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Monday 29 April 2013

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Lundi 29 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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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON SOCIAL POLICY

COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Monday 29 April 2013

Lundi 29 avril 2013

The committee met at 1414 in committee room 1.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

The Chair (Mr. Ernie Hardeman): Seeing that petitions have just ended, we'll call this meeting of the Standing Committee on Social Policy to order. We are meeting for a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

LONDON HEALTH SCIENCES CENTRE

The Chair (Mr. Ernie Hardeman): Our first delegation this afternoon is London Health Sciences Centre, here to help us understand what went on.

With that, first of all, we'll ask the Clerk to do the swearing in, as we will be doing it all under sworn testimony.

The Clerk of the Committee (Mr. William Short): I'll start left—my left—to right. So, Mr. O'Hara, correct?

Mr. Toby O'Hara: Correct.

The Clerk of the Committee (Mr. William Short): Did you want to swear an oath or be affirmed?

Mr. Toby O'Hara: I'll swear.

The Clerk of the Committee (Mr. William Short): The Bible is there.

Mr. O'Hara, 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. Toby O'Hara: I do.

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

Mr. Neil Johnson: Yes?

The Clerk of the Committee (Mr. William Short): Same thing?

Mr. Neil Johnson: Yes.

The Clerk of the Committee (Mr. William Short): Mr. Johnson, 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. Neil Johnson: I do.

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

Mr. Murray Glendining: Yes, same.

The Clerk of the Committee (Mr. William Short): Same thing? Oath? Okay.

Mr. Glendining, 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. Murray Glendining: I do.

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

Ms. Jansen?

Ms. Sandy Jansen: Yes.

The Clerk of the Committee (Mr. William Short): Same thing?

Ms. Sandy Jansen: Yes, please.

The Clerk of the Committee (Mr. William Short): Ms. Jansen, 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. Sandy Jansen: I do.

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

And last, Mr. LaRocca?

Mr. Tony LaRocca: Affirm, please.

The Clerk of the Committee (Mr. William Short): Affirm? Raise your right hand, please. Thank you.

Mr. LaRocca, do you solemnly affirm 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?

Mr. Tony LaRocca: I do.

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

The Chair (Mr. Ernie Hardeman): Thank you all very much, and thank you very much for being here. With that, you will have 20 minutes to make a presentation, opening remarks, and you can make them in any order. Everyone or anyone can make that presentation. At the end of that, we'll have questions from the panel for 20 minutes from each caucus, and we will be starting with the official opposition. With that, the floor is yours.

Mr. Murray Glendining: Thank you. Good afternoon. My name is Murray Glendining. I'm the executive vice-president, corporate services and clinical support, and currently acting chief executive officer of the London Health Sciences Centre. I joined LHSC in June

of last year, and prior to that I was the executive vice-president of corporate affairs at Hamilton Health Sciences Centre.

Joining me today as requested by the committee are, to my immediate right: Neil Johnson, vice-president, cancer, renal and pharmacy services, at LHSC, and regional vice-president, Cancer Care Ontario. Neil is a pharmacist by training and has been with LHSC since 1988, progressing from staff pharmacist to director of pharmacy and through a range of executive responsibilities that included managing EDs, dialysis, medicine and neurosciences. Currently, Neil has a dual role with operational responsibility at LHSC for cancer, renal services and pharmacy services; and Cancer Care Ontario responsibilities that include implementing the Ontario cancer plan in the southwest region.

To my left is Sandy Jansen, director of pharmacy services at LHSC. Sandy is also a pharmacist and has been with LHSC since 2009, and became director of pharmacy in 2011. Prior to joining LHSC, Sandy held a variety of roles in pharmacy at St. Joseph's Health Care in London, progressing from a clinical pharmacist in clinical care to a variety of leadership roles in operations and medication safety.

On my extreme right is Toby O'Hara. Toby is the general manager, health care materials management services. Finally, on my extreme left is Tony LaRocca, our vice-president, community and stakeholder relations, responsible for communications at LHSC.

I would like to open with a few remarks for the committee, after which I will turn to Neil and Sandy to provide you with more information on our response to this issue from a clinical, pharmacy and patient perspective.

First, on behalf of this team and LHSC, let me extend our sincerest apologies to all of the patients and families who were affected by this unfortunate and unsettling issue. We know it has caused them a great deal of stress and anxiety, and, in many cases, has shaken their trust in our organization and in the health system. It is our goal, through close collaboration with all stakeholders and active support of the review process led by Dr. Thiessen, to help rebuild their trust by ensuring that all appropriate safeguards are in place for the patients we serve.

For context, LHSC is one of Canada's largest acute care academic health sciences centres. It provides the broadest range of services in Ontario. Our nearly 10,000 staff and physicians care for the most medically complex and critically ill patients across southwestern Ontario, with more than one million patient visits each year, including 150,000 emergency visits.

At LHSC, two key areas of focus are: improving the patient and family experience and excellence in patient care, service and safety. Underpinning these is our culture as a learning organization, which we hope is clearly reflected in our approach to the chemotherapy compounding issue. Through open and transparent communication, dialogue and collaboration with all system partners, and early and ongoing engagement of patients to help us shape our response, we are committed to being a meaningful partner in rebuilding systems safeguards and trust.

At each step of the process, our focus has been to do right by the patient and to let our action planning evolve from that. Our patient advisers have helped us tremendously throughout this issue and will continue to guide our interactions with impacted patients. The initiatives that we have implemented to connect impacted patients with the support and information they need has been quite successful in helping them to put the situation into context.

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Our focus now turns to process issues and working with the review currently under way to identify any opportunities to improve safeguards, both in-hospital and system-wide, to prevent recurrences.

I will now ask Neil Johnson to provide the committee with a brief chronology of some of the events that have transpired since this issue was discovered.

Mr. Neil Johnson: Thank you, Murray. Before I walk through the sequence of events, I think that a brief overview of our cancer program may be helpful for the committee.

The London Regional Cancer Program at LHSC is one of the largest cancer centres in Ontario. As a research and education-based centre, we have a long history of innovation and research. Today, our centre sees over 7,000 new cancer patients each year, with over 180,000 patient visits to our centre. To put that in perspective, each day that we're open, we see, on average, 28 new cancer patients, and 720 patients visit our centre. With these volumes, it becomes apparent why the chemotherapy dosage issue we are reviewing today impacted so many patients at our hospital.

We first learned of the possibility of this chemotherapy medication issue on Friday, March 22, at approximately 2:30 p.m., when the hospital was contacted by Lakeridge Health and advised of a potential issue. This information was relayed to our director of pharmacy, who immediately initiated steps to have the cyclophosphamide and gemcitabine compounded by Marchese pulled from use. Although the complete magnitude and the facts were not clear at that time, the pharmacy team acted to ensure that no products were available in our organization to use. This action was completed at approximately 3:45 p.m., thus immediately preventing any potential further risk to patients.

Our team also started to reach out to make contact with the medication supplier to obtain procedural information on product preparation. I became involved shortly afterwards as I was completing meetings out of town. Our director of pharmacy notified our group purchasing organization, Medbuy, and was able to speak to a staff member who indicated that she would review her records to see who was purchasing product from Marchese and to notify these organizations.

Over the next few days, our investigation deepened and included a review of LHSC's purchase history. It

was determined that Marchese was awarded the contract to provide compounded IV services to Medbuy hospitals in late fall 2011. Through the Medbuy contract with Marchese, the London Regional Cancer Program began purchasing cyclophosphamide and gemcitabine on March 1, 2012, and the LHSC in-patient pharmacy began purchasing these products on October 15, 2012. Using these purchase dates, an initial data extraction of computerized patient records was commenced to identify patients potentially impacted. LHSC then undertook a number of other steps to begin to better understand the nature and extent of the problem.

To determine that the problem did not predate the start of the Marchese contract, the previous external supplier of these medications, Baxter, was contacted to obtain procedural information on product preparation. It was determined that products had been appropriately compounded. In parallel, we also reviewed Marchese's request-for-proposal submission.

LHSC completed an internal assessment of the Marchese chemotherapy medications by withdrawing all of the fluid of some of the medication bags on hand and measuring that volume. Three bags of each medication were drained and the fluid was measured. They were found to contain an average overfill of 11%.

By March 26, the potential magnitude of this issue was becoming increasingly clear, leading to the initiation of a full incident management team, which convened the following day. At the initial meeting, it was decided to add the co-chairs of our LHSC cancer community advisory group—two patients—to the daily incident review calls to help inform our response and interaction with patients.

That day, calls were placed to leadership at Cancer Care Ontario to notify them of our findings and approach. As well, LHSC's pharmacy manager began to place calls to other regional hospitals, including Windsor, to advise them of the exact circumstances of the facts that we found.

Additional external notifications of the issue were provided to the Ontario College of Pharmacists, HealthPRO, and research colleagues, and a phone message was left with Health Canada, all in an effort to further escalate the matter and ensure that any additional partners in the system that could be impacted were made aware of the problem.

After the data pulled from our computer system was reconciled, the list of impacted patients was shared with respective clinical leaders, beginning in the evening of March 27 for our pediatric patients and the following day for all adult cancer patients and non-oncology patients. Clinical data was then pulled to enable detailed patient record reviews, a manual and very time-intensive process involving many hundreds of files.

In the afternoon of March 28, LHSC participated in a teleconference with Cancer Care Ontario and the Lakeridge and Windsor Regional hospitals to discuss the situation and consider an aligned communication plan that aimed to ensure that, to the extent possible, patients first heard about this issue from their own hospital.

LHSC developed such a plan to notify impacted patients and connect them to the supports and information that they would need, and then to communicate the issue more broadly to key constituents. Given that the greatest patient impact was at LHSC, it was clear that the best efforts to contact patients would take several days after the clinical patient record reviews were completed, and initial rollout plans centred around that timeline.

Also on March 28, LHSC sent a letter to Marchese, clearly articulating LHSC's concern and requesting a reply to questions posed. They acknowledged receipt of the email but provided no official response.

That evening, Marchese did send an email outlining their process for compounding to LHSC's director of pharmacy. A review of patient records ensued, the clinical staff working day and night over the next three days to retrieve all relevant clinical information required by our medical staff in the review of their patients.

On April 1, it was reported that Windsor Regional Hospital had begun to inform their patients. It was evident that this would accelerate broader public awareness before LHSC could effectively communicate with its larger volume of impacted patients. Work then began at LHSC to change our communications and response plans for patients.

While Windsor's position is understandable and puts their patients' interests in the forefront, it created a very unfortunate situation in London, where so many patients heard about the issue in the media first, causing major concern for a much larger group of cancer patients who had received chemotherapy treatment during the period in question, even though the vast majority of those patients were actually not affected.

On April 2, patient disclosure to active LHSC patients commenced. Supports such as toll-free phone lines for pediatric and adult patients and an external website were implemented. Throughout that day and the next, finalized letters were produced for known living patients. As well, attempts to reach all patients by phone were made to notify them of the supports available and the letters that they would receive in the coming days. We also responded to several media interviews that day.

As calls from patients were received, patients in emotional crisis were escalated to receive immediate attention from their clinical teams. Many medical oncologists contacted their patients directly. For deceased patients, best efforts were made to determine next-of-kin addresses, and specific letters were sent to them.

On April 8, 9 and 10, open forums were conducted in our organization, with over 300 patients and family members attending. The goal was to be open and transparent about everything that we knew and to answer any questions that they may have had, to the best of our ability. Each session included a detailed presentation to explain the specific preparation processes for chemotherapy and how we believed the overfill situation for the supplies received had impacted medication dosage.

As well, a review of the chronology of the issue was provided, and a presentation was made by our medical

oncology leaders to discuss clinical implications. Questions followed, and each of the sessions lasted several hours, until all patient questions were addressed to the best of our ability.

On April 9, as part of our due diligence practice, LHSC initiated a second review to ensure that all possible patient impacts were captured in the initial assessment. During this review, it was discovered that the chemotherapy medications may have been used in the in-patient setting earlier than initially believed. This resulted from an internal transfer of subject medications from the cancer program pharmacy to the in-patient pharmacy, which occurred before the in-patient area began purchasing these medications directly from the supplier.

An immediate review of records commenced, and a further 26 potentially impacted patients were identified. These patients were notified by our staff and physicians prior to the media announcement of this development on April 12. At this point, a final tally was completed. All told, 691 patients were affected by this issue, 40 of whom were pediatric patients.

On April 15, LHSC received a verbal report from the Quebec laboratory to which it had sent a sample of the affected Marchese cyclophosphamide product. The lab report confirmed LHSC's internal finding in relation to fluid overfill. The concentration of the medication was less than that of a properly reconstituted vial. Specifically, the concentration of cyclophosphamide was 17.5 milligrams per millilitre, versus the target—if prepared accurately—of 20 milligrams per millilitre.

Our focus is now working diligently with all stakeholders to review the situation and help safeguard the health care system to prevent any reoccurrence.

I'll now ask Sandy Jansen, our director of pharmacy services, to comment in more detail on our pharmacy processes.

Ms. Sandy Jansen: Thank you, Neil. Pharmacy services provided at LHSC are among the most comprehensive of any hospital in Canada. We employ nearly 250 people, and that includes 65 pharmacists and over 150 pharmacy technicians.

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Just to give you a sense of the types of volumes of medications that pass through our doors every year, annually our pharmacy department processes over two million medication orders and we dispense close to five million doses of medication every year. Within that five million doses, we dispense 18,000 bags of IV nutrition, 15,000 bags of chemotherapy to our in-patients, and over 600,000 doses of IV medications to our in-patients.

Chemotherapy doses are prepared in the pharmacy in two very distinct areas. For our outpatients or for our ambulatory patients, we have a specialized pharmacy located right within the London Regional Cancer Program. For our in-patients, we have a specialized pharmacy located on the adult oncology ward.

On any given day, our cancer program in the London Regional Cancer Program sees about 80 patients. They dispense upwards of 185 IV chemotherapy doses every day, and that equates to about 44,000 doses per year. On the in-patient side, we dispense about 20 doses to adults and 20 doses to children, and that's for the children and the adults who are admitted into the hospital.

All of our pharmacists and pharmacy technicians undergo specialized training and certification before they're allowed to participate in the preparation and dispensing of chemotherapy.

How did LHSC come to use Marchese products? LHSC has utilized the services of Medbuy, which is a group purchasing organization, for many years. In the fall of 2011, Medbuy tendered a request for proposal for many products, and included in that request for proposal was IV compounding services. There was a resultant competition between three vendors, and Marchese was the eventual winner, and in March 2012 we began purchasing products from Marchese.

Since receiving this news of concern about the concentration of the chemotherapy products on March 22, 2013, what has LHSC done to ensure the safety of the medications that we're providing to our patients? I can tell you, as Neil mentioned, that we immediately stopped purchasing any IV compounded products from Marchese Pharmacy, and we brought all of those products in-house. They are now all prepared by LHSC pharmacy staff. We have added additional staffing and shifts to accommodate that workload, and I can tell you that we have not delayed or cancelled any treatments as a result of that shift of workload in-house.

In addition, we have implemented reconstitution checks on any stock solution volumes that we make. We also keep a running tally of volumes of these stock solutions so that we can determine how much was used versus how much theoretically should be left in the vial, and that tells us that if we ever were to have an overfill issue again, we would pick it up very quickly. As an added precaution, we've implemented an internal review of all of our compoundings—not just IV and parenteral agents but everything. We're looking at every single process to ensure that we have validated all the controls, the checks and the balances, that they're all in place and all solid.

Lastly, as an academic health sciences centre, we want to use this extremely unfortunate experience as a shared learning opportunity. We're engaging with our peer hospitals to have a conversation about this and to share best practices when it comes to managing chemotherapy in our hospitals.

Mr. Murray Glendining: Thank you, Sandy. I hope we've provided the committee with a better understanding of the circumstances surrounding this entire matter. I would like to reinforce that LHSC is supportive of and actively collaborating with Dr. Thiessen's review and will continue to review all processes and procedures to ensure complete safety of operations based on our learnings and this review process.

Our team will be pleased to answer any questions you may have to the best of our ability.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we'll start with Ms. Elliott.

Mrs. Christine Elliott: Thank you very much for appearing today. You were talking about checking with the previous supplier, with Baxter. Can you tell me how long you had been using these compounded solutions through Baxter and then making the change?

Ms. Sandy Jansen: I can answer that. We've been using Baxter CIVA centre. In 2004, we began purchasing a product from them. Over the years, our use of Baxter has grown. We started purchasing chemotherapy agents, specifically cyclophosphamide, in the fall of 2011.

Mrs. Christine Elliott: I'm sorry. In 2004, you were using the liquid solutions?

Ms. Sandy Jansen: We were purchasing pamidronate, which is another drug that's used within the hospital. Each of these companies has a large selection of things we can purchase, so we select from that.

Mrs. Christine Elliott: And then the RFP was issued in 2011. Can you tell me on what basis the decision was made to switch to Marchese?

Ms. Sandy Jansen: The RFP process took into consideration a number of things. There's a scoring built into an RFP. Things that were considered were quality of their products, their infection safety practices, their labelling, and their ability to supply us drugs in a timely manner. Cost was factored in, but cost was actually very low as far as a weighting—everything is weighted. At the end of the day, when all of the scoring was done, Marchese scored the highest, and that's why they won.

Mrs. Christine Elliott: Was there an internal discussion about that at London Health Sciences Centre before the decision was made, or did Medbuy just come back and say, "This is the one that we recommend"? Did you just go with that recommendation or was there an internal discussion? Because you had been dealing with Baxter, I'm just wondering if there was some concern about switching from Baxter to Marchese.

Ms. Sandy Jansen: No, there was no concern at the time of switching from Baxter to Marchese. All of the due diligence had taken place in the RFP process, and we felt that it was appropriate at that point to switch to the winner of the contract.

Mrs. Christine Elliott: You mentioned that the compounding process was sent by Marchese once it was determined that there was a concern about it. First of all, what did you think of the compounding process as it was explained to you, and secondly, had you ever seen it before?

Ms. Sandy Jansen: Overfill in mini-bags is something that we're very aware of in health care. So when we learned about the oversight of not withdrawing the additional overfill from the bag, it explained everything to us, essentially. We understood that they didn't take out that overfill, and I was alarmed by that.

Mrs. Christine Elliott: They didn't take out the overfill—that would have been Marchese?

Ms. Sandy Jansen: That's right.

Mrs. Christine Elliott: Okay. And they had not explained to you that they had overfilled or explained their process before that?

Ms. Sandy Jansen: No; not before that.

Mrs. Christine Elliott: So you were really just relying on the fact that you were getting a bag of product that was ready to use that didn't have to be changed in any way once it came into your hands.

Ms. Sandy Jansen: The bag was labelled with the exact concentration—4 grams in 200 millilitres—so that is the concentration that we used to base our dosing on.

Mrs. Christine Elliott: Okay. You also mentioned that you've changed your process now for quality assurance and you said that you would now be able to determine if there was any problem with the process. Could you just explain a little bit more about how that would work?

Ms. Sandy Jansen: The two drugs that are in question are actually the only two drugs that are available now as powder; everything else comes to us as liquid. It's very important that when we add liquid to that powder to mix it up and make it into a liquid, that concentration is perfect—exactly what we think it's going to be. As we then withdraw from that vial, we can see that we've drawn out 20 ml, 30 ml, 40 ml, and we can account for how much volume is left in that vial.

Mrs. Christine Elliott: When you first found out about the problem, you indicated that you stopped using the Marchese products. Were you dealing with any other company that was providing prefilled solutions, or did you just switch immediately at that point to compounding in-house?

Ms. Sandy Jansen: That's right. We were only dealing with Marchese for IV compounded products, and we just moved everything in-house at that point.

Mrs. Christine Elliott: Could you tell us a little bit about any interactions you've had with Dr. Thiessen or his group so far, please?

Mr. Neil Johnson: I can start. We had Dr. Thiessen on site for an entire day a week or so ago. He reviewed all of our processes and the chronology. We provided him with detailed information. He has toured each one of our pharmacy areas and met our staff and met our physicians that were involved in the response to this. I think the review process that he engaged—very thoughtful questions, very insightful questions and very appropriate. I think our team is very impressed with his oversight so far.

Mrs. Christine Elliott: It's pretty clear that your view is that it was Marchese that was the problem, not London Health Sciences Centre. Have you had any conversations with anyone there about this whole incident or problem once you reviewed their compounding process and discovered that it wasn't what you thought it was? Can you tell me about any interactions you've had with Marchese?

Mr. Neil Johnson: Maybe I can start. It's important to understand that when March 22 hit for us, unlike some of the other hospitals, we really didn't know exactly what was going on. We heard that there was an individual potential concern, and we spent those next number of days trying to discern what that actual concern was.

There was some initial conversation, as I understand, between our staff and their staff.

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We wanted to verbally understand what their processes were, because we really had no idea what the issue was. Then we tried to dissect: Is this something that's changed, is this a process they have had going on for a number of months, is this one individual? It wasn't until later on, as I've mentioned in my notes, that we actually received their full process for how they make them.

I think we did send a letter to them on the date I indicated in my opening statement, and we haven't received anything back from them—I don't know, Sandy, if you have received any other communication from them. They were, I think, free in giving their information. I don't think our team detected any hesitancy in providing factual information. Sandy, you may be able to clarify.

Ms. Sandy Jansen: No, I can say that when we spoke to Marchese to try to validate how they were making this product, they were very open and transparent with the information they were providing to us, and it was just through our interpretation that we understood the issue.

Mrs. Christine Elliott: Did they say anything to you about feeling that it was your responsibility to have done something other than to have anticipated that the product was exactly as it was stated to be?

Ms. Sandy Jansen: No. They didn't say anything like that to me personally.

Mrs. Christine Elliott: So you haven't really had any pushback from them, I guess, with respect to this whole issue.

Ms. Sandy Jansen: No.

The Chair (Mr. Ernie Hardeman): Ms. Gélinas?

M^me^ France Gélinas: Thank you for coming. I would like to start my remarks by congratulating you on handling a difficult incident and handling it in a way that is as respectful to the people impacted as could have been, under the circumstances. I can see by your opening remarks and by what we've known so far that you really tried to reach out and be as reassuring and open with the people in London and the people affected, and I thank you for that.

My first series of questions will have to be kind of following what—the line of questioning she was following. So the timeline is, you were with Baxter, then the request for proposal went out and then a new provider, Marchese, came in. But then there is a delay between the time that Marchese got the contract and the time you started purchasing from them. What's with the gap in between?

Ms. Sandy Jansen: It just so happens that about the same time as the contract switchover, the drug shortage hit. When the Sandoz drug shortage hit, a lot of things were sidetracked, and the switching over to Marchese was one of the things that got sidetracked.

M^me^ France Gélinas: Okay, so because the pharmacy was busy attending someplace else, you continued with Baxter for that period of time?

Ms. Sandy Jansen: Yes, and some of the drugs needed to be shipped to Marchese. And with the shortage, we didn't know if we even had those drugs. So there was a lot of balancing to figure out what was our supply and what could we get to Marchese.

M^me^ France Gélinas: Okay. So you continued using the chemo drugs that were coming from Baxter until things settled, and then you started the relationship with the new provider.

Bringing you back, when was the last time, except for now, that you did them in-house?

Ms. Sandy Jansen: That we did them in-house? For the chemotherapy agents, we did them in-house prior to October 2011, when we started using Baxter.

M^me^ France Gélinas: Okay. You were there in October 2011 and, I'm guessing, the request-for-proposal process that brought Baxter into the picture. What were the motivations for looking at Baxter coming in as a supplier, rather than—you have quite an elaborate pharmacy structure. Why?

Ms. Sandy Jansen: I can describe it to you: The process for reconstituting both cyclophosphamide and gemcitabine is quite complex. They're currently the only two molecules we purchase that are still in powder form. Everything else is now provided from the manufacturer in liquid form. Each of those vials takes four hours to dissolve. When we add liquid to a vial, it takes four hours to dissolve, and it requires that the pharmacy technician shakes it every 20 minutes.

In the London Regional Cancer Program, we could be using between 20 and 40 cyclophosphamide vials alone every single day, and that takes up an entire hood where we prepare the drugs. With the volume of patients we have coming through, we needed to be able to free up that space and capacity—both space and capacity of our staff—to focus on those other agents and allow Baxter and then Marchese to do that reconstitution for us.

M^me^ France Gélinas: So what has changed now in space and capacity, now that it is back in?

Ms. Sandy Jansen: What we've done is, we still have the same amount of space. We've added staff and we've added shifts, so we can now prepare drugs sort of longer throughout the day so that those vials are reconstituted and ready for use each day.

M^me^ France Gélinas: Why not have done that in 2011?

Ms. Sandy Jansen: Because we had Baxter, which is a reputable provider, and we felt very confident in the services that they were providing. We felt it was an effective and efficient way to do our business, to allow Baxter to reconstitute the vials for us and bring them in-house.

M^me^ France Gélinas: Did you have the same feeling when you went with Marchese, that they were a reputable and good company to work with?

Ms. Sandy Jansen: Yes, we did. We felt that Marchese was a reputable company to work with.

M^me^ France Gélinas: Did you know anything about a grey area of oversight?

Ms. Sandy Jansen: No. At that time, we did not know that.

M^me^ France Gélinas: When did you become aware of this?

Ms. Sandy Jansen: Of the grey area? After all of the events that have transpired, and the information that we've since received that Marchese Hospital Solutions is not accredited.

M^me^ France Gélinas: When you became aware that there was this grey area of oversight, and the people—the specific division fell into that grey area of oversight—did it give you cause for concern?

Ms. Sandy Jansen: Yes, it did.

M^me^ France Gélinas: How come?

Ms. Sandy Jansen: Well, I think LHSC prides itself on the quality of care that we provide to our patients, so we would never knowingly use a provider that is not licensed and isn't providing the same quality of care that we ourselves provide.

M^me^ France Gélinas: Is there a way that you could have known that you were dealing with a branch of Marchese that was unregulated?

Ms. Sandy Jansen: I think hindsight is 20/20. Yes, we could have gone on a website and looked. There would have to have been something to inspire us to be questioning it. We understood we had documentation from them that said they were accredited.

M^me^ France Gélinas: Basically, you had no reason to believe—is it in the practice of a hospital to go and check if the labs you're dealing with—you have so many providers—and not only you, but maybe somebody else—whether it be an X-ray clinic or a lab or pharmacy. Are you in the business of checking who is regulated and who is not?

Ms. Sandy Jansen: I'm going to defer that to Neil and Toby.

Mr. Toby O'Hara: Sure, I can take that. HMMS—that's where I'm general manager—oversees the procurement and sourcing on behalf of LHSC. What I can share is that we do the competitive bidding when we haven't outsourced that to a GPO. In cases where we've introduced a new vendor to the contract team or to the vendor file, and they're unfamiliar to us, it is in all cases a contractual requirement that they meet all legislation. If they're unfamiliar to us, then we typically would check to make sure there's a medical device licence in play or they're registered with Health Canada.

Just to clarify where we're coming from, it's HMMS that would oversee primarily the medical-surgical non-drug sourcing of LHSC.

M^me^ France Gélinas: Do you have the equivalent to you that oversees the drug sourcing?

Mr. Toby O'Hara: The decision for drug sourcing has been essentially outsourced to Medbuy, so Medbuy oversees all the drug sourcing for LHSC.

M^me^ France Gélinas: Okay. Was there a process to make sure that the oversight that you had put in place was carried on? Because you're a member of Medbuy, are you not?

Mr. Toby O'Hara: Correct. All of the terms and conditions, or the scope of services Medbuy provides on LHSC's behalf is defined in that participation agreement between LHSC and Medbuy.

M^me^ France Gélinas: You also shared with us that you went back and reviewed the request for proposal that Marchese had put forward. I think it was you, Mr. Johnson, who told us that.

Mr. Neil Johnson: Yes.

M^me^ France Gélinas: When you did your review, was there anything there that could have led you to believe that they were operating in a grey area of oversight?

Mr. Neil Johnson: I'm just recalling—I don't believe so. It only became clear when we understood, through media reports, that the contract was with Marchese Hospital Solutions. If I'm recalling—and I'll ask Sandy to verify and make sure I have the correct facts here—it was Marchese Pharmacy that did the RFP, responded to the request for proposal. I understood afterwards, after the media announcements came out, that it was another corporate entity that was named. In the request for proposal, I don't believe—and I'll clarify it with Sandy—that there would be anything that would alert us to that fact.

Sandy, you may want to verify that.

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Ms. Sandy Jansen: That's correct. The RFP was answered. The company was described as Mazentco operating as Marchese Pharmacy, and the documentation around accreditation was all under Marchese Pharmacy.

M^me^ France Gélinas: The oversight that you talked about, that you make sure that you deal with a licence, due diligence has been done—you were dealing with a pharmacy, and pharmacies have oversight?

Mr. Neil Johnson: As per Medbuy policies. Medbuy—and this will be a question for them later on, obviously—has a set of policies and practices that would be similar to what Toby's group would have at HMMS. We would understand that that due diligence would have been checked and appropriately dealt with.

Ms. Cindy Forster: Were you aware or did Medbuy make you aware that Marchese Pharmacy—that the business of compounding was new to their operations?

Ms. Sandy Jansen: No, I was not aware.

Ms. Cindy Forster: You weren't aware of that, and Medbuy didn't make you aware, or it wasn't part of their due diligence in the process when they're going out around new RFPs?

Ms. Sandy Jansen: I would defer to Medbuy to speak to their due diligence process. Our understanding was that Marchese had been in the business of compounding prior to Medbuy contracting with them, but I'll probably defer to Medbuy for that.

Mr. Murray Glendining: I think within any group purchasing organization, they confirm to us each year that they do comply with procurement guidelines, and so they attest back to us—whether it's Plexxus, whether it's Medbuy, they all confirm to us each year that they have followed standard business practices and procurement protocols, and we do rely on that.

Ms. Cindy Forster: You said that part of your reason for outsourcing these two particular drugs was efficiency and effectiveness. You didn't say anything about actual financial efficiencies, so did you actually save any money in the process of outsourcing this work?

Ms. Sandy Jansen: No. Outsourcing these two agents was not in any way an effort to save money. It was absolutely around efficiency and around safety and volumes.

Ms. Cindy Forster: How many staff FTEs did you have to actually hire to bring this back in-house?

Ms. Sandy Jansen: Right now, we're still in the hiring process, and we have people working overtime right now to do this. We're probably going to be looking at between seven to 10 additional pharmacy technicians at the end of the day.

Ms. Cindy Forster: Thank you. That's all I've got.

M^me^ France Gélinas: Coming back to the purchasing, had it been identified at the time that the corporate structure of Marchese included an unregulated arm, would you still have gone ahead, or would the procurement process in place—would that be a showstopper?

Mr. Neil Johnson: I would believe it would be a showstopper for me.

M^me^ France Gélinas: Same with you? It wouldn't have gone. A hospital deals with hundreds of outside suppliers of all kinds. There's a role to play for the provincial government, there's a role to play for Health Canada and there's a role to play for the hospital. There's a role to play for all of those players, if you want, in the health care system.

I tend to believe that the role of the government is oversight. We've put in place the college system, the College of Pharmacy, and the College of Pharmacy is the one that makes sure that pharmacies in Ontario are regulated, and pharmacists, as well as pharmacy technicians. Do you figure this is a good role for the Ministry of Health, to be the overseer?

Mr. Neil Johnson: Overseer of compounding pharmacies specifically or—

M^me^ France Gélinas: No. Overseer of the different agencies in the health care system.

Mr. Neil Johnson: I'm sorry. I'm not quite—maybe you could restate your question.

M^me^ France Gélinas: Okay. Within the health care system, there are hospitals, there are pharmacies, there are labs—there are a number of what we will call players in the health care system. A hospital interacts with most of them just because of the type of work that you do. The government oversees hospitals. They oversee labs. They oversee pharmacies. They oversee 27 different health care professionals. Is this a good role?

Mr. Neil Johnson: I can speak generally that I think oversight—and assuredness of products and competencies of various professional groups—is absolutely needed. Jurisdictionally, that might be the issue between Health Canada and the federal government and the provincial government in this particular grey area. I think there is a role for government and oversight of those in broad brush strokes. Specifically down to individual areas, that would probably be beyond my knowledge to comment on that. But we need, as a hospital, as an organization, assuredness that we have high-quality products and services coming into our organization. There's an existing framework and network to assure that in a variety of fashions, including procurement. Any place where there may be an issue of where there's a gap that, for our purposes, needs to be closed, because we need to be assured that products and services that are on our door and go out to our patients meet the test of quality.

M^me^ France Gélinas: Do you ever see yourself, as a hospital, being responsible to oversee pharmacies or labs?

Mr. Neil Johnson: In terms of a regulatory framework?

M^me^ France Gélinas: Correct.

Mr. Neil Johnson: Again, probably out of my political background, but I don't see that. We are in the business of delivering services to our patients. Hospitals are not regulators, and you're talking right now about a large organization with a billion-dollar budget and 10,000 staff and thousands of physicians. You're also talking about hospitals that have 25 or 30 beds and far fewer staff, and so hospitals are very varied in practice and scope. Even the extent that we have taken, as an example, to do some investigation that we have, would be beyond the scope of many hospitals. Our role—and Murray, I invite your comment, or others on this—is to provide service.

M^me^ France Gélinas: I tend to agree with you, and that speaks to some of the concerns that the new draft regulations that the Ministry of Health is bringing forward are sort of a precedent where they're making hospitals responsible for oversight of community partners. I agree with what you just said. You're there to provide a service. Oversight needs to happen. You need to have confidence that the partners you're dealing with are—but I don't think it is your role, either.

We'll let it go around.

The Chair (Mr. Ernie Hardeman): That's all the time you have to answer to that question. Thank you.

Yes, Mr. Berardinetti.

Mr. Lorenzo Berardinetti: I wanted to welcome members from the London Health Sciences Centre for being here today. A lot of questions have been answered already, but just a very direct question, I guess: Has there been any increase in the rate of recurrence or death since these drugs were first administered? In other words, maybe it would be premature to ask this question, we're only going back several months—

Mr. Neil Johnson: I think to answer that question you'd need a full epidemiological study of that, much like actually our clinician scientists did in the post-Walkerton issue, as an example. There are no signals that would say one way or the other on that currently, at present. Our clinicians, who are also researchers, though, are interested in looking at that and following that cohort of patients. We've now got a set of patients and data in three or four centres that could be followed, but we can't

answer that question in the current construct. It would just be impossible to answer.

Mr. Lorenzo Berardinetti: Okay. Just to understand the process that you discussed earlier this afternoon: overfill, which is basically another word for dilution, means you take—you do this in-house now, so you basically take a pouch and mix it with a saline to create the drug that's then administered?

Ms. Sandy Jansen: I'm sorry. Can you repeat that?

Mr. Lorenzo Berardinetti: How does the process work? You're doing this in-house now, but again, and this is maybe just a hypothetical question, how do you think the underdosing occurred when you were administering this drug?

1500

Ms. Sandy Jansen: How did the underdosing occur when we were purchasing Marchese product? Is that your question?

Mr. Lorenzo Berardinetti: Yes.

Ms. Sandy Jansen: Okay. The process that Marchese used when they made these bags—I'll just walk you through it quickly. They took a 250 ml minibag. That bag, we know, contains between 3% and 20% overfill. So let's say that on average it would have 30 ml of extra saline in it. What Marchese did was they withdrew 50 ml to bring the total volume to what they read as 200 ml. In fact, that bag now had 230 ml, give or take, because it had overfill.

Then what they did is they withdrew essentially all of the bag, so they had to withdraw a further 200 ml from that bag to reconstitute two vials of drug. They reconstituted the two vials of drug—that means shake it up until it's in liquid. That 250 ml bag we started with would actually have had about 30 ml or two tablespoons full of saline left in it, so just a little bit of liquid, but it's there.

Then what they did was they took the two vials, withdrew the drug into syringes and put it back in that bag. So that bag—remember I said it had the extra 30 ml?

Mr. Lorenzo Berardinetti: Yes.

Ms. Sandy Jansen: It still has the extra 30 ml. Had they withdrawn the 30 ml and discarded that, like they did with the 50 ml at the beginning, everything would have been fine, because those two vials were exactly the right concentration. Because they didn't account for that extra volume, that diluted the drug.

When that comes in to LHSC, it's called a stock solution. That's a concentrated bag of drug. We don't administer that to a patient; we withdraw aliquots from that. So we might take out a gram or 20 ml of that bag. We withdraw that. That should have the exact amount of milligrams for the patient, but because it was diluted, it wouldn't have had exactly what we needed. But we wouldn't have known that.

Then we take that and put it into a smaller bag, and that's when we dilute it, ready to be administered to the patient. Does that make sense?

Mr. Lorenzo Berardinetti: Yes, that answers my question.

You also mentioned earlier that 691 patients were affected. So this diluted drug was administered to 691 patients.

Ms. Sandy Jansen: That's right.

Mr. Lorenzo Berardinetti: Since they have been affected, you've been keeping an eye on them to see if there's not going to be a long-term effect or health issue with them. And up to this point, to the best of your knowledge, there hasn't been any negative effect in those people we were talking about a few months ago.

Mr. Neil Johnson: That's correct. I was just talking with our head of medical oncology, and they reviewed their case files and haven't made any therapeutic changes to those patients' course of therapy.

I think it's also important to understand that the drugs that are used are part of a larger regimen. For chemotherapy, you'd typically have anywhere between two to five other drugs being administered as well. It's the aggregate synergistic effect of those medications that is treatment for patients.

Each one of those patients' individual case has been reviewed. They've met with all those individuals on an individual basis to review that with them. I think the largest piece clinically has been, actually, the emotional stress and strain and anxiety that this produces in patients who are affected. Also, every patient coming through our centre now has that potential to be thinking about this and not trust that system. So, outside of the clinical issue of their cancer, the emotional impact has probably been the largest thing we've been dealing with, quite frankly.

Mr. Lorenzo Berardinetti: Yes, and to reassure the patients who are coming to get treatment, you've been able not just to emotionally tell them, "Everything's fine," but you've been able to scientifically correct the product so that you're now administering the proper dose. Is that correct?

Mr. Neil Johnson: Yes, and we're going to be taking some other steps over the next months, in consultation with our patient advisers, to really be out front with our patients in trying to rebuild that trust in the overall system, certainly in our organization, but in the broader system as well, so that when somebody comes into our centre through the London Regional Cancer Program or our in-patient area, they can feel confident that we've taken the steps we need to, to make sure they're safe.

Mr. Lorenzo Berardinetti: Thank you. Those are our questions for now.

The Chair (Mr. Ernie Hardeman): Ms. McKenna?

Mrs. Jane McKenna: Thank you so much for being here today.

My first question is, is the London Health Sciences Centre's contract with Marchese? The contract that you have.

Mr. Neil Johnson: The contract is with Medbuy and Marchese, a member organization of Medbuy.

Mrs. Jane McKenna: So who wrote the contract? Medbuy?

Mr. Neil Johnson: Medbuy.

Mrs. Jane McKenna: So you didn't oversee any of that at all? It didn't go through you at all?

Mr. Neil Johnson: As I understand it—and Sandy can correct me if I'm wrong—there is a committee of pharmacy members from all of our member organizations that adjudicates these RFPs and provides input to that. The actual contractual process that's set out in the contract is Medbuy's purview.

Mrs. Jane McKenna: So then Medbuy's solely responsible for that contract that they have with Marchese?

Mr. Neil Johnson: For the contract. Once the pharmacy committee makes a recommendation on a vendor, I believe they do the contract. Am I correct?

Ms. Sandy Jansen: That's right.

Mrs. Jane McKenna: My next question is, do you find it odd that it took so long for anybody to notice this?

Mr. Neil Johnson: That's a question that we wrestle with daily. I know it's affected our pharmacy staff quite significantly. As a pharmacist, it's one of those things that you ask yourself: What could have been prevented? When you actually look at two bags side by side, visually you would never tell the difference between them. As you said, on a 100 ml bag you're talking about a teaspoon or two teaspoons of fluid. It's hard to determine that.

There are some process issues in our setting that are different. The large volume that we have means that we have multiple people working, and so seeing the various products side by side is something that they would never see. Also, if we finish use of one manufacturer's product and bring in another manufacturer, we don't actually have them in the same workplace at the same time, so they're not mixing individual product lines. Unlike, as I understand, the folks who found it, there was never that opportunity for us, that once-in-a-lifetime opportunity, to compare product because it would never be in the same spot at the same time.

Sandy, I don't know if there are other factors that you've come across, but it's one of the ones that we've all wrestled with over the last month.

Mrs. Jane McKenna: Thank God for the person who did have the opportunity to realize that there was a problem for all of the patients who have been impacted.

I just have one other question: Has this shaken your confidence now for outsourcing?

Mr. Neil Johnson: No, not for outsourcing. I think, having sat in front of 300 patients and explained to them the issues that were at hand, the thing that it shakes for me is trying to rebuild their trust in the overall system.

As we said, the products that we were getting from Baxter were of top quality before. We had confidence in them. We have other services that are provided, everything from lawn maintenance to other things that are very high quality. We need to focus in on what we're good at clinically, which is doing cancer surgery, cancer chemotherapy, cancer radiation therapy. But no, not in outsourcing as per se, if the right checks and balances and quality control are there.

Mrs. Jane McKenna: Thank you.

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

Mr. Jeff Yurek: Thank you for coming down. You do a wonderful job in our area of London and southwest Ontario.

A question going to the RFP: You said you had reviewed the RFP and one of the reasons Marchese was chosen was because of quality. What proof did they offer that they provided quality product?

Ms. Sandy Jansen: In the RFP response that Marchese provided to us, they did provide to us detailed descriptions of their sterility checking process. That was very well detailed in the RFP response. In addition, the committee compared their labels to the other proponents' labels and they felt that Marchese labels were more clear than the other proponents'. So those were the two factors that really caused Marchese to win, we understand.

Mr. Jeff Yurek: Was there any proof given of end-product testing at any time, batch testing to confirm concentration?

Ms. Sandy Jansen: No, they did sterility testing; they did not do concentration testing.

Mr. Jeff Yurek: You mentioned that the labelling was clear. The last hospital we had here last week stated that they didn't like the labelling; they preferred the Baxter labelling. What's the difference?

Ms. Sandy Jansen: The labelling that Marchese had in the RFP application was slightly different than what we actually saw when it came into the hospital.

Mr. Jeff Yurek: Did anyone hold them to task over the fact that—

Ms. Sandy Jansen: There was conversation that went back and forth, I understand, between Medbuy and Marchese. I think that Medbuy will be able to speak to that, and they were just getting that clarified with the labels. But in the original proposal, there was good clarification of the concentration—not just the concentration in total milligrams and total volume, but also concentration in milligrams per millilitre.

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Mr. Jeff Yurek: Back to the RFP question: You said that if you were inspired to question their accreditation, you would. Can you just elaborate more? In my world I live in, I think accreditation would have been front and foremost when I'm asking someone to give me a product to use in a hospital. Was that missed in the RFP? Just elaborate.

Ms. Sandy Jansen: No, I didn't mean to imply that we didn't ask about accreditation. Accreditation was a question in the RFP, and Marchese did state that they were accredited with the Ontario College of Pharmacists. So there was nothing to cause us to go back and say, "Are you sure you're accredited?" because we understood them to be accredited, and they provided us documentation of that.

Mr. Jeff Yurek: You said you have a participation agreement with LHSC and Medbuy. I can't officially ask for a copy of it—one of my colleagues can—but can we get a copy of that participation agreement for committee?

Mr. Murray Glendining: Yes, we can. We'll get you that.

Mr. Jeff Yurek: Okay. With that participation agreement, does the Ministry of Health give you any guidelines or standards that you must have when dealing with a third party outsourcer?

Mr. Toby O'Hara: I can speak to—there's legislation overseeing the procurement process.

Mr. Jeff Yurek: But that's the general broader public sector—

Mr. Toby O'Hara: Those are the general broader public sector guidelines; correct.

Mr. Jeff Yurek: Nothing directly with—

Mr. Toby O'Hara: Specific to drug sourcing—

Mr. Jeff Yurek: —drug sourcing—

Mr. Toby O'Hara: —I'm not aware of that, no.

Mr. Jeff Yurek: I found it interesting that HMMS seems to have quite a bit of guidelines in place for purchasing other product but when it comes to purchasing medication, especially—I'm going to say chemo medication right now because that's what we're dealing with. But I'm sure down the line there are going to be other medications out there that the Ministry of Health didn't really seem to have a role to ensure that those standards or guidelines are in place.

Mr. Neil Johnson: I think this one's a little bit different, if I may add, in the sense that drugs that we normally purchase are from Health Canada-approved organizations. They have a drug identification number and so forth, so the regulatory framework is there.

This RFP was actually a services contract, so to take X bag and X drug and compound them in a product that we could either use inside the pharmacy or inside the hospital. It's a services piece. That's maybe splitting hairs, but I think there are probably some learnings there in terms of how to adjudicate those types of RFPs.

Mr. Jeff Yurek: Is using blood products from the blood bank a service or a product? It's the same idea. You're taking a bag from point A and—

Mr. Neil Johnson: That one's a little bit different.

Mr. Jeff Yurek: —point B. You can answer me that later, get it to me.

Mr. Neil Johnson: Yes.

Mr. Jeff Yurek: That's my question. You get drugs from Health Canada oversight; you get blood products from oversight because of the blood scandal that we had years ago. The hips you buy are, I'm sure, coming from a certified, accredited oversight. But what got missed in the whole process was some sort of ensuring oversight over compounded medications. My concern is the Minister of Health missed the boat on that. Would you think it would be fair enough that it's an expectation that the hospitals themselves have to come up with the oversight? There are well over 150 hospitals—I don't know the true number—in this province, so we've got about 150 different standards and qualifications when we want a unified health care system. Do you not think that when we're going to outsource compounded medication, there should be some sort of standard coming down from the Ministry of Health to ensure that it's done properly?

Mr. Murray Glendining: I think the attestation is a good first step, but we are looking for this whole review process to come up with regulations that are far broader and cover the situation far better than they have in the past.

Mr. Jeff Yurek: So there's a big lack in that area.

Do you know anything about the pre-qualification that went out with the vendors for the RFP to ensure that they could actually bid on the product?

Ms. Sandy Jansen: I have seen the questions that went out.

Mr. Jeff Yurek: Could we get a copy of that?

Ms. Sandy Jansen: I think Medbuy can provide that—

Mr. Jeff Yurek: Medbuy has them?

Ms. Sandy Jansen: Yes.

Mr. Jeff Yurek: Okay. Three vendors bid: Baxter, Marchese—who was the third?

Ms. Sandy Jansen: Gentès and Bolduc in Quebec.

Mr. Jeff Yurek: Just a question: Do you know much about them?

Ms. Sandy Jansen: I know a little bit about them.

Mr. Jeff Yurek: Are they a compounding pharmacy or they a manufacturer?

Ms. Sandy Jansen: They're, in my mind, similar to Baxter CIVA in that they're part of Galenova, which is a pharmaceutical manufacturer. They are licensed with the Quebec college of pharmacists, so there's some oversight there.

Mr. Jeff Yurek: How did you know they were licensed?

Ms. Sandy Jansen: Because I called them and asked them, and I got proof.

Mr. Jeff Yurek: Did you not get through to the OCP?

Ms. Sandy Jansen: Pardon me?

Mr. Jeff Yurek: Could you not get a hold of the Ontario College of Pharmacists, or have you tried?

Ms. Sandy Jansen: About Gentès and Bolduc? Well, I would need to go through their college.

Mr. Jeff Yurek: No, I mean if you had to call—the way you said it, it sounded like you had trouble getting through to the Ontario College of Pharmacists.

Ms. Sandy Jansen: No, no. At the OCP everything is online, so I can confirm accreditation there.

Mr. Jeff Yurek: A lot of my questions are for Medbuy. Do you guys have any more? We'll go around.

The Chair (Mr. Ernie Hardeman): Okay, we've just got a minute left. With that, I think we had another question from the government side. Ms. Mangat?

Mrs. Amrit Mangat: Thank you for being here today. My understanding is that the ministry recently introduced regulations with regards to off-site drug compounding. How will it impact your hospital practices?

Mr. Neil Johnson: The regulations?

Mrs. Amrit Mangat: Yes.

Mr. Neil Johnson: I think it would be too early to say. We have not reviewed them in detail. We've been

busy with this issue of dealing with the patients that we're serving right now. To be candid, I have not really looked at that in tremendous detail. That's my task this week, because I know they're coming up. I think in general, though, we would look for things that are comprehensive, but not onerous, in terms of the hospital sector.

Mrs. Amrit Mangat: And how about Health Canada's regulations? They have also recently introduced some regulations.

Mr. Neil Johnson: Again, Health Canada, the Ontario College of Pharmacists and the Ministry of Health—we have not looked at those in detail. The Ontario College of Pharmacists' one just hit my email as a practising or registered pharmacist on Friday, so I have not had the chance to go through them myself. I don't know, Sandy, if you've had a chance either.

Ms. Sandy Jansen: I have looked at each of the regulations, and again, as Murray said, I think they're an excellent first step. I think that we need to get a lot more clarity on them, though, to ensure that any grey areas are eliminated.

Mrs. Amrit Mangat: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. You have one minute left. Mr. Yurek?

Mr. Jeff Yurek: I'd love to use it. You've made mention of what you know about Marchese; you said they're reputable and Baxter is reputable. What made you think Marchese was reputable? What was out there that you didn't even worry about them being a—

Ms. Sandy Jansen: Marchese has been around for quite a while. Certainly, we've known of them in the pharmacy world and some of the work that they've done professionally to promote pharmacy and patient care. From that perspective, I thought them to be a very professional pharmacy and that dealing with them would be fine.

Mr. Jeff Yurek: That's it. Thanks, Chair.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Gélinas, you have a comment?

M^me^ France Gélinas: I just want to make sure it's on the record that we ask that you please table with the Clerk the RFP that was used. You mentioned that the RFP or the process included criteria used for the assessment of the three bidders, as well as weighting for the different criteria. If you could share the system of criteria, the assessment you used, the RFP itself, as well as the weighting and the participation agreement that you signed with Medbuy. If you could table that with the Clerk, that would be very useful.

The Chair (Mr. Ernie Hardeman): Thank you very much for that. With that, that concludes the inquisition. Thank you very much for being here. We look forward to the rest of our deliberations and coming up with a solution to the challenges.

Mrs. Christine Elliott: Mr. Chair, if I could, I would reiterate my colleague's request for a copy of the participation agreement between the hospital and Medbuy.

The Chair (Mr. Ernie Hardeman): Okay. Has everybody heard it?

M^me^ France Gélinas: Yes.

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

CANCER CARE ONTARIO

The Chair (Mr. Ernie Hardeman): Our next deputation is from Cancer Care Ontario. As you're getting settled at the table there, we welcome you and thank you very much for coming in. The Clerk will be swearing you in or affirming you in, whichever is your preference. We'll do that first, before we start the process. Thank you very much.

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The Clerk of the Committee (Mr. William Short): Hi, Dr. Sawka. You can have a seat. That's fine.

If you could just raise your right hand, please. Dr. Sawka, do you solemnly affirm that the evidence you shall give to the committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Dr. Carol Sawka: I do.

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

The Chair (Mr. Ernie Hardeman): Thank you very much, and with that, as we do with the other deputations, you will have 20 minutes to make your opening remarks and your presentation. At the end of the 20 minutes, we will then have 20 minutes' opportunity for each of the caucuses to ask any questions they may have about the presentation. The questioning this time will start with the third party when we get to the delegation.

With that, thank you very much for coming in, and the floor is yours.

Dr. Carol Sawka: Good afternoon, and thank you for having me here today.

This issue is of deep concern to all of us. As a medical oncologist with over 25 years of experience in looking after patients with cancer, I know just how difficult it is to face a diagnosis of cancer, let alone hear that the treatment may have been compromised, so my thoughts and concerns are really with the patients and their families. It's clearly a responsibility for all of us to find out exactly what happened and to put into place everything necessary to ensure that it doesn't affect future patients and their families.

I wanted to begin by telling you, very briefly, a bit about me. As I mentioned, by training I am a medical oncologist. Beginning in 1985, I started my career at St Michael's Hospital. I moved to Sunnybrook's Odette Cancer Centre in 1988, where over the years I managed a variety of cancer types but in later years specialized in breast cancer.

After heading the division of medical oncology and hematology and the systemic treatment program at Sunnybrook and the cancer centre, in 1999 I was appointed vice-president of regional cancer services for Sunnybrook and the cancer centre. In that capacity, I oversaw the comprehensive cancer centre at Sunnybrook, and I

also was responsible for building a network of cancer care.

I continued in that role until February 2005, when I was appointed to my current role as vice-president of clinical programs and quality initiatives at Cancer Care Ontario.

In addition, I am a professor in the faculty of medicine in the departments of medicine of the Dalla Lana School of Public Health and the Institute of Health, Policy Management and Evaluation at the University of Toronto. I was also a member of the Ontario Wait Time Advisory Committee, and I sit on the board of directors of the Canadian Association of Provincial Cancer Agencies and the Canadian Partnership Against Cancer.

Some words about Cancer Care Ontario: CCO is an operational service agency of the Ministry of Health and we are governed by the Cancer Act. We are the government's chief adviser on cancer control services and the system through which these services are provided. Our mandate is to drive quality and continuous improvement in disease prevention and screening, the delivery of care and the patient experience, not only for cancer but for chronic kidney disease.

Specific to chemotherapy, we are responsible for developing and implementing a quality agenda, leveraging our regional cancer programs and partnerships and other clinical networks. CCO does not operate nor manage the hospitals that provide cancer control services. We do, however, have funding agreements with hospitals and other cancer care providers which link funding to a clinical accountability framework and mandate the delivery of system planning data to us.

I'd like to take a moment to tell you about Cancer Care Ontario's role in this issue. I understand that Michael Sherar, our president and CEO, addressed this in his remarks but I feel it's important to recap our work.

On Wednesday, March 27, CCO was notified about the issue by the London regional cancer centre. Immediately, we scheduled a conference call with the affected hospitals known at that time for the next day, to fully review the situation and determine next steps and the roles of each organization. Some time was needed to allow the hospitals to have their own incident management meetings internally prior to the group call.

On Thursday, March 28, in accordance with our MOU with the Ministry of Health, our communications team provided an overview of the issue with the information known at that time to senior officials at the communications and information branch.

That afternoon a conference call was held between CCO and representatives of each affected hospital—this includes regional vice-presidents, pharmacy staff, oncology leads and communication leads—to get more information and to establish appropriate next steps. Included in this call were CCO's provincial head of the Systemic Treatment Program and the clinical program manager.

During this call, we learned early perspectives about the error, the approximate number of impacted patients, operational disclosure plans being considered by each hospital, and that one other jurisdiction was impacted, namely Horizon Health Network in New Brunswick. It was decided that a patient-first approach was most important.

We also received information from London that Marchese was not supplying cyclophosphamide and gemcitabine to other hospitals, but we sought independent verification of this and action was taken to understand the potential broader impact on all of the 77 systemic treatment hospitals in Ontario. This was to be done through CCO's regional vice-president network once a briefing note was completed to ensure the most recent and informed information was shared.

Between Good Friday and the end of day Saturday, all parties worked together to develop this information document. In addition, on Saturday, March 30, CCO was informed that the LHIN and hospital CEOs of the affected hospitals requested a meeting to update them on the issue, as well as their desire to brief the minister directly. CCO recommended that a joint LHIN-hospital CEO call be held on Monday, April 1.

On Easter Sunday, March 31, CCO provided the information document to senior officials at the Ministry of Health's communication branch, a summary of all knowledge gathered to date. That afternoon, CCO contacted its regional vice-presidents at the cancer programs across the province to call their attention to the issue and ask them to confirm that the issue didn't involve any of the systemic treatment hospitals within their regions. The document was also shared with each of the regions.

On Monday, April 1, CCO initiated and scheduled daily incident management meetings with the affected hospitals. Also on Monday, a conference call was held with affected LHIN and hospital CEOs to review the current state and agree on patient outreach. It was decided that patient outreach would be staggered to begin Tuesday through Thursday for Windsor, London, Peterborough and Lakeridge. Windsor advised that patient outreach had already commenced due to patient visits.

CCO advised the Ministry of Health's communications branch of this notification to ensure that they had current insight. CCO also made direct outreach to several parties, including Medbuy, Ontario College of Pharmacists, Health Canada, HealthPRO and Marchese Hospital Solutions. I do note that our messages were not returned from Marchese and Health Canada.

On Tuesday, April 2, CCO issued a press release and sent an advisory notice to all systemic treatment hospitals in the province. That same day, media engagement began.

On Wednesday, April 3, daily briefing calls were established with the Ministry of Health. A teleconference was also held with our systemic treatment program committee, who are the heads of medical oncology and the regional quality leads, to discuss the issue and provide guidance. Dr. Michael Sherar and I were also invited to meet with the Minister of Health to brief her and the deputy minister on the issue and our actions to date.

On Thursday, April 4, a call was held between CCO and Peterborough to gain further information on the

incident beyond what had already been communicated by each hospital.

By Friday, April 5, all regional vice-presidents confirmed that the current issue with gemcitabine and cyclophosphamide did not exist within the other 73 systemic treatment hospitals within their regions.

On Tuesday, April 9, we sent a communication to the systemic treatment hospitals asking them the following questions, with a request for response the next day:

(1) Does your facility prepare or administer chemotherapy IV admixtures?

(2) Have you reviewed the advisory that CCO sent on April 2, 2013—and the advisory was again attached.

(3) Have you reviewed how overfill is managed with the appropriate pharmacy and systemic treatment staff members at your facility?

Final confirmation from each hospital was received by 5 p.m. on Thursday, April 11, to confirm that they had reviewed how overfill is managed at their facilities. Confirmation of these responses was provided to the Ministry of Health.

On April 15, as an added step, CCO began making outreach to private chemotherapy providers to ensure that they were aware of the issue.

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Through all of this, I feel that the hospitals and CCO responded very well to what was obviously a very difficult situation. Our first priority was to ensure that the affected patients were notified, had the right information, and were offered the opportunity to visit with their oncologist. We also wanted to ensure that the drugs in question had been removed from the shelves, and this in fact was the case.

As soon as CCO learned of the issue, my team became actively involved, to work with the hospitals to ensure a patient-centred approach to this issue, and I'm confident in the work that was done and the actions that we took.

I'd like to address chemotherapy safety as a broader issue. The preparation and administration of chemotherapy is incredibly complex, and I think it's important to highlight the safety of chemotherapy treatment in Ontario.

As is the case with all interactions that involve human beings and technology and multiple hand-offs, there does exist a potential for error. So in our health care system, we all work together to place an emphasis on minimizing the risk of an error from happening and impacting the patient. Also, we encourage a positive culture of risk identification and solutions.

Typically when a problem happens, it's not one person's problem, it's a system problem, and we all take it very seriously and look to identify mitigating solutions.

You may have read or heard me quoted in the media these past few weeks, saying that although what has occurred is indeed incredibly unfortunate, it has occurred against a backdrop of what is essentially a very safe chemotherapy system in Ontario.

Why do I say this? Some of you will recall a tragic incident that occurred at an Alberta cancer institute in August 2006. A 43-year-old woman died after inadvertently receiving an infusion of a chemotherapy drug called fluorouracil, given over four hours instead of four days. The cause of death, as determined by the coroner, was sequelae of fluorouracil toxicity.

Upon learning of the incident and reviewing the circumstances, the cancer institute leadership acted appropriately and immediately to implement a variety of actions to reduce the risk of recurrence. In addition, they quite appropriately got the Institute for Safe Medication Practices Canada to come in to provide external expertise and to undertake a root cause analysis of this incident.

Subsequent to this work, additional research was undertaken by the Canadian Patient Safety Institute, together with the Canadian Association of Provincial Cancer Agencies, the Institute for Safe Medication Practices Canada, and five provincial cancer agencies, including Cancer Care Ontario.

We were aware of this work as it was emerging. The final report was produced in 2010, and the report identified three themes of potential error, along with recommendations for their mitigation. The methodology here was not the actual observation of error but observation of facilities, to better understand where error might occur in these settings. The three themes of potential error were around infusion pumps, elastomeric or preprogrammed pumps; ordering and labelling; and pharmacy practices.

Why is this all relevant? Well, when that report was released, and even prior to the final report, our leadership teams at Cancer Care Ontario analyzed the findings to see whether there were learnings to be applied in Ontario. What we learned is that we're very well positioned in Ontario when it comes to chemotherapy safety. In fact, much of what came from that report was already well under way in Ontario.

We also took steps at that time to address all of the other recommendations, to further strengthen our system.

So I think we have external validation from a third party that the things that are important to introduce into a safe chemotherapy system are in place or well under way in Ontario.

Next, I'd like to address the organization of systemic treatment services and describe the way in which quality and safety expectations are embedded in these programs.

In Ontario, we have 14 regional cancer programs. They map almost completely to the LHIN boundaries. These regional cancer programs are the networks of stakeholders, health care professionals, hospitals and other organizations that are involved in cancer prevention and care within each of the LHINs. Each is led by a Cancer Care Ontario regional vice-president.

Each of these 14 regional cancer programs has a regional systemic treatment program. These programs are responsible for ensuring access to safe, high-quality systemic treatment according to best evidence. Within each of those programs, there are medical oncology leads and quality leads who meet regularly with our provincial program. In addition, the quality leads, along with nurses and pharmacists, formed a safety collaborative in 2011

that has since evolved into a regional quality and safety network. This meets regularly to discuss best practices and potential issues to continue to drive chemotherapy quality and safety in our province.

All of this regional work is supported by our provincial Systemic Treatment Program, which aims to improve equitable access to high-quality cancer care for all patients in Ontario. We do this by setting standards and guidelines for all systemic treatments, and it's important to note that all of our guidelines are produced by clinicians, with some backup.

The other thing I'd like to point out is that we also work with oncologists and other oncology professionals to actually make sure that these standards and new research change and improve practice. Not everything has an evidence base that is amenable to a guideline for development, but there are many situations where good practice exists across the province, and it's important that each of the regions share that best practice with one another. So we convene and facilitate opportunities for that to occur.

The Systemic Treatment Program overall is responsible for developing a quality agenda. It does this with input from the regional providers. This quality agenda spans the whole spectrum of chemotherapy.

We follow the corporate quality improvement cycle that uses a concept of gathering and developing the evidence, undertaking knowledge translation and exchange activities. We measure implementation and we plan for improvement. A strong focus on the development of a culture of safety has been a cornerstone for the program.

It's through this overall approach that Cancer Care Ontario has produced a number of guidelines focused on safety issues. Together with the 14 regional systemic treatment programs, a provincial plan for systemic treatment was issued in 2009. During this planning process, the need for additional guidelines was identified, and as they have been produced, they have become the work of the regional cancer programs as well.

This provincial plan represents the work of the dedicated clinical and administrative teams across the province engaged in interdisciplinary and collaborative activities, and it's a clear statement of everyone's commitment to quality and safety.

Our work spans end-to-end activities in chemotherapy within the cancer centres. This includes safe prescribing, safe dispensing and safe administration. I'll give you examples of the work we've done in each category. I understand that you've already received copies of these guidelines.

With respect to safe prescribing, one of the findings of the Canadian Patient Safety Institute was related to the issue of ordering chemotherapy. Chemotherapy regimens are complex, and using a computerized order entry system ensures standardized protocols are available and used by the doctors who prescribe it, by the pharmacists who prepare it and by the nurses who administer it. This is an area in which Ontario has led since 1996. In fact, we were one of the first jurisdictions to adopt a computerized physician order entry system.

Working in conjunction with clinicians, Cancer Care Ontario developed its own computerized physician order entry system specifically for the chemotherapy situation. It's called the Oncology Patient Information System, or OPIS. It supports regimen-based prescribing, ordering and administering. This is very helpful because it eliminates the scenario where a harmful drug error can occur because of incorrect reading of handwriting or incorrect calculation of dosage. It also flags drug allergies, drug-drug interactions or drug-disease interactions when the medications are ordered, thus assisting clinicians in making the most appropriate clinical decisions at the point of care.

As a medical oncologist who started my time in practice with a little handbook of chemotherapy regimens in one side of my lab coat and a slide rule in the other to calculate the body surface area and the doses, after which I wrote down the prescription and handed it in to the pharmacist, I can attest that this system has really revolutionized the way in which physicians are conscious of safety issues and are protected against the error that inevitably occurs when handwritten orders are the norm.

Moving on to safe dispensing, the preparation of chemotherapy can be toxic to both the preparer, the deliverer and the patient if handled incorrectly, and we've developed guidelines for safe labelling, safe handling and safe administration of chemotherapy drugs.

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As an example, our safe labelling guidelines evolved from the recommendations presented by the ISMP root cause analysis, and these were also referenced in the CPSI report. But our recommendations are actually much more detailed than what was recommended in the CPSI report, and they include all of the necessary components and formatting of an intravenous chemotherapy label to maximize safe delivery and minimize errors. And like all of our other guidelines, we collected the evidence and struck an expert panel to review the evidence and supplement that with consensus opinion to derive these series of recommendations.

Lastly, in the area of safe delivery or administration of chemotherapy, we have a number of initiatives in place. We worked closely with the de Souza Institute to develop a training program for nurses to ensure that they have the necessary education and skills that are associated with safe delivery of chemotherapy, and they've all now become certified by their Canadian association.

We have also developed a drug formulary. This is used extensively by health care providers and the public. This contains more than 600 documents on the appropriate use of drugs in the cancer system and contains information on drugs, regimens and patient information sheets.

So these are just a few examples of chemotherapy safety initiatives happening throughout the province, and it's because of initiatives such as these that I can confidently say that Ontario has a safe chemotherapy system in place.

However, as this unfortunate incident has highlighted, there's always more to be done, and I am committed to working with you today and with Dr. Jake Thiessen in his review to ensure that we all continue to better our health care system. Patient care and safety is our number one priority, and we will support Dr. Thiessen in every way we can.

This review will be an important component of the goal of continuous quality improvement and ensuring the best possible care for patients—a goal we all share.

Thank you for your time.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we'll start the questioning with the third party.

M^me^ France Gélinas: Thank you so much for this presentation. It has certainly helped me.

I must say that I've always been a big fan of Cancer Care Ontario. I admire the work that you do. I marvel as to where we are at in Ontario with cancer services. We are one of the best in the world, and a big part of this is because of the fantastic work that CCO does each and every day. This is a part of our health care system we can all be proud of. You have developed the infrastructure, the structure. You look at quality in every part of cancer treatment, prevention and cancer care, and this is what brought us as a province to where we are.

The example that you have given us as to how in depth you go to ensure quality kind of reinforces this. No wonder we're so good. It's because of the work that you do. You put the framework in place. You have the resources. You deploy the resources to do all of that good work, and it pays off. We have an excellent health care system, an excellent cancer care system, and I thank you for this.

Then comes the question: How come we never looked—I'll exclude myself. How come you never looked at subcontracting of the preparation of those chemo drugs? How come it never hit the radar?

Dr. Carol Sawka: Traditionally, hospitals have compounded all of their chemotherapy drugs on site, within the pharmacy. Cancer Care Ontario has actually never been involved with the procurement of drugs or supplies within hospitals.

Within the development of our regional systemic treatment plan, the issue of whether off-site chemotherapy admixture was a good thing was raised. It came up in the context of the Canadian Patient Safety Institute study as well. In fact, there are some theoretical advantages to it in that it takes what is a pretty routine procedure out of a very busy and often chaotic pharmacy environment within a cancer centre, and it offers the opportunity for quality and safety checks.

Our team investigated whether there was any evidence to really support those theoretical advantages in the experience of others and wasn't able to come down one way or another: Is this a good thing or is this not a good thing? With discussion with the hospitals, it was agreed that what we would do is prepare a framework to help hospitals sort through potential risks and benefits of off-site chemotherapy admixture facilities and that the final decision would be made by the hospital. And that's what we did.

M^me^ France Gélinas: So although the early evidence would lead you to think there was evidence that the process of outsourcing was actually going to bring benefits, when you double-checked, you could not replicate this?

Dr. Carol Sawka: Well, there wasn't anybody who had really studied it. There was a lot of anecdotal information that it was useful, but there wasn't any proper scientific study to examine before and after, for example, to determine whether there were safety issues that had been mitigated by having this done.

In theory, the potential advantages are as I mentioned: the efficiencies of having a routine procedure done in a dedicated facility and the potential safety gains, as well as safety to the hospital personnel who are not equipped to deal with toxic chemicals.

On the risk side, there was the need to ensure the quality of the product and the need to ensure that the drugs in question had a long enough stability to allow for them to be transferred from the compounding facility to the cancer centre.

M^me^ France Gélinas: And that proved inconclusive as in one or the other was just as good, or you just didn't know about the outsourced one?

Dr. Carol Sawka: There was no real evidence one way or the other to say that on balance the risks outweighed the benefits. It was left to each hospital to try to determine whether, in their circumstances, they had the opportunity for outsourcing and to make sure that they understood the potential risks and benefits of outsourcing.

M^me^ France Gélinas: I'm guessing you have followed this issue just as much as everybody else. Did you know anything about a grey area of oversight?

Dr. Carol Sawka: I did not.

M^me^ France Gélinas: Did it surprise you?

Dr. Carol Sawka: The issue of procurement of drugs and supplies is not something that Cancer Care Ontario has been involved with. Our work to date has begun from the time the drugs and supplies are within the cancer centre, and we work primarily with the providers and the hospitals in question about the process of care that I described.

What this issue highlighted, though, is the fact that there is work to be done in this area, and that's why we're very committed to working with Dr. Thiessen in his review, because, to date, there has been no role for Cancer Care Ontario in this area, but we're very interested to work with Dr. Thiessen.

M^me^ France Gélinas: Can you see a future role for CCO in procurement?

Dr. Carol Sawka: I wouldn't like to speculate on that. I think we're very committed to working with Dr. Thiessen and understanding the recommendations. Of course, we're all very committed to putting into place what's necessary to ensure this doesn't happen again.

We're working very closely on the working committee to assist Dr. Thiessen in his review.

M^me^ France Gélinas: It is still surprising to me, because CCO deals with drugs a lot, through the committee to evaluate drugs and with all of the new protocols that come in. You guys play a huge role. A lot of the drugs that are now on the formulary are because of the work that you have done. So you do have an interaction with drug manufacturers and drug compounding agencies all the time.

Dr. Carol Sawka: We don't have interaction with compounding agencies. I would say that our interactions with the ministry are around making recommendations around which drugs should be added to the formulary on the basis of effectiveness and cost-effectiveness. We then administer the reimbursement program for a certain formulary of expensive drugs. It's called the New Drug Funding Program. In none of that work have we assumed a procurement role or a procurement oversight role. Each of us has a responsibility in the cancer system. The hospitals have their responsibility, the regulators have theirs, and CCO has had its mandate, which is to focus on the actual appropriate use of chemotherapy drugs and ensure that they're appropriately prescribed and handled within the system.

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M^me^ France Gélinas: But you also reimburse them. You give money to hospitals for them buying drugs without knowing where they buy them, how they procure them. You just pay.

Dr. Carol Sawka: Well, what we do with chemotherapy drugs is no different from any other element of what Cancer Care Ontario does in quality improvement. We make recommendations on cancer surgery without helping the hospitals procure the sutures and the surgical supplies. We make recommendations on appropriate use of pain medication to control symptoms and at end of life, but we don't actually get involved in the procurement of morphine or other narcotics. We make recommendations on pathology and how pathology reports should be formatted and completed, but we don't make recommendations or oversee the hospitals' purchase of the stains that are necessary to make their supplies. Traditionally, we each have a role to play and Cancer Care Ontario has not been involved in the procurement side of the equation. Our work, as I said, starts with the assumption that the supplies and drugs are as advertised and as purchased. If Dr. Thiessen's report suggests that there is something different that should occur in the future, of course we're very interested to hear the results of that.

M^me^ France Gélinas: Actually, I fully agree with you: Everybody has a role to play. I would say that the role of oversight, whether the compounding facility is regulated or not, falls within the Ministry of Health, not with you.

You mentioned something in the opening, that you also reached out to the private chemotherapy providers. Who are they?

Dr. Carol Sawka: The big providers are Provis and Bayshore. There are some smaller providers that provide chemotherapy that is not funded on our publicly available formulary.

M^me^ France Gélinas: Okay. I didn't even know this existed; it's kind of a surprise. There are companies that will offer chemotherapy that are outside of the network of CCO?

Dr. Carol Sawka: Yes. Within Cancer Care Ontario, we have a formulary of drugs in the New Drug Funding Program that we're able to reimburse hospitals when they use them in accordance with eligibility criteria that have been established and agreed upon. If a patient and a physician decide that a particular drug might be useful in that situation and it's not on the formulary, a patient can obtain that drug through third party insurance or self-pay. These private infusion clinics have developed as a mechanism to deliver that type of chemotherapy.

M^me^ France Gélinas: Actually, I knew this. I just didn't realize this is what you were referring to.

I still stand by my opening comments: I have nothing but admiration for CCO. I find that what has just happened has sort of taken your name where it should have never gone. Cancer Care Ontario does provide excellent, quality care and should continue to do so. I don't know if it's a fair question, and you're allowed not to answer if you don't want to, but how damaging has this issue been to the work you're trying to do?

Dr. Carol Sawka: I believe that the public needs to have its trust and confidence restored in the safety of the cancer system. And that's the work that we're doing, right? The remarks that I made today are really intended to reinforce the fact that this really unfortunate incident that we all wish had never happened occurred on a safe platform of chemotherapy delivery. We're all very interested in getting to the bottom of it. We all have some responsibility in ensuring that this never happens again.

M^me^ France Gélinas: When you look at the 14 different regions that you serve, some of them were not impacted at all on a direct basis, as in they never used the diluted drugs and none of their patients ever received any of the diluted drugs. Did the impact of trust go beyond the regions that have dispensed those drugs?

Dr. Carol Sawka: I can't speculate on that. We really supported the hospitals that were affected because our first concern was for the patients and the families. The hospitals have been very active in responding to the patients and families and having open meetings, and have been, I think, responding as effectively as they can to this situation.

It's important to remember that there are 40,000 patients each year who get chemotherapy in this province, and they make 300,000 visits to the cancer centres. So even though one incident is one too many, in context, patients and the public should have confidence in the safety of the chemotherapy system in the province.

M^me^ France Gélinas: I agree with you.

If you look at all of the partners that make it possible for CCO to do the great work that they do, are you worried that there are other partners that you trusted that may have grey areas of oversight?

Dr. Carol Sawka: In a culture of safety, vigilance is really important. Safety is everyone's business, and it's all of our responsibility to be constantly aware of the potential for error. That's our role, and that's every health care professional's role. While I am not immediately aware of any grey areas, one of the important roles that we play is keeping our eye on the system and leveraging all of our partnerships with health care providers and within all of the regions to identify potential new sources of error.

As I mentioned, the health care system is a complex system. It has a lot of moving parts, a lot of people, a lot of trade-offs, a lot of technology. And as much as we do to mitigate the sources of error, another important feature is being very vigilant when a new error crops up, immediately dealing with it and sharing that information so that no other parties will be affected by it.

M^me^ France Gélinas: Were you disappointed that one of your partners, London, was not as quick at identifying the diluted drugs as your other partners? Lakeridge and Peterborough identified it right away; London didn't.

Dr. Carol Sawka: The issue of timing of identification is best addressed by the hospitals in question. I do know that the technician in Peterborough should be congratulated for a pick-up and having this dealt with when it was dealt with.

M^me^ France Gélinas: Have you done that?

Dr. Carol Sawka: Yes, we have.

M^me^ France Gélinas: Thank you.

Do I have any minutes on the clock? I'm going to save my two minutes.

The Chair (Mr. Ernie Hardeman): Mr. Berardinetti.

Mr. Lorenzo Berardinetti: Thank you, Dr. Sawka, for your very thorough presentation today. I really appreciate it. It was very impressive and very thorough.

Toward the end of your presentation, you mentioned working with Dr. Jake Thiessen. The ministry has taken this action, and the minister has also announced the creation of a working group of which you are a part. Can you tell us what the role of the working group will be?

Dr. Carol Sawka: Our president and CEO, Dr. Michael Sherar, is a member of that working group, along with the other parties. Their work, to date, has been to support Dr. Thiessen to make sure that he has all the information that he needs, and they have also been working to ensure that things are in hand with respect to the current situation. We'll be receiving Dr. Thiessen's report, and we'll be deciding on responsibilities for action.

Mr. Lorenzo Berardinetti: How would you characterize your relationship with the ministry in responding to this issue?

Dr. Carol Sawka: All parties took this very, very seriously, and we couldn't have hoped for better cooperation with the hospitals, with the ministry, with everyone we contacted. We all wanted to better understand this and to put into place everything necessary to make sure it wouldn't happen again.

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Mr. Lorenzo Berardinetti: What role has Health Canada played in responding to this issue?

Dr. Carol Sawka: I'm sorry—what role?

Mr. Lorenzo Berardinetti: Yes. In responding to this issue, what role has Health Canada played? Have you been in contact with Health Canada at all?

Dr. Carol Sawka: We are not involved with regulation specifically, but I do understand that Health Canada and the Ontario College of Pharmacists were very active immediately on this situation.

Mr. Lorenzo Berardinetti: The ministry's proposed regulations for oversight—are you aware of the regulations?

Dr. Carol Sawka: Yes, I am.

Mr. Lorenzo Berardinetti: Do you think they're appropriate? Are there any comments you would like to make regarding those regulations?

Dr. Carol Sawka: The ministry announced its intention to ensure that there would be no gaps in oversight, effective immediately, and the steps that have been put into place appear to address that. The Ontario College of Pharmacists have some proposed regulations that are out for consultation, and we've just taken a look at those. We're aware of the Health Canada and ministry regulations as well.

Mr. Lorenzo Berardinetti: Those are all the questions that I have. I don't know if there's anyone else who has any questions from our side. We may save some time for later.

The Chair (Mr. Ernie Hardeman): To the opposition: Mr. Yurek.

Mr. Jeff Yurek: Thank you very much for coming. I also reiterate the great care that cancer patients receive in our province, and you're commended for what you do. Any of us here could probably say we've had family members or we ourselves have been affected by cancer, and great care has gone into it.

I just have a few questions for you. What role does the LHIN have in this process? You mentioned them in your statement, but that's pretty much the first I've heard of them in this whole debacle.

Dr. Carol Sawka: That question is best posed to the hospitals and the LHINs. I don't have any direct information on that.

Mr. Jeff Yurek: You've made note here in your statement—in the Improving the Safety of Ambulatory Intravenous Chemotherapy in Canada report—of one of the three potential errors with regard to labels. The bags coming from Marchese were labelled 4 grams and 250 ml. Do you consider that proper labelling in reducing errors?

Dr. Carol Sawka: Our labelling guidelines were made specifically for individual patient prescriptions, so I could speak to that. They contain patient identification, the chemotherapy drugs, the dose, the volume etc.

Mr. Jeff Yurek: The concentration?

Dr. Carol Sawka: The concentration; exactly. Our labelling guidelines weren't specifically designed for compounding facilities.

Mr. Jeff Yurek: Since the procurement of compounded chemotherapy medication started, have you thought of revising that? Did that ever come up in the various committees you've had, that maybe we need to take a look at how these bags are coming in and standardize the labelling across the province?

Dr. Carol Sawka: That's the work that Dr. Thiessen is doing.

Mr. Jeff Yurek: Just now.

Dr. Carol Sawka: Yes. As I said, I think that what we have done is we have ascertained in a survey to all 77 hospitals that they have policies and procedures in place to ensure that this overfill issue that was apparent in this situation has been dealt with. We're confident that the issue that was at play here doesn't exist in other chemotherapy preparation, but we're very interested to work with Dr. Thiessen and to understand whether there is any role for Cancer Care Ontario to play in the labelling arena.

Mr. Jeff Yurek: Last week, Lakeridge noted that they didn't like the labelling coming from Marchese. One of the reasons they believe Marchese won the contract was because they had bar-coding on the label. I thought it would be great to help with the data that's in the bag, and they said no; in fact, that was used to help inventory control. What are your thoughts on labelling to improve inventory control, whereas there's no concentration on the bag?

Dr. Carol Sawka: I'd refer back to our guidelines. The guidelines state what our experts in labelling recommended.

The issue of bar-coding as a means of patient identification has come up—to match the actual intravenous infusion with the patient. The issue of inventory control is something that would be more relevant within a hospital setting.

Mr. Jeff Yurek: Have you had a conversation with Medbuy with regard to your guidelines on medication, the labelling and such?

Dr. Carol Sawka: No. We do not have a relationship with purchasing organizations.

Mr. Jeff Yurek: I can see why you wouldn't get too involved with procurement, because you only deal with cancer drugs and kidney medications, when there's a whole spectrum of medications out there that could possibly be compounded and brought into the pharmacy, like biologics and such. Do you not think, perhaps, that oversight or standards or guidelines should come from the Ministry of Health and should be there to have a coordination of standardized care for bringing in compounded medications in this province?

Dr. Carol Sawka: I believe that that's what the independent review—

Mr. Jeff Yurek: That's what we're doing now.

Dr. Carol Sawka: —is intended to ascertain.

Mr. Jeff Yurek: Do you think that may have come up at one time or another over the last 15 years?

Dr. Carol Sawka: I am not able to speculate on that.

Mr. Jeff Yurek: You mentioned Bayshore providing infusion clinics. I don't know a lot about Bayshore, but I know they originally started out as a nursing agency. Where do they get their medications for the infusion clinics?

Dr. Carol Sawka: We are not involved with the private infusion facilities. They are responsible for the procurement of their own drug supplies.

Mr. Jeff Yurek: So you don't have any oversight—

Dr. Carol Sawka: No, we have no oversight of private infusion clinics.

Mr. Jeff Yurek: But you're paying them to—

Dr. Carol Sawka: No—

Mr. Jeff Yurek: —the clinics.

Dr. Carol Sawka: The private infusion clinics are not paid for by Cancer Care Ontario or by the public taxpayer. They are paid for privately by patients, either through third party insurance or self-pay.

Mr. Jeff Yurek: And who oversees these clinics? Do you know, by chance?

Dr. Carol Sawka: No, I do not know.

Mr. Jeff Yurek: Interesting. You mentioned HealthPRO earlier today. Can you just give me an overview of what HealthPRO is, please?

Dr. Carol Sawka: HealthPRO is a group purchasing organization like Medbuy.

Mr. Jeff Yurek: Like Medbuy?

Dr. Carol Sawka: Yes.

Mr. Jeff Yurek: And have they been involved in this situation at all? Do they have Marchese getting meds through HealthPRO or—

Dr. Carol Sawka: Again, because we're not involved with procurement, I don't have any first-hand knowledge of the relationship of Marchese with Medbuy or HealthPRO.

Mr. Jeff Yurek: That's all right for now. Do you want to go, Christine?

Mrs. Christine Elliott: I do have a few questions. Thank you very much, Dr. Sawka, for appearing before the committee this afternoon. We really appreciate your input. I just have a few questions just to follow up from my colleague.

The first one was, when you were talking about how you had done an analysis of the issue of outsourcing the mixing of solutions, and you didn't come down one way or the other but had a list of risks and benefits, was that contained—is that something different, I should ask, from the guidelines that you've already provided to us?

Dr. Carol Sawka: Yes. There are many situations in cancer care where people ask the questions, "Is such and such the right thing to do?" or "Is such a treatment the right thing to do?" or "Is there one best way to do something?" So we do a review of the literature to see whether, in fact, there's enough that has been written on this subject to enable a careful analysis. If there is, then that's actually amenable to production of a guideline, which is a recommendation around doing it one way.

But there are many situations in health care where processes of care are best determined locally, because each hospital, and its relationship with its pharmacy and nurses, differs one to the next, so there isn't really one

best way to do things. In that situation, our job is really to bring people together to have them share information about how they're undertaking certain processes of care to enable people to learn from one another, because there are lots of good types of processes of care that are occurring that need to be shared so that people can learn from one another, but they're not amenable to the production of a guideline, which is a single recommendation: "You should do it this way."

Mrs. Christine Elliott: Is there an actual document, then, that outlines these risks and benefits that we could have a copy of?

Dr. Carol Sawka: There's a simple framework that was really put together at the request of the hospitals that I would undertake to provide, yes.

Mrs. Christine Elliott: That's great. Thank you.

Dr. Carol Sawka: You're welcome.

Mrs. Christine Elliott: We appreciate that.

And was that communicated to all of the hospitals that provide chemotherapy programs?

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Dr. Carol Sawka: Yes. The Regional Systemic Treatment Program leaders meet with our provincial leaders on a regular basis, on a monthly basis, so they have an order of business that they conduct. This issue was discussed, and it was agreed upon that the decision about outsourcing would be a local hospital decision.

Mrs. Christine Elliott: Just looking at your presentation, on page 2, just in the chronology of events, you indicated that there was a conference call on March 28 that was involving a number of people, including the Ministry of Health, and from then on, between the 28th and the 30th, it appears that the action that was taken was through Cancer Care Ontario. Was there any action that was being taken that you know of by the Ministry of Health?

Dr. Carol Sawka: We were working with the hospitals to collect all the information. We wanted to know the number of hospitals affected, how many patients were affected, what the notification plan would be. We undertook a facilitation role to bring the hospitals together to communicate most effectively. We did communicate again with the ministry on the Saturday, and then again on the Sunday, to keep them informed of the information as it was unfolding.

Mrs. Christine Elliott: Did the ministry then basically give Cancer Care Ontario the responsibility for doing this investigation and coordination?

Dr. Carol Sawka: Well, it's a shared responsibility. The hospitals are very grateful for having a coordinating body like Cancer Care Ontario to help facilitate their discussions and keep one another informed, and really, the hospitals, the ministry, Cancer Care Ontario—all of the parties—took it very seriously, and they did what they needed to do when they needed to do it.

Mrs. Christine Elliott: You also indicated, I think—it's on page 3 of your presentation—that you and Dr. Michael Sherar were invited to meet with the Minister of Health to brief her and the deputy minister. Did that meeting actually take place?

Dr. Carol Sawka: It did.

Mrs. Christine Elliott: And how long a meeting did you have with the minister?

Dr. Carol Sawka: An hour and a half.

Mrs. Christine Elliott: Until she was fully brought up to date with what was going on?

Dr. Carol Sawka: That's right.

Mrs. Christine Elliott: And approved of all the actions that Cancer Care Ontario was taking in terms of investigating this matter?

Dr. Carol Sawka: The minister was most interested in understanding from me, from a clinical perspective, how chemotherapy is prepared and the more specific issues around chemotherapy. There were many channels of communication going on simultaneously, and her interest was primarily in understanding, making sure she understood how chemotherapy was prepared and delivered to the cancer centres. And that's the information that I was able to provide her.

Mrs. Christine Elliott: On page 6, again, of your presentation, you indicated that safe labelling guidelines were created, and I guess my question to you would be, did Marchese conform to the safe labelling guidelines as you had indicated that they should be followed?

Dr. Carol Sawka: The safe labelling guidelines were really intended for preparation of chemotherapy drugs for specific patients within cancer centres. They weren't specifically designed for the specific scenario that we're in here, where Marchese was supplying bulk drug to a cancer centre that then further used the drug among several patients, and so whether—the guidelines really weren't intended for them; they were specifically designed for individual patient doses.

Mrs. Christine Elliott: I know we're far from completing our investigation of this issue on any level, but do you have any preliminary observations about what you think needs to be done; what areas we should be concentrating on, for example?

Dr. Carol Sawka: It would be premature for me to comment on that. I do know that all of the parties are working very closely together, taking it very seriously, and we all have an interest in making sure this never happens again.

Mrs. Christine Elliott: Thank you. Those are all my questions.

The Chair (Mr. Ernie Hardeman): Ms. McKenna.

Mrs. Jane McKenna: Does Cancer Care Ontario have any policies or guidelines with respect to outsourcing chemotherapy compounds for in-hospital use?

Dr. Carol Sawka: Cancer Care Ontario has not traditionally been involved in procurement of any drugs and supplies, regardless of whether they are secured directly from the manufacturer or through a compounding facility. Our mandate has started from the moment the drugs are actually in the facility, and we work with the providers from that point onward. Our work has really focused on those areas.

Hospitals are responsible for procurement, regardless of whether they're from manufacturers or compounding

facilities. But as I mentioned, we're working—we're very anxious to hear Dr. Thiessen's report because if there are any new suggested roles for Cancer Care Ontario, we'd obviously be very interested in working with the group.

Mrs. Jane McKenna: Okay. And do you have any plans to develop a policy or is it strictly a hospital administrative issue?

Dr. Carol Sawka: We're awaiting the result of Dr. Thiessen's inquiry. We need to have a solid set of recommendations that determines who needs to do what in this area. We all share a responsibility in making sure we have the safest chemotherapy system possible.

Mrs. Jane McKenna: Thank you. That's it's for me.

The Chair (Mr. Ernie Hardeman): Thank you. The third party, Ms. Forster.

Ms. Cindy Forster: Thank you for being here, Dr. Sawka. Just one question: I heard you talk about a report that you kind of developed around the outside procurement, its risks and advantages. Can we get a copy of that report? Could it be tabled with the Clerk?

Dr. Carol Sawka: There was no report per se. It was work that our programs staff undertook to review publications and to try to determine whether there was anything written on the subject. So there was no formal report issued.

Ms. Cindy Forster: It was just really discussion at committees or—

Dr. Carol Sawka: That's correct, yes.

Ms. Cindy Forster: Are there any minutes that kind of flowed out of that committee that we could have tabled with the Clerk?

Dr. Carol Sawka: Yes, we have minutes for all of our committees, and I can undertake to provide those.

Ms. Cindy Forster: Great. Thank you.

M^me^ France Gélinas: When you looked at this, did you look at it with a view of bulk preparation? Because this is what Marchese was doing.

Dr. Carol Sawka: I don't have the details in front of me, so I'd have to undertake to provide you with the minutes.

M^me^ France Gélinas: That's okay. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. The government, Ms. Mangat.

Mrs. Amrit Mangat: Thank you, Dr. Sawka, for being here today. You mentioned in your statement that you're working very closely with the de Souza Institute to develop programs for nurses who deliver chemotherapy. Can you throw some light—what kind of institute is this and what kind of programs are being developed with them?

Dr. Carol Sawka: Sure. The de Souza Institute is a facility that's located at Princess Margaret Hospital that provides training to oncology nurses, to cancer nurses. We all have a goal of ensuring that nurses who provide cancer care have the highest possible training and also are certified by the Canadian Association of Nurses in Oncology. We've undertaken a goal to ensure that all of our nurses are in that capacity.

It's difficult for nurses to acquire that training when they're working shift work and they're working in remote facilities. So the de Souza Institute has developed a combination of in-person and online training, and this has been very helpful to the nursing profession because it's enabled them to achieve the training necessary to then go on and get their CANO certification. It is a program that is also undertaking interprofessional education because of the potential for online training.

Mrs. Amrit Mangat: Thank you. Do I have time?

The Chair (Mr. Ernie Hardeman): Yes, go ahead.

Mrs. Amrit Mangat: What other quality assurance measures are in place to ensure the safety of cancer drugs in Ontario?

Dr. Carol Sawka: We've provided a whole set of guidelines, but in essence we have cancer leaders in each of the 14 regions who work with our provincial programs, and together they help us determine the priority for quality improvement. We then have a process whereby the provincial program works with clinicians to address those priorities, and the regional programs implement them. Together, the programs have tackled a whole variety of topics, as I already described, and are continuing to work together in the areas of quality, appropriateness of chemotherapy, ensuring that patients get the right drugs and don't get the wrong drugs, and also that they are located—that the drugs are given in the centres that are suitable for the type of chemotherapy that's being given.

I refer to the Regional Systemic Treatment Program provincial plan. That was a piece of work that was done to develop regional systemic treatment programs in each of the 14 regional cancer programs. We assisted by preparing a set of standards around chemotherapy delivery for levels of chemotherapy facilities that would be suitable to various complexities of chemotherapy. That was done to ensure that there was a good mechanism, an access, to all levels of complexity within each region, good lines of communication between the facilities, and the appropriate oncology professionals who were trained and suitable to provide the chemotherapy in each of the facilities.

That also described the infrastructure requirements that would be required for the provision of chemotherapy and the organizational elements that would contribute to that.

That's something where we've actually used all of those regional programs. As guidelines and standards and new processes of care become available, we embed them into that work.

Mrs. Amrit Mangat: So are you confident in the safety of the cancer drug supply in Ontario?

Dr. Carol Sawka: I'm confident of the chemotherapy program in Ontario.

Mrs. Amrit Mangat: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. The official opposition: Mr. Yurek? Everybody has had their time.

Thank you very much for participating this afternoon and coming in and enlightening us on how Cancer Care Ontario was involved.

Dr. Carol Sawka: Thank you.

The Chair (Mr. Ernie Hardeman): We are slightly ahead of time; all the time was not used by some participants. We will have to take a small recess until the last delegation comes in. This would be a great time for one of those official breaks.

The committee recessed from 1622 to 1632.

MARCHESE HEALTH CARE

The Chair (Mr. Ernie Hardeman): We call the meeting back to order. Our next presentation is Marchese Health Care. I believe they are here.

As with the others, we will ask first of all that the Clerk either swear or affirm you in for the testimony that you're about to give. So we'll turn it over to the Clerk.

The Clerk of the Committee (Mr. William Short): Ms. Zaffiro, is it? Did you want to be affirmed or swear an oath?

Ms. Marita Zaffiro: Certainly.

The Clerk of the Committee (Mr. William Short): Which one? Affirmed or an oath? Affirmed: You raise your right hand—

Ms. Marita Zaffiro: Affirmed is fine. Sure.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please.

Ms. Zaffiro, do you solemnly affirm 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?

Ms. Marita Zaffiro: I do.

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

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will start the program. You have 20 minutes to make a presentation to address the issues that we're here dealing with today. At the end of the 20 minutes, we will have 20 minutes from each caucus to ask any questions of your presentation. The questions will start with the government side when we get to that time.

So with that, thank you very much for being here, and thank you very much for being here just a few minutes early so we can get started just a little ahead of time. We'll turn the floor over to you to make your presentation.

Ms. Marita Zaffiro: Thank you, Mr. Chairman. Can you hear me okay? Can you hear me?

Mr. Phil McNeely: Speak louder. You're too far away.

Ms. Marita Zaffiro: I will try. Okay, just let me know if I'm not loud enough.

My name is Marita Zaffiro, and I am a pharmacist and the president of Marchese Hospital Solutions and Marchese Health Care. I thank you for the opportunity of addressing your committee on behalf of Marchese.

First, let me say that my heart breaks for the patients and families trying to process and understand what they've been hearing. We are deeply distressed to learn that some patients did not receive our preparations in the manner we expected.

I also want to state that Marchese does not wish to point fingers or place blame for this unfortunate incident. We want to explain our role in the process and help this committee understand what happened in order to make sure it doesn't happen again.

In 1988, I left my job as a young executive to buy a storefront pharmacy in Hamilton. The store was owned by a family friend. I wanted to carry on his tradition of service and build a more patient-focused pharmacy. I am pleased to say that with the help of many others, I believe we've succeeded. Marchese is now a group of Ontario companies that have been in business for over 50 years. Jack Marchese started the pharmacy in Hamilton in 1962. We've grown substantially over the last 25 years. The Marchese companies now employ over 80 Ontarians, including 15 pharmacists and several registered pharmacy technicians.

I am proud of our company, of our staff and of our service to our community. We have a long track record of leadership and recognition in the profession and in the area in which we do business. We have received many awards for our work.

Marchese Health Care now operates three accredited community-based pharmacies in Hamilton, Kitchener and Mississauga. Our pharmacies deliver services to clients who live in diverse communities. We provide these services in more than 10 languages. There is also a home care services business which includes the supply of intravenous medications, infusion equipment and medical supplies for home care patients.

In early 2011, we were invited to enter into a competitive bidding process to supply intravenous preparations—what we call admixtures—to Medbuy Corp. member hospitals. We were awarded the contract and, as a result, we formed Marchese Hospital Solutions, or MHS, in late 2011. The contract was for the supply of intravenous drug preparations to a number of Ontario and New Brunswick hospitals. Among the admixtures were cyclophosphamide and gemcitabine, the two cancer drugs of concern.

MHS was created as a separate division to keep the operations of our community-based and home care pharmacies separate from our hospital admixtures supply business. It was not created to avoid any type of regulation. While MHS supplied admixtures directly to the hospitals' in-patient pharmacy departments, our contract was with Medbuy Corp. Medbuy is a hospital group purchasing organization.

To increase safety, efficiency and the benefits from economies of scale, Medbuy contracts with suppliers like MHS to supply many different products to member hospitals. These are typically hospitals for which formulation of IV admixtures in the hospital pharmacy is either impractical or uneconomic.

Safety is also a very important factor. Some hospitals may be reluctant to have their own pharmacists and technicians preparing chemotherapy drugs. The drugs themselves are potentially toxic to any person handling them improperly. Our MHS personnel are trained to handle chemotherapy drugs and prepare them safely, without exposing themselves to potentially harmful effects. MHS prepares the IV admixtures safely and efficiently in our state-of-the-art facility in Mississauga. They are all prepared under the supervision of an OCP-registered pharmacist, and always have been.

I would like to now clarify for this committee what MHS does to prepare the two chemotherapy admixtures.

We play an important but limited role in the supply chain for medical treatment. Before MHS does anything, manufacturers produce the drugs, the equipment, the IV bags, and the solutions we use to prepare our admixtures. By contract, we take drugs produced by licensed drug manufacturers and ensure that they are combined in a sterile condition. We then ensure timely delivery of the admixture bags to hospital in-patient pharmacies. We withdraw a volume of saline solution from a pre-filled IV bag. The withdrawn solution is then mixed with the powder form of the chemotherapy drug. The mixture or reconstituted solution is then injected back into the bag. To be clear, no additional fluid is added by MHS. As one of the witnesses from the Windsor hospital stated, it is generally known in our industry that pre-filled IV bags are overfilled to account for evaporation while they are in inventory. Overfill also addresses the issue of volume remaining in IV tubing. In fact, overfill was discussed between MHS and Medbuy.

It is important to understand that the labels we place on the IV bags describe the contents only. They do not provide instructions or directions for use. They cannot contain the name of a specific patient, as this is not known to us. We deliver the IV bags to hospital in-patient pharmacies. It is the hospital pharmacist who labels a bag for use in the hospital and dispenses the medication at the direction of the treating physician. Hospital staff administer the contents of the bag to individual patients.

The labelling of our admixtures was discussed in detail with Medbuy both during the RFP process and before any of our preparations were supplied to hospitals. We were told by Medbuy that one of the reasons our response to the RFP was successful was that Medbuy's review team regarded our labelling as superior to that of its previous contract supplier. Medbuy approved all MHS labels before any product was shipped.

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After we began to supply Medbuy hospitals in February 2012, we continued to have discussions with them and some of the hospitals. At all times our labels complied with Medbuy's requirements as specified in our contract or as amended at their request. Until this incident, no issue was raised by anyone that our chemotherapy drug labels were unclear. If Medbuy or the pharmacist at any hospital had identified any problem with our label, we would have addressed it immediately.

There are two types of labelled intravenous solutions provided by MHS under the Medbuy contract. First, there are concentration-specific solutions that contain a defined amount of drug and solution. The concentration of the drug, represented as milligram per ml, and the volume of the solution are specified on the bag label. Second, there are admixtures intended to be administered in their entirety to only one patient. These are non-concentration-specific solutions, and they contain a defined amount of drug. The amount of solution in a pre-filled bag is not measured to a precise volume. A variance in solution amount is not material in a non-concentration-specific bag because the patient receives the precise amount of the medication. Whether a particular patient receives slightly more saline solution, including the overfill I mentioned earlier, with the medication makes no difference.

Interruption.

The Chair (Mr. Ernie Hardeman): Go ahead.

Ms. Marita Zaffiro: Okay, thank you.

I would like to stress for the members that our contract with Medbuy required us to supply cyclophosphamide and gemcitabine preparations only in non-concentration-specific form. We were not told how the previous supplier of these two drugs prepared its IV bags—whether the bags were in concentration-specific or non-concentration-specific form—nor were we provided a copy of the previous supplier's labels. We supplied the type of product Medbuy requested with the labels they approved.

I now want to turn to some of the questions that have been raised about regulation of MHS. Our role, our quality controls and our boundaries of responsibility have always been known to Medbuy, the Ontario College of Pharmacists and Health Canada. Marchese's community pharmacies are regulated by the Ontario College of Pharmacists. Our home care business is accountable under contract to the community care access centre and ultimately the Ministry of Health. A number of companies similar to MHS have emerged in the Canadian medical supply landscape over the last few years. Government authorities have always been fully aware of our presence and of the kind of work we do.

MHS has never attempted to operate without regulatory control. I want this committee to know that before this issue arose, and indeed before we began to service this contract, we went both to the Ontario College of Pharmacists and to Health Canada to inquire about the appropriate regulatory approval. Both the College of Pharmacists and Health Canada declined to regulate MHS.

MHS also approached the New Brunswick Pharmaceutical Society about regulation in New Brunswick. They too declined to regulate.

Even though there was no specific regulation of our admixture preparation services, we still instituted the most stringent quality control measures we could devise. I have always been assured that our organization operated according to the highest levels of quality. It is a core value from which I would not deviate.

My entire career has been devoted to improving patient care. I have worked collaboratively with hospitals, home care providers and pharmacists, and I am deeply committed to preventing incidents like the one that brings us here. But regulation alone does not ensure best practices; training, strong quality controls, constantly reinforced corporate values, and a management that practises what it preaches can—that is how I have tried to build my company.

The committee heard from one witness that Health Canada is planning to regulate MHS and others. Health Canada will require that all admixtures are prepared under the direct supervision of a licensed pharmacist. This is what we have always done. The admixtures at issue were all prepared under the supervision of a licensed pharmacist.

I want to conclude by speaking about Marchese's response to the investigations as a result of this incident. We have spent countless hours responding to inquiries from Health Canada, the college, and the Ministry of Health and Long-Term Care. We have also met with Dr. Thiessen and are co-operating with him to the fullest extent. Health Canada, the Ontario College of Pharmacists and Dr. Thiessen have been given full access to our premises, our people and our processes. They are being provided with all of the documents they have requested. Dr. Thiessen has met with me and my employees. All of us have been and will continue to be open.

We want to prevent these types of incidents as much as anyone else involved. We remain committed to assisting in any way to improve patient care and confidence in our health care system. We are proud of the role that Marchese employees play every day in providing quality health care to thousands of citizens.

Thank you. I welcome the opportunity to respond to the committee's questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. And with that, we'll start the rotation. Mr. Berardinetti.

Mr. Lorenzo Berardinetti: Thank you for your presentation today. I'm going to ask you some questions on an information-gathering basis, I'm not here to cross-examine anybody. I just want to get information here today. So I thank you for being here.

Is the gentleman beside you your counsel?

Ms. Marita Zaffiro: Yes.

Mr. Dominic Clarke: Yes. My name is Dominic Clarke and I'm a partner with the law firm of Blaney McMurtry. I'm here as Ms. Zaffiro's counsel.

Mr. Lorenzo Berardinetti: All right; thank you. I'm going to just go to a quick question. What, in your opinion, do you think went wrong in this process?

Ms. Marita Zaffiro: I believe that it was a communication issue where there were expectations or assumptions. We, at no point, received the information to understand that what was desired by some hospitals—perhaps, not necessarily all—were concentration-specific products. These products were prepared and labelled accordingly in a non-concentration-specific manner, similar to many of the other admixtures that we prepare.

Mr. Lorenzo Berardinetti: So you say it was a communication issue. Can you just elaborate a bit on what that communication issue was?

Ms. Marita Zaffiro: The way products were specified were how they are basically described. A concentration-specific product request would have a specific concentration on the label or on the description of the product. That was not the case with these products. A non-concentration-specific product says something like "4 grams in a 100-ml bag." And so that does not mean absolutely 100 ml; that means "4 grams in a 100-ml bag, plus the overfill that the manufacturer includes in that bag." That's how these products were spec'd.

Mr. Lorenzo Berardinetti: Okay. You mentioned in your presentation that the labelling is usually the responsibility of the hospital or the pharmacist at the hospital.

Ms. Marita Zaffiro: The labelling is the key communication device. Our label set in its entirety was provided to Medbuy, and Medbuy used that to orient the hospital members to the products that we would be providing. That would've been an opportunity to identify that, because there are concentration-specific elements, these two were also concentration-specific. Given that the labels did not indicate that—if that's what they were looking for—that's where that might have happened. That did not happen at any time.

Mr. Lorenzo Berardinetti: So Marchese doesn't do labelling. Your company doesn't do the labelling.

Ms. Marita Zaffiro: We label the bags with the content and descriptions that Medbuy has asked us to do under contract. They approve our labelling.

Mr. Lorenzo Berardinetti: So you do that part, and then you provide it to the hospitals?

Ms. Marita Zaffiro: Right, and as I said, the hospitals label it with the patient name and deliver it to the floor where it's going to be administered.

Mr. Lorenzo Berardinetti: Excuse me; I wasn't sure about your answer there. So the labelling is done by the hospital regarding the patient—

Ms. Marita Zaffiro: Correct.

Mr. Lorenzo Berardinetti: —and what do they put on the label?

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Ms. Marita Zaffiro: Well, you'll have to ask them to confirm, but I believe that they would put the patient's name. They would indicate to infuse the contents over a period of time. Sometimes it's infused over 30 minutes, 60 minutes, etc.

They have other information. There are conventions that are recommended through ISMP for that purpose.

Mr. Lorenzo Berardinetti: Okay. So you provide some of the labelling, but the rest is done by the hospital or the pharmacy that gives it to the patient affected in this case.

Ms. Marita Zaffiro: Correct.

Mr. Lorenzo Berardinetti: If there were to be any problems with the system with regard to the process of delivering the product eventually to the patient, where do you think that problem may have happened?

Ms. Marita Zaffiro: Can you repeat the question? I'm sorry.

Mr. Lorenzo Berardinetti: I'm sorry. If there was a problem—let's say, you produce the drug. Is that correct? You produce the—

Ms. Marita Zaffiro: We produce an admixture, a preparation that mixes an active drug ingredient in a solution.

Mr. Lorenzo Berardinetti: So you compound whatever is required to be compounded, into a product that can be administered by a hospital.

Ms. Marita Zaffiro: That's correct. We compound admixtures. The understanding is that when you have a non-concentration-specific product, the entire contents would be delivered as a unit dose to one patient.

Mr. Lorenzo Berardinetti: Okay. And if there was a problem in the system—I don't want you to point fingers—where do you think that problem may have occurred?

Ms. Marita Zaffiro: I think that our best opportunity to really define that clearly and intelligently is through Dr. Thiessen's inquiry. He has the ability to ask the questions, to inspect the premises, to look at the processes and to really make an informed judgment on that, and the recommendations that will improve.

Mr. Lorenzo Berardinetti: So you are co-operating with Dr. Thiessen—

Ms. Marita Zaffiro: Absolutely.

Mr. Lorenzo Berardinetti: —and his group.

Ms. Marita Zaffiro: And his—

Mr. Lorenzo Berardinetti: And his group, the people that will be working with him.

Ms. Marita Zaffiro: Well, we're not part of his group, but we have spoken to him.

Mr. Lorenzo Berardinetti: Okay. I think there are some other members that want to ask a few questions, Mr. Chair.

The Chair (Mr. Ernie Hardeman): Okay. Go ahead.

Mrs. Amrit Mangat: Me?

The Chair (Mr. Ernie Hardeman): Ms. Mangat.

Mrs. Amrit Mangat: Okay, thank you, Chair.

How long have you been providing compounded chemotherapy drugs to hospitals in Canada?

Ms. Marita Zaffiro: In Canada? This contract began in February 2012, but Marchese as a group has been providing sterile intravenous admixtures on a per-patient basis to home care clients for almost 20 years.

Mrs. Amrit Mangat: Can you please take us through the process of compounding these medications?

Ms. Marita Zaffiro: Sure. I thought I said it in the statement, but I'll take you through it again.

If you have a non-concentration-specific product, it would mean one dose/one patient. You would take a sterile bag with a solution. It could be saline or it could be dextrose, and those are specified through either what the client would like or by the type of drug.

Sometimes, if it's non-specific, you could dissolve the drug in sterile water, depending on the requirements, and just put that into the bag without removing any volume.

Sometimes the drugs you put in are liquid, and you would just add that liquid and you would not take out a reciprocal amount.

Sometimes you would actually remove the diluent. If the diluent, say, was going to be saline, you would put that in the vial, mix it up, take it back out of the vial and put it in the bag.

At the end of the day, you would have the original 100-ml-labelled volume; the overfill, which is a known range in the industry, by manufacturer; whatever added volume you may have added to reconstitute the drug; and any volume displacement of the drug, which doesn't happen too often.

Mrs. Amrit Mangat: Who are your other competitors?

Ms. Marita Zaffiro: Who are my competitors in hospital solutions?

Mrs. Amrit Mangat: In compounding drugs.

Ms. Marita Zaffiro: Baxter, Calea; Bayshore does some. This is compounding generally, not just for hospitals. I don't know other people's, but I know that in the home care compounding there's Rexall and Desjardins.

Mrs. Amrit Mangat: Can you please explain to me, for my own information, how Marchese mixed chemo drugs differently from Baxter?

Ms. Marita Zaffiro: I don't absolutely have the information about what Baxter did or did not do. So that's difficult for me to say. I think that you need to ask the hospital that, because that's sort of the million-dollar question. If we understood that, or if we had some hint that that was the case, through either the labelling or the description of products requested, or because when we were reviewing the products—then we would know. If we needed to make a concentration-specific version, there are different ways that you can do that.

Mrs. Amrit Mangat: Okay. What is your relationship with Medbuy?

Ms. Marita Zaffiro: What is our relationship? We have a contract with Medbuy through Marchese Hospital Solutions.

Mrs. Amrit Mangat: Thank you.

Ms. Dipika Damerla: How much time do I have left, Chair?

The Chair (Mr. Ernie Hardeman): Oh, yes, go ahead.

Ms. Dipika Damerla: How much time do I have?

The Chair (Mr. Ernie Hardeman): You've got about 10 minutes yet.

Ms. Dipika Damerla: Okay.

Thank you so much. I'm just going to revisit the whole issue of concentration, because in my understanding, the simplistic term is, some patients got a diluted version of the drug. But the way I've understood it, it's a sealed bag—

Ms. Marita Zaffiro: Yes.

Ms. Dipika Damerla: —and it's got, say, 100 millilitres plus the overfill; I understand that. I don't know what the variation is, if it's 5% overfill or 2%. Then you put in four milligrams, just for an example, into that,

injected. Now, you say sometimes you pull out four milligrams—

Ms. Marita Zaffiro: That was a general—let me just be clear. On, say, gemcitabine, we actually take the diluent out of the bag. It's a substantial amount and it pretty much empties—it takes 100 mls to actually dissolve the two two-gram vials. So you take out a hundred, you put it back in, but you've left the overfill in there. Then that particular drug expands by about five more mls, so you would have the 100 mls, the expansion volume, and the overfill that was in the bag.

Ms. Dipika Damerla: But your labelling would say four milligrams of drug—

Ms. Marita Zaffiro: In—

Ms. Dipika Damerla: In 100 millilitres—

Ms. Marita Zaffiro: In 0.9% bag.

Ms. Dipika Damerla: —plus expansion?

Ms. Marita Zaffiro: No.

Ms. Dipika Damerla: No, so plus 100 millilitres.

So this is where the dilution would have occurred, then.

Ms. Marita Zaffiro: That's right. If that was a concentration-specific bag, first of all, we would remove the excess and it would be stated as a milligram-per-ml final solution.

Ms. Dipika Damerla: So you were not giving the hospital, or Medbuy or whoever it is, concentration-specific—

Ms. Marita Zaffiro: We were not, nor were we labelling it as such.

Ms. Dipika Damerla: But my understanding, then, just following through the story, is that for some reason some hospitals thought they were concentration-specific, and that's where the challenge occurred.

Ms. Marita Zaffiro: Yes, that's what I understand.

Ms. Dipika Damerla: Now, what does your contract say, with Medbuy? Does it say—

Ms. Marita Zaffiro: The contract describes these products as non-concentration-specific. There are no concentrations, i.e. milligram-per-ml terminology, in the contract, nor on the labels that they approved and oriented the hospitals to.

Ms. Dipika Damerla: So whose responsibility would it have been to tell the hospital pharmacist that these bags—that this labelling is not concentration-specific, so that they could be more diluted? Whose responsibility would that have been?

Ms. Marita Zaffiro: To tell them?

Ms. Dipika Damerla: Yes.

Ms. Marita Zaffiro: I don't know that I can say whose responsibility it would be to tell them.

Ms. Dipika Damerla: Because you were creating them, right? So—

Ms. Marita Zaffiro: We were creating them. Through the transition with Medbuy, we discussed the products, how they needed to be made, how they were labelled. They approved the labels. They brought the labels to the hospitals for their approval and orientation. My expectation was that the professionals all through the chain, the pharmacists at Marchese, pharmacists at Medbuy, pharmacists in the hospital—my expectation is that all pharmacists through that chain would fulfill their responsibility in understanding what was being provided, understanding what the labels said and didn't say, using those products appropriately, and, if that was not acceptable, to identify that to us, and we would have created a new formulation for a different product that was a concentration-specific version of these drugs.

Ms. Dipika Damerla: Okay, so let me rephrase that: Is it common to have non-concentration-specific bags like this given to the hospital pharmacist?

Ms. Marita Zaffiro: It is very common. The majority of products that we make—antibiotics etc.—are made in a non-concentration-specific form, and they are labelled with that very same convention. It is much more unlikely to have a concentration-specific drug.

Ms. Dipika Damerla: But for some reason, some assumptions were made that these were concentration-specific drugs and that's how they were being administered. Would that be your understanding?

Ms. Marita Zaffiro: I would have to speculate that what they received previously might have been in that form if they actually purchased from another provider, but that would be pure speculation. We needed to work with the information we had and our consultation with Medbuy, and Medbuy pharmacists and the hospitals had the opportunity to see through the descriptors and the consistency of what was being provided, or what they could understand was being provided.

Ms. Dipika Damerla: Okay. Thank you very much.

The Chair (Mr. Ernie Hardeman): Thank you. We'll now go to the opposition. Ms. McKenna?

Mrs. Jane McKenna: Thank you so much, Ms. Zaffiro, for being here today.

My first question is this: Your contract is with Medbuy, and Medbuy is actually who wrote the contract, so they're solely responsible for that contract. So was your communication breakdown with Medbuy?

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Ms. Marita Zaffiro: I guess there are two points of communication: with us and Medbuy, and Medbuy and the hospitals.

Mrs. Jane McKenna: When the London Health Sciences Centre was here today, they said that they didn't oversee what was written in the contract. The contract was written by Medbuy, and the contract was between the two of you.

My next question is: London Health Sciences Centre, like I said, was here today and Sandy Jansen, the director of pharmacy services, mentioned that you were one of three on the short list, and when they got the label, that was the reason they decided to go with you, when they saw that with the RFP. But then when they received the label with the product, there was a question of the label was different. She said that she had spoken to Medbuy and I guess to yourselves to figure out what the difference was when they saw it in the short list and when they saw it with the product. Can you explain what the difference was?

Ms. Marita Zaffiro: I'm not sure what she's referring to. I do know that for gemcitabine, as the contract was beginning, it was identified that there was a slash used where the word "in" should be. London Health Sciences identified that, and that was clarified early in the process.

Mrs. Jane McKenna: So that was all rectified? That was cleared up—

Ms. Marita Zaffiro: Well, it was rectified, but it is—but it was clarified such that it said "in 100-m bag." So it didn't clarify to identify at that time that a concentration-specific product was being expected or assumed. But there was a conversation around that particular item.

Mrs. Jane McKenna: Okay. That seems like kind of it was a grey area there with her as well when she was—

Ms. Marita Zaffiro: Yes.

Mrs. Jane McKenna: My next question is: You're licensed by Health Canada. When was your last inspection?

Ms. Marita Zaffiro: I'm licensed by Health Canada? I don't believe I said that in my statement.

Mrs. Jane McKenna: Oh, okay. Sorry, I apologize.

Ms. Marita Zaffiro: It's only recently that Health Canada has laid out the provisions for this kind of activity, and one of them is under the supervision of a licensed pharmacist.

Mrs. Jane McKenna: Okay. Did—okay, go ahead.

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

Mr. Jeff Yurek: Thanks for coming in today. It's good to see you. Can you give us an overview of your accreditations in your pharmacy?

Ms. Marita Zaffiro: In our Hamilton location that previously provided service to most of HNHB CCAC for home intravenous therapy—during the years that we have been providing services to part of that region and then all of that region, we became one of the first pharmacies in Canada and the first in Ontario to be ISO-registered. Further, over time we then adopted the accreditation standards and were accredited by the Canadian Council on Health Services Accreditation, now known as Accreditation Canada. That's the body that accredits hospitals, long-term-care facilities and now many community organizations.

Those are our two accreditations. We're now in the process of actually accrediting our Kitchener location under ISO.

Mr. Jeff Yurek: And that clearly has a lot to do with quality?

Ms. Marita Zaffiro: It does indeed. Way back then, our desire was to be accredited by the American standard on home care infusion therapy, which was called JCAHO, but they unfortunately declined to come and accredit in Canada, and there was no similar standard. After much consideration and analysis, we decided to go to do ISO because Accreditation Canada also wouldn't accredit community pharmacy activities around sterile products preparation.

Mr. Jeff Yurek: And were there clear guidelines on what Medbuy expected from you in compounding the product? You stated earlier that maybe it was a little muddled—or was it clear, "This is the product we want"? Because you're saying—

Ms. Marita Zaffiro: No, I don't think it was muddled.

Mr. Jeff Yurek: No? It was fairly clear what they expected—

Ms. Marita Zaffiro: There was a lot of opportunity for discussion, and we have a lot of documentation going through these products.

Mr. Jeff Yurek: If you were offered, in the contract negotiations, to provide quality testing, batch testing, would you have complied with that?

Ms. Marita Zaffiro: We don't make any batch product. We make every product to order. Much like a community pharmacy would a prescription, if the order is our prescription, we do not combine orders across hospitals. We do not pre-make any product. So if a hospital wants 50 bags, we make that, and that's it. We make to order. The end-product testing is done on a periodic basis, but the need to do it in the same way as if you were batching and keeping stock on a shelf or had prolonged expiries is not as critical. So you're asking if I'd be willing to it? We do do some, and that's something that we could do more as our volumes or our demands increase.

Mr. Jeff Yurek: And have you ever heard any problems from your hospital regarding your labelling? Did they ever call you up? But I imagine they'd call Medbuy. Did Medbuy ever say—

Ms. Marita Zaffiro: No. They would probably call us, actually. That's pretty much how this started, with a call to our pharmacist on site from Peterborough to say, "Hey, the label says this, and there's more in the bag," so trying to understand, and she had identified that inconsistency with how they were using it and how it was labelled and prepared. They were a new purchasing hospital so this was their first dose that they were using, and they immediately identified that, "Oh, this is not right," and so they called us immediately, and that was how this issue began to be unravelled and discussed and understood.

Mr. Jeff Yurek: But the other hospitals never called to question—

Ms. Marita Zaffiro: No, it was never identified to us by any of the other hospitals.

Mr. Jeff Yurek: Would we be able to get a copy of the contract, the wording of it and stuff? Is that possible?

Ms. Marita Zaffiro: Yes.

Mr. Jeff Yurek: Thank you, Chair.

The Chair (Mr. Ernie Hardeman): Ms. Elliott.

Mrs. Christine Elliott: A few quick questions. Thank you very much, Ms. Zaffiro, for coming before the committee today.

You mentioned earlier that you had gone both to the College of Pharmacists and to Health Canada, and they declined to regulate. Can you describe that process and whether there's any correspondence that we could obtain that would confirm that?

Ms. Marita Zaffiro: There is some correspondence. There are also several conversations that are logged and

discussed. Basically, there was not a place—there was a gap—for what we were doing that wasn't covered in one regulation or the other. We informed that we were moving forward. We confirmed what our processes were, that a pharmacist would be overseeing that operation, and our hope was that—and the way we left it—we wanted to be regulated. So we were aware that Health Canada and OCP and perhaps other provinces were working on this, and we were monitoring and hoping to hear that there was soon to be the opportunity for us to be regulated.

Mrs. Christine Elliott: But it was very clear that both Health Canada and the College of Pharmacists were aware of this gap or grey area some time ago?

Ms. Marita Zaffiro: Yes. You understand that this gap has existed for a long time, and several practitioners provide service in this gap.

Mrs. Christine Elliott: Would you undertake to provide us with copies of that correspondence?

Ms. Marita Zaffiro: Yes, I can. I will.

Mrs. Christine Elliott: Thank you. My other questions just really relate to the issue with respect to hospitals seemingly not knowing that it was a non-concentrated solution that they were being provided with. In your opinion, should a pharmacist in a hospital have been able to tell that from looking at the labelling on the bag? Should there have been this confusion?

Ms. Marita Zaffiro: Should they be able to tell from the labelling?

Mrs. Christine Elliott: Yes.

Ms. Marita Zaffiro: All I can say is that the products we provided were not concentration-specific, they were not labelled as concentration-specific, and to use them otherwise would have been incorrect.

Mrs. Christine Elliott: So any reasonable pharmacist knowing how to practise would have been able to tell from the labelling on the bag that it was a non-concentration-specific product?

Ms. Marita Zaffiro: I think that there are a lot of recognized issues with labelling and interpretation and assumption. ISMP has identified that there is a need for a national labelling standard. The interfaces of communication, whether they're Marchese and Medbuy, Medbuy and the hospital, the hospital pharmacy and the floor, or the floor and the administrator: There are a lot of opportunities for that communication not to be as clear as it could be.

Mrs. Christine Elliott: In your discussions with Medbuy that led to your being awarded the contract, was there any discussion about who would be the provider of concentration-specific solutions? If you were to provide the non-concentration-specific one, who else would be providing the solutions that would have been the concentration-specific ones?

Ms. Marita Zaffiro: We would have provided it if we understood they wanted it. So, again, if there had been clarity there, if they had asked us, then I assume that we would have been the provider as well.

Mrs. Christine Elliott: But there was no discussion that you had with respect to the other type of solution and who was going to be providing it?

Ms. Marita Zaffiro: No, none at all. No.

Mrs. Christine Elliott: Thank you. Those are all the questions for now.

The Chair (Mr. Ernie Hardeman): The third party: Ms. Gélinas.

M^me^ France Gélinas: Thank you.

Some general questions: First, can you give me an idea of the size of your company? I'm looking at how many people work for you. Are they professional? If they are, what kind of credentials do they hold? Give me an idea of the size.

Ms. Marita Zaffiro: The group of companies employ 80 people across all those operations and locations. There are 15 pharmacists, several pharmacy technicians who are registered; many pharmacy assistants, customer service people, warehouse technicians etc.; and then administrative people and corporate services people.

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M^me^ France Gélinas: Okay. More specifically in MHS, how many people work in that division?

Ms. Marita Zaffiro: About 20.

M^me^ France Gélinas: And of the 20 who work there, how many pharmacists, how many pharmacy technicians, how many pharmacy assistants?

Ms. Marita Zaffiro: There are two pharmacists, one registered pharmacy technician, several infusion technicians and several warehouse technicians.

M^me^ France Gélinas: You'll have to forgive me; I don't know. What does a warehouse technician do in a pharmacy?

Ms. Marita Zaffiro: Just the logistics of preparing the order to be delivered—to be shipped to the hospital—and the packaging.

M^me^ France Gélinas: Okay. So two pharmacists, one regulated technician—I'm at 17. The infusion and warehouse: What's the breakdown between the two?

Ms. Marita Zaffiro: I don't have the exact numbers, to tell you the truth.

M^me^ France Gélinas: But the other 17—

Ms. Marita Zaffiro: The majority of the staff are infusion technicians. That's who produces the admixtures. So there might be at least 10 of them.

M^me^ France Gélinas: Okay. And the balance would work in—

Ms. Marita Zaffiro: Administration or customer service or the warehouse.

M^me^ France Gélinas: Where do you get your infusion therapists?

Ms. Marita Zaffiro: Technicians?

M^me^ France Gélinas: Technicians—sorry.

Ms. Marita Zaffiro: That's okay. Where do we get them? We recruit them. Many have been trained at our other operations, or we advertise for them, and they are usually college trained and then electively become registered technicians with the College of Pharmacists.

M^me^ France Gélinas: Okay. It's an elective, so they would be allowed to practise whether they are under the College of Pharmacists or not?

Ms. Marita Zaffiro: That's correct. They can be college-trained pharmacy technicians, but they're not necessarily registered technicians unless they get licensed with the Ontario College of Pharmacists.

M^me^ France Gélinas: Okay, sounds good. And could some of them not be college trained?

Ms. Marita Zaffiro: All of our technicians are college trained. Some are historically—they were certified pharmacy technicians. That's no longer a designation. Technicians are now licensed, and they have some additional scope of duty.

M^me^ France Gélinas: Okay. Coming back to some of what my colleague was talking about: You had this opportunity to bid on this new contract, you feel that you're able to deliver, you decide on a different corporate structure to handle this new work, but you were already preparing IV for your home care side. Why the need for the new corporate structure?

Ms. Marita Zaffiro: Marchese Hospital Solutions would have been regulated if it could have been regulated. But it would have been a new company, and it would have been Marchese Hospital Solutions. The reason for a new structure is that it's prudent. But besides that, this is a new business, a new location and a new type of customer. So the desire was to be able to focus on that unique element of our new business unit and to structure it that way.

M^me^ France Gélinas: Okay, but still under the overall corporation of Marchese?

Ms. Marita Zaffiro: It has the same brand name.

M^me^ France Gélinas: Okay.

Ms. Marita Zaffiro: These are separate corporations, and one does not flow into the other.

M^me^ France Gélinas: Okay, I get it.

When you entered into talks with—let's take them one at a time—Health Canada, which declined to regulate you, what was their reason for not doing so?

Ms. Marita Zaffiro: They were of the opinion that we could do what we were doing as a regulated pharmacy.

M^me^ France Gélinas: Okay, and you accepted that it was not in the purview of Health Canada to do this, and then you went to the College of Pharmacists. What happened?

Ms. Marita Zaffiro: They do not regulate the activity that Marchese Hospital Solutions was doing for hospitals.

M^me^ France Gélinas: So they were aware that you were doing those activities. Had you told the college that Health Canada had more or less refused to regulate you?

Ms. Marita Zaffiro: My understanding was that Health Canada and the college were in discussions around looking at this gap and how it was going to be addressed.

M^me^ France Gélinas: Did the Ministry of Health have any way of finding that out?

Ms. Marita Zaffiro: I don't know how.

M^me^ France Gélinas: Okay. You mentioned that there are other corporations that work similarly—you didn't use the word "corporation," but other people working in that grey area.

Ms. Marita Zaffiro: Service providers?

M^me^ France Gélinas: Service providers—good word. Could you name me some other service providers?

Ms. Marita Zaffiro: Yes, I think I did in the record. So—

M^me^ France Gélinas: Oh, sorry, it's been done? It happens.

Ms. Marita Zaffiro: I know.

M^me^ France Gélinas: So there are others that practise in Ontario and that are in the same—what has been called so far—"grey area."

Ms. Marita Zaffiro: We were aware that there was one; there was one provider and only one provider, long-standing—two hospitals for this service.

M^me^ France Gélinas: You started out this new corporation, you tried to get regulation, and you ended up putting in the best practices you could think of.

Ms. Marita Zaffiro: Correct.

M^me^ France Gélinas: When they talked about what you were preparing for them, they talked about bulk. Why would they use this if it was—

Ms. Marita Zaffiro: Who talked about bulk? I'm sorry?

M^me^ France Gélinas: The people who were there before you, when London said that you were preparing the drug as a bulk purchase.

Ms. Marita Zaffiro: No, I believe they were using the product as a bulk product. Please understand that what we have learned now is that hospitals were using our products in a way that we had no idea of. We did not know that they were using these for multi-patient use. It was not specified or discussed at any time during the year-plus of the contract being serviced.

M^me^ France Gélinas: I understand that they were 200-ml bags that you were delivering to the hospitals?

Ms. Marita Zaffiro: Yes, 200 ml plus the overfill.

M^me^ France Gélinas: Plus the overfill. So, in everybody's mind, a dose would have been four grams in 200 ml. Everybody who prepares it in your pharmacy thought that that was going to be for one single patient?

Ms. Marita Zaffiro: We prepare what Medbuy asks us to prepare. We do not evaluate what they ask for in the bag. We put the precise amount of drug in the bag that they request.

M^me^ France Gélinas: When you were dealing with Medbuy to get this contract—actually, we were told that Medbuy was just going to renew the contract with Baxter, and it was when you saw it posted that you asked that you be considered?

Ms. Marita Zaffiro: The way the process works—I'm sure you're all aware that there are procurement laws for public institutions in Ontario over $100,000. So Medbuy posted a notification that, to the best of their knowledge, there was only one provider of these services, and they intended to procure those services from that monopoly provider unless they heard otherwise.

Given that we had the experience and the facilities to demonstrate our capabilities and the desire to do what needed to be done to provide this service, we declared

that we thought we could provide the service if they were looking for an additional provider in their market in two hospitals in Ontario. So they came and visited our site in Kitchener and they seemed to be quite pleased that, indeed, we did have the ability to provide these services. They saw our facilities, our staff working, our systems etc.

So when they left, they said they were going to RFP. So it took some time, but that RFP began or was supposed to have begun, I believe, in February 2011. It didn't conclude till the middle of December 2011, and we provided service beginning the middle of February.

M^me^ France Gélinas: Okay. Who were you with at Medbuy?

Ms. Marita Zaffiro: Who was I dealing with at Medbuy? Actually, it was my staff who dealt with Medbuy directly; I did not. So if you need that information, we can make that available.

M^me^ France Gélinas: Yes, please, if you could table that with the Clerk, the people you that were dealing with. And who within Marchese—which one of your staff handled that—

Ms. Marita Zaffiro: Pharmacists were dealing with pharmacists between Marchese and Medbuy. So again, there was an expectation that pharmacists throughout that chain understand their responsibility in that piece of the process.

M^me^ France Gélinas: So from Marchese you had put a pharmacist or a licensed pharmacist in charge of this and he or she—who was it, anyway? I'll make it easier.

Ms. Marita Zaffiro: It's a she—shes.

M^me^ France Gélinas: She? What's her name?

Ms. Marita Zaffiro: It's shes—it's been several pharmacists that have had that relationship over time.

M^me^ France Gélinas: The initial?

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Ms. Marita Zaffiro: The initial one was—actually, we had a team of pharmacists who would be working on this. Do you want people's names?

M^me^ France Gélinas: Yes.

Ms. Marita Zaffiro: Janie Bowles-Jordan, Laura Savatteri—

M^me^ France Gélinas: You went too fast. Try again.

Ms. Marita Zaffiro: Can I give them to you—

M^me^ France Gélinas: Yes, you can.

Ms. Marita Zaffiro: I want to make sure I give you the right names and all the names, because it was a period of time in terms of that process.

M^me^ France Gélinas: And you know for a fact that the people they were dealing with at Medbuy were also pharmacists?

Ms. Marita Zaffiro: Yes.

M^me^ France Gélinas: Did any of them have experience dealing with oncology drugs before?

Ms. Marita Zaffiro: My staff?

M^me^ France Gélinas: Yes.

Ms. Marita Zaffiro: In the home care environment we had made several oncology drugs, but mostly 5-fluorouracil. Most of the oncology drugs in the home care environment were actually made by the cancer centres themselves and so were not administered in home care settings.

M^me^ France Gélinas: Okay. And for home care, it would all be an individual bag for an individual?

Ms. Marita Zaffiro: Correct.

M^me^ France Gélinas: So they never needed—

Ms. Marita Zaffiro: Which is what admixtures usually are. When we talk about an admixture, an admixture means a dose for a patient. If someplace it says we're making bulk stock solutions, then we understand that to be something different.

Now, you could use a non-concentration-specific product, but it would be very complicated and it wouldn't be worth the manipulation to actually use it for a multi-dose purpose.

Ms. Cindy Forster: I just want to follow up on Ms. Gélinas's question regarding the specific dosage. You were under the impression that these were going to be one dose, one patient. I don't think that we've heard from any of the hospitals at this point as to what a normal dosage of either of these two drugs would be, but I'm assuming that the dosage that was in the bags that you actually prepared is significantly greater than one patient would be administered at any one time, and I wouldn't expect that a minibag would be administered partially and then used again on a subsequent day for chemotherapy. So my question is, was there more than a one-patient dose, based on an average-size body mass, in that bag, and would it be reasonable to expect that pharmacists would pick up on that at your facility if your assumption was that this one bag with this dosage of drug was going to one patient for one treatment?

Ms. Marita Zaffiro: Our responsibility in providing the service to hospitals is to ensure that we combine the products that they ask for in a sterile environment with very high quality-control standards. Our role is not to evaluate what the hospital asks us to make in terms of the clinical appropriateness of what they put in the bag. We are not physicians, we are not working directly with patients. We have that limited role, and we did not see that as our responsibility in this service process.

Ms. Cindy Forster: Do you have any comment, though, with respect to the dosage of the drug that was actually in a bag that you assumed—

Ms. Marita Zaffiro: We certainly have come to understand that the dosage could be—there was four grams in the bag. The dosage could be possibly anywhere from 500 milligrams to 2,000 milligrams per person. But you know what? I'm not an expert in oncology.

Ms. Cindy Forster: Okay. Thank you.

M^me^ France Gélinas: So you put in some effort to try to get oversight, to try to get accredited either by the college or by the federal government. Had the Ministry of Health asked you to comply with regulation, any doubts that you wouldn't have followed?

Ms. Marita Zaffiro: No, of course not. In fact, we have submitted thousands of pages of documents, and my understanding is that Health Canada has indicated that

we have appropriate measures in place. So the lack of regulation or regulations would not necessarily have prevented this incident.

M^me^ France Gélinas: You really focus on communication. You prepared the drugs the way they wanted them to be labelled and prepared—

Ms. Marita Zaffiro: That is correct.

M^me^ France Gélinas: —and they used them in a way that was not labelled or prepared.

Ms. Marita Zaffiro: We had no way of knowing how they're using them. What is becoming apparent is that different hospitals use them in different ways. Reading some of the testimony, it sounds like some hospitals think the labels are okay and accurate and some think that they're wrong. So, again, if there is that degree of inconsistency amongst the hospitals, then you can appreciate that we needed to make a consistent, high-quality, sterile product. Hospitals are responsible for understanding what they're receiving, how they use it, how they administer it and the patients who need it.

M^me^ France Gélinas: We'll save our time.

The Chair (Mr. Ernie Hardeman): You have about three minutes left.

M^me^ France Gélinas: I'll use them wisely.

The Chair (Mr. Ernie Hardeman): Okay. Thank you. Yes, Ms. Damerla?

Ms. Dipika Damerla: Thank you, Chair.

As you know, the government is proposing some new regulations. Can you tell us how that would impact your business?

Ms. Marita Zaffiro: It will be positive in terms of having clear expectations and standards around regulation, but I believe that it will not require a lot of changes in the way we operate, our processes or our systems. I'm fully open to working with the college and Health Canada to help inform those standards and expectations and utilize our expertise and our systems to make that more easy to happen.

Ms. Dipika Damerla: You said that your process wouldn't change much because of the proposed regulations. What would change, though?

Ms. Marita Zaffiro: I think just the clarity of the fact that this kind of service can be conducted under the supervision of a licensed pharmacist. Whether that will be a pharmacy or not, I don't know. They're releasing some potential changes to the regulations for comment. I have not had a chance to review them. So I don't know; it will depend on what they come up with.

Ms. Dipika Damerla: Has the college or Health Canada visited your facility since this issue came to light?

Ms. Marita Zaffiro: Yes, they jointly visited our facility and were given access to both the regulated and non-regulated portion of the facility.

Ms. Dipika Damerla: Can you further describe your communication with the college or Health Canada or Dr. Thiessen?

Ms. Marita Zaffiro: We met with Dr. Thiessen. He met with me and some of my staff. We've been in communication with both Health Canada and the college, several letters—Health Canada, OCP and the Ministry of Health have been working together, and so jointly they requested and, I believe, reviewed documentation that we provided and questions that we answered, along with their site visit, to satisfy themselves that we have appropriate measures in place.

Ms. Dipika Damerla: I'd like to revisit the issue of—you created a new entity which was Marchese Hospital Solutions. You created this after winning the contract. Were you aware that by creating this, you would lose oversight?

Ms. Marita Zaffiro: Yes, but you have to understand, we wanted—actually created it, and we wanted it to be accredited. So we were working, at the same time—this was a very short period of time—to actually get it accredited and get it started up. So Marchese Hospital Solutions ideally would have been an accredited pharmacy or accredited by Health Canada.

Ms. Dipika Damerla: Right. Okay; thank you. I'll turn it over to my colleagues.

Mr. Lorenzo Berardinetti: We're fine.

The Chair (Mr. Ernie Hardeman): Thank you. You have one minute left.

Mr. Lorenzo Berardinetti: Okay. We'll save it.

The Chair (Mr. Ernie Hardeman): Thank you, Mr. Berardinetti. Ms. Elliott?

Mrs. Christine Elliott: Thank you. You've indicated that you've had communications with both Health Canada and with the College of Pharmacists. Have you had any communication, either before or after this problem surfaced, with either the Ministry of Health or with Cancer Care Ontario?

Ms. Marita Zaffiro: The Ministry of Health was involved in arranging the conversation I had with Dr. Thiessen, so there was a phone call there. This was subsequent, of course, to the incident. I have had no communication whatsoever at any time from Cancer Care Ontario.

Mrs. Christine Elliott: And the ministry was aware that you were setting up this new business, I'm assuming, or—

Ms. Marita Zaffiro: How would the ministry know? I'm sorry; I don't know how that—

Mrs. Christine Elliott: But you've never been contacted by anyone until you were approached to have the conversation with Dr. Thiessen?

Ms. Marita Zaffiro: No. When we were contacted through Health Canada, it was clearly stated that their inquiry of Marchese Hospital Solutions and the information they were requesting was done for the purposes of Health Canada, OCP and the Ministry of Health and Long-Term Care to use to understand what we were doing, how we were doing it and what controls we had in place. So the ministry—I mean, it was not a personal contact, but it was through that process that—

Mrs. Christine Elliott: So presumably the Ministry of Health was brought into the loop that there was an issue.

Ms. Marita Zaffiro: I couldn't speculate. I don't know; I'm sorry.

Mrs. Christine Elliott: But they never contacted you directly, and you've not had any contact with them until recently.

Ms. Marita Zaffiro: No, I don't think so.

Mrs. Christine Elliott: Okay. Thank you.

1730

The Chair (Mr. Ernie Hardeman): Ms. Gélinas?

M^me^ France Gélinas: Just to check: Medbuy approved of your labelling, and you complied with whatever labelling Medbuy had asked you to submit?

Ms. Marita Zaffiro: Yes.

M^me^ France Gélinas: Okay. How big a contract was that for you? Just give me a size.

Ms. Marita Zaffiro: Financially?

M^me^ France Gélinas: Yes.

Ms. Marita Zaffiro: Well, I know that we've produced about 460,000 units of infusion bags in the life of the contract, so let me just do some math.

M^me^ France Gélinas: Keep me in the loop there. That's 460 times—

Ms. Marita Zaffiro: I really am estimating; I'm sorry: about $2 million.

M^me^ France Gélinas: About $2 million, and when you first got the contract—there was a competitive process. When you first got the contract, do you figure—you provided economies of scale, you provided economic benefits to the hospital. Had you been way more expensive than hospital staff mixing those drugs, do you figure you would have gotten the contract?

Ms. Marita Zaffiro: I don't think that's the primary reason to outsource admixture production. As you heard, or if you see our facility, it is a large facility. It is built to the standards of 797—a very significant investment to do that. Most hospitals would not be able to do that, nor does it make sense for every hospital to have a 797-level facility. It makes sense in terms that if hospitals aren't, say, making chemo on a regular basis, then their staff can't really maintain their competency if they're not doing it all the time. The opportunity to centralize a repeatable operation, maintain staff competency and ensure a higher level of quality and a higher level of safety, along with economies of scale—that ideally would give you some opportunity to keep more of the health care drug budget in the hospital's hands and direct it to patient care.

M^me^ France Gélinas: So what do you figure in your proposal—they selected you; they could have gone to two different ones. Do you have a feeling as to how come you were successful when the other two were not?

Ms. Marita Zaffiro: What we were told, as I said earlier, is that our labelling, at their request, was able to utilize two or three important safety elements. One was ISMP-recommended, but not required, tall man lettering, and colour coding and alert labelling. They found that this was clear. This was something they wanted. I assume this was something that was not available to them previously.

In terms of price, I have no idea. However, I know that the way we provide this service is a bit of a unique business model, so what they had requested and what we were doing was a little different. We provide the service, and our revenue comes from the service of compounding the admixture. The cost of the medication is a flow-through and is not marked up. That means there is likely a positive financial benefit to the hospitals that use this service over the existing or pre-existing arrangement. However, I am not privy to the exact details of the pre-existing arrangement.

The Chair (Mr. Ernie Hardeman): I'm glad you've used it wisely, because it's all gone. Thank you very much.

The government side, you have one minute left.

Mr. Lorenzo Berardinetti: We're fine, thank you.

The Chair (Mr. Ernie Hardeman): Okay. Thank you. The opposition, do you have any further questions?

Mrs. Christine Elliott: We're fine. No further questions.

The Chair (Mr. Ernie Hardeman): No further questions? Then that concludes the events today. Thank you very much for making your presentation, and we look forward to further deliberation on this issue.

With that, the committee stands adjourned until 4 o'clock tomorrow afternoon.

The committee adjourned at 1734.

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