House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 047 • 1st SESSION • 39th PARLIAMENT

EVIDENCE

Monday, April 16, 2007

Chair

Mr. Rob Merrifield

Standing Committee on Health

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● (1535)

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon (Québec, BQ)): Good afternoon. I'm going to be chairing the meeting today, since the chairman cannot be here. We have our work cut out for us. Over the coming weeks we are going to be assessing the effectiveness of the Common Drug Review Program. We will be hearing briefs from the representatives of several organizations.

Today we will be hearing from industry representatives. Later we will be hearing witnesses from Health Canada, and the Canadian Agency for Drugs and Technologies in Health, as well as experts and patients' groups. This is in fact a topic of concern to various groups in the community that are involved directly or indirectly with prescription drugs.

The fact that today we are hearing industry representatives is not a strategic choice. It is simply due to the availability of those people who were willing to share their perspective with us. I hope that as the weeks go by the members of the committee will be able to form an opinion on these matters. I think that having access to drugs, and the best possible drugs, to treat patients are very important factors.

Before giving over the floor to the groups who are with us today, I would like to welcome Mr. Patrick Brown. He is replacing Mr. Dykstra who had to attend a hearing of the Committee on Justice and Human Rights.

I think that this committee is terrific. Today we will be hearing from four groups: Canada's Research-Based Pharmaceutical Companies, the Canadian Generic Pharmaceutical Association, AMGEN Canada Inc., and BIOTECanada. Each group will have 10 minutes to present their point of view on the effectiveness of this monitoring procedure for the acceptance of drugs. Before a province includes a drug on its list, a whole array of evaluations must be done. Your role is to enlighten us on this matter and to give us your advice, and ours is to evaluate the overall process.

I will now yield the floor to Mr. Williams. You are accompanied by Mr. Ferdinand, is that correct? The floor is yours.

● (1540)

Mr. Russell Williams (President, Canada's Research-Based Pharmaceutical Companies (Rx & D)): Thank you very much, Madam Chair.

Good afternoon, everyone. I am pleased to be here on behalf of Canada's Research-Based Pharmaceutical Companies (Rx&D).

The Standing Committee on Health plays a vital role in ensuring that wherever the federal government invests money to improve the health of Canadians, it is done in an effective, transparent and accountable manner.

We are pleased to assist you in your efforts to evaluate the effectiveness of the Common Drug Review, or CDR as it is commonly known.

[*English*]

We are, however, concerned when less than two business days before the hearings were to begin, the Canadian Agency for Drugs and Technologies in Health, or CADTH, issued a communiqué announcing a significant expansion of CDR. We have to ask ourselves if this usurps the work of the committee and your efforts to establish the true value of CDR.

Today I will make it clear to the members of this committee that the CDR process is, at best, a duplication and, at worst, a barrier for patients' access to medicines. I also believe it is unaccountable and lacks transparency. In short, CDR is fundamentally flawed.

Thirty percent of the funding of CDR and 80% of the funding of its umbrella agency, CADTH, comes from the federal tax dollars of hard-working Canadians. I would be more specific as to what these figures are, but we have found it almost impossible to do so. We have no idea how the federal government money is allocated, and this should be of great concern to us.

[*Translation*]

Innovative medicines and vaccines improve and save lives. They can prevent disease, reduce hospitalization and make our health care system more effective. However, to truly benefit from biopharmaceutical innovation, Canadians must have access to new medicines and vaccines as soon as they are approved by Health Canada.

[*English*]

One of the first steps of making a medicine available to Canadians is the Health Canada review. I would like to commend Health Canada for their efforts to reduce approval times and eliminate their backlogs, but these important gains are offset by CDR. This is counterproductive to patient health.

About 10 million Canadians are affected by CDR decisions through public drug plans, with the exception of Quebec, which, as you know, has chosen not to be part of CDR. Every time CDR says no to innovative medicine, it removes a treatment option for seniors, low-income families, and others who rely on these public drug plans. It is simply not right that so many Canadians are left behind.

[*Translation*]

Before a new medicine reaches a patient, it must be approved by Health Canada. Then CDR conducts its review, and each province and territory conducts its own review. This unnecessary duplication of effort means that patients are forced to wait longer for the medicines they need.

[*English*]

What we find incredibly troublesome is how CDR makes a negative listing recommendation after Health Canada has recognized the value of an innovative medicine. Let me repeat, these medicines have already been approved by Health Canada. But equally troublesome is the amount of time it takes provinces to list the drug that has received a positive recommendation from CDR.

Over the last three years, provinces have taken, and in some cases are still taking, hundreds of days to list these positively recommended drugs. Let me give you one of many examples of how CDR doesn't work in the best interests of patients. When Health Canada recognizes the value of an innovative medicine, it moves quickly and efficiently to ensure that the medicine is available to Canadians on a priority basis. This happened with a medicine known as Sutent, which is a new treatment found to be effective in battling against both gastrointestinal and kidney cancer.

Health Canada recognized the importance of this innovation to patients and fast-tracked it through a priority review. Within four months of approval by Health Canada, Quebec agreed to reimburse this new medicine for treatment of gastrointestinal cancer through the exceptional use program. Ontario also provided access to its patients suffering from gastrointestinal cancer.

What has CDR done? While the indication for gastrointestinal cancer was finally given a “list with criteria” recommendation at the end of March 2007—six months after Quebec made a decision to provide access to it—the CDR has yet to make a final recommendation for the kidney cancer indication. It means that patients are still waiting for access to a drug that was approved some eleven months ago by Health Canada.

Given that CDR is an added barrier to access, I would ask the members of this committee whether they think Canada needs three separate review processes for a single innovative medicine—Health Canada, then CDR, then the provinces.

● (1545)

[*Translation*]

Canadians should be the first to benefit from new medicines. An international comparative study done recently for Rx&D demonstrates this quite clearly. The authors of the study evaluated 50 listing recommendations by CDR with recommendations from other international peer agencies. They found that European countries recommend significantly more new drugs for listing than CDR recommends.

[*English*]

Madam Chair, it's the same molecule. It's the same science, but we have different outcomes. How can we explain this, and is this in the best interests of Canadians?

We believe the CDR places too much emphasis on cost containment and not enough on patient outcomes, but we do not need to look outside the border to find patients who have better access to innovative medicines. As mentioned earlier, Quebec is the only province that does not participate in CDR, and therefore they don't have that extra layer of duplication. They list more drugs, and patients are better off because of it.

In addition, CDR has added to the inequity in the access to medicines for Canadians. Simply put, the many Canadians who have private plans have far more choice and better access than those who are on public drug plans.

[*Translation*]

We, as a community, understand the challenges governments face to sustain funding for the health care system. We strongly believe that investing in new medicines is an investment in the health of Canadians and a stronger and more effective health care system.

[*English*]

Rx&D member companies also believe that all Canadian patients deserve access to the best therapies when they need them.

Madame la présidente, this committee decided to hold these public hearings, and I quote, “on the process used under the CDR to evaluate drugs and obtain your comments on the effectiveness of the CDR”. However, the agency overseeing CDR has already decided to expand, stating that it has met its objectives. In our view, this is not the case. Furthermore, it is not in the public interest to expand a process that clearly is not working.

CDR has had a regressive impact on patients' access to Health Canada-approved medicines. This is particularly true for medicines approved by Health Canada to treat serious, life-threatening, and severely debilitating illnesses and conditions under the notice of compliance and conditions policy. To date, CDR has made negative recommendations for all but two of those NOCC drugs. Therefore, Rx&D urges the honourable members of this committee to recommend to the federal government that funding for CDR be frozen immediately.

In the meantime, we urge the Government of Canada to conduct an independent comprehensive review of its objectives and the accountability, value for money, and health outcomes as they relate to CDR. We must build a better system that avoids duplication and delay and mixed signals. We believe that by taking this action the standing committee will provide a voice to millions of Canadian patients who are waiting too long for access to medicines because of CDR and because provinces are taking too long to make decisions.

Before concluding, Madam Chair, I would also like to make one quick comment about the recently created joint oncology drug review. I encourage the JODR not to make the same delays as the common drug review.

Canadians expect and demand the best health care in the world. Our health care system is part of our social fabric and our identity. Rx&D believes that we have been, and continue to be, part of the solution in improving the health of all Canadians. A process that limits choice or delays or denies access to the world's most innovative medicines is not the answer.

● (1550)

[*Translation*]

Thank you very much, Madam Chair. I will be pleased to answer your questions after the other presentations.

The Vice-Chair (Ms. Christiane Gagnon): The second speaker will be Mr. Jim Keon, from the Canadian Generic Pharmaceutical Association.

Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association): Thank you, Madam Vice-Chair.

I am President of the Canadian Generic Pharmaceutical Association. I'm going to make my presentation in English.

[*English*]

I would like to start by saying that we appreciate the opportunity to make comments before your committee on the common drug review. The Canadian Generic Pharmaceutical Association, or CGPA, is the national trade association representing Canada's generic pharmaceutical industry.

To give a little context to start, according to the Canadian Institute for Health Information, since 1997 Canadians have been spending more on drugs each year than they have on physicians. IMS, the industry source for data, reports that between 1997 and 2006, spending on pharmaceuticals rose from $6.8 billion to $17.8 billion, a 162% increase over the 10 years. It is a trend that will continue to grow as the population ages, as expensive new medicines replace existing ones and as drug treatments form a larger part of patient care. IMS predicts that sales of prescription medicines will grow at 7.5% annually, to reach $23.4 billion by 2010.

The generic industry plays a key role in the health care system. We provide safe, proven, high-quality medicines, and the Canadian generic industry helps maintain the sustainability of government and employer-sponsored drug plans. Generic drugs are used to fill more than 44.5% of all prescriptions in Canada, and yet they represent only 18.1% of the expenditure. As these figures illustrate, generic drugs provide excellent value for money in Canada.

I should start out by saying that generic drugs are not actually evaluated by the common drug review, and you should keep that in mind for my comments. However, we do have some views on the common drug review.

The CDR was established to serve an important function for Canadians. When new drugs are approved by Health Canada, a brand name manufacturer must show that the product for the disease, condition, or ailment for which it is to be prescribed is more effective than a placebo. It must also be proven to be safe, which is obviously a relative term, as all prescription drugs have side effects, some more serious than others. We have seen high-profile withdrawal of such drugs as Vioxx, Rezulin, Baycol, and Propulsid in the past several years.

As has been demonstrated time and again, just because a drug is new does not mean that it is any more effective or any safer than drugs that are already on the market.

The Patented Medicine Prices Review Board, PMPRB, appraises the therapeutic novelty of every patented medicine in Canada to distinguish breakthrough drugs from other medicines, and it publishes these appraisals in its annual reports. Between 1990 and 2003, the PMPRB appraised 1,147 new drugs. Of these drugs, 68, or only 5.9%, met the PMPRB's regulatory criteria of being a breakthrough drug.

What physicians, provincial governments, and patients cannot know simply from the fact that the product has been approved by Health Canada is whether or not the new drug is more effective or safer than drugs that are already on the market. For physicians who need to determine whether and under what circumstances they should be prescribing the drugs, for governments and employers who are trying to determine whether they should be paying for the drug, and for patients who might be prescribed the new drug, these are the most important questions. The common drug review was created to answer those very questions.

There have also been concerns expressed that prescription drug coverage in Canada varies from province to province. A drug might be covered by the government plan in one province but not another. Again, the common drug review is intended to be a tool for helping to address this patchwork of coverage by making recommendations to all provinces on whether or not the therapeutic improvement offered by a new drug justifies its additional cost.

Governments, physicians, and the public must have information regarding the relative safety and efficacy of the product versus other drug or non-drug treatments in order to make decisions about whether to prescribe and pay for these new drugs. Health Canada's current approval process does not provide that information.

I suggest that the spirit of the formation of the common drug review be extended to apply to generic pharmaceutical products. Closer federal-provincial cooperation on the approval and listing of generic pharmaceutical products would benefit patients, taxpayers, and even brand name companies.

When generic drugs are submitted for inclusion on provincial formularies—the list of drugs for which each province will pay—they have already been approved by an exhaustive evaluation process at Health Canada. Yet while Health Canada standards of review are internationally recognized, some provinces continue to operate their own redundant review systems. This needless duplication of the federal approval delays the entry of generic drugs and costs taxpayers millions of dollars every year as provinces continue to pay for higher-priced brand versions for longer than they should.

● (1555)

The approval of generic pharmaceuticals at the provincial level should be a quick and easy process. Once a provincial government has weighed the therapeutic value of a new drug against its cost and decided to pay for it, which they do with a new brand drug, the decision to add a generic—generally 12 or 15 years after the introduction of the brand—to its formulary should be clear. After paying for a brand drug for years while it is under patent protection, the government should start to save money at the earliest opportunity by listing cheaper generic versions as soon as they are approved by Health Canada. Because private sector drug plans often base their benefits on what drugs are covered by government plans, a faster process would also provide Canadian employers and consumers with better access to generic drugs, resulting in even more significant savings. This would also provide the budget headroom so that drug benefit plans could pay for more of the brand name industry's new drugs.

Thank you for your time and attention.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): We will now be hearing from Mr. Daniel Billen, Vice-President and General Manager of AMGEN Canada Inc.

[*English*]

Dr. Daniel Billen (Vice-President and General Manager, AMGEN Canada Inc.): Good morning, Madam Chair, honourable members of the committee. My name is Daniel Billen. I'm vice-president and general manager of Amgen in Canada.

[*Translation*]

I want to thank the committee for having invited me to this hearing and I am very pleased to have this opportunity to present AMGEN's viewpoint on the effectiveness of the Common Drug Review Program.

[*English*]

Too many of us in this room have family and friends who have suffered from cancer, kidney disease, rheumatoid arthritis, or other grievous illnesses. Many of those people are dependent on the government to provide medicine to deal with their disease.

At Amgen, our mission is to serve patients, especially those patients who suffer from serious disease.

Let me begin by telling you about how biotechnology is unique. It's a technology that uses living organisms to make new medicines instead of using traditional chemicals.

Biotechnology is a relatively new science, and advances in biotechnology provide unprecedented opportunities in medicine.

With this revolutionary approach that uses living organisms to make new medicines, biotechnology creates the potential to deal with critically unmet medical needs to treat cancer, multiple sclerosis, renal failure, and Alzheimer's, to name just a few.

The current biotechnology medicines are among the world's biggest breakthrough products—medicines such as Herceptin, Enbrel, and Neupogen. Today, 20% of all approved medicines are biotechnology medicines, and if we look 5 to 10 years ahead, that number will grow to close to 50%.

Let me now turn to Amgen and the impact on the patients we serve. Amgen is the largest biotechnology company in the world, and it prides itself on having served more than 10 million patients around the world for over 15 years. In Canada, half of our patients suffer from rheumatoid arthritis, and a quarter of our patients suffer from cancer or kidney disease.

If we look at Amgen's experience with CDR, it is the patients who have suffered the most. Over the last 15 years, Amgen has had five major medicines approved by Health Canada. Prior to CDR, all three of these medicines received wide public reimbursement across Canada. However, under CDR, zero out of the two remaining products received public reimbursement. Clearly, CDR did not improve patient access to Amgen's medicines.

Let us look at the facts from a global perspective. In an international study conducted by Rx&D in 2006, we can clearly see that Canada reimburses fewer medicines than other industrialized nations such as France, Switzerland, Sweden, the United Kingdom, and even Australia.

Let us focus on first-in-class medicines, or medicines that are the first of their kind. Of the seven medicines that came to market, the countries I just talked about on average recommended that five of them be publicly reimbursed. In Canada, zero of these medicines received a positive recommendation from CDR. Ladies and gentlemen, the picture on this slide is worth a thousand words.

CDR has been a fundamental failure. It has denied access to vital medicines. It puts Canadians at an overwhelming disadvantage compared to other modern countries. This denial of access is absolutely tragic for patients. It is unacceptable for us as Canadians.

So what should we do? We propose three practical, actionable, and deliverable reforms that could be implemented immediately: first, create a separate assessment process for first-in-class medicines; second, improve public accountability with public interest hearings and by making CDR subject to access to information requests; and third, establish an independent administrative appeal process for CDR recommendations.

● (1600)

Our common goal is to improve the human condition by providing patients access to critically important medicines.

Ladies and gentlemen, every day across this country patients hear the following words: "I'm sorry, there's nothing more we can do." Well, ladies and gentlemen, there is something we can do. Can we not agree here and now that our shared goal as a society must be—it must be—to put patients first, to make critically important medicines available to Canadians?

Thank you.

[*Translation*]

I will be happy to answer your questions.

The Vice-Chair (Ms. Christiane Gagnon): We have one last witness, Mr. Peter Brenders, president and CEO of BIOTECanada.

[*English*]

Mr. Peter Brenders (President and Chief Executive Officer, BIOTECanada): *Merci. Madame la présidente*, on behalf of Canada's biotechnology industry, I thank you and the Standing Committee on Health for conducting this important study of the process and effectiveness of the common drug review.

Today we would like to present to the standing committee the challenges that Canada's biotechnology community has faced as a result of the CDR process in bringing innovative new therapies to Canadian patients. Our recommendations, designed to bring Canada up to international standards of patient access, include having the CDR recognize the value of innovation, developing a review mechanism that can evaluate breakthrough and first-in-class products, and ensuring this process becomes fully accountable to the Canadian public by holding open meetings of its review committee.

Beginning our remarks this afternoon is Sean Thompson, director of corporate development for YM Biosciences in Mississauga.

● (1605)

Mr. Sean Thompson (Director, Corporate Development, YM Biosciences Inc., BIOTECanada): Good afternoon.

YM Biosciences is an early stage cancer product development company, which was founded in 1994. We are currently developing new therapeutic products that we have licensed from the Universities of Saskatchewan, Manitoba, and Dalhousie.

Our most advanced product is nimotuzumab, a biologically derived and produced molecule that is being developed for several underserved cancer indications. The lead indication for nimotuzumab is pediatric pontine glioma, which affects fewer than 50 Canadian children each year. In early studies, nimotuzumab has been shown to improve the quality and length of survival for affected patients.

I'm here today because my company is concerned that CDR, given its history to this point, would reject this Canadian-developed product and deny Canadian patients access to this potentially life-prolonging therapy.

A large part of my job is to identify the financial resources that are necessary to bring exciting new health discoveries to market. Often these development efforts are in partnership with leading multinational pharmaceutical companies or through venture capital investments. That job is made more difficult when venture funds and corporate licensing executives observe that the Canadian marketplace provides little or no market access for innovative biologic products as a direct result of CDR recommendations.

If Canada is to realize the full return on our investments in our universities and programs such as the Canadian Foundation for Innovation, Genome Canada, and the Canadian Institutes of Health Research, we must ensure that the fruits of those investments can reach Canadian patients.

To encourage further investment and development of innovative health inventions, Canada, through the CDR review, must recognize the value of innovation. In the United Kingdom, for example, the National Institute for Health and Clinical Excellence, NICE, a common comparator to CDR, explicitly takes into account the innovative nature of technology and wider societal interests. NICE also works with a citizens council in making reimbursement decisions on new medicines.

Incorporating these elements of the NICE system into CDR would begin to demonstrate that the Canadian system can accommodate the needs of vulnerable patient populations and that it values the innovation of breakthrough therapies.

Mr. Peter Brenders: YM is one example of the Canadian biotechnology industry's goal to develop new therapies for unmet needs of Canadian patients and to provide economic opportunity through the development of Canadian biotechnology. The latest data from Statistics Canada, released in January of this year, show that the 303 health biotechnology companies currently employ nearly 11,000 Canadians in high-skilled jobs and spend nearly $1.5 billion annually on research and development. This figure represents over 12% of the total business expenditures on research and development in Canada.

Our Canadian companies, located in every major city and province, are developing new cancer therapies, new treatments for Alzheimer's disease, osteoporosis, Parkinson's disease, and, perhaps most importantly, for rare diseases for which no other therapies exist. In fact, there are at least 27 Canadian companies that have received U.S. Food and Drug Administration orphan product designation for the products they are developing, the very types of products that the CDR has consistently rejected.

For three years, BIOTECanada has advocated that the CDR become publicly accountable for the decisions of the Canadian Expert Drug Advisory Committee, or CEDAC. Under the current system, the 12 CEDAC members meet behind closed doors to offer their collective opinion on the value of new treatments and on whether Canadians should have access to the new life-saving therapies. The CDR then issues recommendations to participating drug plans based on that opinion.

Thousands of Canadian patients live with the reality of CEDAC decisions, and taxpayers foot the bill for their deliberations. Yet the public has no access to the decision-making process that will determine the value of treatments for them. This situation is particularly troubling because CEDAC has rejected every single treatment for an unmet need, leaving Canadians without access to the most modern therapies available and sending a message to the world not to bother to bring innovations here. Moreover, as countries provide some level of public access to all these treatments for unmet needs that CEDAC has rejected, Canada is out of step in treating patients for these often rare and fatal conditions.

A 2005 evaluation of CDR by EKOS Research, conducted on behalf of the CDR, revealed widespread public dissatisfaction with the fairness and transparency of the review process. Not surprisingly, industry and patient advocacy groups felt strongly that the CDR process was not transparent. Canadians must have confidence that the review process to determine an opinion on value is robust and accountable. Accountability cannot be achieved in a process behind closed doors that ignores the views of the public. BIOTECanada maintains our position that accountability can be realized through open meetings of CEDAC that engage the public.

As we have seen, the CDR process has prevented those in need from getting access to innovative treatments. The challenging patient access environment in Canada presented by the CDR is becoming well known around the world, as I mentioned, and places us very much out of step with the global evaluation bodies. These same data, submitted to the CDR, have been used by reimbursement bodies in other parts of the world to approve public access for these products, and many countries have developed unique programs and mechanisms for the review of treatments for unmet needs.

The common-sense issues and concerns described above regarding the process and effectiveness of CDR's system have been repeatedly communicated to the CDR. Moreover, even the previous chair of CEDAC has publicly stated that the CDR process was not appropriate to deal with treatments for rare diseases. So why does it persist without fundamental change? Sadly, the changes we've seen are actually reflected in the provinces' spending more to set up alternative mechanisms to address issues presented by first-in-class or specialty treatments. The JODR is one example.

Our members recognize the complexity of some of these issues and are willing to work with Health Canada, the provinces, and the CDR towards solutions that can bring innovative therapies to the Canadian patients who need them.

I'd like to conclude by pointing out that BIOTECanada recommends that before this government make further investments in the CDR, the organization become fully accountable to the Canadian public through opening the CEDAC meetings. It must develop effective procedures to evaluate novel treatments for unmet medical needs, and it must explicitly incorporate mechanisms that recognize the value of health care innovation into its mandate. We believe Canadians can be better served by a more accountable process. The Canadian biotech industry is looking to help make this happen.

Merci.

● (1610)

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): We will now move on to our question period, beginning with Ms. Brown.

[*English*]

Ms. Bonnie Brown (Oakville, Lib.): Thank you, Madam Chair.

Before I start, I'd like to make a point of order. I'm finding this meeting rather surprising, because while I'm aware that the committee decided to do a study on prescription drugs, and I'm aware that the common drug review is a piece of that rather large puzzle, I'm very surprised that, before starting a study, we have not had a document presented to us, as committee members, called "Terms of Reference for the Study on Prescription Drugs".

In addition to the terms of reference for a study, which is the normal procedure at this committee, we are also, usually, provided with a work plan that tells us what the first meeting will be about, what the second meeting will be about, and so on. None of those things has happened. I don't know why, Madam Chair, but perhaps you could make some inquiries for us.

When one considers that we did a study of prescription drugs a few years ago, one might assume that the health committee could move directly into some of the nitty gritty problems concerning prescription drugs this country faces. However, when you also consider that of the 12 members on this committee, at least six were not present for that rather large study we did, one would realize that we should be following a more formalized structure. We should have Health Canada come and tell us about its responsibilities for prescription drugs. If the CDR is part of our study, as approved in a work plan—a work plan we haven't seen yet—then the people from the CDR should come, and so on.

So it seems to me that we are starting today with a rather thorny issue. Nothing that has been said here so far has surprised me, Madam Chair. Many of us are going to be jumping into this without sufficient background information—the history of the thing, how this came about, and so on—to really understand what's being said. It's obvious that this study has been launched at about stage 7 of a normal study. So I would ask, Madam Chair, that—

● (1615)

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Thank you.

Mr. Fletcher.

[*English*]

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): On a point of order, may I comment?

Actually, I think the member brings up a valid point. Starting at step 7 is not as good as starting at step 1. Perhaps the steering committee could get together and discuss some of the concerns the member has raised so we can do a proper study. I think that's what the member is looking for. So I think that's fair game.

Ms. Bonnie Brown: Thank you, Madam Chair.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Is that okay?

[*English*]

Ms. Bonnie Brown: Yes, I am. Thank you.

I apologize to the witnesses for bringing a point of order, but we've been away for two weeks, and I was very surprised by today's agenda, although I wasn't surprised by anything you said.

Can someone who's here on the panel tell me something? With the exception of Quebec, which never joined the common drug review, how many of our provinces are still carrying on their own reviews?

Mr. Williams.

Mr. Russell Williams: To your question, and I stand to be corrected, my understanding is that the general answer is most. Part of it is the reason I highlighted. One of my concerns is not just the rejections, but how long it takes after a positive recommendation. It ranges, in some cases, to several hundred days, so one would presume that there is something happening during all that time, and again, it's another review. That's why I talked about the three levels of review for the same drug.

Ms. Bonnie Brown: I'm aware of that.

Mr. Russell Williams: If there are any corrections from the other panellists—

Ms. Bonnie Brown: Okay. Now my question has always been about this. It's not whether it's appropriate for the federal government to be ruling on safety and efficacy. I wonder about a federal agency ruling on cost effectiveness when the federal government does not have a drug reimbursement plan for the general public. Do you have any opinions on that?

Mr. Williams, you were a politician. Is it not usual for the person who pays the piper to call the tune?

Mr. Russell Williams: To your question, most politicians, certainly, if they're paying the piper, as you say, like to make the decision.

Again, we talk about a good idea that sounds good on paper, but ultimately, who makes the best decision? Who runs it and who pays? In many cases, it is the provincial government. It is very difficult. You heard presentations from two companies today about the precision of the medications we're talking about. It is difficult to actually come up with a macro decision at a very high level to say that this is good for everybody. Provinces know their own jurisdictions better than anybody else.

Ms. Bonnie Brown: Excuse me, but that's unless that authority is paying. If they're paying, they have the right to say that. But what we have is a jurisdiction that's calling the shots but not paying the piper. It's the lower jurisdictions that pay, which was Mr. Brenders' point.

Mr. Russell Williams: I'm not sure we can call it even a federal one. One of the issues is it seems to fall in between every level of government and the whole notion of appeal, transparency, accountability, and where the buck stops. I wouldn't quite call it a federal level; actually it's a creation of the FPT process. One of the concerns we've heard is that in fact it isn't accountable to any level.

Ms. Bonnie Brown: I have another question here. The joint oncology drug review has now been contracted out to the Ontario government's cancer agency to make these decisions for everybody, I understand. Is that not the common drug review admitting it can't do cancer drugs? My question is, is the same thing true for biologics? Do the people who present those therapies feel that the common drug review is not as capable as they would like? Is the same thing true for drugs for rare diseases?

Dr. Billen would like to comment.

● (1620)

Dr. Daniel Billen: Yes, I would like to take this one. One of the things that would be our recommendation on the JODR is to make absolutely sure that we don't repeat the same mistakes we made with CDR. Our point of view is it's not who's at fault in the process; it is who suffers. At the end of the day it is the patient who is denied access. That's the way we have to look upon it. When a patient is denied access, we rob that patient of any new hope that this potentially important medication could bring to the table.

Our point of view is that CDR had asked to expand into oncology products. I think it was the provinces' recommendation to go with the JODR approach. In reality, in principle, both approaches are fine, to say let's have a common denominator of knowledge to make some decisions. The important part, though, is if we look at the end result. The end result is, will CDR or JODR provide access to important medical breakthroughs? For CDR we can say the answer is no. For JODR, we still have to wait and see. I think the focus of us as Canadians has to be on making sure that patients who need access to important, innovative products get that access. That's the job.

Ms. Bonnie Brown: Mr. Brenders I think wanted to comment.

Could somebody comment on this rare diseases issue?

Mr. Peter Brenders: I will. I think the short answer to your question is there are concerns in terms of whether a CDR process can effectively deal with rare diseases, unmet needs. The former chair, as I mentioned, Dr. Laupacis, has gone on the record as saying that the CDR process as it was set up could not adequately deal with the unmet needs. The structure as it's defined doesn't work. It seems to have set itself up as an adequate review for common drugs, but as a technology process to take a look at unmet needs, rare diseases treatments, clearly with what we're starting to see from provinces that are doing their own reviews or setting up other things like the JODR, you have to wonder, is there a question of confidence in the competence of what is the CDR?

Ms. Bonnie Brown: As you know, we're partway through a vision that came out of a federal-provincial process, which had a national pharmaceutical strategy as part of it, but it seems to me one of their end goals was to have a national drug formulary as opposed to provincial formularies. It seems to me that this is where those thinkers were going at the time this was set up. My concern is if we ever got there, does it concern you that we might end up with a list based upon the CDR experience on a national formulary that essentially is the lowest common denominator?

Would anybody like to comment on that?

Mr. Russell Williams: As to your question, again it sounds interesting and quite positive when you throw out a simple idea: wouldn't it be nice if we...? But in reality, our greatest concern is that we would be moving to the lowest common denominator.

As to your earlier point, I find it difficult to imagine how you're going to create a national formulary, possibly driven by a strategy very oriented to cost containment and that at a certain level will be making decisions about which drugs are available for which patients. Ultimately it will be the provincial level that will be paying for the consequences of those decisions, because I passionately believe that in fact good utilization of innovative medicines not only saves and improves lives but also saves money within the health care system.

So the concern is that the current movement would be towards a reduction of access versus an increase in access.

Ms. Bonnie Brown: Thank you.

Thank you, Madam Chair.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Mr. Keon would like to add some information.

● (1625)

[*English*]

Mr. Jim Keon: Yes, thank you.

On the last issue, we deal with the drug program managers and health ministries in all the provinces, and I think as long as they are paying for the drugs, there is virtually no chance they are ever going to cede authority back to some other agency as to which drugs they pay for.

I would comment again that the common drug review, as Mr. Williams said, is not a creation of the federal government; it was actually coming from the federal-provincial-territorial groups that have been meeting. In many ways, it's actually the desire of the provinces, in particular the smaller provinces, who simply don't have, or feel they don't have, adequate resources to review the cost-effectiveness and therapeutic value of all of these new medicines.

Ms. Bonnie Brown: Thank you, Madam Chair.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Thank you.

Should I have questions for the witnesses, I would ask the members of the committee to give me the permission to remain seated in my chair to do so, rather than moving, which would be time-consuming.

We will now move on to our second round of questions. I will give the floor first to our colleague Mr. Malo. I will have some questions later. Thank you.

Mr. Malo, you have the floor.

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you very much, Madam Chair. Before I put my questions to the witnesses, allow me on this special day to offer you my best wishes for a happy birthday. And may I take this opportunity to wish you the best of health in the coming year.

The Vice-Chair (Ms. Christiane Gagnon): The floor is yours, Mr. Malo.

Mr. Luc Malo: Thank you, Madam Chair.

Gentlemen, thank you for having come here today.

What I understand from the fairly substantial presentations we have heard today is that you have been following this file for a number of years. I conclude that some of the elements of the current program could stand for some improvement, in your opinion.

Mr. Williams, in your presentation you seemed to be saying that for certain patients this program constitutes an obstacle to access to certain drugs. In your work in the field, did you have an opportunity to collect figures, to observe specific cases where this program proved very, very problematical for some patients or groups of patients?

Mr. Russell Williams: Thank you for your question.

I think that the Quebec model answers your question for the most past. Because Quebec does not use the CDR, there are a larger number of drugs listed in Quebec. Up to 62% of drugs are listed and are thus accessible and available to Quebec men and women. Unfortunately, in the other provinces—and each province is different—because of the duplication of the work done by the CDR, these drugs are not accepted or are placed on a waiting list because a decision has not yet been made.

Mr. Luc Malo: Is it because there exists in Quebec a desire to list a greater number of drugs, regardless of their cost, or is this due to other reasons, reasons that involve the effectiveness of the program?

Mr. Russell Williams: I will begin to reply to your question, and Mark will complete my answer.

I think that Quebec has understood that the proper use of innovative drugs and better access to them is a good health intervention because in this way one can improve the health of the population, save money and reduce the number of hospitalizations. There does indeed exist a will to use innovative drugs as a health strategy. In my opinion, the population and patients are the better for it.

Mr. Ferdinand wants to add something to my reply.

Mr. Mark Ferdinand (Vice-President, Policy, Research, Regulatory and Scientific Affairs, Canada's Research-Based Pharmaceutical Companies (Rx & D)): Mr. Malo, I would point out that it is not only a question of access, but a question of choice. Basically, when the health care professionals who prescribe drugs have more choice, they are the ones deciding whether or not their patients will have access to certain drugs. So neither the provinces nor the federal government are deciding whether such-and-such a medicine is good for you or me. It is actually the health care professionals—as is the case in Quebec—who have more choice in curing and treating their patients. In my view, we must understand the following: when we see the number of rejected or negative recommendations from the common drug review, we realize that, regrettably, that is where choice is being interfered with.

● (1630)

Mr. Russell Williams: And it's not just the CDR: in more and more decisions, a barrier is being erected between doctor and patient. I think that Mr. Ferdinand has raised an important point because it seems quite clear in the case of new drugs, which are the ones we are talking about here. If the list is longer, you won't use it all, but there will be more choice. At the moment, it is practically impossible to decide if one medicine is good for everyone at all times. Each province, even each region, as well as each doctor can make the best decisions for their patients.

Mr. Luc Malo: Following that train of thought, Mr. Billen—

The Vice-Chair (Ms. Christiane Gagnon): Your question will have to be a short one.

Mr. Luc Malo: Mr. Billen, just now you were heading precisely in that direction when you said that we often hear doctors saying that they are sorry but that there is nothing more they can do.

Is that because they are not telling their patients that Health Canada recommends a number of drugs that are not yet approved by the common drug review?

[*English*]

Dr. Daniel Billen: Yes, meaning that I think the answer is that at the end of the day patients go through their diseases. Our objective at Amgen is to make sure we find solutions for these very severe patients. That doesn't mean the solutions we are going to come up with are going to help everybody, but it is our mission statement to make sure we provide alternative approaches to very severe diseases. And by doing that you're giving physicians and patients more options.

I think especially in the area of cancer, in the area of rheumatoid arthritis, in the area of kidney disease, there are too many times that the physician has to say there's nothing more we can do, while in other countries around the world there are still other things that can be tried. I think we want to make sure that Canadians have the same opportunity as patients with these very debilitating diseases have in the rest of the world. It is their right, from my point of view, to get that same option that potentially could make a difference from a quality- or a quantity-of-life point of view.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Thank you.

Mr. Fletcher.

[*English*]

Mr. Steven Fletcher: Thank you, Madam Chair.

I have three questions for Mr. Williams and one for Mr. Keon. But before I get to the questions, there was a very helpful suggestion that was provided by Mr. Williams in his speech. That was that there should be an independent, comprehensive review of the objectives, accountability, value for money, and health outcomes as they relate to the common drug review and the Canadian Agency for Drugs and Technologies in Health. That may be something the researchers and the other members of the committee may want to consider in the final report.

First I will lay out my questions, and then I'll let you answer them as you wish.

Mr. Williams, you also say that it is your recommendation that the federal government freeze funding to the CDR. The federal government only provides a portion of the funding, and I wonder what goal that would accomplish, because this is not going to change immediately. What would the goal of that be?

I also wonder if you could explain the statement that you believe the CDR places too much emphasis on cost containment and not on patient outcomes. There is also a complaint that the process is not transparent—you don't have access to information, and it seems to be a bit of a black box. I would be interested in what you have to support that statement and what you estimate are the costs we're talking about. What is the difference between what has been provided and what you would like to have provided, and what would the cost of that be?

Finally, for Mr. Keon, on your suggestion that we substitute generics where possible and maybe increase the substitution for patented drugs, could you explain for us why generic drugs in Canada tend to be more expensive than they are for our neighbours to the south?

Those are my questions, Madam Chair.

● (1635)

Mr. Russell Williams: Thank you for your three questions. I will attempt to answer them, and Mr. Ferdinand would like to add further comments.

On the first point about the message about freezing funding, you're absolutely right that the federal government does not control the overall funding. But I think it would send a very clear message that we need to have this independent review. We need to make sure, because as Mr. Williams said, we're talking about access to innovative medicines, life-saving medicines, for patients. This is not just a study about a government agency.

What we have to do is pass the message clearly that asks what it is doing, what it is supposed to do, and whether it is fundamentally flawed. I actually believe that the model we have in Canadian society is that ultimately these decisions, as for the first questions, are going to be made at a provincial level. So why are we building in duplication throughout that that questions, on one hand, some of the clinical trial information from Health Canada, and then adds in other criteria that maybe other international jurisdictions don't add and that second-guesses pricing? The message would be that it's time for a review.

When I look at a body that makes decisions that aren't binding, that seems to be duplicating information, and that is not accountable, what better mechanism is there than to send a message saying that we're freezing the funding until we actually understand that it is doing what we want it to do? That is a lot better than announcing a week before parliamentary hearings that there is an expansion of the mandate.

In terms of the CDR and cost containment, when you try to understand, when you look at the decision-making process, you come to the conclusion that they're using cost containment. Again, as I mentioned, if you're taking a product that is the same molecule and you're putting it to the same scientific scrutiny but coming up with entirely different responses, it seems to me that there are other ingredients being entered, including cost containment versus patient outcome. But to your point, you're absolutely right, it is difficult to find out the decision-making process.

This is one of the things we're hearing more and more. Canadians, having confidence in our health care system and in our drug system, are saying that they hear that a certain drug, a life-saving drug, has been available for *x* number of months or years somewhere else, and now they hear that Health Canada has approved it, it has gone to this other body that doesn't really seem to be accountable to anybody, it's either been rejected—which is a very mixed message—or it's been recommended again by another level, and it goes to provincial bodies and sits there for a few hundred days. It is very difficult for citizens to understand what's going on. To your point, we have to really open up in terms of transparency.

To your actual questions on the specifics of cost containment, Mr. Ferdinand wants to add some points.

Mr. Mark Ferdinand: Mr. Fletcher, I have just one point. I would encourage members, in response to Ms. Brown's suggestion, to ask these questions of CDR representatives when they appear before the committee.

As a short answer to your question in terms of Mr. Williams' statement with regard to the focus on cost, the point of the common drug review is to undertake analyses of cost effectiveness. There are situations in which they can make such comparisons and take into consideration clinical data that may or may not be available, but at the end of the day, when you look through all of the different types of analyses that they can do, cost-effective analysis is certainly one of them that they have to do—and in one case the one they will have to do—if they don't have certain types of information. So the focus on cost is part and parcel of what the common drug review does.

● (1640)

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Your time is up. I am giving the floor to Ms. Priddy.

[*English*]

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

I do want to second the comments that were made earlier by my colleague, Ms. Brown.

Having said that, it's important for me to say, as I look at this material, that I keep two things in mind. One is that Canadians need access to the most effective drug that will work for them, and they need access quickly. That doesn't always mean it's a new drug, but they need access as quickly as possible, and finances need to not be a barrier to that. I personally would suggest that it be covered, and that would be a debate for a very different time, but that's the position I think I would take. Currently, you can cover it all you want, but still, many people's plans are not going to.

My first question would be—and I think I heard, but I don't wish to put words in anyone's mouth—that mostly people are suggesting, with perhaps one exception, that the CDR really isn't working.

Mr. Keon, I want to go back to you for a moment, because you speak from the perspective of generic drugs. You made a comment about how, if the generic drugs were included in CDR, it might make the route faster for provinces. I'd like you to comment, if you would, on the difference CDR might make for generic drugs, because others have talked about the difference that it does or doesn't make for name brand drugs.

Let's, for a minute, suggest that the CDR is working in some reasonable way, just for the sake of this discussion. Is this a logical route to a national drug strategy or a national formulary? Is it getting in the way of moving in that direction? For people who'd like to answer that—some people think we shouldn't move in that direction, and I realize that—is the CDR helping it or is it getting in the way of moving ahead with a national drug strategy and a formulary?

So, perhaps, Mr. Keon, you could begin with the generic part for me.

Mr. Jim Keon: Yes. Thank you.

In fact, the common drug review, I argued, is an essential part of the Canadian process now for brand name drugs. I think in large part it was recommended by the provinces, asked for by the provinces, and that's how it came about.

For generic drugs, we have a different situation. For a new brand name product—so you're looking at a product that has not been on the market yet—we don't know the full analysis of the therapeutic benefits or the potential harm. We also don't know whether it's worth the cost in relation to existing medicines in those therapies.

For generic drugs, you're looking at a product that's coming on the market 12 years to 15 years later. Generally speaking, the benefits and downsides of that product are well known. We compare our product to the brand name product with Health Canada and they approve our product as being essentially the same, equivalent. They give us a declaration of equivalence.

So we believe that at that point you should let the generic come onto the market based on the Health Canada decision. Our products do not go through the common drug review. We believe it's an entirely different situation.

Ms. Penny Priddy: And you're not suggesting that they should.

Mr. Jim Keon: I don't think the common drug review would want to do that. They would see it as a duplication.

Ms. Penny Priddy: All right. Thank you.

Mr. Jim Keon: If I could just respond to Mr. Fletcher, who asked about generic drug prices, yes, a study last year by the Patented Medicine Prices Review Board showed that generic drugs here were priced higher than those in other countries. In fact, many provinces are now taking measures about that. The Ontario government passed a regulation that is reducing our prices by over 20%.

[*Translation*]

According to the drug policy announced by Minister Couillard last year, Quebec intends to set the same prices as Ontario. At the moment, generic drug prices are dropping considerably.

[*English*]

Ms. Penny Priddy: I know Mr. Fletcher's answer won't count against my time.

Mr. Williams.

● (1645)

Mr. Russell Williams: On your question on the national pharmaceutical strategy, again, it sounds good, but I think it's going to give another false hope, just like CDR did.

If we want to move toward making sure all Canadians are covered and have a catastrophic drug program, I think we have to build in something. In each jurisdiction there are different priorities and different weightings in terms of the various needs. What we have to do is build on something that respects that regional diversity. I would be quite worried that if the notion is that we can create something overall that is centralized, it may not actually give us what we want. What we should do is build on the reality of each region and what it's capable of. Let the regions run it, as they do the other health care systems. But I agree that we should be moving toward....

We've been trying to do some work. Any time the committee wants to study it, we'd love to come and give you a look at our work on trying to develop something that will make sure, across this country, that we have a program that makes drugs available for all Canadians.

Ms. Penny Priddy: Quickly, if you freeze the funding, does that simply not slow down the process that's currently in place?

Mr. Peter Brenders: From our side, I would suggest that it wouldn't really make any difference, because nothing's getting approved, which is the scary part.

To your point about whether this is a framework for a national pharmaceutical strategy, if anything, it should be a lesson for us. When you try to do a cookie-cutter common process for what is coming out of very specialized, unique needs when there isn't a lot of experience out there, it doesn't work. If anything, it should be a concern and a caution that the process does have limitations, and it speaks to what Daniel Billen has mentioned in terms of a different process for first-in-class and what we're talking about in terms of procedures that can evaluate novel treatments in different areas. It doesn't take any societal values into the process, and it doesn't incorporate public opinion.

Ms. Penny Priddy: And as one quick last one, if you—

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): I am trying to be fair to everyone, Ms. Priddy. I am giving the floor to Mr. Batters, but you will have time to speak again.

Mr. Batters.

[*English*]

Mr. Dave Batters (Palliser, CPC): Thank you, Madam Chair, and happy birthday to you.

I want to thank all the witnesses for being here today. They gave some excellent presentations.

Mr. Billen, I don't think I've ever seen passion like that at committee since I've been a member of this committee. You obviously feel very strongly about your position here today.

I'd like to just briefly pick up with Mr. Keon, before going on to the CDR specifically.

My colleague asked about the price of generic drugs and the fact that generic drugs in Canada are far more expensive than the exact same generic drugs available in the United States. You're commenting that you are moving to address that. Are you saying that, nationwide, province by province, generic drugs are soon going to be on par cost-wise with the equivalent drugs in the United States?

Mr. Jim Keon: What I mentioned was that the provincial government in Ontario has already passed a regulation. For the vast majority of generic drugs, the Ontario government will not list them on its formulary unless they are at least 50% lower than the brand name product. In Quebec, they have a rule that says they will only pay the same price. So provincial governments are addressing this issue, yes.

Mr. Dave Batters: I understand that, sir. I'm from Saskatchewan, so I'll be looking very closely at what's done in that province. It really makes no difference to me in terms of a percentage of the brand name drug. The question asked was on the comparison to exactly the same generic drugs in the United States.

Mr. Jim Keon: These prices will probably be lower than those in the United States on the majority of products, yes.

Mr. Dave Batters: Mr. Keon, what percentage of the sales revenue of your participating companies is invested in research and development, to discover new and innovative medicines to benefit Canadian patients? Today, the discussion is about access to new and innovative medicines. My understanding is that the generic drug industry is really not involved in that discussion.

Mr. Jim Keon: That's a very interesting question. Actually, about 15% of our revenues go back into research and development. That meets the definitions of the tax act.

The brand name companies in Canada have been declining. They spend about 8%. Surprisingly, we spend twice as much in Canada on research as the brand name companies do as a proportion of sales. The reason is that generic drugs in Canada are actually made here. They're researched here, they're developed here, they're formulated here, they're manufactured here, and they're sold here. That's why the research is so high in Canada.

Mr. Dave Batters: Can you give me some examples of some new and innovative medicines that have been brought to market by generic drug companies?

Mr. Jim Keon: Generic drug companies are of value to the health care system in that after patents expire we provide products at much lower prices.

● (1650)

Mr. Dave Batters: That's not the question, sir. Can you give me an example of a new and innovative medicine that you've discovered through research and development and that you've brought to the marketplace to benefit Canadian patients?

Mr. Jim Keon: That is not the job of generic drug companies.

Mr. Dave Batters: You just answered my question.

Mr. Williams, if the CDR were to be eliminated through funding cuts, whether it be the 30% federal percentage, the provincial percentage, or both, what would be the consequence—or would there be a consequence, given the duplication you've indicated exists in the system?

Mr. Russell Williams: I don't believe, as Mr. Brenders has responded, that there would be a negative consequence at this point. Obviously freezing the funds and not doing anything isn't what we are recommending. One message is to freeze the funds and then do a complete review so that we can build a system that actually does move innovative medicines to patients more quickly in an effective way, a transparent way, and an accountable way, and first and foremost avoid that duplication.

Right now we have checks—review upon review upon review. The first part about the freeze would be to give the signal to do the review, and then do the review that has a more effective system. That, frankly, I think is built on provincial decision-making versus a duplicated decision-making.

Mr. Dave Batters: Thanks.

For me the issue here today is that it's all about patient access, and the CDR seems to be involved in cost containment. Duplication does exist; the CDR does the same work that provincial plans do and that Health Canada does. There are significant delays, there's lack of accountability, there's non-transparency, and in the end patients suffer.

CDR and CADTH tout evidence-based decision-making. Why is it that other countries such as Sweden, Switzerland, and the U.K. are providing much greater access—more than 50% more—to innovative medicines for their people, given that they are reviewing the same drugs, the same science, the same evidence-based approach? Mr. Williams, why is CDR blocking access to these same innovative therapies for Canadians?

Mr. Russell Williams: Let me start, and Mr. Ferdinand will jump in.

That concerns me a great deal. My belief is that they are building in a cost-containment strategy that allows them to make decisions about cost versus patient outcomes.

I have the darndest time, and I think you would too. How do you look a patient in the eye and say that something approved in the rest of the world, something available in those countries you mentioned, something approved by Health Canada, is not acceptable to CDR? Worse, once it gets through a six-month delay—and we're talking about life-saving medicines, so every day counts—there's a further delay at the provincial level. Your question is exactly the question Canadians are asking.

On the precision of some of the decision-making, Mr. Ferdinand, do you want to add a comment?

Mr. Mark Ferdinand: The only thing I'd add is that it is very difficult to understand. When we did the international comparison, we looked at two jurisdictions, France and Canada, to see if we could look at the reasons for decision. In other words, what were the reasons that resulted in a negative recommendation here in Canada for some medicines, and what were the reasons in France, let's say, for positive recommendations for the same drugs?

One of the things we found was, again, the question of what the role is. We found that it seems as though in France there is a value placed on the therapeutic value of the medicine, which means that if this works better for you because you can tolerate it, or if it works better for you because it has fewer side effects for a specific patient subpopulation, then those are the reasons that maybe France can recommend that drug for approval. Unfortunately, we just didn't see the same types of reasons—the same type of thought, I would say—going into the recommendations that resulted in negative listing here in Canada.

Mr. Dave Batters: Thanks, gentlemen.

The Vice-Chair (Ms. Christiane Gagnon): Madame Beaumier.

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

I think my colleague Bonnie Brown has zeroed in on one of the problems for many of us. I am one of the members who hasn't been here on drug review or drug pricing. And not being that familiar with CDR, according to what I've heard today, I think there's no contest; you should make the recommendation and we should follow it.

We will be hearing from Health Canada. We will be hearing from CDR. I would like to get a commitment from each of you that when we have questions—I for one certainly will have questions—we can call upon you individually to answer some of these questions. As you know, you're amongst the first; there are going to be people coming after you, countering your arguments.

Dr. Billen, you're a scientist. You are so passionate about this, you very well may be the last one to talk to all of us.

● (1655)

Dr. Daniel Billen: I would love to.

Ms. Colleen Beaumier: I don't have any intelligent questions to ask right now, but I do appreciate your presentations.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Mr. Lunney.

[*English*]

Mr. James Lunney (Nanaimo—Alberni, CPC): Thank you, Madam Chair. *Félicitations* on your birthday.

The Vice-Chair (Ms. Christiane Gagnon): Oh, yes—

Mr. James Lunney: It's been well publicized.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): We're not going to talk about my age.

[*English*]

Mr. James Lunney: My first question deals with the concern that exists around the cost of health care delivery. We are all concerned about escalating costs. We're over $103 billion, I guess, in terms of what's spent just on the publicly administered health care delivery.

Currently drugs represent one of the highest and most rapidly escalating costs of health care delivery, and governments have a legitimate interest in managing those costs. But one of the other things is making sure that publicly reimbursed programs include verifying that they're good value, relative to the benefits, over existing therapies.

I would say that one of the challenges in evaluating the value of new therapies is the lack of, or limitations of, evidence that these drugs work for the patients in the long term and fulfill the provinces providing better health and quality of life. In relation to cost containment, we're worried about adverse drug effects and reactions. Often it takes time to evaluate the full effects of medications on patients, particularly those who have chronic conditions.

In my home province of British Columbia, the provincial government has taken the innovative approach of actually paying pharmacists double the prescription fee, or subscription fee, or—what do we call it now?

Ms. Penny Priddy: Dispensing fee.

Mr. James Lunney: Yes, dispensing fee; thank you, former health minister Priddy.

So they actually pay them a double fee—in the last year, that amounted to some $750,000—for not prescribing when there was evidence that the prescription could harm the patient, could be ineffective, or could conflict with other medications they were taking. In the rush to bring in new drugs, although it's great that they may be very innovative, we want to make sure that we're not in fact contributing to other costs when drugs fail if they're not adequately scrutinized before they come in.

What in fact is your industry doing to strengthen evidence of safety and effectiveness of therapies over the life cycle of the products?

Mr. Russell Williams: I'll start, and Mr. Ferdinand can add to it.

We are deeply committed to health and safety and to making sure that the drugs that come out are safe every step along the way. I could spend the rest of the hearings going through each of the various steps.

To my understanding, with regard to the new and innovative types of drugs that are first in class, with no comparators in this country, the very rules of CDR are going to make them not available. I think what we have to do is make sure that we build in a proper surveillance system and continue to monitor those.

So there are risks, and there are risk benefits. We have to monitor all of those. But—

Mr. James Lunney: Sir, could you expand on what you just said? Why is that? You said that the very rules under which CDR operates currently would not make innovative drugs available. What do you mean by that?

Mr. Russell Williams: On the specifics, I'll let Mr. Ferdinand go through the details of the process.

Mr. Mark Ferdinand: As I understand the CDR process—and again I encourage members to ask this question of CDR representatives—if there is no active comparator in Canada for a drug, their process, which is a chart, defaults to a cost-effectiveness or budget impact analysis. This means that the drug will only be evaluated based on its budget or cost impact. That's just the way the process seems to work.

The challenge is that if you're first in class, you have no active comparator in this country against which to measure the drug. So what do you have left but the budget impact analysis?

● (1700)

Mr. James Lunney: May I pick up on that? Wouldn't it seem likely that in developing new products, at least some of them would cost less and still be effective? Certainly in the automotive industry, it's very competitive today. Cars that used to cost a fortune are suddenly coming down, in some areas at least, because of changes in technology, and so on.

Anyway, that's another discussion, but you could make a case, if you examined certain aspects of the automotive industry.

Wouldn't it make sense that at least some of the new drugs being developed would come out with lower costs?

Dr. Daniel Billen: I'll go back to your first question, since I'm a bit behind here. It always has to be a balance concerning the appropriate use of a drug. There's no doubt about it. We are not advocating that new is the best, which often is the most expensive drug for every given situation. But when it comes down to life and death, or to a product that definitely can change a life, it's not all right to take that option away from patients.

I want to congratulate B.C. for being one of the very innovative provinces from a cancer access point of view. One of our opinions on JODR was that if you have to pick a province to align behind, why not pick the best rather than the worst? That said, British Columbia has better access to cancer therapeutics than any other province in this country. Why not give that province the lead in saying, okay, let Canada go in this direction?

It all comes down to what we are talking about. If we're talking about small things where it doesn't make much difference, I'm totally with you. But when we talk about end-of-life decisions, or products that will potentially make an enormous difference in someone's life, I think access has to be the number one goal. Patients have to come first.

Mr. Sean Thompson: I'd like to offer a comment on your previous question, if I may, about the cost of developing drugs. YM Biosciences is one of the group of very small companies that are in the business of taking risks in developing products, which may not be appropriate for a large pharmaceutical company.

For example, I mentioned the drug nimotuzumab, which we're developing for a very small population of patients. This is a risk that a large pharmaceutical company would not take. It's not appropriate for an organization that size.

We've been in business for 13 years. Over this history we've raised about $200 million, and all the money goes into research and development. We have no revenues at this point in time. It is critical for us to get that first drug across the goal line, so that we can continue to exist, and develop and license products coming out of universities.

There are limitations to the resources that would be made available to us, in terms of doing gigantic studies before products are approved. We do what is required by regulatory authorities here in Canada, the United States, Japan, and elsewhere to ensure the safety and effectiveness of our drugs.

Mr. James Lunney: Can I ask another question?

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Your time is up, but there will be a third round. We will have plenty of time before the end of the meeting.

I am now going to give myself the floor, so to speak. I have not been able to ask my questions yet.

By way of comparison, you mentioned France, where access to medicines is much greater and where they are approved in greater numbers. Their evaluation process is probably different from ours. Can you give us an idea of how they evaluate drugs?

Here, we have three separate evaluations: by Health Canada, by the CDR and by the provinces. Four provinces are exceptions, I think. They don't do evaluations, so they can rely on those done by the CDR. Maybe the French model is a goal to aspire to, but we also have New Zealand's. Half the number of registered products are available to the public, and the cost is four times less. No one seems to be saying that patients are disadvantaged in New Zealand. I don't know if you know anything about the evaluation process in that country.

Why would it not be an acceptable model for all of Canada and for Quebec?

● (1705)

Mr. Russell Williams: As you have already mentioned, it's a very complex question. In our study of other countries, we concentrated on the first aspect of the question, choice. European countries do offer more choice. They make more positive recommendations than the CDR.

As regards access, forget all the debate, the list of duplications and so on. We are here to find a way to make sure that medicines are available to patients. The way this is done varies from country to country. It always seems difficult to make an exact comparison of the system in one country with the system in another. According to my information, the New Zealand system makes fewer products available.

The Vice-Chair (Ms. Christiane Gagnon): True: we are talking about 2,500 products, that's half the number in Quebec where there are 5,000.

Mr. Russell Williams: So there is less choice.

The Vice-Chair (Ms. Christiane Gagnon): They consider a number of criteria, including effectiveness and cost. They also consider that, in a number of cases, changing one molecule in a new drug is not going to improve the patient's quality of life. In those cases, they stick with the drug that they already have. The so-called cross deals affect the cost of drugs too. It's quite interesting. We can talk about access to medicines, but the impact of their cost on the entire health care system is an issue too. When we talk about the health care portfolio, we know that a large part of the funding goes to pharmacare and hospitals. They have decided to put less pressure on the entire health care area.

Mr. Russell Williams: I think that we have to be very careful with evaluations of drugs intended for everyone. Our studies show that a drug is very effective for some patients, but less so for others. If the authorities decide that they are not going to make the drug available for that reason, the patients for whom it would be very effective will not have access to it. So we have to be very careful with evaluations that affect everyone rather than target groups.

Mr. Mark Ferdinand: I would add one thing. Again, this is a question of choice, and when we compare all the countries in the world that offer a greater choice, we see that in some that does not necessarily imply an increase in the health care budget. We may ask why, and maybe a future study will give us the answer. In some cases, we may see that it is caused by optimal drug use programs or other measures that let those countries limit their costs at the same time as they offer a greater choice to doctors and their patients.

The Vice-Chair (Ms. Christiane Gagnon): Thank you.

Ms. Priddy.

[*English*]

Ms. Penny Priddy: Thank you.

We haven't touched on this, but there was some discussion in the beginning about transparency and the public input into the CDR, and I would like somebody to briefly tell me how they would see that happening in an objective way. For instance, if you fill the room with a public that wants drug A, what you have is public input, but it's really a roomful of people who are there for a particular drug.

Could you just give me a sense of how you might see that public input happening in a way that is reasonably objective and helpful?

● (1710)

Mr. Peter Brenders: I'd like to offer a suggestion. I think there are a number of ways to deal with that. We see this approach in place in other jurisdictions. A good example is right next door to us, the U. S. FDA. The FDA, before licensing any product, does an open-panel review hearing that allows for citizen engagement. It allows for the companies to sit there and answer questions as well, to be questioned by the committee and the panel in a full public environment. We see public hearings as well.

Our hope is to allow—because remember, at the end of the day, cost effectiveness—Everyone talks about the science of health technology assessment. It's not science. At the end of the day, it's still opinion, and it's opinion of a very select few people in terms of what value is. Our question on that one is to do that in public, have a public meeting. Yes, there may be a big crowd out there, but let the crowd hear what the view is, hear what the debates are, the positives and negatives, and allow for perhaps selected input into that discussion, into that framework.

At the end of the day, it's going to be those people who are most affected, whether they be physicians, pharmacists, patients, or even the manufacturers that have done the research and development to bring it there to be able to inform a group. We find it's particularly important, especially when you're dealing with unmet needs and rare diseases, where there is no 30- to 40-year history in terms of the disease treatment cycle—

Ms. Penny Priddy: I realize that. There are a number I'm aware of like that.

Okay, thank you.

Also I want to say happy birthday to the chair. I don't know if this is how you planned to spend your birthday, chairing a health committee meeting, but I suppose we don't always get to choose. We're thrilled that you're here to do that.

As a cancer survivor from British Columbia, I appreciate the comments around our oncology program.

I have one more, if I might. Certainly, the party I belong to—and I think there are others—is talking about a national catastrophic drug plan. Can you see that happening independently of the common drug review? Is there a way for that to move on without going through the common drug review? Would you want to comment on that?

Mr. Russell Williams: I think if we want to build something that actually responds to all Canadians' needs and make sure they have access to innovative medicines in a national program, we definitely have to move it through without the common drug review.

As Mr. Brenders talked about, it's a different philosophy, and I think what we have to do is sit down and build together with each of the provinces the method that responds to those priorities.

Mr. Peter Brenders: Just to echo Mr. Williams' point on that one, the philosophy—We have to remember that drugs today, as much as they represent a piece of the spending—it's somewhere between 4% to 8% of total public spending. There's still another 92% that's spent on other parts of the health system.

We have a philosophy in the rest of the health system, the trial of life, when we're dealing with severe needs, which is that you will put a patient in an ICU and give him the chance to see if it works. We don't do that with drugs.

Especially with new technologies that are coming out, with unmet needs that are out there where there is nothing else, what we do is we throw them into a CDR review and say let's take a look at it for a few months before we give the patients that choice and that option.

So we're saying if it's catastrophic in terms of life and the needs, then give them the chance.

Ms. Penny Priddy: Thank you.

The Vice-Chair (Ms. Christiane Gagnon): Madam Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thank you, Madam Chair. I wish you happy birthday as well.

Thanks very much to our presenters. I'm new to this discussion, so I don't have a lot of background information on it.

I have some questions regarding some of the statements you made, Mr. Williams. You talked about the agency overseeing CDR already deciding to expand. Could you elaborate on that? Is that along the same lines as the communiqué that was issued two business days ago?

● (1715)

Mr. Russell Williams: Yes.

Mrs. Patricia Davidson: Could you expand on that first, please?

Mr. Russell Williams: I could table it if you like, but it's a public document. The common view is to be expanded to new indications for old drugs. It was a communiqué that came over the wires on April 12. It was a statement that the CADTH believes that the CDR has met its objectives and is moving forward with an expansion. That's why I made that statement.

I found the timing inappropriate at the very best, coming two days before a hearing. It's a public communiqué, so I could certainly table it if that's appropriate.

Mrs. Patricia Davidson: The CDR was started at the request of the provincial health ministers. Is that correct? It is a branch of the larger group that has two or three different branches to it, and 30% of the CDR's funding is federal and 70% is provincial.

Mr. Russell Williams: Yes.

Mrs. Patricia Davidson: Now what about the overall group? Is it funded federally at 30%, or is it a different percentage?

Mr. Russell Williams: My understanding is it's 80% for the overall group.

Mrs. Patricia Davidson: Are there distinct divisions within that overall group?

Mr. Russell Williams: There are distinct divisions, but in terms of the way the federal money is allocated, it's my understanding that we have not been able to determine how the federal money is allocated, particularly on the CDR.

Mrs. Patricia Davidson: Okay. Does that apply to the other two arms of that group as well?

Mr. Mark Ferdinand: It would probably be most appropriate to hear from Health Canada and the Canadian Agency for Drugs and Technologies in Health on that issue.

Mrs. Patricia Davidson: Okay. Thank you.

You also made statements that you feel they're unaccountable and lack transparency. What do you base that on? Is it because you've tried to get these answers?

Mr. Russell Williams: It's difficult to get answers. We were talking about political experience. You want to make sure that somebody is accountable, and this body is not accountable to a minister. It's very difficult to actually put your finger on who is running the CDR and how decisions are being made. When you want to challenge those decisions, it's hard to interface with that body.

Mrs. Patricia Davidson: Then you talked about the medicine Sutent. Within four months of approval by Health Canada, Quebec agreed to fund it. Ontario has also provided access to it. So how did Ontario go about doing this if it wasn't through the CDR? Was it because the different provinces can support different products?

Mr. Russell Williams: That's right. The CDR is not binding. They don't have to listen to it. They don't have to listen to a rejection or a positive recommendation. So Ontario chose to move on part of the indication of that, as Quebec did.

Mr. Mark Ferdinand: The only thing I'd mention here is that if you look over time at the number of negative recommendations that have been made by CDR that resulted in positive recommendations by other provinces or drug plans, you actually see some variation. You see some 14 drugs listed in Quebec, even though they are not a participating plan, that received a negative recommendation from CDR. You see the NIHB with one or so. B.C., I believe, has listed a few that have received negative recommendations, and Ontario has listed 4 drugs that have received negative recommendations.

It just goes to the point that Mr. Williams raised earlier, and it really goes to the heart of the question of catastrophic drugs. Provinces are best placed to make decisions with regard to health care, and they do that across all other medically necessary services, so the question has to be who is best placed to make these decisions. It's our position that it certainly isn't a macro group, even if they are providing recommendations, as you'll certainly hear next week.

The fact is that those end up being de facto decisions in terms of what it means from the individual patient's point of view: do I have a choice of getting this or not? When you see those negative recommendations resulting in waits for a decision that may or may not come from a province, or a negative so we're not listing it, that really ends up being a de facto decision that harms patients.

● (1720)

Mr. Russell Williams: As you heard from Mr. Billen, these are not drugs where you want to have a barrier between the patient and the health care profession; you want to make sure these medicines get to these patients as soon as possible.

Dr. Daniel Billen: On the list I talked about, the seven drugs that were looked at as first-in-class drugs, one of the drugs on there is our own Sensipar. The product is used for people on dialysis, a very serious disease. Today, after a negative CDR recommendation, it is approved in Quebec for reimbursement, and it is actually under certain conditions approved in B.C. for reimbursement.

The irony of this is that this drug is manufactured in Canada for the world, and Canadian patients don't have access to it. It doesn't make sense. It just doesn't make sense. This product is available in France, in Europe in every country, but most provinces in Canada, except for Quebec and B.C., say no to these drugs based on a negative CDR recommendation. It does not do the patient justice.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): Mr. Brown, I think that you are going to be the final speaker. Thank you.

[*English*]

Mr. Patrick Brown (Barrie, CPC): Thank you for your comments here today.

Generally when I look at a government program or any program that's involved in Canada—and I realize this is certainly provincially initiated—I look at how it affects the residents in the riding of Barrie, who I have the pleasure and honour of representing. There have been three occasions where I have had concerns brought to me about the common drug review. I want to bring them up and then get your comments, because I realize when we look at this that there's certainly a balance required between safety and prudence and, on the other hand, access and a patient focus. My concern is on the latter part in terms of the access and the patient focus.

I have had three examples brought to me by constituents. I had a daughter who came into my office and expressed concerns that Iressa was not available to her mother, who was suffering from cancer, and she complained about delays in Ottawa. You saw the frustration in her face and how it affected her family, and in that case it appeared that we had been a hurdle. I understand it has been approved in some provincial jurisdictions, but for some reason, with the common drug review, we inhibited what her doctor had told her mother would be something that would be helpful. I'm interested to know how that emerged.

Another example was a rare disease, Pompe disease. There was a resident in Barrie who suffered from that, and there was a drug available that was approved in Europe. It was approved by Health Canada, but it wasn't approved by the common drug review.

I also had a group of young individuals who suffer from type 2 diabetes who expressed concern about the length of time it takes to go through our channels.

You hear these examples, and I'm sure there are many you don't hear about. What are your sentiments? Is the benefit to safety outweighing this benefit for access? Are there examples of how this has helped with safety and prudence? Are there examples like this, that we're really losing on the other end?

Dr. Daniel Billen: First of all, if we look at Heath Canada, it is going to make the decision around advocacy and safety. So that's the first hurdle. I think they are in the best position to give you that balance. I think the more specialized the product is, the more safety concerns there are going to be as well. And sometimes it comes down to having the right balance between benefit and safety. It really is the jurisdiction of Health Canada.

All the examples you talked about are exactly the things we are talking about here today. Patients are living in a global world and understand what is available; they are holding on to that last hope about what they have out there. I don't think we provide patients with similar hope or access to what they would have in another province, such as Quebec, or in other countries, such as France, Germany, the U.K., and so on. So, really, I think you hit it on the nail here by saying that we will see more and more patients frustrated that there is something out there that potentially—and potentially is what I'm saying—could help them, but which they cannot get access to. They will ask, where did the system fail me?

I think that's where CDR plays an important role. Because their approach is predominately one of cost containment, they are going to deny many of these products to patients who are really at their end and are looking for hope and options.

● (1725)

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): That's your last question. Mr. Batters would like another word. You have taken almost five minutes, you have only about 30 seconds left. But if you want to speak, Mr. Brown—

[*English*]

Mr. Patrick Brown: [*Inaudible—Editor*]

Mr. Dave Batters: For 30 seconds or two minutes?

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): You have about a minute. There's not enough time left to ask a question.

I am giving the floor to Mr. Batters once more.

[*English*]

Mr. Dave Batters: I'll go really fast, Madam Chair.

Gentlemen, whoever wants to answer, which government auditor or auditors review CDR and evaluate if there is value for money for taxpayers?

Mr. Peter Brenders: That's the same question we have.

Mr. Dave Batters: So you guys don't know?

Mr. Peter Brenders: No, we don't.

Mr. Dave Batters: Okay, thanks.

The next question is if CDR receives public funding but is not part of a single government body, then who provides oversight and who is accountable?

Mr. Russell Williams: That's exactly our question, and I think those are the questions you should be asking.

Why I highlighted the press communiqué of two days ago is that while we're moving forward with a review to understand the effectiveness and the efficiency of CDR, there's an announcement saying it is being expanded.

Mr. Dave Batters: And the last question, gentlemen—and I really appreciate the intervention of my colleague Patrick Brown, who really put a human face on what we're talking about here today—is whether patients can appeal a decision by the CDR.

Mr. Peter Brenders: Not that I know of.

Mr. Dave Batters: There's no patient appeal process whatsoever?

Mr. Peter Brenders: Not to the CDR, no.

Mr. Dave Batters: Okay. Thank you.

That's all I had, Madam Chair.

[*Translation*]

The Vice-Chair (Ms. Christiane Gagnon): I know that we would like to continue the meeting, but our allotted time is up. I thank all the witnesses who have contributed to this first look at the CDR. Thank you very much. You are bringing new insight to our deliberations.

The meeting is adjourned.

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

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