Fouse of Commons CANADA   Standing Committee on Health						
		Standing			пеа	
HESA	•	NUMBER 055	•	1st SESSION	•	39th PARLIAMENT
		Mond		IDENCE May 14, 20	07	
				149 119 20		
			-			
			C	Chair		
			Mr. Ro	b Merrifield		

Also available on the Parliament of Canada Web Site at the following address:

http://www.parl.gc.ca

# **Standing Committee on Health**

Monday, May 14, 2007

#### • (1535)

# [English]

The Chair (Mr. Rob Merrifield (Yellowhead, CPC)): We'd like to call the meeting to order. It's pursuant to Standing Order 108(2), a study on prescription drugs, the common drug review. This is our seventh meeting, and we look forward to the presenters we have before us today. We also look forward to being able to quickly get to our report soon after we hear all of the testimony, which is coming up very quickly now.

With that, I want to introduce those we have with us.

From the Canadian Medical Association, we have John Haggie. It's good to have you here. I believe you have Briane Scharfstein with you.

It's good to have you here as well.

From St. Michael's hospital, we have Andreas Laupacis, who is on his way from the airport, I believe, so he'll be joining us very soon.

Then from Mood Disorders Society of Canada, we have Phil Upshall. It's good to have you here.

From Hit the slope for hope, we have Michelle Calvert and Sarah Calvert. It's good to have both of you here.

So with that, we will yield the floor to you in order.

From the Canadian Medical Association, John Haggie, you can start. The floor is yours. You have 10 minutes.

Dr. John Haggie (Chair, Board Working Group on Pharmaceutical Issues, Canadian Medical Association): Thank you, Mr. Chair.

The Canadian Medical Association represents more than 65,000 physicians in Canada, and pharmaceutical issues play a critical part in the everyday practices of these physicians. To help Canada's doctors better serve and treat patients, the CMA is developing a growing body of policy on pharmaceutical issues. In November 2003, we presented its study of prescription drug issues to the House of Commons Standing Committee on Health. Last July, the CMA partnered with four other national organizations representing patients, health professionals, health system managers, and trustees to form the Coalition for a Canadian Pharmaceutical Strategy. That coalition released a framework and principles that we believed should govern the development of pharmaceutical strategy in this country.

The CMA believes that any pharmaceutical strategy must be built on the foundation of two critical principles: all Canadians should have access to safe and effective prescription drugs, and secondly, no Canadian should be deprived of medically necessary drugs because of inability to pay.

Whether the common drug review, or CDR, furthers these goals has been a matter of vigorous debate. Federal and provincial representatives told the committee that the CDR is meeting their needs, and they even said that in some cases it provided them with a higher-quality review than they could have achieved on their own. On the other hand, patient groups have charged that the CDR is an unnecessary layer of bureaucracy and a barrier between them and potentially life-saving new therapies.

We understand the frustration of patients and their advocates when the CDR recommends against public reimbursement, and it can be even more frustrating when the CDR approves a drug but provinces refuse to include that drug on their formularies. In each of these cases, sustainability of the health care system is an important and valid consideration. It would be unfortunate if our limited health care dollars that could have been spent on treating patients and preventing illness were wasted funding expensive drugs, ultimately found to be no more beneficial to patients than other cheaper versions.

There must always be a drug review process. To dismantle it entirely would be unacceptable, both economically and politically.

The primary purpose of a drug review process should be to help ensure access to prescription drugs for which evidence indicates safety and effectiveness in the treatment, management, and prevention of disease and/or significant benefits in quality of life. To help ensure that it achieves this purpose, drug review in Canada should follow these principles.

The review process should be impartial and founded on the best available scientific evidence.

The primary criterion for inclusion in a formulary should be whether the drug improves health outcomes and is an improvement over products currently on the market.

Evaluation of cost-effectiveness should be part of the review process.

Drugs cannot be and should not be evaluated in isolation, but as an integral part of the health care continuum. For example, the review should consider a drug's impact on overall health care use. If a drug reduces a patient's hospital stay or replaces other costlier or more invasive therapies, this should be considered in evaluating its overall cost-effectiveness. It should also consider alternatives to the drug under review. The review should compare a drug's performance to other drugs in the same class and to available non-drug therapies, such as surgery, for instance.

The review process should be flexible, taking into account the unique needs of individual patients and the expertise of physicians in determining which drugs are best for which patients.

The review process should be open and transparent. We support the CDR's intent to publish the rationales for its decisions, including lay-language versions.

The CDR results should be communicated to caregivers and patients as part of an ongoing strategy to encourage best practices in prescribing.

Meaningful participation by patients and health professionals should be part of the review process. Here we would recognize and applaud the expansion of the Canadian Expert Drug Advisory Committee to include members of the public. We also suggest that the CDR experiment with other means of obtaining public input, open forums, for example.

A process for appealing the review's decisions should also be established.

• (1540)

Ongoing evaluation of the review process should be required. The CDR has already undergone an evaluation and is planning to implement some of the key recommendations. Impartial evaluations should continue to take place to assess whether the CDR is having a positive impact on the health of Canadians and their health care system.

The common drug review does not and cannot exist in isolation. It is linked to other issues in prescription drug policy, and there are three specific issues that merit the committee's consideration.

The first is drugs for rare disorders. It has been alleged that the Canadian Expert Drug Advisory Committee's current review standards, which place a high value on large-sample clinical trials, cannot capture the value of these drugs. This issue merits much closer consideration.

The CMA recommends that Canada develop a policy on drugs for rare disorders, that it encourage their development, evaluate their effectiveness, and that these policies ensure that all patients who might benefit have reasonable access to them.

Second is a common formulary.

The CMA recommends that Canada's governments consider the possibility of a establishing a pan-Canadian formulary. Canadian patients need a national standard; having 18 different levels of coverage is simply not acceptable.

Should the CDR form the basis of this formulary? Well, the answer to that question would depend on whether evaluation proves that the CDR is the most effective vehicle.

Third is catastrophic drug coverage. It's now generally accepted that Canada must institute a pan-Canadian catastrophic drug program.

The CMA recommends that governments and private insurers work together to assess the drug needs of Canadians, particularly those who are uninsured or under-insured, and agree on an option for meeting these needs. The underlying principles of this effort must be to ensure that Canadians can get the drugs they need, regardless of where they live or how much they earn.

As a starting point, the CMA recommends that governments give priority to a national pharmacare program to provide necessary drugs for all Canadian children and all Canadian youth.

In conclusion, the CMA believes that a process for reviewing the clinical and the cost-effectiveness of prescription drugs can contribute to improving the health of Canada's patients and our health care system. The value of the CDR in this process will be determined by how well it performs its function on evaluation.

We understand that the CDR study is part of a larger and more comprehensive study of prescription drugs being contemplated by the committee, and we look forward to assisting you with this study.

#### Thank you.

**The Chair:** Thank you very much for your presentation to the committee. It's very valuable as we look for solutions to what we see as potential problems. So thank you.

We'll now move on to St. Michael's Hospital. Dr. Laupacis.

Dr. Andreas Laupacis (Director, Li Ka Shing Knowledge Institute and former Chair of the Canadian Expert Drug Advisory Committee, St. Michael's Hospital): Thank you very much. I've managed to spill my water here.

The Chair: That's not a problem. We'll give you a quick minute.

We could go on to another presenter first. What's your preference?

Dr. Andreas Laupacis: It's up to you.

The Chair: Let's go on to the Mood Disorders Society of Canada.

Phil Upshall.

Mr. Phil Upshall (National Executive Director, Mood Disorders Society of Canada): Thank you for the opportunity to present today. I know it has been difficult squeezing everyone in. I appreciate the effort that you and the staff made, and I appreciate the opportunity to be here today.

Members of the committee, Mr. Parliamentary Secretary, and others, first I want to give you a quick overview of where we stand on the CDR and the questions you've asked. Quite frankly, there is no evidence that I have seen that the current CDR is effectively achieving its mandate. Health Canada continues to review drugs, other countries that have as rigorous standards as ours review drugs, so in my view, the CDR single process of review starts in third place. Then, after much duplication of testing and after consulting with so-called experts whose knowledge of mental illness issues in particular is very unclear, recommendations, usually "no", are followed by the decision-making processes in the provinces, which, of course, unfortunately are frequently "no". So we have a four-stage process, in my view, and I believe we were intending to have a one-stage process.

Quite frequently now in Canada, as I mentioned, most applications receive a "no". Again, from our perspective, straight cost-perpill comparisons used for provincial drug plans and CDR perhaps save money in the health care budgets—and I assume that's how they establish costs—but my argument is that in order for the process to be cost-effective as it relates to people with mental illnesses, it must include the cost to the economy and the cost to the patient consumer. Costs don't just mean cost per pill; they mean recovery, they mean avoiding costs—\$33 billion to the economy, costs to the patients and consumers and their families when they lose their jobs because they don't have adequate or the right medications, or any medications.

Currently the CDR is not patient-centred and it does not engage those who we believe are real experts in the mental health field. Particularly, they don't engage patients and consumers, who quite frankly have the experiential expertise that I think is essential to be at the table at the beginning, the middle, and the end of the process.

As I'm sure is obvious, there's a significant lack of transparency, and quite frankly, while the physicians, scientists, and health care providers at CEDAC are wonderful people, I'm sure, I don't think any of them have significant or adequate expertise in the mental health field to be providing advice as to "no" or "yes" on medications for mental illnesses.

So there you have our answers to the questions. If I can just be a little broader now in my responses, I have filed a reasonably detailed brief with you, which I believe you all have and I hope you and your researchers—your highly esteemed researchers, by the way—have an opportunity to read completely. It's a little broader than what was originally requested, but there is such a need for positioning the issue of mental illnesses as opposed to other chronic diseases that I felt it was necessary to be reasonably broad.

The Mood Disorders Society of Canada is a non-governmental charity incorporated under the laws of Canada. We are not an advocacy group, and I do not consider myself an advocate; I consider myself a manager of an NGO. Our activities include research, communications, and working with provincial and other national organizations in collaborative efforts.

One of the things we're proudest of is the document called *A Report on Mental Illnesses*, which is from 1962. I believe all of you received copies of this. This is the first document ever produced by Health Canada on mental illnesses, one of the most significant aspects of illnesses in Canada. This document was produced in partnership with Mood Disorders Canada and Health Canada. It was one of the original documents that helped the Kirby-Keon committee start its work.

The interesting thing was that Health Canada didn't have the money to produce it, so we had to work as a partnership to get this out, because they didn't want it to be an official government publication. It fell upon me to develop not only the editorial board and the other contributors, but to find the money to print it, because Health Canada didn't have the money to print it.

# • (1545)

You'll see on the back of the document advertising that we had to sell. Two of the advertisers were Wyeth and Pfizer, and I'll get to the reason for that in a minute. The other advertiser was the Institute of Neurosciences, Mental Health and Addiction. They provided the \$90,000 that allowed us to get these 10,000 copies out and around.

Subsequently, I'm sure you've all received our new edition for 2006-07. The interesting thing about this is that there's no advertising. Health Canada has accepted the fact that we need an official publication on mental illnesses. It's a significantly broadened document from the one you have. If you don't have copies of it, please let me know. We made sure that every MP and senator got a copy. It's a very important document that we think will stand the test of time. The only NGO that was involved in the development of this project was the Mood Disorders Society of Canada.

Our operating funds are secured by working on contracts with Health Canada and other departments of the Government of Canada. We also obtain funds from many corporate sources, including pharma. I notice there were a couple of comments in previous testimony about pharma, and quite frankly, our relationship with pharma is quite good. We started on the basis that we have an awareness to raise. We asked for support to help us raise awareness. We worked with four very good pharma companies. We've thrown several out the door because they asked us to manipulate our messages.

That's sort of the standard process, unfortunately, that you run across, whether it's a pharma or any other support you seek. Everyone is looking for a bang for their buck when they invest, even when they invest in charities.

As you may notice in my c.v., I have a reasonable understanding of the scientific community, particularly the neuroscience, mental health, and addictions community. I sat on CIHR's Institute of Neurosciences, Mental Health and Addictions advisory board for five years. I must tell you that I've made a lot of friends in our scientific community, and I'm surprised by one or two of the expert witnesses who suggested that our scientific community is capable of somewhat altering its findings in clinical trials when those trials may be funded by pharma. I've never known a scientist in Canada, clinician or otherwise, who was prepared to do that.

Our concern with the definition of "expert" that CEDAC uses is that it's too narrow. It uses people who don't have any experience in the mental health field, as far as we can see. This makes a difference to us because the stigma of mental illness is so great. I'm sure my physician friends would agree that mental illnesses are not adequately taught in medical schools. Psychiatrists are considered to be at the bottom level of the pecking order when it comes to specialties. The reality is that very few people really take the time to understand what mental illness is all about and what recovery is all about. I'm asking this committee to take note of the fact that a huge population is affected by mental illnesses. In Canada it's about one and a half million to two million people, plus the caregivers who are required to help people. It's a huge issue—as big as cancer and cardiovascular issues—and quite frankly, the experts don't exist to pay enough attention to what our issues are.

One of our issues is the fact that recovery is a process, and access to medication is one of the most important first steps on the road to recovery. With mental illnesses, unlike some other illnesses, trial and error frequently occurs between a patient and the physician as they try to find the right medication that will work for that patient. Restricting the opportunity, because of an incomprehensible cost formula, for people to recover and become contributing citizens again in Canada is an unfathomable rationale for me to understand.

We know there are medications that could be made available to people with mental illness with significant depression, schizophrenia, and bipolar illness. They're not exceptionally costly. If they were made available to those people, we would have the opportunity to try those medications, see what works and what doesn't, and allow the patient who has the experience to enter into the recovery process a lot faster and not sink as deeply into mental illnesses as they could.

# • (1550)

I'll remind you, finally—because I'm sure I'm out of time—that one of the principal factors of homelessness is mental illness. One of the principal reasons we have homelessness is that hospitals closed a significant number of psychiatric beds—more than 60,000. Community supports were supposed to be made available by the provinces and they weren't. So many people fell through the cracks during that time that a lot of them ended up on the streets, homeless. They lost access to appropriate medications that would have helped them recover, to the point where they lost faith in the medical community and in the supports that would have been available if they had been willing to access them.

When we were able to get some people who were homeless off the streets to try medications, provincial formularies said to try the cheapest ones with the most side effects first. Of course that just reinforced the lack of trust on the part of the recipient. Our argument is that if there's a good drug available anywhere in the world, it should be available to everyone in Canada who suffers from a mental illness. Either experts at places such as CEDAC need to have that guidance and direction, or the process needs to be replaced.

Thank you, Mr. Chair.

• (1555)

The Chair: Thank you very much.

We'll now move on to St. Michael's Hospital.

Dr. Andreas Laupacis, it's good to have you here with us. The floor is yours.

# Dr. Andreas Laupacis: Thank you, Mr. Chair.

I'm the previous chair of the Canadian Expert Drug Advisory Committee, which I'll refer to as CEDAC. This committee recommends to the drug plans participating in the common drug review which drugs should be funded and which should not.

I'm also a practising physician and a researcher, and like all of you, my family and I use the services of the health care system.

In previous hearings, you've heard from many others about the common drug review. Therefore, I'll proceed directly to answer the specific questions you posed to me and will not review the CDR. I'll conclude with a couple of remarks that I personally feel are important.

You first asked about the effectiveness of the CDR. As you know, the CDR performs a thorough independent review of all relevant available information on the benefits, the harms, and the costeffectiveness of the new drugs it considers. A summary of the reviews are publicly posted on the CDR website. While I was chairing the CEDAC for three years, the accuracy of those reviews was almost never challenged; and the importance of the independence of those reviews, I believe, can't be overstated.

Your second question was about duplication. The CDR provides one national review of the available evidence about a new drug. However, in our federal system, the final decision about drug reimbursement does lie with each jurisdiction. To my knowledge, the vast majority of jurisdictions, except the CDR, do not conduct their own independent evaluations, and over 90% of the time, CEDAC's recommendations are accepted. Thus, I don't think duplication is a bigger issue than it was before the institution of the CDR.

However, in some provinces there are delays of many months between CEDAC making a recommendation about funding and the province's final decision. In my opinion, that's an unacceptable delay, and the time between the CEDAC recommendation and a jurisdictional funding decision should not be more than a couple of months.

The third issue you asked me to address is transparency. To my knowledge, the CDR is the only drug reimbursement committee in Canada to make the reasons for its recommendations publicly available on its website. For this degree of transparency, the CDR deserves credit. While I fully support calls for greater transparency in the CDR process, the fact is that greater transparency is needed in the whole drug evaluation system. In general, the entire drug evaluation process in Canada is, in my opinion, a transparency free zone.

So let's have transparency and make the protocols of all studies of a drug publicly available, so that anyone can compare the protocol with the study results reported later.

Let's make the pharmaceutical companies' submissions to Health Canada, which contain detailed information about their drugs' benefits and harms, publicly available. Aren't Canadians who will consume and pay for those drugs entitled to this information?

Let's make Health Canada's review of the pharmaceutical companies' submissions publicly available. Aren't Canadians entitled to know what their publicly funded regulator thinks about companies' submissions?

Let's have transparency, as we just heard, about the relationship between the pharmaceutical companies and disease-oriented groups and those who develop clinical practice guidelines. Let's have transparency about the agreements that various jurisdictions and pharmaceutical companies negotiate on the price paid for a drug, and on any rebates or arrangements negotiated.

And yes, let's make the CDR process much more transparent. Let's make public the drug companies' submissions to the CDR, and the CDR reviews and the minutes of the CDR meetings.

The next thing you asked me about was public input. It's absolutely true that the public has had little direct input into the CDR process—although two public members have recently been added to CEDAC, which I think is an important step. Increasing the transparency of the whole drug review process, which I've just called for, will in and of itself increase public involvement. However, I also believe there needs to be greater public input into the CDR. This can be done in many ways, including public submissions, the opportunity for the public to appeal a CEDAC recommendation, and forums for CEDAC and the public to discuss CEDAC recommendations. I think it's important to engage the public in the whole drug evaluation process, rather than only obtaining its input on decisions about individual drugs.

I've been asked to comment on the joint oncology drug review. This has been established since I left my position as chair of CEDAC; therefore, I can't make an informed comment. However, whatever reimbursement process is established for cancer should use the same principles used for other diseases and other drugs. Patients with heart failure, a condition with a high risk of death, should not be treated differently from patients with cancer.

#### • (1600)

Let me now turn to two other issues that I think are very important.

The first relates to the fragmentation of the whole drug evaluation process in Canada. There is virtually no integration between those who make decisions about whether a drug can be sold in Canada, which is Health Canada; those who establish the maximum price of a drug, which is the Patented Medicine Prices Review Board, or the PMPRB; and those who decide whether a drug will be publicly funded, and that's CEDAC or the CDR, and eventually the federalprovincial-territorial drug plans.

Let me give you one example. Both the PMPRB and CEDAC are interested in the price charged for a drug. The PMPRB sets the maximum price that can be charged for a drug in Canada, based upon the price charged in seven other countries, which often has nothing to do with the benefits of the drug. CEDAC makes its recommendations based upon a drug's cost-effectiveness, but has absolutely no input into the maximum price established by the PMPRB and has no authority to negotiate price. The CDR is a relatively small component of the whole drug evaluation system in Canada, and I would respectfully urge you as a committee to look at the whole system.

The final issue I wish to discuss is the price of drugs. As you know, cost-effectiveness, or value for money, is the main criterion that CEDAC uses to guide its recommendations, and here I'd make the very strong point that CEDAC does not just look at which drug is the cheapest; it looks at benefits and costs, and benefits include non-

drug benefits such as avoidance of heart attacks and the future avoidance of hospitalization, etc.

Cost-effectiveness is affected by two factors. The first is how beneficial a new drug is compared with existing therapies. Even a very expensive drug is cost-effective if it is safe and provides a very large benefit.

The other factor that markedly affects a drug's cost-effectiveness is its price. In the last ten years there has been a massive increase in the price of drugs without, generally speaking, a massive increase in their benefits. Only a few years ago, I thought that a drug that cost \$1,000 a year was expensive. Now the average drug submitted to CEDAC costs about \$5,000 a year—that's the average drug—with a number costing more than \$20,000 a year. These drugs in general don't cure disease, and in many instances their benefits are actually quite modest.

In my opinion, the single most important factor limiting access to drugs is skyrocketing drug prices, with no apparent end in sight. Skyrocketing prices are making some drugs unaffordable, and I would point out that the common drug review does not have the authority to negotiate price; CEDAC is simply provided a price by the pharmaceutical company and essentially told to take it or leave it.

We all know that access to quality of care is an important issue in our health care system. In many parts of Canada, patients with arthritis of the knee are waiting in severe pain and immobility for many months before they are able to benefit from a knee joint replacement. Joint replacements are among the most dramatically effective interventions in medicine. One joint replacement costs about \$11,000 to \$13,000, and its benefits last for decades; contrast that with the greater costs and less impressive benefits of some of the drugs considered by CEDAC.

My point is not that joint replacements are always better than drugs—that's clearly not the case—but as parliamentarians, you are aware that the resources available for health care are limited, and difficult choices about what we can afford and what we cannot afford are being made every day. I would suggest that the CDR and the drug plans are not in the business of purchasing drugs; as one component of the health care system, they are in the business of purchasing health outcomes. It is incumbent upon the pharmaceutical industry to ensure that the outcomes provided by drugs are at least competitive with the outcomes that can be purchased by similar investments in other parts of health care.

Thanks very much for the opportunity to address you today.

**The Chair:** Thank you very much for your presentation. I'm sure it has stimulated a significant number of questions.

Now we'll move on to Ms. Michelle Calvert. I believe you're the spokesperson. The floor is yours.

• (1605)

**Ms. Michelle Calvert (Chair, Hit the slope for hope):** My name is Michelle Calvert. This is my sister, Sarah.

Thank you very much for the opportunity to share our experiences, and for considering our ideas. We both feel privileged and honoured to be here as a voice of the public sector with regard to the current study on the CDR.

**Ms. Sarah Calvert (Spokesperson, Hit the slope for hope):** Sunday, May 13, 2007, yesterday, marked the first Mother's Day we've spent without the presence of our mother, Gloria Calvert.

Mom died last summer on July 25, 2006. Several months later, I received a letter, dated October 26, from our member of Parliament, Patrick Brown, informing me that Tony Clement wanted Patrick to pass on to me information about Mom's next step in the drug process and about cancer. It began with an apology about the delay in responding.

In the next paragraph, he began by stating that cancer is a serious disease, which seemed a little redundant, as if we didn't already know this. At that time, this very delayed response seemed insensitive, inappropriate, and inept in every way. We therefore felt sad, frustrated, and then, obviously, angry. However, those powerful, yet not really positive or purposeful emotions eventually transformed themselves into something else, something that whispered to us to do something and take action. It was most certainly Mom's voice. She was always interested and active in local politics and believed in the benefits of living in a democratic society. It was then that Hit the Slope came to fruition.

This now annual fundraiser, held at Horseshoe Resort outside Barrie, Ontario, is to honour our mother and to help build the Simcoe-Muskoka Regional Cancer Centre at Barrie's Royal Victoria Hospital. It's a great hospital where, unfortunately, we spent a lot of our time.

Mom's voice also defused our anger and confusion when we received those letters and we heard her voice echo, "What's done is done." Although her life here is done, we'd like to offer just a few suggestions, based on our concrete experience, as to how we can avoid such situations in the future, particularly you honourable people who actually have tangible power and opportunity to make change.

We would like to address the effectiveness of the current CDR and give some of our insights on what we think about the addition of a new layer of bureaucracy, the lack of transparency, the lack of public input, and the lack of timely access to new drugs.

We'll begin with the last issue: lack of timely access to new drugs.

Mom was diagnosed with lung cancer in April 2005. I wrote numerous letters and had a visit with our MP, Patrick, and wrote two letters to the health minister, from whom I received no reply at all until Patrick became our liaison. Mom's prognosis was not great, and it was inferred that she had about six months to live. It took about six months to hear any sort of reply. In addition, the reply we got offered no real solution, and I was advised that my concern was a provincial issue and that I should contact the Minister of Health, which I had already attempted to do twice, six months prior to this. This is what I would call defer, defer, and it seemed to me to be a little bit of passing the buck, as they say.

When you're dealing with a life and death situation, time is of the essence, and there's no time for bureaucratic back and forth. We never know how long we have, but when it's something like cancer, we know it's not long. So I'm sure you can see why we would have been frustrated.

**Ms. Michelle Calvert:** Mom finally received the drug we had been searching and striving to obtain, based on the suggestions of Bryn Pressnail, Mom's amazing acting oncologist in Barrie. She began taking this drug in July 2006, 15 months after her diagnosis, and three weeks before her death. The drug, called Tarceva, did not have time to work. We believe that had she had access to the drug, her quality of life would have improved immensely, and she could still be alive. We do not say this with false optimism, as a family friend, a doctor who was also diagnosed with lung cancer, had the opportunity to participate in a study using Tarceva. He continued to live for almost a decade, and during this time he continued to hike and enjoy his life at his cottage with his friends and family.

You can surely see why the lack of timely access to the drugs is our main concern. In addition, we believe that drugs like Tarceva should be covered under OHIP if the patients meet the criteria and their lives are depending on it.

This drug we refer to is specifically for the treatment of non-smallcell lung cancer and advanced pancreatic cancer patients. This is used for those patients who aren't able to take chemotherapy or receive radiation or surgery, meaning the cancer is at a very progressive stage. Tarceva has the power to prolong a cancer patient's lifeline and quality of life. It is sometimes their only hope, and unfortunately that hope has a big price tag attached to it. The average person could never afford the drug.

According to Tarceva's website, Tarceva is the first and only oral treatment and inhibitor proven to significantly prolong survival rate in second-line lung cancer patients. However, the Canadian study shows that in Ontario the drug is only getting to the third-line cancer patients, according to Bryn Pressnail. This doesn't make much sense, to distribute this to a patient whose cancer has metastasized so much so that the drug won't work to its full potential.

According to the Cancer Advocacy Coalition, statistics from their 2007 report on current incidence and mortality show that the number of lung cancer cases, both men and women, is greater than the number of either prostate or breast cancer. Additionally, lung cancer remains the leading cause of cancer death for both men and women. On the whole, there is a staggering estimated 159,000 new cases of cancer, where 73,000 deaths from cancer will occur in Canada in 2007. With those statistics, we can be sure that if hasn't already affected all of us, it will. This could be your wife, this could be your brother, it could be your daughter.

• (1610)

**Ms. Sarah Calvert:** We will next address the issue of bureaucracy and lack of transparency.

Although my sister and I are both university educated, as a teacher and a business professional, we found the present amount of bureaucracy and the jargon and vernacular of forms and applications often really difficult to discern and pretty daunting. So imagine the numerous people—and as we know the number is pretty staggering —battling cancer who are less educated, have less money, and have limited access to information, due to not having Internet access or just having the misfortune of having a doctor who is not very good. And unfortunately, during our journey throughout cancer, we had to deal with a couple of those doctors. The majority of them were great, but there are always the few who aren't. These people are thus ostracized and are not even aware of the CDR.

In our hospital there were no pamphlets, and it was only because our oncologist recommended we look specifically into Tarceva personally by writing to the health minister and our MP that we pursued obtaining the drug for Mom. A major concern for most doctors, specifically overworked oncologists like Bryn Pressnail in Barrie, is that there is already too much bureaucracy. Dr. Pressnail is currently the head of oncology in Barrie, where there will soon be a regional cancer centre implemented. He is consumed and involved with the cancer centre and, furthermore, is inundated with patients from all over, with numbers rapidly rising on a daily basis.

According to him, he is also responsible for the requesting of certain drugs for his patients that are extremely effective yet are not covered, such as Tarceva and the like. When these requests are denied, which they often are, he must then write letters and appeals. There are simply not enough hours in a day for one man to perform all of these tasks. He's concerned that the amount of time wrapped up in bureaucratic matters is hindering his ability to care for all of his patients effectively. So basically, as his job scope is broadening, his cancer patients are suffering.

Based on the points that we've just made, I'm sure you'll be able to guess that we think there are some serious inherent flaws with the CDR and its effectiveness. As caregivers to our mother, we've already gone through the heartbreaking. yet common, would-haves, should-haves, and could-haves. Why didn't we just go to Ottawa? We should have done this and could have done that. But no good is going to come of the would-haves and should-haves, so instead, we are here before you now with hopes of not only honouring our mother's memory and her struggles, but also benefiting the future generation that will inevitably have the same struggles.

Thank you for hearing us.

The Chair: Thank you very much.

Now we'll move on to the question and answer part of the meeting.

We'll start with Ms. Brown. The floor is yours; you have 10 minutes.

Ms. Bonnie Brown (Oakville, Lib.): Thanks very much.

I'm a little mixed up by the story of the Calvert sisters. There seem to be many factors at play, as there are in every medical history.

Do you know the reason for the delay in your mother's having access to Tarceva? Was it a new drug that was being reviewed by Health Canada for approval? Was it approved by Health Canada but not yet approved by the CDR?

• (1615)

**Ms. Sarah Calvert:** I think it was the latter. Dr. Pressnail was saying it looked as though it might get passed. It looked as though he was just crossing his fingers, waiting.

**Ms. Bonnie Brown:** Do you have any evidence that the CDR was slow with it? It comes to the CDR after Health Canada approval; that's usually for a drug that is pretty new and where the manufacturer has applied. In other words, I don't know whether the length of time that Tarceva took to go through the process was normal for a new drug, or whether there was some undue delay and it was just your mother's bad luck to need it exactly when she did, before it was really approved.

**Ms. Michelle Calvert:** As far as I know, it's still not covered. That's as far as I know; I'll find out.

Ms. Bonnie Brown: Well, that's a different issue.

Ms. Michelle Calvert: I'll find that out.

**Ms. Bonnie Brown:** That's a different issue, coverage. Approval comes first. There are the three steps, the third of which is the provincial agreement to cover it.

Would your mother have been in a position to have it covered out of hospital?

Ms. Sarah Calvert: I'll answer that.

We're luckily in a situation where we could have afforded to.... We were going to pay for it, but It hadn't been approved yet, so it was a holdup—

**Ms. Bonnie Brown:** So it wasn't to do with listing for coverage; it was to do with the length of time—

**Ms. Sarah Calvert:** It was to do with accessibility. Dr. Pressnail just said it had been taking a really long time but that he had his fingers crossed. So I think it was like the waiting game.

**Ms. Bonnie Brown:** A very long time compared with what? Did he know how long it takes every new drug?

**Ms. Michelle Calvert:** He probably would. I'm not sure. We can get all that information and let you know, though.

**Ms. Bonnie Brown:** So we can ask about this when the CDR people come back?

Ms. Michelle Calvert: Certainly. We'd like to know it as well.

Ms. Bonnie Brown: Okay.

Now, my next question-

The Chair: The doctor has an answer.

**Dr. Andreas Laupacis:** Tarceva came before the CDR when I was the CEDAC chair, and to the best of my recollection, it was dealt with in the five months' time process, and to the best of my recollection it was recommended for funding under certain criteria.

I don't know whether those criteria were the ones your mom would have had, but certainly, to my knowledge, it wasn't delayed.

Is one allowed to make a comment?

I think the question raises one of the issues I talk about, which is the lack of integration within the whole system. I think for drugs that are truly advances, one would like to have CDR starting to review the drug at the same time as Health Canada is reviewing it, so that they don't have to wait all that time and then start all over again.

My understanding is that the CDR has started to have a few pilot tries at looking at the information that's provided to Health Canada. That can only happen, obviously, with the drug company's approval. That would be another example of the lack of integration, which does lead to a longer time than it probably should take.

**Ms. Bonnie Brown:** Thank you, Dr. Laupacis. We've had that suggestion from other witnesses as well. As you say, I think there are some pilot projects.

But I want essentially to let the Calvert sisters know that this wasn't a particularly slow thing for this drug, which it might have felt like from their end. It was the usual process, and Dr. Laupacis is here to witness to that. Your lack of access was more to do with the newness of the drug than anything else, not the CDR.

**Ms. Sarah Calvert:** Okay. I'm just wondering.... It is a family friend to whom we referred; he had access to the drug almost 10 years ago. Granted, it was a study, but it was effective for him.

**Ms. Bonnie Brown:** It was in clinical trials then. That's a totally different kettle of fish.

#### Ms. Sarah Calvert: Okay.

**Ms. Bonnie Brown:** Dr. Laupacis, I'm very interested in your statement that the main barrier to access for most people is the skyrocketing cost of drugs. You gave good examples from about 10 years ago rather than from today. I don't know whether you'd want to comment on this, but you will know that the big pharmaceutical companies claim that these huge costs are what it takes them to develop a new drug.

Do you think the costs of developing a new drug have accelerated by the same factor as the prices of new drugs today?

**Dr. Andreas Laupacis:** I honestly don't know how the industry spends its funds, in terms of the proportion that goes into advertising versus basic science research, etc. I think things are changing markedly with the emergence of biotech drugs, etc.

What I would say is that eight or nine years ago industry reported that it cost them \$300 million to produce one drug. Understandably, there are many failures along the way. Now that figure is up to \$800 million per new drug. I'm in no way disputing that those figures are correct; I'm just saying, when does that increase end? We were perhaps under the impression that the genetic revolution would make the discovery of drugs more efficient. It sure doesn't look like that's the case.

As for what goes into those increased costs, you should ask the pharmaceutical industry. I don't know.

#### • (1620)

**Ms. Bonnie Brown:** You also made a comment about the seven or so countries that guide the decision-making of the Patented Medicine Prices Review Board. Do you think those are the right countries, in the sense that they're all countries for which the export of pharmaceuticals is one of their industrial strengths? One has to

wonder about the prices they allow in their home country, knowing that the export of those drugs to other countries improves their balance of trade situation.

**Dr. Andreas Laupacis:** This isn't an area I'm an expert in, but I would make two comments.

First, as best as I understand it—and certainly I don't have any problem with those seven countries, although I can't rhyme them off to you—the legislation says the price in Canada can't be higher than the median price of those seven countries. So I guess my first question would be how the prices in those other countries are set. It seems to be what the market will bear, not much relation to what the benefits of the drug are.

Second, my understanding is that Canadian prices are compared to the list price. France, for example, enters into all sorts of volume price agreements. The list price might be the price they'll pay for the first 500,000 people for the drug and they'll pay a much lower price for the next 250,000, just for an example. We're comparing our price with the list price of those drugs for those countries when in fact the actual prices that are paid might be lower.

There are others who are much more expert in international drug pricing than I am.

**Ms. Bonnie Brown:** I thank you for pointing that out about the list price vis-à-vis the actual price a French patient might have to pay. This is what I mean about the countries that are part of that group. They have reasons for pricing things the way they price them.

I think we're going to have some very good questions, Mr. Chair, when we get to that stage in our study. We're focusing, for a couple of meetings, on price.

Thanks very much.

The Chair: Thank you.

Monsieur Malo.

# [Translation]

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

Thank you for being with us this afternoon, ladies and gentlemen.

Mr. Upshall, I want to check that I have fully grasped your comment. Is it your position that the people in the CDR who study the drugs are so-called experts because they are not familiar with each area of expertise, especially the area of mental illness? You made it clear that this is a specific area.

I would just like to know if, in your opinion, these groups of experts should be made up of people with expertise in each illness or medical specialty so that their evaluation of the drugs is of high quality.

#### [English]

#### Mr. Phil Upshall: Thank you.

My sense is that the expertise should be as broad as possible. I limit my comments to mental illnesses, but mental illnesses are so pervasive that I think the need for expertise is apparent to anyone, other than the people who appoint people to CEDAC.

I think the reality is that if they're going to advise appropriately, they must be experts in the field. As far as I'm concerned, they must have significant expertise. It exists in Canada, from the scientific level down to the community level, and it should be accessed. Also, I think expertise should be accessed as the drug moves through various approval phases.

# • (1625)

#### [Translation]

**Mr. Luc Malo:** At the moment, anywhere in the world, are there drugs that can improve the situation of people with mental illnesses or mood disorders, or studies that seem to show that certain drugs can?

#### [English]

**Mr. Phil Upshall:** We know that in a number of countries effective medications for mental illnesses are available, and they're certainly not available in Canada. We know that throughout Canada there's no consistent policy. Quebec, as you may know, is the leader in terms of making available medications for people with mental illnesses.

There's no real understanding that I can find among the decisionmakers that medications for people with mental illnesses are significantly different in the way in which they work compared to medications for cardiovascular, for instance. The broadest choice is not available to people in Canada, and it should be.

#### [Translation]

Mr. Luc Malo: That leads me to ask Dr. Laupacis a question.

Mr. Upshall seems to be saying that more drugs are approved and available in Quebec than in provinces that have to operate under the rules of the CDR.

Are you in a position to explain the difference?

#### [English]

**Dr. Andreas Laupacis:** I think Quebec has traditionally always had a more liberal view about the reimbursement of drugs. I've never sat on the Quebec drug reimbursement committee, so I can't really comment.

I guess I'd make three comments about this general issue. One is that there's no question that one needs expertise in a particular disorder. Certainly, the common drug reviews always obtain the input of one or two experts in a particular disorder. I can well remember conference calls around some drugs for psychiatric illnesses where we had two experts on a teleconference with the whole committee discussing the drug.

But at the same time, I think it's important to have people who have a broad view of health care and the use of these drugs in the system. I think Mr. Upshall indicated that there were 1.5 million people with mental illness in Canada. There are not enough psychiatrists to look after those 1.5 million people. They're largely looked after by family physicians, nurse practitioners, other health care workers.

I think one of the things that CEDAC is faced with is assessing what the likely cost-effectiveness of a drug is going to be and how it's going to be used in the real world, which is considerably different sometimes from the way the academic, hospital-focused—which is me, actually—researchers see the world.

Then the final point I would make is that there's an obvious benefit to rapid access to a drug if it turns out to be clearly beneficial and non-harmful. I think we've seen some examples...Vioxx, for example, where the drug was used, in retrospect, probably more widely than it should have been, and it probably caused a few heart attacks. There have been issues around some of the new antipsychotic drugs, about their causing an increased risk of stroke and heart attack.

I think we have to balance, as best we can, rapid and appropriate access to drugs and trying to get the best possible information we can to make those decisions.

#### [Translation]

Mr. Luc Malo: When ...

#### [English]

The Chair: Your time is up.

Mr. Luc Malo: My ten minutes are gone?

The Chair: No, your ten minutes aren't, but your five are.

Mr. Fletcher, you have five minutes.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): First, let me say to the Calvert sisters, I really appreciate what you had to say. I certainly can empathize that when you're injured or need help, you're not thinking about whether you're a provincial responsibility or a federal responsibility; you just want the help and you want it now.

Mr. Upshall, let me congratulate your organization on this booklet that you've handed out, *Mental Illness & Addiction in Canada*. It's very informative. However, due to the time, I'm going to have to focus my questions on the CMA.

In your presentation, you had a recommendation for a national formulary to harmonize the 18 different formularies. I wonder, given the reality of Canada and that much of what we're talking about falls within provincial jurisdiction, if the CMA has given any thought on how such a program could manifest itself.

Also, what would the CMA suggest to prevent a national formulary, if it's even possible, from going down to the lowest common denominator rather than the highest common denominator? And how would it be possible to change the coverage as new drugs came on? It seems as if it would be such a large monolith that it would be very difficult to change. At least now the provinces, if they want to exceed the CDR standards, have the ability to do so.

Those are my questions.

#### • (1630)

**Dr. John Haggie:** Well, in no particular order, the view of the Canadian Medical Association is that whatever drug review exists, it exists as an informative exercise based on outcomes, so it's evidencebased. The funding is a separate issue, which is a provincialterritorial responsibility, but the idea behind this is to produce a level of drugs that are generally accepted as being best in class, with some alternatives to allow for flexibility. It then becomes a separate issue as to how the provinces choose to fund those, and there are other options. You can't deal with the drug review simply in isolation, as just one fix, and we tried to allude to that in terms of the other elements we were talking about with rare drugs and catastrophic coverages. So I think you have to factor that into the mix.

How it's going to be funded is a separate issue in many respects. But we would see whatever drug review as being a lot bigger than it is at the moment, in terms of its staff and its ability to respond. We've heard from various witnesses, both today and on previous occasions, that the system is too slow and too cumbersome. That doesn't necessarily mean the system shouldn't be there; it means that perhaps it should be revised and altered in some way to make it more flexible and to make it work faster so that new drugs and first in class, which are difficult to deal with because there may not be anything with which to compare them, may need in the early stages some surrogate approach.

Ultimately what we're focused on is what happens at the sharp end with the patient. Does the patient get better with this drug in a more cost-effective, more humane way with the least side effects compared with existing treatments, or are the older treatments better?

The other thing about this, which I think people forget, is that rather than being an instructive arrangement, we as a profession would love to have access to these reviews and to this data, because by doing that and disseminating that, our physicians would be able to find the right drug for the right patient at the right time, which is what we're after.

The problem at the moment is that for most physicians in regular day-to-day practice, their main source of education on new pharmaceuticals is the lady or the gentleman from the drug company. Of course, they're not there to educate; they're there to sell. It's very difficult to get what we need, which is independent, arm's-length advice. Something like a review, funded at the federal level, would be untainted. It would be truly independent. It wouldn't have to deliver the funding, because that's a provincial responsibility. It would not be seen, by advocates for patients, as holding purse strings. Equally well, it would be at arm's length from pharmaceuticals, because it would not be open to the price deals that can be done on a provincial level.

So rather than throw out the baby with the bathwater, I think we need to change the bathwater, perhaps.

I hope that answers some of your questions. I realize I may have strayed a bit.

Mr. Steven Fletcher: Yes, no problem.

The Chair: Thank you very much. Your time has gone.

Now we'll move on to Ms. Priddy. The floor is yours, and you have five minutes.

## Ms. Penny Priddy (Surrey North, NDP): Thank you, Mr. Chair.

To Ms. Calvert and Ms. Calvert, your mom did well. She raised two great activists. That's terrific. She must be really proud of what you're doing, because not everybody can pick up and decide they're going to take on a cause. Congratulations. You're doing it for all kinds of other people who don't have the voice to do it.

I have a question for the CMA, if I might. I want to be sure I've understood your presentation correctly. I think the nationalprovincial-territorial ministers have said something similar, that there is a need for a national formulary, correct? But there is a need for some flexibility within that, because as soon as you have a list of anything, there will be an exception to that rule, so there needs to be some flexibility within that formulary.

In terms of who does that formulary, and I've heard you say that if it's done federally it would be "less tainted", I think was your phrase—I can't think of another one. But if it is done federally, do you think it is possible for the CDR to do that, with some revisions to CDR? I think you have been very careful; you've said that if it is the CDR to do that, then these are some things.... Do you think it's possible for the CDR to do that, with some changes?

• (1635)

**Dr. John Haggie:** I think the answer to that is that it depends. If you put in place an evaluation process, you will answer that question. And if CDR works, that's fine; if not, find out what's wrong with it and fix it.

**Ms. Penny Priddy:** My second question to you would be, have you noticed a change in the approval time? I'm going to ask the same question to Dr. Laupacis. From the physicians you work with, have you noticed a change in the approval time of drugs coming back from your physicians since the CDR was in place? Are people saying it's longer, it's shorter, it's way longer? We hear data all the time, that it's six days longer than it used to be, and so on. And other people say no, it's way longer than it used to be.

So I'm wondering if you've had any feedback from all of your counterparts across the country about whether indeed it's taking what they perceive as a longer period of time.

**Dr. John Haggie:** I will just speak on a very local basis, and perhaps I'll let Briane Scharfstein answer the more national question. On a local basis, our problem is on a provincial level, with trying to get what we call special authorizations in the province.

Ms. Penny Priddy: Yes, I'm familiar with that.

**Dr. John Haggie:** And the difficulty there is that there's a feeling amongst physicians that this is an economic rationing exercise rather than necessarily one that's focused on outcomes, because the data just don't seem to be there to support the outcome issue.

But perhaps Briane has a better national perspective.

**Dr. Briane Scharfstein (Associate Secretary General, Canadian Medical Association):** Just quickly, I think Dr. Laupacis made the point that for the front-line practitioners, they don't understand the process, nor do they wish to. What they understand is that drugs become available in a variety of ways, they become aware of it, and then there's a long time before they're able to write a script that's covered. And whether it's tied up at CDR or the lack of integration with other processes—the original approval process, other testing, monitoring, etc.—they're not aware. So I don't know that for the average practising physician it's necessarily that specific process, but the entire process seems somewhat complex and difficult to understand.

I would like to make a quick comment as well on the doability of a national formulary. It's interesting, if you think of it, that we have the equivalent of a national formulary for physician care. We seem to be able to manage that in the context that all physician services are covered under similar terms and conditions, and in fact the cost of physician services in Canada is actually less than the cost of pharmaceuticals now. So I think if there's a will, there's certainly a way, and we've shown that.

I would make another supplement to John's answer to the question of supporting a national formulary. The degree to which the provinces have variability in their formularies, I think, does compromise its integrity, at least in the eyes of the physicians. If there's great variability in what's covered, you begin to question the science that's used to make those decisions. And we're looking for a scenario where in fact the CDR process would be seen as infallible, would be the gold standard. You would trust it implicitly as a way to influence prescribing behaviour, and we'd like to see that. When it becomes used as a tool to ration or to manage the drug budget, our view is that it does compromise, then, its integrity to some extent, and it would be nice if it could be avoided so that you could trust the science, I think.

Ms. Penny Priddy: Thank you.

Dr. Laupacis, you made a comment-

**The Chair:** Your time is gone, I'm sorry. But it was a very good try.

Ms. Penny Priddy: But maybe it will come back-

The Chair: Yes, possibly.

**Ms. Penny Priddy:** —about the five months and what we hear is 735 days. But surely you'll speak to that later.

The Chair: Yes, I'm sure we will.

Thank you, Ms. Priddy.

We'll now move on to Ms. Davidson.

• (1640)

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

Thanks to each of the presenters who have been here. My special thanks to Michelle and Sarah for having the fortitude to come and tell us their story and to advocate for others, to help them.

My first question would be to Mr. Upshall. You talked about a lack of expertise in the CDR when you're looking at drugs that are

needed for your particular area. Are there drugs available in other countries that are not available in Canada because of this? Are some of the drugs that are being reviewed basically by CDR and rejected being picked up by the provinces? Are they being approved at the provincial level? Or are we as Canadians just not having the use of the drugs that other countries are having?

**Mr. Phil Upshall:** In many cases, we don't have access to the drugs that our community has in other countries. I can't tell you why that is, other than that it's probably a combination of the CDR process and the lack of will in the provincial formularies to fund the availability of these medications.

The other issue is timeliness. It does take longer in Canada to have these drugs reviewed and approved than it does elsewhere.

I would like to point out to you, as well, that our community is very globally integrated. People in Canada who have mental illnesses are in communication with other people in other countries who have mental illnesses through other advocacy groups and on the net. Very frequently—and I think the medical profession will agree with this—patients ask the doctor if they can be prescribed this medication.

Particularly when it comes to medications for people with mental illnesses, they are not as precise or targeted as other medications are. It's absolutely essential to have a menu of medications available as early as possible. I think, again, we all know that the earlier the intervention in a mental illness situation, the less harm can be done, the more likely recovery is, and the more likely the return to being good taxpaying citizens.

#### Mrs. Patricia Davidson: Thank you.

To the CMA, one of the points you made was that there should be a process for appealing the review's decisions. What would that process look like?

**Dr. John Haggie:** I have no preconceived ideas. I think you would need to involve the individuals concerned and perhaps make sure that whatever.... The prime thing is that it has to be transparent. It has to be visible to all.

I think these appeals have to be along the same lines as the drugs and the mechanisms that CDR, or whatever it's called, will use. So it has to be outcome-based, it has to be based on some scientific evidence, and it has to be open for everyone to see. I think one of the problems with the whole process is that it's the black box; you just don't know what's gone on inside.

Other than that, as long as you adhere to the principles we've laid out, I don't think I would prescribe any form. I think it will follow the function that's laid out.

**The Chair:** Dr. Laupacis, are you interested in answering any of that, on an appeal process, since you are the chair?

**Dr. Andreas Laupacis:** There is an appeal process now. I've observed that every time, with maybe one or two exceptions, we recommended that a drug not be funded, it was appealed, and we reviewed that appeal.

I would agree that the appeal should be more transparent and open, but that would mean the pharmaceutical companies would have to agree to allow all the information they submit to the CDR, which they frequently ask us to keep confidential, be open and public. I would be very supportive of that.

**The Chair:** On that, for the committee, the appeal process now is appealing to the same body that approved the decision the first time?

Dr. Andreas Laupacis: Exactly, yes.

**The Chair:** If you were to recommend an appeal process to the committee that would be appealing to another group, who would that be, and how would that look?

**Dr. Andreas Laupacis:** That's an interesting question. I guess the question is what one is appealing. Is one appealing that the CDR got the science wrong? The CMA reps have almost been implying that the science is going to be clear-cut, and it ain't. Sometimes it's really clear-cut that a drug is fantastically effective and safe. Other times it's clear-cut that it's not. And a whole bunch of times we don't know. We don't know how this drug is going to work in the real world, because Health Canada only needs six months of data and this antidepressant is used for six years, etc. I want to make that point, that science isn't going to solve all this.

There's a values process, which is why I personally pushed very hard to add public members to the CEDAC committee. I thought it was really important to have. We can argue whether two may not be enough and whatever.

So there's the science part and there's a values part. Is this drug really good enough value for money to justify putting on the formulary, given the other things we could spend health care dollars on?

I would agree that in general it would be reasonable to appeal to another body, but you would want to appeal to another body that's using the same principles as CEDAC uses. My understanding is that Hungary does that; they have a second group that hears appeals that is similarly constituted to their first group.

• (1645)

The Chair: Thank you very much.

Now we'll move on to Madame Beaumier.

Ms. Colleen Beaumier (Brampton West, Lib.): Thank you.

I think the number one concern we hear from most people is that CDR does not approve drugs fast enough. I notice that in recommendation number one, Mr. Upshall is saying that the drugs for mental health don't have the same priority as those for, say, cancer and physical health. I think we can all acknowledge that many times mental health is just as deadly as cancer or diabetes or any of these other terminal illnesses.

Are we short-staffed? Is that why there are backlogs? Should there be different decisions, whereby drugs for mental health are perhaps measured in a different kind of way for approval? I understand that you need families and communities involved, because when someone is suffering from mental health it affects not only the patient; it affects the family and oftentimes the entire community. Should we have different divisions? I think we all recognize that we have to get these things processed faster, and with the advances of science, drugs are coming on, new ones are coming quicker and quicker, and they're piling up.

So I'm just wondering what the solution for this is, because everyone wants their area to be prioritized.

**Dr. Andreas Laupacis:** First of all, I fully agree. I work at St. Michael's Hospital, which is an inner-city hospital in Toronto, and there are a lot of homeless folks around St. Mike's, many of whom have mental illnesses. My dad died of dementia, so I'm fully aware of the devastating effects of mental illness. I guess my comment about the cancer review that's been set up—the name of which I've forgotten—is that I don't think, in terms of the principles of how we make decisions about which drugs should be funded, that we should be differentiating between trying to treat cancer and mental health and then arthritis. Clearly some of these disorders kill people, and others affect their quality of life. We have to try to make sure we are treating all of these as importantly and equally as we can.

I don't have all the information on the CEDAC drugs before me that we reviewed, but I can remember a couple of mental health drugs, and we processed those exactly as we did the other drugs. So I don't think, at least from a CDR perspective, it's a matter of somehow speeding up the mental health drugs process compared to that for others. If there's a sense that the whole system is too slow, then we should talk about that, but I certainly don't think there's any discrimination, at least from where I sit, against drugs for mental health.

Ms. Colleen Beaumier: Thank you.

Mr. Upshall.

Mr. Phil Upshall: I just have a couple of quick comments.

With regard to terminality of mental illnesses, Mood Disorders Canada has a website that counts suicides. To date, since the turn of the century, 30,000 Canadians have committed suicide, all of whom, or a vast majority of whom, have been impacted by serious and difficult mental illness. So it does kill. Mental illnesses do kill.

#### • (1650)

**Ms. Colleen Beaumier:** By the turn of the century, do you mean the year 2000?

**Mr. Phil Upshall:** Yes. Some 4,000 Canadians a year kill themselves, and we don't care. That's roughly 150—I forget; I did the calculation last week—Boeing 747s crashing, and that's just suicides. Our jails are full of people with mental illnesses. Far more people are in jails than are in hospitals or on the street with mental illnesses. As the Honourable Justice Ted Ormiston will tell you, when he was in charge of the Canadian mental health court, he was the biggest warehouser of people with mental illnesses.

When I talk about access to medications, I mean access to medications for people with disabling mental illnesses. Medications are very frequently our canes, our wheelchairs, our curb cuts. So when we talk about cost of medications, I talk about the cost to society of not making the medications available, and that goes far beyond health care costs. I understand restricting the calculation of costs to health care, but even in the costs of health care, the medications for people with mental illnesses are frequently at the low end of the cost scale, and certainly nowhere near where immunosuppressant drugs are or where cancer drugs are. The bang for the buck for readily available mental illness medication is quite great.

I think maybe in the new CDR you might want to consider a fasttrack process for medications that have been approved and used around the world, that are safe and facilitate recovery quickly. I don't know. There are some scientific issues, and others, but there has to be a way to get our medications to us more quickly.

The Chair: Thank you.

Mr. Brown.

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

I have a few questions today. The first is a general question for whoever is able to answer it.

The thing I struggle with, and an argument I haven't seen presented yet, is how the CDR doesn't contain overlap. We've heard a lot of rationalizations throughout these hearings about how there is an overlap. If we bring up a particular case, there's always a reason it was delayed. But if you look at the structure of this, the very base of it, we have two different decision bodies. We have the provincial aspect of it and we have the national aspect with the CDR.

How is that not inherently an overlap? How is that not inherently two groups doing the exact same job?

It gives you the impression that there are certainly going to be some delays. I hear many stories like the moving story we've heard from the Calverts. It's very sad that we have doctors within our community—not just in my riding but, I'm sure, around the country —who are saying, cross your fingers, hopefully the CDR will approve this.

I want to know what the root of the problem is. We shouldn't be crossing our fingers. If the problem is not overlap, if the problem is not two groups doing two things and making it longer, what is the problem? That's something I'd like to probe into. Is the problem that it takes so long because there's a lack of resources, a lack of staff? What is it? I've never heard that brought up.

One thing I did hear brought up by proponents of the CDR was that it helped bring national standards, helped bring uniformity to the process and more commonality amongst the provinces. They said that was one of the reasons it was set up a few years ago. But if you look at where we are today, we are seeing cancer drugs rejected by the CDR and approved in certain provinces. We saw an example of that in British Columbia. If the point of it was to get a set standard, that hasn't been achieved.

I know I've said a few things, but feel free to comment.

**Dr. Briane Scharfstein:** One observation, perhaps, is that we would have seen the processes as being quite distinct. At the national level you would have a process that would simply provide the objective information—the best evidence, using recognized and acknowledged experts up front, so that you wouldn't argue later about having the right expert—transparently. It would basically provide objective information—this is drug A, and it does X, has X benefit, and X cost—and perhaps give some sense of how much more or less that would be than other therapies that may also do the same thing.

Each jurisdiction that funds, then taking that objective information and hopefully not repeating or challenging that exercise, or if it does, doing it once, transparently, would then decide whether they wanted to pay for it or not, but not once again reinvent the process and say they've come to a different conclusion as to what this drug actually costs or what its benefit is.

So we would see them as quite distinct and not necessarily duplicating. If they are duplicating, then maybe there should be some reconsideration. The extent to which the national process, so to speak, gets into the business of deciding whether it should be covered or not is probably duplicating the provincial job and ought not to. It ought to be more objective.

• (1655)

**Mr. Phil Upshall:** The cynic in me tells me the reason there's overlap—it's been created by some very intelligent deputy ministers and others—is to save initial money in the provincial health care budgets. The longer you can delay an approval, the less likely you are to have to pay for the drug. That's a cynical approach. It may well be that I'm wrong in my cynicism.

The other comment I have is that Health Canada and all the provinces have what's called a patient-centred approach. Everyone talks about the patient-centred approach. The patient ain't at the centre of anything I've seen in this process. I think it's about time the patient got to the centre as expert, as adviser, and as the person who says I want or need this drug.

I think you have to go back to the bureaucrats and ask them how many bureaucracies they have to create in order to make a drug available.

I agree, there needs to be one national organization, but I think it has to be able to take some recognition of what's gone on in other major countries when they've processed the medications. We need to have deep investigation, but I don't think we have to reinvestigate. I think that adds significant cost to the pharmaceutical companies, and significant delays.

Those are my comments, for what they're worth.

The Chair: Thank you very much. Your time is gone.

We have one more questioner. This part of the meeting is actually supposed to stop at 5 o'clock, so we'll allow Ms. Kadis a few minutes to ask her questions.

Mrs. Susan Kadis (Thornhill, Lib.): I appreciate that, Mr. Chair, and all the presentations.

I'm particularly interested in what I guess is a bit of a running theme, and that is the issue of whether our investment in our current research in potential breakthrough drugs—new drugs for new and sometimes rare diseases, as well, and others—is actually benefiting Canadians. In other words, in terms of the disconnect that I'm hearing or perceiving from some of our witnesses, previously and today, between the drugs that are recommended for approval by the CDR and the people accessing those drugs, and the money that's being put into the investment and the research to ensure that we have these new, innovative drugs available, do you believe that there is a disconnect? That's something that I am picking up.

**Dr. Briane Scharfstein:** I'm not quite sure I get your question, in terms of what the disconnect is that you're perceiving.

**Mrs. Susan Kadis:** We're investing so much in research in Canada. We have for the last several years. The issue is, is that being factored in enough? Are Canadians benefiting from that? Or is it getting stonewalled when it hits the recommendation level, such as at the CDR?

Mr. Phil Upshall: Perhaps I could just make a very quick comment.

Canadians fund \$700 million, \$800 million, \$900 million of research through CIHR. Very, very little of it goes to clinical trials, very little of it. Most of it is basic, although we're trying to move them forward. The vast majority of clinical trials are undertaken by pharmaceutical companies outside of the federally funded research activities. They're solely oriented to the marketplace.

To my knowledge, pharmaceutical companies are going to work on drugs that are going to be available and be demanded. A number of disease groups that I'm aware of don't have the advantage of the kind of research that would be available to them if we had a level playing field in research.

I would urge you to ask Dr. Bernstein to come and provide you with the advice of our research community as to what can be done— Dr. Bernstein is the head of the CIHR, an institute I'm used to—and Dr. Rémi Quirion, who could also provide you with some excellent advice.

The Chair: He has been to committee so many times, we call him Alan.

## • (1700)

**Dr. John Haggie:** I think you have to bear in mind the comments of Mr. Upshall about research and pharmaceuticals. We had some data presented to the CMA by an expert in genomics that suggested that the biological companies had three main areas of interest in their research programs that they were expending a vast amount of money on. One was hypertension, the treatment of high blood pressure. The other two were male pattern baldness and obesity. You can make of that what you want, but I think it's difficult to know sometimes what the results of pharmaceutical company research really are in terms of the amount of value they get for the money that they expend, because a lot of that data is proprietary and never sees the light of day.

I'm not sure that I can answer your question. I'm not sure anybody but the pharmaceutical company could answer that. **The Chair:** Our time has gone. I really hesitate.... You're okay? Good. He wanted to talk me into going another round, and once we get into that, we're in serious trouble.

We'll call this part of the meeting over.

We want to thank you very much for coming. Your presentations to the committee will be valuable as we sit down to draft up our report. Thank you very much for coming and sharing with us.

With that, we'll call this part of the meeting over. Then we will clear the room to a degree, whoever wants to. It's still public, so don't feel you have to leave at this point.

Then we'll deal with a notice of motion that has been presented by Ms. Brown.

Thank you very much. We'll pause for two or three minutes.

• (1700) (Pause) \_\_\_\_\_

• (1705)

The Chair: I call the meeting back to order. I ask members to take their seats and we will move on.

We'll start with Ms. Brown's notice of motion. She presented a notice of motion and we will ask her if she is prepared to move that motion.

Ms. Bonnie Brown: Yes, I am, Mr. Chair. I move it.

I'd like to add something to it, if I may.

The Chair: Go ahead.

**Ms. Bonnie Brown:** With the indulgence of the committee, I handed this in to the clerk at the last meeting and I introduced it verbally to you, but I realize, now that I see it, that I forgot about the Canadian Food Inspection Agency. I think I mentioned it verbally, but forgot to write it into the motion.

It seems to me there's a fair bit of media coverage right now about a number of items having to do with the health of Canadians. To run through them quickly, the Canadian Food Inspection Agency is the body that would be responsible for keeping the tainted wheat gluten out of the human food supply. Maybe they're doing it well, but I don't know that, and as a member of the health committee, I would like to know that.

There are a couple of other issues around food under question today in the media. I think one of them had to do with seafood or something. But before the meeting, we could get a couple of questions ready for them.

Concerning the Pest Management Regulatory Agency, those of you who were in the House for question period today heard me talking about one pesticide, in any case, for which the standards are much lower in the States and it looks as if we're adopting their standards. So we need to hear from those people what they're doing and why they are doing it. I have heard that the Hazardous Materials Information Review Commission, which is another agency at arm's length from the government that protects Canadians' health.... I would like to know if they're changing any of their regulations, because I think we were simply lucky we uncovered this, the reduction in standards that seem to have been suggested under the Quarantine Act in order to harmonize with the American standards, and I'd like to know about these other agencies.

**The Chair:** That's a different issue, I believe. Hazardous materials are not food, right?

**Ms. Bonnie Brown:** No, there is food, there are pesticides, and there are hazardous materials, all of which have an impact on health and all of which belong to arm's-length agencies. We've never had them in, but they're in the news.

The Chair: Patrick, then we'll go to Mr. Fletcher. Go ahead.

Mr. Patrick Brown: Thank you, Mr. Chairman.

I had a few amendments I wanted to make, and one of them was relating to the Canadian Food Inspection Agency, so I'm glad you raised that. I was going to suggest that it would be more appropriate to have the Canadian Food Inspection Agency than the Hazardous Materials Information Review Commission in order to actually get at what I think you're hoping to achieve with this motion.

That was my first suggestion, that the amendment replace "Hazardous Materials Information Review Commission" with "Canadian Food Inspection Agency".

The second amendment would be to replace "any regulatory changes" with "regulatory changes pertaining to the harmonization with the United States under NAFTA". And this would be helpful in restricting the scope of the motion to focus on what I think we're all hoping to see here. And given the media attention to this, I think if we could focus on that, it would make us more productive.

The last thing is to replace "a special meeting" with "before May 30", because I think that would be a bit more specific in dates. At the same time, the reason I'm suggesting "on May 30" instead of "a special meeting" is that we all have very busy schedules. I know many of us are on numerous committees, and if we're to have an additional meeting, I think it would put an onus on us that we may not need.

**The Chair:** Let me help with this, and maybe the mover will see these as friendly amendments.

On the first one, the CFIA, she's already agreed to. That's fine.

As for the special meeting, I have said we could do it on June 6, and schedule June 6. If you want it earlier than that, we could do it on May 30, but that would mean moving the CDR final report back until June 6. So it's going to be tight, potentially, depending on when we rise for the summer.

• (1710)

**Ms. Bonnie Brown:** Don't we have something on the Monday? That isn't June 6, it's June 4.

The Chair: Yes, we have Bill C-42, and the Quarantine Act as well on June 4.

I'm fine with that, but it's so the committee understands where we would be going with this.

Ms. Bonnie Brown: We might need an extra meeting.

**The Chair:** To not have a special meeting, I think we could put it in here.

**Ms. Bonnie Brown:** Let's have it on May 30 then, and then we might have to have a special meeting for the report.

The Chair: Fair enough. So then we've eliminated the special meeting on it.

Ms. Bonnie Brown: That's fine.

The Chair: The other one was the-

**Mr. Patrick Brown:** [*Inaudible—Editor*]...regulatory changes pertaining to harmonization with the United States under NAFTA.

The Chair: Are you okay with that?

**Ms. Bonnie Brown:** I agree that this is essentially the purpose, and we know that. But if we put that, they're liable to say that we're making regulatory changes but that they have nothing to do with harmonization and therefore they won't tell us anything. I want to know about any regulatory changes, and we'll decide if it's to harmonize.

The Chair: Yes, but isn't the intent to harmonize with NAFTA?

**Ms. Bonnie Brown:** It is not with NAFTA; it is with the security and prosperity partnership.

The Chair: So do you see it as a friendly amendment, or not?

**Ms. Bonnie Brown:** No, I don't. I see it as restricting it and giving the bureaucrats or the officials an out so they can go around their answers, whereas if we ask for regulatory—

**The Chair:** Okay, that's all I need to know. You see two of the items as friendly and the other one as not friendly.

So there we have the situation. So actually, the amendment would only be one amendment, which would be the one on NAFTA.

**Ms. Bonnie Brown:** I agreed to take out "Hazardous Materials Information Review Commission". I agreed to add "Canadian Food Inspection Agency".

The Chair: All right, so we would be adding CFIA.

So the amendment, Mr. Brown....

Are you all right with just adding that?

Mr. Patrick Brown: That's fine. I think most of this we've been able to accommodate.

The Chair: Fair enough.

So we have, then, what I would see as an amendment just on the regulatory changes.

Go ahead, Mr. Fletcher.

Mr. Steven Fletcher: Actually, I just wanted-

The Chair: We'll speak to the amendment now, I would imagine.

**Mr. Steven Fletcher:** Oh, we're speaking to the amendment. I was going to speak in favour of the motion as amended.

I think the intent of the amendment is just to focus on what I think has been coming out in the media, which is what your intent is. Now, there's nothing that prevents us from revisiting this again afterwards if you don't get satisfaction. I think the amendment would be helpful just to help us pinpoint which officials you would like to deal with.

We can bring the officials in to deal within that scope, but if you want to deal with everything, I'm sure the officials would be able to talk to that as well. I'm just concerned that we'd have to bring in too many officials. So that's fine.

Ms. Bonnie Brown: Could I ask a question to clarify?

**The Chair:** Yes, you can ask me, and then I'll have him answer. How's that?

Ms. Bonnie Brown: Okay, Mr. Chair.

The parliamentary secretary has said something interesting. If the parliamentary secretary knows that in each of these three agencies there is a person assigned to harmonization with the Americans, and he's willing to bring those three people in, that's fine. There certainly was a person with the Quarantine Act. There was the one fellow.

Mr. Steven Fletcher: Can I answer that, Mr. Chair?

The Chair: Yes.

**Mr. Steven Fletcher:** I think I can say that we'd bring in the people who would be able to address the concerns I think they're raising through the media reports. There are a gazillion officials working on regulations.

**The Chair:** That's the offer. Everybody has heard it here. I'm sure they're going to address the concerns.

Okay, are we good to go?

Pat.

**Mrs. Patricia Davidson:** Yes, I just need a point of clarification. I'm really not sure what the amendment is now. I'm a little confused about what's left in after Mr. Brown's amendment and what was accepted.

• (1715)

**The Chair:** I see that two of them were friendly, and the last one was that the regulatory changes be moved to.... I don't know. What was it?

**Mr. Patrick Brown:** Mr. Chairman, I think the gist of my concern was met. So we can take off the floor the final amendment.

**The Chair:** Okay, so we'd just leave it the way it is. Fair enough. So actually, then, we don't have an amendment. It was just seen as a friendly suggestion. So the amendment is off.

We have the motion. We've just debated it.

We've added the date, "on May 30", and we've added the food agency, "Canadian Food Inspection Agency".

Mr. Steven Fletcher: Could I say something, Mr. Chair?

We'll make sure that the officials who come in are experts, or can at least address the concerns based on what has come out in the media, just because there could be a lot of additional people, otherwise.

The Chair: Okay, fair enough.

(Motion agreed to [See Minutes of Proceedings])

**The Chair:** Boy, we get a lot of things done when we get along. Isn't it amazing?

We'd like to move in camera now. We're going to take a 30-second pause, and then we will move in camera.

[Proceedings continue in camera]

Published under the authority of the Speaker of the House of Commons

Publié en conformité de l'autorité du Président de la Chambre des communes

Also available on the Parliament of Canada Web Site at the following address: Aussi disponible sur le site Web du Parlement du Canada à l'adresse suivante : http://www.parl.gc.ca

The Speaker of the House hereby grants permission to reproduce this document, in whole or in part, for use in schools and for other purposes such as private study, research, criticism, review or newspaper summary. Any commercial or other use or reproduction of this publication requires the express prior written authorization of the Speaker of the House of Commons.

Le Président de la Chambre des communes accorde, par la présente, l'autorisation de reproduire la totalité ou une partie de ce document à des fins éducatives et à des fins d'étude privée, de recherche, de critique, de compte rendu ou en vue d'en préparer un résumé de journal. Toute reproduction de ce document à des fins commerciales ou autres nécessite l'obtention au préalable d'une autorisation écrite du Président.