



House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 060 • 1st SESSION • 39th PARLIAMENT

EVIDENCE

Wednesday, June 6, 2007

—
Chair

Mr. Rob Merrifield

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

<http://www.parl.gc.ca>

Standing Committee on Health

Wednesday, June 6, 2007

• (1535)

[English]

The Chair (Mr. Rob Merrifield (Yellowhead, CPC)): We'll call the meeting to order.

I want to thank the members, the ones who are here, for being here on time. The others I'm sure will be here very shortly.

We're into our last meeting with witnesses on the study on the common drug review, pursuant to Standing Order 108(2), a study on prescription drugs, the common drug review.

We want to make sure that we let everyone know and realize that this is leg one of a study on prescription drugs. We'll be getting into further studies after we issue a report on this. This is our last set of witnesses on the common drug review before we discuss and present the recommendations and a report to Parliament.

To wrap this up, we have with us John Wright from the Conference of Deputy Ministers of Health. It's good to have you here as co-chair and as Deputy Minister of Health, Government of Saskatchewan. And from the Canadian Agency for Drugs and Technologies in Health, it's good to have Jill Sanders, chief executive officer, with us. You're the two presenters.

We'll start with Mr. Wright. The floor is yours.

Mr. John Wright (Co-Chair and Deputy Minister of Health, Government of Saskatchewan, Conference of Deputy Ministers of Health): Thank you, Mr. Chair and members of the committee. I am indeed pleased to be back before you to assist in your final deliberations.

Before I begin my formal remarks, I wish to advise the committee that, as I'm sure you can appreciate, Dr. Sanders and I are neither of us in a position to make any commitments here today to you. However, we are certainly happy to listen to your thoughts, your words of wisdom and suggestions and recommendations, and take them back to the Conference of Deputy Ministers for their deliberations.

Mr. Chair, you and other members of the committee should be in receipt of a letter I sent you dated June 6. I would like to take this opportunity to read that letter into the record as part of the formal presentation on behalf of the Conference of Deputy Ministers of Health.

Over the course of the seven hearings held by the Standing Committee on Health related to the common drug review, there have been a number of themes continuously repeated and reinforced by both the pharmaceutical industry and their patient advocacy partners.

I believe these themes or messages, as portrayed, are inaccurate and misleading. I wish to correct these inaccuracies for the committee in five specific areas: ownership, accountability to Canadians, CDR transparency, duplication of process, and compliance with CDR recommendations.

I go to the first item: ownership.

The committee has been led to believe that CADTH and the CDR are not "owned" by anyone and as such, are not accountable. This is not appropriate.

The CDR is owned by the 13 provincial/territorial deputy ministers of health and the federal deputy minister of health that established it.

As stewards of their respective health care systems, these deputy ministers take this ownership and the work of CDR very seriously and they report back regularly to their elected ministers of health. Under this governance structure, CADTH and the CDR are very much accountable. I quote from the presentation I made to the Standing Committee, which states the federal/provincial/territorial position: "We want to assure you that CADTH, which is owned and governed by the Conference of Deputy Ministers of Health, is fully accountable to the CDM. In fact, in our opinion, CADTH is one of the most accountable national agencies existing in Canada today."

The second item is accountability to Canadians.

The CDR is not failing Canadians. In fact, through the rigorous, objective, and independent information obtained by the CDR, governments are able to make decisions that protect the public from harm, ensure improved health outcomes, and contribute to the long-term sustainability of Canada's health care system.

The Canadian public, as patients and taxpayers, expect nothing less of their governments in determining which drugs should be made available through the publicly funded drug benefit system.

Canada has faced drug recalls that have harmed Canadians. Governments must do whatever it takes to manage such risks. The CDR contributes to this goal, it is working, it is helping Canadians, and it is here to stay.

The third item is CDR transparency.

Industry has consistently attacked what it views as a total lack of transparency in the CDR's processes. This is far from the truth. To my knowledge, the CDR is the only drug reimbursement committee in Canada to make the reasons for its recommendations publicly available. This is a significant improvement from what existed prior to the establishment of the CDR.

The CDR continues to set new transparency standards for drug reimbursement in Canada and abroad. Based on the 2005 evaluation of CDR, further steps have already been taken to improve transparency. Chief among these was the appointment of two public representatives as voting members on the Canadian Expert Drug Advisory Committee. In addition, with the CDM's new funding, CADTH is implementing plans this year to produce lay versions of CDR recommendations, the reviews upon which these recommendations are based, and to publish the minutes of the CEDAC meetings.

While the CDM wholly supports calls for greater transparency in the CDR process, the fact is that greater transparency should be a two-way street. For example, we would recommend that drug companies make their submissions to the CDR public. Greater industry transparency could be achieved by making the protocols of all studies available so that comparisons can be made with the final clinical results. We also suggest that the financial relationships between pharmaceutical companies, the disease-oriented groups they support, and those who develop clinical practice guidelines should be fully disclosed.

• (1540)

I go to the fourth item, duplication of process.

The committee has been told repeatedly that the provincial and territorial drug plans repeat the work of the CDR. This is a gross misrepresentation of the facts. I am aware the committee has received individual submissions from most provinces. In those submissions, the provinces clearly state that they do not duplicate the work of the CDR, rather they consider the CDR recommendations in light of their own jurisdictional priorities, needs, and resources. The rigorously derived clinical and cost-effective evidence the CDR provides, combined with the other considerations, is an essential step in the drug plan coverage decision-making process and will continue to take place.

Prior to the CDR, the pharmaceutical industry played the provinces against one another. They would attempt to have the drug approved for coverage in one province and then apply pressure politically in the other provinces. This was not in the best interest of Canadians. With the CDR providing the same high-quality evidence and advice to all drug plans, industry no longer has this option open to it. Instead, through intensive lobbying over the last year, they've decided it is in their best interest to make the CDR look as though it is not working. You have heard directly from the provinces—CDR is working and it is meeting the objectives set out for it. The CDM is steadfastly confident it will continue to do so.

With respect to the fifth and final element, compliance with CDR recommendations, the individual submissions made to the committee by the provincial drug plans clearly state that their decisions are in compliance with the CDR recommendations. A detailed table identifying all drugs reviewed by the CDR and the level of compliance by jurisdictions is attached to my letter. It shows there is

a 90% compliance rate with the CDR recommendations across all jurisdictions, and the deviations relate to specific listing conditions rather than a complete reversal of the recommendation. Given that the funding of drugs under provincial drug plans is entirely the decision of each province, a compliance rate of 90% is very high. In fact, the CDR offers the opportunity to move toward even greater standardization in drug coverage across jurisdictions, which is a publicly stated objective of the Conference of Deputy Ministers of Health.

The message being conveyed by industry is that there is a lack of compliance with the CDR recommendations. Let the facts speak for themselves.

In closing, the Conference of Deputy Ministers of Health wants to thank the standing committee for giving it the opportunity to set the record straight. The CDM fully supports the CDR as an invaluable service to Canadians. As the owners of the CDR, the CDM will be interested in the observations brought forward by the standing committee.

Thank you, Mr. Chair.

• (1545)

The Chair: Thank you very much.

Now we'll move on to Dr. Sanders.

Dr. Jill Sanders (President and Chief Executive Officer, Canadian Agency for Drugs and Technologies in Health): Good afternoon, Mr. Chair and members of the committee.

I'd also like to thank you for inviting us back for a second appearance, and I hope we can help you and contribute further to your study. I am Dr. Jill Sanders, the CEO and president of CADTH, and I'm joined today by Mike Tierney, vice-president responsible for the common drug review, here to answer any additional questions.

As Mr. Wright has already noted, over the past few weeks this committee has heard various points of view from a wide range of groups and individuals regarding the common drug review. It continues to be our position that the CDR program is not only working but it is working very well, and this position, as you've just heard, is supported by the federal drug plans, the 13 provincial and territorial jurisdictional stakeholders, and the majority of the independent experts who have appeared before you.

Yes, there are challenges in this complex and crucially important element of the drug reimbursement continuum in Canada, but I am pleased to note that throughout the past three-year history of the common drug review, it has shown it has made changes and it will continue to evolve to meet the challenges on behalf of Canadians.

I'd like to take a minute just to reiterate the critical elements, the critical stages of the CDR process, because I feel this is important to provide context for some of the other remarks I will be making.

As you know, the process starts with a drug manufacturer making a submission for their new drug to the CDR, and that includes clinical data and an economic evaluation.

The CDR program then establishes a review team of both internal and external experts that include clinical specialists with direct expertise related to the drug under review. This review team is engaged at all stages of the review process. Using vigorous and universally accepted processes, the review team conducts the independent systematic review of the available published and unpublished clinical evidence, and it appraises the cost-effectiveness of the drug, including both cost and value to Canadians, based on the economic model provided by the manufacturer.

The manufacturer is then provided with a copy of the reviews for comment and the CDR responds to any of the manufacturer's comments.

CEDAC, which is the independent committee that makes the recommendations comprising its clinical and scientific experts and two public members, reviews the noted materials and makes a listing recommendation. The members of that committee are nominated and selected by a national nominating committee, which ensures a balance of expertise, including medical, scientific, clinical practice, economic and evaluation expertise, and public representation. The membership of CEDAC is not selected along geopolitical lines.

CEDAC itself may also choose to call upon some experts who may not have already been called to the process, and they may also ask for additional information to be brought forward if they feel there is a need.

The CEDAC recommendations and reasons are sent to the manufacturer and the drug plans in confidence, and we have what we refer to as an embargo period, during which the manufacturer may request a reconsideration based on specified criteria and the drug plans can ask for a clarification. The final recommendations and reasons are sent to the manufacturer and drug plans and released publicly, or if a reconsideration is requested, CEDAC undertakes this process.

I hope you find this quick summary helpful in demonstrating very briefly that the CDR process affords equal opportunity to all parties to have extensive input into the process—the manufacturer, the drug plans, the experts, and the expert advisory committee that comprises some public members.

This notwithstanding, it is still important to ask if there is room for more improvement. Our response would be yes, of course. In fact, under the leadership of Minister Clement, the co-chair for the FPT Ministerial Task Force on National Pharmaceutical Strategy or the NPS, many of the areas of improvement sought by those appearing before this committee have been identified in the NPS report that was issued last September.

This NPS report sets out clear recommendations, all of which are aimed at further harmonizing reimbursement decision-making among the federal, provincial, and territorial jurisdictions and thereby supporting more consistent access for Canadians to safe and effective drugs.

The framework for action outlined in the NPS report will guide much of the future work for CDR. Nonetheless, we continue to be open to exploring different avenues for improvement of the ongoing work on behalf of Canadians.

• (1550)

Chief among these is the issue of increased transparency. The CDR has, as Mr. Wright has just noted, set new standards of transparency for drug reimbursement in Canada and internationally. We still continue to make enhancements in transparency. As Mr. Wright has noted, work is well under way to implement the initiatives arising from the evaluation of fall 2005.

In addition to these concrete measures already in progress, we remain open to other possibilities to increase transparency and will take forward options for consideration to the participating drug plans. These may include, for example, consideration for industry, patients, and other stakeholders to play a role in the CEDAC process, and a review of the current reconsideration, or what some would term “appeal”, process.

It is important when considering these potential changes that the aggressive CDR timelines, which facilitate timely patient access and have all been met to date, are not compromised. In addition, there are cost implications, and these must be evaluated with the participating jurisdictions.

It is equally important to note that transparency must be applied to all sides of the equation, as Mr. Wright has noted, if we are to improve on current processes. In other words, and as briefly mentioned, industry submissions to both Health Canada and CDR should be made public. The justification for the price of individual drugs should be provided, and patient advocacy groups and those who develop clinical guidelines should disclose the nature of their relationship with the industry.

A second area I would like to speak about is the concern expressed by the pharmaceutical industry and their patient advocacy partners regarding access to innovative drugs and drugs for rare diseases. It has been said that CDR is a barrier to access of new treatments for patients. The fact is that in the five years prior to CDR, the largest drug plan in Canada—the Ontario drug benefit program—approved approximately 44% of the drugs they reviewed, which is just slightly lower than the 50% average that CDR has to date. These numbers are similar enough within the statistics to be considered very equal. The drugs recommended by CDR have also included new biologics for rheumatoid arthritis and psoriasis, seven HIV/AIDs drugs, three cancer drugs, and a new drug for life-threatening infections. In other words, the facts do not support the stated claim that CDR is a barrier to new treatments.

Further to the matter of access, I know you're aware that comprehensive recommendations to address this issue were contained in the NPS report. We will continue to work with the NPS to achieve its stated objectives pertaining to increased access, including a common national formulary; a national framework for expensive drugs for rare diseases, which we would like to see developed sooner rather than later; and post-market surveillance.

Once these directions and policies have taken place, many of the concerns you've heard about in the course of your study will have been addressed. However, you have been led to believe that CDR is the root cause of all of these issues. This is simply not true. The CDR is just one player, and as I believe you'll appreciate, it will take all of us working together to address these important issues. For its part, CDR is very willing and would look forward to continuing to work with the industry to establish how clinical trial evidence and economic analyses for drugs serving small populations can be best produced and then utilized in the drug reimbursement decisions. In other words, if we work together, it will be to everybody's benefit.

A third area of criticism you have heard repeatedly is that CDR is only about cost containment. Again, I feel it's necessary to set that record straight. The health outcomes of the target population group of the drug in question are of paramount importance when CDR undertakes a review. Cost-effectiveness is considered only once improved health outcomes have been demonstrated. And to be clear, our cost-effectiveness assessment does look at other costs within the health care system, such as doctor visits and hospitalization. And importantly, CDR does look at improvement in survival and quality of life for Canadians.

You've heard the testimony of at least two independent international experts that Canada is a recognized world leader in how it conducts its drug reviews because the CDR focuses on costs less than all countries except the U.K.

• (1555)

When Steve Morgan from the University of British Columbia appeared here as a witness, he responded to the statement that was made, that CDR is solely preoccupied with cost containment, and I quote: "Although CDR is criticized for that, I think it's patently incorrect, because Canada is one of the exceptions to the extent that it focuses on science rather than economics."

At the end of the day, what the analysis must show is whether a new drug is clinically superior to existing comparable therapies and whether it represents good value for Canadians and the health care system. It is the full picture that is assessed, and we believe this is what the public, as taxpayers and patients, would expect.

The last area I will touch on relates to timely access. The CDR continues to meet the aggressive timelines established for it, and we're not a barrier to access. The CDR process currently makes up about one-third of the total time from a submission to Health Canada for licensing to a listing decision within a public drug formulary. CDR has no influence or control over the Health Canada licence approval timelines nor the drug plan decision timelines.

This said, we are continually looking at ways to build more efficiency into our system, and as a result, for example, CDR will continue to streamline its processes for less complex drugs. We will continue to work with Health Canada on collaborative review processes, and we will continue to encourage industry to make their submissions to us in a timely fashion.

These are just the beginnings of initiatives we at CADTH intend to carry out. As I've already noted, throughout the short history of the CDR, it has been shown that we have evolved and will continue to evolve to meet new challenges on behalf of Canadians.

If there has been one unifying thing during the past few weeks of often conflicting presentations, it is that the demands placed on Canada's publicly funded health systems in Canada are enormous. At CADTH we understand that achieving the balance of optimized care, accessibility, equity, affordability, and sustainability for all Canadians is every government's goal. This naturally means that difficult decisions must be made throughout the system. The CDR has played a positive role in assisting with the critical decision-making around pharmaceuticals.

At the recent CADTH symposium, Steven Fletcher, Parliamentary Secretary to the Minister of Health, addressed the reception on behalf of Minister Clement. Mr. Fletcher noted, and I quote:

Canada's new government is committed to supporting work to ensure that emerging technologies are not only safe but also effective and cost-effective. While most new drugs and technologies hold significant promise, it is important that we invest wisely in those products that can bring the greatest improvements to the health of Canadians.

We couldn't agree more. This statement speaks to the very core of CDR and its value to the Canadian health care system.

Before I conclude, Mr. Chair, I would ask if it's possible for you to take a few moments to tell us what the next steps are, the timelines, and what expectations you might have from us as the process moves forward.

Finally, thank you very much for your time. Thank you once again for inviting us back. As always, we're happy to answer questions. Thank you.

The Chair: Thank you very much.

We'll now move on to the question and answer period. We'll open the floor to Ms. Susan Kadis.

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

Thank you for your presentations today.

I'd like to ask specifically, initially, Dr. Sanders to tell us a little bit about how the recommendations are made public. I know we've touched on this before, but could you elaborate on that, and on whether it's just the actual recommendations—the decision—that's made public, or whether, as is the case in the U.K., they're giving much more information, as you noted, justifying why that particular decision has been made?

What I have gleaned from a lot of the witnesses, and I think others here have as well, is that this frustration seems to be significantly related to a lack of information and understanding. Of course, you can't have understanding without information, and it is completely related to the accountability of any process.

What are you presently making available to the public?

• (1600)

Dr. Jill Sanders: I'm going to ask Mr. Tierney to answer the question, but also to refer to what we're about to implement.

Thank you.

Mr. Mike Tierney (Vice-President, Common Drug Review, Canadian Agency for Drugs and Technologies in Health): Currently we make public the recommendations, the key reasons for those recommendations, and a summary of the other information considered by the committee. That document is typically one and a half pages to two pages long. It would provide details concerning the design of the clinical trials and the results of the clinical trials, as well as a comment on the economics and cost-effectiveness of the drug.

We realize—and this in part was addressed in the evaluation of CDR done in 2005—that there can be more transparency. In the coming year, we will be publishing more in-depth reviews of the committee considerations, and those will probably be in the range of 15 to 20 pages, to summarize the clinical and economic aspects of the drug in question.

Mrs. Susan Kadis: Along those lines, how would you characterize the information that is currently being put out there publicly? Would you say it's of a more general nature, or more summarial or superficial, and you would be looking to giving more depth and detail and elaboration down the road?

Mr. Mike Tierney: It will certainly be more in-depth and more detailed. Right now there is technical information and numbers—i.e., the percentage of patients who respond to a certain therapy, any changes in morbidity, mortality, in percentages—but it's more like an abstract of the study. In future there will be much more detail provided.

As well, the information is presented right now in quite a technical format. It's written for the drug plans and for health care professionals. Again, in the coming year we'll be making available lay versions of those reasons for recommendations.

Mrs. Susan Kadis: What about in terms of membership and participation on the decision-making bodies of the CDR in particular, in terms of expanding that? Is that something you would be considering? Recent testimony seemed to be fairly consistent that various groups would like to have some participation and definitely more input into the decision-making process itself.

Mr. John Wright: If I may, on behalf of the council of deputy ministers, that's something we would look at and take under advisement or recommendation. Certainly we've added, as a result of the 2005 review, two public representatives to the review committee.

I certainly wouldn't want to get into a situation whereby we had advocacy groups as members of the committee. We need to keep the independence of this group, the professionalism of this group, quite clear. But we'd look at it, as long as we didn't end up in situations where there would be foxes in henhouses.

Mrs. Susan Kadis: Also, in terms of first-in-class drugs, one of you mentioned that you're not providing a barrier to new drugs and therapies, as some have maintained. Those concerns were put forward at various times along the way in our testimony. The impression I was getting was that it's a very low level of first-in-class drugs being recommended for listing.

Is that inaccurate information, then, that some have suggested to us?

Mr. Mike Tierney: First of all, it's difficult to agree on what are first-in-class drugs. One of the ways we've tried to analyze this is that manufacturers can submit to us a drug for priority review on clinical grounds. A drug that the manufacturer believes to be available to treat a very serious or life-threatening condition, for which no other treatment is available in Canada, you could consider to be a first-in-class drug.

When we've looked at those drugs that we've reviewed and the percentage of those that have received a positive recommendation, it's about the same for all of the other drugs. It's around 50%. So we don't believe there's a difference in how we review those drugs that get priority review.

Mrs. Susan Kadis: To all of you, or as many as we have time for, would you say that you'd acknowledge that some, anyway, of the frustrations put forward by witnesses have been legitimate?

You say in here that it is “not only working but it is working very well”. That would suggest that you don't think there are too many significant issues associated with it, going forward, that it's on pretty solid ground. I guess I'd like to hear if you believe or acknowledge some of the concerns that have been raised since we've been hearing this issue. It's been quite a while now, and it's been fairly extensive and, again, fairly consistent with some of that frustration.

• (1605)

Mr. John Wright: I have not reviewed all the transcripts, all the information, but on what I have been informed of, I see no legitimacy to the issues that have been brought to my attention. The Conference of Deputy Ministers discussed this as recently as two weeks ago, and briefly again last week. We haven't seen legitimate objections to the current CDR process.

Mrs. Susan Kadis: It's a little bit of a discrepancy, then. I just heard today that you believe there are ways that it can be made and should be made more transparent even than what it is today—and more accountable.

Mr. John Wright: There's always room for improvement. There's always room to make it more transparent, more accountable. But the concerns that have been brought to my attention I don't view as legitimate.

Mrs. Susan Kadis: Finally, do you believe—up to this point, anyway—the CDR process is accountable?

Mr. John Wright: Yes.

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

The Chair: Thank you.

Madame Gagnon.

[Translation]

Ms. Christiane Gagnon (Québec, BQ): Thank you.

Mr. Wright, at the beginning of your presentation, you said that the CDR was an efficient organization. We understand that it is not our job to make recommendations on how to improve the understanding and efficiency of the CDR. However, witnesses have told us the exact opposite. Some even told us that the CDR should not even exist at all and that it has not improved the situation. Others chose their words more carefully.

Is it true that every single first category drugs and 75% of natural drugs were rejected when they were evaluated by the CDR?

Quebec has its own process. It seems to be much more open to these types of products than the CDR. Does this mean that our role is to make sure a drug is effective, but at a reasonable and fair cost? Does it then follow that this is not Quebec's priority? If you want to give patients what they need to improve their quality of life, don't you think that you are missing the main objective, which is to make the best products available to patients?

I would like you to answer these questions, Mr. Wright.

[English]

Mr. John Wright: Governments have multiple responsibilities and they have to balance them. They are responsible to taxpayers—that's where the revenue comes from. They are responsible to patients for the health care system.

When I was here last, many of the members of the committee spoke about the need for innovative therapies—well, of course, but also those that are cost-effective. One has to recognize the role of the taxpayer in this, otherwise in due course we'd all be bankrupt as governments. There's no question about that.

So I think this is a balancing of interests—the interests of the taxpayers, the interests of the patients, and of course let us not forget the drug companies. Many drug companies have their own particular interests.

As to the priorities of the Quebec government and how it conducts its business, it would be very unfair of me to begin to comment on that.

I appreciate that people have said to blow it up, and from their perspective perhaps that's correct. But here we have 13 provinces and territories and a federal government that have come together in a unique relationship to build a process that we consider extremely promising—one that works and balances the interests of the patients and the taxpayers to provide innovative therapies that are cost-effective to the people of this great country.

• (1610)

[Translation]

Ms. Christiane Gagnon: Some witnesses told us that when a province informed them that the CDR had rejected their application, they didn't know to whom to turn even if that drug worked better for certain patients. You keep on passing the buck. Since people can't appeal their cases to a tribunal or an independent committee, do you think we should recommend the creation of such a body?

[English]

Mr. John Wright: Let us remember what the CDR does. The CDR makes recommendations to provincial and territorial govern-

ments. It's up to the province to accept that recommendation or reject it. In Saskatchewan we have an extremely good record of accepting the recommendations of the CDR, but in some cases we've said no. We've gone in a different direction for socio-economic, political reasons.

If people have a problem, it's not so much with the CDR per se; at the end of the day it's with the province or the provinces. I certainly welcome at any time any patient, any advocacy group, or even any drug company to write me a letter, come to visit, and state their objections. That's what provincial governments do, and they do it very well. Certainly there are appeal mechanisms within Saskatchewan and in most, if not all, other provinces and territories.

So please remember again that CDR simply makes recommendations to the provinces, and it's up to us to accept or reject them.

[Translation]

Ms. Christiane Gagnon: It seems that rare or orphan disease haven't been properly addressed since there is a lack of data. Some witnesses have told us that it might be a good idea to look at international data. That way, we would have a better idea of the effectiveness of a product.

Do you think it would be a good thing to increase our consideration of certain drugs? Or should we simply be more open-minded about ways to treat rare or orphan diseases?

[English]

Mr. John Wright: Expensive drugs for rare diseases are a unique creature. The provinces and the federal government are dealing with Fabry's disease, and that's the one that's been most public. We've come up with a made-in-Canada approach to dealing with this. In the next three to ten years we're going to see an awful lot more of what I'll simply call designer drugs, designed specifically for genetic diseases. Pompe disease is another example, and I could go on and on.

These are extremely expensive. They cost not \$10,000, \$20,000, or \$50,000 per patient; they cost hundreds of thousands of dollars per patient per year, if not \$1 million. As a consequence, all of the provinces have come together, including Quebec, to take a look at how best to approach this. As you so rightly point out, there just isn't enough evidence out there. Fabry's disease is a very good example. The drug for it hasn't been around a sufficiently long time.

We need to come up with some parameters around this that balance the interests of the taxpayers and the interests of the patients. That's why we have an awful lot of good work going on relevant to the national pharmaceutical strategy. In fact there's a subcommittee to look at this and how we should approach it.

That's the best answer I can give right at the moment. I'm certainly very open to recommendations and would love to consider recommendations on expensive drugs for rare diseases. But that doesn't really relate at this moment to the CDR itself. This is something the provinces are considering just slightly outside of the CDR process, because of the very unique qualities and nature of it.

The Chair: Thank you very much.

Mr. Fletcher.

• (1615)

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

Thank you to the witnesses for presenting today.

This is not directly related to the witness testimony; it's really for the committee's information. You may recall that a couple of meetings ago we had a witness from the Best Medicines Coalition talking about their position on CDR. I asked about their funding sources, because they did not disclose that in their material. It came out that they had about a \$250,000 operating budget. It was also very interesting that half their funding comes from the pharmaceutical industry and half the funding comes from Health Canada. I pointed out that when an NGO advocates for CDR to be transparent it would be helpful that the NGO be transparent as well.

Louise Binder, who was testifying on their behalf—and I'm quoting from the committee evidence here—said, “We're totally transparent about our funding.”

Well, the Monday after that meeting, in a variety of newspapers across the country, including the *National Post*, the *Montreal Gazette*, the *Times Colonist*, and other papers.... I'll quote what they said there: “...the Best Medicines Coalition receives 100 per cent of its funding from Canada's pharmaceutical companies—the very industry that stands to profit most from a governmental decision to approve new and expensive drugs for use and coverage in Canada.”

And then it goes on to quote an Alan Cassels from the University of Victoria saying that, “They're all conflicted. These groups are getting money from the very companies whose drugs we're talking about”. The article continues on and says: “Binder said the group actually receives all of its \$250,000 operating budget from the pharmaceutical industry. ... Although it received half its funding from Health Canada last year, it was an anomaly, in the form of a grant for a research project.” The claim was hardly totally transparent about the funding.

I'd like to draw to the committee's attention that we have to be wary of some of the groups that come to committee. I'm actually quite disappointed that this individual's organization, the Best Medicines Coalition, was not totally transparent about the funding. It would have been very helpful if they had disclosed at the outset where their funding came from. We would still have listened to their point of view.

My question to the witness, maybe Mr. Wright, is whether this been an issue in the past: groups advocating that may be conflicted in a financial sense. Perhaps you can provide some guidance to this committee on how to deal with these situations.

Mr. John Wright: Mr. Chair, many years ago I had the great honour of being a deputy minister of finance in the Government of Saskatchewan. Indeed, I don't think it matters if you're in health care or you're running a power company, as I used to do; or an insurance company, as I used to do; or a department of finance; you'll always find situations whereby individuals and companies and lobby groups come forward who are conflicted. They will, from time to time, finance fronts, to be blunt with you.

All you can expect in this world is for people to be honest. All you can expect is for people to be transparent. That's about the best you can do. I don't think there are any guidelines. I wish there were. I wish I had pixie dust or a magic wand every time a witness or an individual came to me in any of the roles I've enjoyed in my career.... But you're not going to get it.

So it's by luck and by chance, and hopefully people are transparent, like the CDR, and hopefully people are honest, like the CDR.

The Chair: Okay. I think that's the end of the time. I hope there's no pixie dust on that.

Ms. Penny Priddy.

• (1620)

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

I thought pixie dust came with the job, but apparently not.

Thank you to the witnesses for being here. Thank you both for your papers. They're both very good, though maybe that's just because I agree with them.

I have a couple of questions, if I might.

Dr. Sanders, you have really already spoken to this, but I just want to reaffirm that I'm understanding it correctly. I'm pretty careful about this.

I want to follow up on what Mr. Fletcher said and clarify what I understand Dr. Sander's paper to say. You're actually making the suggestion at the bottom of page 4 that patient advocacy groups and all the others involved with clinical guidelines should disclose the nature of their relationships with the pharmaceutical industry. You have made that very clear in your paper as well—just so we get that out. That is what you intended.

Second, it may sound like an odd question, but one of the criticisms we've heard—and it seems a bit odd to me—is that while the makeup of the CDR review teams is made public, whether you have an epidemiologist, hematologist, or whoever, the names of the individuals are not. I don't very often see committees made up of people whose names I don't know, so from my experience in ministries and governments and so on, I don't know how to answer the question of why people's names aren't made public.

The Chair: Does someone have the answer to that?

Mr. Mike Tierney: I would clarify that the members of CEDAC, our expert advisory committee, are made public, and their biographical sketches and conflict of interest disclosures are available and are on our website.

Perhaps what you're referring to are the researchers who develop the reviews for consideration by CEDAC. We do not disclose those publicly at this point.

Ms. Penny Priddy: I know. Why?

Mr. Mike Tierney: Because, one, the reviews are not disclosed publicly; and two, some of the researchers have actually told us that they would prefer to remain anonymous because they would be subject to lobbying.

Ms. Penny Priddy: I see. Okay. I'm not sure if I buy the reason, but I understand the reason.

Secondly, in previous meetings...and I think, Dr. Sanders, you have noted this. Mr. Wright, I don't know if you have or not. The CDR does look at improvement in survival and the quality of life of Canadians. I want to go to the phrase "quality of life of Canadians", which is on page 6 of Dr. Sanders' presentation. One of the things that some of us have asked for on a fairly continuous basis...and I gather we've asked ethicists if they have time to make a submission to us. I have remained very concerned that I don't understand the way CDR is able to look at the ethics, because as Mr. Wright states, we have drugs that may cost \$1 million per year per person. Is that cost-effective? Well, no, probably not; however, that doesn't mean they shouldn't have it.

When you talk about how you consider quality of life, can you tell me a bit about how you do that? You don't have an ethicist involved in those decisions, do you?

Dr. Jill Sanders: We're going to just talk a minute about QALYs, and that might help you, and then if you need further information I can take it further.

Ms. Penny Priddy: Yes, go ahead. I've heard about QALYs.

Mr. Mike Tierney: In terms of the assessment of quality of life, many of the clinical trials that are done with new drugs now include measurements of quality of life that the committee will look at, and that helps in assessment of what's called the cost per quality-adjusted life, which is a frequently used standard to assess cost-effectiveness of the drug.

We don't have an ethicist on the committee per se, and as to how to incorporate an ethical framework into the decision-making process, I may turn to Mr. Wright to address that. The mandate of our process is to look at the evidence on the clinical effectiveness and safety and the cost-effectiveness, and to make a recommendation on that basis.

Ms. Penny Priddy: Except that's not what this says. This says that CDR also looks at improvement in survival and quality of life of Canadians. That's more than cost-effectiveness, it's more than cost-efficiency, and it's more than whether it's safe and so on.

• (1625)

Dr. Jill Sanders: The quality of life referred to in my speech is the medical quality of life terminology, not the socio-ethical values of the society. That is a challenge to all decision-making in health care. It's a very difficult challenge.

Ms. Penny Priddy: So you're talking about medical quality of life.

Dr. Jill Sanders: Yes, based on the scientific evidence, because CDR, as you know, is about the scientific and clinical evidence. Dealing with socio-ethical values, the willingness to take risk, the willingness to pay, and some of the things Mr. Wright just touched on, is outside of the CDR process. This is strictly clinical.

Ms. Penny Priddy: I know I'm done, but it seems to me that it's hard to separate out medical quality of life from other qualities of life. I guess that would take me back—and I'll leave it at this—to when Mr. Wright referred to the cost of rare disorders.

I think it was Steve Morgan, actually, who talked about looking at international data. Even looking at medical quality of life, it's pretty hard to do with a very limited database. Yes, it was Steve Morgan from UBC who talked about looking at more international evidence for this.

That still leaves me with this niggling little concern.

The Chair: You are done, actually.

Ms. Penny Priddy: I knew that!

Some hon. members: Oh, oh!

The Chair: Mr. Brown.

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

I have four questions, and I'll state them first and leave the remaining time for you to answer them.

Number one, in previous testimony before this committee, one of the things I heard presented was that one of the motivating factors or aspects of the creation of CDR was to bring together some more national standards and commonality in decisions. I wanted to know your opinion about if that's been achieved at this point, or if there's been progress towards that.

Number two, are there other examples internationally that you know of where there are two layers of review like this in the drug approval process?

Number three, when this process was created, was there a sense that decisions previously made by provincial bodies were inadequate or weren't based on enough information and that there was a lack of process? Are there any examples of decisions previously made that gave, I guess, cause for concern?

And my last question is that in many organizations—and it sounds, Mr. Wright, as if you've been involved in many—there is a tendency to do evaluations or independent reviews; it's a common business practice. Do you think the CDR would be well served if they took the opportunity or occasion to have an independent review to examine opportunities for improvement or changes?

Mr. John Wright: If I can, Mr. Chair, I'll take a stab at this. In Saskatchewan there's a famous phrase, "What the deputy minister meant to say"—and Dr. Sanders, I'm sure, will use that in a few minutes!

Voices: Oh, oh!

Mr. John Wright: With respect to an evaluation, Mr. Chair, we just undertook a very extensive evaluation back in 2005. It had a series of excellent recommendations, including recommendations about transparency, such that we added, for example, two public reps to the board. Certainly, I'm not sure another independent review would be required. There's been an awful lot of discussion here and a lot of good work by the committee members and the analysts, and others, I'm sure, and I'm looking forward to the final report. I think there's an awful lot of good work we can do going forward, rather than having a reflective independent review. That would be my perspective on the first item.

With respect to national standards, the CDR has actually brought things together in a number of ways. Using Saskatchewan as an example, we had our own groups that would do evaluations—mostly on the clinical effectiveness side of the equation. Saskatchewan is not a big province, nor is New Brunswick, nor is Manitoba, nor are others, and we couldn't bring the cost-effectiveness and economic analysis together. By pulling CDR to a national framework, we've achieved economies of scale in our ability to tap into national resources, and that's been very, very useful for the provinces and is leading us closer, I think, to that goal of a national pharmaceutical program, which could have a common formulary.

With respect to the two layers, I'm just going to comment that Canada is unique, let us not forget, as health care is the responsibility of the provinces. In many other countries, like the U.K., health care is the responsibility of the national government as well. Dr. Sanders will correct me, but I think that's in part why we have this two-layer bit of business here.

You mentioned what went on in the past and whether there were inadequacies, and so on. I can't speak to any of those, but I do know that with the economies of scale we've achieved, the quality of the review has now improved—certainly from Saskatchewan's perspective and, I'd like to think, from the perspective all provinces and territories, because that's why we're all participants in this.

• (1630)

Dr. Jill Sanders: I just want to clarify. The two layers you're referring to are the regulation of drugs and then the reimbursement. Those are the two layers? That's what I was checking on. Yes, you were talking about two different layers, I think.

Having two layers that deal with regulation and reimbursement is pretty standard practice across the world. Regulation gives permission to market and sell a product, which a citizen may buy, and that is separate from any system that has publicly funded drugs, whereby those paying for those publicly funded drugs would have a system in place to determine which of those that are marketable they will pay for. That's standard in any publicly funded health care system, yes.

The Chair: Thank you.

Carolyn Bennett.

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

Thank you for coming back, because I think we had a few questions that came, as you could tell, from the hearings. I think the committee wants to go forward, not backwards. I don't think

anybody wants to see the kind of collaboration Mr. Wright has talked about going backwards; we want to go forward.

What keeps coming back to me is, are we doing this upside-down? I was a family doctor, and I have great sympathy for the Best Medicines Coalition because it really did come together from a couple of groups that knew, because of their unbelievable networks, whether it was HIV/AIDS or cancer, that people were getting drugs in other places around the world that they weren't getting access to. This came from a real patient empowerment, networking, self-help approach, in terms of, "How come they can get this in Buffalo and I can't get it, and it may save my life?" The story around the kidney cancer drug upset us. That obviously was something about which the community felt very strongly.

If we were really going to move to a formulary, which is where we want to be, and with the way we would make these decisions, wouldn't we start with clinical guidelines first and then defy any government to not pay for something that's on a clinical guideline? This is about patient empowerment and saying the best drug for this is that. I would have assumed that the kidney cancer drug, Nexavar, or whatever it was, would have ended up in a clinical guideline if you asked a bunch of kidney cancer doctors what to do.

From the empowerment of patients who know what's happening around the world now, from the Internet, to actually pushing the medical profession to get going on clinical guidelines, to then making your jobs easier—because if it were in a clinical guideline, surely when the people who know the most about these diseases... Now we have some stupid extra cancer system, and we're worried that everybody else is going to want a separate system if we don't get this right. It has to be what's best for patients and what brings Canadians in line internationally.

I'd like to hear a plan for going forward. How do we get the clinical guidelines? Also, how are you planning to involve—

• (1635)

The Chair: Your time is up.

Ms. Christiane Gagnon: You've had your five minutes.

Hon. Carolyn Bennett: This is not funny.

It is the reason we're doing this.

The Chair: Yes, but we need a question fairly soon.

Hon. Carolyn Bennett: What I want to know is the plan for going forward and the plan for involving citizens and informed stakeholders like the physicians working in these special diseases.

The Chair: Okay.

Mr. John Wright: Let me try it very quickly at a high level, and then Dr. Sanders can pick up from there.

With respect to the clinical effectiveness, there are about 400 oncology drugs in the pipeline right at the moment, and each one of these has an approximate cost for treatment of about \$50,000 per patient. You work out the numbers, and in a little province like Saskatchewan, if you approved all of these clinically, it'd be about \$600 million a year incremental cost. We have to consider not just the clinical effectiveness but also the cost-effectiveness on this.

With respect to the go-forward game plan, there really is a great plan out there. The foundation currently is the CDR. It is CADTH, it is the CDR. Again, when I was here last time, we talked about the national pharmaceutical strategy. Saskatchewan is working on the common formulation. B.C. is working on expensive drugs for rare diseases. Alberta and Manitoba are working very closely on a catastrophe program. We've set up a new oncology review process, piggybacking off the Ontario system as a pilot for many of the provinces, given drugs that have come on, which have been very expensive, and we're not certain about their cost-effectiveness.

So the game plan at the end of the day would be, from the perspective of many provinces, let's have a national pharmaceutical system, number one. Number two, let's have the common drug review and let's incorporate oncology drugs into that review.

Dr. Jill Sanders: First of all, Dr. Bennett, I understand that the patient-based care is different from population-based care, and that is something that we have to be clear on. The decisions made around reimbursement must be population-based, not individual patient-based, as you know.

But the first point that occurs in CDR is clinical effectiveness. That is the first barrier, the first gate that a drug must pass before entering into the cost-effectiveness phase, if you like. At the cost-effectiveness phase, the CDR is asked to comment on cost-effectiveness. And as Mr. Wright has said, it is up to the provinces to decide either with a yes on affordability within that province, or on a no, that actually they can't afford it. But this comes back to sustainability.

The most recent statistics from CIHI, the Canadian Institute for Health Information, indicate that health care costs went up by between 55% and 60% between 1999 and 2006. But drug costs, in the same period of time, went up by 110%, so the percentage increase of drug costs over health care costs doubled.

I'm not making a judgment call on those numbers, but they're reality numbers that the provinces have to deal with. And yes, there may be savings elsewhere in the system from certain drugs, and we understand that, and so do the decision-makers, but in looking at the sustainability of the system, these are all matters that must be considered.

However, getting back to the common drug review, our job is to look first at patient outcomes. And with respect to the drug that you're referencing, it was the patient outcomes that were in question.

The Chair: Okay. Thank you.

Dr. Jill Sanders: Finally, perhaps I may comment on the joint oncology drug review. As Mr. Wright has indicated, it won't stay a separate system or a separate process. For now, the provinces were looking for something to get started with, and that was an efficient way of having a pilot, and it's a one-year pilot. At the end of the

pilot, the deputy ministers will decide, and the common drug review, or CADTH, is one of the options where that process may go. So it will take away the two....

The Chair: Thank you.

Monsieur Malo.

[*Translation*]

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

Dr. Sanders, a few moments ago, in your opening statement, you recognized that the process could be changed or improved. You said that we should work together to make these improvements and address these situations in a less antagonistic way.

I was just wondering how you would like all stakeholders to think more serenely and positively about these things, when you said in your statement that what other witnesses had told us was wrong, and that you wanted to set the record straight. I am convinced that if we were to call back the people who already appeared before us, they would perhaps also say that you are wrong.

Given everything we have heard so far about the drug review process and the process to recognize their effectiveness, we get the feeling that it will be difficult to find a common ground. I am simply wondering what solutions you have in mind to get everyone to pull in the same direction to provide patients in need with the best possible drugs, since they are probably the ones who are suffering the consequences of these disputes, arguments and misunderstandings.

• (1640)

[*English*]

The Chair: Do you have a question?

[*Translation*]

Mr. Luc Malo: Yes, I asked my question.

[*English*]

Dr. Jill Sanders: We, as a matter of course, do meet with patient advocacy groups. As a matter of course, we meet with industry and industry groups. So the process is already in place; it was started at the beginning for CDR. At the very beginning of CDR we had consultation sessions with both those groups, and we continue to talk to those groups.

There is a place for input from everywhere, but I feel I'm compelled to point out for the committee that the stakes for the industry are huge. The amount spent in Canada on drugs is over \$20 billion. On prescription drugs alone, it's \$17 billion. The stakes are huge. We all play different roles and we all play those roles to the best of our abilities, but we have to recognize we do have groups with very large stakes in this process.

The Chair: Okay.

[Translation]

Mr. Luc Malo: Can someone tell me what role ordinary Canadians should play in this process? Is there room for them? If so, should they play a bigger or a smaller role? Because, after all, ordinary Canadians are the ones who take their medication every day.

[English]

Dr. Jill Sanders: Perhaps you'll excuse me for a second. I sometimes bemoan the fact within our organization that millions of people watch *Canadian Idol*, but if we were to have a show that sought the opinions of all Canadians on their opinions around health care decisions and societal values, we probably wouldn't get even 5,000 people voting or even watching it. That it's a challenge is what I'm telling you.

Yes, I believe that societal values are something we'd all like to understand better. They move, they change—and I just mentioned willingness to pay, willingness to risk. All of these things are crucial elements, and capturing some measure into the process is tricky. We have two members on CEDAC who are public members or non-expert members chosen for being non-expert. But do two people represent the public? No. If we had a committee of 30, would that represent the public? No, not really. So it is tricky.

So where does the rubber hit the road? Well, it actually hits the road in the provinces, where the decision...and this is where Mr. Wright and his department do hear from the public on quite a significant level, I believe. So it happens through another way. We don't have a process where we can engage millions of Canadians to find out how they would act or behave or vote in a certain situation. However, we do know through the feedback, and deputy ministers then guide us with that information they hear from the public.

Do you want to add to that?

•(1645)

Mr. John Wright: I'd simply also add that one of the things we'll be trying through the CDR is to put some of these recommendations to the provinces in simplified language so that my father-in-law can sit there, read it, understand the rationale for the decision, and so on. That's one way of engaging and involving the public, putting very complex reviews into simple language.

Indeed, as Dr. Sanders has pointed out, at the end of the day the letters my minister receives or the letters the Minister of Health in B. C. receives, or others...the public is very much engaged, let me assure you.

The Chair: Thank you very much.

Our last questioner will be Ms. Bonnie Brown—and she doesn't really have a question, she has a small statement—and then we'll close this off. I have one quick question for you.

Mr. Steven Fletcher: Actually, Mr. Chair, I have a question as well.

Ms. Bonnie Brown (Oakville, Lib.): I just want to say that when you start talking about \$17 billion a year, I wonder how many Canadians realize those kinds of costs, that it actually outstrips the

military, which is one of our big responsibilities here. From that perspective, I don't think you can ever keep everybody happy.

So just by hearing you defend what you've been doing, I want to thank you. I consider the job you have is somewhat thankless, because the realities of the decisions you have to make are enormous. I think we have to be careful not to be swayed by the individual stories and the individual tales, which are very heart-rending and sad. But the fact is that we have to have these decisions made, and let's put it this way, I'm glad it's you and not me.

The Chair: Thank you.

One quick question, Mr. Fletcher.

Mr. Steven Fletcher: Mr. Wright, on the issue of transparency, you say that CDR is transparent. I have to say, in fairness, a lot of the push-back that we've heard from a lot of different stakeholders is that CDR is not transparent. Transparency includes how the decisions are made, what factors are included in that, who's making the decisions, the information from manufacturers, and so on. I think it would be helpful for the committee to get your point of view on that criticism, which I have to say I think is a fair criticism.

Mr. John Wright: Very quickly, Mr. Chair, let me say I understand the criticism, and there's always more that one can do. Let me assure you on that. I say, Mr. Chair, to you and to all members of the committee, we welcome the deputy ministers to take a look at mechanisms that can improve transparency; there's no question about that.

But we have gone a long ways since the review in 2005. We've added review processes; we've added public representatives; we've tried again to put things in simplified language; we're going to be publishing more and more on the CDR, instead of the one- to two-page abstract that Mike talked about, going to a 15-page....

If there's more that we can do, Mr. Chair, and you and your committee members have suggestions, certainly we'll take them into consideration as we move forward.

The Chair: Thank you very much.

Dr. Jill Sanders: Could I add to that?

The deputy ministers approved and have provided funding for us to publish the minutes of the CEDAC meetings. That will start in the fall. That is a fairly significant step toward answering Mr. Fletcher's question, I think.

The Chair: I have one question on behalf of the committee.

We have a statement issued on April 1, 2005, I think. It's a grant to the Canadian Coordinating Office for Health Technology Assessment, which is actually suggesting that there will be a planned audit and evaluation on the common drug review, a health technology assessment, the Canadian optimal medication prescribing and utilization service, those three or four things. The common drug review is there, supposedly to be issued by the end of June.

Can you tell me about that? This was actually news to the committee up until a short time ago. We were a little surprised that nobody had mentioned that this was happening.

•(1650)

Dr. Jill Sanders: In fact, the evaluation that is being referred to in the grant is the evaluation actually of the other funding for CADTH. So the specific programs that would be under that evaluation would be our health technology assessment program; the optimal medication prescribing and utilization service, which is called COMPUS; one other element that is specific, which is the liaison officers that we have across the country; and in general, an evaluation of the agency.

The Chair: It also says CDR.

Dr. Jill Sanders: Because the CDR was evaluated as recently as fall 2005, and because the implementation of those measures is only now rolling out, it is not part of the evaluation that will be delivered in June.

The Chair: Okay. That's information that we needed to know, because—

Dr. Jill Sanders: I understand. I can see the confusion.

The Chair: We didn't know how fast to come out with ours, because—

Dr. Jill Sanders: Yes, you're all right.

The Chair: We didn't want to get too mixed up in all of these reports on CDR.

I want to thank you very much for coming in.

With that, we will call this part of the meeting over, and we will move in camera to discuss the report.

Thank you very much.

[Proceedings continue in camera]

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

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

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

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

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