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Chair

Mr. Rob Merrifield

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● (1535)

[*English*]

The Chair (Mr. Rob Merrifield (Yellowhead, CPC)): I'd like to call the meeting to order pursuant to Standing Order 108(2), the study on prescription drugs, the common drug review. This is actually our fifth meeting on the common drug review.

I'd like to welcome our witnesses today. We have a range of them. We have, first of all, from the Fraser Institute, Brett Skinner. We'll allow you to start with your presentation. We'll start with yours first, but I'll just introduce who else we have here.

We have the Canadian Diabetes Association and the Canadian Organization for Rare Disorders. We'll introduce those individuals as we yield the floor to them.

With that, we'll ask Mr. Skinner if he would start with his presentation. We're looking forward to it.

Mr. Brett Skinner (Director, Pharmaceutical and Insurance Policy Research, The Fraser Institute): I'd like to thank the chair and members of the committee, and the clerk of the committee for facilitating my appearance here today.

To be brief, I'll just jump right into my comments. I have circulated an outline of what I'd like to present today.

The three main points that I'd like to address are to provide, first, some estimates, based on some of my own—

The Chair: This information was provided in English, and so we don't have it because it has to be translated. I see everyone is looking through their papers, so I will just mention that.

Mr. Brett Skinner: I apologize. The date of my appearance was changed and I only had last night to deliver the information electronically.

I would like to present some evidence from a report I recently published that attempts to measure the number of reimbursement approvals by the provinces and compares that to the number of positive CDR recommendations issued. That same report attempted to measure the total wait times to access new medicines for those who are dependent on provincial drug plans. And I'd like to discuss some reasons that I belive the CDR process itself is really not necessary.

To begin, a recent report that I published compared the number of provincial reimbursement approvals versus CDR recommendations. What was found was that CDR recommended for reimbursement slightly less than half of the pharmaceuticals and only about 31% of the biological drugs that it reviewed during 2004 and 2005. This is based on data supplied by Brogan Inc., a database that summarizes much of what is available from Health Canada.

Even though the CDR approved a small number of drugs that it reviewed, the provinces themselves approved far fewer. In fact, on average, less than 20% of the new drugs that were reviewed by the CDR were accepted for reimbursement approval by the participating provinces. Interestingly, Quebec approved more new pharmaceuticals for reimbursement than the CDR itself. Quebec is not part of the CDR process, as you all know.

We also observed a large variation between the provinces in terms of reimbursement decisions. This suggested that cost factors, not scientific assessments of value, were driving reimbursement decisions. If science were the basis of this, it would be objective and they all would come to a similar standard. By separating the analysis for biological medicines versus pharmaceutical medicines, we also noted that far fewer biologicals were being approved for reimbursement relative to pharmaceuticals.

In terms of the wait time, including the delay for Health Canada approval on safety and effectiveness, and we also broke it down in terms of the CDR and provincial reimbursement time, we measured a total wait of 930 days, on average, across all drug submission types. This covered both biological and pharmaceutical medicines together. That was a total of two years and seven months, on average. Those people who are dependent on public drug programs wait up to two years and seven months to access a new drug.

We broke that down a little further into segments that measured the Health Canada delay for biologicals, with 633 days on average. The CDR added an additional 186 days, and provincial reimbursement across the provinces, on average, added an additional 187 days. That breakdown analysis did not include Quebec. Similarly for pharmaceuticals, Health Canada added 397 days to the wait; CDR added 257 days to the wait; and the provinces themselves, on average, added 201 days to the wait. For biologicals, we have two years and ten months that people were waiting for access to new biological medicines, and it was two years and five months on average for people to wait for access to new pharmaceuticals.

For a number of reasons, I believe the CDR is not necessary.

First, drug expenditures are not making public health insurance financially unsustainable. There is a misguided war against medicines going on in Canada. I publish research on an annual basis that measures the growth in public health expenditures in the provinces versus their total revenues from all sources, including federal transfers. That analysis shows that public health expenditures in every province are growing much faster than the ability of the provinces to pay for them. The blame for this, over time, has been shifted from doctors to hospitals, and now to drugs. The components of our health spending are being blamed for the unsustainable growth in public health expenditures. I believe this is misguided.

● (1540)

In the case of drugs, in particular patented medicines or new drugs receive most of the blame. But again, this is misguided. Patented medicines made up only 6.8% of public health expenditures in the most recent year, 2006, and even less in past years.It's simply impossible on a statistical level for patented medicines to make a major contribution to the unsustainable growth rate in public health expenditures overall. Therefore, cost containment measures of the nature that we see with the CDR are really unnecessary.

In fact, over 31 years, there is no statistical relationship between the rising percentage of public health expenditures going to drugs and changes in the overall growth rate of public health spending in Canada. The two are simply not linked. Drugs have increased as a percentage of overall public health spending, but it has not affected the growth rate.

Drug utilization is up, and this accounts for the rising share of expenditures going toward drugs. But as I mentioned, this has not had an impact on overall expenditure growth rates, because medicines are simply a cost-saving and cost-efficient substitute for other kinds of health technologies and treatments.

In fact, I decided to hypothetically eliminate spending on drugs in this analysis. Even if we spent zero on drugs, both patented and non-patented drugs, how would the other components of health spending grow? What would be the rates of growth? I found that all other components of health spending are growing at unsustainable rates, while accounting for more than 90% of public health spending. Therefore, the singular focus on drugs as a cost problem in health care is really misguided.

In fact, if public health insurance were designed differently for either our individual drug plans or public health insurance in general, there would be no need for a CDR.

Alternatively, we could introduce or should introduce deductibles, because insurance should only cover catastrophic expenses and not affordable expenses. Most drug expenditures are in fact affordable. According to Statistics Canada data, on average, most people spend less on pharmaceuticals every year than on things like alcohol, tobacco, and games of chance.

We could also introduce flat percentage co-payments. There should be a price at the point of consumption for health care goods and services, not only for drugs but for other health services.

We should have comprehensive coverage, including drugs, so there is an equal application of deductibles and co-payments to all types of medical treatments to encourage efficient substitution among competing health care options. Because drug plans only cover about one-third of the population and private plans or cash out-of-pocket payments cover the rest, the effective price at the point of service for drugs is much higher than for those things drugs might substitute for that are under the medicare package.

It does not mean I'm an advocate of expanding the medicare umbrella to include drugs. I think there are international examples of systems that introduced private insurance that is comprehensively inclusive of drugs that are more sustainable, better able to provide value for money, and preserve consumer choice.

Last, I would like to point out that even advocates and representatives of the CDR have stated that the real rationale for the CDR is to remove the element of inter-jurisdictional policy competition among provinces in terms of what they list for coverage under their drug plans. I believe this reduces accountability for rational decisions. It's part of the strength of our democracy and federalism in Canada to have policy competition among jurisdictions.

Unfortunately, the people impacted on by policies such as the CDR do not represent a lot of votes. About 4% or less of the population face catastrophic expenditures for health care in any given year. These people simply represent too few votes to have a voice in the absence of groups like the Diabetes Association, for instance, who are here today.

That is the sum of the details of my presentation. I'd be happy to accept your questions.

● (1545)

The Chair: Thank you very much.

We'll now move on to the Canadian Diabetes Association. We have Michael Howlett. I see that we have Karen Philp, as well. I don't know who's presenting.

Michael, go ahead.

Mr. Michael Howlett (President and Chief Executive Officer, Canadian Diabetes Association): Thank you, Mr. Chairman.

First of all, thank you for inviting us here today. We appreciate it. I would also like to take the opportunity to introduce Karen Philp, our vice-president of public policy.

The Canadian Diabetes Association asks for your assistance. Today, the common drug review isn't working for Canadians with diabetes. We believe that with your support, we can make it work better or all Canadians, and we offer you our recommendations for your consideration during your critical study of prescription drugs.

Why is getting the CDR right important to Canadians with diabetes? First of all, there are more than two million people living with diabetes who need a mix of anywhere from five to eight prescription drugs in order to manage their diabetes effectively and to avoid heart attacks, stroke, kidney failure, and blindness. Being able to get the drugs prescribed by their doctors is the single biggest challenge identified by Canadians with diabetes in our survey undertaken for our *Diabetes Report 2005*, which I believe you all have.

Diabetes, as you know, is a progressive disease, and the longer you live with it, the harder it is for you to manage it. Canadians with type 1 diabetes need insulin daily or they die. Canadians with type 2 diabetes are often initially prescribed lifestyle changes before their doctors recommend oral medications and/or insulin as well as drugs for the prevention of complications, such as medications for lowering blood pressure and cholesterol and kidney-protecting drugs. After a few years, most Canadians with diabetes learn to self-manage their disease with a cocktail of between five and eight prescription drugs each day. In consultation with their health teams, they evaluate the effectiveness of their disease management on a regular basis.

Diabetes is responsible for 10% of all admissions to acute care hospitals. Yet research shows that if Canadians are able to manage their diabetes effectively with medications prescribed by their doctors, they may avoid the serious complications. This, Mr. Chairman, would free up more than 280,000 hospital beds each year for other Canadians waiting for surgery or acute care. By helping Canadians manage their diabetes effectively, all Canadians will benefit. By reducing the rates of serious complications related to diabetes, health care resources can be invested in better health care for all of us.

Recent research illustrated that for every dollar invested up front in managing diabetes, the B.C. government saved four dollars a year by not having to have complications treated in other parts of their health care system.

Over 70% of Canadians believe that the long-term savings from helping Canadians manage their diabetes effectively justifies government paying the cost of diabetes medications, devices, and supplies.

We all know that Canada has a unique heritage as a world leader in diabetes research that began with the discovery of insulin by Dr. Banting and Dr. Best. Canada continues to lead the world in diabetes research and innovation, whether it's through the islet cell transplants in Edmonton or the $25 million DREAM international clinical trial for the prevention of type 2 diabetes, led by McMaster University researchers. The Canadian Diabetes Association believes that Canada's leading role in diabetes research may be undermined if the CDR continues working as it currently does.

Finally, the common drug review is the foundation for a national pharmaceutical strategy as well as for a national catastrophic drug plan. Therefore, we believe the common drug review must have clear processes in place, be accountable, and be more transparent in order to give all Canadians greater confidence in its role in pharmaceutical policy-making.

All Canadians may need to access prescription drugs at some point in their lives, but Canadians living with chronic diseases like diabetes need them daily to live healthy and productive lives.

Our association welcomed the introduction of the common drug review in 2002. However, in our view, the common drug review has not, and is not, meeting its promise in 2007. To put it bluntly, the CDR is not working for Canadians living with diabetes.

● (1550)

Our association reviewed all CDR recommendations relating to four diabetes medications. All four medications the CDR recommended as not to list, yet all four of these drugs have been listed by at least one participating drug plan in Canada and are being provided on an open listing in at least four other countries.

After review, we concluded that there are serious flaws in the CDR drug review process. These flaws include unnecessary duplication and delays. All participating drug plans continue to review or even enhance their drug review process. Another flaw is too much of a focus on costs and not enough on helping drug plans establish a place in therapy for medication. It's irresponsible for the CDR just to say no.

Finally, CDR lacks transparency and accountability. We outline in detail in our written submission our concern about this, but in particular, the lack of independent appeal process is simply unacceptable.

Having said all this, we also propose a way forward for you to consider. Our association proposes that the health standing committee recommend that the Minister of Health appoint an independent panel to review the original mandate of the common drug review in relation to the roles of Health Canada, the Patented Medicine Prices Review Board, and provincial and territorial drug review processes.

Our association also asks you to recommend that the health minister create a new conditional listing for drugs approved by Health Canada as safe and effective. This new listing could be for anywhere between three to five years, while government and industry—and we believe industry must be involved in the design if we are asking them to pay the cost of the research—as well as health organizations undertake a research program that identifies the real-world economic costs and health benefits of a new drug. Governments would then make a final decision once the research results were known and published.

Finally, we ask you to recommend the immediate implementation of a number of steps while the independent panel undertakes its review and makes its recommendations. First, introduce greater transparency while maintaining a rigorous, objective drug review process by requiring CDR to cite all publicly available clinical studies and research used in their listing recommendation; release the criteria used to evaluate the cost-effectiveness of a medication; enter in discussions with CIHR on investing in research in Canadian universities to generate the much-needed economic and cost-effectiveness data; invite all interested parties to provide CDR with recommendations of qualified reviewers for their consideration in the selection of their reviewers of the scientific and clinical evidence for each drug; publish an annual list of these individuals contracted to review the scientific literature after a listing recommendation has been made public; and finally, introduce an independent appeal process that does not include individuals who have the initial recommendation for listing.

Mr. Chairman, we get the opportunity of travelling this country from coast to coast several times a year, and I won't give you all of the sayings or the requests by many of our stakeholders, but Mr. Ron Whipple, who lives in Fredericton, New Brunswick, made a comment that I thought is relevant to this committee. He stated very clearly that he would like to die with his diabetes and not because of it.

Thank you very much.

● (1555)

The Chair: Thank you very much for being here and contributing to the debate.

We'll now move on to the president of the Canadian Organization for Rare Disorders. We have Durhane Wong-Rieger.

Ms. Durhane Wong-Rieger (President, Canadian Organization for Rare Disorders): Thank you very much. That was perfect.

I am Durhane Wong-Rieger. I am actually the volunteer president of the Canadian Organization for Rare Disorders.

CORD is a national network of patient organizations and groups representing Canadians who have rare disorders. There are about 5,000 to maybe 7,000 rare disorders in Canada, which affect, we believe, up to 10% of the Canadian population. Most of these disorders do have a genetic base. Most of them affect infants, children. CORD's mission, then, is to provide a common voice for those affected by rare disorders, and we do education, support, and advocacy.

I optimistically entitled my presentation to you—which I apologize for not having in front of you—"How Canada's Common Drug Review is Failing Patients With Rare Disorders and How to Fix It".

In the decade before 1984, there were about 34 new drugs for rare disorders, in that entire decade. In the two decades since 1983, when the United States passed the Orphan Drug Act, there have been more than 300 new therapies introduced, approved for patient access. Similarly, since the European Union passed their orphan drug act in 2000, there have been more than 30 new therapies approved for market access in Europe.

The reaction from our patients and from health care providers has been one of hope. We hear oftentimes, "Thank goodness we finally have a chance for life. Hopefully, there will soon be a therapy for our condition." We contrast that with the reaction from our drug plan gatekeepers, who tend to say, "Oh my gosh, how can we afford this? And how many other therapies are there in the pipeline?"

Therein lies our conundrum. Patients anxiously await each new therapy because it offers them a chance for life, and what we get are drug plan managers who view each new approved drug as a cost centre threatening to overrun their already oversubscribed drug budgets.

What we would like to maybe move to is to talk about what would be the desired outcomes of an effective drug review process for rare disorders. I think what we would want to see is that in fact Canadians with rare disorders would have the same access to new therapies as those with more common ones.

It means that those with rare and oftentimes severe and life-threatening disorders would receive therapies that are equivalent to the standard of care and best practices of other countries; that therapy would be approved and available for patients similarly through the public and the private drug plans, and they would be based on evidence of safety, effectiveness, and tolerance.

Importantly, we would expect that therapy be made available to appropriate patients based on some reasonable extrapolations from the available evidence, and we would want to see timely feedback on real-world safety and effectiveness for each patient, as well as a collection of aggregate information that would advise all stakeholders, including patients and health care providers, as well as the regulators and manufacturers, in terms of their longer-term effectiveness and safety.

Sadly, what is the current status? It is a sad but true fact that Canadian patients with rare disorders have probably the worst access among all patients in the developed world to new therapies—and I don't say that lightly. These are often treatments for severe, debilitating, and life-threatening disorders, sometimes the only treatment.

What are some of these new therapies? There are therapies such as the treatments for metabolic disorders, for Gaucher disease, and what we've heard recently a lot about, Fabry disease, MPS, and now recently Pompe disease, all severely debilitating, life-threatening disorders that now have a treatment available.

There are treatments for rare blood pressure and blood disorders. For pulmonary arterial hypertension, the first new therapy, the first therapy ever, was introduced in 1995; now we have three therapies available. Hemophilia, thrombocytopenia—these are all newer therapies that can improve clotting with less risk.

There are treatments for pituitary, thyroid, and parathyroid-related diseases. One of the ones that we've recently had introduced in Canada, which in fact was rejected, is a treatment for acromegaly, which untreated would cause gigantism.

Many of the disorders that are rare are childhood disorders, and we're now seeing, for instance, for the first time, new treatments for childhood leukemias.

About one third of these orphan drugs are for some rare forms of cancer.

Unfortunately, in our experience, the common drug review process is inherently biased against what we call “orphan drugs”, these drugs for rare disorders. The pharmaco-economic process that is used by the CDR relies often, and almost exclusively, on large-scale randomized clinical trials, and clinical trials that have long-term evidence in terms of benefit. That is patently impossible when you're talking about a rare disorder, which has very small patient groups available for clinical trials.

Also, we do not have the long-term evidence. Often we don't know a whole lot about the natural state of the disease, and we certainly have not had the drugs long enough to collect the long-term evidence.

● (1600)

As evidence of the fact, of the 11 drugs submitted for rare conditions since the CDR has been in business, all of which are for debilitating or life-threatening disorders, almost every single one has been rejected. These are all drugs, interestingly enough, that are available to patients through public drug funding in most other developed countries, and even in developing countries.

These drugs include Somavert, for gigantism; Replagal, for Fabry disease; Fabrazyme, for Fabry disease; Amevive, for chronic pIaque psoriasis; Aldurazyme, for MPS I; Zavesca, for Gaucher disease; Forteo, for a rare form of osteoporosis; three drugs—Sensipar, Nexavar, and Sutent—for rare forms of kidney cancer. The last one, Exjade, is for transfusion-related iron overload, which actually just this past week, we were notified, had a recommendation for very limited use.

The result is that we end up with this two-tier process. All of these drugs, interestingly enough, are available if you have a private drug plan, the kind of private drug plan most politicians and bureaucrats who are actually managing this process have access to, but that anybody on a public drug plan does not have access to.

Sadly, to the best of my knowledge, there is no drug for a rare disorder being paid for currently by a Canadian public drug plan that has not been put on the plan without some strident patient advocacy. Despite what most people believe, patients do not like to go through this process.

We end up also with some very bizarre kinds of things happening. I think of Naglazyme, a treatment for MPS VI that the manufacturers chose not even to submit. Through advocacy, it is being paid for by the Ontario government, though now only available through a special access program. It means there's no safety monitoring, no ongoing monitoring of the drug.

The same thing happened with a recent case in MPS II. Elaprase is a drug still going through Health Canada. There was advocacy on the part of the parents. B.C. said yes. Interestingly enough, in two cases in Ontario, the Ontario government said no, let's wait.

We've seen this happen with regard to AIDS drugs and cancer drugs, where strident advocacy was required. We would submit that if the CDR had been in place when the first AIDS drugs came into use, they would have also been rejected by the CDR, and in fact all of those patients would have been experiencing the same fate as many of our patients with rare disorders: they would have just died.

There are some other very bizarre things that I want to point out to you in terms of how this CDR process actually doesn't work.

Zavesca, for Gaucher disease, is a second-line therapy, a first oral therapy. The first-line therapy Cerazyme was introduced about ten years ago as the first breakthrough therapy for this type of lysosomal storage disorder. Zavesca was turned down by the CDR. They said it didn't have enough evidence and it cost too much.

The irony of it is that in fact it came to the CDR with better clinical evidence and cost less than Cerazyme, and yet it was still turned down. So we know that if Cerazyme had been introduced today, none of those patients would have gotten access, and the ten-year data we now have for Cerazyme, which demonstrates definitively that it's effective—All of those patients would have never been on the treatment. Many of them would have died.

We know that too because, as I mentioned, three other enzyme replacement therapies similar to Cerazyme have been systematically turned down by the CDR as having not enough long-term data and not enough evidence of statistical significance, objecting to the use of surrogate markers in terms of long-term clinical outcomes.

I'll give you one final example, which we think is very bizarre. That's Nexavar. This is one of the kidney drugs that were turned down. I think it's really bizarre, because in my opinion it was turned down because the evidence was too good.

What happened with Nexavar? In phase three clinical trials, interim data was coming through showing very clearly that the drug was effective. The U.S. FDA suggested that patients who were on the control arm for ethical reasons be given an opportunity to cross over to the treatment arm. Many of them chose to do that.

Well, lo and behold, by the time the clinical trials were concluded, we did not have enough patients in the control arm to actually achieve statistical significance to say that the drug was more effective than the placebo.

The U.S. FDA got it; the European Union got it; even Health Canada got it. They all approved the drug. The CDR said no, thank you, that they didn't have sufficient evidence of long-term clinical benefits, and they could not seem to understand that there was no way that evidence was going to be forthcoming.

● (1605)

The CDR has said repeatedly that they know these longer-term trials could be done, because they've seen evidence from the Cerazyme example. We now have longer-term evidence from the Fabry disease for drugs that have been approved and are available elsewhere. They're saying, fine, do the long-term studies. We're saying it is unethical to expect that patients in Canada will wait 4 to 10 years while these trials are being done, while patients have access elsewhere in the country. And quite frankly, once the drug has been approved through the clinical trials and is available elsewhere, what motivation is there for any company to do this kind of clinical trial for our very few rare-disorders patients? It means that our patients end up being the control group, quite frankly. I think we are very concerned about what's happening in terms of the trend here.

It is our opinion, though, that we could in fact have a much more effective process. Interestingly, we do not disagree that publicly funded health care programs should assess drugs and other technologies for safety, efficacy, and even cost-effectiveness. Moreover, we agree there should in fact be randomized control trials where possible. However, we think these trials have to be appropriate to the patient population, and the standards that are used have to be appropriate.

Internationally, there have now been agreed-upon standards by which you would actually do clinical trials with small patient populations. There's international agreement around what surrogate markets are available and how they should be evaluated. Why is it that everybody except for the Canadian common drug review can get on board with this?

As I say, our real quarrel is not with Health Canada. We think Health Canada gets it. And we think the progressive licensing framework provides a vehicle by which some of this can actually be done. Unfortunately, when we get to the common drug review, they oftentimes re-review what Health Canada has done; they oftentimes come out with different conclusions. They claim it's because it's real world versus what would happen in a laboratory. We contend that if you don't in fact make the drug available to people in the real world, how will you ever collect real-world evidence? It is being collected elsewhere. We need to be a part of these international collections.

I think there is a little disagreement that the Canadian common drug review is failing Canadian patients. I'll give you an example. Other than rare disorders, 14 innovative therapies were reviewed by the common drug review over the last two and a half years. Of those 14, 12 were turned down. It's the same problem: a lack of long-term sufficient evidence, or it costs too much. Of the two that were actually approved, by their own admission, one was approved with the same lack of evidence, but it cost less than the standard of care, and somebody said, hello, it's okay for you to approve a drug that has not your standard of quality evidence just because it's cheaper.

I think what we want to move towards in this country is a process that's appropriate. We can look at other countries, and I've given you some examples that you can look at when you get the written submission.

There are two things that we want to suggest in terms of fixing the common drug review for rare disorders, and maybe for any innovation therapy.

First of all, there needs to be a separate process. We look at what the Dutch have done; we look at what the U.K. has done. We need to have a separate process that is run by experts who understand rare disorders and will use appropriate processes of evaluation. We do not object to health technology assessments. We don't even object to pharmaco-economic assessment. But it has to be done with the right tools, and it has to be done within the right framework of what we're talking about here. So it has to be a separate process.

The other thing we're suggesting is that there be a separate fund—again, as the Dutch have done, as the U.K. has done in many cases—allocated just for rare disorders. That would help even the playing field, because under the current circumstances, rare disorders can never get access in the same way as more common drugs. We're recommending, based on some of our international experiences and on what's available currently, that 2% of the public drug fund should be allocated separately for rare disorders. It should be handled by a separate committee, by a separate process, and this fund, then, should be established nationally and shared by all the provinces. We would actually like to call upon the federal government to kickstart this by putting together that fund and making it available, and then helping to set the terms of reference and guidelines by which those drugs would be reviewed and accessed.

We don't object to safety and assessment. In fact, patients don't want drugs that are not safe and don't have long-term effectiveness. I think the U.K. has a very innovative program, which we think is very valuable, and that is, when a drug is deemed safe and has sufficient evidence of efficacy, it's made available to patients where there's a high risk in terms of debilitation or death. And the patient then signs an agreement that says, after *x* amount of time, if you don't get the effectiveness, then you're taken off the drug.

● (1610)

I will just finish by saying that the question was asked to our U.K. visitor, what happens when you take patients off the drug? He says it has never happened. He says the patients take themselves off. Nobody wants to take a drug that isn't working and isn't considered to be safe. We've never had that problem. We would contend to you there's enough good international evidence about how an effective process could be done. We certainly believe, as an aside to it, is that the more appropriate use of HTA should be applied not only to the rare disorders, but also to some of the more common disorders and certainly to innovative therapies.

Thank you.

The Chair: Thank you very much.

Obviously you're all very passionate about this issue and you've given us something to consider.

We'll now turn it over to the questioning. We'll start with Ms. Carolyn Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thanks very much.

I think we get it: you don't think this is working.

If we are going to design a system that works, I guess one of our concerns after hearing from the cancer folks is that if you end up with every single disease having a separate system, this is going to be pretty difficult. And there's the fact that rare diseases clump themselves together, and obviously diabetes is hugely common.

I would like you to tell me what you think a system that worked would look like. I worry when we're trying to go constructively forward that if we say that people die, and you can't tell who has died, then we lose ground. If you say that people are dying in the streets, we actually lose credibility on this file. If we pull out numbers like 2%, in the sense that we want 2% assigned for rare diseases, then people ask, where did you get that from?

We know that in the national pharmaceutical strategy there is a view to getting to a national formulary and having the best possible people come together to make these decisions. Can you describe what you would prefer and how we would get the provinces and territories and the five federal formularies to come together to actually do something that would work?

Dr. Karen Philp (Vice-President, Public Policy, Canadian Diabetes Association): We don't advocate for a separate formulary and process for the diabetes medications, nor for other drugs. We agree with you that if the common drug review was working, if it was open and transparent, and if there was some ability for Canadians to identify that the right people were being consulted, and if we understood what the economic analysis was, we would be supportive of it. That was the promise that this common drug review gave back when it was created.

We also know that the provinces and territories and the federal government, all the participating drug plans, also said that once the common drug review was up and running, they would stop doing their own reviews and just do the budgetary cost impact. Well, they haven't. Ontario, in fact, has introduced changes to their drug system that enhance the role of the committee to evaluate drugs. They review the same materials and information, and do their own cost analysis, actually, on those drugs, to reach the same conclusion as the common drug review does. Sometimes it's a different conclusion, actually.

So the duplication in the system hasn't been removed; in fact, it has been increased. That's the delay in access, right?

● (1615)

Hon. Carolyn Bennett: I understand that in certain countries—and I would just like to know more about it—there are places where the people who know the most about these things, the patients and the providers, come together to decide in an inclusive decision-making process where they feel comfortable with the international evidence and the other reality. They are then prepared to make things available. I also think that we would want it moved, then, to the real-world ongoing tracking of what happens when it's out there, as to whether it works or doesn't work and whether it's cost-effective, but you make that decision, then.

Are you comfortable with a system in which there would be much more input from stakeholders and patients as to whether they're prepared to accept the risk and the evidence? How would you design something? I guess Michael had a go at saying, but if you guys were writing the recommendations for our report, what would they say?

Dr. Karen Philp: The thing is, we really think you need to review. We'd work from the premise that there needs to be evidence, and we would like there to be an independent review of the current processes, just to get to the bottom of what's happening, mainly because we have been working and discussing with the vice-presidents of the common drug review. We've met with members of the Canadian Expert Drug Advisory Committee to talk about various things to try to understand why their clinical science reaches a different conclusion than our clinical reviews. We have over 660 volunteer researchers, endocrinologists and physicians who worked for about three years for free to evaluate all the science, and they came to a different conclusion on a number of the recommendations the CDR made around drugs.

So we really would encourage you to look at what's happening, because right now the public can't find out. We can't find out how it works.

But if you were to look at a model, we think that the U.K. and Australia have some interesting models you should look at. The U.K.'s model, NICE, which is what the Ontario government is looking at, includes a citizens council that would engage the citizens of Canada in the debate on pharmaceutical policy. That would give you more credibility when decisions are being made on a drug being listed, because right now I think that's the major problem for the common drug review: people don't understand how they've reached the conclusions they've reached.

Hon. Carolyn Bennett: Maybe Durhane could answer on why she wants a separate system.

Ms. Durhane Wong-Rieger: If we look at what's happening internationally—and I think we all agree that we have to use an international framework, especially with rare disorders—we can see exactly what you're suggesting. That is, the Europeans and the U.S. actually work quite collaboratively, including the Japanese and the Australians, with regard to international review bodies agreeing on what constitutes an appropriate clinical trial. So I certainly think that with rare disorders we need to make sure we are linked internationally.

I think it's happening, as you can see, with the progressive licensing framework, where there's harmonization with the international review bodies so that we're not reinventing or redoing it. Even more so with rare disorders, we don't have enough patients. When you have a disorder affecting two, five, or even thirty patients in Canada, we cannot actually do a separate process. On the other hand, we do want to make sure the process is internationally linked.

So what we're suggesting then is a process that certainly has a place within what is happening in terms of reviews, both regulatory and in health technology assessment, in Canada, but also then has a place within the international framework.

While it may seem untidy to you to say, well, we're going to have a lot of separate bodies here, what we're really suggesting is something that actually makes a lot more sense, in terms of having exactly what you're talking about: agreement around what constitutes appropriate evidence; agreement around what constitutes appropriate costing; agreement around what constitutes long-term monitoring; and the necessity then of collecting that information to determine ongoing safety and effectiveness. I don't think we can do it in Canada separately.

So if you're going to have this, then the important thing is that every European country we looked at—and also the European Union—all have bodies that have now been designed specifically for rare disorders. The models are there. The U.K. has a whole program around it. The European Union has a collaborative framework that includes patients and researchers and clinicians. The French have one within their own country. The Dutch have one. So I think if we looked internationally, we would see there has been strong agreement that these diseases need to be considered separately.

It is unfortunate that Canada sits as the only developed country I know of that does not have an orphan drug program. And it puts us at a severe disadvantage in terms of working internationally, to make sure that we do have the right information to provide the drugs and also to provide the long-term safety and efficacy you're talking about.

● (1620)

The Chair: Go ahead, Brett.

Mr. Brett Skinner: I would take a different perspective on this, one that is focused on consumer empowerment.

The CDR is a central planning mechanism focused on cost concerns. It needs to evaluate the pharmaco-economic value of drug technology and other health technologies—if we expand it to those—only because a government is the central payer that funds 100% of the costs in many of our plans. Countries that have an expanded formulary and make more drugs available to patients, or who have private insurance—which in fact makes all drugs declared safe and effective by Health Canada available to patients—employ different mechanisms. They preserve consumer choice by having deductible ranges that simply exclude those kinds of expenditures that are affordable for people and for which they should be paying out of pocket, and reserve insurance for things that are catastrophic or unaffordable on an individual basis, things that we should pool collectively. Those types of insurance programs also have co-payments that shift some of the costs to the patient, not just to shift costs, but also to influence their decisions on whether they should use the drug. They assess the value of it. If 100% of the cost is paid by their neighbours, they'll try it. But if there's a cost at the point of consumption—

Hon. Carolyn Bennett: I recommend Malcolm Gladwell's article in *The New Yorker* to you on that sort of moral conversation you're having with yourself.

I think that's appalling. If you have Fabry disease, I just don't think that you can make that argument. You'd rather not get Fabry disease. You'd actually rather function properly. We risk-share in this country. We don't punish the people who get diseases that require the expensive drugs.

Mr. Brett Skinner: I would ask the member not to put words in my mouth. You may find disease examples where the catastrophic expenses are quite high. But for most people and the drugs that they access through our drug plans, that is not the case.

A co-payment is a common strategy in private insurance that works very well to increase access to pharmaceuticals and other health treatments. That is a private sector invention, by the way, and not something that was invented by governments. This works very well in the private sector for increasing access to pharmaceuticals.

Hon. Carolyn Bennett: There's no evidence—

Mr. Brett Skinner: Deductible ranges help exclude those kinds of expenditures that are affordable and that people should be paying for out of pocket.

Those are alternative ways of doing this. Not just the private sector does it, but of course, countries such as France have much higher expenditures on pharmaceuticals and much lower rates of growth in their overall health expenditures. I think we should be thinking about drug expenditures in a bigger envelope here in terms of the entire envelope of health expenditures and the impact of drugs on that envelope.

The Chair: Thank you very much.

Monsieur Malo.

[*Translation*]

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

Ms.Wong-Rieger, there are some points from your recent exchange with Ms. Bennett that I am trying to understand. Given the fact that there are so few cases in Canada in which clinical studies have shown that a drug is effective for rare disorders, do you think that Canadian cases should be linked with other international cases in order to conduct more conclusive studies?

[*English*]

Ms. Durhane Wong-Rieger: Actually, it's the only possibility. You're absolutely right. And in fact, most of these studies are carried out internationally. Even the follow-up registries that monitor ongoing safety and effectiveness work only if they are international. I think that's why we go back to saying that if we had a separate process—That process, though, needs to be linked internationally. In no way can it be a stand-alone process.

In fact, the cobbled response to Fabry disease and the MPS disease—The CDR turned it down. Strong advocacy got the government to come back. All the health ministers came back and said, fine, we'll put together a research project. And quite frankly, we think what they've done is ridiculous. They've created a very tiny little research project all by itself.

We need to be linked, and we need to link those research projects as ongoing registries to international studies. We cannot afford to do this in isolation. Part of our problem, though, is that we end up making these decisions very much in isolation. So you're absolutely right, all of this has to be done internationally. We can learn something only if we do it internationally.

● (1625)

[*Translation*]

Mr. Luc Malo: How long have you been advocating this? Who have you spoken to about this? What were the reactions of the various researchers and decision-making bodies to your proposal?

[*English*]

Ms. Durhane Wong-Rieger: We had our first Canadian conference on rare disorders and an orphan drug policy program just last week. It was a two-day international conference. We had, in fact, some of the top international experts come to Canada to provide us with their expertise and advice. We also had, quite nicely, some representatives from provincial and federal governments there.

I hope that the idea has gotten some traction that people do recognize. I don't know if people are aware that in 1997 Health Canada came out and said, we don't need an orphan drug policy; we already have adequate access. And sadly enough, what was said was that other countries were already developing new drugs, so we didn't have to do that, and we didn't have to encourage that.

Of course, we think that's irresponsible. Canadians have every responsibility and every ability to contribute to it. We think it's an idea whose time has come. This has been discussed for a number of years now, ever since the U.S.—It hasn't gained a lot of support, but we're now beginning to feel that we're getting some attention and that it is gaining some traction. So actually, we're quite hopeful that we're going to be able to get some very positive response.

As Karen also indicated, we've had some very good response, for instance, in terms of how this program might fit in with the new drug legislation in Ontario in terms of their review process. Also, it fits in well with the kind of transparency that people like Helen Stevenson are promoting within the drug strategy secretariat.

We think there are things coming into place that are going to be much more supportive in making this happen now, whereas ten years ago the answer was categorically no.

[*Translation*]

Mr. Luc Malo: Mr. Skinner, earlier on in your remarks, you stated that:

[*English*]

"There is a misguided war against medicines".

[*Translation*]

Do you think this war will end some day, and how do you think it will end? Will people speak to each other? I think that the main problem lies within the lack of mutual understanding between players. Do you think it is possible to bring this war between the parties to a positive conclusion?

[*English*]

Mr. Brett Skinner: The point of calling it a misguided war against medicines is simply to draw attention to the fact that the focus on cost containment and the focus on what we spend our health care dollars on is really misguided. At various points in the history of medicare, costs have been focused on what we spend on doctors, and we have held their rates down to below market levels over time. After adjusting for inflation, for instance, Ontario doctors make no more today than they made in the early 1970s.

We have held down expenditures on hospitals. We have amalgamated hospitals. We have allowed them to deteriorate in terms of their modernization. Now, drugs are the latest—

Mr. Luc Malo: You didn't answer my question.

Mr. Brett Skinner: I'm getting to that.

Drugs are now the focus of attention on cost, and that is misguided. We shouldn't be focusing on what we spend our health care dollars on, but on how we finance the system, because how we finance the system introduces incentives for how we prescribe and use medications, the kinds of medications that are demanded by patients, the decisions that are made in terms of efficient substitution between competing health care treatments.

Those kinds of things don't exist in our system. If we properly designed our public health plans, including our drug plans, with things like deductibles and co-payments, we could introduce proper economic incentives that would encourage the right decisions on those things. It would also free up spending to allow us to include a larger number of new health technologies, including new drugs, and give us the capacity to provide, under public plans, more of what is provided under private insurance. If you compare access to drugs under private insurance plans in the country, it's immediate and it's comprehensive, as soon as Health Canada says a drug is safe and effective. That does not occur under public drug plans. So if we simply mimic some of the things that are done in private plans, we could achieve the same thing.

● (1630)

The Chair: Thank you.

I will allow a very quick answer and then we'll move on.

Dr. Karen Philp: I have a quick point of clarification.

The CDR recommendations go to the participating plans, and except for—In all of the provincial plans, the only people who are really cover most of them are seniors and people on social assistance. The vast bulk of Canadians have private sector plans. So when we're talking about CDR recommendations, it's low-income seniors who are most affected by the decisions taken by CDR. Since Quebec is not participating, I think they have a far better program in Quebec than they do in provinces like Ontario or in Atlantic Canada.

I wanted to make sure you're clear that we are talking about a small group.

The Chair: Thank you very much.

Mr. Fletcher, you have five minutes.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Thanks, Mr. Chair.

Thank you to the witnesses for coming here today.

I found it interesting that the Canadian Diabetes Association recommended an independent review. We've heard that. It seems to be a recurring theme here at the committee, and I'm sure the researchers are taking note of that.

I have a few questions. This is a very complicated issue and I only have five minutes.

One question that keeps coming up is having national standards. Madam Bennett suggested coordinating all the different plans. I wonder what the safeguard would be to preventing all the drug plans from going to the lowest common denominator versus the highest common denominator, and once you had established a highest common denominator over time, it would seem to be a lot more difficult to change the bar if you made it somehow compulsory for all the participants to agree on a certain standard. If a province, for example, wanted to exceed the standard, it would be very difficult for it to do so.

I'd like a comment on that.

This is the second question. I'd like the Canadian Diabetes Association to elaborate a little bit more on the proposal for conditional listing. It sounds like you want to replace the recommendations not to list with conditional listing recommendations. Would that not entail a lot more process at the level of the provinces, which then have to adjudicate each request on a case-by-case basis?

Finally, maybe for the Fraser Institute, if you had your wish, what is the cost estimate? You've said the CDR uses cost as a major consideration. If we removed that, what dollar figures are we actually talking about?

Those are my questions, Mr. Chair.

Mr. Brett Skinner: We'll start on the last question. It was directed to me.

My point was that the CDR was focused on cost and not on the actual value of the medications, that it's an exercise in cost containment, and for that reason I don't think it serves patients very well. So I'm providing an alternative approach to the CDR, something that would essentially say that if we do this, we don't need the CDR; we don't need central planning control over the kinds of drugs patients get. We can simply allow that decision to remain in the hands of patients and their physicians by redesigning our drug plans.

B.C., by the way, has a deductible for eligibility for drug coverage, and other plans have co-payments. Private sector plans have co-payments. The international jurisdictions of the OECD have co-payments and deductibles and user fees as part of their plans as well. So this is not radical stuff; it's being done all over the world quite successfully.

The point is that by introducing those things you create the financial capacity to pay for new expensive technologies and you allow people to pay for affordable things, which is what insurance is supposed to do. Insurance is supposed to cover those things that are impossible for individuals to afford on their own. So I'm simply suggesting that it would free up the capacity to pay for the things through the public programs we're talking about here today.

● (1635)

Mr. Steven Fletcher: On the conditional listing and the common denominator issue?

Dr. Karen Philp: The conditional listing idea is Australian. Australia operates it, and they have a similar government structure to ours. So I think we could look at them in more detail and adapt it for the Canadian situation.

We think there are a lot of stakeholders at the table right now who aren't communicating through the common drug review process. A conditional listing would help get those drugs that have been approved as safe and effective by Health Canada, so it would still go through the safety review with Health Canada. It would be a drug that's also been given a price point by the Patented Medicine Prices Review Board.

At that stage, the company and the federal government—and if it were the common drug review, it would go to them to negotiate—would bring the company to the table, bring an organization like ours with the expertise that could help design a research program, work together, and identify the research program to identify the real-world health outcomes and the real-world costs. A lot of the cost estimates that are being made are based on clinical trials or other studies that aren't based on the real world or in the Canadian context. So we think there's a real gap here that needs to be addressed.

If we could do that, then government has ultimately the ability to ensure that the questions they want answered are asked. Industry knows they have a responsibility to pay for the research, but they also have an opportunity to have a contribution and input into the design of the research project. Organizations like ours can be assured that the expertise that needs to be there to ask those research questions is at the table. Right now, there's no ability for us to do any of that quality assurance.

We think the conditional listing is the way to go. It's also, I think, very similar to what Health Canada introduced back in February in its white paper on a progressive licensing model. Australia is the model we'd suggest you look at.

The other thing around national standards is that it really shouldn't matter where you live in Canada if you have diabetes, but it does. There are 17 diabetes medications that have been approved by Health Canada as safe and effective, and the Patented Medicine Prices Review Board has allowed them to be for sale. Right now if you have money you can go out and buy those drugs if your physician or doctor prescribes them, but if you're on a drug plan in Ontario, you have access to six of them; if you're in Atlantic Canada, it ranges. So every province has a different number. The national standard issue is very dear to our heart, and we want everybody to rise up.

Mr. Steven Fletcher: I'm going to try to get in one more question quickly.

The Chair: It's too late. Your time has gone, Mr. Fletcher.

We'll move on to Ms. Chow now, for five minutes.

Ms. Olivia Chow (Trinity—Spadina, NDP): I understand the CDR needs to be transparent and accountable—this would be to the Diabetes Association—and that it must coordinate with all the other reviews that are happening. I also know you agree that the CDR is the foundation for a national drug strategy, and that we want the highest level of coverage.

So how would we increase the role of CDR? It is supposed to be the first step. The provinces came together two years ago, saying they want a national drug formulary. It is a priority area. What is the status and the progress toward that push for a national drug formulary? That's number one.

Number two is, how would CDR get provincial drug plans to implement its recommendations, assuming the recommendations are faster, more transparent, better at peer processes, and all those things you're pushing for?

Dr. Karen Philp: We think the catastrophic drug plan...that's our ask, actually. There needs to be a national catastrophic plan that ensures that no Canadian pays more than 3% of their annual income on prescribed medications, devices, and supplies. Because the common drug review isn't working, we're arguing that any drug approved by Health Canada and given the opportunity to be sold in Canada through the Patented Medicine Prices Review Board should be covered. Right now we have this problem, with each of the provinces providing different levels of access.

When the common drug review was first introduced, we thought, well, here's the foundation; it's going to be open and transparent, it's going to engage the stakeholders, we're actually going to move forward, and we will get closer to a catastrophic drug plan or some sort of national pharmacare program. It's not happening with the common drug review.

We could go to the model where the federal and provincial and territorial governments sit down to try to negotiate, but that, I hate to say, takes forever. So we would really encourage this committee to look at what's happening with all the four steps in the review process and see if there's some way to either make the common drug review work or find another model.

We were just talking. We weren't sure if diabetes is the only disease, but there's not been a single diabetes medication reviewed by the CDR that has been approved since it started. We don't know why.

Secondly, there's so much coming down the pipeline in new therapeutic treatments and new research discoveries that we're really afraid that Canadians with diabetes are going to end up with lower health outcomes than people with diabetes in Australia or the U.K. or in parts of Europe.

We have to get this right, and that's what we would encourage the committee to do.

● (1640)

Ms. Olivia Chow: Right now, because it's not coordinated—recently there's even been a new body to study the cancer drugs. There are many more layers, and then even if one is recommended, it's not mandatory that the drug plans respect it, so it's all over the map.

I think one of the recommendations you had was for the conditional listing for new medications, right? That would at least deal with the ones that are approved by Health Canada. Is that one of the recommendations?

Dr. Karen Philp: Yes. What could happen is that, for instance, it could be under special authority; that's what they do in Australia. Your physician makes the case that other treatments haven't been successful for you, so it might be a second- or third-line treatment. You could then apply to be part of this research program; you'd have to agree to be part of it.

If you're a Canadian with diabetes and you are not having the best health outcomes from your current treatment and your physician thinks this new drug might be useful, then you could enter the research program. That's what we were thinking.

Ms. Olivia Chow: This is my last question.

Do you think this agency, CDR, can actually expand its mandate and recommend how long the drug should be protected under patent? If you make that recommendation, then—I'm thinking completely outside the box—the generics would be able to come in sooner, perhaps, therefore lowering the cost of some of these very expensive drugs. Is that a role this agency could play, possibly?

Dr. Karen Philp: I think you might find it such a big review that you would never get through it in the time you have allotted for it. That would be my concern.

It's a slightly separate issue, relating more to the innovation side of the question, and I would keep the common drug review focused on processes and on trying to streamline them so they're more effective.

The Chair: Thank you very much.

We'll now move on to Mrs. Davidson.

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

I would like to thank our presenters.

My first question is going to be for Ms. Wong-Rieger, please.

I have two constituents who suffer from Fabry disease , a mother and a son. The son underwent tests through a project in the States and is now undergoing one in Canada, and they're getting funded right now for the drug for a three-year period. Is this the test you were talking about?

Ms. Durhane Wong-Rieger: This is the disease we're talking about.

Mrs. Patricia Davidson: Yes, I know it's the disease, but you referred to—

Ms. Durhane Wong-Rieger: No, no, not at all.

Actually, here's the bizarre solution that came out of this with Fabry. Because there are two drugs available, one of which got an NOC, one got an NOC/c, etc., it added some confusion to the whole situation.

What happens now is that all of the health ministries agreed to make the drug available through a research protocol. The research protocol then allows those patients who have been on the treatment through the clinical trials that have been done to get it approved to continue it. Now, the mother and son—and I think I know who you're talking about—are on the treatment. The son is actually in an expanded clinical trial, so he's getting the treatment through the clinical trial process.

What Canada came up with, then, is a separate research protocol to say, okay, for those patients who were not on the treatment previously, we're now going to give them a chance to go on the drug. First of all, they set standards that were very different from the international standards—much more stringent standards. So a lot of people who would qualify internationally for funding and treatment in their countries would never get it in Canada. But beyond that, what happened is that they said, we will now randomize you to one of those two drugs, and we will then see whether or not, over the long term, one drug is more effective than the other, etc.

So they've introduced this other research protocol.

● (1645)

Mrs. Patricia Davidson: So what happens at the end of the three years?

Ms. Durhane Wong-Rieger: Well, this is the disaster of it. Even Dr. Laupacis, when this was presented to him, said, there's no way we're going to learn, with the small number of Fabry patients in Canada, whether or not either drug is more effective, or more importantly, at the end of three years we're not going to have that definitive evidence that we need. This can only be done internationally.

Mrs. Patricia Davidson: So since the son was involved in clinical testing in the States, is that evidence being used here as well?

Ms. Durhane Wong-Rieger: That is evidence being collected by the manufacturer as part of their post-market surveillance, and it's a post-market registry.

We're suggesting that, in fact, we should not set up a separate registry, which is what has happened as a result of this agreement, and that we should all be part of this international registry, because that's where you're going to get the bulk of the information to know whether these drugs are safe and effective. Unfortunately, again, because we were dealing in isolation, separate from what's happening in the international community, we've ended up with what I consider to be, quite frankly, a very expensive exercise—a time-delayed exercise, because there had to be a research protocol and it had to go to each one of the five central hospitals to be approved. I mean, two and a half years later, we're only getting our very first patients enrolled under that research protocol, and the evidence that will come out of it will actually have no real benefit because it is not part of the international registry.

Mrs. Patricia Davidson: So none of this evidence, then, goes back to the CDR and is used by CDR as a—

Ms. Durhane Wong-Rieger: No, CDR said this was useless, quite frankly. They thought it was useless. It was a political solution—I hate to say it—to a very badly handled situation. Honestly, it cost about $1 million extra that we would have rather seen go into the actual funding of the treatment, letting the patients be part of an international registry.

Mrs. Patricia Davidson: Okay.

To Karen, I think you said that there were different clinical conclusions between your research and CDR's research. What did you mean by that? Did it show a different benefit? Did it show a different cost?

What did you mean by different clinical conclusions?

Dr. Karen Philp: Insulin glargine, which is also known as Lantus, is recommended in our clinical practice guidelines, which are developed by our professional volunteers. In 2003 they recommended that for nocturnal hypoglycemic patients who suffer from going into comas at night, their physician should consider putting them on insulin glargine as a third line.

So they weren't saying if you have diabetes, right away—

Mrs. Patricia Davidson: Who's they?

Dr. Karen Philp: The health professionals.

It's all based on the science. This is what the published peer-reviewed clinical trials and research showed. If you have trouble with going into lows while you're asleep, then your physician should seriously look at using insulin glargine as a way to keep you stable.

When the recommendation came out of the CDR not to list, we were very surprised. We wrote letters saying, "This is what our review of the science shows." We illustrated what each country did. We said, "It's listed in all these countries. How did you reach a different conclusion?"

Well, we chatted with them, and we could not agree. They couldn't give us the information. One of the challenges has always been that they will say it's not cost-effective. We say, "Well, okay, share with us the economic information that you have to make that decision," and they'll say, "No, we can't, because industry has made us sign a confidentiality agreement. We can't release that information to you." We then go to industry, and we say, "Will you share the economic analysis with us?", and industry says, "No, CDR won't let us share it with you."

We can't find the economic rationale that they used, so we can only surmise that they're using the same studies as we used to come up with a cost-effectiveness number that says it's not cost-effective. And that seems to be their main recommendation—it's not cost-effective, and it's not useful.

The Chair: Thank you very much.

We'll now move on to Ms. Susan Kadis.

Mrs. Susan Kadis (Thornhill, Lib.): I understand one of the purposes of the CDR is to have uniform standards across Canada. Clearly, Mr. Howlett, you're representing something very different in terms of where you live accords what drug you receive. We've heard evidence today and on other days. You believe there's been a failure by the CDR and actually an obstruction or an impediment to access for patients with a variety of diseases. To what do you attribute that? What would be the motivation, when it was set up, to actually be more beneficial, more efficient, and more uniform across Canada and to go toward a national pharmaceutical standard?

● (1650)

Dr. Karen Philp: The common drug review is where federal, provincial, and territorial drug plan managers sit at the table, but the recommendation they make is to the provinces on the participating plans. They actually decide what to put on the formulary according to the plans.

They look at the impact on the provincial budgets. For Atlantic Canada, where they don't have the tax base or the population numbers, it's extremely difficult for them to afford to put on more drugs. For access in Alberta, they list 12 of the 17 drugs that have been approved. It's Ontario, with the full listing of only six, that we have a question mark around, in particular. It depends on where you live and on the provincial decision as to whether or not the drugs are listed.

Until the common drug review takes everyone to the table and does a bigger analysis on what should be available for questions of fairness, in our view, you're always going to have this challenge. It is why we consistently ask for a national catastrophic drug plan, because it's the only way we're going to get to a consistent national standard.

Mrs. Susan Kadis: You referenced clinical guidelines, if doctors are prepared to set clinical guidelines and approve drugs accordingly.

Dr. Karen Philp: Right now the Canadian Diabetes Association issues world-class clinical practice guidelines for the prevention and management of diabetes in Canada every five years. Those guidelines go out to every single practising physician in Canada. The problem is often that the physicians are very busy or they know their patients have low incomes and can't necessarily afford the drugs they might want to have.

I'm going to drop that line of thinking. I'm sorry.

We know that 50% of people with type 2 diabetes in Canada are not at the recommended target according to the scientific evidence. The physicians are making the best choices they can make, but they are obviously struggling to make it happen as well. We think one solution might be something like academic detailing, and we are talking to other provinces about this. British Columbia had a pilot. In Atlantic Canada, they have academics who sit down with the physicians and explain what the new drugs are, how they work, and what might be best for their patients.

The other thing we recommend is something that both B.C. and Ontario do, which is to have flow sheets for diabetes patients that give them a series of prompts according to our clinical practice guidelines. They ask those questions of their patients every time they come in. They get $100 from the provincial payment system, it goes into administrative data, and it ends up in the national diabetes surveillance system.

From our perspective, it's a beautiful little model to make sure they're managing patients according to clinical practice guidelines.

Mrs. Susan Kadis: If I have another minute or two, Mr. Chair, I'm particularly concerned in regard to patients accessing new therapies. In consideration of the investment we made in research, and you and other guests have referenced it before, are Canadians with diabetes not benefiting from new therapies because of CDR or other mechanisms?

Dr. Karen Philp: Yes. The answer is yes.

Mrs. Susan Kadis: Where do they go if they can't get them?

What are they doing for the low-income seniors you talked about? What do they do? What is their ultimate alternative, or do they have one?

Dr. Karen Philp: They don't have an alternative, but they come to us and ask for our help. We train them to be advocates and send them to your office.

Mrs. Susan Kadis: Thank you, Mr. Chair.

The Chair: Thank you very much.

We'll now move on to Patrick Brown.

Mr. Patrick Brown (Barrie, CPC): Mr. Chair, I have questions for all three groups today. I'll ask them first, then feel free to let me know your responses.

For the Diabetes Association, you mentioned concerns with the delay in duplication. I know many MPs, a few months ago, had the pleasure of having some kids with type 2 diabetes, I think it was, come up and visit our offices to express different things that we need to do federally to assist their concerns. I had a constituent, Rebecca Morrison from Barrie, who mentioned a few things, obviously including more research. But also, one of the things she expressed concern about, as did the group with her, was the CDR.

Now, in terms of the delay in duplication, from your perspective, how does this inhibit assisting in combating diabetes? Is it the delay or is it the waste of resources? Could you expand a little bit on that?

In terms of the Fraser Institute, I didn't hear anything about the financial cost of duplication. I was really hoping we might get a bit of that perspective from your organization, if you could touch on that.

And for Durhane Wong-Reiger, I'm happy you're here today. I've actually heard very good things about you from John and Nancy McFadyen. I appreciated your input on the rare diseases. I have heard that once in my constituency office too, where there was a case where the CDR formed a bit of a hurdle on that.

You mentioned 14 therapies that were unable to be utilized. If you could expand a bit on that, I was interested in what areas that was in, and what diseases, to maybe give the committee a bit of a glimpse of how this might have been a roadblock, and what type of people it affected.

● (1655)

Mr. Brett Skinner: I would like to ask the chair for permission to leave early today. I have to catch a flight, and I had mentioned it to the clerk, actually, in advance of the meeting. So if that's okay, I would like to go first and then, after this answer, perhaps exit.

In terms of estimating the costs of the delay, if there was no CDR, it would be only a few million dollars saved. So the real cost is in the impact on patients and any additional expenditures on health care that wouldn't have been necessary if people could have accessed drugs sooner.

We simply haven't done that analysis at the institute. We've just started to measure the problem and to engage in the public debate about the value of the CDR and some of the impacts of delays and so on, and access to medicines. I look forward to doing that analysis in the future.

I would focus your attention on what the greatest impact on costs would be on lost health opportunities for patients and what that means for expenditures overall in the health budget.

Dr. Karen Philp: Before the CDR, there were three steps. There was Health Canada, the Patented Medicines Prices Review Board, and then it went out to the provinces.

Now we have Health Canada reviews for safety and efficacy, Patented Medicines Prices Review Board reviews for the price, and the CDR reviews both of their studies and brings in some additional studies from the pharmaceutical industry or a manufacturer of the drug, we think, and then they make their recommendation.

Then the provinces continue to do the same reviews they used to do. They all had, if you remember when they set up the common drug review, promised to dismantle their review processes. They haven't. In fact, Ontario has increased and enhanced its drug review process. So we already have an example there where they're actually making their review processes at the provincial level stronger. B.C., in response to the Auditor General's report and a George Morfitt report from 2004, are also looking at other models for their drug review processes. In fact, they're looking to Oregon.

It seems to us that the common drug review was supposed to take away a layer, and it's not; in fact, it's just added another layer. So how is that not duplication and delay?

Mr. Patrick Brown: But in terms of those who are suffering, for example, the constituent I met with type 2 diabetes, how is this hurting them? When we're thinking about our constituents, are there potentially available drugs that are being delayed two years, or drugs that are being turned down that someone like her, a constituent like that in my riding, is not going to be able to have access to because of the CDR?

Is that where your concern lies?

Dr. Karen Philp: Yes. There have been four diabetes-related drugs reviewed by the common drug review. All four have been recommended, no listing. Fortunately, or unfortunately, Ontario and Veterans Affairs Canada have been proactive and actually listed all of these drugs anyway.

There may be a bit more paperwork, because they don't necessarily list them openly.

Mr. Patrick Brown: So Ontario listed them, but not the CDR?

Dr. Karen Philp: That's right. They're conditionally listed on the Ontario formulary.

Other provinces are still reviewing them as well, like Alberta, Manitoba, and P.E.I. These drugs go through another review process after they leave CDR, and they don't necessarily listen to the CDR recommendation at all. It used to be a joke that if CDR said yes that still meant no provincially, and if CDR said no it meant no. But that's not what's happening in diabetes; it's all over the map. People are doing their own thing, so we're not sure of the value of CDR when the provinces don't appear to be listening to their recommendations.

● (1700)

The Chair: Thank you.

Go ahead for a quick answer, and then we'll go on.

Ms. Durhane Wong-Rieger: I think you asked about the innovative therapies. They're for a lot of different disease categories. I think the common factor is that they're mostly considered to be "first in class" so they're a new therapy. They are for cancers and some of the rare disorders. We've had some breakthrough therapies for diabetes as well. The problem, as we said, is that the common drug review process uses a very narrow yardstick. If it is a therapy, they compare it to an existing therapy. If it's cheaper than the existing therapy, they will approve it.

Their process is inherently biased, so drugs that primarily get recommended are those for which there's already a category of drugs. They compare them and just compare the costs. They're already biased against drugs coming in for which they don't have an automatic cost comparison.

The other thing they look at is long-term evidence in clinical outcomes. When you're a new therapy, a first in class, you're not going to have those. These are often therapies for people who may be resistant to the current treatments. For instance, with the renal cancer groups, these are patients who actually have very advanced kinds of cancer for which no other therapies are available. Nexavar, for instance, was the first new treatment for kidney cancer in 12 years. Again, there isn't that long-term evidence.

So the process they use, which they seem to be very proud of, in fact uses a very narrow set of assessment tools, when in reality health technology assessment includes a whole range of tools that they absolutely ignore.

The Chair: Thank you very much.

Madam Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): I would like to follow up on the issue raised by Mr. Brown.

Ms. Philp, you stated that all the new diabetes drugs had been rejected by the CDR analyst. Why? Was cost a factor?

When the CDR official came before us to explain the program and its effectiveness, he told us that this type of decision regarding new drugs was made when only one or two new molecules had been added. It was not felt that this improved the quality of life of individuals.

Could you give us some examples of drugs that would improve the lives of people living with diabetes, even though those drugs were rejected?

I'm thinking along the same lines as Mr. Brown. The drugs appear to be assessed on the basis of their effectiveness, and we're being told that adding one or two molecules to some drugs does nothing to enhance their effectiveness. Therefore, they are not recommended for listing.

Provinces reject drugs for another reason, and that is, their ability to pay for the drugs.

Do the provinces not apply any pressure? The fact that they cover 70% of the cost of CDR means that no authority is given to have the drug covered by a drug plan.

This is a two-part question. Could you please respond?

[*English*]

Dr. Karen Philp: All of the drugs that have been reviewed by the common drug review were approved by Health Canada as being safe and effective, upon their reading of the scientific and clinical evidence. Because the Patented Medicine Prices Review Board is responsible for ensuring that Canadians don't pay more than they should for their medications, the median price of seven countries is selected as the maximum price point for a company to sell that drug in Canada. They then send all of that information to the common drug review.

Because of the lack of transparency and openness at the common drug review, we don't know what else they're looking at. That's where we lose the trail, because they won't tell us. Then CDR makes their recommendation and their application goes to the provinces. You're absolutely right, that's where provinces look at their budgets and say, "Can we afford this medication? Can we afford to provide it to our citizens in our province?" At that stage a decision is taken that we can or can't afford it.

Our concern is, what's the added value of the common drug review? What is the added value they're bringing to the table, when we can't see what they're bringing to the table? That's why we'd love a review to tell us there's good stuff happening there, and there's a reason why they're making their decisions. We would be supportive if we knew what the reasons were, but we just don't know. That's the lack of transparency and accountability.

We do know that if a decision is made that's contrary to our clinical practice guidelines—our review of the evidence—we have no avenue of appeal. We can't say we don't understand why they made this decision. Only the company can appeal a decision, and it goes right back to the very same individuals who made the original decision. So how can you have confidence in this system? It has flaws.

So if you could review it and let us know that it's working effectively and there should be more transparency, we would go back to supporting it, because we think it is the foundation for a national catastrophic drug plan.

That's where we're at. Does that answer the question?

● (1705)

[*Translation*]

Ms. Christiane Gagnon: Do you have anything to add? No.

I would like to ask a question and I do not know who should respond.

On February 22, 2007, the provinces and territories established a common oncology drug review called the JODR.

Is this the joint oncology drug review or is it another stage of the process? The provinces have just announced another stage called the joint oncology drug review and it will focus on oncology drugs. Could you respond?

[*English*]

Ms. Durhane Wong-Rieger: Quite frankly, I don't think we object as much in terms of what the common drug review does, and it isn't as if there's a complete duplication.

What's happened is that the common drug review has taken over a pharmaco-economic assessment that the provinces used to have to do anyway. Only a few provinces were able to do it. So what they said was, okay, let's bring it all together. As Karen said, it was a good idea in spirit; we don't need to have 17 jurisdictions doing this.

The provinces were then supposed to take up the information and make some decisions around the budgetary impact. That didn't happened, and that's a concern.

Now, regarding JODR, instead of the recommendation coming out of the CDR.... They're still going to do the assessment and go to each cancer agency to say, okay, do you want to list it, or not? The cancer groups got together and said, let's have one common process that in theory will pick up the recommendations from the CDR and take them to the next step, which is to look at what in fact our ability to do it is, based on the number of patients, etc. They would then make a common decision as to whether to list it, going towards a bit of what Karen was talking about, in terms of—hopefully—a national standard.

I think the problem is twofold. First, as you've heard over and over, the CDR uses a very narrow process, so very few drugs actually get recommended. This is a problem for cancer patients, and certainly for some of us who are looking at the rare cancers.

This goes back to Steven Fletcher's question. You used to get very advanced and very good expertise from places like B.C. They said, we are going to disregard that; obviously this is not a good recommendation that the CDR is giving us. We're going to go ahead and list it.

Where you have some good expertise provincially, you get some uptake. You also get some of the ability to leverage and play one off the other, etc., except that this is not the way you really want to run a drug plan. But that has happened.

In theory, is JODR a good idea, a bad idea, or a total duplication? Not really. On the other hand, in practice, you get bad recommendations coming out of the CDR.

With JODR, it's the same as with some of the provinces. You still have to go back and do some other kind of reassessment.

For instance, in Ontario, we know that the Committee to Evaluate Drugs does kind of a first level of what the CDR does. They don't just take it and say, thank you very much, good job, and we'll sort of move with it. They do their own bit of pharmaco-economic assessment.

So there has been duplication. In theory, if they had more confidence in the CDR, they would be able to pick it up.

Alberta has announced that they're not going to do that anymore. Alberta said, we will take the recommendations that the CDR gives us and implement them. I think patients are really frightened about that, because the recommendations coming out of the CDR are so lousy.

In some respects, the hope was...you get to Ontario, and sometimes you can have some hope that they will make a more enlightened decision, or that JODR will make a more enlightened decision. We've seen that happen, even with rare drugs. Some were turned down by the CDR, and the province said it would pick them up.

The problem is twofold. One is a lousy process coming out of the CDR, and there is a lack of confidence among the provinces in terms of what to do about it.

So there are still two steps of the process that would need to be done, but the problem is that there's a huge amount of overlap in the middle. Would one seamless process be better? Probably.

● (1710)

The Chair: Thank you very much.

Mr. Fletcher, then Ms. Brown.

I would remind the committee that we wanted to go through an in camera session to deal with the steering committee meeting that we had yesterday

Mr. Steven Fletcher: I have two questions. I would like both parties to answer the first, and then the final question is for the Canadian Diabetes Association.

First, with respect to the suggestions for improving the transparency and accountability of the CDR, you offer that all interested parties could provide CDR with recommendations of qualified reviewers for its consideration. Can you share with us what kinds of measures should be implemented to ensure that the process is free of conflict of interest prior to the initiation of the review? How do you think reviewers should be chosen?

Question number two is for the CDA. I gather that the CDA disagreed with the recommendations that the CDR made on four specific diabetes drugs. Could you be a bit more specific about why you think the CDR erred in its consideration of these drugs?

What I want to know is whether the objection is based on the concept of CDR-type reviews and reimbursement recommendations, or the manner in which CDR conducts its reviews.

Dr. Karen Philp: Can I answer the last one?

Basically, our objection is to the process. We have never, and will never, advocate for a specific drug. We have never asked CDR to re-examine drugs they've made a recommendation on, but over the last year and a half we have used the one drug that is recommended in our clinical practice guidelines to have some of the discussions around surrogate markers and all these other issues. We disagree with the process of CDR. Their recommendations are their recommendations.

On the process around the reviewers, right now the common drug review contracts reviewers to go through the literature and the clinical trials and draw up a summary of what the science says. Those people are confidential. That's fair enough. That's good. But you can never find out who they are, and you can never have the confidence that they're asking the right people to undertake these contracts.

We're suggesting that organizations like ours could be invited on an annual basis to give them a list of qualified experts on diabetes or endocrinology or even meta-analysis. It goes into a pool. They continue doing it the way they do currently, which is to look for the best-qualified person for the drug they're going to be examining. They contract that person. It doesn't have to be made public at that time; they just continue doing what they're doing. After they've made their recommendation public, a year later, without tying the individual to the study, they publish the names of those people they consulted over the last year. Then we can say they used them. It would give us a better sense of confidence that they're using the right people.

Ms. Durhane Wong-Rieger: We would actually take the process a whole lot further.

I don't know if people here recognize that Canada is probably the last bastion of these closed-door meetings. If you look at the U.S. FDA, when they have hearings around new drugs, they're televised, for goodness' sake. You can come in and testify at them. When the EMEA holds its reviews, they're open to patients and they're open to the public. You can actually sign up and be heard, depending on the particular drug, etc. Unfortunately, I think Canada remains in some kind of a backwater in terms of openness, transparency, and accessibility. To me, transparency means opening the doors and inviting people in.

Somebody mentioned that they understood we had the opportunity to make an appeal to the common drug review on the Fabry issue. I said no, we came in with pickets and the TV cameras and we kind of stormed the offices while they were having their meeting. We made enough of a fuss that Jill Sanders actually held a meeting with the patient groups. She insisted that we had no opportunity to see the committee members, but that she would listen and take our information to the people there. That is not a meeting. That's not transparency.

Transparency means having open access. If you want to have confidence in the process, open it up. Let people come in, and let people participate. I think that's the only way we're going to end up with a truly accountable process. The CDR says that it will publish minutes. That's much too late—after the fact. We know you can make minutes look like anything you want them to look like.

We all know what in camera sessions look like. If there's something that's truly confidential, close the doors. That's fine, nobody objects to that. But for goodness' sake, we have to get out of the dark ages and make the drug review process a truly accountable one.

Health Canada says they're going to try to do it, but they can't get the regulations to change in order to do it. Fine. We encourage them —

● (1715)

Mr. Steven Fletcher: How do you choose the reviewers?

Ms. Durhane Wong-Rieger: How do you choose reviewers to sit on the committees?

Mr. Steven Fletcher: Yes.

Ms. Durhane Wong-Rieger: I think there should be an open nomination process. I think everybody should get a chance to nominate people. In fact, the selection process should be open also, so all the stakeholders are able to participate. That's the only way you have true transparency: engage people in the process and make the process openly available to everybody.

The Chair: Thank you very much.

I want to thank you, witnesses, for coming forward and for your passion about this issue. We've heard a considerable amount on both sides, and we'll hear more as we continue this study. I want to thank you for coming.

Now, if there's no objection, we'll move in camera and finish up the meeting.

[*Proceedings continue in camera*]

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