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Mardi 31 mars 2009

Standing Committee on Government Agencies

Comité permanent des organismes gouvernementaux

Intended appointments

Nominations prévues

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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON GOVERNMENT AGENCIES

COMITÉ PERMANENT DES ORGANISMES GOUVERNEMENTAUX

Tuesday 31 March 2009

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The committee met at 0903 in room 151.

INTENDED APPOINTMENTS

SCOTT WALKER

Review of intended appointment, selected by third party: Scott Walker, intended appointee as member, Committee to Evaluate Drugs.

The Chair (Mrs. Julia Munro): Good morning, ladies and gentlemen, and welcome to the Standing Committee on Government Agencies. This morning, we are going to begin with the intended appointment review. I'd like to call upon Scott Walker, the intended appointee as member, Committee to Evaluate Drugs. Good morning.

Mr. Scott Walker: Good morning.

The Chair (Mrs. Julia Munro): Welcome to the committee. We have set aside 30 minutes. You may use any amount of that time and then we will go in rotation to ask questions with the remaining time. So if you'd like to make any comment, please begin.

Mr. Scott Walker: I have prepared an opening statement.

I'm a hospital pharmacist. I currently work in the department of pharmacy and the division of clinical pharmacology at Sunnybrook Health Sciences in Toronto. At Sunnybrook, I work in an analytical lab. One of the functions of this lab is to complete stability work on intravenous formulations. In all hospitals in Ontario, many drugs are given intravenously. Generally, the manufacturer recommends, because of the possibility of contamination and bacteria growth, that these products be discarded if they have not been used within 24 hours. However, in many hospitals the products are prepared in a sterile environment and contamination is unlikely. We complete stability studies to demonstrate that many of these products can be kept in the fridge for much longer than 24 hours. If we don't have to discard the medication, we can supply it to another patient and reduce our wastage. This saves Sunnybrook about $150,000 annually. Since we published this data, and it's widely used in every hospital pharmacy in the province, the savings to the system are probably in the millions of dollars annually.

I also have an appointment as an assistant professor at the faculty of pharmacy at the University of Toronto. At the faculty of pharmacy, I've taught pharmacy students pharmacokinetics. Pharmacokinetics describes, in mathematical terms, the absorption, distribution and elimination of drugs from the body. Pharmacokinetics serves as the foundation on which bioequivalence studies are completed. Bioequivalence studies are used to evaluate generic drugs prior to approval by Health Canada and prior to listing on the Ontario Drug Benefit Formulary. In this area, I have also served as a member of the Scientific Advisory Committee on Bioavailability and Bioequivalence for Health Canada. This committee advises Health Canada on proposed changes to regulations and the conduct and evaluation of bioequivalence studies, and I've served on that committee since 1995.

As you're aware, I've also served as a member of the Committee to Evaluate Drugs since 1996. On this committee, my advisory capacity has been strongest in two areas. The first was to bring expertise to the committee in the evaluation and review of submissions for generic drugs. Shortly after I joined the committee in 1996, the drug programs branch began a process to streamline the generic approval process. More recently, considerable effort has gone into the evaluation of interchangeable brand name products that were never listed on the Ontario formulary. This so-called off-formulary interchangeability was related to Bill 102, which was passed a couple of years ago.

I think it's important to say that bioequivalence evaluation is not restricted to generic submissions. Questions of bioequivalence and bioavailability become important when a brand name manufacturer wishes to expand their product line, introducing new product strengths or sustained release formulations. I would like to point out that I'm involved in reviewing all generic submission reports and present the reviews for all of these products to the committee for discussion and approval.

The second area that occupies a good deal of my time as a committee member is the review of glucose test strips. This actually fits well with my experience with an analytical laboratory and another course that I've taught at the University of Toronto on drug analysis. Here I'm looking to assure the committee and the drug programs branch that the glucometer test strips provide accurate and reproducible glucose concentrations in diabetic patients and that these results wouldn't be affected by the drugs that the patient was on, the humidity or temperature of the environment. I have reviewed every glucose strip submission in the past eight years.

In summary, I think I bring a unique set of skills to the committee. The expertise of the committee is exceptional and I think the committee provides a valuable and thoughtful service to the Ministry of Health and the people of Ontario. I've always been proud to be a member of the committee.

The Chair (Mrs. Julia Munro): Thank you very much. We'll begin with the official opposition. Ms. MacLeod?

Ms. Lisa MacLeod: Welcome, Mr. Walker. I appreciated your presentation to us today, and the official opposition will be supporting your candidacy.

I have a couple of quick questions; I'm just reviewing the materials. The CED makes recommendations to the executive officer on which drugs should be listed. This isn't really about whether or not I think you're suitable to be on the committee, but it is a matter of curiosity. I notice that in 10 instances the CED recommended that certain drugs either be listed or not listed, and the executive officer made in 10 instances a recommendation to do the opposite. I'm wondering how that process works.

Mr. Scott Walker: In some respects, this might be a matter of perspective, although those 10 identified instances in the package imply that the executive officer might have gone against the advice of the committee. Perhaps it's the way the recommendation went forward from the committee. True, the committee could have suggested that we accept it as long as there was a price reduction from the company, or we could recommend that the product be rejected, knowing that in the current process the government then goes forth and tries to create a licensing agreement with the company and obtain a better price. Once this better, lower price is obtained, this actually could make a drug which might appear to initially be financially unattractive to list, reasonable or more reasonable to list. So that document might not identify 10 instances where the executive and the CED are at odds with each other; not at all.

0910

Ms. Lisa MacLeod: So it's less likely that these decisions to make a decision that doesn't reflect the CED's recommendations are more based on price than actual impacts to those who need to take drugs?

Let me give you an example here: Sipralex. Its generic name is—and I'm going to get this wrong—Escitalopram—

Mr. Scott Walker: Yes, Escitalopram.

Ms. Lisa MacLeod: —was recommended not to be listed in November 2008, but was listed. That was the decision of the executive officer. In that case, would that be a monetary issue or would it have certain effects that you would have considered to be unacceptable for the Ontario patient?

Mr. Scott Walker: Many of these decisions get into very complicated other side issues. The chemistry involved in this is that there are other products available on the formulary already. They are listed. This drug came in at a higher price and is basically the same drug.

Ms. Lisa MacLeod: I see.

Mr. Scott Walker: The difference from a chemical point of view is that the drug that's listed has both isomers. They talk about this as being right- and left-handed, and one of the two—and this would be the racemic drug—is the common form in which it's available, but after the drug has been on the market, say that the company discovered that only one of these isomers is active, the S isomer, and that's why it's called S or ES, Escitalopram. So the company, then, brings out this new version of the drug. It has the same activity, but it's just very much more expensive. Sometimes there could be a difference in side effects, but I don't believe this was true in this case, so it's possible that in this particular case price actually is the leading and perhaps the greatest issue.

There may be other drugs where a difference in side effects between standard therapy and the new drug is one or another consideration. It may be a difference in how effective the product is. So it doesn't always get down to price, but we end up trying to compare these products—financially is how it ends up having to be done—to determine whether this drug actually provides value to the Ontario taxpayer.

Ms. Lisa MacLeod: Thank you very much. That's very fascinating. I'm not sure if my colleague has any questions at this time.

Mr. Gerry Martiniuk: No.

The Chair (Mrs. Julia Munro): Thank you very much. Ms. Gélinas.

M^{me} France Gélinas: Welcome to Queen's Park, Mr. Walker. I would like to continue the discussion you were having with my colleague. That was not my drug of choice, but given the particular example you have given, the committee made the decision not to recommend it, that it not be listed, but then the executive officer decided to list it. There seems to be a disconnect and a lack of accountability there. How do we bring that back so that when those kinds of reports are published—do you have any idea how it went from your committee saying, "Don't list it," to the executive officer actually making the decision to list it?

Mr. Scott Walker: I don't recall precisely the wording of the recommendation from the committee to the executive officer or the ministry. Following that discussion, there would have been a fairly detailed discussion prior to the vote and the recommendation, but it's very likely that in this discussion, although it might have been, "Don't list the product," and that might have been the recommendation, the side discussion that would have gone on would have said that this product should be priced at a level of the products currently listed, and it was coming in much higher. So the committee, then, recommends that we not list it based on its current price because at its current price it is overpriced relative to its comparator. In this particular case, the government takes that recommendation and enters into a licensing agreement or discussion with the company and says, "The only way you can get this product listed is to bring it down to the price of the comparators." When that is agreed upon,

then the executive officer can list the product and the committee doesn't feel as if we are at odds with any decision made in that particular case because that fit in with the discussion that preceded the recommendation.

M^me^ France Gélinas: Okay. Were you around when Lucentis was—because Lucentis is another one where the committee said, "Don't list it; it is too expensive," but yet the executive officer listed it.

Mr. Scott Walker: This is another case where there are comparators that have the same side effects and the only difference was price. So, after the listing agreement which brought the price down, yes.

M^me^ France Gélinas: So whether the committee recommends to list it or not list it, the executive officer is still free to negotiate with the drug company whether they will list it or not as long as they only negotiate price? Is this how it goes, or could they also negotiate a change in the formulary of the drug?

Mr. Scott Walker: I didn't understand—a change in the formulary?

M^me^ France Gélinas: You're saying that as long as the Committee to Evaluate Drugs says, "Don't list it," solely on the price issue, the executive officer is free to go and negotiate the price down with the drug company, and if the price comes down, the executive officer is free to list it? Or could they negotiate other things?

Mr. Scott Walker: First of all, in my view, the CED is an advisory committee. We make recommendations based on efficacy, side effects and price, and I think that it is well within the purview of the executive officer to negotiate whatever they feel is reasonable and can get out of the company to improve the expense of this particular product for the value that it's bringing to patients who receive it. So the acquisition price is one item, but there may be other things that could be negotiated. I'm not sure of the full extent of their leeway and what they can go after.

M^me^ France Gélinas: You have great experience with the CED; you've been there for a long time. Do you figure that it is safe for the Ontario public that the CED is an advisory committee only and not a deciding body? I haven't been in politics very long, but the number of drug companies that have come to advocate for different drugs is overwhelming and I'm thinking that if they come to me, they must go to the executive officer also. If they spend all that time, resources and energy trying to influence my little wee bit of decision-making that I have, knowing nothing about drugs—why is there so much lobbying being done at the level of the political process, and then we see that the people who have the knowledge to make assessments regarding the therapeutic value, the cost effectiveness, the impact, the side effects etc. only in an advisory role? Doesn't that put the public at risk? Shouldn't the CED have more than an advisory role?

Mr. Scott Walker: Perhaps members of the committee might feel initially better if they had complete control, but then they too would be put in the position that you find yourself in—to be, we'll say, lobbied—and they wouldn't have time for this. I have no problem with the CED being an adviser to the Ministry of Health, and I think that the executive officer can deal with—has to deal with—this lobbying and these efforts, and if you have somebody who has a conflict of interest in the situation—they wish to make money—you can easily see through that. The executive officer often comes to the committee and bears witness to the discussion and would therefore know all of the reasons why the drug is not being recommended for listing. So I'm not sure that this is a decision that is up to me to make.

M^me^ France Gélinas: No. You have been there a long time; I just wanted your opinion.

Have there ever been times where you've seen that a drug that you've done the analysis on, the committee is in consensus that it should not be listed, but yet it got listed and came to the committee as a surprise or caused friction: "Hey, how come this was listed? We clearly said it shouldn't be"?

0920

Mr. Scott Walker: Since 1996, I'm going to say that there have been very few instances—maybe two or three—where the committee was surprised that something got listed. But there may well have been other things in the background, well behind the committee, that determined the listing. I don't think I've ever been aware of why. Maybe it was a lobbying effort; maybe it was lobbying with other things behind it. So it's pure speculation on my behalf on why such things occurred. I don't know that this truly causes friction, because the committee, again, is an adviser to the Ministry of Health, and the Ministry of Health may make the decisions they feel are best suited for Ontarians.

M^me^ France Gélinas: But in the chain of communication, there's no reporting back? If the executive officer makes a decision—the CED says not to list and the executive officer decides to list, there is no communication back to the CED to explain? Wouldn't there be lessons learned in there for the CED, which says, "Well, if we know that the executive officer is of that opinion, maybe we should take that into account when we make our recommendation"?

Mr. Scott Walker: Some of this might be reflected in how—shortly after Bill 102 went into play or became enforceable and we had an executive officer, the process changed a bit, and so maybe with some of the recommendations the committee might initially revise them or revise their stance so that they no longer say, "Accept, but try to get the price down." They say, "Reject, and bring the price down." That actually probably gives the executive officer a little bit more clout when they go to the table. So the committee may well have revised the way in which they handle and word decisions. But—well, I'll just leave it there.

The Chair (Mrs. Julia Munro): Thank you very much. We've run out of time. Ms. Van Bommel?

Mrs. Maria Van Bommel: You have definitely demonstrated your knowledge, and we certainly appreciate the fact that you're offering your expertise again to the CED.

My colleague, Liz Sandals, has a question she would like to ask.

Mrs. Liz Sandals: I just wanted to clarify from the discussion we've been having. What I understand you to be saying is that the committee looks at the medical efficacy of the drug, side effects and those sorts of things, and then you also look at the value for money with respect to comparators. When the executive officer has changed the decision, I don't hear you saying that the medical decision has been changed. It's always a question of the price point having been changed, or possibly, as you've said, it's too expensive compared to the comparators, and the executive officer might allow it for exceptional use but not general use. It isn't like your medical advice is being overlooked; it's got to do with the value for money relative to comparators that may shift after it leaves you. Is that a correct assumption from what I'm hearing?

Mr. Scott Walker: Yes, but stated in this fashion, it sounds like price drives everything. The basis on which the value for money is made is through the science of pharmacoeconomics. If I could take you through an analogy, let's say we have a company that wishes to bring forth a new antibiotic. The standard current antibiotic is effective in 75% of the people; it actually achieves cure in 75%. But the new drug is coming on and it appears to have about a 90% effectiveness. We're going to enter sufficient patients into a study and randomize them to either the new drug or the standard therapy and track a number of things: how fast the infection is treated; the number of days in hospital; the acquisition cost of the drug. When somebody fails the drug, they actually have to—because they still have an infection, we're going to have to give them something else, and that will have some cost as well. And we will total up all these costs.

In the ideal situation, this brand new drug, because it cures more people, and maybe faster, and reduces hospital stay, that increased acquisition cost might be justified by the reduction in other costs. In the ideal world, it actually might save the system money, but the reality is that it doesn't truly save money. There will always be, because of the price of the drug, an incremental cost to it. When that incremental cost is very small, the likelihood of a listing is very high. But as the cost of the drug goes up, you could see that the incremental cost of adding this drug to the formulary would also rise, and we will eventually get to a point where the drug is so expensive—because maybe it isn't 90% effective, maybe it's only 85%. So now we're starting to get to slicing off the roast and things are a little bit tighter, so there's less of a difference between the new drug and the old drug. So we could find a spot where the drug company comes in and says, "We want $5,000 for every course of therapy." Well, at $5,000, if there's only a marginal benefit, it's not worth us spending the money. We could not list that drug, continue to recommend the old drug, and everybody would do fine. We might actually save money.

So price affects the overall decision because of this incremental cost, and that price is balanced against side effects and against efficacy. It's bringing those all together that actually allows the committee to make not what I would say is an arbitrary decision with respect to price, but the price is mixed in with side effects and efficacy to come up with a reasonable recommendation that says that we should go forth and list or not list.

Mrs. Liz Sandals: So it sounds to me like the committee is providing highly informed, highly nuanced, very sophisticated advice. Obviously, you're very, very qualified to do that. So thank you very much.

The Chair (Mrs. Julia Munro): Thank you very much. That concludes the time available. We certainly appreciate you coming here today.

Mr. Scott Walker: Thank you very much for having me and letting me speak.

The Chair (Mrs. Julia Munro): We will now proceed to concurrences. We will now consider the intended appointment of Scott Walker, intended appointee as member, Committee to Evaluate Drugs. Ms. Van Bommel?

Mrs. Maria Van Bommel: Thank you, Chair. I would move the concurrence of the appointment of Scott Walker to the Committee to Evaluate Drugs.

The Chair (Mrs. Julia Munro): Concurrence in the appointment has been moved by Ms. Van Bommel. Any discussion? Seeing none, all in favour? Opposed? The motion is carried.

That concludes our business on intended appointments this morning. We will now proceed into closed session for the purpose of report writing.

The committee continued in closed session at 0928.

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