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Tuesday 23 April 2013

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Mardi 23 avril 2013

Standing Committee on Social Policy

Oversight of pharmaceutical companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la réglementation des entreprises pharmaceutiques

Chair: Ernie Hardeman
Clerk: William Short

Président : Ernie Hardeman
Greffier : William Short

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Hansard Reporting and Interpretation Services
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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON SOCIAL POLICY

COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Tuesday 23 April 2013

Mardi 23 avril 2013

The committee met at 1601 in committee room 1.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

LAKERIDGE HEALTH

The Chair (Mr. Ernie Hardeman): I call the Standing Committee on Social Policy to order. We're meeting today to continue a study relating to the oversight in monitoring and regulation of the non-accredited pharmaceutical companies.

This afternoon, we have with us the Lakeridge Health Corp. We want to thank them very much for being here. I guess before we start, we'll ask the Clerk to have you all sworn in. I'm sure there was no doubt about it at all, anyway, but that you will swear it's the truth, the whole truth and nothing but the truth.

With that, we'll turn it over to the Clerk.

The Clerk of the Committee (Mr. William Short): I'll just start on the end of the table.

Ms. Motz; correct?

Ms. Leslie Motz: Correct.

The Clerk of the Committee (Mr. William Short): Did you want to swear an oath or be affirmed? The Bible's there or if you want to be affirmed, just raise your hand, whichever—

Ms. Leslie Motz: No, I'll swear an oath. That's fine.

The Clerk of the Committee (Mr. William Short): Okay. Thank you.

Ms. Motz, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Leslie Motz: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Mr. Empey?

Mr. Kevin Empey: I'll do an oath.

The Clerk of the Committee (Mr. William Short): Swear an oath as well? Okay.

Mr. Empey, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Kevin Empey: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Dr. Leta Forbes? Ms. Forbes, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Dr. Leta Forbes: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Mr. Tom McHugh. So, Mr. McHugh, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Tom McHugh: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you all for that. Now, as we have been doing with others, we will have 20 minutes for you collectively to make a presentation and then we'll start with questions. We'll start this time with the government side, Ms. Jaczek.

Ms. Helena Jaczek: I start—

The Chair (Mr. Ernie Hardeman): With the questions, when we get there, yes.

Ms. Helena Jaczek: Didn't I start last time?

The Chair (Mr. Ernie Hardeman): No.

Interjection.

Ms. Helena Jaczek: Okay.

The Chair (Mr. Ernie Hardeman): This is the third delegation and we started with the opposition side, so it will be you who gets to start.

With that, again thank you very much and we turn the floor over to you for starting with your presentation.

If I could, just for a moment, each one who speaks, if you would introduce yourself for Hansard to make sure that we get the correct person on the record for having said it. The floor is yours.

Mr. Kevin Empey: Okay. Thank you very much. Good afternoon and thank you for inviting us here to speak with you today. You've invited a number of members of the Lakeridge Health team, so I'll do most of the introductory speaking and introduce everyone.

I'm Kevin Empey, president and CEO of Lakeridge Health. I've been here since 2008. Before that, I was an executive vice-president at University Health Network and I've had senior executive positions at Peel Memorial, which is now part of William Osler, and then St. Michael's Hospital.

Over to my left is Tom McHugh. He's the regional vice-president of cancer services for our whole LHIN, the Central East LHIN, as well as vice-president of clinical services at our place, Lakeridge Health. He came to us last year and was previously the CEO of Tillsonburg District Memorial Hospital, as well as Alexandra Hospital in Ingersoll.

To my immediate left is Dr. Leta Forbes. Leta is the chief and medical director of our oncology program at Lakeridge Health. She is also the quality lead for systemic therapy for the Central East LHIN. She's a medical oncologist, joined Lakeridge in 2004 and became chief in 2011.

To my right is Leslie Motz. Leslie is the senior director of clinical services for Lakeridge Health. She has leadership responsibility for both our pharmacy program and our surgical program. She's a registered nurse with 14 years of hospital leadership experience.

The other two you invited are behind me: Tamara Dus—oh, I'll start at the left. Aaron Lazarus is our senior director of communications. He may be a familiar face to some of you, and he joined our team just over a year ago.

Then beside him is Tamara Dus, who's our admin director, as we call them, of the cancer program at Lakeridge Health and for cancer services in the Central East LHIN. She's a registered nurse who has been with our oncology program for 17 years and has had leadership positions at Lakeridge for the past six years.

I'd like to start by apologizing. We're all here today because hundreds of people and their families, who were already in a vulnerable state, were dealt some incredibly unsettling news. That's difficult for all of us, but the anxiety people are feeling is very real, and I'm truly sorry that any of this happened.

We will talk about how we managed each of our patients shortly.

Health care is a complicated business, and mostly because each patient encounter is unique, let alone that there are many players and, in this case, it's not just about Lakeridge. There were many organizations providing health care whose circumstances were different.

We at Lakeridge Health did not make decisions in isolation. We have been working together with the other affected hospitals as we work through this situation. We've been working with Cancer Care Ontario, the Ministry of Health and Long-Term Care, the Ontario College of Pharmacists, Health Canada, our LHINs and the other hospitals. We've been supporting Dr. Jake Thiessen as he's started his independent review.

I want you to know that this is important to us as individuals. Every one of us is involved in health care and got involved to improve the lives of patients. Our priority is therefore those same patients, and this team has done everything it can to comfort and reassure those directly affected.

While we regret the circumstances, we are pleased to be here with you because this gives us a chance to talk about this situation, how we responded and how we're working to make things better in the future. It allows me, as the CEO, to publicly state the pride I have in this team and the individuals involved for what they have done. They are all trying to do the right thing. It's an opportunity to outline how our response reflects the culture at Lakeridge Health and the culture of everyone trying to do our absolute best.

So I want to start and tell you a little bit about what Lakeridge Health is, who we are and our culture, because that identity has informed how we've dealt with this situation that we're here to talk about.

Lakeridge Health is one of Ontario's largest community hospitals. Every day we care for thousands of people. We do this in locations that are actually spread over six legal municipalities. First, we have four hospitals in Whitby, Oshawa, Bowmanville, as part of Clarington, and Port Perry, as part of Scugog. Additionally, we have the superb Pinewood Centre for addictions and withdrawal management. Pinewood has multiple locations, not only in Durham region but through Scarborough to Clarington. And then we have six other community clinics.

We are proud to offer high quality in what is one of your largest regional community hospitals. We're a regional centre for strokes, for cancer, for mental health and addictions, for eye care, for kidney care and diabetes. And in Oshawa, we run one of the busiest emergency rooms in Ontario.

We advance science as well. We train over 1,600 students every year: medical students from the University of Toronto and Queen's University; nursing and other professional students coming to us from UOIT, Durham College, Trent University and numerous other colleges. We also run and participate in hundreds of clinical trials, mostly for new drugs and many of those within our cancer program.

Two years ago, we did an extensive consultation both within our hospital and with our communities in order to develop priorities and develop a strategic plan. Our community told us that we were good, but they wanted us to strive to be better. Our strategic plan reflects that and is named Excellence—every moment, every day. It has really focused the team on driving improvements in safety and quality. Those are pretty buzzy words today in health care, so I want to explain a little about what it means for us

Basically, it means that everyone at Lakeridge Health is responsible to improve. It means identifying where we need to improve and setting really clear, measureable goals so we know that we're making a difference.

One area I'd highlight is a program called antimicrobial stewardship, of all of our different programs. Our team works to ensure the patients are on the right antibiotic for the right length of time and not overusing them, because we know superbugs like C. difficile can mutate and become resistant to antibiotics the more they are used

I'm very proud of the team's efforts. The combination of things like emphasizing handwashing and other infection prevention control activities, in addition to the stewardship program, has resulted in a decrease in C.

difficile rates at Lakeridge Health of over 90% in less than two years.

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As with C. difficile, every year we identify where we can improve and develop programs to introduce changes and teach all of our staff the new methods. We're also changing how we communicate with patients and are developing other improvement programs. For example, we developed a new falls strategy to help prevent patient falls, and are spreading that across our hospital. Sick patients need to get up and move. That mobility is key to speeding up healing, but if it's too early, it introduces the risk of slips, trips and falls. Our falls prevention strategy helps us balance their need for independence against that risk. So we're really serious about the safety of our patients and always working to improve quality.

It's not just about safety; it's about instilling a culture that learns and innovates. It means that when something goes wrong, like the issue for which we're here today, we have a no-blame culture. It doesn't mean we're not accountable; we are. We definitely need to fix it. But it means that we want everyone to feel comfortable and confident to raise concerns, investigate and come forward with information and opportunities to learn so we can always improve. And that means we encourage our teams to always come forward with suggestions for improvement. An example: When our occupational health team felt that too many nurses were getting injured lifting heavy IV bags over their heads to attach to a standard hospital IV pole where the IV is fairly high, they looked around. They couldn't find a better solution, so they invented a better option themselves with a private vendor, and now we have the first redesigned IV pole in more than 80 years that hospitals around the world are interested in—from front-line staff. Also, our Whitby hospital is the first hospital that introduced a model of care in which a nurse practitioner coordinates and leads the multidisciplinary team.

Our latest initiative is called patient-driven care, and a major component of that project is focusing on the relationship we have with the people who are coming through our doors every day because at the end of the day, these folks are our neighbours, our families and our friends. They deserve the very best. They expect that their hospital is going to take good care of them, but they also expect that we will be honest with them about anything that might have gone wrong, and that brings me to the current situation around chemotherapy medications.

Our cancer program, the Central East Regional Cancer Program, is unique in Ontario. While the Durham regional cancer centre is located in Oshawa at Lakeridge Health, we are also accountable for the cancer programs across four other hospitals, covering the territory from Scarborough to Cobourg and Peterborough.

That same relentless drive for quality and safety improvements applies to our cancer program. Central East has a Regional Systemic Treatment Program—chemotherapy—that consists of nurses, pharmacists, physicians and administrators from every hospital in Central East. They work together to develop best practice solutions around chemotherapy administration and safety to ensure we provide consistent, high-quality care at every institution. As a result, in 2012, Cancer Care Ontario ranked us the number one cancer centre in Ontario for performance.

You're going to hear, or may have heard already, about the connection between the Peterborough Regional Health Centre and Lakeridge Health, so I want to take a moment to explain that connection, as I understand Peterborough will be presenting here next week. Peterborough is our first partner, and their program has grown with our support. The cancer program offered at Peterborough Regional is "owned" by Peterborough. They're an independent hospital. But we share clinical resources, including oncologists and pharmacists, between the hospitals, including Dr. Forbes. All oncologists come from Lakeridge Health and are cross-appointed at Peterborough. So we ensure that the quality of services in Peterborough are as great as they are in Oshawa. That's just one of the ways that our two institutions are connected. Peterborough and Lakeridge are also connected in a number of joint clinical services, such as thoracic and vascular surgery.

Lakeridge has many other partnerships with hospitals and other service providers in the LHIN, so partnering is in our DNA. We apply the same philosophy to purchasing. I was personally involved with the Ministry of Finance as they were considering creating OntarioBuys. The challenge we discussed then was the impact on vendors if buying groups became too big. We need more than one vendor for products in Ontario. I can gladly share anything about that with you today, if you desire.

More specifically, Lakeridge Health has joined different joint purchasing organizations for different types of purchases, and we currently are members of three buying groups: Medbuy, Plexxus and HealthPRO.

Generally, the idea behind all of these buying groups is that groups of hospitals making purchases together will drive economies of scale that we would not otherwise achieve. But lower prices are just one potential benefit. By joining together, we will have tighter purchasing practices and be able to leverage training for new products and equipment that can improve patient safety.

There are different buying groups with different purposes, and I'll tell you about two of them today. I was a co-founder of Plexxus, which is a partnership focused in the GTA only, and Lakeridge Health is one of the founding member hospitals of Plexxus. We use Plexxus for specific product lines: medical-surgical, office products and logistics. When it comes to medications, Lakeridge Health is a member of Medbuy. Medbuy is different in that it's a national organization.

Using chemotherapy drugs as an example, the broader public sector supply chain guidelines require that we go to tender regularly. At regular intervals, Medbuy will go through a process to contract particular medications, depending on the availability of vendors. If we always

stayed with the current vendor, the whole process would be a farce, so tendering is serious business. We can provide more information on the process, but it's important in the context of this situation that you know that once a new vendor is identified, the transition has to be worked out, and each hospital can transition over to that supplier at different times.

You of course know by now that the situations in Windsor and London are somewhat different than for us at Lakeridge Health and the Peterborough Regional Health Centre. We only made the transition to this new supplier in mid-March of this year.

Let's talk about this specific matter. We switched to the new vendor for two premixed chemotherapy drugs on March 12, 2013. Our staff became aware on March 20 of concerns around these two particular products, and our team took immediate action and removed them from our supply—and as I say about our culture, they did not wait for executive approval.

Our pharmacy and cancer teams immediately pulled folks together and began investigating, our patients and how they may have been impacted being the foremost priority of the team. We believed that a number of our patients had been under-dosed with one of their chemotherapy drugs. While we knew we still needed to verify the concerns, we had to determine exactly who would have been impacted. That involved a detailed review of patient charts.

Because we had only been using the new supplier for a matter of days, we were able to quickly identify 37 patients who would have been potentially impacted. While that review was started, we considered that patients at other hospitals could be impacted as well. That's when we began calling other cancer centres to let them know we had concerns.

Those conversations led to a table being established through Cancer Care Ontario and the LHINs just prior to the Easter weekend, in order for us to share what we had learned and coordinate our efforts to inform our patients and our communities. We worked through that weekend to coordinate our efforts to inform everyone, and we began the process to inform our patients on Tuesday, April 2.

Remember that we had just recently transferred over to this supplier, so all 37 patients impacted in our hospital were actually still in active treatment. We identified that some of those patients were coming in for their next treatment on Tuesday, April 2. This created an ethical issue, and we concluded we had an obligation to inform people at the earliest opportunity. They also needed to speak to a physician, preferably the physician they were dealing with, to discuss what impact it could have on their treatment.

Our team spoke directly with patients who came in that day, the 2nd, and one patient who came in the next morning. We telephoned the remaining patients to speak with them directly about this, and by 9 a.m. on April 3 all patients affected had been informed.

All patients were given an opportunity to discuss their situation with a physician as soon as possible. Some spoke to their physician at the time of disclosure, and others by phone immediately. All patients were offered an appointment with their physician as soon as possible.

We then issued an update to patients generally and the media via a news release that was also placed on our website, but we also knew as the news broke publicly that others who were not directly impacted would be worried nonetheless, so we set up a dedicated phone line for people to call and get more information. We posted notices in our cancer centre letting other patients know about the situation, and reassuring them that they were not impacted, and we sent couriered letters to the 37 impacted patients to follow up and make sure they had all of the information available in writing.

Dr. Forbes can speak to this further, but in a nutshell, patients were told that there were 37 patients impacted. Those patients had gemcitabine treatments between March 12 and March 20 or cyclophosphamide treatments between March 18 and 20. Some 31 of our impacted patients had only one dose with a lower than anticipated concentration, and two had two doses.

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These medications are used in a variety of malignancies, such as lymphoma, breast, lung and bladder cancers. You also might not realize that often these drugs are used to palliate symptoms, and, in our case, 27 of these patients were actually receiving chemotherapy for incurable disease, and 10 were receiving chemo in the curative setting.

You've heard about oncologists suggesting concentration. Oncologists also do not adjust the concentration of these kinds of chemotherapy—I'm sorry—do adjust these kinds of chemotherapy, depending on how a person is reacting to the side effects. So it's not uncommon to reduce the dose of one of these medications to ease side effects, often by as much as 10% or 25%. The difference in those cases is it's a decision that's made between the patient and the doctor. In this case, that was not the case. Again, we deeply regret that this has happened.

We are very sorry for the anxiety it has caused people—those going through treatment and those who called, wondering about their loved ones who maybe had passed years ago, and even those who are not in treatment but now have had their confidence shaken.

To everyone, I would like to say we are all working to identify what gaps existed that allowed this to happen, what we have to do together to close those gaps and what are the lessons we can learn from what has happened and apply those lessons to how we conduct ourselves.

Providing health care is an awesome responsibility that none of us takes lightly. It's all we can do in situations like this to investigate, review, learn and improve. That's what we're doing at Lakeridge Health because we believe we owe that to each other. It's the only way we will get to the point of truly delivering excellence every moment, every day. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We have one minute left, but I think we'll just use that in the circulation here. Ms. Jaczek?

Ms. Helena Jaczek: Thank you for your presentation. I'll just start by echoing some of your sentiment. Certainly I think I can speak on behalf of the whole committee, all of us here, that our concern is with those patients. You have relatively few, obviously, compared to Windsor, who we heard from yesterday, with 290, but of course we're very cognizant of the effect that it no doubt has had on those patients and their families and their concerns around the situation. We're here, obviously, to do what we can to make sure this sort of situation does not occur again.

I'd like to start off by saying we're aware that an individual in the Peterborough hospital took it upon themselves to test the product that was new in the hospital. Can you describe to us exactly what happened? Why this happened? Does it relate to your quality assurance program? Because, clearly, you were the one who discovered this problem.

Mr. Kevin Empey: None of us were actually there to know exactly what happened other than that this—whether you want to add anything thing, Leta—technician identified that the size of the bag, the contents of the bag, looked out of line.

Ms. Helena Jaczek: So as far as you're aware, it was a visual, that somehow there was additional saline or something. Can anyone explain how this happened?

Ms. Leslie Motz: We received the call from the Peterborough hospital by one of their technicians to indicate that they were uncomfortable with the bag. They did not give us details on any further testing beyond that. Lakeridge Health actually took that information and then they started to do an analysis of the bags at the Lakeridge hospital and then closed the loop back with Peterborough to share our findings. I'm unaware of any specific tests that were performed at Peterborough, but they could answer that.

Ms. Helena Jaczek: So what was done at Lakeridge, then?

Ms. Leslie Motz: At Lakeridge Health, we sequestered all of the—both the gemcitabine and the cyclophosphamide right away. We sequestered it, put it in a safe environment in a locked pharmaceutical room.

We initially—before management was even advised of the issue—had three pharmacy techs and a pharmacist who actually took one of each of the bags—one gemcitabine and one cyclophosphamide—withdrew all contents and measured the contents by mls, and that was enough for them to know that there was more in the bag than the 100 c.c.s or 200 that was thought to be in the bag. From that point on, we weighed each of the bags, but we did not interfere with any of the other bags. We kept them secured and sequestered.

Ms. Helena Jaczek: So the date that Lakeridge did the testing was—

Ms. Leslie Motz: On March 20.

Ms. Helena Jaczek: That was all March 20.

Ms. Leslie Motz: Absolutely.

Ms. Helena Jaczek: And so then, communication to whom? Who did you contact first?

Ms. Leslie Motz: The pharmacy staff, who did that testing, as soon as they felt that there was an issue, they called the manager of the pharmacy department.

The day was done, so there was no further chemotherapy being given that day. There was a stop order put on, and she advised them to sequester the medication. At that point, I was notified as well that the medication had been sequestered, and that's when we reviewed our stock to ensure we had enough supply in house to continue to service our patients without any disruption.

Ms. Helena Jaczek: Previously, how had you prepared these products? Before you purchased them through the group buy situation, how had you obtained cyclophosphamide?

Mr. Kevin Empey: Before this contract?

Ms. Helena Jaczek: Yes.

Mr. Kevin Empey: We were purchasing them from Baxter before. We were outsourced before as well, and we switched vendors.

Ms. Helena Jaczek: I see. So that was through the tendering process. Why did you choose to go with this? Was it a cost issue with this particular product?

Mr. Kevin Empey: For any purchasing process, any contract, you have to set up decision criteria. I don't have the actual results myself, but there were decision criteria involving price, quality, ability to deliver. What Medbuy, the buying group, does is—they actually have different committees, so they engage members from the field of all their hospitals. Our former director of pharmacy was involved in this, but none of us sitting here today. They form an advisory group that does the tender evaluation.

Ms. Helena Jaczek: How would they have evaluated quality? Are you aware?

Mr. Kevin Empey: I wasn't a party to it so I don't know what is behind, exactly what specific things they were looking for.

Ms. Helena Jaczek: Okay. Now, in terms of notification beyond your institution, when was the Central East LHIN notified? When was Cancer Care Ontario notified?

Mr. Kevin Empey: I guess I'll pass to you, Tom. We first notified another hospital. It was pharmacy to pharmacy, was it not? Or was it cancer to cancer to London?

Mr. Tom McHugh: We did make a call between pharmacies to London and then—I just have my calendar down here—we had intended to notify the LHIN on Tuesday the 2nd, but in fact, all three LHINs affected were notified on the 31st, which was a Sunday, Easter Sunday.

Ms. Helena Jaczek: On the 31st of March.

Mr. Tom McHugh: That's right.

Ms. Helena Jaczek: And you were aware March 20?

Mr. Tom McHugh: That's right.

Ms. Helena Jaczek: I see. So you sort of looked after your situation yourself very intensively as you've described, and I guess we can say thank God this was discovered so quickly, so as you've described, there were only 37 patients impacted. Okay, well thank you for that.

Perhaps we can just talk a little bit more about what has happened since. We know that Dr. Jake Thiessen has been appointed as an expert reviewer. Have you been

involved? Has Dr. Thiessen contacted you? Can you describe that process?

Mr. Kevin Empey: I guess I should declare that we've had two different contacts. The Ministry of Health has set up a daily phone call with all the parties, and Dr. Thiessen attends those phone calls if he's available. So I'm part of a phone call almost every day, if he's there. That's one contact.

Secondly, he has started travelling to visit the hospitals as his first point of contact. He has kind of followed us in order. He was at Peterborough last Tuesday, Lakeridge last Wednesday, and then he has now visited Windsor and London.

Ms. Helena Jaczek: On this daily phone call, you're talking about the working group?

Mr. Kevin Empey: The working group that the Ministry of Health has set up.

Ms. Helena Jaczek: What kind of discussions are occurring with the working group?

Mr. Kevin Empey: More than anything else, it's just confirming what is happening; for example, the release that came out from Health Canada on Friday and the amendments to the Public Hospitals Act. Catherine Brown informed all of us Friday that those were coming out. We're just kind of getting updates from everyone, and Jake is giving us an overview of not the particular details he's getting in the interviews, but let's say his sense of how the interviews are going and whether everyone's co-operating and whether he needs any more help from the advisory panel.

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Ms. Helena Jaczek: Were any of you aware of what I guess we're calling this "grey area" in terms of oversight between Health Canada's responsibilities around manufacturing of pharmaceuticals and the College of Pharmacists' oversight of pharmacists in pharmacies?

Mr. Kevin Empey: No, we were not. This is an unfortunate learning experience for all of us.

Ms. Helena Jaczek: I see. Okay, now that you've heard about the actions of Health Canada and the proposed regulation, do you feel that this is something that will assist in terms of quality assurance in the future? Can you express an opinion?

Mr. Kevin Empey: Yes. I kind of equate it to let's call it the other devices and tools that we use. So if we buy bandages or a hip from a supplier, we know that they're certified by Health Canada. We buy—we obtain blood products; we don't buy them. We obtain blood products so we know that the blood products have been certified. Drugs themselves get a DIN number, and the manufacturers are certified by Health Canada. So it would be great for all of us to have a simple regulation that kind of expands to this group of products as well.

Ms. Helena Jaczek: Maybe I'll just turn to Dr. Forbes and maybe talk a little bit more about the impact on your particular patients—and Mr. Empey, to give us an overview. Could you just explain to us a little bit more, from your professional opinion, about the impact on these 37 patients?

Dr. Leta Forbes: The drugs that were affected were one drug within a multi-drug regimen and, in many cases, were actually not the most active agent of the multi-drug regimen. This was one dose for 31 of our patients and two doses for six of our patients. So in the big picture, this is one small under-dosing of one drug of multiple cycles of multiple agents. So the actual clinical impact, we think, is very minimal.

Ms. Helena Jaczek: Well, that's very good to hear. So how are you preparing these compounds currently, since March 20? How are you getting your supply?

Mr. Kevin Empey: We stopped buying them from Marchese, and our pharmacy has taken the work in-house.

Ms. Helena Jaczek: I see.

Mr. Kevin Empey: So our pharmacy is doing the compounding and the preparing for these chemotherapy drugs.

Ms. Helena Jaczek: Mr. Empey, when you were giving us your overview, you mentioned your relationship to one of these group-purchasing organizations, Plexxus. You were a co-founder. Are you in any way connected to Plexxus in your current position?

Mr. Kevin Empey: Yes. Lakeridge still remains a member of Plexxus, so we do our contracting through them, and this last fall I joined the board of Plexxus.

Ms. Helena Jaczek: I see.

Mr. Kevin Empey: So I'm a board member.

Ms. Helena Jaczek: Can you just detail for us perhaps—you must be a believer in group purchasing. Could you just give us some insight into the advantages of a process like this that you were engaged in?

Mr. Kevin Empey: Sure. I think there are a number. One of them is definitely purchase price. Many of us believe that if you can increase the purchase quantity—so a whole bunch of hospitals going out together—you will get a better price, and Plexxus has generated significant purchase-price savings over its eight or so years.

Secondly, something I mentioned in the speech is what I call the standardization of the process of hospitals going out together. You now have one process with one set of criteria versus, say, seven or eight hospitals going out themselves with individual criteria and doing very different evaluations on the exact same thing.

Then, anytime you make a change, like take Baxter to Marchese, you have to have an implementation period, and if it's something new like, say, a new IV pump, you have to go through an awful lot of training with your staff. So getting that standardized approach to the training and getting support from the vendor is really critical to make sure that we implement it properly.

Sometimes we will make a contract choice where the price actually goes up, but we're making the change for an improvement in quality or safety.

Ms. Helena Jaczek: Can we assume that when you started your original contract with Baxter, your very excellent pharmacy technicians and pharmacists took a very cautious approach, the way they did with this particular product? Is this the norm in your institution, that

there is a very careful analysis of the new product received?

Mr. Kevin Empey: Unfortunately, none of us would have been involved in this when we started buying from Baxter, to be able to answer what we would have gone through, but yes, you have to do that. You have to do an evaluation when you first receive it to make sure that you're buying what you said you were buying.

Ms. Helena Jaczek: How much time do I have left, Chair?

The Chair (Mr. Ernie Hardeman): You have about a minute and a half.

Ms. Helena Jaczek: Okay. I'll save my minute and a half. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. The opposition, Mr. O'Toole.

Mr. John O'Toole: Thank you very much, Kevin and the Lakeridge experts. I just wanted to be here out of respect for the work you do. I'm very impressed with the report you have given to the committee, and I recognize the empathy you have for your patients or clients, however you describe them. I also want to recognize as well that Christine Elliott, our health critic, couldn't be here today. She reminded me to perhaps attend out of respect for that discussion.

I would also say that I was made aware and had access to a full briefing. As you know, I think we had a full breakout in the number of patients, the 37. To be helpful in terms of not making a bad situation worse—people's knowledge and the reaction, I think, was professional and respectful. I say that without being a full member of this committee but I am very interested in health care generally. My colleagues are here to question or at least bring to light some clarification in your report.

Thank you very much, Kevin. That's primarily all I have to say. Thank you again for coming.

The Chair (Mr. Ernie Hardeman): Thank you very much. Mr. Yurek?

Mr. Jeff Yurek: Thank you very much for coming today. I appreciate the work you do in your community. I'd also like to commend the pharmacy technicians for their professionalism and detail to their job in finding the error. I think that was great. That shows the level of competence in our health care professionals throughout the province, that that was picked up by them. I appreciate that.

My first question of all is with regard to procurement policy. Outside of the broader public sector directive from the Ministry of Finance, does the Ministry of Health have any procurement policy put together in regard to obtaining compounded medication outside of the mainstream drug manufacturers?

Mr. Kevin Empey: Do you mean a policy applying to hospitals?

Mr. Jeff Yurek: Yes.

Mr. Kevin Empey: I don't know that there's a discrete policy other than all of our responsibilities under the Public Hospitals Act to follow rules and regulations, generally.

Ms. Leslie Motz: And the College of Pharmacists has numerous standards around the preparation of compounded medication, and many best practices and training received as well from the college.

Mr. Jeff Yurek: I'm a member of the college.

Ms. Leslie Motz: Sorry; I was unaware of that.

Mr. Jeff Yurek: Just to give you the information.

The Chair (Mr. Ernie Hardeman): He's the plant.

Mr. Jeff Yurek: I'm the plant.

You noted earlier that with blood products, you have to make sure they come from a certified provider. Drug manufacturers, of course, are certified through Health Canada. You buy hips from certified providers. But there was no direction that compounded medications have to come from an accredited, certified provider. Is that what was maybe missing from the Ministry of Health?

Mr. Kevin Empey: Well, this was honestly a gap in our knowledge. We didn't know there was a distinction. Medbuy themselves, all the people involved in this, we didn't catch the distinction between the legal structure of different companies and whether there was any difference from the Marchese pharmacy—that we should be looking for anything different. All the vendors are asked in every tender if they are selling us a legally licensed product, so we can only assume that conversation happened and no one on our side caught any impact of a structure or regulatory grey area.

Mr. Jeff Yurek: So to your knowledge, does Medbuy have a pre-qualification for manufacturers that want to sell product to Medbuy, to the hospitals? Is there a pre-qualification to ensure that they're accredited?

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Mr. Kevin Empey: I don't know. I can't comment on whether or not they have a pre-qualification. I know that all of us are very interested in making sure that they're valid products, so Medbuy has those questions as part of every tender process.

Mr. Jeff Yurek: With regard to March 20, when you found out about the possible error, was there any policy coming from the LHINs or the Ministry of Health to inform them of a potential error in the system so that they could spread the knowledge to all hospitals?

Mr. Kevin Empey: I wouldn't say there was a policy as much as a practice—but also, we're cautious. We do not start spreading until we have a pretty good idea that we really do have a problem. This first detection, as Leslie Motz said—we wouldn't start talking to other institutions until the pharmacy has done more review and we're really convinced we have a problem. So we don't even raise the alarm to the LHIN until we're convinced.

Mr. Jeff Yurek: It's up to the individual hospital to contact other hospitals? There's no overriding central part of the system that would do an alert across the province?

Mr. Kevin Empey: There's no central system. I'd say that there are channels. Cancer Care Ontario only has responsibility for the cancer centres. This happens to be cancer, but if it wasn't cancer, our two channels would be to the LHIN and to the Ontario Hospital Association. The

Ontario Hospital Association has been actively involved in this, in sending out information to the rest of the 154 hospitals. That tends to be our process.

Mr. Jeff Yurek: My understanding of the drug system, as you know, is that when there's a recall per se of a drug, Health Canada sends out an alert to pharmacies across the province, and then it's followed by mountains of paperwork from both Health Canada and the supplier. But there's nothing in place that would occur for a hospital if they found an error with a product they have procured outside of manufacturers—

Mr. Kevin Empey: I honestly don't know whether we would be subject to lawsuits if we did what you just said. We have to be careful of whether we're defaming a vendor publicly, so we tend to do it with phone calls. In this case, there aren't just cancer centres, but there are 71 hospitals that provide chemotherapy. So Cancer Care Ontario orchestrated a phone call to every one of those hospitals.

Mr. Jeff Yurek: The point of my question is not to defame any vendor. If you look at our water system out there, if there's a problem, the medical officer of health of that area is contacted. At least there's somebody who has dedicated responsibility—probably a former Chief Medical Officer of Health—that there's a problem. But I don't see any linkage from the Ministry of Health that would have that system put in place.

Mr. Kevin Empey: Right. I'm not aware of any regulation or any demand that says, "You report this way, using this purpose."

Mr. Jeff Yurek: From what I'm listening to and from the other days of testimony—not testimony, because you're not on trial, but I think you understand—there are no guidelines from the Ministry of Health or LHINs for procurement of compounded medication in the system. Basically, the broader public sector definition is about all you get from the Ministry of Finance.

Mr. Kevin Empey: Right. The ministry does not get involved in our specific procurement process or our specific procurement decisions. Some hospitals buy in buying groups, like we do; some hospitals are purchasing on their own.

Mr. Jeff Yurek: Nor would I want them involved in the day-to-day operation. But I'm looking at some standards to ensure quality or quality control—

Mr. Kevin Empey: Well, in effect, the public sector supply chain guidelines created those standards. This is the expectation of, when you go to tender, what you have to involve in the evaluation process. But they don't get to the point of stating, "These are your decision criteria," because, honestly, our decision criteria are very different depending on what the type of drug is.

We were having a conversation earlier that depending on what the product is, whether you involve the clinicians or whether the clinicians are involved in the hospital—in the case of drugs, pharmacy and therapeutic—process of getting a drug onto what we call the formulary. So we have different processes depending on what the product is. If it was a rigid one-shop, we would probably all have problems as institutions.

Mr. Jeff Yurek: My concern is the fact that the broader public sector supply kind of encompasses anything from laundry service to whatever product, and this procurement of medication outside the hospital is rather new, especially with compounded medication.

Last Friday, the ministry announced that they're changing the regulation. They can only purchase from accredited, licensed or otherwise approved suppliers. Common sense, in my mind, dictates that it should have been the standard—

Mr. Kevin Empey: That's a normal question anyway.

Mr. Jeff Yurek: —it would have been the standard in that process.

My concern with the system was that was lacking when this new type of procurement occurred; that the Ministry of Health, which has a deputy minister of the health system accountability and performance division, has a whole section of people, and this was missed when a new type of procurement—to me, that relates to the dawn of the Internet and allowing hospitals to switch to the Internet, but don't put in any new policies. Don't rethink what's going on; the old rules will suffice.

I guess that's more a statement than a question, but if you have any thoughts on that I would be appreciative of any response.

Mr. Kevin Empey: I don't know that I could add anything to your statement.

Mr. Jeff Yurek: We'll hold our minutes till the next round.

The Chair (Mr. Ernie Hardeman): Okay, very good. Ms. Gélinas.

M^me^ France Gélinas: It's a pleasure to see you. Thank you for coming to Queen's Park. I have no doubt that you've probably had a couple of tough discussion days, and I thank you for all the work that you've done to help people manage that news and, I would say, turn the page on something that should have never happened, but did.

I was quite impressed with—I'll call it your mission statement—your excellence every moment, every day. This is something to be proud of. As you started to explain, it means that when something goes wrong like the issue, there is a no-blame culture; that you are still accountable and that everyone feels comfortable and confident to raise concerns—I'm reading from your notes. And it worked; it worked. You had a pharmacy technician who noticed something and felt empowered enough to move this issue forward. It got tested by your pharmacy, and basically you exposed what we now know as the diluted chemotherapy.

I would be interested in knowing who this technician is, if you could share that with us, as well as the names of the people who did the initial testing. In answers to my colleague, you made it clear that you didn't call it a problem until you had paid due diligence, that there was a team within your pharmacy that made sure that we had

a problem. It was not just a hunch. If you could table that with the Clerk—or do you know it by heart?

Mr. Kevin Empey: I do not know the technician's name.

M^me^ France Gélinas: Okay.

Mr. Kevin Empey: I did not ask. Everyone is trying to approach this technician, but you will have Peterborough visiting you next week.

M^me^ France Gélinas: Okay. The Clerk will follow up with you, if you could table that information with the Clerk.

Another little piece that I was interested in also is that you note that there are decision criteria that were used to decide which supplier was going to—but you didn't know what those criteria were off the top of your head, which I understand. This is something else that I would like you to table with the Clerk. Will is our Clerk. He will also follow up with you so that we have a better understanding as to how that particular decision was made.

Going into some of the questions, I'll continue with you, Mr. Empey. It has to do with some of the statements you've already made. You didn't know about the grey area. I don't blame you for this; it's not your job to know that kind of stuff. But just to be on the record, had you known that this was an unregulated agency that was procuring you the drugs—if that had been a known fact, do you figure you would have still made that purchase? Any of you can answer.

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Mr. Kevin Empey: I guess I could just say, morally, that we really work hard to conform to regulations. We really work hard to make sure our vendors are giving us safe, evaluated product. I think what it would come down to is this current question: Do we have the capability of doing something in-house or do we have to go out? If we have to go out, are they the only choice? If all other criteria are equal, we would go with a certified vendor. If we knew this, we probably wouldn't have switched vendors—if we knew that there would be this uncertainty about their status. But if they were the only vendor out there, then our next step would be to do an evaluation of whether we could be sure that they had a quality manufacturing process that we could be happy with.

M^me^ France Gélinas: Makes sense. Thank you.

I'd like to ask you a few questions, Dr. Forbes. I take it that you're a practising oncologist?

Dr. Leta Forbes: Yes.

M^me^ France Gélinas: Do you solely practice in hospitals or do you do community? Do you have a practice outside of the hospital as well?

Dr. Leta Forbes: I have in-hospital practices in Oshawa, Peterborough and Cobourg.

M^me^ France Gélinas: I take it you rely not only on hospital services but also the lab reports that come from outside of the hospital, not just within. Am I right?

Dr. Leta Forbes: Yes, that's a fair assumption.

M^me^ France Gélinas: I'm also making a pretty educated guess that in order to do your work, in order to come to the decision as to, this is the treatment plan for this particular patient, you rely on many, many sources of information, be it the lab, the X-ray, the MRI, the CAT scan etc., and you trust those results to be true. Am I right?

Dr. Leta Forbes: Yes. I think that's a fair assessment.

Mr. Kevin Empey: But if I could answer that: not always. We, a big hospital, have a big lab and we have a big radiology service. Sometimes radiology might determine they're not necessarily happy that that place—wherever—has the same quality of diagnostics that we do, so then we will ask to do the test over ourselves. So if we have any reason to believe we're not happy that their equipment is as current as ours or up to the same standard, we might decide for our clinicians to do something new. Otherwise, we will rely on everyone being regulated and that the clinicians can rely on that test.

M^me^ France Gélinas: Okay. How would you come to the realization of that, that you would like a test redone because you're questioning the quality or you're questioning an outside supplier? How are those decisions made?

Mr. Kevin Empey: Not usually based on facts; maybe based on clinicians' past experience with not being happy with a diagnosis or a test result, and so deciding to do it again ourselves just for caution.

M^me^ France Gélinas: Back to Dr. Forbes: When you practise, do you feel that the information that you get—that it is your job to check if those suppliers are supplying you with right and accurate—that they're accredited and that they are regulated? I'll let you answer that.

Dr. Leta Forbes: When you're practising medicine, every decision you make has a lot of different contributing factors, so you look at the patient. You look at how the patient is; you look at their physical status. You correlate that with what you see on their labs. You correlate that with what you see in their radiology. You never make a decision in isolation. Anytime you have something that's not consistent, then you may end up repeating it or doing a different test. It's not within the scope of a physician to ensure that their supplier is accredited. It is within the scope of a physician to use our clinical judgement to be able to tell if a test is consistent with the clinical picture.

M^me^ France Gélinas: Makes sense. Thank you.

Did you have a question? Go ahead. Don't tell me; tell them.

Ms. Cindy Forster: Ms. Gélinas asked for the information to be tabled with respect to the criteria used with the supplier; she asked you to table that with the Clerk.

I think her question was around the chemotherapy drugs, right? But could you also table the criteria for any drugs that you're actually outsourcing? If you have other drugs within your system that you're having mixed elsewhere outside of the hospital, could you table the criteria that you use to determine that and evaluate it?

Mr. Kevin Empey: So, do we have any other contract other than Baxter now?

Ms. Leslie Motz: No.

Mr. Kevin Empey: We only have one contract for outsourcing compounded medication. It would be all under this contract that we're talking about. There are different drugs, but all under the one contract.

Ms. Cindy Forster: All under the one contract? Thanks.

M^me^ France Gélinas: I'll start with you. How much of a surprise was it to you that there was this grey area and that the part of Marchese that had been supplying—although for a short period of time—these chemotherapy IV drugs, was not regulated?

Ms. Leslie Motz: It was a great surprise to me. I would have expected for the label to reflect the content.

M^me^ France Gélinas: You would? And what do you base this on? Your experience?

Ms. Leslie Motz: Yes, it's my experience, the experience of the pharmacists and pharmacy techs. There is a general practice that there's a significant amount of trust put in the label and the accuracy of labels. Since there is really no internal way of checking that, beyond an investigative sort of role, there is a lot of trust put in the label.

M^me^ France Gélinas: And you are comfortable with that trust because years of experience in the system had shown you that they are trustworthy? I shouldn't have said that. You're comfortable with that trust because—

Ms. Leslie Motz: You said it beautifully. Years of experience, and no quality concerns identified—certainly in my experience—in the past.

Mr. Kevin Empey: If I could add?

M^me^ France Gélinas: Sure.

Mr. Kevin Empey: In our industry, the majority of the vendors are very big companies. So, right there, they're an American international company, regulated in many forums around the world, so you also have a degree of comfort in who you're dealing with just because of the size of the institutions, like a Baxter.

M^me^ France Gélinas: I think you went exactly the way I thought you would go; that is, because of the layers of regulation within the system, everybody within health care feels secure—and trusts—that what they're getting, whether it be a result, whether it be a drug, whether it be an artificial hip or knee, has gone through so many layers of regulations that you can trust that what you got is what's written on the package or what you can see. It came as a huge surprise; it came as a surprise to all of us.

Then come the tough questions for you, and I'll see who wants to be the tough person answering that.

We knew, since 1997, that there was this grey area with no regulation. Do you have anything to say about a 15-year gap in action? Why did it take 15 years to act and close that grey area? I can feel that the CEO is ready to be the brave one on that one.

Mr. Kevin Empey: But my answer won't satisfy you, because the answer is I didn't know that. We heard reference to that in one of the earlier hearings, earlier meetings. We talked amongst ourselves, and none of us had heard that this issue had been raised before. We, as buyers, knowing that, should have been ultra-cautious with the vendors.

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M^me^ France Gélinas: Had you known.

Mr. Kevin Empey: Had we known, we probably would have changed how we'd approached the tender.

M^me^ France Gélinas: Okay. I'll save my time.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Chair. Mr. Empey, you've obviously explained that hospitals are independent entities and that they have their own board of directors, and therefore purchasing decisions are made, essentially, locally. However, yesterday, when Windsor Regional was here, of course, they reminded us of the Excellent Care for All Act and, pursuant to that, the need for a quality improvement plan. Within that quality improvement plan, they certainly have a very detailed medication-error type of reporting and analysis on an ongoing basis.

Could you just tell us how that works at Lakeridge, in terms of medication errors and the process you follow?

Mr. Kevin Empey: Well, we have a general process for errors, and a system we call the better system, where people record incidents of any kind. Medication would fall under that, and then we have specific people assigned to review the item noted and then draw it to the attention of whether it's the director of pharmacy or others. Then, they collectively decide whether that warrants a review or not. So we have a very formal process to try and make sure that people are actually identifying the errors, or even what we call near misses, because we can learn as much from those as we can—so we don't have anything different for pharmaceuticals. It falls under our overall errors-and-issues protocol.

Ms. Helena Jaczek: And this is reported through the quality improvement plan, I presume?

Mr. Kevin Empey: Not necessarily. The quality improvement plan allows a fair amount of leeway, meaning the objective isn't for us to just focus on five things. The objective is for us to identify the things that are most important for Lakeridge to work on and to improve. There are some mandatory items. We put what's called medication reconciliation, matching the drugs that a patient comes with versus what the doctors might prescribe in the hospital, and we put the falls program that I referred to—things where we knew we needed to improve. We identified those in our quality improvement plan.

Ms. Helena Jaczek: And the quality improvement plan goes to the Central East LHIN and gets approved?

Mr. Kevin Empey: No. Actually, our formal reporting for quality improvement plans is to Health Quality Ontario. We give the LHINs a courtesy copy, but the LHINs don't approve our quality improvement plan. Our board approves it, and then it goes to HQO for review.

Ms. Helena Jaczek: Okay. Thanks.

The Chair (Mr. Ernie Hardeman): Ms. Jaczek, that's the end of your time. We'll now go to Ms. McKenna.

Mrs. Jane McKenna: I just want to jump in and say that we're very grateful that you're here today, giving us the information that you're giving us. My first question is: Do the 37 people have a direct line to the oncologist?

Dr. Leta Forbes: The 37 patients who were contacted were all provided contact information, so a direct line to call in with concerns. They were all spoken to by phone by our staff personally. They were given handouts with a phone number, and yes, they all have a line directly to the oncologist that they normally see.

Mrs. Jane McKenna: Okay. Thank you very much. My next question is: Does the hospital have a contract with Marchese directly or with the broker, Medbuy?

Mr. Kevin Empey: This incident has raised this other curiosity that I must admit I wasn't aware of. We signed a contract with Medbuy and participate in their negotiations of contracts. Medbuy actually has the contract with the supplier.

Mrs. Jane McKenna: So who actually develops the contract? Is it Medbuy that puts all the information into that contract, is it you, or who is that?

Mr. Kevin Empey: It's Medbuy, as a legal entity, that takes the responsibility, but they involve people from the field. They have hospitals like us, customers like us, across the country, so they involve those in the determination of the criteria and the final contract, but Medbuy writes and signs the final contract.

Mrs. Jane McKenna: So they're responsible for that contract and everything that's in it.

Mr. Kevin Empey: Yes, so that's why it was more important for us to contact Medbuy than it was the LHIN in evaluating the contract.

Mrs. Jane McKenna: Right; okay. My next question is: Marchese maintains its drugs were not defective, suggesting the problem was how the drugs were administered at hospital, not how they were prepared. How easy is it to make this kind of compounding error if you're a qualified pharmacist?

Mr. Kevin Empey: I'm an accountant, so one thing that the team had to educate me on was that most of us do not realize that an IV bag says it has 100 c.c.s in it; it almost never has 100 c.c.s in it. Every IV bag has a randomness to it. The clinicians can correct me for saying this wrong, but that doesn't matter that much when you're injecting a medication into the IV bag and then you have an IV drip and you're going to dispense the whole bag into one of us, because you know you're getting the whole medication. The difference with chemotherapy drugs is, it's that ratio of medicine to IV that is critically important, so we need to know how many c.c.s are in that IV bag. Kind of, for the other IV bags, don't worry about it. So that's the significant difference of this product. We need to know how many c.c.s are in that bag.

The Chair (Mr. Ernie Hardeman): Mr. Yurek?

Mr. Jeff Yurek: I've just got a couple more questions, thanks.

With regard to the labelling of the bag coming in from Marchese, we heard yesterday they labelled it four grams and 250 mls. Did any pharmacy staff ever have concerns with the way the bag was labelled, perchance? My concern is, I don't know why—it's easy to do math with a concentration on the bag, let alone just four grams and 250 mls.

Mr. Kevin Empey: Honestly, it was apparently one of the reasons Marchese was picked, according to one of the other hospitals. It was that their bag labelling was much clearer and much more precise than the other vendor—ironically.

Mr. Jeff Yurek: Okay.

Mr. Kevin Empey: So the labelling was great; it was just this issue about the vagary of the amount of IV saline that was in it.

Mr. Jeff Yurek: We also heard yesterday one of the reasons this drug is procured is just because of the difficulty to get the powder into the solution, and the time. I imagine it would be more of a time problem. Has that been a problem—switching back—to the hospital, with regard to staff time and such?

Ms. Leslie Motz: Has it added workload and challenged the capacity? It has. Are we comfortable and confident that we are doing it and meeting all best-practice standards? We are.

Mr. Jeff Yurek: And your staff are all trained up to date with chemotherapy—that mixture?

Ms. Leslie Motz: They absolutely are.

Mr. Jeff Yurek: Okay. That's good.

The Chair (Mr. Ernie Hardeman): Thank you very much. France?

M^me^ France Gélinas: So I can use my time wisely, how many minutes have I got left?

The Chair (Mr. Ernie Hardeman): Four.

M^me^ France Gélinas: Four. Wow.

The Chair (Mr. Ernie Hardeman): Starting now.

M^me^ France Gélinas: We'll have to speak really fast. I may have to switch to French; you just don't know.

I take it that you have a relationship with Medbuy, since they do some of the purchasing for you. Who is your primary contact?

Mr. Kevin Empey: The primary contact would be pharmacy to pharmacy. We have a second primary contact, which is that our vice-president of finance is on the board of Medbuy.

M^me^ France Gélinas: No, I mean—okay, so who is that person at Medbuy who you deal with?

Ms. Leslie Motz: On a day-to-day basis? Is that what you're asking?

M^me^ France Gélinas: Yes.

Ms. Leslie Motz: There's a director at Medbuy who is our direct first contact.

M^me^ France Gélinas: And his name is?

Ms. Leslie Motz: Her name—

M^me^ France Gélinas: Her name.

Ms. Leslie Motz: —is Ann Kelterborn.

M^me^ France Gélinas: Could you say the last name again?

Ms. Leslie Motz: Sure. It's Kelterborn.

M^me^ France Gélinas: For this particular contract where you decided to procure the chemotherapy through Medbuy, who was the person you dealt with at Medbuy?

Ms. Leslie Motz: I wasn't part of the contract, so, I'm sorry, I can't answer that.

Mr. Kevin Empey: It was our former director who was on that contract team, so we would have to go back to learn who was the main contact that she was dealing with. For us, it's an operational issue, the day-to-day contact with the day-to-day players.

M^me^ France Gélinas: Okay. If you could table that with the Clerk, please, who it was that your hospital negotiated with at Medbuy regarding that particular purchase—the supplying of the chemo drugs.

So the minister on Friday put the draft regulation in place that basically says, "You will have to purchase from accredited suppliers." How will you do that? You didn't know that they were not accredited. Had you known, you wouldn't have. So how are you going to fulfill that?

Mr. Kevin Empey: I don't know the answer to that question other than do what we did during the tender, which is to ask the question, "Are you accredited?" So then we're still reliant on them. We larger hospitals may have more opportunity with bigger purchasing functions to do more investigation of the company, but it would be a concern for small—smaller hospitals don't have those resources to be investigating all the vendors.

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M^me^ France Gélinas: But small hospitals also purchase chemotherapy and also provide cancer treatment.

Mr. Kevin Empey: My answer was thinking broader than chemotherapy—products in general.

M^me^ France Gélinas: Okay. So, basically, you will still be reliant on whatever they tell you.

Mr. Kevin Empey: Right, and they are accredited by the College of Pharmacists. We didn't understand that distinction, so a lot of hospitals, not knowing this, would have just accepted that.

M^me^ France Gélinas: Absolutely. So would I, and so would everybody else.

It feels like a transfer of responsibility. The Ministry of Health is the overseer. They are the steward of the health care system. They don't deliver care; good people like you do this. They make sure that the system has oversight, is regulated, is basically accountable. Would you see it as reasonable to ask the ministry to do this accountability to make sure that the suppliers out there are regulated?

Mr. Kevin Empey: Let's say it would be simpler for the field if we didn't all have to come up with our own answer to that question. Whether it's the Ministry of Health or Health Canada, it would be really simple to know that there's one body we're relying on.

M^me^ France Gélinas: Would you say it would make sense to have it with this one body, either Health Canada or the Ministry of Health?

Mr. Kevin Empey: I'm just saying it would make it simpler for all of us in the field.

M^me^ France Gélinas: Okay. I get you.

The Chair (Mr. Ernie Hardeman): This being your last question.

M^me^ France Gélinas: Oh, no. How did that happen?

Interjection.

M^me^ France Gélinas: Huh?

Mr. Jeff Yurek: We'll ask them for you.

M^me^ France Gélinas: You'll ask them for me?

Did you want the last question?

Ms. Cindy Forster: No, go ahead. You're on a roll.

M^me^ France Gélinas: I guess the last question will be to you, Dr. Forbes. We're all really sorry for what has happened. You were very reassuring today when you told us that for the 37 people who were affected in your hospital, it was one dose of a mix, sometimes two doses of a mix. You were pretty explicit in saying that for those people, you feel pretty confident that the rest of the treatment will do whatever it was aiming to do.

Would you feel just as confident to say that the trust factor was as easy to convince than the actual aim of the treatment?

Dr. Leta Forbes: I think you're going to have to be a little bit more clear. Who are you referring to?

M^me^ France Gélinas: Mainly patients, families, people who deal with your hospital, people who deal with the cancer program that you are a part of. The issue of trust is integral in providing care. Once the trust is broken, it's a lot tougher to provide care. I'm trying to see how much of an impact you figure this has had, for good or for bad.

Dr. Leta Forbes: Our patients have a great deal of faith in us as their clinicians. We have excellent relationships with them. They trust us completely. There is a concern amongst patients who weren't affected and patients who were affected that other drugs that they're receiving are not what we say they are, so we are doing everything we can to reassure them that we have taken all the steps we need to do to give them what we say we're giving them. But there has been trust affected in the population. There's no doubt about it.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. McKenna.

Mrs. Jane McKenna: First off, I want to say that there are 362,000 pieces of regulation. You being in the hospital would know that, at times, it's overwhelming to have all of these regulations to even get to the front line of the patients themselves. Considering that this was a grey area since 1997, my first red flag tells me that it's time that we actually go and look at each piece of these regulations to see what works and what doesn't work—because you can't continue adding on red tape and regulation after regulation, because here's an example here of what happens: One hand thinks the other hand is doing it.

I have a question. The more players involved, the greater the opportunity for mistakes. Would you say that the need for regulation and oversight is even greater when you have so many people with their hands in one situation?

Mr. Kevin Empey: The one situation specifically being chemo drugs, you mean, or drugs in the system of health care?

Mrs. Jane McKenna: The whole thing. Either or.

Mr. Kevin Empey: Well, the system of health care has the problem in that it's even greater. You have long-term-care homes, retirement homes, EMS, CCACs, home care and hospitals all procuring drugs on their own and all slightly subject to different regulatory frameworks—because we have the overriding Public Hospitals Act, and not all of the rest of those have that, like the Ambulance Act for EMS.

Any group of people, any institution in this sector has to be careful. We deal with EMS; we deal with the CCACs. We have to talk to them to make sure of whose regulations take precedence. I doubt you'd get one overall regulation that deals with the whole health care system, though. It's too complicated, which is why there are so many different acts.

Mrs. Jane McKenna: I'm not disputing the fact that you can't have one, but what I am saying—I'm just saying we need to look at what's there. This is a tragedy that we need to be able to look at to see how we could miss the gaps in the overlap.

I guess my next point is, if it was so noticeable to the technician—the other hospitals would have had the bag from before and then the new bag. They would have seen exactly what the technician saw at your hospital if it was so noticeable. My question is, how come nobody else noticed it?

Mr. Kevin Empey: We can't really answer that, but I can just bring you back to the point of why I talked about the variability in IV bags. People get used to the fact that every IV bag has a different quantity in it.

Mrs. Jane McKenna: Right.

Ms. Leslie Motz: I could add a little bit of detail. When we switched vendors, the previous vendor had been preparing in an empty bag, if you will, so the look and the feel and everything were different about it. With the exception of this one astute person who had a guttural reaction to something, I'm not sure anyone else would have been able to recognize 20 c.c.s in a bag of 200. That would not be that noticeable compared to the previous provider, which was using an empty bag. So they were adapting to a new system as well.

Mrs. Jane McKenna: It's just amazing to me that this person did. If it's 20 c.c.s and it's minimalistic, it's just amazing to me that this person did.

The Chair (Mr. Ernie Hardeman): Mr. Yurek, do you have another question?

Mr. Jeff Yurek: Sorry, just with regard to the labelling of the product, you made the comment that Marchese actually had better labeling. What did Baxter—what was on the labeling of their bag?

Ms. Leslie Motz: Both labels, from my recall, were ISMP. There was no concern around meeting the qualifications of the label. The difference is that the Baxter label provided the concentration whereas the Marchese label did not provide that concentration.

Mr. Jeff Yurek: That would tell me that the Baxter label was a little more informative for a health care professional.

Ms. Leslie Motz: I'm sorry?

Mr. Jeff Yurek: That tells me the Baxter bag would actually be a little more informative for a health care professional using that bag in order to create the accurate dose. It just makes the math a little easier.

Ms. Leslie Motz: The other difference was the bar-coding. Marchese offered bar-coding on their labels. The previous label did not offer bar-coding.

Mr. Kevin Empey: That's a detail I wanted to add. Our health system is laggard in the use of bar codes. More and more, we hospitals, our buying groups, are demanding that as one of the criteria in making a selection. If you give too much weight to it, you're not necessarily balancing the other because we need to move to the electronic age with bar-coding.

Mr. Jeff Yurek: So what would the bar code information inform the pharmacy technician of?

Mr. Kevin Empey: I can't read a bar code or anything off of it, but a bar code allows you inventory control and product control using electronic inventory systems. It's much faster and much more efficient in terms of inventory management—

Mr. Jeff Yurek: And bar codes for the inventory management, not for transfer of what's on the label or anything.

Mr. Kevin Empey: Not for transfer of the medication information, no.

Mr. Jeff Yurek: Okay. So that's separate.

The Chair (Mr. Ernie Hardeman): Thank you very much, Mr. Yurek. That does conclude the time. The inquisition is over.

Thank you very much for being here to help us out with some of these issues. You've been very informative, and we very much appreciate you taking time away from what you could be doing on this nice spring afternoon. Thank you very much for being here.

That concludes the committee meeting this afternoon. The next meeting—we will reconvene here on April 29—that's next Monday—at 2 o'clock. Thank you all for being here.

The committee adjourned at 1720.

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Mr. John O'Toole (Durham PC)

Clerk / Greffier
Mr. William Short

Staff / Personnel
Ms. Elaine Campbell, research officer,
Legislative Research Service