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**Official Report
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(Hansard)**

Tuesday 7 May 2013

**Journal
des débats
(Hansard)**

Mardi 7 mai 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

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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

**STANDING COMMITTEE ON
SOCIAL POLICY**

**COMITÉ PERMANENT DE
LA POLITIQUE SOCIALE**

Tuesday 7 May 2013

Mardi 7 mai 2013

The committee met at 1601 in committee room 1.

The Chair (Mr. Ernie Hardeman): Mr. McLaughlin has been sworn in. We welcome you all here.

**OVERSIGHT OF PHARMACEUTICAL
COMPANIES**

MR. CRAIG WOUDSMA

The Chair (Mr. Ernie Hardeman): I'll call the meeting of the social policy committee to order this afternoon. We are here on the study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

The Chair (Mr. Ernie Hardeman): We'll start the day with Mr. Woudsma. You will have 10 minutes to make a presentation, and you can use all or any part of that. When your presentation is finished, we will have 10 minutes from each party to ask any questions of your presentation. That circulation will start with the official opposition this time around. With that, the floor is yours to make your presentation.

We have two delegations this afternoon. Just before we start the delegations, I just wanted to clarify—and this is for the media that is with us today—that we've had some concern in the last number of days about the media and the cameras interfering with the members along the committee table. You're quite welcome, and we're happy to have you here, but we would hope that you would stay either behind the Chair or behind the presenters but not along the two sides in the committee room. Okay?

Mr. Craig Woudsma: Okay. Thank you very much, Mr. Chair and ladies and gentlemen of the committee. I would like to begin my remarks by thanking the committee for supporting our request to limit today's statements to myself and my colleague Judy. Our pharmacy, which is assigned to the cancer clinic, has a normal complement of four assistants and one senior assistant, for a total of five.

With that, we thank you very much for being here. In order to start the hearing, we do ask that the witnesses be sworn in or affirmed, and we'll turn it over to the Clerk to get that done.

With one of our colleagues on medical leave and the quality assurance processes requiring at least two assistants—

The Clerk of the Committee (Mr. William Short): I'll start with the first witness. It's Craig Woudsma?

The Chair (Mr. Ernie Hardeman): Excuse, me. Could you speak into the microphone?

Mr. Craig Woudsma: Yes.

Mr. Craig Woudsma: I'm sorry. Is that better?

The Clerk of the Committee (Mr. William Short): You wanted to be affirmed?

The Chair (Mr. Ernie Hardeman): That's much better.

Mr. Craig Woudsma: Yes, please.

Mr. Craig Woudsma: Do you want me to start over?

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

The Chair (Mr. Ernie Hardeman): No, that's fine. Carry on.

Mr. Craig Woudsma: I do.

Mr. Craig Woudsma: Requiring the attendance of three of us would have resulted in the clinic's closure for one day and the cancellation of up to 45 patients. Judy and I sincerely appreciate your flexibility and understanding, and I am pleased to say that the full schedule of patients will continue to be treated today.

The Clerk of the Committee (Mr. William Short): Okay. Ms. Turner, you had asked to swear an oath?

Ms. Judy Turner: Yes.

My name is Craig Woudsma, and beside me is Dr. Peter McLaughlin, who I am certain you will remember from his attendance before this committee on April 30.

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

The Clerk of the Committee (Mr. William Short): Thank you. Mr. McLaughlin was already been sworn in.

I began my interest in pharmacy as a co-op student in high school during a placement in a retail pharmacy in Cobourg, Ontario. Following this experience, I began my studies in health sciences for one year at the University of Toronto and then subsequently transferred to Trent University in Peterborough to study English and history.

Throughout my studies, I continued to work in a retail pharmacy setting for a total of 10 years.

In 2007 I was certified through the Ontario College of Pharmacists and began to work at the Peterborough Regional Health Centre in the fall of 2009. After two years at PRHC, I received in-house certification to work in oncology in 2011.

I am pleased to report that I wrote my board examinations on March 20 of this year, three days after the incident, and I am in the final stages of registration as a pharmacy technician. My jurisprudence examination is scheduled for May 23. I am a member of the code brown hazardous materials spills and the code white violent individual teams, a union steward and a two-term co-chair of PRHC's occupational health and safety committee.

I realize that you've heard a detailed account from Laura Freeman during her testimony on April 30. Laura's report to you was quite in-depth so I will attempt to avoid duplication.

On the morning of March 20, 2013, the supply of gemcitabine from Baxter, the previous supplier, had been depleted. As part of the prescribed treatment regime, a patient scheduled for the afternoon was to receive gemcitabine. The new supply of gemcitabine was from the new supplier, Marchese, and was used for the first time that afternoon.

The new supply of Marchese gemcitabine stock was located in our pharmacy's refrigerator. My fellow pharmacy assistant noted at that time that, unlike the new Marchese bag, the previous Baxter supply did not require refrigeration.

As is our normal quality assurance process, I reviewed the label on the Marchese product. Unlike the bag of the predecessor supplier, neither the total volume nor the final concentration were included on the Marchese bag.

As the Baxter bag was still available from the treatments earlier that day, I compared the product labelling. The previous supplier's label listed a total of 4,000 milligrams, a total volume of 105.26 millilitres and a gemcitabine concentration of 38 milligrams per millilitre. On the other hand, the Marchese label indicated only four grams in 100 millilitres. I also noted that the electronic preparation worksheet used to calculate the dose used was 38 milligrams per millilitre, which was the Baxter final concentration.

With these important details outstanding, I was unclear whether the final concentration was 40 milligrams per millilitre, 38 milligrams per millilitre or otherwise. I consulted with our on-site DRCC pharmacist by phone regarding the bag labelling, the concentration and whether the electronic worksheet had the correct concentration for the Marchese gemcitabine bag. The pharmacist instructed me to hold treatment until hearing back from them.

I also consulted with Judy, our senior pharmacy assistant, regarding the concentration of the Marchese bag. The on-site pharmacist came to the pharmacy, as Judy, our senior assistant, went to place a call to Marchese for

clarification. You will hear about that call in her testimony.

The on-site pharmacist provided instruction to dispense the product. The medication was then released from the pharmacy to nursing for administration to the patient. Our manager of cancer care was in the area, and Judy made her aware of the potential issue and further inquiries. During her testimony, my colleague Judy will outline the steps she and I undertook with Marchese to make further inquiries. Since the incident, I participated in an in-depth interview with Dr. Thiessen.

Now I will be pleased to take any questions.

The Chair (Mr. Ernie Hardeman): Thank you very much. If that's all in your presentation, we will start the questioning, so we'll go to—

Mr. Jeff Yurek: Judy's next, isn't she? Oh, sorry.

The Chair (Mr. Ernie Hardeman): No, the witnesses will be done one at a time.

Mr. Jeff Yurek: Okay.

The Chair (Mr. Ernie Hardeman): And so the questions will start with the official opposition.

Mr. Jeff Yurek: Sorry about that, Chair.

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

Mr. Jeff Yurek: Thanks, Craig, very much for coming in, and thank you for the job you've done at the hospital in finding that error in the bag. I worked with a lot of pharmacy assistants and technicians, and I know how difficult a job it can be for you sometimes, but being alert and on the ball bodes well for you and it bodes well for the hospital. Congratulations and thank you very much.

Mr. Craig Woudsma: Thank you.

Mr. Jeff Yurek: And congratulations on working towards your regulation technician; that's a long process too—

Mr. Craig Woudsma: It really is, yes.

Mr. Jeff Yurek: Good luck on that exam coming up.

My question is, just in general with regards to Medbuy, do you know of or is there a policy at the hospital that if you're unhappy with the product you're receiving, you could contact Medbuy and say, "Look, I don't like what I'm receiving." Do you know of a process, or are you involved in one?

Mr. Craig Woudsma: I'm not involved with Medbuy at all. That's kind of a removed process. It's above where we are, so I don't really know.

Mr. Jeff Yurek: So with that product, you just go to the senior pharmacy assistant or the pharmacist, and then they would take it further?

Mr. Craig Woudsma: Exactly.

Mr. Jeff Yurek: Okay. You know what my question's going to be, Judy, when you're up, right?

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So the Baxter product wasn't refrigerated. Have you checked if the product needs to be refrigerated at all? Like is that just a—

Mr. Craig Woudsma: In the moment, the question of whether it needed to be refrigerated or not came up. Then

we noticed on the label that it did say for the Marchese bag to be kept refrigerated.

Mr. Jeff Yurek: Have you ever checked into that, into the literature to see if that was actually a necessity or not?

Mr. Craig Woudsma: Not up until this point, no.

Mr. Jeff Yurek: So you had no problem with the Baxter bag you had been using for the last year. Then when you switched over to the new bag, that's when you noticed the problem.

Mr. Craig Woudsma: That's right.

Mr. Jeff Yurek: Could you explain the worksheet that you work with?

Mr. Craig Woudsma: Certainly. It's an electronic worksheet that is the result of the physician doing a computerized order entry. Then it goes to the pharmacist for checking. When it comes to us in the pharmacy, it has the patient's name, all their pertinent information—height, weight, BSA, that kind of thing. It has the regime that they're taking, the drugs specific to that regime. Then there's a breakdown of milligrams that the patient will be receiving, then an associated volume and then areas for doing a written check.

Mr. Jeff Yurek: And do you have someone check the work that you do?

Mr. Craig Woudsma: Our quality assurance process involves two assistants.

Mr. Jeff Yurek: Right.

Mr. Craig Woudsma: One is inside the biological safety cabinet actually doing the admixing. Then there's someone on the outside of the cabinet doing checks as well.

Mr. Jeff Yurek: So explain to me the process of making the bag, at the end of the day. Do you put a new label on a new bag? Is it patient-specific when you're done? Just go through the whole—

Mr. Craig Woudsma: I can go through the whole thing. The doctor does the order entry. It goes to the pharmacist for checking. We get a label, and then the pharmacist passes us a copy of the computer-generated worksheet.

From there, the assistant on the outside of the biological safety cabinet takes the correct bag, the drug, and makes sure the line for the bag is primed. It gets passed in, labelled, to the pharmacy assistant inside the hood, as well as the drug and associated items that they're going to need to withdraw the medication and then admix it to the bag. The assistant inside the hood does a non-verbal check of everything, and the assistant on the other side of the hood also does a non-verbal check of everything. Then, there's a final verbal check at the end before the bag gets admixed, so the drug gets added to the bag. From that point, it gets wiped down, placed in a chemo transport bag and then, in our case, gets put into a pass-through window, which is where nursing retrieves the medication.

Mr. Jeff Yurek: How has your workflow been since the incident? I imagine you're doing more compounding now than you were beforehand.

Mr. Craig Woudsma: Previously, yes. But before the medications came already mixed, we were doing everything by hand, as it were. We were mixing the vials etc., so it really hasn't impacted our workflow at all.

Mr. Jeff Yurek: Have there been any problems with the compounding in the hospital at all?

Mr. Craig Woudsma: No.

Mr. Jeff Yurek: You had no problems. I will pass it on.

Mrs. Christine Elliott: Good afternoon, Mr. Woudsma. I'd really also like to thank you very much, you and Ms. Turner, for coming forward to the committee. I know this has been a very difficult time for all of you, but I think it's really critical that we hear from you about what actually happened. Contrary to some of the news reports we've heard which suggested that you compared the actual volumes in the bags, it sounds to me that you were first alerted by the fact that the Marchese product, the new product, needed to be refrigerated, and then you investigated further. Is that fair to say?

Mr. Craig Woudsma: That would be correct.

Mrs. Christine Elliott: Okay. You did refer to the labelling on a Baxter bag. Was that an empty bag that you looked at or was that a filled bag?

Mr. Craig Woudsma: That was a bag that had a remainder of medication in it that wasn't sufficient to administer to a patient. So it was kind of just a leftover. It was the transition from the last of that stock to the new Marchese stock, so it was handy that we just had it on hand.

Mrs. Christine Elliott: But did you consider that the Baxter product labelling was ever a problem, or was it always very understandable to you about what the product contained?

Mr. Craig Woudsma: It was quite clear.

Mrs. Christine Elliott: Okay. And it was very apparent from the Marchese bag that it wasn't clear, is that correct?

Mr. Craig Woudsma: It was vague. So it just kind of begged the question.

Mrs. Christine Elliott: Okay. Is it very common for you to dispense a whole bag to one particular patient, or is it more common to use one bag for more than one particular use per patient?

Mr. Craig Woudsma: In this case, the medications are patient-specific and regime-specific. There are a whole bunch of variations just on the medication itself. In this case, with the gemcitabine, you give partial doses out of the larger stock bag.

Mrs. Christine Elliott: Would you ever have dispensed a whole bag to one patient?

Mr. Craig Woudsma: I don't know.

Mrs. Christine Elliott: Have you ever?

Mr. Craig Woudsma: I haven't, but I couldn't say that that couldn't happen. That's beyond my scope of practice.

Mrs. Christine Elliott: Could you tell us a little more about the conversation, as you knew it? I don't think you were the one who spoke directly with the Marchese rep,

but can you just tell us what you heard about that conversation?

Mr. Craig Woudsma: There were several conversations that happened. I was party to one conversation at the end when a pharmacist called us back, and it was involving their admix process for preparing the bag, which raised more questions.

Mrs. Christine Elliott: Because it was pretty clear that they thought the entire bag was going to be used for one patient.

Mr. Craig Woudsma: It was pretty clear, yes.

Mrs. Christine Elliott: And the pharmacist who actually allowed the dosage to be administered to the patient, notwithstanding some concern about the concentration and the volumes—do you know why the pharmacist made that decision to dispense the product?

Mr. Craig Woudsma: Again, that's above my scope of practice.

Mrs. Christine Elliott: You weren't involved in that, then?

Mr. Craig Woudsma: No, I was not involved in that decision.

Mrs. Christine Elliott: I think that's it. Thank you very much.

The Chair (Mr. Ernie Hardeman): Okay. The NDP: Ms. Gélinas.

M^{me} France Gélinas: It's a pleasure to meet you, Mr. Woudsma. I too want to congratulate you for your keen eye and basically for doing your job extremely well. I hope many other people took the occasion to thank you and to congratulate you. We're really proud of what you have done. I know that coming here doesn't seem like a reward, and I'm not going to pretend. We'll do our best to make that brief and let you go back to your work that you seem to be really enjoying. I think you've made a wise choice.

My first question follows up on the one you've heard. Right now, the pharmacy assistants are doing the whole preparation of gemcitabine. You go from the powder to the mixing to the concentration—all of this in-house.

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: Is this something you had ever done before?

Mr. Craig Woudsma: Yes, it was something we had done before.

M^{me} France Gélinas: And then you went to Baxter, then you went to Marchese and then you came back to that?

Mr. Craig Woudsma: That's correct.

M^{me} France Gélinas: And were you worried about having to mix those drugs?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: No? You feel you're competent to do this?

Mr. Craig Woudsma: Absolutely, yes.

M^{me} France Gélinas: And can you see any reason why you didn't simply continue to mix those drugs the whole time?

Mr. Craig Woudsma: I couldn't really speak to that. It was a decision that was made above us working in the pharmacy.

M^{me} France Gélinas: Had you ever asked for those drugs to not be mixed in-house?

Mr. Craig Woudsma: No. No, I didn't.

M^{me} France Gélinas: You didn't feel worried about it; you didn't feel it was too hard to handle or took too much time or anything of the sort?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: You feel pretty competent about it all. You've convinced me.

You said that now you're mixing it all, from the powder form all the way to the delivering it to the nurse in-house. Is this a bigger workload than you used to have? Are you guys working longer hours or are other people being brought in?

Mr. Craig Woudsma: No. It hasn't affected our workflow at all. It's a readjustment of what our daily process was. Every day we prepare for the next day, so that just became part of that process. Again, it was something, like I said, we had done previously. It hasn't been a problem.

M^{me} France Gélinas: It hasn't changed the number of staff, the number of hours or anything like this?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: Okay. I want to come back—he knows pharmacy way better than I. I also noted that the electronic preparation worksheet used to calculate the dose used 38 milligrams per millilitre, which was the Baxter final concentration.

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: Who had written that down, the 38 milligrams per millilitre?

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Mr. Craig Woudsma: I don't know. That gets pre-programmed in, and I'm not sure who was actually responsible for that.

M^{me} France Gélinas: So the physician had given you—the number of milligrams was on the prescription, as to how many milligrams were going to be delivered to that patient?

Mr. Craig Woudsma: That's right.

M^{me} France Gélinas: And you were to do the calculations from the concentration that you saw, and then you were to calculate it back how many you were to draw?

Mr. Craig Woudsma: Well, the calculation is already done. The worksheet indicates the milligrams the patient is supposed to receive, as well as the volume that is associated with that, and from that you can infer the concentration that they're using. That was, in that case, 38 milligrams per millilitre.

M^{me} France Gélinas: All right. So the 38 milligrams per millilitre that were on your worksheet, basically you had no way of knowing if this is what was in the bag? Somebody had taken for granted that this is what was in the bag?

Mr. Craig Woudsma: I can't speak to that. All I can say is that we caught it with our QA process and

identified that there was an inconsistency on some level that needed clarification.

M^{me} France Gélinas: Okay. I'm still curious as to, in the process of putting those electronic worksheets together, who works on that?

Mr. Craig Woudsma: I don't know.

M^{me} France Gélinas: It just comes to you; it just comes?

Mr. Craig Woudsma: Exactly. It comes as a program, and that's kind of just what we go on.

M^{me} France Gélinas: And this is where you start to work.

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: Okay. Sounds good.

You did say that you "consulted with our on-site DRCC pharmacist by phone regarding the bag labelling, the concentration and whether the electronic worksheet had the correct concentration" for the Marchese bag. Who was that pharmacist?

Mr. Craig Woudsma: I'm prepared to provide that if we could provide that to the Clerk afterwards.

M^{me} France Gélinas: Sure. No problem. You can provide it to the Clerk after.

From the time you were at the hospital, do you know how long this drug had been prepared on-site versus how long it had been outsourced, either to Baxter or to Marchese?

Mr. Craig Woudsma: From my perspective, when I started in oncology in 2011, in the spring of 2011, at that point we were compounding them by hand. It was shortly thereafter that they were brought in premixed. Like I said, I wasn't part of that decision or anything like that.

M^{me} France Gélinas: It just happened.

Mr. Craig Woudsma: It just happened.

M^{me} France Gélinas: Do a lot of drugs get outsourced like this?

Mr. Craig Woudsma: Not in the oncology pharmacy.

M^{me} France Gélinas: No? Are the two drugs that we have been dealing with the only two that you know of, or are there more?

Mr. Craig Woudsma: No. In our clinic, there was gemcitabine, the cyclophosphamide, as well as pamidronates and fluorouracil infusers.

M^{me} France Gélinas: That are off-site.

Mr. Craig Woudsma: That were produced off-site, yes.

M^{me} France Gélinas: Do you know if the pharmacy at your hospital and your cancer treatment centre have ever done it in-house?

Mr. Craig Woudsma: Absolutely. We do those in-house as well, subsequently, and that was done beforehand as well. They were made in-house.

M^{me} France Gélinas: Are you now making all of them in-house again?

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: You are, eh? The outsourcing was fun but really not that much fun. All right.

When we look at the website for Medbuy—Medbuy are actually the people who help with the outsourcing—

their website is really clear: They are there to save money. Do you feel that this is why some of the drugs had been outsourced, in an effort to save money?

Mr. Craig Woudsma: I couldn't say. I don't know.

M^{me} France Gélinas: You don't know. But as far as the staff schedule, number of hours, none of this had changed?

Mr. Craig Woudsma: No. Nothing like that was affected.

M^{me} France Gélinas: And now that you have this extra workload for those four drugs, nothing has changed either?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: And do you know if any of your co-workers are worried about preparing those drugs, like they liked it better when it came already premixed? Are you the only one who feels comfortable, or all of you?

Mr. Craig Woudsma: I can't speak to the opinions of my colleagues, but it's a process that we used to do, and it's a process that we've been doing now for a little bit of time. We're all extremely well trained and competent in what we do, so I feel confident.

M^{me} France Gélinas: Everybody is comfortable with the process.

Did you want to go?

Ms. Cindy Forster: Keep going. You're on a roll.

M^{me} France Gélinas: Okay. The process of outsourcing: Has this ever been discussed? I take it you have department meetings?

Mr. Craig Woudsma: Those are high-level conversations that don't happen with the regular pharmacy staff.

M^{me} France Gélinas: Okay. But do you have department meetings at your level? Do you ever meet as a group?

Mr. Craig Woudsma: Yes, absolutely.

M^{me} France Gélinas: And were there ever worries raised at your level that you didn't want to prepare some of the drugs, that you didn't feel comfortable preparing some of the drugs?

Mr. Craig Woudsma: No. Not that I'm aware of, no.

M^{me} France Gélinas: It never came from you guys? This was never an issue?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: When it became known and you started to talk to people, why was it that you were so reluctant to speak?

Mr. Craig Woudsma: I'll speak in my case specifically. What we do is for patient care. We're not looking for glory or anything like that. What we do is kind of the same thing, day in, day out, and we're there for the patients. We didn't want to add to the spectacle that it kind of became.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes your 10 minutes. It goes a lot quicker than the 20.

M^{me} France Gélinas: All right, then.

The Chair (Mr. Ernie Hardeman): Thank you. With that, then, Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair, and on behalf of the government, we would like to thank you so very much for being so alert and on top of the situation, and questioning and doing everything right, so our congratulations as well.

My colleague has been focusing on the outsourcing and what has happened since you've brought the process back in-house. You've been working at Peterborough since 2007. When outsourcing was started, was there any decrease in your normal complement of assistants or any changes?

Mr. Craig Woudsma: Well, I started in 2009. I just want to clarify.

Ms. Helena Jaczek: Okay.

Mr. Craig Woudsma: Not that I'm aware of. There hasn't been a decrease from the outsourcing at all, no.

Ms. Helena Jaczek: So in 2009, you had the same complement assigned to the cancer clinic as you do now?

Mr. Craig Woudsma: At the time when I started—I didn't actually start in the cancer clinic until 2011, and I don't recall the complement of people who were in cancer care at the time, but when I was brought on, nothing has changed since that point.

Ms. Helena Jaczek: Okay. And when you were brought on in 2011, you were compounding yourself?

Mr. Craig Woudsma: Yes.

Ms. Helena Jaczek: Yes. Okay. I just wanted to make that clear. So there was no real change due to outsourcing that impacted the staff complement assigned to cancer care.

Mr. Craig Woudsma: No.

Ms. Helena Jaczek: Thank you. You were originally certified through the Ontario College of Pharmacists, so you are a pharmacy assistant going through training to become a pharmacy technician.

Mr. Craig Woudsma: Yes.

Ms. Helena Jaczek: Could you just tell us what the difference in scope of practice will be once you're through your training?

Mr. Craig Woudsma: Okay. The previous process was certification through OCP, the Ontario College of Pharmacists, and then subsequently legislation came out that allowed for the regulated pharmacy technician title, and it became a protected title. So we, assistants, were given the opportunity to do bridging programs to achieve a regulated status, and that is making it kind of an even playing field. So when you say a pharmacy technician, you know that they've gone through a certain process and they'll have the same competencies. It's different in every jurisdiction as to the exact rules, and they're kind of always in flux, so we're always checking the OCP website to see exactly how things have changed.

Ms. Helena Jaczek: But you're expecting to have essentially the same type of work?

Mr. Craig Woudsma: In the hospital setting, again, there are differences if you were in a community-based practice versus a hospital-based practice, and in the hospital it's kind of a continuing of duties, but there's an

added level of responsibility and accountability coming from a legal perspective.

Ms. Helena Jaczek: And has the hospital been encouraging you to upgrade, or how is that working?

Mr. Craig Woudsma: It was made mandatory to achieve it by March 2014, and they've provided financial compensation to achieve that.

Ms. Helena Jaczek: Okay. Thank you. In terms of this electronic preparation worksheet—I guess we're really all concentrating on this. So you really are not clear who prepares that. I mean, is it the physician, the pharmacist? Would you have any idea?

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Mr. Craig Woudsma: Well, it's the physician who makes the order and the pharmacist who checks the order, but the actual programming of the concentration of the medication, I don't know. I know values are put in by the doctor for what they want to achieve for the patient, but the broader scope of how the program was put together, I'm not aware of.

Ms. Helena Jaczek: I think we're all kind of making an assumption that the 38 milligrams per millilitre was used because everybody knew that's what Baxter provided. I mean, it just seems logical that Baxter was always 38 milligrams per millilitre, and so nobody, other than you, was necessarily aware that the product suddenly was going to say four grams in 100 millilitres.

I'm sort of wondering if the worksheet had actually had 40 milligrams per millilitre, would you have questioned the concentration in the Marchese bag?

Mr. Craig Woudsma: I don't want to, kind of, conjecture. The labelling raised questions on its own, independent from the concentration on the worksheet, and I think that speaks for itself.

Ms. Helena Jaczek: That's what started it for you.

Mr. Craig Woudsma: Yes.

Ms. Helena Jaczek: Okay, we're clear on that.

Again, this relationship—you have an on-site DRCC pharmacist and then there is an on-site pharmacist. I'm wondering, you would normally report—and this is why you consulted with the DRCC pharmacist, because you're the cancer piece of the pharmacy. You got conflicting views on administration—

Mr. Craig Woudsma: The DRCC on-site pharmacist is the on-site pharmacist.

Ms. Helena Jaczek: Oh, it's the same pharmacist.

Mr. Craig Woudsma: Yes.

Ms. Helena Jaczek: Again, then, I'm a little unclear. The first instruction was hold treatment and then that same individual said, "Go ahead and administer."

Mr. Craig Woudsma: That's correct.

Ms. Helena Jaczek: Okay, I got that.

Your hospital pharmacy's relationship with the Durham Regional Cancer Centre is essentially very direct. I mean, the DRCC on-site pharmacist may be physically located in Peterborough but is essentially the responsible pharmacist for the administration of chemotherapy. Is that correct?

Mr. Craig Woudsma: The DRCC pharmacist who is on site is responsible for checking the orders that come from the physicians that we have there in the clinic.

Ms. Helena Jaczek: Okay. You mentioned your in-depth interview with Dr. Thiessen. Can you share what the conversation was about?

Mr. Craig Woudsma: It was an in-depth look at the exact events of that day, kind of from every step. He had some very pointed questions, and we answered them completely openly.

Ms. Helena Jaczek: And so another tipoff, apart from this discrepancy between the electronic worksheet and the concentration, was this issue of refrigeration or not. Baxter didn't have to be refrigerated, and Marchese did. Would you be aware of why that would be? I mean, essentially you've got the same products in the mixture.

Mr. Craig Woudsma: I couldn't say.

Ms. Helena Jaczek: Okay.

Mr. Craig Woudsma: They could have used a different product to make it, or whatnot. It's hard for us to say there in the pharmacy. All we can do is question it.

Ms. Helena Jaczek: I think that we've covered as much as we need to. Thank you very much.

Mr. Craig Woudsma: Thank you.

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

Mrs. Christine Elliott: Thank you. I just have a few follow-up questions.

Mr. Woudsma, were you the first person to use the new product. Had everybody else that day been using the remainder of the Baxter product?

Mr. Craig Woudsma: That is correct. This was the first patient to use stock from Marchese.

Mrs. Christine Elliott: So you were the first assistant to notice the different products and to be alerted to the fact that there were some differences between the two.

Mr. Craig Woudsma: Well, we were all aware that a new supplier was being used instead of Baxter, but myself and my colleague were the first ones to encounter having to use this medication specifically.

Mrs. Christine Elliott: And this is your colleague who's going to come at a later time, or wasn't able to come today?

Mr. Craig Woudsma: Wasn't able to come today.

Mrs. Christine Elliott: Okay. Did anybody else notice it? Any of the other assistants, did they notice a concern when the product came in and the fact that it had to be refrigerated? Were there questions that were being asked about the new product?

Mr. Craig Woudsma: I can't speculate. I think there were some questions about stability because it was a different supplier, so there might be variations. But I can't speak to that because I wasn't involved in any process with that. It hadn't gone through our rigorous QA process that we use when administering, so that was the portion—that's how it got picked up.

Mrs. Christine Elliott: Thank you very much.

Mr. Craig Woudsma: Thanks.

The Chair (Mr. Ernie Hardeman): Thank you. Did you have another couple of questions? We have a little mix-up here with my time.

M^{me} France Gélinas: Thank you, Mr. Chair. Just in follow-up to Dr. Jaczek, you said that you participated in a meeting with Dr. Thiessen. Who else was there at the meeting with you and how long did the meeting last?

Mr. Craig Woudsma: At the time, if I remember correctly, there was myself, Judy and our fellow colleague who is not with us today; there was Dr. Thiessen, as well as the hospital's lawyer. I can't remember—I believe Margot DaCosta was there; she's one of our directors. I can't recall. It lasted for about an hour.

M^{me} France Gélinas: For about an hour?

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: Did you have any preparation before coming here? Did anybody talk to you about coming to Queen's Park?

Mr. Craig Woudsma: We had some preparation insofar as what we were going to say and what we could anticipate because it's a rather unique situation for us.

M^{me} France Gélinas: Who helped prepare you?

Mr. Craig Woudsma: It was a combination of staff at the PRHC executive level who helped with that.

M^{me} France Gélinas: Could you name them for me?

Mr. Craig Woudsma: Certainly. Dr. McLaughlin, Arnel Schiratti, Brenda Weir. As well, our manager was sitting there at the time, Karyn Perry.

M^{me} France Gélinas: And what did they say?

Mr. Craig Woudsma: It was kind of just going through what our statements would entail and the kind of questions that we could anticipate. Like I said, it being kind of a unique situation, we're not—

M^{me} France Gélinas: Who wrote your statement for you?

Mr. Craig Woudsma: It was a collaborative process of us indicating our information as well as a detailed report of the events that had transpired. That kind of came together at that.

M^{me} France Gélinas: And who was part of that team that put it together?

Mr. Craig Woudsma: I believe Arnel Schiratti—he's our communications—and I believe his assistant as well. I don't know her name, I'm sorry.

The Chair (Mr. Ernie Hardeman): Okay. It's your last question; make it a good one.

M^{me} France Gélinas: Oh no. The issue of whether the drugs were prepared in concentration-specific or non-concentration-specific has been an issue here. As far as your understanding of the drug that you were going to draw from, was it your understanding that this drug was supposed to be concentration-specific?

Mr. Craig Woudsma: All our drugs are concentration-specific based on the dose and the patient's specific information.

M^{me} France Gélinas: Okay. So—

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

Ms. Helena Jaczek: Well, I think it's probably a follow-up. When you saw on the Marchese label "4 g in 100 mL," that is essentially a concentration, is it not?

Mr. Craig Woudsma: It leads you to believe that the concentration, perhaps, would be 40 milligrams per millilitre, but it doesn't explicitly say that, so we questioned it.

Ms. Helena Jaczek: So did you then—because I don't see it in your presentation—actually take the bag and measure the total cc's or millilitres in the bag?

Mr. Craig Woudsma: No. That wouldn't be something that we would do because that would be manipulating the solution, and we try to keep manipulations down to a minimum for sterility purposes.

Ms. Helena Jaczek: Was there ever any check done on that bag to find out what the actual concentration was?

Mr. Craig Woudsma: No. What was done was a question to the company to provide clarification as to what the exact concentration was.

Ms. Helena Jaczek: And then what was that communication back to you? What did they say?

Mr. Craig Woudsma: In the conversation that I was a party to, it was reiterated that the four grams in 100 millilitres was sufficient and the concentration wasn't pertinent. Then we indicated the concentration would be pertinent, given their method of preparation, and then they said they would follow up.

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Ms. Helena Jaczek: Because I think we've read somewhere that the actual volume was 107 millilitres. I'm wondering where that came from.

Mr. Craig Woudsma: Right. I think that speaks to overfill—

Ms. Helena Jaczek: Right.

Mr. Craig Woudsma: —and there's overfill in some bags, so that raises a question.

Ms. Helena Jaczek: So when you were party to the conversation with Marchese, did they allow as much, that there could be overfill, or did they maintain there was 100 millilitres in the bag?

Mr. Craig Woudsma: They maintained there was four grams in the bag and that the overfill wasn't pertinent because the concentration wasn't pertinent.

Ms. Helena Jaczek: I see. Okay. Thank you.

I think we are satisfied at this point. I think we're probably out of time, as well.

Interjection.

Ms. Helena Jaczek: How much time do we have left?

The Chair (Mr. Ernie Hardeman): You have another minute left.

Ms. Helena Jaczek: Okay. I think we'll just conclude by saying thank you again, and good luck to you in the future.

Mr. Craig Woudsma: Thank you.

The Chair (Mr. Ernie Hardeman): Okay, thank you. You have one question, Mr. Yurek?

Mr. Jeff Yurek: I have two questions.

The Chair (Mr. Ernie Hardeman): Make them quick; you don't have that much time.

Mr. Jeff Yurek: I just perked up when you said you were in a conversation with someone who said the concentration wasn't pertinent in this case?

Mr. Craig Woudsma: That's correct.

Mr. Jeff Yurek: Who were you talking to at that point?

Mr. Craig Woudsma: A pharmacist at Marchese had called the pharmacy and had discussed their method of preparation. We had reiterated that overfill was an issue in the concentration—is an issue. The response was quite clearly that the concentration didn't matter; there was the understanding on their part that the full four grams was administered to the patient.

Mr. Jeff Yurek: At that point, they thought—

Mr. Craig Woudsma: At that point.

Mr. Jeff Yurek: Their idea was that the whole bag was given?

Mr. Craig Woudsma: That's right.

Mr. Jeff Yurek: Okay.

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

Mr. Jeff Yurek: Oh, do you still use empty bags? Do you fill from empty bags now, or do you withdraw solution and fill in?

Mr. Craig Woudsma: What we do is, we—sorry, do I respond?

The Chair (Mr. Ernie Hardeman): Yes, go ahead and answer the question.

Mr. Craig Woudsma: With the medications that we have prepared in vials, we withdraw a specific amount of fluid and, based on stability and the whole range of information for that drug specifically, we further dilute it. There are some medications that are administered through direct subcutaneous access, but by and large, the medications all require further dilution.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes that presentation.

MS. JUDY TURNER

The Chair (Mr. Ernie Hardeman): We will now start the second presentation this afternoon. Judy, as with the previous one, you have 10 minutes to make your presentation, and then we'll have questions from each party. This time, the questioning will start with the third party.

Ms. Judy Turner: Thank you, Mr. Chair, and good afternoon, members of the legislative committee. As my colleague Craig said, I'm the senior pharmacy assistant in the cancer clinic.

I began my training and career in health care as a registered nursing assistant for 10 years at the Peterborough Civic Hospital. I went on to receive further pharmacy-specific training at Humber College. At the beginning of my pharmacy career, I worked for four years in the main pharmacy, and have spent the last 15 years specializing in the oncology pharmacy. I am a code brown hazardous materials spill trainer, and assisted in

all training and certification for hospital staff at the Peterborough Regional Health Centre.

I sit on the Central East regional pharmacy committee, where we developed a new safe handling manual for chemotherapy agents. I was also proud to represent PRHC at a safe handling seminar in Colorado. I have completed all of my pharmacy technician registration exams and am awaiting notification of the final stage.

In my testimony, I wish to focus on the events of the afternoon of March 20, 2013, beginning at 14:30, when I became involved in further exploration and investigation with Craig.

Upon comparing the bags, I noted that the Marchese bag was mixed in a Hospira bag, which has a known approximate overfill of seven millilitres. It was not clear from the labelling on the Marchese bag if the overfill had been included to determine the final concentration.

At 14:33, I called the pharmacist to sit in on a call to the supplier, Marchese, to seek clarification about the concentration. When I asked about the overfill and the impact on the concentration, the Marchese staff member responded that it was still four grams in 100 millilitres. They also offered to have me speak with a Marchese pharmacist. I agreed and awaited the call.

A Marchese pharmacist contacted us shortly thereafter and advised us that the final concentration would not change due to the overfill because the entire contents of the bag would be administered to the patient. We explained the process for our dose delivery, that the patient would in fact not receive the entire contents of the bag, and that the entire four grams would therefore not be given to a patient. The Marchese pharmacist stated that they would need to investigate further and get back to me.

At 15:30, I made the manager of our cancer clinic aware of a potential concentration issue.

Further to the direction from the DRCC pharmacy, PRHC immediately discontinued use, and the supply of gemcitabine was quarantined in the PRHC pharmacy.

I would later receive an email from Marchese indicating that they were working on a solution and would provide follow-up.

Since that incident, I've participated in an in-depth interview with Dr. Thiessen.

This concludes my remarks about the events of March 20, 2013. However, I want to close by making a few brief comments about our team.

I'm very proud of the group of professionals I have the privilege of working alongside. I also wish to recognize the exceptional team of physicians, nurses, pharmacists and other health care professionals who help our patients get the care and support they need in their personal battle against cancer.

Finally, on behalf of everyone at PRHC, we would like to publicly acknowledge and thank everyone at Cancer Care Ontario, the Durham Regional Cancer Centre and Lakeridge Health who have been behind PRHC every step of the way.

Without their support in the development of our cancer services at PRHC, cancer patients from Peter-

borough and beyond would have little choice but to travel to Oshawa for care multiple times weekly in all types of weather.

Soon we will be complementing our existing services with the opening of the Norm and Jessie Dysart radiation suite at PRHC. We're looking forward to that day in June, when patients requiring radiation treatment will be able to remain closer to home.

Thank you, and I'd be happy to take questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We will start this round with the third party.

Ms. Cindy Forster: Thank you. Thanks very much for being here. In your presentation, you talked about, "I later received an email from Marchese indicating that they were working on a solution and would provide follow-up." Did they follow up?

Ms. Judy Turner: No, they didn't.

Ms. Cindy Forster: Thank you. Are front-line staff in your pharmacy ever asked to review, assess or evaluate products?

Ms. Judy Turner: No, they're not.

Ms. Cindy Forster: They're not. Okay.

Can you expand upon the issue of refrigeration? I'm still not quite clear on that. Two particular medications that were sourced through Marchese you formerly got from Baxter. The Baxter sourcing didn't require refrigeration, but Marchese did. Did you do any kind of investigation into why the differences?

Ms. Judy Turner: That would be beyond my scope.

Ms. Cindy Forster: Someone indicated in their presentation that a pharmacist directed the medication as it was labelled, the four grams in 100 millilitres to be administered. I'm assuming that this was based on the specific dose for the patient and not to actually administer the entire bag.

Ms. Judy Turner: Can you repeat the question?

Ms. Cindy Forster: Somewhere in somebody's presentation, they had checked with a pharmacist, who said to go ahead and administer that first bag that was in question. So I'm assuming that that direction was based on the specific dose from your electronic order sheet and not to administer the entire four grams.

Ms. Judy Turner: Just a clarification: So—

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The Chair (Mr. Ernie Hardeman): Excuse me. Ms. Forster, could you move your mike closer? Ms. Turner too. Speak directly into the microphone.

Ms. Judy Turner: Is that better?

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

Ms. Judy Turner: Your question is, did the pharmacist direct the assistants to administer—

Ms. Cindy Forster: —a dosage that was on your electronic worksheet.

Ms. Judy Turner: Yes, right, as opposed to the full bag.

Ms. Cindy Forster: As opposed to the full bag. Okay.

Now you're mixing the medications in-house again. I wasn't quite clear, with the answer that went to Mr.

Yurek, about whether or not you use an empty bag, mix your medications, fill that bag and then use that bag for multi-dose, or whether you're using a bag which in one situation has 107 millilitres in it generally, and mixing your drug and then adding it to the bag.

Ms. Judy Turner: On our bags that contain our drugs, once they're put into the bag, on our label it will tell you a total volume.

Ms. Cindy Forster: Right. But how do you know what the volume is in that particular bag, if the bags have overfill?

Ms. Judy Turner: Right. We have a chart, and the overfill is listed on the chart, so it would be on the label.

Ms. Cindy Forster: So every bag has the same overfill.

Ms. Judy Turner: Depending on the company, it's plus or minus.

Ms. Cindy Forster: Okay. Today, when you are actually doing your own mixing of these drugs, are they still multi-use, multi-patient-use bags that you're mixing, or are they individual patient doses?

Ms. Judy Turner: They're individual.

Ms. Cindy Forster: They're individual patient—

Ms. Judy Turner: —doses.

Ms. Cindy Forster: —doses. Was Marchese preparing any other medications, other than those two chemo agents, for your pharmacy?

Ms. Judy Turner: Yes. They prepared pamidronate and the fluorouracil.

Ms. Cindy Forster: Which are also cancer agents?

Ms. Judy Turner: Yes.

Ms. Cindy Forster: Any other drugs beyond those, that you're aware of?

Ms. Judy Turner: Not that I'm aware of.

Ms. Cindy Forster: Okay. Thank you.

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

M^{me} France Gélinas: Since then, aside from the bag that alerted you, did you go and check on the other drugs that you were receiving from Marchese? Or you simply refused to use them?

Ms. Judy Turner: Everything was quarantined when we had the directive from the DRCC.

M^{me} France Gélinas: Okay. In your testimony, you say that you called Marchese. "When I asked about the overfill and the impact on the concentration, the Marchese staff member responded that it was still four grams in 100." Who was that staff at Marchese who said that?

Ms. Judy Turner: Her name was Bobbi Young.

M^{me} France Gélinas: Okay—oh, my pen just died—Bobbi Young. Then, "A Marchese pharmacist contacted us shortly thereafter." Who was that pharmacist?

Ms. Judy Turner: I only have the spelling of her first name, and I'm not even sure if the spelling is correct.

M^{me} France Gélinas: Try me.

Ms. Judy Turner: It's K-A-W-T-H-E-R.

M^{me} France Gélinas: Basically, she introduced herself by her first name, and she's the one who told you

that the drugs—the whole bag was going to be used on a single patient.

Ms. Judy Turner: That's correct.

M^{me} France Gélinas: Okay. You have been at the pharmacy for 11 years—

Ms. Judy Turner: Fifteen.

M^{me} France Gélinas: Even longer; for 15 years. I missed four years, somehow. Would you say that in your time in pharmacy—was there a time where all the drugs were done in-house, or did you always outsource?

Ms. Judy Turner: There was a time when they were all done in-house.

M^{me} France Gélinas: Do you have any supervision responsibility as the senior—

Ms. Judy Turner: Not supervision responsibility, no.

M^{me} France Gélinas: No? So what does it mean to be a senior assistant?

Ms. Judy Turner: In my role, I do billing, I do certification for the assistants coming into our cancer clinic, I sit on committees and I work inside the preparation room two days a week.

M^{me} France Gélinas: All right. In the committees that you sit on, were you ever part of discussion as to—have you ever requested that some drugs be outsourced?

Ms. Judy Turner: No.

M^{me} France Gélinas: You've never requested that. Have you ever heard anybody else at those committees that talks about the need to outsource?

Ms. Judy Turner: No.

M^{me} France Gélinas: Do you feel quite confident that it doesn't come from the pharmacy that drugs be outsourced, it comes from someplace else in the hospital?

Ms. Judy Turner: I'm not really sure where it comes from.

M^{me} France Gélinas: But it doesn't come from where you worked, anyway?

Ms. Judy Turner: No.

M^{me} France Gélinas: Or the committee that you're part of.

Ms. Judy Turner: No.

M^{me} France Gélinas: That's good.

I will come back to this issue of concentration-specific and non-concentration-specific: Would you say that this is something out of the ordinary for the work that you do or is it pretty basic pharmacy practice to make sure that you check concentration?

Ms. Judy Turner: In our area, it's very basic that you check concentration.

M^{me} France Gélinas: This is the way work is done all the time?

Ms. Judy Turner: Yes.

M^{me} France Gélinas: Are there other areas of pharmacy where concentration doesn't matter that much?

Ms. Judy Turner: I can't comment on that.

M^{me} France Gélinas: Because you would have seen antibiotic IV bags already prepared where you give the whole bags, no?

Ms. Judy Turner: No.

M^{me} France Gélinas: Never in your life?

Ms. Judy Turner: Not in my area.

M^{me} France Gélinas: Not in your area. Did you want to add something to this? No? Okay.

Who are some of the people that coached you before you came here?

Ms. Judy Turner: There was our communications director; there was our lawyer; Brenda Weir; and Dr. McLaughlin

M^{me} France Gélinas: What's the name of your lawyer?

Ms. Judy Turner: Kate—I'm unsure of her last name.

M^{me} France Gélinas: A good friend of yours? No?

Who prepared your written statement?

Ms. Judy Turner: We had input into it, and then the communications director.

M^{me} France Gélinas: And you felt that it reflected what you wanted to tell us?

Ms. Judy Turner: Yes.

M^{me} France Gélinas: When you talk with other people who work in pharmacy, this is being done—the outsourcing is to save money is something that we hear a lot. I mean, we go onto Medbuy's website, and it's there in black and white. This is why they exist. Would you agree that this is a motivation for the hospital to outsource drugs—to take advantage of what Medbuy is saying and to save money?

Ms. Judy Turner: I don't really have an opinion on that.

M^{me} France Gélinas: Or were you told not to have an opinion?

Ms. Judy Turner: We're not part of the Medbuy—we wouldn't be privy to those conversations.

M^{me} France Gélinas: No, but you've worked in a pharmacy for a long time.

Ms. Judy Turner: Yes.

M^{me} France Gélinas: You've seen that you're plenty capable, willing and able to prepare those drugs. This is your livelihood; this is your job. All of a sudden, your job is being outsourced, and you don't have an opinion?

Ms. Judy Turner: It would be a directive that came from up higher. It wouldn't come from the pharmacy in our institution.

M^{me} France Gélinas: But the result of it affects you. I'm not asking you what the lawyer told you to say. I'm asking you: What is your opinion of outsourcing the job that you do?

Ms. Judy Turner: I think we're there for patient safety, and that's paramount to me—if we can do it in-house safely, or it can be outsourced safely.

M^{me} France Gélinas: Do you figure it was outsourced safely?

Ms. Judy Turner: We're waiting for Dr. Thiessen's report.

M^{me} France Gélinas: Really? You don't have an opinion on that?

Ms. Judy Turner: I can't really comment on that.

M^{me} France Gélinas: Why not? Everybody else is commenting. It has been the top of the news for over a

month. It has been on the front page of the paper for six weeks. This is your livelihood; this is what you do. This is why you do it, because you want to help people. Yet, you're standing here under oath, and you don't have an opinion? There are 13 million Ontarians out there that have an opinion, and they know way less than you do.

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Ms. Judy Turner: I think if it could be outsourced safely, and save the taxpayers' money, possibly; but if it can be done in-house, then we're prepared to do that.

M^{me} France Gélinas: Then it should be done in-house.

The Chair (Mr. Ernie Hardeman): You have one more question?

M^{me} France Gélinas: I'll save it.

The Chair (Mr. Ernie Hardeman): Okay. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Ms. Turner, for your alertness in responding, and the initiative that, obviously, both of you demonstrated, especially in initiating the call with the supplier in a very timely fashion.

You've been 15 years specializing in oncology pharmacy, and that time has been in Peterborough?

Ms. Judy Turner: Yes. That's correct.

Ms. Helena Jaczek: It has. As you look back over those 15 years, in terms of the complement of pharmacy assistants that have been working in the chemotherapy area, what has happened through the years? Have you been pretty stable with the personnel or have you increased? What has been the story through the years?

Ms. Judy Turner: Historically, we've increased as our clinic has gotten busier and our patient load has gotten heavier.

Ms. Helena Jaczek: So more people, obviously, are coming closer to home, and all that good stuff.

Ms. Judy Turner: Yes, that's correct.

Ms. Helena Jaczek: When were these products outsourced to Baxter for you?

Ms. Judy Turner: Sometime in 2011, I believe.

Ms. Helena Jaczek: Okay. And during that time, you were satisfied, clearly, with the labelling. You had no anxieties with the product?

Ms. Judy Turner: No. The labels were very clear.

Ms. Helena Jaczek: And as you've told us just most recently, you don't have any personal feeling that there's inappropriate outsourcing, obviously with the proviso that patient safety is secured. Having heard that the ministry, working with the College of Pharmacists and working with Health Canada, will be putting in place oversight in terms of the College of Pharmacists being able to go into outsourcing facilities, inspect, and do their due diligence in terms of the competency of the pharmacist supervising etc., would you find that that reassures you?

Ms. Judy Turner: Yes.

Ms. Helena Jaczek: Thank you. Just to get back to this mysterious electronic paper worksheet: Are you aware of who actually prepares that, or how it gets created?

Ms. Judy Turner: It's a program somebody creates. I'm not aware of who it is.

Ms. Helena Jaczek: So in other words, your DRCC pharmacist, to your knowledge, is not involved in plugging in numbers and getting the worksheet prepared?

Ms. Judy Turner: Are you talking in terms of concentration?

Ms. Helena Jaczek: I'm talking in terms of the document that Mr. Woudsma told us had the information on it. I understand: The physician writes the order. There's a dose that is required. I guess it's puzzling that we don't seem to be able to track, from that doctor's order, how the electronic preparation worksheet gets to you.

Ms. Judy Turner: The drugs would be built in a drug dictionary. I'm not aware of who does it. Then it would flow into a physician's order; the physician would put it in. It would flow to the pharmacist. The pharmacist would check the dose, the volume and the blood work. Then it would flow to the assistants in the prep room. They would get labels and they would check their labels against the electronic order, and then the preparation takes place.

Ms. Helena Jaczek: When you called the DRCC on-site pharmacist, and said, "We've got an issue in terms of the fact that we don't know if the concentration delivered to us from Marchese is, as it always used to be with Baxter, 38 milligrams per millilitre," what was the response from the pharmacist?

Ms. Judy Turner: So, for my part, I called the DRCC pharmacist on-site and asked her to come and sit in with me on a conversation when I called Marchese. I wasn't part of that initial conversation.

Ms. Helena Jaczek: Okay. Was that Mr. Woudsma then?

Interjection.

Ms. Helena Jaczek: Yes. Okay. Then you took it sort of the next step—"Let's check this concentration." You had the conversation, and then it was you who noticed that the bag was what you knew to normally contain 107 millilitres, and that's when you had the conversation with Marchese. Then you were clearly not satisfied. When you heard that the response was that the entire bag—Marchese understood that the whole bag was going to be administered to the patient and, therefore, the patient would get four grams and you said, "No, that's not the way we do it," were you surprised at that response?

Ms. Judy Turner: I was.

Ms. Helena Jaczek: In other words, because of your experience in oncology chemotherapy, you would have also expected that the compounding facility would have the sort of knowledge that this would not be a likely dose for one patient?

Ms. Judy Turner: Right.

Ms. Helena Jaczek: So that's when the alert took place. Then immediately after that, the DRCC pharmacist said, "Hold everything. We're not using the product." Is that—

Ms. Judy Turner: Correct.

Ms. Helena Jaczek: Okay. Thank you. I think we will reserve any time for the next go-round.

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

Mr. Jeff Yurek: Thanks, Chair. Thanks for coming in. Good job, good work, your staff.

You're a senior technician assistant?

Ms. Judy Turner: Almost there.

Mr. Jeff Yurek: Almost technician.

Ms. Judy Turner: Almost.

Mr. Jeff Yurek: You said you had—just fill us in. You're waiting for the final stage to become registered. What's that entail?

Ms. Judy Turner: Paying insurance.

Mr. Jeff Yurek: Insurance?

Ms. Judy Turner: Insurance to the college.

Mr. Jeff Yurek: Do you have any oversight of any staff, or are you just the one with the most experience?

Ms. Judy Turner: I'm the one with the most experience.

Mr. Jeff Yurek: And a lot of people rely on your thoughts and how to do stuff in the pharmacy?

Ms. Judy Turner: The assistants.

Mr. Jeff Yurek: I'm sure the pharmacists do, too.

Since you started reconstituting the two medications, the chemo drugs back in the hospital, have there been any chemo spills, any safety issues that have arisen from that?

Ms. Judy Turner: No.

Mr. Jeff Yurek: You also had a statement here—this is on page 2, I guess. You said, "We explained the process for the dose delivery"—to the Marchese pharmacist—"and that the patient would in fact not receive the entire contents of the bag, and that the entire four grams would therefore not be given to a patient." Now, this is just your thought—I want your thought on this—but wouldn't you think that Medbuy would have explicitly explained that to Marchese when awarding the contract? Does that make common sense?

Ms. Judy Turner: I would have to assume that that discussion may or may not have taken place.

Mr. Jeff Yurek: Yes. You'd think, though, it would be common sense to explain what you expect the provider to provide, wouldn't you think?

Ms. Judy Turner: I would think the expectations would be made known.

Mr. Jeff Yurek: I asked the question earlier and I said I would ask you this question: Is there a process to send a complaint to Medbuy or does it have to go through the hospital to send to Medbuy—is there a process to say, "You know, I'm not happy with the product you've procured for me"?

Ms. Judy Turner: We're not part of the procurement process.

Mr. Jeff Yurek: So if you get a faulty product, is there not—you have quality assurance there, naturally. Is there not a process that you would take your concern to?

Ms. Judy Turner: We would fill out an incident report—our internal incident reporting system.

Mr. Jeff Yurek: Okay. And where would that go?

Ms. Judy Turner: Then that would go to our med safety officer.

Mr. Jeff Yurek: And has there ever been a problem with faulty product that had to go, a response to Medbuy in the system?

Ms. Judy Turner: No.

Mr. Jeff Yurek: Not that you know of?

Ms. Judy Turner: Not that I'm aware of.

Mr. Jeff Yurek: Okay. Has the hospital had to upgrade its facility at all to handle the preparation of the chemo drugs?

Ms. Judy Turner: No.

Mr. Jeff Yurek: And the other—just one more question for this point. It's an easy one. The College of Pharmacists: You're now becoming registered with the College of Pharmacists. What are your thoughts on the College of Pharmacists actually inspecting and regulating internal hospital pharmacies?

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Ms. Judy Turner: I think it may be beneficial at some point.

Mr. Jeff Yurek: Okay.

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

Mrs. Christine Elliott: Yes, thank you, Ms. Turner. I also would like to thank you for being here today and for the great work that you did with your team and with Mr. Woudsma in uncovering this problem.

You examined the bags that the Marchese product was mixed in and you discovered that it was a Hospira bag, which had a known overfill limit. Did you ever encounter that issue with the Baxter product, and what type of a bag was it packed in?

Ms. Judy Turner: The Baxter product would be prepared and then put into an empty Viaflex bag. In the conversation with Marchese, they stated that they took the fluid out of the Hospira bag to reconstitute the vials. That's how we got to the point of the overfill.

Mrs. Christine Elliott: So they didn't indicate to you that they dealt with the overfill; it was just that it contained the four milligrams in the bag, but the volume wasn't known.

Ms. Judy Turner: Correct.

Mrs. Christine Elliott: And then, can you just tell us how you got your DRCC pharmacist involved and the name of that person? Who was the pharmacist you spoke to?

Ms. Judy Turner: Can we provide that to the Clerk?

Mrs. Christine Elliott: Certainly. Is that what's normally done, Mr. Chair, the name of the pharmacist from DRCC Ms. Turner was dealing with?

The Chair (Mr. Ernie Hardeman): Yes. You can table it with the Clerk if you so wish.

Mrs. Christine Elliott: Sure. Okay, that's fine. If you can provide that, that would be great.

Can you just tell us the nature of your conversation with the pharmacist to and through the conversations with Marchese?

Ms. Judy Turner: I called the pharmacist and asked her to come to sit in on the call with Marchese and we

went through the reconstitution practice at Marchese with a staff member from Marchese. The DRCC pharmacist sat and listened to the conversation.

Mrs. Christine Elliott: Did the DRCC pharmacist have any direct conversation with the Marchese pharmacist?

Ms. Judy Turner: No.

Mrs. Christine Elliott: Did he or she express concern to you about the product, based on the conversation that you had with the Marchese pharmacist?

Ms. Judy Turner: Not at that point.

Mrs. Christine Elliott: And they made the decision to administer the product to the patient, notwithstanding the concern with respect to the concentration of the solution. Do you know why they made that decision or on what information they based that decision?

Ms. Judy Turner: I don't know. I wasn't part of that conversation. That was a conversation that took place with the DRCC pharmacist and the assistants in the prep room.

Mrs. Christine Elliott: Okay. So you had nothing to do with that whatsoever. I think that's it. Thank you very much.

Ms. Judy Turner: Thank you.

The Chair (Mr. Ernie Hardeman): You have one very short question left.

M^{me} France Gélinas: You took part in the meeting with Dr. Thiessen. Who do you remember being there and how long do you remember the meeting lasting?

Ms. Judy Turner: The people present were Karyn Perry; Kate, the lawyer; Dr. Thiessen; Craig Woudsma; Tamara.

The Chair (Mr. Ernie Hardeman): Is that it?

Ms. Judy Turner: Yes.

M^{me} France Gélinas: And for how long?

The Chair (Mr. Ernie Hardeman): Okay. That's the end of the questions. Your time is up. Ms. Jaczek?

Ms. Helena Jaczek: How long do I have?

The Chair (Mr. Ernie Hardeman): Seven minutes.

Ms. Helena Jaczek: Oh. Perhaps you could explain to us a little bit about what quality assurance programs you have in place within the oncology chemotherapy part of the pharmacy at Peterborough.

Ms. Judy Turner: Certainly. We have a rigorous QA and it involves checks at different parts of the process. The first would be that the physician enters the orders. The pharmacist does the check. It comes to us. The assistant gets the order or the electronic copy and the labels, and does their first check. Then they would take the the bags, whatever specific bags they require, put the labels on, get the drugs and compare the drugs to the labels. Then they would pass it in to the biological safety cabinet, where the second assistant is going to prepare. The second assistant will look at the electronic copy of the doctor's order and compare the label. There will be a volume on that electronic copy. They draw up the volume for whatever drug they are preparing. Then there's the third check, a verbal check. Then it's put into the bag.

Ms. Helena Jaczek: So essentially, two pharmacy assistants are basically checking each other's work.

Do you have any visits from Durham Regional Cancer Centre to come and check the pharmacy?

Ms. Judy Turner: We're certified once a year. I was certified through Durham, and then I trained and certified the assistants.

Ms. Helena Jaczek: Do they come physically and visit you? Is that part of the certification process?

Ms. Judy Turner: No.

Ms. Helena Jaczek: What does the certification process look like?

Ms. Judy Turner: When you first become part of our team, you spend four to six weeks on the job learning about the chemotherapy agents and the biological safety cabinet. Then, after four to six weeks, they do a written test, and they also do a manipulation test based on questions in our safe handling manual. They must achieve a certain percentage to continue on.

Ms. Helena Jaczek: We heard from the College of Pharmacists yesterday that there is a different process in different provinces related to the college of pharmacy oversight in hospital pharmacies. Were you aware of that?

Ms. Judy Turner: No, I was not.

Ms. Helena Jaczek: Prior, perhaps?

Ms. Judy Turner: No.

Ms. Helena Jaczek: So the College of Pharmacists in Ontario is doing a consultation, I guess, pretty much across the country and with Health Canada as to whether this would be advisable to incorporate that. Do you have any opinion on the matter of College of Pharmacists oversight within a hospital pharmacy?

Ms. Judy Turner: It might be beneficial at some point.

Ms. Helena Jaczek: You'd say it couldn't hurt, I guess.

Is there anything else you'd like to tell us? Something that hasn't come up in the last hour and 20 minutes that you feel you want to say?

Ms. Judy Turner: I don't think so.

Ms. Helena Jaczek: Thank you.

Ms. Judy Turner: Thank you.

The Chair (Mr. Ernie Hardeman): The official opposition, further questions?

Mr. Jeff Yurek: She can go home.

The Chair (Mr. Ernie Hardeman): You're done?

Mr. Jeff Yurek: We're tired.

The Chair (Mr. Ernie Hardeman): Well, if everybody is done—

Mr. Jeff Yurek: Chair? I'd just like to request legislative research to find stability data on compounded cyclophosphamide and gemcitabine. That will answer the refrigeration question for the committee. It's all about stability. If you can look up the stability data.

The Chair (Mr. Ernie Hardeman): Okay. Very good.

Ms. Helena Jaczek: And Chair, could we somehow, from Peterborough regional hospital, find out a little bit more about this electronic preparation worksheet, who produces that?

The Chair (Mr. Ernie Hardeman): Okay. We'll leave that with the Clerk to see what he can find out.

We thank you very much for being here this afternoon, making your presentation and helping us get deeper down into figuring out what happened. Thank you very much for being here.

With that, there being no further business of the committee, the committee stands adjourned till Monday.

The committee adjourned at 1719.

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