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Monday 10 June 2013

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Lundi 10 juin 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
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Hansard Reporting and Interpretation Services
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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON SOCIAL POLICY

COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Monday 10 June 2013

Lundi 10 juin 2013

The committee met at 1522 in committee room 1, following a closed session.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

The Chair (Mr. Ernie Hardeman): I call the meeting to order. Thank you all, first of all. We thank all of you for being here this afternoon to help us as we proceed in looking at the issues of the day here on the committee, looking at the chemotherapy—here it is. I was looking for the right page: a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies. And with that, thank you very much. We do conduct these hearings under oath or affirmation to make sure that we're getting the facts as you see them.

MARCHESE HEALTH CARE

The Chair (Mr. Ernie Hardeman): I believe the first one is the president. I believe she has been sworn in at a previous meeting, so that swearing-in will be sufficient. With that, we'll turn it over to the Clerk for the rest of the delegation to be sworn in or affirmed.

The Clerk of the Committee (Mr. William Short): I'll just start on my right to left, I believe. So Ms. Francis-Pringle, correct?

Ms. Sophia Francis-Pringle: Yes.

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

Ms. Sophia Francis-Pringle: I would rather affirm.

The Clerk of the Committee (Mr. William Short): Okay, so just right hand in the air, please. Ms. Francis-Pringle, 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. Sophia Francis-Pringle: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Then Ms. Cuerrier, I believe.

Ms. Kathy Cuerrier: Yes.

The Clerk of the Committee (Mr. William Short): You wanted to swear an oath?

Ms. Kathy Cuerrier: I will.

The Clerk of the Committee (Mr. William Short): And you have the Bible in front of you there?

Ms. Kathy Cuerrier: Yes.

The Clerk of the Committee (Mr. William Short): Thank you. Ms. Cuerrier, 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. Kathy Cuerrier: I do.

The Clerk of the Committee (Mr. William Short): Thank you. And Ms. Bowles-Jordan: Did you want oath or affirmation?

Ms. Janie Bowles-Jordan: Oath.

The Clerk of the Committee (Mr. William Short): Ms. Bowles-Jordan, 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. Janie Bowles-Jordan: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Ms. Gilbreath, same thing. Oath? Ms. Gilbreath, 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. Stephanie Gilbreath: I do.

The Clerk of the Committee (Mr. William Short): Thank you. And Ms. Zaffiro, you'll just remain under oath.

The Chair (Mr. Ernie Hardeman): Thank you very much for that. And with that, we will start. Collectively, you will have 20 minutes to make your presentation. Upon the conclusion of your presentation, we will have some questions, 20 minutes from each caucus. We will start this round with the official opposition.

With that, the floor is yours.

Ms. Marita Zaffiro: Thank you, Mr. Chairman, for inviting me back to assist your committee further. I appreciate the opportunity to address any additional questions you may have. To assist the committee I have invited Marchese pharmacists Stephanie Gilbreath, Janie Bowles-Jordan, Kathy Cuerrier and Sophia Francis-Pringle. I would ask that they now briefly introduce themselves, their backgrounds and their roles.

Ms. Stephanie Gilbreath: Good afternoon. My name is Stephanie Gilbreath. I have been a pharmacist registered with the Ontario College of Pharmacists for almost 15 years. I have worked at Marchese Health Care for over six years and have gained experience in palliative

care, home infusion, diabetes, injections, immunizations, and smoking cessation.

In late 2011, I became the designated pharmacist manager of the Hamilton site of Marchese Health Care. I've also been a preceptor for fourth-year University of Toronto pharmacy students for many years, and am currently a preceptor for an international pharmacist intern.

I was one of six pharmacists involved in checking the mixture breakdowns for the Medbuy admixtures. When Marchese was first awarded the Medbuy contract, we developed a project plan with various tasks of implementation. These included facility needs, IT, regulation, policies and procedures on admixtures, costing, quality measurement, and administration, including hiring. We developed what we call mixture breakdown protocols for making each of the approximately 120 Medbuy products.

The pharmacists worked independently on checking the mixture breakdowns. We then double-checked—sometimes even triple-checked—the other pharmacists' work for each product. Our checking ensured that the proper ingredients, amounts, stabilities, and calculations were all correct.

I believe that having multiple pharmacists involved, checking and consulting with each other, would lead to the most accurate way possible of producing the Medbuy products as described and specified on the list given to us. I believe members of the Marchese team were doing their due diligence to support a successful transition. I was informed that the hospitals had been receiving these items previously and that Medbuy had approved the labels Marchese had developed in response to Medbuy's list.

Ms. Janie Bowles-Jordan: Good afternoon. My name is Janie Bowles-Jordan. I graduated from the University of Toronto in 1990 with a bachelor of science in pharmacy, and I completed a hospital residency and was licensed in 1991 by the Ontario College of Pharmacists.

Between 1990 and 1996, I worked at St. Joseph's hospital as a clinical pharmacist. That's in Hamilton. In 1996, I began working for Marchese pharmacy. I was involved in specialty compounding and formulating custom medications, including sterile preparations.

Between 2000 and 2006, I was the pharmacy services manager for Marchese Health Care in Hamilton. My responsibilities included management of sterile facilities, training staff, and development of sterile compounding procedures to service clients with infusion medications. From June 2006 to the present, I have worked part-time at Marchese Health Care as a staff pharmacist in Hamilton. Since 2010, I have been an adjunct clinical assistant professor at the University of Waterloo's School of Pharmacy.

I was involved in the start-up of the Medbuy transition as part of the pharmacy team. My main responsibility was to research best practices to comply with USP 797 standards and research data for the products on the Medbuy list. At the time, I was informed that the listed products had been produced by the previous provider, Baxter CIVA. We were not provided, however, with the previous supplier's labels or formulas. Our focus was on the physical stability of the formulations to ensure the highest-quality product.

Our understanding was based on the following: Clinical patient parameters were not provided and we were neither able nor required to check doses; policies and procedures for administration to patients were based on each individual hospital's standards; and oncology pharmacists in hospital would be involved in these clinical responsibilities.

Ms. Kathy Cuerrier: Good afternoon. My name is Kathy Cuerrier. I am a licensed pharmacist and received a bachelor of science in pharmacy from the University of Toronto in 1991.

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I have worked part-time at Marchese Health Care since 2010. Between 2008 and 2010, I worked at Marchese as a relief pharmacist. I have been involved in dispensing, infusion services, special health product services and medication management.

I also had some responsibility for checking the mixture breakdown protocols you just heard about from Stephanie and Janie. As she said, when Marchese was awarded the Medbuy contract, a number of pharmacists checked and rechecked the preparation procedures to ensure that all procedures and calculations were correct.

We were guided by the list of products provided by Medbuy and the labels we prepared that were approved by Medbuy. Since the admixtures we prepared were not patient-specific, we deferred all clinical considerations concerning dispensing, administration and management to the hospital professionals who would deal with individual patients.

Ms. Sophia Francis-Pringle: Good afternoon, ladies and gentlemen of the committee. My name is Sophia Francis-Pringle. I'm a pharmacist qualified in Ontario. I was originally educated at the University of Technology, Jamaica and later at the University of Florida, Gainesville, USA. I hold a doctor of pharmacy postgraduate degree from the University of Florida.

I'm also a board-certified ambulatory care pharmacist and a certified geriatric pharmacist. I was granted certification of licensure as a pharmacist by the Ontario College of Pharmacists in 2010.

I was employed full-time by Marchese Health Care from May 2010 to May 2012. Before working at Marchese Health Care I worked in the Cayman Islands for seven years in various capacities as a pharmacist.

While at Marchese, I was involved in checking the mixture breakdown protocols that my colleagues have spoken about. I agree with their comments about being guided by the list of products provided by Medbuy. I also agree that clinical considerations respecting dosage were deferred to hospital professionals.

The Chair (Mr. Ernie Hardeman): Thank you. Back to you.

Ms. Marita Zaffiro: Thank you. I would also like to address a number of issues that have arisen since my last appearance:

(1) Why did Marchese Hospital Solutions supply concentration-non-specific gemcitabine and cyclophosphamide?

(2) Why did Marchese Hospital Solutions think the IV bags would be used as single doses?

(3) Why was outsourcing to Marchese Hospital Solutions appropriate?

(4) Why Marchese Hospital Solutions had appropriate standards in place.

(5) Why Marchese Hospital Solutions' pricing structure is consistent with high-quality admixtures.

As I stated when I first appeared before the committee, our belief was that the chemotherapy drugs were intended for a single patient. This was a good-faith and reasonable understanding on our part for a number of reasons.

The obvious starting point was our contract with Medbuy. The contract specified the services Marchese was to provide. As you know, the contract contained an alphabetical list of about 120 admixtures. This list of preparations was the basis of our understanding of the non-concentration-specific nature of gemcitabine and cyclophosphamide.

Medbuy listed the preparations in two basic formats: Some were listed in concentration-specific format; other, and indeed most, preparations were listed in concentration-non-specific format. This included various IV solutions of antibiotics, amino acids and stomach acid suppressants.

In listing the two chemotherapy drugs at issue in a concentration-non-specific format, this suggested to us that the contents of the IV bags for these preparations were intended for use in a single patient.

As part of the RFP process, Marchese was asked to supply a set of sample labels. Medbuy provided copies of Marchese's proposed sample labels to the committee. Those initial sample labels submitted as part of the RFP process were exactly that: samples. They were examples of all the possible data fields on the labels which could be populated if desired, and this included concentration specificity.

After the sample label formats were approved, Marchese then focused on Medbuy's list as contained in the contract. It described gemcitabine and cyclophosphamide in a concentration-non-specific format.

After our technical review process, we prepared a complete library of 124 labels for Medbuy's approval. I want to emphasize to the committee that the description of admixtures on the list was prepared by Medbuy without input from Marchese.

It was not our role to review Medbuy's list to determine whether it was clinically appropriate. We understood that Medbuy's pharmacists and member hospitals had made that determination before the list was made a schedule to the contract. Our responsibility was to ensure that our labels and admixtures conformed to what was ordered, as specified in the list which was a schedule to the contract. The labels Marchese prepared for all admixtures, including cyclophosphamide and gemcitabine, were sent to and approved by Medbuy's pharmacy team and their hospital members before any admixtures were shipped.

Marchese was never provided copies of Baxter's labels or mixture breakdown formulas. We were told that they could not be provided to us for proprietary reasons. Had we seen Baxter's labels, we would have noticed the difference. We would have inquired as to why there was an apparent change. Baxter's labels for these two preparations specifically indicated a milligram-per-millilitre concentration statement, which we understood to be a concentration-specific admixture. Our preparations did not include this statement, as it was not included in the Medbuy admixture list.

Similarly, we understood from Medbuy that the hospitals had been given our labels for review and training purposes. Had Medbuy or one of the hospital pharmacies noticed the difference, the issue could have been raised and addressed before preparation and delivery under the contract.

As it was, we understood that the majority of preparations, including cyclophosphamide and gemcitabine, were to be supplied by Marchese in a concentration-non-specific format and that this was acceptable to Medbuy and its hospital members.

Also, in January 2012, a month before the contract commenced, there was an exchange between a Marchese pharmacist and Medbuy's manager of clinical services and patient safety referring to the chemotherapy preparations. The email string, copies of which I have brought with me today and provided to the Clerk, concerns the attachment of various lines or tubes to the bags. We had raised with Medbuy the possibility of attaching a line to the bags as a safety precaution to protect nurses who administer them from any unintentional exposure to these toxic drugs. Medbuy's representative said he didn't want the lines because he expected different hospitals might have different requirements. He stated in this email, "Members will still be putting on a patient-specific label in the pharmacy and can attach a line, if desired, at that time."

This also suggested to us that Medbuy's understanding, and therefore our understanding, was that these bags would be used for a single patient.

I would like to respond to questions raised by the committee as to whether outsourcing the preparation of admixtures is an appropriate practice or whether this should always be undertaken in hospitals.

Dr. Thiessen discussed this issue with the committee after visiting the MHS premises in Mississauga. He described the process for reconstituting cyclophosphamide and gemcitabine. He indicated that it can take up to four hours to prepare, which can be a burden on a busy hospital pharmacy department. Dr. Thiessen's opinion was that it was a "big advantage" to have an outsource supplier prepare admixtures for hospitals.

I agree with Dr. Thiessen's observations. Providing high-quality admixtures is complex and technical. It is better undertaken by specialists in sterile, state-of-the-art

facilities, leaving hospital pharmacies to focus on direct clinical patient care.

I would also like to respond to general questions about the quality of Marchese Hospital Solutions' facilities and processes, as well as any suggestion that our practices, staffing or products were somehow inferior to the previous supplier or others in the industry.

Dr. Thiessen informed this committee that, "Only quality, approved pharmaceutical products and diluents were used." He continued, "There is no evidence of any malicious or deliberate drug-sparing dilution in preparing the bags of cyclophosphamide or gemcitabine by Marchese."

Dr. Thiessen told the committee about the benefits MHS brought to hospitals by providing admixing services. He said we have the "finest facilities" and added that no hospital he had visited had a facility to match ours. He commented that it is "splendid in its configuration, in all the things that they have as checks and balances. They have very detailed requirements around how things are produced."

Dr. Thiessen is not alone in his views that MHS is well-equipped to supply admixture services. Medbuy member hospitals have inspected our premises. The consistent testimony before this committee has been that our processes and standards are of the highest level. Our customers have repeatedly told us we operate at a high professional standard.

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The Marchese team of pharmacists and technicians collectively bring years of professional experience to bear. However, they are only one third of the triumvirate described by Dr. Thiessen. Pharmacists at Medbuy and in the hospitals are also engaged, and each has a different role. The system is designed for the three parties to work together, but each with distinct roles. We must all ensure preparations ordered by a GPO are precisely those required by its member hospitals. Furthermore, we must communicate to ensure that the admixture service prepares exactly what is ordered by the hospital, and that the hospital pharmacists fully understand the admixture supplied to them.

The hospitals have clinical contact with patients. Marchese Hospital Solutions has no individual patient information. Therefore, our role does not include any assessment of clinical factors.

The incident demonstrates that the system did not work in this case, but the failure could have been avoided. A simple line in the contractual requirement, milligram per millilitre, would have provided the appropriate concentration specificity, and none of us would be here today. An opportunity to review and compare our label with that of our predecessor would also have prevented the problem.

I would now like to deal with the question of the pricing of our admixtures.

Last week, after Baxter Corp. appeared, concerns were raised about our pricing for the two chemotherapy admixtures. It is misleading to suggest that there is any link between the incident and any difference in price between Baxter CIVA and MHS. As specified in the RFP process, we were not required to include in our price the cost of the drugs included in the admixtures, only the cost of labour, overhead, containers, packaging materials and shipping. We believed it made sense to price based on the size of the bag that preparations would be delivered in—50, 100, 200 or 250 millilitres—rather than pricing individual admixtures based on the type of drug, amount of processing time or value added to the hospitals.

The same meticulous quality control process was set up in our facilities to prepare all admixtures no matter what drug was admixed or what preparation steps were involved. There is no basis in fact for any suggestion that the miscommunication on concentration specificity had anything to do with pricing. There is no rational connection between pricing and this incident, in our opinion.

So what happened here? We still have to wait for your report and Dr. Thiessen's report to understand everything, but what we now all know is that there was miscommunication and an unsuccessful transition that resulted in needless anxiety to many patients. Marchese took the position early on that we could best serve patients by only talking about things that we were certain of. We decided that we should focus our energy on working together with the other members of Dr. Thiessen's triumvirate to understand what happened and how to prevent a recurrence.

However, in spite of this, we were publicly accused of consciously watering down cancer drugs for profit—this was not true, as Dr. Thiessen noted; manufacturing substandard products—this is not true, as the committee has already heard; ducking regulations—the evidence clearly shows that nothing could be further from the truth; and disregarding the health of patients—which is the exact opposite of Marchese's philosophy. Patients are the reason we are all involved in health care.

We all owe a debt of gratitude to the people in Peterborough who very quickly and competently saw that there was a mismatch between their hospital's expectations and the admixture in their hands. From the moment we heard about the issue, we have been trying to fully understand what went on and help fix the system so that no patients ever have this experience again.

We would be pleased to answer your questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your statement today. With that, we will start with the questions from the official opposition.

Mrs. Jane McKenna: Hi. Thank you so much for coming back, Ms. Zaffiro. Just a few questions from myself, and then Ms. Elliott will take over.

When we had Baxter in here, they said that they had been doing this process for 27 years, and when they found out that they had lost to you, they asked why they had lost, and they clearly told them that it was not the fact that it was the price; it was everything to do with the label. So I said to them, "Gee, after 27 years of being in business, I would want to know specifically what that was, just because"—you know, that's your business. So

27 years, and all of a sudden, now you've got a label issue.

I think you've said this already, but at any time did you see their label at all—Baxter's label?

Ms. Marita Zaffiro: No.

Mrs. Jane McKenna: So the next thing is, when you were in here before, you had mentioned—the committee has said a few times that when they got the RFP, the label that you had sent over, it was different than when they actually had the delivery of the label. So what was the difference?

Ms. Marita Zaffiro: This is in my remarks.

Mrs. Jane McKenna: Yes, go ahead.

Ms. Marita Zaffiro: We provided sample labels and we populated every field that could be populated. So we have a program where line 1 would be the name of the drug etc. So everyone had every possible piece of information on it so they could see what was possible, along with the bar-coding, the boxed information, the tall man lettering and the other enhancements to the label. So they could see basically the menu of what they could have on their labels, what was possible. Those were the samples of what we could produce.

Mrs. Jane McKenna: Next, do you understand—like this huge difference in pricing. Yours was $5.60 and Baxter's was $34. That would have been a red flag for me, but besides that, what is the massive difference from your pricing to their pricing? I know you can only speak on your own, but I'm just saying that's a huge difference.

Ms. Marita Zaffiro: It is. I could only speculate and I'd rather not speculate here.

Mrs. Jane McKenna: No, no, that's fine—

Ms. Marita Zaffiro: If you have to have a business conversation outside—

Mrs. Jane McKenna: Yes.

Ms. Marita Zaffiro: —because it would be pure speculation. I have no idea.

Mrs. Jane McKenna: Okay.

Ms. Marita Zaffiro: I couldn't even possibly say. It wouldn't be right for me to speculate on that, but I think it's a reasonable question.

Mrs. Jane McKenna: Yes.

Ms. Marita Zaffiro: If you had the full analysis—I don't think I said it in my remarks, did I? For example, you may find that they priced on a value-added basis. Chemo is complex. Chemo is dangerous. They might have weighed their pricing in that regard. Forty per cent of the volume I think was cefazolin and 50 millilitres of diluent—easier to do, simple, high volume. So maybe Baxter's price is lower than mine. I don't know. So their pricing strategy could have been vastly different, but we were told the same thing in our debrief, that it wasn't about price, that on price it was very close. So if you added one unit of everything that we quoted on and totalled that up, that may be the case. Again, I'm not privy to that, but that would be one way you could arrive at that and a strategy that might cause that kind of discrepancy.

Mrs. Jane McKenna: Then my next question is, when Baxter was here—because they had the contract prior to going through Medbuy, they continued the process with the hospital like they didn't have a contract. What I mean by that is that they were constantly communicating back and forth with the hospital. They just continued what they were doing prior to having Medbuy come in. So was your relationship with what you were doing similar to what Baxter was doing, communicating back and forth with the hospital? Or yours was just strictly with Medbuy and no communication at all with the hospitals?

Ms. Marita Zaffiro: We had communications back and forth with Medbuy, Medbuy pharmacists, some of the hospital member pharmacists directly and through Medbuy during that transition process, and that's what informed the final label set. So that communication I read to you was once of those communications.

Mrs. Jane McKenna: Okay. So the communication going back and forth was strictly yours with Medbuy?

Ms. Marita Zaffiro: Medbuy was the quarterback, I guess I would say, in that transition. So the expectation was not that we visited 30 hospitals to talk about 124 products before we prepared them; that would be pretty impossible. These products were already specified. They'd been using them. They had developed them over those 27 years with Baxter as the only provider in the market, so this was an opportunity to look at, can these very technically specific products be prepared by another provider at a better price?

Mrs. Jane McKenna: I'm just saying for myself, like if I had a financial planner, that would be a broker that should know the product they're selling and the product they're explaining to me. Do you feel that Medbuy being the broker, knowing what they were getting from you and also selling to the hospitals, your communication was—I realize that it wasn't obviously what it was supposed to be. But to me, I'm not sure how you would have known the questions to ask if they didn't give you all the details on what to ask. To me, that's where the communication drops because—I'm not an insurance person, so I don't have all the questions to ask. It's the person who is the insurance broker who tells me what to ask so that I know what the heck I'm buying.

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My question to you is: When you're in that situation—because this was your first situation here; you hadn't done it before. You were the ones who actually came to Medbuy to say that you could bid on this RFP. Did you have enough information to come to the table with that, or did you feel that it was up to Medbuy to educate you on what you needed to know?

Ms. Marita Zaffiro: I think that Medbuy, through their hospital members, who are Medbuy—if they've delegated their diligence to the pharmacists at Medbuy. But we have a chain of pharmacists here. So our role was the technical, quality, accuracy and consistency of the final product, and we used what we had available to us to define what that was and we confirmed that with Medbuy.

Medbuy, as we said, took the label set and any information that we shared—that would be our expectation—back to the hospitals. So we feel that we've had a process that has taken multiple pharmacists' brains and experience to work both independently and to consult, to question and to create questions that went back to Medbuy, and then to bring that back to our final product. The reflection of that work is the label set, and the opportunity to identify that these two products were out of alignment was the lack of a specific concentration that pre-existed on Baxter's product. So if what happened in Peterborough happened with the very first shipment in the very first hospital and the very first dose, then we would have been able to make the product that was required. It was a different product, and it would have a different code, but we would have been able to respond in a very short time in that regard.

Mrs. Jane McKenna: Okay. Christine, go ahead. That's good for me, thanks.

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

Mrs. Christine Elliott: Thank you. I'd also like to thank you, Ms. Zaffiro, for coming today with your pharmacist colleagues. I'd like to just ask a few more questions along the same lines as what Ms. McKenna was asking you. When you first received the RFP, can you explain to us the process of due diligence that you went through? What happened in order for you to be able to put your proposal together?

Ms. Marita Zaffiro: First of all, prior to the RFP being released, you're aware that they released a notice, I guess, under procurement that said, "We think there's only one company that can provide this. If you think that you can offer an alternative, let us know." We indicated that we thought we had the expertise to do that based on our many years of doing sterile intravenous products to the home care market as CCAC providers. So we indicated that. Medbuy came and inspected our current facility in Kitchener and was satisfied that, indeed, we could provide that service. I'm not sure that we were known to Medbuy, per se, before that.

When we responded to the RFP—and we have a lot of experience in responding to RFPs, because the value-for-money competitive model that CCACs use is very, very well developed. We would have talked about what our experience was; what our quality systems were; what kind of KPIs, or key performance indicators, we would monitor; how we monitored customer feedback—in this case, it would be hospitals—how we tracked that and what our record was; what our staffing was; what our experience was etc.

Most importantly we would have looked at that list of products in G2 and said, "Can we make these?" So, again, technically, we had experience with various types of products, and we felt that we could make these products in our sterile facilities.

Mrs. Christine Elliott: Did you have any face-to-face meetings with Medbuy before you submitted this proposal with respect to these two particular products?

Ms. Marita Zaffiro: No. A lot of it was handled by our general manager, and I don't think that we did. We had some communications because this proposal was indicated or anticipated to come up much earlier than it did, and there was a bit of a time pressure, I believe, because the contract with Baxter was expiring. So it came out, it had a fairly short time to respond and then it was evaluated quite quickly. And once it was awarded—again, a very short time to implement.

Mrs. Christine Elliott: Okay. And so you based your decisions with respect to the proposal on the understanding—and most of your document talks about your understanding that they were going to be single-use bags of solution. Was that ever specifically discussed with Medbuy? Did you ever specifically ask that question and get an answer to that?

Ms. Marita Zaffiro: I think the contract actually specifies that these are single doses to patients, if I recall. These are single doses. The majority of products are. I think the logic would tell us that if they weren't, that would be specified as multi-use product. That would have been the important factor to have been told.

Then we're looking at all sorts of different considerations if this was a multi-use product. I mean, some of the research—I'm not sure why you would take a cytotoxic product and then further manipulate it. I understand that these are very patient-specific in terms of their dosage calculations, so it would probably make sense to just be done in the hospital to begin with. The value of doing a cytotoxic and then further manipulating it and taking the risk around expiry dates, sterility etc., once you're using it in any way, it invalidates everything that we've done from a quality control perspective and any control we had or warranty over that, as soon as it's accessed a second time.

Mrs. Christine Elliott: Okay. My next questions relate to the pricing issue. I heard from the previous question that you didn't want to speculate on why there was such a discrepancy in price.

Interjection.

Mrs. Christine Elliott: Yes. But did Medbuy, in the whole process, ever come back to you at any time and say, "Are you really sure this is your price? What's included in the price?"

Ms. Marita Zaffiro: Not to my knowledge.

Mrs. Christine Elliott: Did they ever make any inquiries?

Ms. Marita Zaffiro: Not to my knowledge, no.

Mrs. Christine Elliott: Okay. Next, with respect to the discovery of the problem by the people in Peterborough, our understanding through the course of hearings here is that there were several conversations between one of your pharmacists and a pharmacist both at Peterborough as well as at the Lakeridge cancer centre. Can you identify who that person was?

Ms. Marita Zaffiro: I think they're up next.

Mrs. Christine Elliott: Okay. So can someone speak to that?

Ms. Marita Zaffiro: What would you like to know? I'm sorry.

Mrs. Christine Elliott: Well, I'd like to know what the nature of the conversations was, if it was the same person who spoke to both the person in Peterborough and the pharmacist at the Lakeridge—

Ms. Marita Zaffiro: I believe so.

Mrs. Christine Elliott: —cancer society and the nature of the conversation.

Ms. Marita Zaffiro: We have Kawther Salman, who's a pharmacist, and Roberta Young, who will be speaking to you after we're done. They're going to tell you in detail about who they spoke to and what those conversations were about.

Mrs. Christine Elliott: Okay.

Ms. Marita Zaffiro: I think that would just be clearer because—

Mrs. Christine Elliott: Sure, that's fine. I just wanted to make sure that we covered that.

Another part of the proposal that you submitted was an amount of $20,000 that was going to be included as, I believe, a donation—

Ms. Marita Zaffiro: The research and education fund?

Mrs. Christine Elliott: The research and education fund. Can you tell us how you came to that figure and whether that's something that you've ever done before?

Ms. Marita Zaffiro: No, that was a requirement of the contract. Again, this was the first time we were doing an RFP with a GPO for hospitals. We took a look at what our contribution needed to be, and whether that $20,000 came out of the price for the products or came as a separate allocation to their fund, that was basically a neutral decision. Again, the customer indicated that this was how they wanted us to quote on this service.

Mrs. Christine Elliott: Yes, I was just wondering how you came to the $20,000 figure.

Ms. Marita Zaffiro: I have no idea, really. I didn't make the call, exactly, but it was looking at the total contribution—what did we need—that we felt we needed to cover our costs, as indicated in my statement and our return, and what amount did we want to take out of that to actually put as an allocation to this fund, since that's what they were asking for.

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

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

M^me^ France Gélinas: Thank you for coming back. I think you've put it really clearly that the list that you got, some of the 120-some products there were concentration-specific. I have the list in front of me. I can see—I don't know how to pronounce this—fentanyl, 10 micrograms per millilitre. Then they're asking in 0.9% sodium chloride and they want it in the 100-millilitre bag. By reading this, you know that they want concentration-specific.

Ms. Marita Zaffiro: I have to see what you're reading from there.

M^me^ France Gélinas: It comes from your—it has the little X beside it.

Ms. Marita Zaffiro: Sorry, which one is—the fentanyl?

M^me^ France Gélinas: The first one.

Ms. Marita Zaffiro: The first fentanyl? Right—

M^me^ France Gélinas: Correct. But they're all the same—

Ms. Marita Zaffiro: —10 micrograms per millilitre, and 1,000 micrograms in the bag. Right.

M^me^ France Gélinas: Right, as in that would indicate—

Ms. Marita Zaffiro: That's a specific concentration.

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M^me^ France Gélinas: That's concentration-specific. It happens to be just two products underneath the cyclophosphamide, which said, "Two grams in 0.9% sodium chloride, 100 millilitre bags"—and this one is not concentration-specific.

Ms. Marita Zaffiro: What I find interesting under the Cs is that you go from cloxacillin and a whole row of antibiotics right to cyclophosphamide, without any differentiation. It's an alphabetical listing, with no suggestion, by product categorization, that these chemo products are differentiated from the other products I mentioned that are concentration-non-specific, be they antibiotics, stomach acid suppressants, amino acids etc. When we looked at it, very quickly our eyes went to the concentration-specific—milligram per millilitre, extra information etc.—to understand that these products needed to be very concentration-specific because of their therapeutic index. We confirmed, in our dialogue with Medbuy, through emails and conversations, that that was the case: that the products we identified on that list as concentration-specific were the only products that are concentration-specific.

M^me^ France Gélinas: Had this list said "four milligrams per millilitre," none of us would be here today?

Ms. Marita Zaffiro: It's actually not four milligrams per millilitre.

M^me^ France Gélinas: It's 0.38?

Ms. Marita Zaffiro: Right.

M^me^ France Gélinas: Yes, 38 milligrams, or whatever they would have wanted it to be.

Ms. Marita Zaffiro: We're aware that Baxter's label on the gemcitabine not only had a concentration, it had a funny kind of volume on it. I don't know if you're aware. It said 105-point-something millilitres, and we understand why that is now. Those are a couple of pretty significant indicators of a very unique label for that particular preparation.

M^me^ France Gélinas: I take it that you have followed the proceedings here. You saw how Medbuy got that list that they sent out.

Ms. Marita Zaffiro: How did they get that list? Remind me.

M^me^ France Gélinas: It's in Hansard from last week, when we were talking to Baxter. It's Baxter that supplied the list to Medbuy, and then Medbuy took the list. I asked Baxter if there had been any changes to the list. Baxter affirmed that, no, the list is exactly the way they had

submitted it to Medbuy. Medbuy took the list of these 120 products that they used to get from Baxter and they put it out for tender, and you answered to this. The issue of checking which one needed to be concentration-specific was not picked up at any point.

Ms. Marita Zaffiro: It was not picked up—I'm sorry? By whom?

M^me^ France Gélinas: It was not picked up, as in Baxter gave that list to Medbuy, Medbuy didn't ask questions, and it took that list and put it back out without ever questioning if some of them should be concentration-specific.

Ms. Marita Zaffiro: There were products on there that were actually designated as concentration-specific—

M^me^ France Gélinas: Because they came from Baxter's list that way.

Ms. Marita Zaffiro: Do you know why they wouldn't have had that piece of information that was on their labels on the product list they gave Medbuy?

M^me^ France Gélinas: No.

Ms. Marita Zaffiro: I know it's not my place to ask questions.

M^me^ France Gélinas: No, they didn't.

Moving on, you took it for granted that the list you had in front of you was clear and that if they wanted concentration-specific, it was written, and if it was not written, it's because they did not need concentration-specific.

Ms. Marita Zaffiro: We took it as our starting point. We had verbal conversations with Medbuy to identify, "Are we correct in our assumption that these are the only concentration-specific products?" That answer was, "Yes, you are correct." So that was how we fed our interpretation of that list back around the issue of concentration specificity.

M^me^ France Gélinas: How can I have proof that this discussion happened, that you asked if there were any other concentration-specific products and you were told, "The list is the list"? Are there any facts to support this?

Ms. Marita Zaffiro: Yes, there are emails.

M^me^ France Gélinas: There are emails? Would you share those with the committee, please?

Ms. Marita Zaffiro: Of course.

M^me^ France Gélinas: Thank you. So your starting point was the list that you got. You went back to Medbuy and asked, "Anything else that needs concentration-specific?" Do you remember if any other products needed to be adjusted?

Ms. Marita Zaffiro: Not that I recall. The team did most of the work. Was there anything else that was non-specific—

Interjections.

Ms. Marita Zaffiro: I don't believe so.

M^me^ France Gélinas: No?

Ms. Marita Zaffiro: It's been a while now, so—

M^me^ France Gélinas: I realize. Okay, so you took it for a starting point, but that wasn't enough. You went to Medbuy and checked: "Anything else? Any concentration-specific?"

The answer back to you was no, so you went to work. You felt reassured because them telling you gave the assurance—

Ms. Marita Zaffiro: There are five chemotherapy products; three of them are expressed as concentration-specific and made as concentration-specific. So in the context of our reasonable judgment and the judgment of six pharmacists or more in the cross-checking of calculations and the context of what our role was, that's the conclusion that we came to. I think one more piece of information might have saved everybody a lot of distress.

M^me^ France Gélinas: You're not kidding.

When you were talking to Medbuy and asking them if there were any other products that should be concentration-specific, who were you talking to?

Ms. Marita Zaffiro: I wasn't talking to them, but we talked to their pharmacist team, so Ron Swartz, Ann Kelterborn—I think there are a couple of other people; Maria somebody. I don't know them, but I can get you that information.

M^me^ France Gélinas: And you're a pharmacist?

Ms. Marita Zaffiro: I'm a pharmacist.

M^me^ France Gélinas: You're a pharmacist and you were talking to other pharmacists. You—

Ms. Marita Zaffiro: I wasn't, but my pharmacists were talking to other pharmacists. I was not—

M^me^ France Gélinas: Okay—were talking to other pharmacists.

Ms. Marita Zaffiro: Yes.

M^me^ France Gélinas: And we will have email trails of that to show that pharmacists answered back, "No, if we wanted concentration-specific we would have told you."

Ms. Marita Zaffiro: Well, those aren't their words, but there is evidence there that we asked the question and received an answer.

M^me^ France Gélinas: And received an answer.

Ms. Marita Zaffiro: Yes.

M^me^ France Gélinas: Okay. Do you want to go?

Ms. Cindy Forster: Yes, thank you. Thank you for being here again today. I'm going to put on my nurse's hat, and I'd actually like to ask the pharmacists who were involved a question, particularly about the fact that you thought this was a single-patient dose bag of an oncology pharmaceutical.

Did you ever second-guess yourself to say, "There is too much drug in this bag for one patient"? Because we heard from Baxter and we've heard from basically every witness that has been here that the amount of drug that was in that bag was enough for a six-foot, 900-pound man. As somebody who has administered medications for many years in a variety of departments, I often questioned myself or questioned a colleague if I thought that there was perhaps an error in the dosage of a drug ordered. That's my question. If I could start with Janie Bowles-Jordan.

Ms. Janie Bowles-Jordan: I came into the process to do research and evaluation. Because I came in in January of the process, a lot of the questions had already been asked of Medbuy and I was informed that yes, the

concentration-dependent products had been identified and we were not responsible for checking dosage because these have been long-standing product items. We were just going to continue the contract and providing quality product, so the focus was on quality, stability, physical and chemical products—

The Chair (Mr. Ernie Hardeman): If I could just stop you for a moment, could you speak a little bit more into the microphone so the rest of the world can hear?

Ms. Janie Bowles-Jordan: Sure. Thank you. The clinical stability had already been vetted, and these had been long-standing products. We were going to be focusing on the physical stability and the drug stability, so we were providing quality products to the hospital that were of a high standard.

Ms. Cindy Forster: Did you have any experience from your past with oncology drugs?

Ms. Janie Bowles-Jordan: I had very limited oncology experience when I was at St. Joe's hospital in Hamilton. However, we did have one experience that I'd like to share with the committee where we did ask a hospital about a dose of vancomycin. It's not referring specifically to this chemotherapy situation, but it was a high dose of vancomycin that could cause red man syndrome if given too high. We questioned the dose and we were told back by the hospital—and this was into the contract—"Don't ask questions. Provide the product. We know how we're using it." So it was under our assumption that there were established protocols and procedures that were at the oncology units that had been vetted through other specialists and this wasn't going to address us.

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M^me^ France Gélinas: Do you have any way of showing the committee that this discussion you just talked about happened? Are there emails? Do you remember who you talked to, which hospital, when it happened?

Ms. Janie Bowles-Jordon: I was not the person directly involved with the conversation. However, my colleagues can probably find email trails on that. As far as the rest of what I've just spoken to, if the discussions had happened prior to me coming on board with the team and therefore I think they're in the emails that Marita has spoken to—that we can find and bring up.

M^me^ France Gélinas: Do you remember who had told you this story, where they reached out, thought the dosage was wrong and were told, "Don't ask questions. Just provide the product"?

Ms. Janie Bowles-Jordon: I think some of my colleagues at Marchese Hospital Solutions would be better to speak to that than I.

M^me^ France Gélinas: No idea of whom I should start with? You have a big staff.

Ms. Janie Bowles-Jordon: Well, Kawther and Bobbi will be coming after, and they will probably be best to talk to that.

M^me^ France Gélinas: Okay. We'll ask them. Thank you.

Ms. Cindy Forster: Could I ask that same question of Kathy Cuerrier?

Ms. Kathy Cuerrier: My role in the development of the mixture breakdowns and whatnot was not a clinical nature at all. When I came on board, I was asked to make sure that the mixture breakdowns were correct for calculation and that the products we were using were the correct ones and that we were following protocols and everything to provide, as Janie said, a superior product, to make sure we were doing everything correctly in the technical sense.

I at no time had any idea that I was to be doing any clinical checking. That was not my role as a pharmacist on the team.

Ms. Cindy Forster: Is there not something though—we heard about last week, kind of in the world of pharmacy, that you go back to and check against—I can't remember what the word in it was now. It's some kind of process that you go back and check your admixtures against.

Ms. Janie Bowles-Jordon: I could probably speak to that. Usually, if we were getting a patient-specific drug, we would be very diligent in checking allergies, weight, dosage and being very specific on the route. We do that with all of our drugs, whether it's infusion or oral dispensing. In this case, we were not given patient-specific information, so we couldn't check if the dose was above an average weight or in what conditions it was being used for, because we didn't have renal function, we didn't have surface area, we didn't have weight. So we didn't have the clinical capacity to perform those functions that we would do on a patient-specific basis.

Ms. Cindy Forster: And what about your oncology experience, oncology pharmaceutical experience?

Ms. Kathy Cuerrier: Mine?

Ms. Cindy Forster: Yes.

Ms. Kathy Cuerrier: I worked at the Juravinski Cancer Centre outpatient dispensary for two years, from 2006 to 2008, so I was involved with providing supportive medication to cancer patients. I didn't have any direct experience with IV chemotherapy at all. There were a few oral chemotherapy medications that I dispensed to patients.

Ms. Cindy Forster: And Stephanie Gilbreath, could I ask you the same kind of two questions?

Ms. Stephanie Gilbreath: Sure.

Ms. Cindy Forster: Your experience with oncology pharmaceuticals and—

Ms. Stephanie Gilbreath: My oncology experience is limited. As a student years ago, I was preparing chemo, but that was a long time ago. As I stated in my statement, I have some home infusion experience from working at Marchese, where we did a bit of chemo. That's about it.

Ms. Cindy Forster: And Sophia, could I ask you the same questions, please?

Ms. Sophia Francis-Pringle: Very limited; pretty much none. My experience has been in general pharmacy, ambulatory care, but not chemo—oncology-specific.

Ms. Cindy Forster: Okay. Thank you.

M^me^ France Gélinas: To change the topic completely, I want to come back to the $20,000. You have prepared

medications for third parties for a long time. You have a contract with CCACs, you have an entire business of doing this. Have you ever been asked for that kind of money in other contracts?

Ms. Marita Zaffiro: No, we've never been asked. Again, we are very supportive of inter-professional collaboration and education. We also try to be very innovative as we've been pioneers in providing to home care.

So among innovating the depot delivery system and the predecessor IT system that allowed CCACs to create POs of their own, we, at one point, provided a bursary of $5,000 in our proposal that was to be used to have a nursing agency staff member, a Marchese pharmacy staff member and a CCAC staff member do some education jointly at a particular conference. So that's the closest that we've ever come to when we proposed that.

M^me^ France Gélinas: And did that ever come to fruition?

Ms. Marita Zaffiro: Did we ever use it?

M^me^ France Gélinas: The bursary. The $5,000.

Ms. Marita Zaffiro: I can't remember for sure. It was a long time ago, and it's not something that we continued doing. We started when it was still the home care program. It was very collaborative. Over time, there became very strict requirements around that kind of thing. That wasn't requested and you didn't have the opportunity to make innovative or different kinds of suggestions. It was very prescriptive.

M^me^ France Gélinas: And, in your dealings with hospitals specifically, had you ever been asked to make that kind of a—

Ms. Marita Zaffiro: No.

M^me^ France Gélinas: No. Okay. So we'll save our minute.

The Chair (Mr. Ernie Hardeman): Thank you. That concludes your time.

M^me^ France Gélinas: Oh.

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

Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Thank you for coming back, Ms. Zaffiro.

I'd like to turn to the issue where the miscommunication occurred, which is, of course, this concentration-specific format. You used that in your presentation and you have it sort of in italics: "concentration-specific." Is this something standard in the practice of pharmacy that "concentration-specific" is a widely recognized term, and you mean per smallest unit—in this case, per millilitre?

Ms. Marita Zaffiro: I think it's what we recognized in differentiating the items listed on Medbuy's schedule. We saw it as a key differentiator of the products as they were listed. Now, in concentration-specific—it's an important factor because, as we said, unit dose in a mini-bag, you infuse the entire bag to get the entire dose.

So in the absence of other information and the context of this service and this transition, we were not looking at the existence of multi-dose bags. We would have thought we would have been informed if one of these bags was multi-dose. It would have had a different consideration around a preservative, potentially. So that was the assumption based on how the information was presented.

We make oral solutions. We make other sterile solutions as well. If we are making a reservoir from which we then make patient-specific dilutions in our home care or in our specialty compounding business, we use preservatives. We make them concentration-specific, and we label them as such.

Ms. Helena Jaczek: See, to the average person—I am a physician. If I saw a label that said four grams of the compound in 100 millilitres, I would mentally just make the division and assume it was 40 milligrams per millilitre. So am I somehow an outlier?

Ms. Marita Zaffiro: No, I don't think so. I really appreciate that, because I have a very good friend who is the VP of nursing at a hospital. I was relaying to her this particular situation, and she said to me, "Do you mean that bag that we hang that says X antibiotic grams in 100 millilitres isn't exactly four grams per millilitre?" She was very surprised, and she's a very seasoned both administrator and nurse. I said, "Yes. That's the reality."

So what it really brings home, for all of us, I think, is the need for a national labelling standard. We need to have the same understanding. Whatever logic or convention we apply against it—I mean, we don't know that one hospital doesn't interpret something different than another.

The P&T committee would educate the professional staff, I believe, on how do you read these bags. What do we mean when we say this? And to the degree that that's effective, and to the professionals or support staff who actually understand that, there are probably many, many gaps and many opportunities that are subject to interpretation.

At the end of the day, it is an art ,and we want it to be more of a science, I think, in terms of how we label these products.

Ms. Helena Jaczek: So you're looking forward to Dr. Thiessen's recommendation?

Ms. Marita Zaffiro: Absolutely.

Ms. Helena Jaczek: Now, when Baxter came in, they made a major point of—and perhaps Ms. Forster was getting at this—that they use the product monograph in terms of the reconstitution of gemcitabine. Did that occur to any one on the team whether that might be a way of reconstituting this product?

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Ms. Janie Bowles-Jordan: We always use the product monograph as our basis. We use evidence to support all of our reconstitution and our monographs, so if there is a monograph that states specific dilution requirements, that's always put as part of our procedures.

Ms. Helena Jaczek: But then, as they explained to us, if you do it the way the product monograph suggests you would end up with 38.5 milligrams per millilitre because you have to replace the displaced volume from the powder in the vial.

Ms. Marita Zaffiro: Yes. I think we understand that, but again, in the context, we were putting that into a pre-

filled mini-bag and drawing out a portion to create all that, so the final volume was that 105 plus the average overfill that would be in that bag.

Ms. Helena Jaczek: But it never occurred to your team that you might want to do it that way?

The Chair (Mr. Ernie Hardeman): If I could just have your attention again, can you speak closer to the mike? Hansard is having trouble picking it up.

Ms. Janie Bowles-Jordan: We have multiple products in our database where we do pull out volume based on that concentration specificity. As you know as a physician, if we're making an antibiotic and you put one gram into a 100-millitre mini-bag, you're not pulling out volume; the whole bag is hung as one complete unit. If the product has been defined as concentration-specific, we always pull out the volume that we're going to be injecting, and make those adjustments.

In fact, when we were checking the calculations for our mixture breakdown sheets, we were double-checking for that if we were triggered that it was necessary in the process. But if it wasn't meant to be concentration-specific, it's an added step that we don't usually do unless we know it is supposed to be to a defined concentration.

Ms. Helena Jaczek: This gets back, of course, to the question of whether this was destined for one single patient. Again, as a physician, if I'm not very familiar with a drug, I pull down the CPS off the shelf and I look at the appropriate dosage. I guess with such a team it's just surprising that no one did that. Can anyone—

Ms. Marita Zaffiro: Again, we approached it as there were multiple minds. In the context of 124 admixtures, these two admixtures were stated in the convention of non-concentration-specific, and the concentration-specific products were clearly stated differently.

In the context of the work that we were doing and the amount of work that we had to do to effect a transition in 45 days, to have done a clinical review and to have included that on our protocols where we would state, "Here's the minimum dose and the maximum dose, and how you calculate this dose. Here are the indications"—which we're fully capable of doing—would have been a whole other level of requirement that was not designated in the contract, nor do I believe it was expected in any way, shape or form.

Ms. Sophia Francis-Pringle: May I just add that the issue would also be how would we arrive at a particular dose for a particular patient, because we would really need the specifics of the patient in terms of diagnosis, weight and all the other issues, really, to come to that decision. So we honestly weren't privy to all the patient specifics that really have to be considered to arrive at the dose. I know it sounds a bit bizarre, but it's just that when you do consider—for example, if you're filling a routine prescription, you're really given more information than you would have in doing this type of manufacturing.

Ms. Helena Jaczek: I guess it would simply be that if you had the experience that Baxter had originally where they were in direct communication with hospital pharmacies, you would have immediately understood that this was a stock bag for multiple patients and it was supposed to be concentration-specific, and this is the problem that we're facing, this miscommunication of what was required.

Actually, you're Ms. Francis-Pringle?

Ms. Sophia Francis-Pringle: Yes, I am.

Ms. Helena Jaczek: Attached to your presentation to us that the Clerk certainly handed to me are a couple of extra pages.

Ms. Sophia Francis-Pringle: Oh?

Ms. Helena Jaczek: Yes, and I was just wondering—it was not read into the record. It was attached. It was numbers 6, 7, 8 and 9 under "Process." This is not something that you wanted to discuss with us? Because it does have some interesting information.

Interjections.

Ms. Helena Jaczek: It's not part of the record, but it certainly was attached to mine.

Interjections.

Ms. Helena Jaczek: Anyway, no problem. I'll just leave that with you, but there's some interesting information there.

If we could then just move on because, in fact, Ms. Francis-Pringle, you've alluded to the fact that if it's patient-specific there's a lot more information.

I'd just say, Ms. Zaffiro, I know we heard from Laura Savatteri last week about the, I would say, really quite extraordinary efforts that were made to look at the regulatory framework in terms of supervision by the College of Pharmacists, the regulations related to what Health Canada is potentially looking—we've heard this grey zone. Will you welcome this kind of oversight, Ms. Zaffiro?

Ms. Marita Zaffiro: Absolutely. As you may be aware, the college floated initially their regulatory and bylaw changes. We commented on them quite extensively. They then had their meeting and passed their regulatory changes. They are now in the process of creating the standards and forms and processes to actually be able to begin inspections and notifications etc. We've indicated our desire to assist, to comment and to make ourselves available as the first recipient of their inspection. As you had said, our desire was always to be regulated, and so we welcome the opportunity for that regulation to now occur.

Ms. Helena Jaczek: In general, and you've alluded to it, what do you see as the benefits of a procurement process for these types of admixtures outside of the hospital?

Ms. Marita Zaffiro: The benefit, again, is the quality, consistency and accuracy, the competency of trained staff who are doing this all the time, particularly in the complex or toxic products. Again, these particular chemo products don't necessary lend themselves to be outsourced for patient-specific dose creation unless there were standardized protocols of some sort.

I think those are some of the benefits. They are technical and repetitive. So the ability to use those kinds of

management systems to manage the quality, consistency, repeatability etc. are where the benefit comes from. And if that's a better use of resources, human and financial, then that allows our health care system to benefit from that.

Ms. Helena Jaczek: We'll save our time, Chair.

The Chair (Mr. Ernie Hardeman): Thank you very much. The opposition? No further questions. Then you have to finish, because that's the end of the day. Thank you.

Ms. Janie Bowles-Jordan: I think if I could just add—

Ms. Helena Jaczek: Sure. Go ahead.

Ms. Janie Bowles-Jordan: In the fact that there are USP 797 standards that are becoming compulsory in the US and are in the process of coming into Canada, and in that the facilities have to be very strictly done to meet various bacteria parameters and so forth—it's very hard for a lot of the hospitals to meet this high standard of facility that's required in order to produce these chemical products. In doing that, we can have a specialty area that would meet these specifications and meet the standards.

Ms. Helena Jaczek: Was some of that part of the discussion with Dr. Thiessen when you met with him? So we may see some of these recommendations forward?

Ms. Marita Zaffiro: In the absence of regulation, the management systems and standards that we put in place came from USP 797, OCP, Health Canada etc. We adapted all the available standards—those and more—to put in what we thought was the most diligent and appropriate quality management system for what we produced. That was very important given that we were venturing to provide a very, I think, valuable, needed service alternative to Ontario hospitals.

Ms. Helena Jaczek: Perhaps we could just look at the email that you presented with us, I guess, the email chain from Laura Savatteri to Ann Kelterborn, who was a pharmacist at Medbuy, I presume, that was then responded to by Ron Swartz.

Ms. Marita Zaffiro: Yes.

Ms. Helena Jaczek: Could you just perhaps explain to us what this meant to Laura, and subsequently to you, in terms of that response from Mr. Swartz? How was that interpreted?

Ms. Marita Zaffiro: I guess the key piece of information here was his comment that, "Members will still be putting on a patient-specific label in the pharmacy" on the bags of chemo that we were providing, because the other three chemo products are not in bags. That was a confirmation—not a direct confirmation, but certainly not any kind of indicator that these bags were not patient-specific and are used in that way.

Ms. Helena Jaczek: So the interpretation, in essence, was that the bag as a whole would be labelled patient-specific in the hospital pharmacy, and the assumption was that the entire bag would be used. That was—

Ms. Marita Zaffiro: Which is how the other non-concentration-specific products were—

Ms. Helena Jaczek: So it was sort of a confirmation in terms of your consumption.

Ms. Marita Zaffiro: It was a confirmation.

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Ms. Helena Jaczek: Okay, I understand that. Then you will be sending us—my colleague Ms. Gélinas—the emails to confirm some of this backwards and forwards between Marchese and the pharmacist team at Medbuy.

Ms. Marita Zaffiro: Yes.

Ms. Helena Jaczek: That would be very helpful. We have no further questions.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes your presentation today. We thank you very much for coming in and helping us out again with the process as we move forward through this.

Our next delegation is also from Marchese Health Care: Roberta Young and Kawther Salman. Thank you very much for being here. As with the previous one, we do ask all delegations to be sworn in or affirmed for the presentation. With that, we'll let the Clerk do his thing, and then we will carry on with the rest of the presentation.

The Clerk of the Committee (Mr. William Short): I'll start left to right. Roberta Young?

Ms. Roberta Young: Yes.

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

Ms. Roberta Young: Oath, please.

The Clerk of the Committee (Mr. William Short): The Bible is there. Ms. Young, 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. Roberta Young: Yes, I do.

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

Ms. Kawther Salman, you requested a copy of the Koran, which is in front of you.

Ms. Salman, 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. Kawther Salman: Yes, I do.

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

The Chair (Mr. Ernie Hardeman): Thank you very much. Being the only two witnesses, we will start the presentation. You will have 20 minutes to make your presentation, and then we will have opportunities for questions from each caucus for 20 minutes. This round will start with the third party.

With that, thank you again for being here, and the floor is yours to make your presentation.

Ms. Roberta Young: Thank you and good afternoon, Mr. Chairman and ladies and gentlemen of the committee. My name is Roberta Young. I am known to my colleagues and my family as Bobbi.

I hold a certificate from a pharmacy technician program. I have also successfully completed my Pharmacy Examining Board of Canada, or PEBC, evaluation

examination. I am currently working toward my certification from the Ontario College of Pharmacists as a regulated pharmacy technician.

I have 11 years of retail pharmacy and IV infusion experience. I have been employed by the Marchese companies—either Marchese Health Care or Marchese Hospital Solutions—for five years. Between 2008 and 2011, I was an infusion technician at Marchese Health Care's premises in Hamilton, Ontario. From January 2012 to the present, I have been employed as an infusion technician at Marchese Hospital Solutions'—MHS—premises in Mississauga.

Before working with Marchese, I was employed for two years by a large retail pharmacy chain. I was not involved in any commercial negotiations leading to the contract between MHS and Medbuy. I was, however, involved in recruitment and hiring new staff, purchasing equipment and supplies, and set-up of the new clean room established at MHS's premises in Mississauga to prepare admixtures under the Medbuy contract.

I am familiar with the preparation of MHS's IV bags and have responsibility for ensuring prompt and accurate delivery of our IV admixtures to Medbuy hospitals. I have direct knowledge of the IV bags containing gemcitabine and cyclophosphamide prepared at MHS, based on my experience either preparing or observing preparation of those admixtures.

The following steps were taken by MHS in preparing a 100-millilitre IV bag containing four grams of gemcitabine:

—within a segregated biological safety cabinet in our clean room, we started with a pre-filled 100-millilitre IV bag supplied by Hospira;

—we withdrew two 50-millilitre amounts of saline solution from the pre-filled bag;

—the two 50-millilitre amounts were then injected into two vials, each containing two grams of gemcitabine, to reconstitute the drug;

—after the gemcitabine was dissolved, the contents of the two vials were injected back into the pre-filled bag;

—because the gemcitabine mixtures we prepared were not required to be concentration-specific, the small amount of overfill in the bag was not removed; and

—the final admixture in the bag was delivered to a hospital with the label "4 g in 100 mL," meaning it was not concentration-specific.

In the afternoon of March 20 of this year, MHS received a call from a woman named Judy. I understood that Judy worked in a pharmacy department at one of the Medbuy hospitals. At first, I thought Judy was in Oshawa but later learned she was in Peterborough. Judy had a technical question about our 100-millilitre gemcitabine bags.

The call was originally taken by one of our business people at MHS, Bert Notarius. Bert asked me to participate in the call with Judy when he understood she had a technical question.

In the call with Judy, I explained our process of preparing gemcitabine bags. There was a specific discussion of overfill and concentration. I indicated that the bag was non-concentration-specific and therefore it was our assumption that it was for single-patient use. I suggested to Judy that someone from the hospital should speak with the Marchese Hospital Solutions pharmacist if they needed further clarification.

Later that afternoon, the Marchese Hospital pharmacist, Kawther Salman, spoke with a Peterborough representative. I will let Kawther explain to the committee her recollection of the communications and describe the timeline from there.

Following the call, Kawther sent an email to me and others. She informed us that she had been told that the overfill created a problem for the Peterborough hospital's infusion pumps. Kawther suggested that we should either remove all overfill from the bags or use sterile empty bags to prepare the solution. A copy of Kawther's email dated March 20, 2013, has been provided to the committee.

Given the communications with Peterborough Hospital, we thought it was prudent to contact London Health Sciences Centre, the largest Medbuy hospital purchasing cyclophosphamide and gemcitabine bags from Marchese Hospital Solutions. The next day, March 21, 2013, Bert called Ian McKechnie, the manager of pharmacy operations at London Health Sciences Centre, to get insight on the way that they were using our chemotherapy admixtures. An email exchange between Bert and Ian followed. That has also been provided to the committee. Ian suggested that I speak with Charlene Jones, the pharmacy coordinator at London Health Sciences Centre's oncology area.

Later that day, on March 21, I spoke with Charlene. In the call, I asked her how the hospital was using our product. I also explained how we prepared the product. I learned from Charlene in that call that our product was being used as a reservoir to create other IV bags at the hospital. In the call, Charlene did not express any immediate concern about the existence of overfill in our bags.

On March 21, 2013, Bert also telephoned Linda Skinner, the pharmacy manager at Lakeridge in Oshawa, to set up a conference call to discuss the issue. Linda informed us later that day that a call would be set up for the next day: March 22, 2013.

On March 22, 2013, at 8:30 a.m., Bert and I spoke with Linda Skinner and, I believe, one other Lakeridge employee who I believe was Janet Slesser. Kawther also participated in this call. In that call, we proposed removing any overfill from the bags, and I understood that the proposal was acceptable to Oshawa. We told them that we needed to address the issue with the other hospitals purchasing these products and would get back to them. In the interim, Linda told us that Lakeridge was halting all orders of cyclophosphamide and gemcitabine.

On Monday, March 25, 2013, London Health Sciences Centre called and asked us to hold all further shipments of cyclophosphamide and gemcitabine.

On Tuesday, March 26, Bert was in contact with Medbuy. A brief summary of facts was sent that day to

Ann Kelterborn, a pharmacist at Medbuy. Ann informed us that she was aware of the concerns raised by the hospital.

On Wednesday, March 27, 2013, Bert and Laura contacted Horizon Health Network hospitals in New Brunswick to inform them of the potential problem. Later that same day, Bert and Laura also spoke with John Devlin, the pharmacy manager at Windsor Regional Hospital.

On Thursday, March 28, Bert sent an email to all Ontario and New Brunswick hospitals offering to change our production processes and labelling to meet their needs for a concentration-specific admixture. These details of my own, and other communications I was aware of, are provided to show the committee that once the problem was raised with one of our admixtures, we did not remain silent. We took the initiative by warning Medbuy and other hospitals about the issue. As another witness, Sandy Jansen from Lakeridge regional health hospital, told you, we were "very open and transparent" with information we provided. Had any hospital, or Medbuy, raised the problem earlier, I am confident that the result would have been the same.

I will try and answer questions that the committee may have.

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

Ms. Kawther Salman: Good afternoon, ladies and gentlemen of the committee. My name is Kawther Salman. I am a pharmacist qualified in Ontario. I was originally educated at the pharmacy school of Baghdad University in Iraq. I came to Canada with my family in 2003. I was granted certification of licensure as a pharmacist by the Ontario College of Pharmacists in 2009.

In the 10 years since coming to Canada, I have worked at a variety of retail pharmacies in the greater Toronto area. I have been employed in both full- and part-time positions as a pharmacist. I have also acted as a relief pharmacist on several occasions.

I first began working, on a part-time basis, with Marchese Health Care in their retail pharmacy in Hamilton in June 2012. In July 2012, I began taking part-time shifts for Marchese Hospital Solutions at their premises in Mississauga. I only began working full-time for Marchese Hospital Solutions in Mississauga in early March of this year. I continue to work one day a week in a retail pharmacy to keep my skills for direct patient care updated.

I was not employed by Marchese Health Care or Marchese Hospital Solutions when the contract with Medbuy was awarded. By the time I began working with Marchese Hospital Solutions in Mississauga, the production processes for IV bags, including bags containing the chemo drugs gemcitabine and cyclophosphamide, were well established.

I worked directly in the clean room at the Mississauga facility, checking preparation of all admixtures for quality, sterility and accuracy. The admixtures included gemcitabine and cyclophosphamide.

On March 20 of this year, Bobbi asked me to speak with Judy, a hospital technician in Peterborough, about our 100-millilitre gemcitabine bags. In the call, Judy asked me about our process for preparing the bags. We spoke about overfill and the hospital's intended use for the bag. In the conversation, I stated my assumption that the bag was intended for single-patient use because the concentration was not specified. In the call, Judy told me the hospital was having difficulty with overfill because their infusion pumps required a specific unit of milligrams in milliliters. At the end, she said that she would speak to the Lakeridge pharmacist and would call me back the next day.

The same afternoon as the call with Judy, I sent an email to Bobbi, Bert Notarius, the business development manager, and Laura Savaterri, a fellow pharmacist, suggesting two possible solutions. My first suggestion was that we could make the gemcitabine solution concentration-specific by removing any overfill from the bag. My second suggestion was that we could order empty sterile bags and inject the reconstituted solution into the empty bag. My email dated March 20, 2013, has been provided to the committee.

Two days later, on Friday, March 22, 2013, I participated in a conference call with two employees of Lakeridge hospital in Oshawa. In that call, we proposed removing any overfill from the bags and preparing an appropriate concentration-specific label. I understood that the proposal was acceptable to the hospital. We could have easily accomplished the change in procedure.

I haven't been directly or substantially involved in the steps taken since the concentration issue was discovered. I am aware that MHS notified the hospitals promptly.

I will attempt to answer any questions posed by the committee.

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will start with the third party. Ms. Gélinas, or is it Ms. Forster?

M^me^ France Gélinas: I will start with Ms. Young. Do you have any experience dealing with chemotherapy IV drugs?

Ms. Roberta Young: Before working at Marchese Hospital Solutions in Mississauga, I was trained on chemotherapy by my supervisor in Hamilton. We purchased a chemotherapy training kit that we went through together, and she certified me with chemotherapy preparations.

M^me^ France Gélinas: Same question for Ms. Salman: Have you got any experience working with IV chemo drugs?

Ms. Kawther Salman: Before working with Marchese Health Care, I never got any practical experience with chemotherapy, just theoretical, or knowledge that we got from study in pharmacy school.

When I worked part-time at Marchese Health Care as a retail pharmacist in Hamilton, the pharmacist Stephanie, the designated manager, trained me to check IV admixtures, because she said, "Maybe we will need you to work in our facility in Mississauga." So the first

training for IV regular order was in Hamilton. In July they sent me to work in the Mississauga facility to check IV fluid or supervise IV fluid preparation. When I went there, Laura was there, and other pharmacists. Laura trained me for checking regular orders. I started in July. My first chemo checking was in August. So I gained my experience from working with people who have experience in chemo preparation.

M^me^ France Gélinas: Thank you. I will go back to you, Ms. Young.

Somebody answered the phone at Marchese when the phone rang, coming from Peterborough, and decided to transfer it to you. Why to you?

Ms. Roberta Young: Because I knew how we made the bags. They were asking specifically what our preparation procedure was, and I could answer that question better than a business manager could.

M^me^ France Gélinas: Okay. And how long was your call?

Ms. Roberta Young: I don't think it was that long. I can't remember specifically how long the call was, but long enough to explain the procedure and answer any questions that they had.

M^me^ France Gélinas: Once you realized that they were using it as a "reservoir"—I think is the word you used—what was the first thought that came into your mind?

Ms. Roberta Young: I suggested that they speak with the pharmacist, because at that point it was out of my scope of practice. I don't make decisions of that magnitude, so I suggested that they speak with the pharmacist to get more of the clinical knowledge that they would require.

M^me^ France Gélinas: And do you know why it went to Ms. Salman as the pharmacist? Just because she happened to be there at the time?

Ms. Roberta Young: She was the pharmacist who was there at that point.

M^me^ France Gélinas: Have you prepared concentration-specific IV products before?

Ms. Roberta Young: I have.

M^me^ France Gélinas: Okay. Do you ever inquire why some are concentration-specific and some are not?

Ms. Roberta Young: With this contract in particular, all of that information was done by the committee of pharmacists and was double- and triple-checked, as they stated in their testimony. At that point, it was just my job to prepare the product to the specifications that they had set out.

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M^me^ France Gélinas: So you felt that you could trust that the committee of pharmacists was asking you to prepare the drugs in the way they should have been?

Ms. Roberta Young: Correct.

M^me^ France Gélinas: And you held that in trust because that's the way it works, because you were told?

Ms. Roberta Young: Because of prior experience. When I was doing the CCAC work, the pharmacists did pre-checks and calculated all the dosing or whatever else. I wasn't involved in the process of preparing the calculations for a lot of the mixture breakdowns. Knowing that they weren't patient-specific and that these were pre-existing formulations, they did what they needed to do with giving us the proper dilutions and to make them the product that they were asked to make.

M^me^ France Gélinas: In the other setting that you had worked in before, were you ever preparing medications that were going to be patient-specific?

Ms. Roberta Young: Yes. All of them were.

M^me^ France Gélinas: All of them were? Okay. Would it be, then, within your scope of practice to make sure that what you are preparing is appropriate for a patient?

Ms. Roberta Young: For us at that point? No, it was not our scope of practice to do that.

M^me^ France Gélinas: I'm basically trying to understand within a technologist's scope of practice. Do you have access to information such that when it is appropriate, when you're preparing something that is patient-specific, you would know what dosage is appropriate for a patient? Or you never know?

Ms. Roberta Young: It's not for us to determine if it was the proper concentration. That's what the pharmacist did the pre-checks for. They would determine. They would do all the calculating. They had all the information—the body weight, the testing and whatever background needed to be done for that patient. They would have made that conclusion. There have been instances where a technician, just from experience, has caught the odd thing that we had questioned along the way, but that's not a requirement of us.

M^me^ France Gélinas: I take it that you were in the room—and I'm not too sure who I should ask my question of; I have a feeling it will be the pharmacist. There were conversations that were relayed to us that at some point you saw that the concentration of vancomycin was not appropriate. Somebody called the hospital pharmacist and was more or less told not to ask questions, just to provide the products. Do you know who had that conversation?

Ms. Roberta Young: I do. It was Laura Savatteri.

M^me^ France Gélinas: What else do you remember from that conversation?

Ms. Roberta Young: We were asked to provide a higher-than-usual dose of vancomycin. Due to our experience with vancomycin in the patient-specific formulations, we knew that that was a higher dose that had the potential to cause this syndrome. She sent an email regarding that to the pharmacist in, I believe, Thunder Bay. I can clarify that once I look at the email. Not in as harsh words as "It's not your business to ask us," but politely writing back, "We're aware of the situation and, you know, we're asking you to make this. We are taking steps to ensure that we administer it properly to avoid that situation."

M^me^ France Gélinas: Are you aware of other instances where flags—you're noticed that some of your colleagues have picked up flags before when something was being prepared that raised a flag. Are you aware of

other instances where yourself, a technologist, or people you work with kind of picked up on, "Hmm, maybe we'd better check"?

Ms. Roberta Young: Not really. Only mostly with this product, because all of the other products that we prepare were already established products on the list that was given to us. This was something that was asked for in addition to the existing Medbuy list.

M^me^ France Gélinas: I see. I see. Which is why—

Ms. Roberta Young: It was questioned.

M^me^ France Gélinas: —it raised red flags.

If I was to ask you the same thing, Ms. Salman, in the course of your work as a pharmacist, did you ever pick up red flags that you were about to prepare a medication that is not within a proper dosage?

Ms. Kawther Salman: Do you mean my work with Marchese Hospital Solutions, like IV fluid, an IV fluid? Like now, in Marchese Hospital Solutions, right?

M^me^ France Gélinas: No, in your career as a pharmacist.

Ms. Kawther Salman: In my career, if it is retail pharmacy, if I have a patient, I have the prescription. I'll double-check; even I ask another person with me to double-check everything—the dose, if it is the right administration. We will double-check everything.

But in Marchese Hospital Solutions, no. Because when I started, if you see, they started production in February; I started with them in the middle of July. Everything was ordered by hospitals, and there wasn't any issue with the production, with the order by hospitals. The breakdown was created. We considered—me and the IV technician—they considered the breakdown as a bible for us. We just follow the breakdown. We don't have to check it again, because it's already created by a team of experienced pharmacists.

M^me^ France Gélinas: I'm trying to understand what makes you so confident that, although you have the knowledge and skills to check for dosages that are appropriate for patients, you found yourself in a situation where it was okay not to check. Is it because you really had confidence in the team that had prepared the bible list?

Ms. Kawther Salman: Because I trusted the team, because there wasn't any issue with the orders, so why I should check? If something is right for me—we are producing these orders on a daily basis, and hospitals are getting these orders since February, and there wasn't any issue, so why I shouldn't be confident?

M^me^ France Gélinas: So that gives you the confidence—

Ms. Kawther Salman: Yes.

M^me^ France Gélinas: —to not have a look and to not go any further.

When you had your first telephone conversation with—I take it that it was also with Judy—do you remember how long this conversation lasted?

Ms. Kawther Salman: It's less than five minutes.

M^me^ France Gélinas: And what was your initial reaction when you realized that they needed the concentration-specific and you hadn't been doing that?

Ms. Kawther Salman: As I said, I was working in the anteroom and checking, and Bobbi told me they wanted to clarify about the concentration of the admixture that we are preparing. So when I called her, I told her, "This is the way that we are preparing." She asked me, "Do you remove the overfill from the bag?" I told her no. She said, "So the concentration will not be 38 milligrams per millilitre?" I told her yes, and she said, "So we have a problem with the computer."

I have no idea how the hospital use, and I have no idea that they will have a problem because their computer, I understood, accepts specific concentration and will not accept the concentration with the overfill. So, at that moment, I just wanted to help her to solve the problem, and I said, "Is it possible to give it as a whole bag, like by gravity?" She said no. At this moment, I realize that they have a problem. She said, "Okay, I'll speak to the pharmacist in Lakeridge, Oshawa, and I'll call you back." Right away, when I finished my call with Judy, I wrote my email. I think you have it.

M^me^ France Gélinas: Right away, you knew the solution was to change the way you were preparing those two products—that product, anyway, to have it concentration-specific?

Ms. Kawther Salman: Yes. Our product doesn't meet their requirement. Their requirement—they want a concentration-specific solution. Our admixture is concentration-non-specific.

M^me^ France Gélinas: How big of a surprise was it to you?

Ms. Kawther Salman: Sorry; say it again.

M^me^ France Gélinas: Was it a big surprise to you to get that call, to realize that your product was not meeting—

Ms. Kawther Salman: Yes. Yes.

M^me^ France Gélinas: It was a big surprise?

Ms. Kawther Salman: Yes, because we realize the hospital have a problem, so the patient will have a problem. The patient will not get their medication. We address right away to the management team, who can make change, who can make communication.

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M^me^ France Gélinas: Since that phone call, have you ever gone to check what the normal dosage is for those drugs?

Ms. Kawther Salman: After this? Yes.

M^me^ France Gélinas: And what did you find out?

Ms. Kawther Salman: I found that it's by the surface area and there is no specific dose. It depends on the patient's weight and height.

M^me^ France Gélinas: Knowing what you know now, are you still willing to say that this bag could have been used for a single patient?

Ms. Kawther Salman: It depends.

M^me^ France Gélinas: Do you figure there's a single patient that could use four milligrams?

Ms. Kawther Salman: No.

M^me^ France Gélinas: Why do you say that?

Ms. Kawther Salman: Because according to that dose, it's too much for one patient.

M^me^ France Gélinas: Is it close to a single dose or far away from a single dose?

Ms. Kawther Salman: I cannot say. I don't know, because it depends. We have to calculate the patient's surface area and we calculate how many milligrams the patient will need.

M^me^ France Gélinas: We were told by other pharmacists that we would need to have a standard male who was 5 foot 10, 900 pounds to ever need such a dosage. Do you figure that's accurate?

Ms. Kawther Salman: Sorry, say that again? What was accurate?

M^me^ France Gélinas: When the bags that you were preparing—if they had to be used on a single patient, that patient would have had to weigh 900 pounds.

Ms. Kawther Salman: I think we'd have to make a calculation to find the weight of the patient.

M^me^ France Gélinas: Since this happened, have you looked at the use of this drug at all?

Ms. Kawther Salman: Sorry, have I what?

M^me^ France Gélinas: Since you were coming here today, we were going to talk about those two chemo drugs. Did you look at them at all to see how those drugs were being used?

Ms. Kawther Salman: Yes, for sure. I reviewed the monograph for both of them.

M^me^ France Gélinas: And what can you tell us about them?

Ms. Kawther Salman: It's chemo medication. It can be given alone or in a cocktail with other medication. The dose depends on the patient. We have to get the patient's surface area from the height and the weight of the patient. There are many regimes of chemo medications. There is no specific regime to give this medication.

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

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

Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Thank you for coming in. Certainly what you presented to us was very, very clear.

I'll turn to Ms. Salman first. Once you, in particular, understood that Judy at the hospital was having difficulty with the overfill because she required the concentration-specific dose to calculate the correct dose for the individual patient, you came up with a couple of solutions. If you had to produce the admixture in either of the two ways that you suggested, would it have been much more time-consuming? Would it have been a difficult process? Could you describe to us what difference that would have made in terms of the time for preparation?

Ms. Kawther Salman: For the preparation of concentration-specific and non-specific?

Ms. Helena Jaczek: Yes.

Ms. Kawther Salman: It's the same. It's just one step, that we would remove the overfill. It's a bag of 100. Usually the technician, at the same time, withdraws 50 millilitres from this 100 and injects it into the vial of two grams of gemcitabine. And then a second 50 millilitres is injected in the second vial of two milligrams and shake it to reconstitute. This takes maybe one minute to check the overfill, dispose of it and then, after reconstitution, re-inject.

Ms. Helena Jaczek: So basically a very trivial difference in the process.

Ms. Kawther Salman: Yes.

Ms. Helena Jaczek: I know that we are clear that you weren't involved when the process was decided upon originally by Marchese, but if you had been told it's concentration-specific, it would have been a trivial difference for you to prepare the admixture in that way. It wouldn't have resulted in much more time for personnel—I'm trying to see if this would have had any impact potentially on the price of the bid.

Ms. Kawther Salman: On the price? I don't think so.

Ms. Helena Jaczek: You wouldn't assume so because the—

Ms. Kawther Salman: No.

Ms. Helena Jaczek: And that would be your experience, Ms. Young, as well, that it would have been—

Ms. Roberta Young: Correct, especially with the 100-millilitre bags. There was very minimal overfill in those bags and the syringe would easily remove it with one step, and it would be very little time.

Ms. Helena Jaczek: You both have considerable experience in retail pharmacy and, no doubt, were subject to inspections by the college of pharmacy in terms of the retail—is that correct?—when you were involved in the retail operation, Ms. Salman, as a member of the College of Pharmacists?

Ms. Kawther Salman: So your question is if I was inspected by—

Ms. Helena Jaczek: I'm just saying, were you knowledgeable of the College of Pharmacists' role in retail pharmacy?

Ms. Kawther Salman: Yes. In retail pharmacy, we have to follow the standards mentioned by the OCP, the requirements in the retail pharmacy. To run a retail pharmacy or to work in a retail pharmacy, there is some requirements we have to meet.

Do you want to say about how to run a pharmacy or how to work in a pharmacy, as a community pharmacy, as a staff pharmacist? As a staff pharmacist, I have to have competency that is required by the OCP. I have to have knowledge of pharmacy. I have to be concerned with the patient care, to have direct patient care and to make sure the right medication, the right dose will go to the right patient.

Ms. Helena Jaczek: Were you surprised when you moved to Marchese Hospital Solutions that the College of Pharmacists was not so involved?

Ms. Kawther Salman: Yes, but at the same time, I knew that they are working to get a regulation, either by Health Canada or OCP.

Ms. Helena Jaczek: Who was working—

Ms. Kawther Salman: I don't know the details, but absolutely the management.

Ms. Helena Jaczek: So you understood that Marchese Hospital Solutions was looking for some sort of regulatory oversight?

Ms. Kawther Salman: Yes.

Ms. Helena Jaczek: Do you think that the fact that now the government has introduced some regulations here in Ontario for more oversight—do you think this is a good thing?

Ms. Kawther Salman: Yes. I know that for the OCP, they have a new regulation. It was made into force on May 15, and they agreed on May 10. On May 15, it was published and right away I sent them to Susan James; she's the adviser or practitioner. I told her that I'm working in DPP; the facility that prepared IV fluid they named as DPP. I told her that I am working now in DPP, so I want any form to fill, because they said any pharmacists, according to the new regulation, should be registered with the OCP if they work in DPP and any professional who supervised the preparation of IV admixture should be registered with the OCP.

So right away, on the same day, I sent them an email. I told them I want to register with the OCP. There is a specific form to complete if we need to get a licence to the facility. They said in the law, I have to write the date I started, and I asked them, "Do you want the date before the new regulation or after the regulation?" I also asked them, "Do you want me as a pharmacist to stay in the facility from the beginning"—like, for working hours, because the facility business hours are from, I think, 7 to 5:30, but I work from 8 to 5. I told them, "Is it just the retail pharmacy? You want me to stay there?" Susan told me, "Thank you for your question, your response so quickly. Now we are working on the form that's to be completed. I think she will send me the form to complete this week. I have your name now." I also provided her with the regulated technician who works with me and the part-time or casual pharmacist also to cover me when we need her. She told me that because it's not a retail pharmacy, you don't need to stay all day when the facility is open. You just need to work your hours.

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Ms. Helena Jaczek: So, in summary, you're doing everything you can to ensure that you're doing the right thing by the regulation?

Ms Kawther Salman: Yes, everything.

Ms. Helena Jaczek: You said you didn't have to provide the name of the pharmacy technician?

Ms Kawther Salman: No. They ask for any professional who supervises and who checked the IV preparation. Currently, I am the full-time pharmacist, and I also have a regulated technician who has the privilege to check and sign the orders.

Ms. Helena Jaczek: Were you present when Dr. Thiessen came to Marchese? Were you both—

Ms Kawther Salman: I was there. I was in the checking room. I finished by 5:30. He was there in the last few minutes. I didn't speak to him; I just saw him.

Ms. Helena Jaczek: Ms. Young, were you there, by any chance?

Ms. Roberta Young: Yes.

Ms. Helena Jaczek: Did you find it a useful exchange in terms of discussing the situation as it arose and potential recommendations?

Ms. Roberta Young: Yes, I thought he was very thorough. He asked a lot of questions. He was adamant about gathering all the proper information to make a very informed decision.

Ms. Helena Jaczek: Thank you. We have no further questions.

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

Mrs. Christine Elliott: Thank you, Ms. Young and Ms. Salman, for being here today. I just have a few questions of Ms. Salman.

You mentioned that when you started at Marchese Hospital Solutions, you asked a number of questions about what the job entailed and so on. You said that the procedure was already well established by the time you joined.

Ms. Kawther Salman: Yes.

Mrs. Christine Elliott: Did you ask any questions, or did you have an orientation session with people who were already in the department? First of all, did anyone talk to you about what this contract was for and the work you were going to be doing with it?

Ms. Kawther Salman: When I was trained by Stephanie, she trained on narcs order. I asked her what I should—like, you can get help or you can get experience from another one who has experience by asking what things we should concentrate on or what we should look for. I asked her, should I—like, for compatibility, because I worked in Iraq. I was a clinical pharmacist in a children's hospital, and when we prepare or give a patient any medication by IV, the first thing we check is the compatibility. I ask her, "Do I have to check the compatibility?" She said no, because this is all—we took over this contract from another supplier, which has been like for many years, so there is no problem.

Mrs. Christine Elliott: Did you have any conversations with any of the people you were working with about the fact that it wasn't a concentration-specific bag and what it was going to be used for ultimately, and would the people using it know that?

Ms. Kawther Salman: No. But when I started, from the first week I noticed that the weight of the bags is not even. I checked each single bag. I checked the label. I checked is it the right bag, is it saline, is it the right volume. Then I checked the bag to see if there is any foreign object and any precipitation.

I can't tell if there is a difference in the weight, so I said, "What's this difference?" I asked right away. They told me that there is overfill in each bag, which is within an acceptable range. From that, I have the assumption that there is nothing wrong, because it's acceptable; it's within the acceptable.

Always when I have doubts about the weight of the bag, I take it and weigh it. We have a scale which is a calibrated scale. I weigh the bag, and we know—I am not

talking about the chemo; any order—that this bag, before injection, should be within this range. After injection, it should be within this range. We make sure that it is right, it's injected—the right thing, the right volume.

Mrs. Christine Elliott: So you were initially concerned when you noticed that the volume in the bags was different—

Ms. Kawther Salman: Yes. I didn't discuss or ask, "Is it concentration-specific or non-concentration-specific?" But I noticed right away that there is a difference in the weight of the bag. I knew from that moment that there was overfill in the bag, and we don't remove the overfill. It's the contract saying—or, I don't know. That's it. This is the right weight they are doing.

Mrs. Christine Elliott: Okay. But you were told that that wasn't something to worry about; that all you needed—

Ms. Kawther Salman: Yes. It's within the acceptable. There is no problem.

Mrs. Christine Elliott: So you really just checked to make sure that the overfill was within the acceptable range.

Ms. Kawther Salman: Yes.

Mrs. Christine Elliott: Thank you.

Mrs. Jane McKenna: I just have a couple of questions.

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

Mrs. Jane McKenna: Ms. Young, I'm just looking at page 3 here, number 12. You have in here, "I indicated that the bag was not concentration-specific and it was therefore our assumption that it was for single-patient use." The word "assumption" worries me when it has to do with drugs. When you were finished talking with Judy, what did you do after to assure yourself that you weren't assuming that it was a single-patient use?

Ms. Roberta Young: After I spoke with Judy, I immediately went to Kawther to tell her of the concern that the hospital had. It's not my clinical background to know what a dosing of a patient was, and it wasn't in our specificity to inquire about dosing because these were predetermined formulas—recipes per se—that we inherited from the contract. We didn't need to look into that, because this was something that was pre-established. I let Kawther know that they had an issue with the concentration, and she took over from there.

Mrs. Jane McKenna: I guess, Ms. Salman, I'll ask you, then: If someone is on the phone with me talking, and in the second part of that sentence, "our assumption that it was for single-patient use," and then she has passed that over to you, I would want to know if it was or wasn't, because it's not specifically said there. Did Judy get the answer that it was or wasn't for single-patient?

Ms. Kawther Salman: She did not specifically say it's for a single patient. She said, "No, we cannot," because I asked her, "Can it be given as a whole bag by gravity to the patient so you can escape this problem with the computer?" She said, "No, we cannot." That's it. And she said, "Okay, thank you. I'll speak to Oshawa and I'll call you back tomorrow."

Mrs. Jane McKenna: Okay. Knowing what you know now and the outcomes of what you had—and I'm going to ask both of you this question, so I'll ask you, Ms. Salman, first—is there anything in the steps that you have done that you would have done differently?

Ms. Kawther Salman: Can you say it again? Sorry.

Mrs. Jane McKenna: Just because you've been through the process now—and it's like anything: Once you're out of it, you sit there and think, "Gee, maybe I would have thought of that," or "Gee, I would have done this differently." Now that you've had time to digest what exactly has transpired, is there anything you would have done differently?

Ms. Kawther Salman: Yes, for sure. I would make sure about the concentration, about how the hospital will use it, and we would prepare it according to their requirements.

Mrs. Jane McKenna: How would you have done that? What specifically would you have done?

Ms. Kawther Salman: Either by removing the overfill or by using sterile empty bags, and we'd reconstitute each vial of gemcitabine, two grams, with 50 millilitres, and we'd inject it in the empty bag.

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Mrs. Jane McKenna: But who would you have told that to? You just wouldn't have gone and done that without doing anything different. You just wouldn't have done that by yourself, so who—

Ms. Kawther Salman: My responsibility in this facility is—you can say checker or supervisor of production. I will address it to people who can make the decision to change and to do the right thing.

Mrs. Jane McKenna: Now that you're outside of the process, did it seem like an obvious thing to be doing or not an obvious thing to be doing? Is it because of the red flag that people came to you and addressed it? There are a lot of pharmacists that this went through for a year, and nobody picked up on this. I guess we can all say this here, but I'll only speak for myself—there was no time that anybody at any time questioned that until after you were brought to the attention of Judy, who called you to tell you this? Never?

Ms. Kawther Salman: Yes, because for this time no one noticed this problem. If the hospital noticed this problem from the first production, management would probably change the way that we prepared it so we prepared it in the right way. But I think because all this time we did not receive any calls and we did not receive any concerns about the bag concentration, we continued to produce it this way until Judy in Peterborough discovered this.

Mrs. Jane McKenna: Okay. Go ahead, Ms. Young. Is there anything you would have done differently now that you're out of the process?

Ms. Roberta Young: If we were given the same information at the start that we had originally received, I believe we probably would have proceeded in the same direction that we did initially. If it was given to us in a concentration-specific format, we would have proceeded

with the concentration-specific formulation rather than the way that we did do it.

Mrs. Jane McKenna: Okay. Just one more question. I'm only asking all of you this because of the severity of what's going on. There's a lot through this page here—page 4, number 15—when Bert has actually picked up the phone to talk to Ian, and then somehow it goes back to an email exchange. I'm only asking all of you this because I like to phone everybody and then follow up with an email so that the information is correct back and forth. I absolutely dislike emails because—you're already in such a situation right now with what has happened—emails get miscommunicated, and then people think they're reading something when they're not. Do you have a process in place right now where everybody is actually talking? Let me ask you this: Was it ever set anywhere where people were told, "Pick up the phone, talk to the person, and then go back and forth with an email specifically of what you said"? I was just wondering why Bert called Ian, and then somehow it then went to an email exchange. Did he not actually talk to Ian?

Ms. Roberta Young: No. He actually left a voice mail because we did try to do the call first. The call was the first option for us. The voice mail wasn't answered quickly enough; I guess Ian was involved in other things going on that day, but he did respond to his email. The email was the secondary option to try and get hold of him as quickly as possible, which he did reply to and said, "I'm busy. Can you please direct this to Charlene Jones?" I believe that's who it is. Yes. Then I proceeded to call her. She was unavailable at the time. I left a voice mail for her, and she did call me back in the afternoon.

Mrs. Jane McKenna: Okay. That's it for me.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Gélinas.

M^me^ France Gélinas: I'll go to Mrs. Salman. Do you get calls from hospitals on a regular basis?

Ms. Kawther Salman: Regarding?

M^me^ France Gélinas: Anything.

Ms. Kawther Salman: No, not too much.

M^me^ France Gélinas: Do you ever call hospitals regarding the work you do for them?

Ms. Kawther Salman: No.

M^me^ France Gélinas: No? So there's not much communication there at all?

Ms. Kawther Salman: No.

M^me^ France Gélinas: You know what has happened. You were preparing non-concentration-specific drugs when the hospital needed concentration-specific products. How do you figure that happened? How could it be that you were sure you were preparing the right products, yet it wasn't?

Ms. Kawther Salman: Do you mean how do I can figure out if it's the right thing we are doing or not?

M^me^ France Gélinas: How do you figure it happened? How come?

Ms. Kawther Salman: If there is an issue, like from the hospital, if they have concerns and they call us—they have issues with it—we know there is a problem.

Ms. Roberta Young: I think what she's trying to get at is nobody voiced a concern over this before this initial phone call. We had met the specifications of the contract, and nobody had issues with it before that point. Once the issue had arisen, then we took every step possible to try to rectify that as fast as possible.

M^me^ France Gélinas: Are you still working for Marchese Hospital Solutions?

Ms. Roberta Young: I am, yes.

M^me^ France Gélinas: How about you, Mrs. Salman?

Ms. Kawther Salman: Yes, I do.

M^me^ France Gélinas: How many days a week?

Ms. Kawther Salman: Five days a week, eight to five.

M^me^ France Gélinas: Okay. Thank you.

The Chair (Mr. Ernie Hardeman): With that, we'll go back to the government side.

Ms. Helena Jaczek: No further questions.

The Chair (Mr. Ernie Hardeman): PCs?

Mrs. Christine Elliott: We have nothing further.

The Chair (Mr. Ernie Hardeman): No further questions.

Thank you very much for your presentation. We very much appreciate you taking time out of your busy schedule to be here and help us out with this review. Thank you very much and what do I say? Keep mixing it up.

Ms. Roberta Young: Thank you for the opportunity.

The Chair (Mr. Ernie Hardeman): With that, the committee stands adjourned.

The committee adjourned at 1726.

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