House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 056 • 1st SESSION • 39th PARLIAMENT

EVIDENCE

Wednesday, May 16, 2007

Chair

Mr. Rob Merrifield

Standing Committee on Health

Wednesday, May 16, 2007

● (1530)

[*English*]

The Chair (Mr. Rob Merrifield (Yellowhead, CPC)): Seeing as we have enough members around the table, we will call the meeting to order.

I want to thank the witnesses for coming forward. This is our last official day of witnesses before we bring in the department for one more look at it, so we're crowding very close to the end.

I'll just let the witnesses know that we want to leave a bit of time for the committee to be able to discuss the report in camera, right at the end of the meeting.

So with that, we will want to welcome our witnesses who are coming forward to present on this important issue. This is pursuant to Standing Order 108(2), the study on prescription drugs, the common drug review. I believe this is our eighth meeting.

Thank you for coming. We look forward to your presentation to the committee.

We have with us, from the University of British Columbia, Dr. Steve Morgan. Steve Morgan, it's good to have you with us. You're from the Centre for Health Services and Policy Research.

Also, from the University of Alberta, we have Dr. Devidas Menon. It's good to have you here from the School of Public Health.

And, as an individual, we have Jean-Claude St-Onge. It's good to have you here as well.

With that, we will open the floor in that order, with the University of British Columbia, starting with Dr. Morgan.

The floor is yours. You have 10 minutes. We look forward to your presentation.

Dr. Steve Morgan (Assistant Professor, Centre for Health Services and Policy Research, University of British Columbia): I'd like to begin by thanking the committee for the invitation to speak today.

I'd like to take a moment to particularly acknowledge the support of the Canadian Institutes of Health Research, the CIHR, both for my personnel support and for my program of research. Without the CIHR, frankly, academics like me would be unable to attend meetings like this.

As evidence of the international recognition of Canada's CDR, I would also like to acknowledge the U.S.-based Commonwealth Fund for providing us with a grant to study the common drug review in an international context, with an aim to providing lessons for Canada and for the United States.

Before turning to an international context, I want to quickly go over a few questions about why one would review medicines.

I'm an economist by training, and I perhaps look at markets in a slightly distinct way from other health policy analysts. I want to first reflect on an example that we would consider on the idea of market discipline.

It is the idea of using the market to find and reward value for money in a marketplace. This would occur if consumers were well informed about their needs and wants; if they could reliably judge a product's ability to meet those needs and wants; if they had a variety of options to meet their needs and wants, including the option of not consuming; and finally, if they faced the full costs of the purchases they make. Under such circumstances, as you would find in most shopping centres, consumers could in fact find and reward value for money in the marketplace.

However, the pharmaceutical sector is different. Pharmaceuticals are not consumption goods; they are inputs into care. We are not in the business of purchasing pills and tablets in this sector. Whether you are a patient or it's a drug plan, you're in the business of purchasing health outcomes.

If you are an individual who has a need for improved health incomes, it is likely that you are vulnerable in some circumstance. Therefore, as a consumer, you may not necessarily have the time or the ability to appraise and judge the options available for your needs.

In fact, to establish the effects of treatment options is very difficult. It is tough to decide whether nature, placebo, or the drug in question is responsible for changes in the health of a patient or the health of a population. Therefore, we require large clinical trials. In fact, because no one trial is typically definitive, we tend to require the meta-analysis of many trials involving thousands of patients, or what is referred to as health technology assessment.

Another unique characteristic of the pharmaceutical sector is that patients do not pay. This is not a condemnation of either private or public insurance, but it's an acknowledgment that when selecting treatment options for a given need, patients will not typically be as price sensitive as consumers in a regular marketplace. Similar to patients, physicians may not be price sensitive, even if well informed, given the fact that doctors seldom pay for the prescriptions they prescribe.

What are the implications of this? From an economic perspective, pharmaceuticals and their consumers are non-standard in economic terms. I would argue that imperfect information about value for money is the single greatest market failure in the pharmaceutical sector. The lack of a financial incentive to act on information about value for money would be the second.

I'm going to skip the topic of expenditure in Canada as classified by the PMPRB, but I'd be glad to take questions on this.

I'd like to turn to the fact that around the world we are seeing an increasing number of national drug review processes to help correct market imperfection about information concerning value for money. But why do they exist?

Well, as acknowledged, drugs are not ordinary goods. They are inputs into care. The licensing process required to bring a drug to market is designed for purposes that are different from the intent of drug coverage policy. Drug coverage policy requires comparative information and economic data. The science is extraordinarily complex. Therefore, it requires that expertise and capacity be built in a country to be able to handle the task of technology assessment.

I think these are some of the reasons that countries have what we would refer to as central drug review processes.

Turning to what the goal of these things is, I would argue that it is largely around economic efficiency and decision-making, in light of the fact that public and private budgets are limited. We do not have infinite resources. Therefore, we require some basic evidence and some simple economics to make better decisions around how we allocate those limited resources.

The kind of information we need to know is this. For example, is a product less effective, equally effective, or more effective than comparators? Is it less expensive, as expensive, or more expensive than its comparators? With those three bits of information on each dimension of cost and effectiveness, decisions can be informed through central drug review processes.

● (1535)

Some of the decisions will be easy, such as that when a drug is less effective but more costly than alternatives, surely no one will consume it. Other decisions will be ones in which you will require deliberation with the public and the payers to decide whether a drug, for instance, that is more effective but more expensive is actually worth the additional cost to the public budget or to private budgets. Similarly, some decisions will require negotiation between purchasers and providers, such as in cases where drugs are about as effective and about as costly as alternatives.

In the study we conducted on behalf of the Commonwealth Fund in the U.S., we studied the Canadian common drug review process and the process for a centralized drug review in the United Kingdom, Australia, and New Zealand. We also studied one of the processes in the United States.

I'm going to quickly talk about the cases of Canada, the U.K., Australia, and New Zealand. Just note that the processes themselves are extraordinarily complex, there's no doubt. This is a tough business to be in, appraising products to help inform coverage decisions.

There are a few commonalities, and the first is that all of these processes are distinct from licensing. The goals of the licensing process are different from the goals of a process to inform coverage policy.

The second is that all of these processes involve some form of clinical assessment of evidence and some form of assessment of economic evidence.

Third, the commonality of these things is that there is a centralized appraisal; that is, a committee of experts that sits to determine the meaning of the scientific and economic evidence in the context of decisions for a given country or given region.

One of the differences between the countries we studied is in the decision-making context—or more to the point, the funding context—in which decisions are taken.

Turning to Australia, there is an organization called the Pharmaceutical Benefits Advisory Committee, or the PBAC, which makes centralized review guidance for the national formulary in Australia.

The context of Australia is one of a national pharmacare benefit, and it uses a national formulary. The centralized review is required, and in fact the minister cannot list a medicine on the national formulary without the PBAC making a recommendation to do so.

It's a pragmatic process that involves a 17-week cycle to review approximately 100 drugs per year, including generics. The rationale is published on the Internet and made available to the public through those mechanisms as well as through public input in various stages of the review.

Prices in the Australian context are in fact negotiated as part of their review process. Following a recommendation of the PBAC, price negotiation begins between government and supplier.

Turning to New Zealand, we have an environment there with universal pharmaceutical coverage and a national formulary managed by a centralized management agency, referred to as PHARMAC. Centralized review by the Pharmacology and Therapeutics Advisory Committee, the PTAC, is required under the process for coverage in New Zealand, but in fact PHARMAC may make listing decisions that differ from PTAC recommendations, in part because listing decisions are conditional on price negotiation.

The process in New Zealand is pragmatic, in that the organization reviews between 30 and 40 drugs per year. Selective information is available on the Internet. As mentioned, price negotiation is tied to the process.

Turning to England and Wales, the organization, the National Institute for Health and Clinical Excellence, otherwise known as NICE, is an organization that does some of these assessments in the context of universal coverage for pharmaceuticals, but uniquely in the U.K. they operate under what's called a negative formulary. Ostensibly, all products on the market in the United Kingdom are eligible for public coverage, and it is devolved to the regional decision-makers to make implicit rationing decisions about what will and what will not be prescribed in a given context.

It's under those sorts of contexts that the NICE has evolved a very selective process. Only drugs that are deemed to be controversial or of high impact to the health system are reviewed and centrally appraised through the NICE process. As a result, NICE reviews only approximately 11 drugs per year, and the reviews are exhaustive processes of consultation and negotiation with stakeholders that take up to one or more years per review.

The guidances recommended by NICE at a national level become mandated at the regional level. There is no price negotiation in the context of the English and Welsh system.

Turning to Canada, whose system you all are intimately familiar with, we are involved in a system that involves mixed coverage. We have a multiplicity of different formularies in Canada run by public, private, federal, and provincial drug plans. The common drug review is required by most public plans except Quebec's, yet decisions unique to the context of Canada remain centralized. “No” and “yes” both mean “maybe” in some sense in the context of the Canadian system.

● (1540)

The initial focus was on new chemicals and combinations of chemicals, probably for budgetary purposes, in my view, just to keep the process pragmatic as they got off the ground.

It is a pragmatic process involving a target of about 25 drug reviews per year. Summaries of rationales are posted on the Internet, and as you know, there are now public representatives on the expert advisory committee. Unique to Canada and the U.K. is that there is no price negotiation tied to the CDR process. It is simply an assessment of appraisals or evidence at the price listed by the manufacturer.

Turning to the international context, or at least international experience, I had the fortune of interviewing decision-makers from all the countries that we have studied, as well as meeting them personally at a meeting I hosted in Vancouver last year, and again in Wellington, New Zealand, just last March, to discuss the challenges that common drug review processes face around the world.

I could suggest—I think objectively, because I do not work for and have never worked actually with the common drug review—that it is rapidly becoming an internationally recognized and respected peer among the agencies internationally. I would argue that it's probably underfunded, but we could talk about that later.

The CDR and its peers face several common challenges, one of which is drugs that are approved for sale based on surrogate markers of their effectiveness; that is, they are effective at doing something to the biological structures or systems of the body, but we do not yet know whether that will in turn relate to health outcomes. This is problematic around the world.

Drug review processes suffer or deal with poorly designed trials. In particular, most trials involve drug-to-placebo rather than drug-to-drug comparisons, and in the context of making rational economic decisions, we need to know drug to drug: is this better than its alternatives?

There are serious challenges with respect to transparency and confidentiality in that drug review processes are limited to the extent to which they can report to the public about the data they use for decision-making processes, and this is true not just in Canada but around the world.

And finally, there is an issue with respect to real-world indication creep. Manufacturers often rightfully claim that their products are cost-effective in certain segments of the population. However, as is often the case, when products are on markets it's difficult to prevent the use of those products from creeping into areas where there may be better or alternative treatment options from the perspective of cost-effectiveness.

So my closing point really is that I think the CDR is well respected, and I think that processes like the CDR are indeed necessary so that we can provide incentive, or in fact obligation, for manufacturers to bring the kind of evidence that is necessary for a rational drug policy.

Thank you.

The Chair: Thank you very much for your testimony.

We tried to get representatives from the United Kingdom and Australia through video conference but were not able to, so perhaps you'll be able to answer a significant number of questions that we might have been able to pose to them. So thank you very much.

From the University of Alberta, Dr. Menon, the floor is yours. You have ten minutes.

● (1545)

Professor Devidas Menon (Professor, School of Public Health, University of Alberta): Thank you, Mr. Chair, and thank you to the committee for this invitation to be here today.

In fact, I'm filling in for someone who I think you actually wanted, who happens to be a young colleague of mine with whom I have done most of this work. Her name is Tania Stafinski, and I do want to mention her. She is unable to be here.

The Chair: Just to clarify from the committee, she said you're the best.

Prof. Devidas Menon: It behooves her to say that since I'm actually her supervisor.

But I do want to give her credit and go on record as saying that most of this work was done with her, but she's unable to be here. So I hope I can contribute meaningfully to your deliberations and decisions as you come to a close.

I will give you a bit of background on the sorts of work we've been involved in, so you understand the context.

Over the last few years, we've done a number of research projects funded by organizations such as CIHR, which Dr. Morgan mentioned, on differences in provincial formularies across the country—on differences in access to cancer drugs, in particular—and we've looked at international models of catastrophic drug programs, as well as how economic information is, or could be, used in the decision-making on drugs.

What's interesting here, and I suppose the reason I'm here, is some work we did on what I call existing centralized drug review processes around the world. Dr. Morgan has given some details on three of the countries we looked at. I'll try to limit myself to reporting on that, because since it's an international panel, I thought we'd start with that.

Our objectives were to identify the centralized drug review models in existence in the world, which we did about two or three years ago. Like foolish academics, we thought that if we were to do this while people were trying to construct the common drug review in Canada, it might actually help. But it has taken some time before anyone has paid attention to it.

We were looking at things such as the management frameworks, the governance, and the review processes and appeal mechanisms, if any. And we compared, where possible, certain common aspects of the review process itself. We did not look at things such as the effective times to coverage, the times to approval, or the number of drugs per country. Other people have done that; Dr. Morgan has done some work in this area. So that wasn't the focus of what we wanted to do.

What we found at the time was that there were 16 countries with predominantly publicly funded systems, where there were what we would call centralized drug review systems. I'll quickly run through the countries: Australia, Austria, Belgium, Denmark, Finland, Greece, Ireland, Italy, the Netherlands, New Zealand, Portugal, South Africa, Sweden, and the U.K. There are many different approaches and different models, in particular, because of the different health care structures. Some are old and some are newer.

Let me quickly go over what we found.

As far as the structure, governance, and role are concerned, there are different organizational models in the different countries for managing this common drug process, ranging from a government body within the ministry to a free-standing organization. So there is a variety of these models.

In seven of the sixteen countries, the body that is equivalent to CEDAC—the Canadian Expert Drug Advisory Committee, which is the review committee for the CDR process—developed recommendations regarding reimbursement, coverage, and listing of a drug. In seven others, they have a regulatory role and actually make the decision determining the fate of a drug, as far as coverage is concerned. In Norway, the body does both, depending on the nature of the reimbursement request. Some actually set the level of reimbursement; so this gets into the pricing part of this, which is not something we have here. Some are involved in other things, such as decisions regarding maximum usage guidelines, prescribing indications, and the like.

The membership of these CEDAC-like bodies, if I could call them that, typically contain physicians, both general practitioners and specialists; health economists; pharmacists; clinical pharmacologists; and government representatives from ministries, agencies, as well as from insurance funds in some countries. In New Zealand it's entirely comprised of doctors and clinical pharmacologists. This is not an academic question, because a key to the entire process is the structure and the membership of the decision-making bodies, and whose voice is heard. So we wanted to take a look at that.

In Australia, Sweden, and the U.K.—the U.K. organization being called NICE, as has been mentioned—there are public members as well, either citizens or taxpayers or patient representatives.

● (1550)

The membership numbers range from a handful of, I think, six in Greece to 60 in the U.K. The U.K. also involves epidemiologists and other methodologists, and it can be said to be the broadest representation of sectors in this entire process.

The coverage criteria also vary, depending on the system. Typically—and Dr. Morgan has mentioned some of this—the criteria include the therapeutic value of a drug, which means things such as clinical usefulness, efficacy, and if there is actually a treatment available for the condition already. The severity of the condition, the community need, and the potential public health impact are also criteria as indicated by these bodies. It's not very clear from public documentation how these are weighted. That would be a key aspect of combining these criteria.

In recent years there's been a huge growth in the interest of the cost-effectiveness of drugs by most of these centralized reviews. Incidentally, Canada has been one of the leaders in this area of cost-effectiveness—the use of cost-effectiveness methods and the development of cost-effectiveness methods for decisions on programs and health care in general, not just on drugs. Some countries consider only costs. Some countries exclude costs completely in their discussion.

Some agencies in addition look at budget impact, which is somewhat different from cost-effectiveness. Cost-effectiveness typically compares two things to determine the cost-effectiveness benefit of one over the other. In some countries, or at least in two countries, one criterion is whether the drug is self-administered, because the priority for that organization is not hospital-based drugs, so that becomes a criterion. There are countries that look at the alignment with government priorities and also the potential rate of misuse.

These are the general sets of criteria. The information to assess against these criteria, typically the controlled trials that Dr. Morgan talked about, are comparative studies with other therapies, and this bears repeating. Dr. Morgan made this point.

The question is asked: if Health Canada has already done a review, why should anyone else do a second review? I think fundamentally the objectives of those reviews are different. Even the data requirements will be different. Whereas Health Canada typically looks at trials, and they may be big trials and more often than not they use a placebo as a comparator, when it comes to reimbursement of coverage decision-making, it's to look at what alternative it's being compared against, what practical alternative there is. The trial information that Health Canada might have may not be there. That's a challenge for the common drug review, in any case.

The disease pathology, the incidence, the burden of the disease on society, and the potential public health impact are all bits of information that are used. As I said, economic evaluations are now strongly recommended in 13 of the 16 countries. Also, manufacturers are often asked to provide estimates of expected volume so that there may be budget preparation done for that.

I believe Dr. Morgan talked about the assessment and appraisal stages of the process. Assessment means looking at the data, and the information appraisal means judging that, and there's a separate body that does that.

Again, who does this in these different countries? It varies. Who can submit requests? In most countries it's the manufacturer or the marketing approval agency, the agency that approves for the purposes of sales.

In Australia a medical body, a health professional, or even an individual can request the review, but I'm not exactly sure how the priorities work there.

They also differ in who puts the information together, when it's put together, and so on.

Finally, they also differ in whether there are formal consultations with other groups during the process.

With regard to appeal, which is a bone of contention among some sectors, when we looked at it we saw that mechanisms for appeals of decisions were reported only for France and the U.K. But this may have changed. In the last couple of years there's been huge pressure on these bodies to open up the process and engage more people.

● (1555)

I'd just like to conclude by making five points that I think are relevant to what we've done in the Canadian situation.

First of all, in most countries there isn't a Health Canada-like review process in addition to the coverage review. If you look at these 16 countries, except for the U.K., Australia, and New Zealand, in many of them it's the same body that deals with both aspects of it, whereas we have separated, in a sense, through PMPRB, Health Canada, and the provinces, certain functions that relate to certain aspects of drug therapy. In some of these countries, it has evolved together, in a sense, and so there isn't that division.

Secondly, there isn't a provincial-type review in any of these countries, because the decision of the common drug review body there or the recommendation to a minister or ministerial committee is what's acted upon. So there isn't a second level of deciding whether to fund it or not. I think that does make a difference when people talk about length of time to listing.

Thirdly, the kinds of coverage decisions in these different bodies cover off a wide spectrum, and that is in part because of what I just said, which is the mixture of roles that these countries may have. In some cases the body actually sets the reimbursement level. It can say, we'll approve this drug at 65% of the prescribed level. Here, this is done by the provinces, and quite often by negotiating with manufacturers.

I think this is something I would like to leave the committee to think about. That is, there has been a lot of interested talk, at least, if not movement, to encourage broader involvement in this common drug review process. The U.K., for example, has a citizens jury that advises the entire work of NICE. I believe in New Zealand there's the Consumer Advisory Committee. The people are trying different ways of taking this process from what has been a technical, scientific, and clinical process to one that somehow incorporates values for people. It's a challenging situation and people are trying things, but I think the fact that the CDR now has public representatives is a great step. I'd say, go further and hold these meetings, just like your meetings, in public.

Finally, what may be touchy to some provincial governments is that when we looked at these CDR-type bodies, at least one of them is permitted to make delisting recommendations, which is that you go and look at drugs that are there, look at the basket of drugs, and if you are going to add a drug, is it possible to recommend removal of one?

I think part of the challenge is that when people get worried about the rise in expenditures for drugs, it's because hardly anything falls out at the bottom. The question has to be asked, not just of drugs but all health technologies: what do we have now that has been replaced and that we should de-invest in? I think it would be useful for the common drug review here to consider how that might be at least examined.

Thank you, Mr. Chair.

The Chair: Thank you very much. I'm sure we'll have lots of questions as we get into that part of the meeting.

For now, we have a professor and author.

Mr. St-Onge, the floor is yours. You have 10 minutes.

[*Translation*]

Mr. Jean-Claude St-Onge (Author and Professor at Lionel-Groulx College, As an Individual): Thank you, Mr. Chair.

Good afternoon, ladies and gentlemen. I wish to thank the members of the committee for giving me this opportunity to address them.

You will find all the references at the end of my text. By way of introduction, I will say that drugs account for 17.5%—

[*English*]

The Chair: We don't have your text, because it wasn't translated. Nonetheless, if you go slowly, we'll follow.

[*Translation*]

Mr. Jean-Claude St-Onge: Drugs accounted for 17.5% of health expenditures in 2005, a substantially higher percentage than that paid to physicians. Drug expenditures have become the most inflationary component in our system and they are increasing twice as fast as the health budget as a whole. Furthermore, in Canada, almost twice as many prescription drugs are prescribed as in the Netherlands and Denmark – even though the major health indicators are practically identical in these three countries.

Canada is not the only large drug consumer, but these products are expensive, indeed unaffordable for certain segments of the population, and they weigh very heavily on the public purse. Recently, the Patented Medicine Prices Review Board showed that in 11 industrialized countries generic drugs are cheaper than in Canada–sometimes by a considerable margin. Also, patented drugs cost less everywhere else, except for the United States and Switzerland.

For example, generic drugs in New Zealand are sold for 77% less than in Canada, in Spain, 42%, in France, 29% and even in the U.S., 35%. For patented drugs, the figures are: 21% for New Zealand, 27% for Spain and 15% for France. There is no mention of the United States.

When the prices are adjusted to take into account buying power, patented drugs are 37% less expensive in Spain than in Canada.

In 2005, a group of researchers led by Dr. Morgan published a study in the British Medical Journal showing that 80% of the increase in the price—

● (1600)

[*English*]

The Chair: Slow it down just a little and we'll be okay.

[*Translation*]

Mr. Jean-Claude St-Onge: —of drugs in British Columbia was attributable to the introduction of new products or new indications that contribute nothing or little in therapeutic terms. These products, which are called me-too products, are equivalent molecules to those already found on the market. The efficacy of these new indications is often not tested in the field. Consumption of new products that have replaced old ones doubled drug expenditures in British Columbia between 1996 and 2003.

According to the Patented Medicine Prices Review Board, between 1990 and 2003, only 5.9% of these new products were breakthroughs in therapeutic terms. That is the worst of it. Likewise, the FDA reported that three-quarters of the drugs put on the market in the 1990s had nothing new to offer over old treatments.

The foregoing shows the importance of a rigorous review of the drugs appearing in provincial formularies, that is, a probing and pertinent review conducted by independent experts. A study published in the Journal of the American Medical Association, involving 1,140 clinical trials, indicated that trials funded by the industry were 3.6 times more likely to result in conclusions favourable to the sponsor's product. These are the studies that are submitted to the control agencies for approval.

For example, let us highlight the new antihypertensives proposed as first-line treatment, which are no more useful for the vast majority of people than the old drugs, but which cost infinitely more. Dr. Furberg, a senior researcher in a huge study done on antihypertensives, has calculated that American consumers have spent from $8 to 10 billion unnecessarily on these new products.

Mr. Robert Goyer, former head of the Conseil du médicament du Québec, estimated that the most popular and most expensive antiulcerant cost $60 million too much, since less expensive alternatives were available and were just as effective in most cases.

The Green Cross has also reported the existence of major differences in the prices of drugs paid by various government agencies. The cost of one drug in the Ontario formulary was entered as $1.90 and the same product was sold to the Department of Defence for 45¢. Four times as much.

New Zealand is showing us the way for optimum drug use. In 1973, this country set up a Crown entity, Pharmac, made up of independent scientists and groups of patients. Pharmac is a group pharmaceutical buying centre that can negotiate prices. Through competitive bidding among manufacturers, it causes them to compete with one another.

Pharmac prepares a list of the best drugs on the basis of scientific criteria. It chooses the one that that will become the reference product and selects a number of alternatives, which are reimbursed at the price of the cheapest reference product, except in cases of intolerance or contraindications. Agreements called cross-deals are negotiated with manufacturers. When a new effective and safe drug arrives on the market, it is entered in the formulary, provided the manufacturer agrees to a discount on a product already on the list. Pharmac also practises the system of maximum expenditure. A contract is concluded with a manufacturer with a view to the sale and reimbursement of a certain quantity of drugs based on a needs analysis. If expenditures surpass this maximum, the firm reimburses the difference to Pharmac. Finally, any products that have not demonstrated their superiority over existing treatments are not reimbursed. Such was the case of Celebrex and Vioxx before they were taken off the market on account of their cardiovascular toxicity. Incidentally, Vioxx won the Galien Prize in 1999, I believe, which is really the Oscar of drugs. Thus the New Zealand formulary contains 2,600 products, compared to 5,000 in Quebec.

● (1605)

Allow me to broach a related topic, though one in keeping with the foregoing. The review of drugs begins long before the authorities ask questions about the appropriateness of entering them in the formularies, that is, as soon as they are submitted to the Therapeutic Products Directorate. In this regard, we should hope that improvements are made in the assessment of the effectiveness and safety of drugs.

Are Health Canada's licensing criteria rigorous enough? For a drug to be approved, it must as a rule show that it is more effective than a placebo. Should it not be required that a product be tested against a drug that is already on the market, whose toxicity profile is already known and that is much less expensive? Furthermore, clinical trials are generally short-lived. They are designed to assess the effectiveness of the drug and not its toxicity, and the patients recruited are ideal patients. The consequences may be dramatic. This is how much later the undesirable effects of numerous products are discovered. Over a 25-year period, 10% of the drugs received the most severe warning from the FDA, the black box warning, and 2.9% were withdrawn from the market, while the monograph for 51% of them was changed on account of the safety problems discovered after they were marketed. The research by Dr. Joel Lexchin, of York University, shows that, over a 40-year period, 39% of the drugs taken out of circulation were removed between 1993 and 2004, a much larger proportion than in previous decades. Were some of them approved too quickly?

Many experts have sounded the alarm about the problem. In the U.S., a lot of literature talks about the credibility gap concerning the drug licensing process, and since the regulatory process is practically identical in both countries, we have cause for concern.

This credibility gap motivated the United States Institute of Medicine to make a whole series of recommendations on the regulatory process. Among these recommendations, the Institute proposed that a black triangle be placed on new drugs for a two-year period in order to indicate that not all the undesirable effects of the product are known; it suggested increasing the FDA budget; it suggested getting rid of what are called user fees, which are the charges manufacturers pay to have new drugs approved. These fees have existed in the United States since 1992 and in Canada since 1994. In exchange, manufacturers obtained a reduction in the approval time for new products. Numerous observers think that, since it was implemented, this practice has been responsible for the increase in the number of drugs withdrawn for safety reasons. One internal FDA survey conducted at the turn of the century stressed that 36% of the Agency's scientists—they had four answers to choose from—had no confidence or had moderate confidence in the safety and effectiveness of the drugs they approve and 18% said they had been pressured to approve drugs, in spite of the reservations they had concerning their toxicity.

Dr. Robert Peterson, the former Director General of Health Canada, confided to the Canadian Medical Association Journal that international safety regulation is adequate in 75% of cases and that Health Canada does not have any legal powers, notably that of requiring follow-up studies after marketing to check the toxicity of drugs. Most of the phase IV trials requested by Health Canada are simply not carried out. Furthermore, Health Canada is studying proposals to modify the licensing process to emphasize risk management. This raises concerns on the part of numerous observers, fears that were stated in a very recent article in the Canadian Medical Association Journal.

In view of the foregoing, should the principle of precaution not prevail over risk management, particularly since the reviews indicate that 10,000 Canadians die each year from the undesirable effects of drugs, even though they have followed the instructions to the letter?

● (1610)

By way of conclusion, Health Canada should have extended powers and adequate funding to review drugs. Would it not be a good idea to use a few of the millions in our huge surpluses to guarantee a better quality of life and greater safety for Canadian citizens who deserve it? And why not restore the Bureau of Drug Research, which was closed in 1997?

Thank you.

[*English*]

The Chair: Thank you very much for all three of your presentations.

We'll now move into the question and answer part of the meeting.

We'll start with Ms. Brown. The floor is yours.

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

Welcome to all our presenters.

Dr. Morgan, on one page of your easy-to-read presentation, one of the points is a list of common challenges faced by the CDR and its peers, and it says, "surrogate makers with no validation", but I think when you said it out loud you said "surrogate *markers* with no validation". I still don't understand what it means, whether it's "makers" or "markers". Can you explain it?

Dr. Steve Morgan: Yes, thank you, and thanks for pointing out that typo. It's always good to be on the record when you're doing that.

It is "surrogate markers", and what we mean by that is that drugs are often approved for licensing and are submitted to drug plans for coverage on the basis that they affect a biologic organism within the body. They have some effect on sensitive process. So for instance, a drug might be approved because it lowers your cholesterol level or lowers your blood pressure.

We have reason to believe that the surrogate marker—that is, the lowering of cholesterol or blood pressure—will in fact result in the desired health outcome, which is the lowering of the risk of cardiovascular disease, heart attack or stroke. In many cases, we receive drugs that are approved on the basis of surrogate markers—or what sometimes are called "subclinical markers"—that have not been validated.

For instance, we just heard about the COX-2 inhibitors. When they first came to market, the safety profile of those drugs was much touted with respect to gastrointestinal bleeds and ulcerations. That risk profile was actually based on subclinical bleeds or subclinical risks; that is, ones that had to be inspected by a physician using a scope, not ones that were reported by patients. Later on, it was discovered that in fact some of those medicines don't have the benefits that were touted with respect to the gastrointestinal risks, and of course we later discovered the cardiovascular risk as well.

Ms. Bonnie Brown: This whole presentation from the three of you is not giving me a lot of confidence in the fact that we use so many medications and prescription drugs.

I think a couple of you mentioned this whole idea about clinical trials being done against placebos. Do you think it's time that Health Canada and other regulators or approval bodies insist that these clinical trials be done in a comparison against drugs already suggested or approved for the condition?

● (1615)

Prof. Devidas Menon: The short answer would be yes. It's how to do it that would be the challenge.

There are some real challenges, in that these trials, which are typically called phase three trials, which are the human, reasonably large-population trials on the basis of which an application for licensing is submitted, take time. I know one worry might be that it may take enough time that what was a comparator when the study was designed may not be a comparator anymore when it's completed, and how does it affect the marketability of the product if that was the comparator used? That's one question that does get asked when that question comes up.

However, as far as I know, there are companies who do earlier trials using existing treatments instead of placebo. So I think somehow we should encourage, if nothing else, a move to that. But that requires some agreement on what a comparator will be.

Australia was one of the first countries to develop guidelines for what a submission should contain for reimbursement purposes, particularly the economic part of it. Canada followed soon after. These were the two leading countries in the early 1990s. At the time, in Australia the industry would ask that question: tell us what comparator you want. Typically, what the companies are told is to provide all the information they have, and then we will judge it.

So I think that if a comparator is to be used instead of a placebo, there should be some agreement beforehand by all parties that it would be accepted as a comparator in a reasonable amount of time. It just can't be rejected because a new, more effective technology in the meanwhile has come in and has taken over the bulk of the practice.

Ms. Bonnie Brown: On some of these facts that Dr. St-Onge put forward, such as Quebec having 5,000 drugs on its formulary but New Zealand only having 2,600, I'd like all three of you to answer this: do you think we've been too easy on the drug companies with respect to the licensing of drugs, particularly considering some of the problems you have raised—the comparator being a placebo or this business of surrogate markers with no validation? Is that why we have 5,000 and New Zealand only has 2,600? Are they approving fewer drugs for licensing, and that ends up with their having fewer to put on their formulary?

[*Translation*]

Mr. Jean-Claude St-Onge: It is true, for instance, that New Zealand has two cholesterol lowering drugs, while Quebec now has six. New Zealand has always refused to approve Celebrex and Vioxx, because their superiority over traditional anti-inflammatories has never been demonstrated, and also because, right from the beginning, it was suspected that Vioxx could cause cardiovascular problems. The data were there.

Study 090, for example, before the approval of Vioxx, showed that the people who took Vioxx had had three times as many heart attacks as those that took Naproxen or a placebo. Already the data indicated to New Zealand that these products should not be reimbursed and should not figure in the formulary.

A study conducted by Zhou and his colleagues at McMaster University showed that all the anticholesterols were equivalent with respect to secondary prevention. When there are already two or three drugs on the market, why approve a fourth, a fifth or a sixth, whose toxicity profile is unknown? That poses a number of problems.

Obviously we do not always have the data necessary for us to say that we have enough drugs of this type and that it has not been demonstrated that such and such a new drug is more effective than its competitor. Certainly some efforts need to be made in this regard.

[*English*]

The Chair: Did you want all three to answer?

Ms. Bonnie Brown: Yes.

The Chair: Okay. Go ahead.

Prof. Devidas Menon: I have a couple of points. One is that the difference in numbers typically comes from having many more of a certain class of drug in a formulary in one place than in another. New Zealand is a case in point, where there are fewer of a certain type of drug on the formulary.

The advantage of having choice is that one could use that to differentiate in prices among products in a class, and I think that's done now in places in Canada. I'm not totally familiar with it, but generics only go onto formularies at a certain percentage of the price of the original patented medicine of which it is a generic. So there may be an advantage in that choice.

One has to be careful about simply comparing numbers of drugs on formularies. That is quite often equated, particularly by the industry, as access. However, these formularies all have different formulary coverage policies. A jurisdiction could quite easily list a larger number of drugs than another, but include a high co-payment, so that there is a shift.

On that question of access, I think one has to include affordability as well because there is a cost-shifting from the public to the individual. And is that desirable in order to have more access, or is that discriminatory against those who can't afford it?

● (1620)

Ms. Bonnie Brown: I know we're here talking about drugs reviewed and then placed on formularies, but I'm trying to get back to the earlier stage that talks about how easily and how quickly we approve drugs in the first place, particularly with this whole thing about not all side effects being known. For example, we might have a clinical trial that goes for two years and the negative side effects might not show up for seven years. In other words, before we worry about what we're going to pay for and what we're going to put on the formulary, shouldn't we be absolutely sure that we're only licensing drugs in a very rigorous manner?

Dr. Morgan, would you respond to that?

Dr. Steve Morgan: I'll address that and then get back to the question around New Zealand.

First of all, I think you raised an important point. We want to make sure that the drugs that are coming to market are in fact safe and effective. One of the most concerning trends is the trend towards notice of compliance with conditions, an NOC/c, which is basically a conditional licensing. So early trials are promising but not good enough, or there's not enough data collected to establish the actual safety and effectiveness, but we'll license it anyhow and hope that the risks are minor in the real world.

I'm an economist. I study industrial organization and innovation policy. I think the mechanism to promote competition that we would want, and innovation that we would want, is to continue to maintain high standards at the regulatory level and in fact perhaps raise the bar. I think the bar has been lowered slightly through processes that we've heard about today. In exchange for that, I would argue that we need to reconsider our patent laws and reconsider or reopen the debate around patent term restoration. That's a debate that's well beyond the subject of this discussion today, but I think it's something we need to discuss. It's certainly going on internationally.

The Office of Fair Trading in the U.K. has put out a number of interesting recommendations to that effect, and the U.S. is constantly debating what's referred to as patent term restoration, which is basically giving a longer patent in exchange for longer clinical trials, because effectively the patent is useless in some sense until the product is on the market. But we can talk about that later.

I want to touch on the issue with respect to New Zealand. The New Zealand formulary has fewer “drugs” on the market. They also have fewer different dosage sizes, packaging, and what not than Canada does. We actually have a proliferation, if you will, of different packages, strengths, and dosages of roughly speaking the same chemicals. If you were to take the formularies and look at them at a therapeutic or chemical level, you'd find they're actually quite comparable.

New Zealand has made no decisions around very controversial drugs, like the COX-2 inhibitors such as Vioxx. On the whole, it actually has a fairly comprehensive formulary.

The Chair: Thank you very much.

We'll move on now to Madame Demers. It's good to have you back to the committee. You have five minutes.

[*Translation*]

Ms. Nicole Demers (Laval, BQ): Thank you, Mr. Chair.

I am also very pleased to be with you. I have missed you all.

Gentlemen, thank you for being with us. It has been a long time since I sat on the Health Committee; I have not taken part in the studies completed. However, as a consumer and an individual, I have often needed drugs. We are always worried when we are given drugs. I can understand the concerns of my colleague, Ms. Brown, because when we need drugs we want to be sure that the drugs provided are the right ones.

From listening to your presentations, I noted that there seemed to be a bit of dissension among the various perceptions. It was said that in countries like Sweden, Switzerland and France, about 50% more drugs are approved and recognized than here, in Canada. Is there a greater frequency of error in those countries, because more drugs are approved? This worries me. Should we focus more on the Common Drug Review of new drugs? I remember that, on the Health Committee, we heard people with HIV who were demanding access to a drug that was under review. Unfortunately they could not have access to that drug, which might save their lives. Because this drug was being reviewed and it was taking a long time to be approved, these people were not given the possibility of obtaining it. Is that also part of the problem? If the Common Drug Review does not report to Health Canada, who determines the value of the information and the reviews? Who reports to government? Who determines whether a drug should be marketed or not?

Mr. St-Onge, you talk about the large number of drugs on the Quebec list. It is true that I have benefited from them. I had cancer six years ago and I was very pleased to have various choices so that I could take the appropriate drug for the type of cancer I had. I have a hard time taking a position on such an important subject. I know that in Quebec reviews take place more quickly.

● (1625)

[*English*]

The Chair: The question, please.

[*Translation*]

Ms. Nicole Demers: I am asking several questions at the same time, Mr. Chair.

[*English*]

The Chair: Okay, quickly.

[*Translation*]

Ms. Nicole Demers: Is less attention being paid? Is less care being taken? I do not know why it is like this. I am asking you.

Mr. Jean-Claude St-Onge: I am not sure where to begin, but I want to take the example of a cancer drug called Iressa. I went to the Health Canada site, among others, which are quite good with regard to the undesirable effects of drugs. This is a drug used for lung cancer. Now it is also being used outside of indications to treat such things as neck and head cancer.

The reviewers at Health Canada specify that this drug, for instance, has not succeeded in reducing mortality or in increasing survival without the disease progressing and without the symptoms becoming worse.

To come back to what Dr. Morgan said awhile ago, this is a drug that was approved using surrogate endpoints. It was observed that this drug reduced cancerous tumours and that is the basis on which it was accepted.

At least four clinical studies were done and they all demonstrated that the drug did not improve survival without disease progression or any of these things. Consequently the consumer protection organization in the U.S., Public Citizen, drafted a petition now circulating in the U.S. for this drug to be taken off the market. In addition it had some very serious undesirable effects. Go to the Health Canada site and you can see which ones; I do not wish to give them to you.

Perhaps these are things that should not exist. When a drug is approved on the basis of a surrogate endpoint, we should be very, very cautious about this drug and demand that the company that makes it conduct clinical trials to demonstrate that it is truly important and it actually decreases mortality, that it improves quality of life, etc.

● (1630)

[*English*]

The Chair: Thank you very much.

We'll now go to Mr. Jaffer for five minutes.

Mr. Rahim Jaffer (Edmonton—Strathcona, CPC): Five minutes. That's fine.

Thank you to all the presenters for being here today. I'm sort of new to this common drug review. I joined the committee just recently.

Dr. Menon, I was interested in particular in what you mentioned in your summation points—the fourth point, I believe—the idea of the public participation, public representatives, in the jurisdictions in the U.K. and Australia. I think they were called the citizens jury or citizens council. It seems to me an interesting process, and I know we have, to some extent, something like that here, but in those particular jurisdictions, to what extent are the public involved in the process of their drug reviews? Are they quite extensively asked for their advice? Are they involved in the process? And how are they selected or appointed in those particular jurisdictions?

Prof. Devidas Menon: I can speak more knowledgeably about the U.K. situation, so let me focus on it. When NICE, the National Institute for Health and Clinical Excellence, was created, it was with the view that priority setting for such things as health technology assessment reviews ought to involve a broader sector than what was traditionally driving the system, which was technical, clinical, and methodology experts. Experts reviewed, experts designed, experts made recommendations, and the public essentially bore the results or the brunt of those decisions.

They created something called the citizens council. I should point out that the citizens council does not get involved in review of individual products. What they do is look at the classes of drugs or technologies that are important to them, that ought to be examined, at the aspects, other than the very technical and scientific things that are measured in trials, that ought to be considered.

It was a nationwide advertisement that went out. People were invited to apply. I can't remember now whether it's 20 members that the citizens council has. They were selected on the basis of that process to represent the population of the U.K. I've attended two of their meetings. They include everything, to be representative, from an ethnic mix to unemployed, employed, age—all of that.

They've come together, and it's phenomenal watching them work. They don't make any decisions about what ought to be listed or not. There was one in particular where they were dealing with orphan diseases. It was important for NICE, before it went out to commission trials, to understand what that meant to families of people with orphan drugs and what citizens felt.

What was important and good to see was that citizens, through this process, began to understand that all of these decisions are trade-off decisions. In a sense, the Health Canada licensing process is not a trade-off process; you can add any number, if you think it meets scientific standards. But the formulary coverage, CDR decisions, are trade-offs. When people in general understand that they are trade-offs, I think they're more accepting of these decisions.

Mr. Rahim Jaffer: On that note, then, I think you mentioned that the CDR has public representatives. I'm not as familiar with that. You mention that the process for appointment in the U.K. is quite broad and that they try to touch on different backgrounds. Is that your impression of what's happening here?

You mentioned as well that they could enhance their role or public consultations. Maybe you could tell us what you think that role should be.

Prof. Devidas Menon: Dr. Morgan might know more about the process. I believe there are two public members on the CEDAC. As far as I know, it was a call that went out on the website. I'm not sure about the process that was used to select them.

Dr. Steve Morgan: It was a call. There are two members who sit on CEDAC. They're non-voting public representatives of CEDAC.

I think the public representation is an important question, and I just want to highlight some work about coverage processes in general—pharmaceuticals in health care and technology more broadly.

There is an interesting ethical framework referred to as the accountability for reasonableness, which sounds like a reasonable framework. It suggests that there are four criteria you would want to have for a decision-making process. First is that it has relevance, that it is using relevant criteria to make decisions. That, which Dr. Menon is referring to, is precisely when public engagement is important: engage the public in helping us determine what the criteria are for making a decision, but don't necessarily involve them in direct democracy, in the sense of making them make those tough choices. That's the responsibility of public servants and experts, frankly.

Publicity is another criterion in this framework; that is, that the rationale for decisions needs to be public. After you've made them, you should be able to defend them. The limiting factor on that criterion right now is confidentiality clauses enforced by the manufacturers. I don't think, frankly, Canada can go it alone on this one. We are going to have to cooperate internationally with other countries on how to develop what you might call a minimum data set, a minimum standard of transparency for decision-making processes, and require that manufacturers and other groups participate to that level of publicity or transparency.

The next question with respect to these criteria or this decision-making framework is revision. There should be opportunities, effectively, for appeals and for a reconsideration of decisions if there have been procedural problems.

Then finally there is enforcement. The decisions should be binding; there should be some mechanism by which they are enforced.

Canada's CDR does fairly well, or as well as it can in the context of our jurisdictional issues around drugs and the transparency limits due to confidentiality. Canada's CDR lives up pretty well to the others. The question of relevance of criteria and the involvement of patients in establishing those criteria is definitely worth pursuing.

They've done some work to include people in the committee. You might want to have a national citizens jury or panel to establish a list of criteria. In New Zealand, there are nine of them that they must consider. In Canada, maybe there would be 16, since that's how many drug plans we have.

● (1635)

The Chair: Thank you very much. We'll now move to Ms. Priddy.

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

My first question would be that one of the goals the national pharmaceuticals strategy talks about is the development of a national drug formulary. Some of us would see this as a first step toward establishing a national drug plan, which has also been called for. Can you offer me very briefly—because I have a couple of other questions—your thoughts on a national drug formulary? Yes, no, good, bad, maybe.

Prof. Devidas Menon: Maybe, I would say.

Looking at what the common drug review has or has not achieved, I think people tend to forget, when they criticize the common drug review, that prior to the common drug review each province had some mechanism, as everybody knows. Has that changed decision-making? I'm not so sure. So how would we ever get to a situation where the provincial governments would agree to a common formulary when they can't make the same decision based on common evidence and recommendations right now?

To me, the best I would hope for—and maybe I'm a cynic—is to have a certain basket of pharmaceuticals in a common formulary. It would be hard to judge what they may be. There would have to be criteria to decide, because then there would be advantages to bulk purchasing and so on, as a result.

Ms. Penny Priddy: Right.

Prof. Devidas Menon: But I cannot see how there would be one single formulary that all provinces would deal with in a similar way.

Ms. Penny Priddy: Okay, thank you.

Dr. Morgan.

Dr. Steve Morgan: Yes, I'm a policy pragmatist. I realize that in the Canadian context a national pharmacare program is still a way off—or yes, pragmatist, or pessimist, I suppose.

I think the national formulary is a way forward. Dr. Menon just alluded to a recommendation that Bob Evans and I have recently written about in a book forthcoming from the IRPP on policy challenges in Canada. We wrote the chapter on drugs and health care more generally. Our recommendation for Canada is to start with a national drug plan based on the five leading chronic diseases in Canada: diabetes, hypertension, high cholesterol—you can pick your favourites.

If you started with the big classes and had a national formulary around those essential medicines, within those classes exactly as Dr. Menon is referring to, I think you'd build toward a national pharmacare program, and I don't think the issues around what would go into the basket of drugs to treat hypertension, cholesterol, diabetes, etc., would be as hotly contested.

● (1640)

[*Translation*]

Mr. Jean-Claude St-Onge: This would indeed by desirable, if only for the sake of efficiency. If such an agency is created, it will have much greater negotiating power, provided it is given negotiating power. I know that the RAMQ, for example, does not have the power to negotiate with the pharmaceutical companies.

There are some fairly absurd things sometimes. I was talking with the pharmacist in a big hospital in the Montreal region not too long ago, and she told me that the hospitals have the right to negotiate with the pharmaceutical companies. They receive PPIs, proton pump inhibitors, antiulcerants. They pay one cent a pill for them, and the RAMQ pays $1.80 for them in reimbursement. The difference between the two prices is quite incredible. And this does not apply just to PPIs; there are lots of other examples.

Obviously we know why the manufacturers do that. They do it to accustom doctors to prescribing drugs and to accustom patients to taking them. But if there were an organization that could make purchases and negotiate prices, it would be excellent for both patients and the public purse.

The Quebec issue is a different one.

[*English*]

Ms. Penny Priddy: Thank you.

One thing that is obviously up for consideration and is being done is the expansion of the current role of CDR, which is to look at existing drugs. I don't know what you've said about other countries, but could you very quickly give me your opinion on the expanding role of looking at existing drugs as opposed to only new ones?

Dr. Steve Morgan: I'll quickly jump in.

I think it's essential. It's part of the original business case for the CDR. The Americans have a group that runs what's called the Drug Effectiveness Review Project, DERP, and their slogan is “globalize the evidence, localize the decision”.

The CDR in many ways does that in the Canadian context. Right? It nationalizes the evidence and it keeps localized decision-making, which might be right for Canada, but to do this appropriately and to deal with the whole spectrum of pharmaceutical agents on the market, as Dev was referring to earlier, we need to think now about looking at classes of medicines, new and old medicines, and establishing, if you will, what might be considered the drugs of first choice in Canada.

So absolutely, yes, I think it's going to require a significant resource commitment. I believe the federal government can take a leadership role in this, but it's going to be non-trivial, because the science involved is costly in terms of assessing and appraising in a transparent fashion, and I think involving the public in whatever way in that process would be quite useful.

Ms. Penny Priddy: Excellent. Thank you.

The Chair: Thank you very much.

We'll now move to Mrs. Davidson.

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

Thank you very much for your presentation today. We've heard some things that I don't think I've heard before.

Dr. Morgan, I'm going to direct my comments to you first. You said in your presentation that the CDR has rapidly become a respected peer among review processes on the global stage. It's something I don't think I've heard before from the presenters we've had.

We're heard there's non-accountability, duplication, and no transparency. It's focused on cost containment rather than benefit. There's a lack of an appeal process. But in all fairness, they're not comparing it to the global stage. Could you make some comments in reference to that? Why is it looked at so much differently globally than it is internally?

Dr. Steve Morgan: I think you've probably heard from industry and its various representatives with those comments. They would say that about any process that reviews medicines to make transparent, evidence-based coverage decisions.

Industry doesn't like any of these processes around the world, because in some sense it's easier to have a free market for pharmaceuticals than to have an agency look at the science. But Canada's process is actually respected, and I think Canadian scientists who are engaged in these appraisals and assessments are respected.

On the lack of an appeal process, by default, the CDR has an appeal process because you can re-submit. Manufacturers are able to re-submit if there is new evidence brought to bear on a decision.

There are criticisms made of the CDR that are flatly not true.

On the international stage, Canada was invited to attend meetings of agencies like the CDR because Canada's process is respected. All processes around the world could use some improvement. Through actually collaborating and communicating with other processes, I think we're going to get there.

We learn from the success stories. For instance, I think the public participation on the Australian advisory committee truthfully informed the CDR's movement toward that kind of engagement. I think we could learn issues with respect to transparency and dialogue during a review process, for instance, from the process in the U.K.

I think I've written five papers on the CDR in the international context. Those are among the most requested papers internationally that I've written in my career, and I've probably written 50 or 60.

● (1645)

Mrs. Patricia Davidson: Can you tell me this? Do you think the CDR evaluations tend to focus more on cost containment than other countries do, or are they all done much the same way when it comes to cost?

Dr. Steve Morgan: Although I've never been in the room and I'm not part of the process, from an outsider's perspective and having done candid interviews with the people involved in processes in five of these countries, I would argue that Canada actually focuses on costs less than all countries, except for NICE in the U.K. Canada and the U.K. really stand alone in their nearly exclusive focus on relative effectiveness and then a secondary consideration of costs.

Although CDR is criticized for that, I think it's patently incorrect, because Canada is one of the exceptions to the extent that it focuses on science rather than economics.

Mrs. Patricia Davidson: In your presentation, you talked about Australia doing 100 drugs per year, including generics. Are other countries doing generic reviews as well as Australia? What percentage of the 100 drugs would be generics?

Dr. Steve Morgan: About half or so are generic medicines.

The reason the Australian process vets their generics through the whole process is that, as I mentioned earlier, Australia uses a price negotiation and price setting system that's exceedingly complicated. Drugs have to go through the process to establish the therapeutic benchmarks that you're going to compare them against when doing price considerations. It's why they have such a big list of medicines that are vetted through their reviews.

Mrs. Patricia Davidson: Are they the only ones that do generics?

Dr. Steve Morgan: Of the five countries that I've studied, yes. Dev could probably speak to the 16 or more that they've looked at.

Mrs. Patricia Davidson: Could you do so, please?

Prof. Devidas Menon: I can't remember the exact number, but some European agencies look at generics as well.

Mrs. Patricia Davidson: Thank you.

The Chair: Thank you very much.

We'll now move to Ms. Kadis.

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

Thank you, everyone, for coming today, as we move toward drawing up our interim report.

There's been a lot of witness discussion and concern regarding rare diseases and the issue of the expense, of course, and the fact that they're not getting their proper due. I would like to ask you this. In those other countries, in the U.K. and Australia, do they have a specialized process or a different set-up for rare diseases, and if so, what is it?

Prof. Devidas Menon: I can't answer extensively across all countries. The problem with rare diseases—and some of them will fall into the catastrophic disease category as well because of the cost—is that there is not a lot of scientific evidence that can be generated to help make the kinds of decisions that CDR has, because if a disease is very rare, there's going to be a small patient base for it, and so to do a trial to collect enough data to make meaningful conclusions is next to impossible. Add to that the fact that rare or orphan drugs, as they're called, will be much more expensive because typically they cost more to produce and they're produced for a smaller market. So all of that complicates the process.

Ultimately, one has to decide for such classes of drugs whether or not one is prepared to accept different levels of evidence. This is an argument that methodologists have. In the U.K., in NICE, they've tried to tackle this. They've even gone to look at what they call ultra-orphan diseases, which are even rarer. I mean, there are numbers in terms of prevalence. In fact, on the citizens jury that I talked about, one of the meetings I attended was when they were trying to decide how differently they would handle ultra-orphan drugs. The reality is that you can't have the same expectations for data or evidence. It just isn't possible.

In Canada, we've had similar discussions with drugs like Fabrazyme. I'm not exactly sure where CDR has ruled on any of those. As far as I know, both rare and catastrophic drugs are being discussed somewhat differently in terms of the amount of data needed to make these decisions.

● (1650)

Mrs. Susan Kadis: Mr. Morgan, can you comment?

Dr. Steve Morgan: I would just add that, as Dr. Menon says, different countries take different approaches. In Australia and New Zealand, for instance, they actually vet drugs that are for rare/orphan diseases through their centralized process, but they also have, under political pressures, probably rightfully in some cases, created separate funding envelopes for drugs for rare diseases. I think that owing to the unique ethical considerations and social responsibilities that we may have related to some of these conditions, you might argue for a national silo of funding, earmarked and capped in terms of budget, from which you would make a decision about rare diseases, using a slightly different algorithm with respect to cost-effectiveness.

I still believe that the phrase “globalize the evidence, localize the decision” should hold. These drugs should be subject to the same rigorous standards of proof. What we don't want to be doing is buying promise, hope, or hype. We want to be purchasing health outcomes here, and so we want to know whether these drugs work. In this context I believe “globalize the evidence, localize the decision” should begin to be taken literally. Oftentimes there are not enough patients in a given country to actually properly assess those drugs in one country, so we should be looking to partnerships with our colleagues around the world to figure out how we can develop the best possible approach to being ethical and responsible about these products and patients, showing compassion while also making sure that we're doing the right thing in terms of buying appropriate outcomes.

Mrs. Susan Kadis: There's this disconnect that keeps reappearing with witnesses in terms of our hearing that it's working very well and it's been expanded, and yet other witnesses—health advocacy groups, industry—are saying that it is not working well, there are obstructions. What do you attribute this disconnect to? There is a running pattern through many of our sessions. Obviously we're trying to understand what we can attribute that to. Is it because they're not going to be happy, no matter what system we have, or because the system really isn't efficient and meeting their needs?

Dr. Steve Morgan: Again, as an outsider, I would say this is a system that's working reasonably well. I went into my study, which was started a couple of years ago, expecting to find flaws, to be honest, and I was surprised at how well Canada's system runs.

I think what you're finding is the inevitable politics of any program that has to allocate scarce resources—someone wins, someone loses, and the losers invariably have to complain. I'm not making a moral judgment here. They want entitlement to those scarce resources, and so they're going to want to contest and worry about the process.

I can say, as an outsider, that this process is very good. I would argue it's possibly one of the best drug policies that's happened at a national level in Canada ever, because we've had so few national drug policies, truthfully, aside from regulation.

The Chair: Thank you very much.

Mr. Patrick Brown is next.

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

I have a few comments to make, and a few questions.

First of all, a comment I've heard today is that when we've heard comments, they might have come from industry. I'd just add that the comments I've been getting, the concerns over CDR, have not been coming just from the pharmaceutical industry; they have been from patients and from physicians I know in my own riding, and we've had individuals come up and tell their personal stories about some of the challenges they have faced with the process. We've had numerous deputations from various charitable groups that are raising funds and representing individuals who have various illnesses within Canada. There has certainly been a wide variety.

The one I found the most moving was a presentation by, I think, the Canadian Cancer Society about kidney cancer and some of the challenges they've had with the CDR. We are hearing a wide variety of opinions, and that's one of the tough things to reconcile. People have completely different images of the usefulness of CDR.

One thing I heard from previous proponents of the CDR is that one of the reasons it was created was to bring national standards to the drug approval process in Canada and get more commonality amongst the provincial drug plans. I asked that question. I asked if that has changed today, if we have that commonality, if we have those national standards. I wasn't satisfied with the answer, so I'd look for some comments on that today. If the purpose of this several years ago was to bring about that commonality, why do we have provincial drug plans completely ignoring what CDR is saying? Why do we see cancer drugs at the national level rejected by CDR and approved, for example, in British Columbia or Ontario? That is perplexing.

There is another question I wanted to throw out there. I haven't posed it from this perspective. We always talk about patient access. Prior to the CDR, how did this process hurt patients? How is the system better today than it was before? Can you tell this committee that Canada's health care system, its drug approval process, is serving patients better today than it was when this was created several years ago?

Could I please get comments from any of you three who would like to offer a perspective.

● (1655)

Prof. Devidas Menon: Those are very good points indeed. There is a difference of opinion, and we can't attribute it all to the industry.

I would step back first and ask a question that I think people tend to forget: why was the common drug review instituted in the first place? Did anyone ever say that the common drug review would make access to drugs common across the country? Everything I have read—

You might want to know that I was the first executive director of CCOHTA, the predecessor to CADTH, for the first seven years, so I have some idea of the provincial-federal play in this area. When the CDR was first talked about—and I think Dr. Morgan alluded to this—it was to make the review of drugs for formulary decision-making more efficient and to reduce duplication. Those were the first goals. To translate that into improved patient access or improved patient care, I would have to ask what one means by improved patient care. Was the assumption that decisions made previously jeopardized patients? Is that the assumption? Frankly, I don't know that.

To me, if anything, what the CDR has done is this. There's one submission, and there are standards for that submission. There are guidelines; they have to be met, so in that sense there's conformity with standards. The fear I have is that the standards are still so technical and clinical that other people's views and values don't get injected into it. I think that may be where the disconnect is coming, because you have standards that are based on very strong methodology.

I know you're running out of time, but I just want to make one comment. This just reminds me. My colleagues would hate me for this, but there's a joke that I like to tell: what's the difference between a methodologist and a terrorist? You can negotiate with a terrorist. In some cases I feel we're strapped because of the methodological development and we tend to forget that there are people. I think that's where really the disconnect comes.

As for the allegations that it isn't working, I would have to say, did we expect the common drug review would increase access to more drugs? Did we reasonably expect that? If we did that, we're making the assumption that we were denying people treatment before, and I just don't have the evidence to back that up. It may be the case. I think it now allows people to make decisions that are more defensible from a scientific point of view.

The Chair: Thank you very much.

We'll move on now to Monsieur Malo.

[*Translation*]

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

Thank you for your presence this afternoon.

Professor Morgan, awhile ago, my colleague, Ms. Demers, asked you a question which you did not have time to answer. Do you have any studies that prove that more errors are committed in countries where there are more drugs approved under a faster review process, because of the fact that these drugs are approved more quickly and in larger numbers?

● (1700)

[*English*]

Dr. Steve Morgan: The answer is no, I don't. I'm not familiar enough with the literature around pre-market regulation, and so I would have to defer to my colleagues who are experts in regulatory process and impact.

I would note, however, that there are reasons, for instance, why countries like France and elsewhere have lots of drugs listed. In part, it's part of the global licensing and marketing strategies of drug companies, and that is to get a drug into a market like France first, where they are able to secure higher prices and actually get approvals slightly more readily than elsewhere. That creates a precedent, if you will.

If they first attempt to license in a country that is deemed to have a difficult or tough regulatory stance—and arguably, the United States is actually one of those countries—and are turned down, it sets a poor international precedent for them.

There are lots of drugs in some countries, in part not because the consumers in those countries really need thousands of medicines, but because they need to get them on the market there first and then proliferate from there.

[*Translation*]

Mr. Jean-Claude St-Onge: There is one study, among others, that was done by the U.S. Government Accountability Office, which revealed that in the United States, before user fees were charged in 1992, 1.6% of drugs were taken out of circulation. User fees have meant that the approval time has been cut in half. It was shown that, towards the end of the decade, 5.4% of drugs were taken out of circulation because of the danger they posed.

A study appearing in Pharmacoepidemiology and Drug Safety in 1995 demonstrated that from 1974 to 1993, ten products were withdrawn from circulation in the U.S., while from 1997 to 2001, after the introduction of user fees, there were 12 withdrawals, including nine drugs that were approved after 1992. According to many observers, corners were probably cut and drugs approved a bit too quickly. One of the results was the worst medical catastrophe, namely the Vioxx catastrophe.

Mr. Luc Malo: At the session the Committee held on Monday, we heard two young women telling us the story of their mother, who, suffering from cancer, did not have access to a drug that had been subject to prior testing in a pilot study. The doctor simply said to the patient that he was crossing his fingers in the hope that the drug would be approved.

What do you think about this sort of situation, where the family was dealing with a serious illness, with cancer?

[*English*]

Prof. Devidas Menon: I would feel exactly the same way. From the point of view that I bring here, as a researcher, I don't have the answer to the question.

Quite frankly, personally, I'm here today to speak to you because of drugs. I spent the first 10 weeks of this year in hospital, six of those weeks in intensive care. So I can identify very much with those individual situations. And I think that's where we run into a problem, pooling everyone into populations and ignoring that they're individuals. Somehow one has to be able to accommodate that, and that's not really through the science of big controlled trials.

[*Translation*]

Mr. Jean-Claude St-Onge: Anyhow, in Canada there are ways of having access to experimental drugs.

Suppose someone has HIV and all the drugs he has taken up to now are not working anymore. If a new drug arrives on the market and is promising, even though it may also have undesirable effects, that we do not know everything about, if the person, who is in the terminal phase or about to die, wants to try it out, I do not think we can stand in his way.

The same is true for someone, for instance, who is in the terminal phase of cancer. We are talking here about very serious cases. We are not talking about problems like arthritis, for which drugs that have already been proven are on the market. You can market a new product, whose undesirable effects you are not aware of, when there are drugs that have already been proven.

Dr. Graham of the Food and Drug Administration, the FDA, said though that the first thing he learned at medical school was never to be the first to test a new drug. When a disease is not life-threatening —In my case, I would not be the first to try out a new drug. In other circumstances, however, it may be different.

● (1705)

[*English*]

The Chair: Thank you very much.

We'll close off this session with the final questioner, Mr. Fletcher. You have four minutes.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Thanks very much, Mr. Chair, and hopefully those are metric minutes.

I have a couple of questions. One deals with transparency. In the CDR, the issue of commercial confidentiality is imposed by the manufacturers. Is that the case in other jurisdictions as well, that the manufacturers say you can't show this or that?

Dr. Steve Morgan: Yes, it is, and I think we need to engage in dialogue, for instance, with people from the U.K., because the disclosure documents that NICE produces actually have a lot more information than the CDR is able to produce. And believe me, I've interviewed members of the CEDAC, and they'd love to put out more information. They just feel like they are restricted, not unlike Health Canada is restricted in how much it can disclose around a regulatory process.

Mr. Steven Fletcher: It seems that the concern of the manufacturers is that the information is going to get out. If it's out in one part of the world, it's out. So why not just release it in Canada? Because the competition is going to have it. What's the push-back from the manufacturers to that statement?

Dr. Steve Morgan: That's an important policy process, right—I mean, pointing people towards where the information is. That's what we might do. But I also think we should collaborate and cooperate and work with the manufacturers to say, what's a reasonable level of disclosure?

Mr. Steven Fletcher: Just to shift gears for a moment, the issue of values plays into this whole discussion in a big-time way, although I don't think we've really discussed it thoroughly in our review as a committee. The values of quality of life and quantity of life—somehow putting a quantitative value on that is something that happens all the time, I suppose, in one way or the other. But when it comes to prescription drugs it seems to be more up front.

I wonder if the panel members could provide some guidance to the committee on how other jurisdictions deal with these value assessments and what you would recommend this committee do to make sure that issue is addressed properly in our report.

Prof. Devidas Menon: I'll give you a brief answer to that, if I may.

To begin with, the whole issue of quality of life and values are not identical. Quality of life is in fact measured scientifically in many of the drug and even non-drug technology trials. There are validated methods of doing that, to see if there is an improvement in quality of life in a particular patient population. Suddenly, values are connected with that, but values as such have never been explicitly discussed to any extent by almost any of these bodies. I think it's only in the last three to four years that this has come up, and the international agencies for health technology assessment are beginning to try to understand where and how values could be introduced.

Then it becomes a methodological sort of question: how do you seek them, how do you elicit them, and from whom do you do this? Part of my research program is to try to incorporate citizen engagement in cancer drug decision-making. We've just received a five-year grant from CIHR to create a new team to do this. So in my view, it's still very early days for us in incorporating values into health care resource allocation decision-making. I don't think we have a great example that we can point out to follow. This is where I think Canada can again take the lead, as it has in the past.

● (1710)

The Chair: Does anyone else wish to comment?

That's a touchy one anyway.

We'll call it there as far as the questioning is concerned.

We want to thank our witnesses for coming in. Your presentation has been very valuable to us as we work towards a report with regard to the CDR and this important study, so we want to thank you for coming in and contributing to that.

We'll now break for a moment or two as we move in camera for discussion on future business and our report.

Thank you very much.

[*Proceedings continue in camera*]

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

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

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