But do we know whether that in fact is going to translate into decreased death at the end of the day?

That's what we're not looking at. I think with post-marketing surveillance we can start collecting this information, analyzing the data, and seeing whether indeed our patients are doing better at the end of the day. We're missing out on that end. Unless we have somebody who then takes on the role of doing that post-market surveillance or does a phase four with that intent as an outcome, we never know whether we're treating with a drug that really is going to have a benefit.

Hon. Robert Thibault: Who do you see as having that role now?

● (1140)

Ms. Diane Brideau-Laughlin: I think it has to be multi-factorial. I think it belongs within industry, to a degree, and it belongs with the clinicians, to a degree. We're treating our patients for various reasons with various products. We are all included in this. I don't see it as any one specific group's role; I think it's all intertwined. But somebody, at the end of the day, needs to collate this information and provide it to the practitioners and industry, so that we have superior elements to work with.

The Chair: Thank you. I think our time is running out.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): I would like to come back to the off-label use of medications. When a drug is prescribed off-label, is the patient sufficiently informed of the side effects or adverse effects of the drug, or the fact that it could be dangerous? When we read in the newspapers that a drug has killed someone, one wonders how such a thing is possible. The people in the immediate entourage of the patient, or the parents, are shocked and often challenge that use of the drug.

[*English*]

Dr. James Gowing: It's incumbent upon and actually a legal obligation for the physician to inform the patient of the potential for benefits and the potential for doing harm. That's the only way you can get informed consent. There are many legal opinions on this. Certainly, as a practising physician, I tell the patients what could happen, and I'm obligated to do it.

One of the problems that you allude to is the family's not knowing. In my practice, I try to bring the family into it, but there's a confidentiality problem here between the patient and me. The patient may not want the family to know, and then I'm obligated not to tell them. But I am totally obligated to tell the patients what they can expect from any procedure I do to them, including giving them a drug.

[*Translation*]

Dr. Yola Moride: I am very pleased that you've raised this issue, because it has been clearly demonstrated that, by providing information to patients, they are necessarily more involved in their own treatment. That is the whole principle behind patient empowerment, and it is quite clear that, particularly in light of media coverage in recent years, patients are now demanding a lot more information. In fact, we have noticed that spontaneous reporting by physicians often occurs following a visit from a patient who has gone to complain about adverse effects. That prompts the physician to report the event.

So, it is very important that the patient be informed. Of course, in a doctor's office, the physician doesn't have time to provide all the information. That is what happened with antidepressants. So, additional programs are needed to provide patients with that kind of information.

Ms. Christiane Gagnon: As regards antidepressants, I remember that, a few years back, patients were unaware of the fact that there has to be a period of desensitization before the treatment is discontinued, and that you can't just suddenly stop taking antidepressants. That can even lead to suicide, because the patient feels very badly and there are psychological effects, as well as an effect on a person's mental balance. Few physicians actually told their patients that. Again, that was something that appeared in the headlines, and that is how we found out that some patients were experiencing extremely adverse effects, which could even lead to death.

I would like to come back to Dr. Gowing, who says that he is collating a lot of information and has a lot of data about adverse effects that are not really being passed on. There seems to be a number of different ways of reporting the information, in order for people to be made aware of the adverse effects of certain drugs. I am a little surprised to hear you say that, because we are always told that the practitioners, who most often are professionals, are the ones reporting the most information to Health Canada through the various data banks, including MedEffect, but there is also the Canadian Health Network, which collates certain kinds of information.

Could you suggest a mechanism that would be more efficient, since the information does not seem to be getting out, and that is exactly what we would like to see happen?

● (1145)

[*English*]

Dr. James Gowing: I think what someone really needs to be looking at is how health care information can be collected and disseminated appropriately. Health care management across the country, in terms of information technology, is about 10 years behind the rest of industry. Why that is, I really can't answer, but it seems odd that I can get money out of my bank account using a card in the middle of the jungle and I can't get information on a patient who is seen in the next town. There's something wrong in our system here.

I don't think that is what I came here today to talk about with post-marketing, but it is a huge problem and you've identified it. I don't have the solution for it.

I have two sons who are computer engineers. They might have a better answer for you.

[*Translation*]

Ms. Christiane Gagnon: It's true that there are clinical trials before a drug is marketed, but we would like there to be greater vigilance. One of the Committee's objectives is to increase post-market surveillance. So, there is a need as well to know all the details of what happens when a medication is taken, once a product has been marketed. You are very important players, just as important as the patients, when it comes to delivering that information, so that people know exactly what to expect when they take a drug. Very often, the clinical trials conducted on certain drugs may have been shortened; I'm thinking in particular of Gardasil, which has apparently caused a number of fatalities in Europe and the United States. It is currently available on the market, but we have to continue to be vigilant.

Dr. Yola Moride: That is also the principle behind active pharmacovigilance. For example, we can use sentinel physician networks for new products coming on the market. We can also consult specialists who are likely to be caring for this type of patient, and solicit active reporting, rather than relying on a passive system.

Ms. Christiane Gagnon: But, do you think that…

[*English*]

The Chair: Your time is up, Madame Gagnon.

Ms. Wasylycia-Leis.

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

Thanks to all of you for your presentations.

I want to touch a bit on the off-label question and the whole area of what I would see as a problem, and that is the involvement of the industry throughout the process of post-market surveillance.

There have been concerns raised about the government's new direction around risk management and the progressive licensing system as it relates partly to the off-label issue. That is, it might actually lead to a fairly rapid approval of already approved drugs for new indications without that company having to go through the rigour of the clinical trials and the surveillance and full disclosure before an old drug just gets automatically licensed for new indications.

Is that not a problem, from any of your points of view?

Ms. Diane Brideau-Laughlin: That is a significant problem, particularly in the older drugs that have been on the market for several years. Most of these drugs are not even available through the originating company or industry that actually created the molecule. Aspirin comes to mind. It's ancient, yet it's used primarily now for indications completely separate from what it was intended for years ago.

The difficulty then lies in who's responsible for the clinical trials, who is going to do the research, and where the funding is going to come from for the research. So, yes, it is definitely a problem.

In terms of new medications, I think that should be included within the progressive licence process. As indicated by my colleague, if at the outset, within phase two trials, within that licensing it's implied that off-label use for predictable other uses should be considered, that needs to be in the plan for the continuation of that product so that the evaluation continues.

● (1150)

Dr. William Hryniuk: However, if I can just add to that, the history of the indications for these drugs is such that you get it into the marketplace, you find that it works for the initial indication, but you soon find with off-label use that it has many other, completely unexpected ramifications. So it's not always possible to predict which off-label use is going to come up in your post-marketing plan. That's the good news.

The bad news, as you pointed out, is that it may occur in an unrestricted, unorchestrated way, and you have to strike a balance between these two. But I would hate to see that off-label use was prevented, particularly since—in response to another question—many of these indications are for rare diseases or uncommon conditions, and clinical trials would not ordinarily be conducted for those indications. They're either too long or too expensive, and you wouldn't want to prevent the use of these drugs in an off-label situation when it was quickly discovered that it was effective. The balance has to be struck in the legislation and the handling of this issue.

Ms. Judy Wasylycia-Leis: I appreciate the balance that we have to try to strike. I guess what I'm worried about is that we have a system with an incredible lot of influence by the brand-name drug companies over the whole drug approval process. I want to make sure that we end up with recommendations that actually protect against that. So what I want to know from all of you is, how do we do that? What is the best way?

I'm especially curious because the Cancer Advocacy Coalition of Canada does get a lot of backing from drug companies. In fact, I think every drug company in the western hemisphere has donated to your organization.

From the Expert Advisory Committee's point of view, I don't know about your committee, but some advisory committees in Health Canada have indicated that there are industry members on those committees. So how do we ensure that if we move to this risk management model and this progressive licensing model, we have that independence of opinion and surveillance right across the board, every step of the way?

I think that's what Canadians are most interested in, so we're grappling with whether or not we need an independent board or body that actually evaluates prescription drug safety. We've grappled with the need for a complete listing on the government's website of all drug approvals and non-approvals. We're grappling with whether or not there shouldn't be a complete review of all clinical trial data used to reach any decision made and that being made available to the academic community.

Those are a few ideas. Are there other—

The Chair: Ms. Wasylycia-Leis, just to make you aware, we have only two minutes left for them to answer.

Who would like to take that question on for Ms. Wasylycia-Leis?

Dr. William Hryniuk: I'd just like to address one point you made.

The Cancer Advocacy Coalition of Canada gets unrestricted grants from the pharmaceutical companies. We provide them with a list of things that we're going to do, and they either do or don't support them. As you can see from this year's report card, only two of the 10 articles had anything to do with drugs, and our emphasis is on much wider aspects than that.

That said, I think we also have to say, on behalf of the drug companies, that they're not all bad people. They have their interests, and this is a capitalist society, after all. If they didn't work, we wouldn't get the drugs. So I don't think it's fair to impute motives to them that are beyond the ethical boundary.

That said, I agree with your point. An independent body needs to be doing this surveillance, but the essence of the success will be draining off the information from all the electronic systems that are already getting this information in medical records across the country, particularly for cancer drugs. The information is there; we're just asking that it be drained off for surveillance and addressing the issues you've just raised.

Dr. Yola Moride: There were several issues raised, and I don't think I can discuss each of them, but the first one you brought up was the question of a new indication. You felt that maybe the system would allow the new indications to be evaluated too fast.

I think what we've seen so far—and I'm talking about my experience at the international level by other agencies—is that the same level of rigour in terms of clinical trial data must be provided to the assessors. It's important also to realize that the risk management plans afterwards not only include or concern the new indication but also the older indication. So basically pharmaceutical companies must make sure they really want to have that new indication, because the ramifications are very important in terms of drug safety surveillance.

● (1155)

The Chair: Thank you, Dr. Moride.

We'll now go to Mr. Tilson.

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

I'm trying to determine the issues you've raised. Obviously you all seem to think the system needs to be improved; we need to expand on the system.

My questions to you may have been asked in another form by some of my colleagues. I have a number of questions with respect to that. Who should do this? Should this be government? Should Health Canada take it all on and do everything? Should it be privatized? Should one of you do it?

I say that with a twinkle in my eye. Should someone other than the government do it, or should a partnership do these things?

The Chair: Who are you addressing that to, Mr. Tilson?

Mr. David Tilson: Everybody.

And then you get into issues of privacy. Let's say you have other people do it other than government. Are there issues of privacy? I don't know. And finally, does anyone have a vague idea of what this is all going to cost?

Let's start with the Professor.

Dr. Yola Moride: There's a difference between who should do it and who should pay for it. Actually, what we've seen things evolving into is that regulatory authorities set up departments of risk management where they negotiate the plan with the companies very early on and then they agree that such a study needs to be done.

There has to be monitoring of how the study is done because we have to ensure that high-quality data will be generated. What we've seen and what could be very applicable in Canada is to create a network of centres for excellence in, for example, pharmaco-epidemiology or observational studies. I think this is already on the map. Certainly the studies could be conducted through that network and funded by the companies, and we've seen that this model is actually taking place in both the U.S. and the EU.

Mr. David Tilson: Professor, you've looked at this issue, I gather, in other countries. Do you have any idea what such a process would cost Health Canada? I assume you're going to say "Well, the government should pay for it all".

Dr. Yola Moride: Actually, no. That's the thing. Now the model is such that in the U.S. they're thinking about a user fee to evaluate the plans just to administer departments of risk management within regulatory authorities, but the individual studies are paid for by the industry as part of their commitments. Otherwise the drug approval is denied.

Mr. David Tilson: How do we know industry is going to report things? Right now the industry reports. They're the only ones, and I think we're talking about the hospitals joining in, but there's no obligation for the doctors to do it or the pharmacists to do it. So how do we know? Let's say some doctor fills out a report and sends it off. How do we know it goes anywhere?

Dr. Yola Moride: But this is the current system—the passive pharmaco-vigilance.

What we're evolving into is not to rely only on the passive, spontaneous reporting, but to introduce new tools, like registries, epidemiologic studies, database studies, active surveillance, prescription event monitoring. All these activities do not rely on spontaneous reporting.

Mr. David Tilson: Does anyone else have any comments?

● (1200)

Dr. James Gowing: In terms of the cost, I'm not in that field, but I would think that the cost should not be that great. If you take the example of one computer screen to put this information into and then the information is all collected electronically, it's really setting up the program that would be the major cost. I would have no idea, but I think the analysis in the end, particularly in cancer drugs, could be taken up by the National Institute of Cancer and academic organizations like that.

It's making the data available. There will be an upfront cost in organizing the electronics, but once that's there.... As I said in my presentation, if you ask physicians like me and my colleagues to fill in 18 pages, forget it, it just won't happen. The technology is there to collect this data, and I think very inexpensively.

Mr. David Tilson: Would you comment, Ms. Hyland?

Ms. Sylvia Hyland: Yes, and thank you for your question.

I think Health Canada's approach to collaborating with partners and coordinating efforts of different groups interested in safety and pharmaco-vigilance is the way to go, and I think it's to be commended. As was mentioned before, there are various pockets of information in different databases, and their outputs can be coordinated. We've heard about claims databases, we've heard before about coroners' offices reports, and there are poison information centres, so there will always be pockets of information that we can analyze differently and coordinate in terms of outputs. I understand that Health Canada is considering the idea that there are various databases that we can pool together and learn from together.

With regard to privacy and transparency, I also think Health Canada's efforts to bring the adverse reaction reports online are to be commended. Yes, they are planning to improve the database and the searchability of that information; however, there is now information online, and it's transparent. Transparency is the way to go; in terms of privacy legislation, provided the information is de-identified and factual, it can be shared. There are ways to share important information in a transparent way that falls under the umbrella of privacy legislation and privileged acts.

As has been stated, we are moving in the right direction, and working together is the approach.

The Chair: Thank you, Ms. Hyland, for your very insightful answers.

I'm sorry, but we're out of time. Please accept my apologies.

We're now going into the second round, and I would remind members that this is a five-minute round. We'll begin with Ms. Kadis.

Is Ms. Kadis not here? Well, then, would anyone like to go first?

Dr. Bennett, would you like to go ahead?

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

Quite often what the committee really would like to know is what would be in the report for you if you were writing the report. What would you like the recommendations to be that would just make our job easier, so that you'd say the committee got it—that this is the infrastructure that needs to be in place and this is the role of the federal government in how they would interact with the provinces, industry, and clinicians? How could this work? Have you seen it done well anywhere else?

Dr. William Hryniuk: I could bring it down to a very practical approach, to answer the previous questioner.

It's never the cost; it's whether you want to do it and how much you want to do. If you had a pilot study of expensive cancer drugs for two years, sampling major cancer centres' use of those drugs for adverse events and efficacy, and learned from that pilot study as a start, you would have a major step forward in addressing the issue in respect of these expensive but effective cancer drugs.

Ms. Diane Brideau-Laughlin: I'm going to add a comment to that.

One of the recommendations from the Expert Advisory Committee at our last meeting was exactly that statement. Instead of going very broad to begin with, let's start small; let's try to work through the bugs and see what will work and what won't work. We hadn't actually....

We don't identify specifics; we just give broad recommendations in terms of policy, but we did feel that in order to make this as efficient and effective as possible, you can't attack everything at the same time, because every aspect of the care in medicine is so complex and so patient-specific. If you target a small group, you can at least identify the bugs that will prevent you from working through the process.

● (1205)

Hon. Carolyn Bennett: I actually thought that's what the cancer agencies did across the country. What are the cancer agencies doing, and what happened to the cancer strategy, if we aren't actually keeping track of the drugs that work and those that don't?

Dr. William Hryniuk: I don't think the strategy is concerned with that, because of its mandate.

But to answer your question, the specific program we're talking about isn't being done, but it could easily be done. All the western provinces now have electronic data systems, which could easily be interrogated—to answer a previous questioner—and have the data drained off and the adverse effects and failure to respond also made immediately available. This isn't a big deal for the western provinces.

For the provinces that don't have cancer agencies and don't have electronic data systems, it is a big deal. But as I said earlier, if you want to start small, with a pilot study for these expensive cancer drugs, go to the systems that have electronic data systems, drain off the information, and see what you have.

Hon. Carolyn Bennett: Okay.

The Chair: Ms. Hyland, did you want to make a comment?

Ms. Sylvia Hyland: In terms of the report and recommendations, I think our organization would like to see, where there are databases that do contain reports about preventable harm from medications, that there is a method for analysis that considers the practice concerns, the clinical significance, the systems issues, and the potential preventative measures, because there are two different ways of analyzing the information that comes to us around adverse drug events.

Dr. Yola Moride: My recommendation would be to recognize that Canadians deserve more and that you should start thinking about introducing guidelines. Start with the guidelines and follow up with the legislation to effectively monitor drug safety in the post-marketing setting.

The Chair: You only have about 50 seconds, Dr. Bennett.

Hon. Carolyn Bennett: My point is that it's not only adverse effects; it's whether things work or not, and whether something would work better.

A witness: You're absolutely right. It's the benefit-risk—

Hon. Carolyn Bennett: So I think we get a bit confused when we keep talking about adverse drug reactions but actually want to know more broadly than that what's out there and cost effective—the benefit-risk; that's right.

The Chair: Thank you so much.

We'll go now to Mrs. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): I'd like to thank our presenters for being here this morning. We seem to be going around and around with this issue of post-market surveillance, and we hear a lot of different things.

My first question is going to be, who should be defining adverse effects? We have different definitions of what we're talking about.

Does anybody want to answer that? And what do you think that definition should be?

Dr. James Gowing: I think any unwanted effect is an adverse effect. This is why I include failure to work as an adverse effect. Any unwanted effect from any intervention is an adverse effect. That's how I would define it.

Dr. William Hryniuk: I think it comes in two packages, known and unknown. We've historically thought of adverse events as something down the road that was unexpected in chronic use and wasn't predicted from the initial studies. That's one category.

The major category, as far as the physician is concerned, is the untoward effect you can expect from the initial studies, which can occur if you go beyond a certain dose.

But as Jim says, the other adverse effect is failure to respond. So those are the three categories: known, unknown and unexpected, and failure to respond.

Mrs. Patricia Davidson: Would the rest of you agree that those things should all be included?

Ms. Sylvia Hyland: Yes. I would just like to add that you're correct, the definition is extremely important. Different definitions are used in studies and reporting programs. The message would be that whatever reporting program it is, there needs to be a clear definition of what it is that's expected to be reported, who's expected to report, and how it's going to be analyzed.

It is true, there are different definitions, and clarity of the definition is very important to the success of reporting programs.

For example, is there a difference between the critical incident reporting program in Saskatchewan and the adverse reaction reporting program of Health Canada? And what are those nuances and those differences? How can we standardize information so that outputs from the different reporting programs can be compiled together?

● (1210)

Mrs. Patricia Davidson: Does that come through Health Canada?

Ms. Sylvia Hyland: Well, Health Canada has the MedEffect program, and it is the adverse reaction reporting program. There is a regulatory definition for an adverse reaction. There is also acceptance by the adverse reaction program for adverse event reports that might extend past the regulatory definition.

So there are options to look at that data in different ways.

Mrs. Patricia Davidson: I would like to ask whoever would like to answer this. We've talked a lot about mandatory versus voluntary reporting and who should be doing the reporting. I think we've gone the full gamut of who does it and who doesn't do it.

In your opinion, who should be doing it, and should it be mandatory?

Ms. Diane Brideau-Laughlin: I'm going to comment on that.

My original reaction to mandatory reporting of adverse events by all health professionals was a negative response, primarily because I felt it was going to add more noise than quality to the reporting. Part of my concern was that we may end up with more than we need or with elements that are not necessarily bringing any value. However, one of the comments brought to us during our last meeting was the fact that when you mandate something, you show that it's important, and we feel this is important. If we look at it from that perspective, then I'm totally supportive of mandating reporting.

The concern we have is how to ensure that the reporting we get is the reporting we want.

Mrs. Patricia Davidson: How do you ensure that it doesn't become a paperwork nightmare?

Ms. Diane Brideau-Laughlin: That's going to be a challenge. There is also the challenge of having to re-educate people. Health providers, people who've been out working for decades, were not taught how to report adverse events. We knew it was part of our review of the patient, whether it be lack of efficacy or an adverse event. We knew it was part of the risk of drug therapy, but taking the next step, which was to report this to a body, whatever body that may be, was not included.

I think we need to start looking at that and return to our universities and get our students to do this. Their practicums need to include this in their training. We've been remiss in that.

We have people who have been involved with clinical trials. They have that knowledge and skill. They do it regularly, because it's part and parcel of a clinical trial. But the great majority of practitioners are not involved in that. It has to become the day-to-day routine. If we had an electronic means of transmitting the information from all practitioners in the country, I think we would have an amazing array of information, which we then would have to have someone analyze, obviously, to make it useful for the practitioners.

The Chair: Thank you, Ms. Brideau-Laughlin.

We'll go to Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Professor Moride, in terms of the different experiences internationally, is there a country out there which could be a source of inspiration? Are you aware of legislation that would be consistent with what you would like to see in place here?

Dr. Yola Moride: We are still in the early stages, even in countries where the concept of risk management has been introduced. In the United States, this only began in 2005, and in 2007, the latest definitive guidelines were adopted in Europe. Of course, we can say that in Canada, we are talking about 10 provinces with a different culture, in the sense that the risk minimization processes probably differ from one province to the next. So, that is a challenge. However, in Europe, we are talking about 27 different countries, and they, too, face that kind of challenge. So, is there one country whose situation closely resembles that of Canada? I'd say that the concept of risk *per se* is not a global issue. Canada should be developing measures that will probably be different from those in place in other countries.

Mr. Luc Malo: I am trying to make the proper connection between two pieces of information that we have been given. First of all, you said a little earlier that antidepressants often do not work because the treatment is interrupted before six months have elapsed. In fact, in the notes prepared by our researchers, Health Canada is quoted as saying that, in patients suffering from moderate depression, drugs are ineffective—that they have a placebo effect. So, I am wondering whether, when information seems contradictory at first sight, it's because there haven't been enough studies conducted in real life circumstances, or because every group of individuals is completely different. Last week, we heard from physicians. They told us that in terms of adverse drug effects, it is possible for there to be completely opposite effects—such as sleepiness and insomnia, constipation and diarrhea. Basically, we could study these things to death, but ultimately, we are talking about different individuals, and therefore different adverse effects in each case.

● (1215)

Dr. Yola Moride: That is precisely the problem. With clinical trial data, we are talking about very limited patient groups. In the actual practice setting, we are dealing with subgroups of patients who will not all react the same way. Yet we are unable to get at the subtleties and small details on the sole basis of the clinical research. That is precisely why it is very important to have the same volume of information from actual practice settings or based on observation. At the same time, the data you are referring to should be interpreted cautiously, in my opinion, because we have to be sure to compare apples with apples. The fact is I was not referring to exactly the same concepts.

Mr. Luc Malo: So, an ordinary member of the public receiving this information could easily become confused.

Dr. Yola Moride: Yes, of course. We need better systems of communication. We should not be waiting until the newspapers pick it up or the information becomes sensationalized. That is one of the major perverse effects of risk surveillance. People have to be very well informed and be given adequate information.

Mr. Luc Malo: Who should be conducting studies on the subgroups? Who should be taking responsibility for those studies?

Dr. Yola Moride: We were talking about that earlier. It's important to distinguish between who should be paying for the studies and who should be conducting them, because the primary goal is to conduct studies that are valid using the best possible expertise. There are a number of models out there—centres of excellence in pharmacoepidemiology, for example, which could conduct studies funded by the people who have the products—in other words, the pharmaceutical companies. That would be a good idea.

Mr. Luc Malo: I now have some questions for the physicians. Gentlemen, have you noted completely opposite effects from one patient to the other in your own practices—as I was saying earlier, very different effects between two patients receiving the identical treatment?

[*English*]

The Chair: Dr. Hryniuk.

Dr. William Hryniuk: Yes. As a matter of fact, there exists an example of a drug that was given to improve the hemoglobin level so that the anemia from the chemotherapy drugs is alleviated without the need for transfusions, only to find that the drug that improves the blood also makes the cancer grow faster. So that's been the basis for the withdrawal or the black box warning on the use of these drugs.

The Chair: Thank you for that, Dr. Hryniuk.

Now we'll go to Mr. Fletcher.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Madam Chair, I'm just going to pass my time to Patrick Brown. I'll go after him.

The Chair: Absolutely.

Mr. Brown, please.

Mr. Patrick Brown (Barrie, CPC): Thank you, Ms. Chair. I thought that was the order, but I guess we got mixed up there for a second.

I have a few questions. I'll raise them all at the beginning, and then you can comment on them where appropriate.

I've asked previous witnesses, as they gave us their expert advice, about the use of new technology and the role you believe that could have. One thing that was mentioned before was a hand-held device where there would be real-time access to Health Canada updates. We were told by the Canadian Medical Association that sometimes notices are mailed out or faxed out, so the time period to get them can sometimes be quite lengthy. I want to see if you have any suggestions on that.

We also heard from an individual, Terence Young, who spoke on behalf of a victims' advocacy group about the need to better share international data, saying that if a pharmaceutical company does a study, it should be shared with Health Canada within 48 hours. If that pharmaceutical company is producing pharmaceutical products in Canada, they should be required to share studies they've done abroad. I want to know your thoughts on that and whether that would be helpful.

I also want to know if you could comment on the Beers list. We heard at this committee that there is information compiled about how a specific pharmaceutical drug could affect a specified category of individuals—in this case, seniors. What ability would you suggest Health Canada should have to create other lists, and is that our role? Should there be a list of drugs that could adversely affect women or children, in the same sense that we've had that Beers list that was compiled?

● (1220)

Ms. Diane Brideau-Laughlin: In my real-life world I'm a drug information pharmacist. What I do is evaluate information as it comes forward to me. We find one of the important things in terms of being able to support our clinicians is that they do get access to real-life information as quickly as possible. So any tool that can be used to provide that information to the front-line practitioner is definitely beneficial.

People who go around with their PDAs and have drug information resources that maintain and track either FDA or Health Canada alerts are very useful, and clinicians very much appreciate them.

What the ideal process would be, I'm not sure. Who would fund these? I don't know. But I believe that front-line practitioners do require this information as quickly and as succinctly as possible for it to be useful for their patients.

Dr. William Hryniuk: If you have a question on anything in the world, you Google it and you usually find the answer. I don't see the reason why we couldn't have the same kind of mechanism to address the issues you've raised here from Health Canada, for example.

We've looked at the Health Canada website. We have had to work with it for the last three or four years in researching the effectiveness of cancer drugs and the procedures whereby they are approved, and it's a clunky site. It's not very easy to navigate. With some improvements and an eye towards user-friendliness, these kinds of issues could be addressed quite usefully, so that if a physician in his or her office encounters a question, simply tapping up the Health Canada site and getting the answer could be done.

Dr. Yola Moride: I just want to come back with some supplementary information.

To involve pharmacists also would be a very efficient way of providing up-to-date information. For example, if they dispense a drug, it could come up on their screen that there's a new warning and they could see their patient. It's not just the prescriber or the practitioner who prescribes, but also the pharmacist would be a good channel, an efficient channel.

Mr. Patrick Brown: Are there any comments on the creation of a specified list in terms of categories of Canadians, like there is the Beers list for seniors?

Ms. Diane Brideau-Laughlin: You're talking about the Beers list. There are drug information resources out there that do have disease-class drug interaction types of programs. They are available.

Mr. Patrick Brown: Should Health Canada be compiling that?

Ms. Diane Brideau-Laughlin: I guess I hesitate. The Beers list is one that we recognize, but we also recognize that it's not a black and white issue. Unfortunately, that's the problem with the practice of medicine. Yes, the list is there. Yes, we know that patients at risk will have greater risk with these drugs, but it doesn't mean these drugs are necessarily, absolutely contraindicated in these patients.

Is it the list you need or is it the increased awareness that patient groups are at risk?

The Chair: We are out of time now, Ms. Laughlin. Are you asking that direct question to Mr. Brown?

Ms. Diane Brideau-Laughlin: No.

The Chair: Okay, thank you.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you, Madam Chairperson.

I want to come back to the issue of independence in decision-making, because I didn't get a chance to hear a comment from everyone and I just want to go through it again.

Everything I've read on this whole issue points to dealing first with the secrecy that surrounds the whole drug approval process. We can extend that pre-market approval process now to the post-market surveillance issue. How do we best do that? How do we ensure that all decisions relating to clinical trials and to adverse reactions are available to the academic community, so that they can address these issues and advance the concerns, and available to the public, who are looking for some wisdom as they make these difficult decisions?

● (1225)

Dr. William Hryniuk: The Cancer Advocacy Coalition is struggling with just that question of transparency and accountability to the public for just exactly the reasons you have outlined.

The mechanism that seems to be working—at least it's evolving, for example, for the joint oncology drug review mechanism—is that patient representatives are on the committees, sitting there and adjudicating all of this, and they have access to the data. Those committee members, representing patients' voices—the public voices—also have connection to the non-governmental organizations of other cancer patients. They are able to deliver a consensus of opinion of those other organizations to the committee and also provide the information from the committee to these organizations. So mechanisms like that can be set up.

Ms. Judy Wasylycia-Leis: What about a website that gives people everything they need to know about drug approvals and non-approvals? Is there any problem?

Dr. William Hryniuk: There will always be some issues that the drug companies won't want to disclose. We would hope to keep those to an absolute minimum, because that secrecy element has impeded, in our opinion, the transparency issue. The website issue is always going to be, who's going to put it on it and who's going to read it? At the end of the day, you really want somebody sitting there in the committee meeting, being able to listen and report back.

Ms. Judy Wasylycia-Leis: Okay, then, let me ask this question, and I know you will want to jump in.

Right now drug regulation in Canada is completely shrouded in secrecy. What we're talking about is a very marked departure. Today even the names of drugs in the approval process are not disclosed. All the information that industry submits, including clinical trial data on safety and effectiveness, is deemed confidential, and it can only be released with the permission of the company, even when you have an access to information request. So we're talking about a complete departure from that.

I want to know if you're in agreement, because this gets to the heart of the overall issues around drug surveillance.

Yola...and maybe the others.

Dr. Yola Moride: The problem is, when you assess the benefit-risk at the time of drug approval, the process is not transparent. What usually happens is you have a group of experts who weigh the benefits against the harms and make a decision. There's no magic formula. They don't come up with a magic number that says the drug is approved or not. This is probably the most disturbing aspect—how decisions are taken.

I can tell you, having worked on this issue, that there is at present no mechanism or system that would provide additional information. However, I am involved in some initiatives designed to define the parameters in the decision-making process and come up with explicit criteria that could be communicated either to the practitioners or the public.

It's a difficult question to answer. It's extremely relevant, but I don't have any answer at present.

Ms. Judy Wasylycia-Leis: Does anyone else want to comment?

Let me ask you, Dr. Gowing. Do you see a shift from a secretive approach to one that requires full disclosure every step of the way as a problem in light of the competitive nature of the business?

Dr. James Gowing: I think it's good to move to more transparency. We've been advocating that for a long time. In Ontario, Bill 102 was supposed to provide this transparency. I don't think it has, but all the regulations have not come through yet and we're waiting to hear.

Certainly, the secrecy about these things is wrong. I'd like to know how these expert panels come up with what they come up with. It's impossible for a prescribing practitioner to know how they made the decision that allowed him to prescribe the drug. I disagree often with the decisions of these groups. I don't have any mechanism to argue the point because I don't know how they made the decision.

● (1230)

The Chair: Thank you, Dr. Gowing.

Mr. Fletcher.

Mr. Steven Fletcher: A lot of the discussion has been at the 30,000-foot level. I want to ask some questions from right on the ground.

Twelve years ago, when I was in the hospital looking at the doctor's notes, I assumed the doctors were literate, though you'd never know it from reading their handwriting. Fast forward to the present. The doctors I've seen over the years are definitely not technically savvy. Today there are reports in the media that doctors are one of the main culprits in spreading superbugs in hospitals, because they don't have time to wash their hands.

The issue of compensation has come up. How will doctors be compensated for the time they're going to be spending filling out reports?

How would this work at the ground level? What stimuli could be provided to the doctors? It's easy to talk about cultural change, but we're talking about a massive change in the way doctors operate.

Dr. James Gowing: We're in the electronic age, and any physician who is not in the electronic age is a dinosaur. I think this bears on a lot of the questions that have been raised here today. I have a computer on my desk. I'm using it constantly throughout the day. Not too long ago, I was computer illiterate. I think my grandchildren are still ahead of me.

The technology is there and it's very simple. This is a point we've been trying to make. You need one computer screen for reporting the data we're asking for. If you go further, the doctors will be out washing their hands and not filling in the forms.

Mr. Steven Fletcher: Madam Chair, I think I've just been told that I should go to Jurassic Park for a medical clinic.

Some hon. members: Oh, oh!

The Chair: All of your hands went up, but go ahead, Ms. Hyland.

Ms. Sylvia Hyland: I want to respond that health care is a little behind in utilizing technology, but there are efforts under way to implement computerized order entry systems, recognizing that there are problems with handwritten notes. There are also initiatives under way with manufacturers to look at voluntary bar coding standards, so that bar coding technology can be utilized in health care where appropriate. This is also an opportunity to look at the labelling of products, as there are a lot of products that do not have bar codes on them. This is an opportunity for improvement.

The other thing we have done, and which is being adopted, or being considered for adoption, in the accrediting standards for hospitals, is...the use of dangerous abbreviations. We recognize that there are abbreviations that are dangerous if used in the handwritten form, and in the electronic form. Those can be avoided.

Also, I do believe that when a prescription is handwritten, the patient should be able to read that prescription; it should be legible and not be in Latin. That is a safety thing, as well, for the pharmacist. As a pharmacist, I would like to be able to read the prescription.

I just wanted to comment on that.

Mr. Steven Fletcher: The government has $1 billion in Infoway; in fact, it added $400 million in the second to last budget. It would seem to be a natural vehicle to help with what we're talking about here today.

What have your experiences been with Infoway thus far?

● (1235)

Ms. Diane Brideau-Laughlin: Within my province of New Brunswick, we're currently at the level where all of our health regions will soon be tied in through these electronic health records, which makes us extremely happy. We are looking at moving outside of just the institutions and including physicians' offices and pharmacies, so that everybody will be able to share the information.

There is concern, of course, about patient confidentiality and information confidentiality, but we also recognize that the people who should have access to this information are professionals who should, under the auspices of their professions, be able to use this information in an appropriate fashion.

It would be a huge step in providing better sharing of information.

The Chair: Thank you, Ms. Laughlin, and thank you, Mr. Fletcher.

If you don't mind, I would just like to ask a question as chair of the committee. There's one aspect I was just wondering about. When we're talking about drugs, I know that drugs for something like chemotherapy are very expensive; usually you're prescribed four, five, or six drugs, depending on the level of chemo. And sometimes those drugs don't work.

Have there been any answers as to who picks up the cost of those medicines that absolutely do not work? If you're experimenting, whether it's with cancer or another disease that is very dependent on the medication, has there been any examination of that in the medical world?

A doctor could prescribe a pill and really do the best he or she can in doing that, and they might spend a lot of money on that bottle of pills, but they might find out after you've taken one pill that, oops, we have to go to another one. Has there been any examination of that kind of predicament that patients get into?

Dr. Yola Moride: That's the daily job of the provincial reimbursement agencies; that's exactly what they do. They weigh the benefits and the risk of a drug. Part of the benefit, of course, is that if a drug doesn't work and is extremely expensive or very risky, they won't pay for it—or they will introduce restrictions on the payments.

Dr. William Hryniuk: The problem, however, in that situation comes when the funding agency—in this case, the provincial government—won't even fund the drug from the beginning for anybody. What has been proposed—

The Chair: I think you misunderstood my question. My question was about approved drugs, drugs that are given out, but the person then has to change their medication.

Dr. William Hryniuk: There is at least one example that I'm aware of where the company has come to an agreement with the funding agency that if the drug doesn't work in the first few cycles, no charge will be forwarded by the company to the agency. If the drug does work, then the agency will pay for the drug.

For these expensive cancer drugs, that may be one mechanism we should pursue.

Dr. James Gowing: I think you were asking about leftover drugs.

The Chair: That's right.

Dr. James Gowing: That's a real problem, and everybody deals with that differently. In the clinic that I'm in, we thrive on the leftover drugs, to use them on patients who otherwise wouldn't get them. So if a drug isn't working, we'll keep it in the refrigerator and give it to someone who needs it.

The Chair: Very good. Thank you so much.

Ms. Kadis.

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

To our witnesses, in your experience, how serious a problem do you feel adverse drug reactions are in terms of the health and well-being of Canadians? How much are you seeing in your respective areas and organizations, and how much do you feel falls through the cracks?

Dr. William Hryniuk: In cancer medicine, the disease we're treating is so serious and the drugs themselves have enough side effects that we know of that the patients are willing to put up with this. So the issue of adverse effects in oncology drugs is not the pressing problem that it might be with more widely used drugs and other diseases.

That said, the most adverse effect is the failure of the drug to work, and that's the one we're concerned with here today, given the expense of these drugs.

Mrs. Susan Kadis: So you have a different threshold and a different context.

Dr. William Hryniuk: Yes.

Mrs. Susan Kadis: Thank you.

Ms. Diane Brideau-Laughlin: My answer to your question is that we all think it's very important and that there is definitely a problem. And yes, we're not reporting everything that needs to be reported, and that is also a problem. But it's such a wide spectrum, as indicated by the oncologists in the room. When you're dealing with oncology, it's completely different from dealing with a drug that's being used for blood pressure control, for instance, where your tolerance for adverse events is going to be minimal to nil.

So again it boils down to what is significant. Unfortunately for the individual who's being cared for, "significant" is what is happening to that person.

● (1240)

Ms. Sylvia Hyland: I thought of a quick addition. In answer, yes, there is a serious problem, and we use a fair number of drugs in this country. We do have a privileged health care system, but we also have access to a lot of drugs. I think one of the interesting areas that isn't yet accessible is usage, really being aware of how many drugs are used and to what extent. If one day we can also have transparent information on the usage of drugs, that would help put a lot of things in perspective in terms of the number of adverse events and the usage of drugs in this country.

Dr. Yola Moride: In my opinion, adverse drug reaction is a real public health issue. We're talking populations. Even though a drug may have a small risk, if you have 10% of the population exposed, it's going to result in a very large absolute number of cases.

Eventually the serious effects will be picked up by the pharmaco-vigilance. My problem here is that it's not timely enough. If additional measures could be introduced right at the time of marketing, the adverse effects could be picked up sooner.

Mrs. Susan Kadis: Also, do you feel that the public has sufficient access to forums to enable or allow them to report their experiences with drugs? Clearly, we're talking about communication being a major issue here.

Ms. Sylvia Hyland: That's a good question. Overall, there isn't great awareness amongst the public of the fact that they can report adverse reactions to drugs they are taking. I do believe that is one of Health Canada's post-marketing surveillance strategies: to increase education to the public, to let them know that they themselves can report adverse effects that they experience with a drug.

Mrs. Susan Kadis: Thank you, Madam Chair.

The Chair: Thank you so much.

Now we'll go to Mr. Keddy.

Mr. Gerald Keddy (South Shore—St. Margaret's, CPC): Thank you, Madam Chair.

Welcome to the witnesses.

This is not usually the committee I sit on, so I'm finding this discussion quite interesting and a little alarming.

There's the whole discussion on informed decision-making. If you don't have a process that's entirely transparent and you don't have that risk versus benefit list, how can you make informed decisions? I guess that's more of a rhetorical statement than anything else, but it's very difficult. I don't know how you do that.

The other thing I'm quite shocked about is the electronic health records. I listened to my colleagues talk about doctors' handwriting, which is an old joke, but they're not alone. Most people have illegible handwriting today. There's hardly a kid in school who can write so you can read it, but everyone can use a keyboard.

I think we've looked in the wrong area. We've been blaming the doctors when we should be giving them more assistance in filling out the electronic records. They're busy; they're trying to see as many patients as they can in a day. Frankly, there's no reason why a doctor shouldn't be able to tell their assistant to fill out a prescription for the pharmacy so that it comes to you in typed format.

I don't understand why we don't have a complete electronic record in this day and age, especially at the hospital level. It just doesn't make any sense. It would be easy to do. You wouldn't even need a patient's sheet to write on. You would have a keyboard instead. It would come up on the screen and automatically go out to everybody.

I don't know how many drugs are allowed into Canada and registered every year, but I assume there are hundreds of them.

Ms. Diane Brideau-Laughlin: There are 23,000 medications.

Mr. Gerald Keddy: There are 23,000, so no one person can keep all those drugs in their head, nor can they know what the adverse effects of one drug are on the other 22,999. If you have a patient with multiple drugs in their system for various issues, without an electronic database how do you do that?

● (1245)

Ms. Diane Brideau-Laughlin: I think we're all in agreement on that.

Mr. Gerald Keddy: I don't know if that's a question or a statement, but I marvel that it's not there already.

Ms. Diane Brideau-Laughlin: I think we all agree with that. With the difficulties that have been encountered in the hospital setting, the electronic record is definitely where we need to go. How easy is it to implement? In a small hospital like ours, we have 3,000 staff people. Of those 3,000, probably 1,500 need to be able to use this system, and the system has to be readily accessible to them at the moment they need it. We don't educate our staff in that world, so that is part of the problem. It's part of the challenge, and it needs to be addressed very early in the training.

You also have a lot of dinosaurs who've been out for a long time—

A voice: Be careful where you look.

Some hon. members: Oh, oh!

The Chair: Order.

Ms. Diane Brideau-Laughlin: Thirteen years ago I absolutely would not have turned on a computer; I would not have been able to turn on a computer. Now my question to myself every day is, “How did I ever work without it?” You need to evolve into it.

When you're teaching clinicians to be clinicians, you're not teaching them to be IT people. It's not part of the role, so that needs to be incorporated. It needs to be part and parcel. In some way they need to almost be mandated to do that. Institutions start doing that and then the learning curve comes into place. That's where you have a lot of resistance.

Mr. Gerald Keddy: It's not mandated in any way, shape, or form. So we have 23,000 drugs being listed every year in Canada for use, and there's a very difficult.... I don't think we can just simply put it back on the shoulders of the physicians. I think we all have to take a little responsibility here.

Dr. Yola Moride: In Quebec there has been a very strong movement toward what we call integrated care or chronic disease management, where the patient not only navigates through a fragmented health care system but through a team. In order for that team to be functional, everything needs to be electronic, because it's going to include the physician, the case manager, nurses, pharmacists, etc. By definition, as a consequence of that, what you're suggesting will be implemented.

You're right that we're not there yet. We're just starting to implement it.

Mr. Gerald Keddy: The other issue that was being discussed here is the whole after-market question. You have a drug that's put on the market, now it's being prescribed to more people, and all of a sudden we're finding...you know, the Vioxx story, or others. The only way, I would suggest, to follow that in any realistic manner in real time would be to have electronic monitoring. So all of a sudden you'd start flagging this issue. It's coming up, and it has happened a dozen times, instead of 12,000 or 50,000 times.

That's all.

Dr. William Hryniuk: I'll respond to something you said.

I think the practical solution to the 23,000 drugs problem is one that I encountered when I was practising in Detroit, at the cancer centre there. The pharmacist was in the clinic with us, and he or she had access to the electronic database. At about every second patient, we would have to interact as a team to make sure the drugs were the right drugs—and not just the cancer drugs, but all of the other drugs. So there are practical solutions to that.

To answer Mr. Fletcher's question about having just been released from the park because I've promised to use electronic systems, the synoptic reporting system that is being introduced in a wide variety of clinical circumstances will greatly simplify that. You just tick off the boxes, and the questions are arranged in a way that you can't escape giving the right answer. That system actually works quite well.

The Chair: I want to thank you very much. We've come to the conclusion of the questions the committee wanted to ask today.

I really want to thank each and every one of you for having come here today and given your expertise and your advice. This is a very important study, and a lot of your information has been very insightful and very useful to all of us. So I certainly want to thank you for that and wish you well. I look forward to hearing more from you in the future, I'm sure, on other topics as well.

For the committee, there is another committee coming in, so we are going to be adjourning very shortly.

Next committee, Thursday, we have just a small group of witnesses coming in, and we will also be doing committee business at that time.

Thank you, ladies and gentlemen.

The meeting is adjourned.

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