ISSN 1710-9477

Legislative Assembly of Ontario

Second Session, 40th Parliament

Assemblée législative de l'Ontario

Deuxième session, 40e législature

Official Report of Debates (Hansard)

Monday 3 June 2013

Journal des débats (Hansard)

Lundi 3 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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Room 500, West Wing, Legislative Building
111 Wellesley Street West, Queen's Park
Toronto ON M7A 1A2
Telephone 416-325-7400; fax 416-325-7430
Published by the Legislative Assembly of Ontario

Service du Journal des débats et d'interprétation
Salle 500, aile ouest, Édifice du Parlement
111, rue Wellesley ouest, Queen's Park
Toronto ON M7A 1A2
Téléphone, 416-325-7400; télécopieur, 416-325-7430
Publié par l'Assemblée législative de l'Ontario

LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON SOCIAL POLICY

COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Monday 3 June 2013

Lundi 3 juin 2013

The committee met at 1420 in committee room 1.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

The Chair (Mr. Ernie Hardeman): I call to order the June 3 committee on social policy, a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

MS. NANCY FROUDE

The Chair (Mr. Ernie Hardeman): The first delegation we have today is Lakeridge Health centre: Nancy Froude. If Nancy would take a seat at the front of the table.

There are a number of items on the committee's desks that we will be discussing after we have our delegations today. We haven't forgotten about those.

With that, we want to thank you for coming in today, Nancy. We do want to point out, obviously, that we're doing this committee hearing under oath. So the Clerk will deal with that. Either you will affirm or swear the oath before we start the presentation. Mr. Clerk?

The Clerk of the Committee (Mr. William Short): Would you prefer an oath or an affirmation?

Ms. Nancy Froude: An oath, please.

The Clerk of the Committee (Mr. William Short): The Bible is in front of you, there.

Ms. Froude, 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. Nancy Froude: I do.

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

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will start the presentation. We have 20 minutes for you to make your presentation. You can use any or all of that. Then when you've completed the presentation, we will have questions for 20 minutes from each caucus. This time, the rotation will begin with the official opposition.

Thank you very much again for coming in. The floor is yours.

Ms. Nancy Froude: Thank you. Good afternoon, everybody. My name is Nancy Froude, and I would like to thank you for inviting me to address the Standing Committee on Social Policy today.

I'd like to begin by telling you a little bit about myself, my qualifications and experience, and then I will address the events that occurred on March 20.

I am a member of the Ontario College of Pharmacists, in good standing, and graduated from the University of Toronto with a bachelor of science degree in pharmacy in 1992. Upon graduation, I began my practice in various community pharmacy settings, experiencing settings that varied from a small, independent pharmacy to a big chain drugstore.

In 2006, I began a temporary position at Lakeridge Health in the pharmacy department to cover a maternity leave. I took the position because I wanted to gain the experience of working in a more clinical hospital setting. Following that contract, I returned to work in a community pharmacy in the Port Perry area. I was subsequently contacted by Lakeridge Health as they were recruiting for their pharmacy team in the R.S. McLaughlin Durham Regional Cancer Centre. I was hired in 2008 by Lakeridge Health to join the pharmacy team within the cancer centre, where I have worked ever since.

My main role there relates to the retail pharmacy within the cancer centre. It is a dispensing pharmacy for our outpatients within the cancer centre so our patients can access medications for oral chemotherapy to be taken at home, anti-nausea medications and other injectable medications related to their care that may not be available in a typical community pharmacy. This also provides a chance for a pharmacist to review prescriptions for oral chemotherapy and to provide thorough counselling to our patients.

My other duties in the cancer centre include reviewing chemotherapy treatment orders, blood work, checking of doses and monitoring for drug interactions.

I am part of the multidisciplinary team and work closely with the nurses, physicians, dietitians and, on occasion, social workers. I am also part of the oncology clinical trials team and work closely with other members of that team. We comprise one of the largest community oncology trials teams in the country.

Most recently, I was asked to take on an additional role as the Central East region lead for the smoking cessation program. The role as regional lead will provide me with the opportunity to work with Cancer Care On-

tario and leads from other cancer centres in the province to help improve the lives of cancer patients and their families.

On March 20, I received a call in the afternoon from Sarah Hickey. Sarah is a pharmacist and colleague of mine who works out of the cancer clinic at Peterborough Regional Health Centre. On occasion, Sarah will call in to the cancer centre pharmacy in Oshawa, particularly regarding computer issues, to consult or to seek a second opinion.

That day, Sarah told me a pharmacy assistant in Peterborough had noticed a difference in the labelling on the medication bags for gemcitabine that we had recently begun receiving from a company called Marchese—a change from our previous supplier, Baxter. Sarah told me the concern was over the concentration labelling on the bag. The Marchese product was labelled as four grams in 100 millilitres, whereas the previous bags were labelled as four grams in 104 millilitres. I looked up the drug entry for gemcitabine in our computer to verify the concentration that our computer system was working off of, and realized that something was not right. Since I was unsure of the scope of the problem, I told Sarah that I needed to investigate the discrepancy further and that I would call her back.

I then immediately went into what is called our "clean room," which is the area where the chemotherapy drugs are prepared, to speak to our pharmacy assistants who handle the drugs directly. I asked to see the product, and the first thing I thought was, "This just doesn't seem right." The company was using a Hospira 100-millilitre pre-filled IV solution bag and there would be overfill, so I wondered how the supplier was using these bags to make the gemcitabine. I was told by the assistants that our previous supplier had been using empty Viaflex bags in their production process.

We then decided as a group that the only way to be certain about the volume within the bag was to pull it all out and measure using syringes. One of the pharmacy assistants then went into what is called "the hood," or the biohazard safety cabinet, and withdrew the entire volume out of a bag of gemcitabine into syringes to be able to verify the actual volume within the bag. She called me back into the clean room when she was finished and we looked and saw that it was actually 111 millilitres, not the 100 millilitres as labelled on the bag. This led us to believe the likely issue was that the supplier did not pull the overfill out of the bag as part of their processes.

Our next thought was, "What else are we getting from them?" The pharmacy assistant then advised me that we were also receiving cyclophosphamide from the same manufacturer. When we looked at that medication, we saw it was in a 250-millilitre pre-filled IV solution bag, which to me seemed even more wrong. We went through the same process of pulling the volume out of the bag, and it was clear they had again not accounted for the overfill in their production process. In what was labelled to be a 200-millilitre volume, there were actually 223 millilitres. We came to the conclusion that the difference here was more significant.

The results of these two tests made it clear to us that we needed to call the manager of the pharmacy immediately to let her know. While one of the pharmacy assistants started the process of calling and then paging the manager, I phoned Sarah Hickey back at the cancer clinic in Peterborough. I had a very brief discussion with Sarah and advised her that they should not use the product from Marchese any further.

By then, the manager of our pharmacy had come to the cancer centre pharmacy and we went over our conversations and the volumes we had found in the bags. The decision was made that we were not going to use the product the next day and to use the vials as supplied directly from the manufacturer.

This is where my involvement ended.

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I would like to put on the record how proud I am of the pharmacy teams at Lakeridge Health and the Peterborough regional cancer centre. We definitely have to keep asking questions because no matter how many computerized systems are in place or how many checks and double-checks are involved, we're all just human, and we are all subject to the frailties of human error, miscommunication and misunderstanding. But we all got into health care and into the profession of pharmacy because we want to use our skills to help people feel better and live healthier lives by having the safest pharmacy with the highest possible standards.

After working a summer job during high school at a small family-run community pharmacy, I was immediately drawn to the profession. One particular pharmacist there made a real difference in people's well-being, and that has stuck with me. I enjoy the daily interaction with patients, and have developed relationships with them and their families as they come in to pick up their prescriptions and ask for medication-related information.

I have high expectations and standards set for myself, and when I have prescriptions filled for my kids and family, I expect my colleagues to have done the same, and that is what our entire team at Lakeridge Health brings to our pharmacy.

I'd like to thank you for the opportunity to address you all today, and I look forward to answering your questions to the best of my abilities.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. As I said previously, we'll start with the official opposition, Mr. Yurek.

Mr. Jeff Yurek: Thank you, Chair. Thank you, Ms. Froude, for coming in and spending your day with us—or afternoon. Just a few questions that have come up: In your comments, you mentioned that Baxter's bags were 104 millilitres before, not 100 millilitres.

Ms. Nancy Froude: Correct.

Mr. Jeff Yurek: That's interesting. Did you have any knowledge of the contract with Medbuy at all?

Ms. Nancy Froude: I did not.

Mr. Jeff Yurek: And you worked in the retail part of the hospital pharmacy?

Ms. Nancy Froude: Right. So we have an outpatient pharmacy within our cancer centre, so that patients can get medications filled there to take home with them.

Mr. Jeff Yurek: And that's separate from the hospital pharmacy?

Ms. Nancy Froude: Correct. Well, it's within the cancer centre pharmacy, so we're in the same location geographically.

Mr. Jeff Yurek: Because your section, being the retail, would be inspected by OCP?

Ms. Nancy Froude: We're not a fully accredited pharmacy, so no, we are not.

Mr. Jeff Yurek: Okay. How much time had elapsed between you getting the first call from Sarah and then going and figuring out what went wrong and then calling Sarah back? How quick?

Ms. Nancy Froude: It was probably a little over an hour. I'm not sure of the exact times. There was a lot going on at the time, but somewhere around that time frame.

Mr. Jeff Yurek: But it was a fairly quick response?

Ms. Nancy Froude: Yes.

Mr. Jeff Yurek: My other question is—then I'm going to pass it on to the third party and then I'll carry on later—with regard to the product supplied from Medbuy, if there's a problem with a product, is there some sort of procedure in place to which you could send the complaint to Medbuy to give them your cautions or warnings of why you're not happy with the product?

Ms. Nancy Froude: I'm not aware of any formal process that's in place.

Mr. Jeff Yurek: Where would you report that to? To your manager—

Ms. Nancy Froude: I would, yes. I think it would depend on the issue that needed to be questioned as well a little bit.

Mr. Jeff Yurek: Okay. But you don't know of any process at all of—

Ms. Nancy Froude: I'm not aware of any formal process.

Mr. Jeff Yurek: Now, if you have a product from GlaxoSmithKline that is defective, do you have a process to deal with that product?

Ms. Nancy Froude: We do have a pharmacy assistant who deals with inventory and ordering, and she can sometimes be a resource or, again, depending on what the issue is, I may take it upon myself to call GlaxoSmithKline as a pharmacist and speak to somebody in their medical department.

Mr. Jeff Yurek: Okay, but you don't have anything for Medbuy?

Ms. Nancy Froude: Correct.

Mr. Jeff Yurek: Okay. I'll hold until later and pass it on.

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

M^me^ France Gélinas: Thank you for coming, Ms. Froude. The first question I'd like to ask is from your statement. You say you get the phone call from Sarah. You immediately go and talk to a pharmacy technician dealing with those drugs, and then you go back to the computer. You say, "I looked up the drug entry for gemcitabine in our computer to verify the concentration that the computer system was working off of, and realized something was not right." What exactly are you looking at when you make this statement?

Ms. Nancy Froude: Basically, I looked at the computer first to see what we had entered as the concentration for gemcitabine.

M^me^ France Gélinas: What had you entered?

Ms. Nancy Froude: It was entered as 38 milligrams.

M^me^ France Gélinas: Where do you figure that entry came from?

Ms. Nancy Froude: That entry is entered, again, by pharmacy staff.

M^me^ France Gélinas: Where would they have gotten this number, the 38?

Ms. Nancy Froude: Based on the product monograph.

M^me^ France Gélinas: From Baxter or from Marchese or both?

Ms. Nancy Froude: The 38 would have come from Baxter.

M^me^ France Gélinas: And that same information from the monograph was carried forward although you had changed suppliers.

Ms. Nancy Froude: Correct.

M^me^ France Gélinas: I don't want to put words in your mouth. You realized something was not right because some of the information for the monograph came from one supplier while you were looking at a different supplier?

Ms. Nancy Froude: No, I made that conclusion because when I looked in the computer, it said 38 milligrams per millilitre. Going by what they had on the bag, the four grams in 100 would make it 40 milligrams per millilitre. So I knew that something wasn't matching.

M^me^ France Gélinas: What you had in the computer should have matched what was on the bag. How come it didn't?

Ms. Nancy Froude: I don't know the answer to that.

M^me^ France Gélinas: Have you gone back since then to see where the disconnect happened?

Ms. Nancy Froude: I have not.

M^me^ France Gélinas: Why not?

Ms. Nancy Froude: That's why I involved our pharmacy manager: to deal with those concerns.

M^me^ France Gélinas: Are you confident that everything else that comes from the monograph that is in your computer is accurate, or could that kind of disconnect happen with other drugs?

Ms. Nancy Froude: I'm confident that what is entered in our computer system is accurate.

M^me^ France Gélinas: And you're confident because—

Ms. Nancy Froude: Because of the staff that we have working. Things are checked and double-checked.

M^me^ France Gélinas: Things were checked and double-checked for that one also. But then you knew that something was wrong.

Ms. Nancy Froude: Correct.

M^me^ France Gélinas: What am I missing here?

Ms. Nancy Froude: I'm not sure.

M^me^ France Gélinas: All right. You go on to say, "I then immediately went into what is called our 'clean room'—the area where chemotherapy drugs are prepared—to speak to our pharmacy assistants...." Which one was it that you spoke to?

Ms. Nancy Froude: I spoke with Jodi Stamp.

M^me^ France Gélinas: She's the one who went under the hood and retrieved the liquid from the bag?

Ms. Nancy Froude: Yes, she is.

M^me^ France Gélinas: She's also the one who remembered that the products from Baxter came from Viaflex bags.

Ms. Nancy Froude: Yes.

M^me^ France Gélinas: You went on to check for the other cancer drug, the cyclophosphamide, then did your other little experiment, and found out. You called the manager of the pharmacy. Remind me who the manager is again.

Ms. Nancy Froude: Her name is Linda Skinner.

M^me^ France Gélinas: What was your conversation like with Linda?

Ms. Nancy Froude: You can imagine how everybody was feeling at that point. We had a lot of information to get across to Linda. We reviewed the information that we had retrieved from doing our sampling volume from the bags so she was aware of what processes we had taken and what the results of that process were, and explained to her the issues that would have, what approximately the percentage difference may be on the dosing, and just basically informed her of what we had discovered.

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M^me^ France Gélinas: What did she say? How did she react?

Ms. Nancy Froude: Like the rest of us, I think, shock and disbelief and sort of not sure how big the problem was at that point.

M^me^ France Gélinas: Were all three of you, Linda, yourself—who made the decision to say, "Let's not touch this anymore. Let's mix our own"?

Ms. Nancy Froude: Linda Skinner did.

M^me^ France Gélinas: And you supported that?

Ms. Nancy Froude: Absolutely.

M^me^ France Gélinas: You knew it was the right decision to make.

Ms. Nancy Froude: It was really the only decision to make at the time. There was no way we could continue to use a product that wasn't right.

M^me^ France Gélinas: So the next day, you said, "The decision was made that we were not going to use that product the next day and use the vials as supplied directly by the manufacturer." If you were getting them premixed, why did you still have them in vial form in your hospital?

Ms. Nancy Froude: We always have a backup supply.

M^me^ France Gélinas: And that was part of your backup?

Ms. Nancy Froude: Yes.

M^me^ France Gélinas: Had you been using backups while you were with Baxter? Do you use them when you run out?

Ms. Nancy Froude: They would be on hand in case we needed them if we had issues with supply from Baxter. I don't know whether or how often we needed to use them, but I know that we did have a small supply on hand.

M^me^ France Gélinas: And you had enough for the next day?

Ms. Nancy Froude: Yes, and then arrangements were made to order more.

M^me^ France Gélinas: And who do you get your vials from?

Ms. Nancy Froude: I'm not sure currently what brand we're using. I don't work directly with the products. I can't answer that question.

M^me^ France Gélinas: How much of it would you say you use in a typical week or typical day?

Ms. Nancy Froude: Both of those drugs are quite frequently used oncology products, so we would use them regularly through the day. They're used for various types of treatments for cancer patients.

M^me^ France Gélinas: When we talk specifically about cyclophosphamide, was there any doubt in your mind that 250 millilitres could ever be used on a single patient?

Ms. Nancy Froude: With a knowledge of oncology, no. It just wouldn't seem reasonable to use that type of a dose.

M^me^ France Gélinas: How well known, would you say, would that be to most pharmacists?

Ms. Nancy Froude: Oncology is a very specialized field, but really, if any pharmacist is working with a product they're not familiar with, they need to make themselves familiar with it.

M^me^ France Gélinas: So a pharmacist who had been working with cyclophosphamide, you would expect that pharmacist to know how it's being used to treat patients and which concentration.

Ms. Nancy Froude: Definitely, yes.

M^me^ France Gélinas: And you knew that this was a medication that has to be concentration-specific?

Ms. Nancy Froude: Yes.

M^me^ France Gélinas: What do you know about—and the word just escapes me—how long this thing is good for? It's called—

Mr. Jeff Yurek: Stability?

M^me^ France Gélinas: Stability, thank you. What do you know about the stability? We'll take them one at a time. We'll start with cyclo. What do you know about the stability of this drug, cyclophosphamide?

Ms. Nancy Froude: Again, I don't handle the drugs necessarily directly, but we do definitely have references

available within the pharmacy to find that information. If you want that, I could leave it with the Clerk.

M^me^ France Gélinas: Sure, but I'm also interested as to where you would go. You're a working oncology pharmacist right now in a hospital, in a cancer centre in Ontario. Where would you go to find that information at work?

Ms. Nancy Froude: There are various online sources that are available to find that information. Probably the most common one I would reference or go to is the British Columbia Cancer Agency website. There are multiple references available.

M^me^ France Gélinas: What happens if the manufacturers have done their own? How would you find that out?

Ms. Nancy Froude: A lot of manufacturers, if they've done in-house studies, will not always release their information, so it is difficult information to access.

M^me^ France Gélinas: Okay, so I'll tell you what I'm trying to do and you tell me how it works in the real world.

Ms. Nancy Froude: Okay.

M^me^ France Gélinas: We are told that one of the cancer agents is stable for four days at room temperature. We know, through the supply chain, that your cancer centre is getting this at room temperature. What we don't know, or what I don't know: I don't see any dates on the information that was shared with us. How do you know when the date is up? Where is this information carried through to you?

Ms. Nancy Froude: I'm not sure I understand your question, so if I don't answer you properly, please let me know.

Drugs would come with that expiry date on them, if we've gotten them from a manufacturer. As part of the labelling, there's an expiry date. Sorry, does that answer your question?

M^me^ France Gélinas: Yes, that's exactly what I'm looking for, except that on the labelling that we get for cyclophosphamide—we have found out that at room temperature, its expiry date is basically four days from manufacturing, but on the labelling that is available to you, that you have shared with this committee, there are no dates. So I'm guessing it's probably in a computer—I have no idea. I won't guess.

So if it's not on the labelling that was photocopied to us—we have a photocopy of the labelling on the bag. We see the names of the drugs, we see the number of grams, we see the 250 millilitres, but we don't see a date.

Ms. Nancy Froude: There should be an expiry date on the label.

M^me^ France Gélinas: There should be expiry dates on the labels. Okay. All right. So the one date that we see on the label would be the expiry?

Ms. Nancy Froude: It depends what reference is made in regard to that date. Some might have a produced on date. Others may have an expiry date.

M^me^ France Gélinas: Okay, but it should be on the label, no matter what. That information is information you expect to be available on the label.

Ms. Nancy Froude: Correct.

M^me^ France Gélinas: Is it also available someplace else?

Ms. Nancy Froude: I guess if I had to question it, I could call and ask for the—because they'd have to have a record of a lot number. I guess there's a way to trace it back, but I've never had to deal with that, so I'm not—

M^me^ France Gélinas: But the way that information is carried from the manufacturer to you is, basically, right on the label you will see the expiry date.

Ms. Nancy Froude: Correct.

M^me^ France Gélinas: Okay. This is where you expect to see it, and this is where it would be most useful.

Ms. Nancy Froude: That's the first place I would look, yes.

M^me^ France Gélinas: Okay. I'm going to let it go around.

The Chair (Mr. Ernie Hardeman): Okay, thank you very much. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Ms. Froude, for coming in. Again, I think we all feel that it was Peterborough and Lakeridge first to detect this problem, and we congratulate you and your colleagues for being part of that discovery.

Just a few questions. When you did discover that the volume with the gemcitabine apparently inside was 111 millilitres, did it ever occur to you to simply work out what the concentration was, based on 111? I know you've referenced the electronic worksheet, but in theory, you could maybe have done that and come out with a concentration less than 38.

Ms. Nancy Froude: Exactly.

Ms. Helena Jaczek: Did you consider that option? You obviously came to a different conclusion, and you didn't follow it.

Ms. Nancy Froude: Right.

Ms. Helena Jaczek: So what was your thinking?

Ms. Nancy Froude: We were actually done making our chemotherapy treatments for the day, so we really had, at that point, no need immediately to use any more gemcitabine for the day. To be able to do what you're suggesting, which is absolutely right—you could do that process. That overfill amount in the bag is not consistent, so even though we got 111 millilitres out of that particular bag, you could take a random sample of 10 bags and they all could potentially have a different volume.

Ms. Helena Jaczek: It also occurred to me that if you couldn't be sure that the volume was correct, perhaps you might not be sure that the gemcitabine was correct. I mean, that's another possibility.

Ms. Nancy Froude: Absolutely.

Ms. Helena Jaczek: Okay. At Lakeridge, when you discovered this problem, obviously you put a moratorium on the use and you returned to using vials. I'm wondering, does the Peterborough satellite oncology clinic have those vials as well? Would they have been able to quickly make up that new solution?

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Ms. Nancy Froude: I don't work out of the Peterborough cancer centre, so I don't know the information to answer that question.

Ms. Helena Jaczek: We heard from the pharmacist on-site at Peterborough last week that she made the decision—in the best interest, as she strongly felt, of the patient—that, rather than interrupt the therapy for that patient, they went ahead and they administered that dose, which as we know was slightly under. Do you think, as a fellow pharmacist, that was a reasonable decision to make?

Ms. Nancy Froude: I think it's really hard to go back and put yourself in somebody else's shoes. You could question several different pharmacists clinically about what they would have done and you could probably get a lot of different answers to that question, and all of them could probably be backed up very soundly, so I'm not really comfortable speaking for what somebody else's decision was.

Ms. Helena Jaczek: I appreciate that. I think personally that when she made that point to us last week, I felt she was convinced herself that she had used her clinical judgment and gone ahead. As you say, there are always going to be differences of opinion.

In terms of the concept of having chemotherapeutic agents compounded off-site, could you just perhaps give us your opinion as to the advantages and disadvantages of this, ignoring the fact that there was an error in this case?

Ms. Nancy Froude: Okay. I think there are definitely advantages for us as far as the workflow within our chemo preparation area. For example, gemcitabine takes a lot of time to dissolve from its powder form into the liquid form. When we receive gemcitabine directly from the manufacturer it's a powder, so we have to dissolve it before we can put it into an IV administration bag. It takes, I think, probably several hours for it to actually dissolve in, depending on the batch and different variability. That is a very time-consuming process to be doing yourself when you have a drug that you're using in fairly high demand. I think just from a workflow and efficiency standpoint, there are definitely advantages to having things outsourced.

I think the disadvantage maybe is, you don't have control directly over the product yourself, but I think probably for us the advantages at the time definitely were more advantages than disadvantages.

Ms. Helena Jaczek: In terms of oversight, as we've heard, this admixing of compounds through Medbuy was something that obviously had been going on for some time. Were you aware of what we've come to call this grey zone, that there was no direct oversight of that process?

Ms. Nancy Froude: I wasn't really involved in any of the contracts or purchasing of the products or decisions that were made in that regard, so I don't have any input or answers to those.

Ms. Helena Jaczek: Now that we've discovered that in fact neither Health Canada nor the College of Pharmacists was doing that type of inspection, do you have any opinion on what sort of regulatory oversight might be the best?

Ms. Nancy Froude: Definitely, I feel the Ontario College of Pharmacists should be inspecting any manufacture of drug products. If you work in community pharmacy, they have very regular inspections of community pharmacies, and they're quite thorough inspections. Having been involved in that process—they'll check the references you have available, your records, how clean your shelves are, how many graduated cylinders—it's quite a detailed process and a lot of it is probably historical, but we continue to do those checks. To not have those checks everywhere where drugs are being produced or handled, to me is just not the way we should be controlling our pharmacy supply of medications.

Ms. Helena Jaczek: We've also heard that there is no particular oversight, or not to the same extent, in hospital pharmacies as there is in community retail pharmacies, rather than, of course, the pharmacists are accredited through the College of Pharmacists. Do you have an opinion as to whether it would be wise to include oversight of hospital pharmacies?

Ms. Nancy Froude: I have a very strong community pharmacy background. I was very surprised when I started working in hospitals that the college does not have any role in the pharmacies that are in hospitals, especially given the types of products that are made and handled and utilized within hospitals. For the college not to have the ability to go in and inspect them and make sure that they're meeting certain standards and guidelines—again, to me it's an unsafe process, not to have some sort of double-checks in place. I really think that the college does a good job of following up with community pharmacies.

Ms. Helena Jaczek: Have you been involved with Dr. Jake Thiessen's process at all?

Ms. Nancy Froude: Yes. Dr. Thiessen spent probably a little over an hour with myself and other members of the pharmacy team at Lakeridge Health.

Ms. Helena Jaczek: And basically, the conversation was much as you've told us about, the events of March 20?

Ms. Nancy Froude: Right. We went over exactly the events that occurred. He asked some further questions about the drugs a little bit and how they were handled, and just about our processes within the pharmacy and the production of our chemotherapy.

Ms. Helena Jaczek: Will you be looking forward to his findings? As a pharmacist, this is obviously an issue that I imagine is of considerable interest.

Ms. Nancy Froude: Yes.

Ms. Helena Jaczek: From what we've heard, Dr. Thiessen is a very well-respected member of the pharmacy community.

Ms. Nancy Froude: Definitely. Yes, he was actually one of my professors at university.

Ms. Helena Jaczek: No further questions at this point.

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

Mr. Jeff Yurek: I think Dr. Thiessen taught about 30 years' worth of pharmacists.

Ms. Nancy Froude: That's right.

Mr. Jeff Yurek: Just a quick few questions. Have you before at your pharmacy had any problems with any product Medbuy had procured for you? I guess one that would be admixed?

Ms. Nancy Froude: We only really have four products that we receive within chemotherapy through Medbuy sourcing out.

Mr. Jeff Yurek: What were the other two?

Ms. Nancy Froude: The other two were pamidronate and fluorouracil or 5-FU.

Mr. Jeff Yurek: When they changed over from Baxter to Marchese, was staff given a notification, "Hey, we've switched suppliers"? How was that—

Ms. Nancy Froude: Yes, there was notification that we were switching suppliers.

Mr. Jeff Yurek: Was it given out as a formal letter, memo, meeting?

Ms. Nancy Froude: There was no meeting. I believe it was just through electronic means, like emails. We have an internal system called the MOX, where messages are sent to staff. There were also some pharmacy meetings within the main pharmacy when their products were switched over, but I don't recall having one specific for the chemotherapy agents.

Mr. Jeff Yurek: Did they go over any changes they were expecting in the system? Or did they say everything would just be normal?

Ms. Nancy Froude: Right, just a notification that we were switching manufacturers.

Mr. Jeff Yurek: I just want to get back to your retail pharmacy. That's not accredited, so OCP doesn't have access to review your pharmacy. They're not part of your outpatient pharmacy.

Ms. Nancy Froude: Correct.

Mr. Jeff Yurek: You've brought up a new grey area out there: the hospital pharmacy dispensing medications to the public. Being in a community pharmacy, you would know that if the public has a problem with the medication they receive, they can either do a formal complaint with the college of pharmacy on the pharmacist, or they could do it on the pharmacy if there's a problem, so they have two avenues to seek changes in the system. Whereas with your retail pharmacy—correct me if I'm wrong—not being accredited by the OCP, they could only go through the pharmacist and not the pharmacy. They could have no recourse to lodge complaint for investigation.

Ms. Nancy Froude: That seems correct.

Mr. Jeff Yurek: Also—correct me if I'm wrong—the accredited pharmacy has to have a designated manager, which is—if you can explain what the designated manager does for the retail pharmacy.

Ms. Nancy Froude: Sure. The designated manager is the manager that's on record for that pharmacy at the college. They would have certain responsibilities above the staff pharmacists: ensuring that standards are being met, that proper reports are being run and submitted, just maintaining the standards of pharmacy.

Mr. Jeff Yurek: So not being accredited, your retail pharmacy doesn't have a designated manager?

Ms. Nancy Froude: That responsibility, I believe, would go back on to our pharmacy manager, Linda Skinner.

Mr. Jeff Yurek: And who would oversee that pharmacy? In a retail pharmacy, the OCP oversees to ensure a third party uninvolved with the company—who would do that at the hospital level?

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Ms. Nancy Froude: I guess it would go up one level, up again, to the director of—

Mr. Jeff Yurek: But that's still within the same corporate structure.

Ms. Nancy Froude: Right.

Mr. Jeff Yurek: Also, pharmacies—this might answer some stability questions. Retail pharmacies have to belong to a drug information service—

Ms. Nancy Froude: Correct, yes

Mr. Jeff Yurek: —which they can call and get all the information they want. A hospital pharmacy, unaccredited, does not. Is that correct?

Ms. Nancy Froude: Correct, although—

Mr. Jeff Yurek: They have to do their own research and stuff?

Ms. Nancy Froude: We would have access to those same databases.

Mr. Jeff Yurek: But it's not a requirement.

Ms. Nancy Froude: It's not a requirement, right.

Mr. Jeff Yurek: Do you bill the Ontario drug benefit plan?

Ms. Nancy Froude: We do. Yes, we do.

Mr. Jeff Yurek: Even though you're not accredited?

Ms. Nancy Froude: Yes. We have an account with Ontario drug benefit.

Mr. Jeff Yurek: Okay. So that would just, I think, reiterate the point I've been making. As I said earlier, you would agree with the college of pharmacy kind of expanding the scope to cover hospital pharmacies, which would take care of this grey area we've just found out about today.

Ms. Nancy Froude: Yes, right.

Mr. Jeff Yurek: Okay. Jane?

Mrs. Jane McKenna: Thank you, Nancy, for being here today. I guess my first question is—usually for myself, after something's happened and it was unexpected, I can usually sit back and then go through everything over and over again and I usually have a different outcome of what I would have done differently. Now that you've had time to think and go through the process again, would you have done anything differently?

Ms. Nancy Froude: I don't think so. I think we did a very thorough, quick check and then handed it along to the appropriate people.

Mrs. Jane McKenna: So because you have not been in a situation like this before and, sadly, there are firsts in everything or so many things, were there the proper checks and balances on who was to talk to whom and who was going to take the next level of where it would

go? Was everybody very clear on what they were supposed to be doing in the process and how it went down?

Ms. Nancy Froude: Sorry, you mean after we discovered the—

Mrs. Jane McKenna: Yes, yes.

Ms. Nancy Froude: Yes, I think so. I mean, I spoke to my pharmacy manager, who then did what she felt involved the next level up in our care system within Lakeridge Health. I think we have a very clear set of who should escalate problems to whom and when.

Mrs. Jane McKenna: Okay. Is that Linda that you're speaking about?

Ms. Nancy Froude: Right. Linda's our pharmacy manager.

Mrs. Jane McKenna: Okay. So would Linda, in the process of finding this out, which we are very grateful for, have known at the very beginning that Windsor had been using the same product for a year?

Ms. Nancy Froude: I don't know that information for sure. My impression was that she did not right that day.

Mrs. Jane McKenna: Right that day. Yes, because I'm saying, when everything's so new and then you would be wondering, because you saw it, how come another hospital had gone a year without seeing it and they're still continuing doing it, which means there haven't been any tragedies that anyone would know of or someone would have found this out by now.

Ms. Nancy Froude: Right.

Mrs. Jane McKenna: Were you concerned at all—and someone might have asked this question; I'm sorry, I came in later—when you saw the label and you, I understand, saw the label from Baxter, were you concerned? Is that what concerned you or red-flagged you right at the beginning, that the labels were different?

Ms. Nancy Froude: My biggest concern versus when I looked at the bag and that they were using a commercially available 100-millilitre bag—and I know there's overfill in that bag. It didn't seem logical to me for them to use that type of system when you don't know what the overfill is. The only way to know is to pull everything out and then just put back in what you need, which doesn't, just from an efficiency standpoint and safety standpoint, make sense to me to do it that way, if you need to be specific about the concentrations.

Mrs. Jane McKenna: Now that you're sitting back thinking about it, did it not cross your mind why it was so matter of fact to you, how you're describing what you would do, how it was not matter of fact for a hospital doing it for the last year, that nobody else had that matter-of-fact attitude?

Ms. Nancy Froude: I ask myself that every day since this happened. Honestly, I think putting the two things together—getting that call from Peterborough saying that there's something different with the label and then looking at the bag and putting those two pieces of information together is what triggered things for me that I'm not sure that this right.

Mrs. Jane McKenna: Right.

Ms. Nancy Froude: And the only way for me to know that was for us to pull things out of the bag.

Mrs. Jane McKenna: Right. Because I think that's our biggest—as we're sitting here, we're trying to figure that out as well. Because, clearly, there was not only a miscommunication somewhere, but someone that has your qualifications was clearly doing that in Windsor hospital, and yet, that's a long time, a year.

Ms. Nancy Froude: Right.

Mrs. Jane McKenna: Okay, thank you very much. That's all I have.

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

M^me^ France Gélinas: Continuing on this train of thought, the series of events leads us to believe that it could just as well have gone undetected. You had been using it. What happened in Peterborough looks like a fluke to me, and that had they not called you, had you not put the two pieces together—you come from the retail sector, you started to think, "This is not a very efficient way to mix things because of the overfill"—this could have been undetected. It feels really, really unsettling to think of things like that.

When you do buy drugs like admixtures, what are the checks and balances to make sure that what you get in there is what you're supposed to have?

Ms. Nancy Froude: I don't know, honestly, what the process was in dealing with the company to get that product to us.

M^me^ France Gélinas: But were you taking it for granted that somebody had done the check, it just wasn't your job, or that you don't know if a check exists?

Ms. Nancy Froude: I don't know what checks were done in the process. I think there's also a level of trust that we have when we're dealing with drug manufacturers, that there's a trust that the product that you get is what you're getting. I think we have that trust every time we take a Tylenol or every time we take some cough medicine, that what the company says is on the label is what's in that bottle. I think, as a society, we've come to have that trust in the pharmaceutical industry.

M^me^ France Gélinas: Okay. Did you yourself communicate with Marchese at all?

Ms. Nancy Froude: Yes, I did.

M^me^ France Gélinas: Can you describe how it happened?

Ms. Nancy Froude: Prior to March 20, we did have some concerns with a shipment of pamidronate that came to us just in regard to the storage direction that was given on the label for the pamidronate.

M^me^ France Gélinas: And what were those concerns and how were they settled?

Ms. Nancy Froude: The pamidronate that we had been receiving previously we were storing in the refrigerator according to that manufacturer's guidelines. When we got the pamidronate from Marchese, it actually was labelled just to store at room temperature.

M^me^ France Gélinas: And how was it settled? Was it because—

Ms. Nancy Froude: Through a series of phone calls that were made by myself to Marchese and to the company that we had previously been receiving it from.

M^me^ France Gélinas: And did you end up putting it back in the fridge, or did it stay at room temperature?

Ms. Nancy Froude: It's at room temperature.

M^me^ France Gélinas: It's at room temperature.

Ms. Nancy Froude: Well, we're no longer using it, so it's—yes.

M^me^ France Gélinas: So that was part of the four drugs that you were getting premixed. You're now doing all four of those drugs in-house?

Ms. Nancy Froude: We are, yes.

M^me^ France Gélinas: Does that involve more work for you or for members of your team?

Ms. Nancy Froude: It does not make more work for me, personally, but definitely makes more work for our team.

M^me^ France Gélinas: And how are they coping with it?

Ms. Nancy Froude: Some overtime, and also relying on the main pharmacy within the hospital to do some extra work for us.

M^me^ France Gélinas: Okay. If you think back to checks and balances—you come from an environment that had college supervision, that had oversight, checks and balances—where do you think would be the reasonable place to have this kind of oversight done?

Ms. Nancy Froude: I think there are probably several steps along the way. I was not aware that the college was not inspecting or regulating these companies that were doing these admixtures for hospitals. I think that absolutely needs to be done to ensure that there are standards being met there. I think that was kind of something—a big point that was missed in that step of the safety chain of the drugs, definitely. Also, I think that having that college inspection done at every hospital pharmacy is essential, too, to make sure that standards are being met and maintained.

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M^me^ France Gélinas: Not only the outpatient but also the regular pharmacy of the hospital, you figure, should have oversight?

Ms. Nancy Froude: I do, yes.

M^me^ France Gélinas: Okay. I'm not a pharmacist. Some of them are; not I. The issue of drugs being concentration-specific vs. non-concentration-specific: Is this something that is always on your radar when you work, or is this a one-off specific to oncology?

Ms. Nancy Froude: I'd say it's fairly specific to oncology, because we are using those products differently than, let's say, an antibiotic. An antibiotic bag is made, and the entire bag is run; although concentrations need to be looked at, they're not really as important, because that whole bag is being given. If there is a gram of an antibiotic in a bag, whether it's in 100 millilitres or 104 millilitres doesn't make a difference if the whole bag is administered, whereas for chemotherapy we weren't using those bags in that manner, so the concentrations are imperative.

M^me^ France Gélinas: And do the volumes of medication vary greatly from one person to the next?

Ms. Nancy Froude: The doses?

M^me^ France Gélinas: The doses, yes.

Ms. Nancy Froude: Yes, because it's dosed according to height and weight. Even for one type of cancer compared to another type of cancer, the doses may be different. For example, one regimen may say that they get 100 milligrams per metre squared; another regimen may only say 50, so there are different doses depending on what disease you're treating. Often we'll do dose reductions for chemotherapy, based on how patients are tolerating chemotherapy. Sometimes we'll only give half of the recommended dose if they're having a lot of side effects or not tolerating. So there can be a wide range of dosing.

M^me^ France Gélinas: Would what you shared with me be considered basic knowledge for pharmacists working with oncology? You would know that dosages vary greatly and you need to pay attention to the concentration so that you get the right dosage for the right patient at the right time?

Ms. Nancy Froude: Exactly. Like I said before, if you're not working in oncology, even if you're handling those drugs, as a pharmacist, you need to be familiar with what you're handling.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time. To the government side: Ms. Mangat?

Mrs. Amrit Mangat: Thank you, Chair. Thank you, Nancy, for your presentation. Given your experience, since you have worked in various community pharmacy settings, from independent, private pharmacies to big chain stores, including hospitals, can you share with the members of the committee what kind of process checks are normally undertaken in the preparation of compounded drugs?

Ms. Nancy Froude: I'm sorry; could you just repeat the last—

Mrs. Amrit Mangat: What kind of process checks are normally undertaken in the preparation of compounded drugs?

Ms. Nancy Froude: If we're compounding drugs for our own use—so, what we're doing now, basically, right?

Mrs. Amrit Mangat: Yes.

Ms. Nancy Froude: We have a series of worksheets our technicians will use. There's always a double- and triple-check of volumes and the drug product itself, what's being added—there are lots of checks along the way, so there's never just one person making something. Things are always initialled by two technicians in that process.

Mrs. Amrit Mangat: Are there any guidelines or policies with regard to that?

Ms. Nancy Froude: Within our program in oncology, we do have a set of pharmacy guidelines that will state that.

Mrs. Amrit Mangat: What other quality insurance measures are in place, other than guidelines and principles?

Ms. Nancy Froude: Like I said, we have multiple checks along the process of making those products, and various safety things put in place. For example, we'll only have one drug in the hood at a time. Multiple people are looking at what's going in and what's coming out after it's made.

Mrs. Amrit Mangat: Are you confident in the safety of the drug supply which was being supplied at the Durham Regional Cancer Centre?

Ms. Nancy Froude: What we're making ourselves?

Mrs. Amrit Mangat: Both what you are making yourselves, or whether it was given by Marchese or Baxter.

Ms. Nancy Froude: I'm confident in what we're making ourselves because I know the staff who are working, and they're very committed, proficient individuals who have had a lot of years of experience in pharmacy and in chemotherapy.

As far as what's being outsourced, I'm not sure that my opinion is what it would have been three months ago, but I am still confident in what's coming from outsourced pharmacies.

Mrs. Amrit Mangat: So why is it important that drugs should be removed or quarantined? Why is it important to remove the drugs or to quarantine the drugs?

Ms. Nancy Froude: So not to continue using Marchese?

Mrs. Amrit Mangat: Yes.

Ms. Nancy Froude: Mostly because the volumes are going to be so inconsistent now, we'd have to pull everything out of every bag. It's also not safe for us to do that.

Mrs. Amrit Mangat: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. To the opposition: Any further questions? If not, that concludes the time.

M^me^ France Gélinas: Can I ask one quick question?

The Chair (Mr. Ernie Hardeman): You'd have to ask for time from the other parties.

M^me^ France Gélinas: Can you give me a minute? When you were talking about the monograph, who enters that into the computer, and how often is it checked? When you get a new—I don't know how this thing is done.

Ms. Nancy Froude: We do have staff members who are dedicated—that's part of their role to do that. I'm not one of them, so I'm really not sure what all their safety checks and processes are.

M^me^ France Gélinas: But would it be done every time you have a batch, every shift, every 24 hours? How often are those entered?

Ms. Nancy Froude: The drugs would only be entered when we start using them. So each drug entry would just be done once, and then it stays in the computer system.

M^me^ France Gélinas: Unless it's changed.

The Chair (Mr. Ernie Hardeman): Thank you very much. It's like a photographer that says, "Just one more, just one more." But we do thank you very much for participating this afternoon. I'm sure you've been of great assistance to the committee. Thank you very much.

Interjection.

The Chair (Mr. Ernie Hardeman): We'll just wait a moment. The next witness is on her way up from the basement. She should be here momentarily.

MS. LAURA SAVATTERI

The Chair (Mr. Ernie Hardeman): I think our next delegation has arrived: Laura Savatteri. If you want to take a seat at the head table there. Good afternoon, and thank you very much for being here.

Ms. Laura Savatteri: Thank you. Good afternoon.

The Chair (Mr. Ernie Hardeman): As with all the delegations that we've been hearing from, you will have 20 minutes to make your presentation. It goes along with a thank you for being here. Then each caucus will have an opportunity for 20 minutes to ask any questions they may have about your presentation and the events that we're referring to. The questioning and the comments this time will start with the third party.

With that, the floor is—oh, you've got to be sworn in. My apologies for the oversight. We'll ask the Clerk to swear you in or to affirm you.

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The Clerk of the Committee (Mr. William Short): It's Ms. Salvatore?

Ms. Laura Savatteri: It's Savatteri.

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

Ms. Laura Savatteri: Yes.

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

Ms. Laura Savatteri: I'll swear an oath.

The Clerk of the Committee (Mr. William Short): The Bible's in front of you there. Thank you. Ms. Savatteri, 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. Laura Savatteri: I do.

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

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will start your presentation. The floor is yours.

Ms. Laura Savatteri: Thank you, Mr. Chairman. Good afternoon. My name is Laura Savatteri. I thank you for the opportunity to address your committee.

I am a pharmacist licensed by the Ontario College of Pharmacists. I am also a member of the Ontario Pharmacists' Association, the Hamilton and District Pharmacists' Association and the National Home Infusion Association. I received a bachelor of science degree in

pharmacy from the University of Toronto in 2009. Since graduating, I have been employed by Marchese Health Care as a registered staff pharmacist.

My passion for pharmacy began in my teens. Before graduating and becoming a pharmacist, I was employed as a pharmacy assistant for seven years at a large retail pharmacy. I was also employed as a pharmacy student by Marchese Health Care.

In addition to my employment, I am involved in a number of community initiatives related to my profession. For example, since 2009, I have been a guest lecturer in the Mohawk College-McMaster University pharmacy technician program. I have also made a number of presentations to health care professionals and patients, as well as primary and secondary school students, on the importance of medication safety. On a weekly basis, I also participate in interprofessional palliative team rounds at a local hospice, and I'm a pharmacist resource to the Hospice Palliative Care Network Advisory Committee.

Between December 2011 and July 2012, I was also interim manager of Marchese Health Care's accredited pharmacy in Kitchener. In that capacity, I oversaw provision of home infusions and medical supplies for home care clients served under a local community care access centre.

I was part of a team of pharmacists and other Marchese staff involved in the start-up of Marchese Hospital Solutions. One of my contributions, a small part of my total responsibilities at Marchese, involved phone calls and email exchanges with Health Canada and the Ontario College of Pharmacists, or OCP. All of those exchanges were conducted professionally and amicably.

Before providing details on these communications, I wish to convey that I am saddened that any person would have to go through the distress caused by this issue. My hope is that we all end up with a better system and a safer system for everyone.

I have prepared a booklet containing, in chronological order, notes and emails relating to my communications with Health Canada and OCP. I understand that some of these communications have already been provided to the committee. I also understand that there may be other email exchanges that I have not yet found. The documents I have provided are the ones I was able to locate and that I believed would be helpful for the committee to understand the nature of our inquiries.

The notes and email exchanges in the booklet focus on my communications with Health Canada and OCP in early 2012. They are email exchanges I was involved in and any notes I made based on my knowledge of telephone conversations.

While I'm aware that Marchese staff also had exchanges with Health Canada and OCP, I can really only speak with confidence about my own communications. I hope the booklet will be helpful to the standing committee's inquiry.

My communications with Heath Canada began in early 2012.

My first note, at tab 1(a) of the booklet, reflects my note of a call with a Health Canada representative on January 18, 2012. As I noted, this representative thought we were "manufacturing" and recommended I call Health Canada's Therapeutic Products Directorate, or TPD. The follow-up emails can be found at tab 1(b).

At tab 2 of the booklet you will see my note dated February 1, 2012. I called TPD. After a series of transfers, I was connected to a Health Canada representative from TPD. He told me he believed Marchese's situation was unique. He offered me four contacts who might be in a better position to assist us. I called all four, left messages where appropriate and, in particular, left a message for a compliance specialist in the drug GMP inspection unit of Health Canada's Products and Food Branch Inspectorate.

From my note at tab 3 you will see that on February 7, 2012, I finally spoke with this particular representative. She informed me that there were many unregulated entities conducting similar operations. She named three, one of which was Baxter-CIVA.

In our conversation on February 7, 2012, this Health Canada representative informed me that she understood we were compounding products with DINs, or drug identification numbers, in IV bags. My notes of her initial observation were that we were "manufacturing," but because we were supplying hospitals based on history of patient need, we were "not technically manufacturing." She explained that Baxter-CIVA was doing the same thing, but we were better off because there was a pharmacist on-site.

I will read directly from my note:

"She explained Policy 51—pharmacy can outsource to whomever they want. Her opinion is that the patient-health care professional relationship is still maintained since the pharmacy that cannot provide the product has a relationship with the patients and the outsourced partner has a relationship with that pharmacy and so the relationship is indirect.

"Sarah explained that we generally should not be concerned because it seems that we are doing everything we can from a quality-control perspective and that the worse that can happen is 'compliance and enforcement discretion action': If HC decided we were contravening any regulations, they have the right to shut us down."

You will see from tab 4 that on February 18, 2012, I sent a follow-up email, attaching a document summarizing Marchese's operations. I also asked her for any guidance that could be provided by her or her team.

At tab 5 you will see a copy of the document that I attached to my February 18 email. The document describes Marchese Hospital Solutions' business in detail. The last paragraph describes Marchese's efforts in seeking regulatory guidance. I would like to read the last paragraph to the committee:

"As discussed with Sarah Skuce of GMP unit, at this point, Marchese has entered into many discussions with authorities from Health Canada, the Ontario College of Pharmacists, New Brunswick pharmacy regulatory

bodies, GMP consultants and CanReg to ensure documented due diligence with respect to regulations. It continues to be unclear as to what regulation(s) we will be required to satisfy going forward, as we commit ourselves to navigating this grey area. It is Marchese's intent to meet or exceed quality and regulatory standards to provide excellent products and services that meet patients' health care needs and that uphold the Marchese reputation built over 15 years of providing innovative services to enable better health through better care."

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On February 28, 2012, I sent an additional follow-up email requesting a status update, reminding her that I had also left a voice mail message the week before. That email is found on tab 6 of the booklet.

At tab 7 of the booklet, I have reproduced the response received on March 1, 2012. She told me she had not yet contacted OCP and did not know who she should be speaking with. She also asked for information about Marchese's OCP contact.

Later in the day, I responded by providing a name of a contact at OCP. I also raised the possibility of becoming a facility partially licensed under GMP, if required, and with an OCP accredited pharmacy occupying the other portion of the premises. That email, also dated March 1, 2012, is found at tab 8 of the booklet.

At tab 9 of the booklet, I have provided a copy of a further email I sent on April 5, 2012, requesting further clarification regarding Health Canada regulatory requirements. I re-attached the document at tab 5 previously sent to her on February 18, 2012. I informed her that Marchese had been in contact with the OCP about accreditation of the Mississauga facility. OCP had explained to me that, under policy 0051, Health Canada had the authority to override provincial regulations when it is unclear whether a facility was compounding or manufacturing. I suggested that Health Canada contact OCP directly to discuss the matter. I also suggested a meeting involving Marchese, OCP and Health Canada to expedite the discussion and allow Marchese to move forward with certainty.

On May 8, 2012, I sent a follow-up email to Health Canada requesting dates for a meeting with OCP. That email is found at tab 10 of the booklet.

If you turn to tab 11, you will see that on May 9, 2012, I received a reply from Health Canada stating that she had spoken with her manager about a meeting with OCP. She also informed me that a meeting was scheduled in June between Health Canada and the National Association of Pharmacy Regulatory Authorities, or NAPRA, to discuss policy 0051. Because this Health Canada representative thought jurisdictional decisions could be made at this meeting, she suggested that this meeting occur before meeting with Marchese and OCP.

In her May 9, 2012, email, Health Canada also asked for details of the initial feedback Marchese received from OCP. The Health Canada representative also stated that Health Canada would work with the colleges to ensure that all activities relating to compounding and manufacturing had regulatory oversight, but Health Canada did not overrule provincial law or jurisdiction. She stated that if Marchese's operations were compounding, then Health Canada would not have oversight of the facility.

I will now turn to my involvement in communications with the OCP.

At tab 12, you will see an email I sent to OCP on March 21, 2012, requesting information on accreditation of the Mississauga facility as a pharmacy. I also asked for a meeting with OCP representatives to discuss requirements for OCP accreditation. The same day, a description of Marchese's operations and a floor plan were requested.

On March 27, 2012, I sent a floor plan, together with another document, which provided a detailed description of Marchese Hospital Solutions' operations. A copy of my email and its attachments is found at tab 13.

A teleconference was scheduled with OCP on April 3, 2012, involving myself, and other Marchese representatives. I will read directly from my note, which can be found at tab 14:

"The take-home point that OCP feels much the same as HC in that they don't believe that MHS operations falls under their jurisdiction. He explained that based strictly on our Medbuy business, OCP would not accredit us. Greg explained that if we wanted to become an 'accredited pharmacy,' we would need to have patient-specific prescriptions transferred to that site. Therefore, he suggested seeking accreditation based on the plan to move some of our Hamilton business ... to the Mississauga site. He also explained his understanding of policy 51, which was that Health Canada has the authority to override provincial regulations when it is unclear whether a facility is compounding or manufacturing. We later learned from Sarah Skuce that this interpretation is not correct. Lastly, when asked about shipping admixtures to New Brunswick hospitals, Greg stated that he does not believe any of this operation falls under OCP jurisdiction and therefore, he could not comment on it."

At tab 15, you will see a copy of an email I received from OCP on April 26, 2012, regarding an application to open a new pharmacy. The questions were operational in nature, and I provided the answers. This discussion was forwarded to an OCP pharmacy inspector, who confirmed her intention of attending an opening inspection before May 30, 2012.

At tab 16, you will see an email from OCP to the Ministry of Health and Long-Term Care dated June 15, 2012. The email indicated that OCP had accredited a pharmacy, Marchese Health Care in Mississauga.

Through all of these conversations and email exchanges with Health Canada and OCP I have outlined today, Marchese was seeking regulatory guidance. We wanted to know which organization was the appropriate regulatory authority for activities that Marchese staff had described in detail. After participating in these communications and discussing them with the Marchese team, it was my understanding that neither Health Canada nor OCP regarded the activities conducted at

Marchese Hospital Solutions as falling within their regulatory jurisdiction.

If you have any questions, I will do my best to answer them.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. The questions this time will start with the third party. Ms. Gélinas.

M^me^ France Gélinas: Wow. Thank you very much for your presentation. It was easy to follow, it was informative, it was well done. Thank you so much.

Ms. Laura Savatteri: Thank you.

M^me^ France Gélinas: I will take you right to the end, where you say, after having done all of this, you made the conclusion, "It was my understanding that neither Health Canada nor OCP regarded the activities conducted at Marchese Hospital Solutions as falling within their regulatory jurisdiction." Do you remember the date that you came to that conclusion, who was there at the meeting? How did that come down?

Ms. Laura Savatteri: That's an interesting question. It's difficult for me to decide what date that would have been. What I can tell you is that my primary role was to be an information-gatherer. As I've presented today, all of my communications with Health Canada and with the Ontario College of Pharmacists were brought back to the Marchese Hospital Solutions executive team and a corporate decision was made to proceed. But of course, as you know today, that clarification is an ongoing thing.

M^me^ France Gélinas: As you gathered all of that information—much of it you have shared with us—who would you report to at Marchese?

Ms. Laura Savatteri: That would be the executive management team.

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

Ms. Laura Savatteri: It would be our general manager and president and CEO.

M^me^ France Gélinas: And who is the general manger?

Ms. Laura Savatteri: Ross Kearns.

M^me^ France Gélinas: Is he a pharmacist?

Ms. Laura Savatteri: No.

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M^me^ France Gélinas: And who is the president?

Ms. Laura Savatteri: Marita Zaffiro.

M^me^ France Gélinas: Okay. And is she a pharmacist?

Ms. Laura Savatteri: Yes.

M^me^ France Gélinas: So by the beginning of the summer of 2012, you've gone through an extensive amount of effort and energy to try to get those people to look at you. You submit all of this information to the general manager and to the president, and then you're basically told, "You've worked hard enough on this file. This is as far as we're going to get with those two agencies."

Ms. Laura Savatteri: Well, I have to say that I don't know that it was black and then white. It was really a continuous communication that was occurring. There comes a point where you've gathered quite a bit of information and a corporate decision needs to be made, taking into account that there are a lot of quality control measures in place.

M^me^ France Gélinas: So you figure that this is what happened? We haven't got anything past June 2012, and that's because your role in trying to gather information from Health Canada or from the Ontario College of Pharmacists more or less ended there?

Ms. Laura Savatteri: Right. My involvement with Marchese Hospital Solutions at that point had really subsided. I'm actually not an employee of Marchese Hospital Solutions directly; I was serving as a resource at the time, sort of working on that project, but my involvement is at Marchese Health Care in Hamilton.

M^me^ France Gélinas: In Hamilton, okay. Have you ever worked in oncology before?

Ms. Laura Savatteri: I have not worked directly in oncology. My IV pharmacy experience personally has to do with servicing of home infusion clients through the Hamilton Niagara Haldimand Brant CCAC contract, and also managing our Kitchener accredited pharmacy to service home infusion clients under the Waterloo Wellington CCAC.

M^me^ France Gélinas: If you came across an admixture, or the company is required to prepare an admixture, of a new drug, how do you become informed about new chemotherapy drugs? What are the tools at your disposal so that you know how it is used? What does a pharmacist do?

Ms. Laura Savatteri: What does a pharmacist do? Are you referring to with respect to an accredited pharmacy, where we're dispensing directly to a patient?

M^me^ France Gélinas: Sure, let's start there.

Ms. Laura Savatteri: If that was the case, there are a lot of different things that the pharmacist would have to consider. First of all, we would evaluate the prescription to make sure that it's a valid prescription and a valid order. We would take a look at the patient's clinical parameters, depending on what the drug is. We might look at allergies and concomitant medications, see if there are any drug interactions, see if the patient has any other comorbid conditions that we need to take into account, and then we would see, based on all of those things, if the dose was appropriate. Then, ultimately, how do we ensure that we're going to mix this product in a manner that ensures sterility and stability? Then, of course, there's the aspect of patient counselling, to ensure that the patient uses the medication in the most appropriate way.

M^me^ France Gélinas: Very good. Now I'll take you back—in the notes you have given us, it's on page 5, but you read it into the record—to where, basically, you're in conversations with a Health Canada representative. They're actually getting back to you, which is a nice change, because they seemed to be ignoring you quite often. They say:

"My notes of her initial observation were that we were 'manufacturing,' but because we were supplying hospitals based on history of patient need, we were 'not technically manufacturing.' She explained that Baxter-

CIVA was doing the same thing but we were better off because there was a pharmacist on site."

Who was the pharmacist on site who made you better off?

Ms. Laura Savatteri: My interpretation of this conversation is not who the pharmacist is on site, but that there is a pharmacist on site. So she was satisfied—she was commenting on the fact that there would be a registered pharmacist on site supervising the activities.

M^me^ France Gélinas: Okay, and she had known that because, on tab 5, we have the explanation as to how you would be doing the admixing?

Ms. Laura Savatteri: Precisely.

M^me^ France Gélinas: Okay, very good. Then she goes on to say, "Her opinion is that the patient-health care professional relationship is still maintained since the pharmacy that cannot provide the product"—I take it that's the hospital pharmacy—"has a relationship with the patients"—which is true—"and the outsourced partner has a relationship with that pharmacy and so the relationship is indirect." Does that make sense to you?

Ms. Laura Savatteri: It makes sense to me in the context of differentiating between compounding and manufacturing. My understanding is that one of the main differences between compounding and manufacturing is the patient-health care professional relationship. I can't speak on behalf of this Health Canada representative, so I prefer not to speculate on what she meant, but it did mean something to me.

M^me^ France Gélinas: All right. I'm just trying to understand what she's saying. When she's explaining policy 0051 to you in order to justify that you are not manufacturing, the justification is based on the fact that there is always a patient-professional relationship, though an indirect one. Is this what this is saying?

Ms. Laura Savatteri: That would be my understanding.

M^me^ France Gélinas: Knowing how Marchese health solutions works, tell me how this link is actually made.

Ms. Laura Savatteri: Sure. Marchese does not batch admixtures in bulk. What Marchese does is make to a hospital-specific order. For example, if hospital X goes through admixture Y five admixtures per week, they will order five of admixture Y from Marchese hospital per week.

M^me^ France Gélinas: All right. But then the patient relationship is sort of lost there because the hospital does not necessarily require it per patient; it requires it for a group of patients.

Ms. Laura Savatteri: It's based on a trend. What the hospital does is they order—my understanding of what a hospital does is, they order based on a trend of usage.

M^me^ France Gélinas: For the different patients that come through weekly or—

Ms. Laura Savatteri: Right.

M^me^ France Gélinas: Do you know if you ship weekly? How often do you send those products out?

Ms. Laura Savatteri: As I've mentioned, I'm not an employee of Marchese Hospital Solutions, but my understanding is, for a particular hospital, an average of one to three shipments a week.

M^me^ France Gélinas: That many, eh?

Ms. Laura Savatteri: Right.

M^me^ France Gélinas: Okay. Are you familiar at all with the drug cyclophosphamide?

Ms. Laura Savatteri: Cyclophosphamide: I have some familiarity.

M^me^ France Gélinas: Any idea what the dosage for this drug would be for people undergoing chemotherapy?

Ms. Laura Savatteri: Marchese Hospital Solutions prepares admixtures for these hospitals based on specifications in the contract. The expectation is that the health care professionals at the hospital would know how to prescribe, dispense and administer it appropriately for that patient, if appropriate.

M^me^ France Gélinas: The specification in the contract—who at Marchese would be negotiating that or would be reviewing that to make it make sense?

Ms. Laura Savatteri: Sorry, can you rephrase the question?

M^me^ France Gélinas: You talk about Marchese preparing the admixture based on specifications in a contract.

Ms. Laura Savatteri: Right.

M^me^ France Gélinas: Who at Marchese has the clinical knowledge to understand those specifications in a contract? I'm trying to understand.

Ms. Laura Savatteri: Right. The role of the pharmacist team with respect to Marchese Hospital Solutions is to provide the contractually specified admixtures in a manner that ensures sterility and stability.

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M^me^ France Gélinas: So it would be a team made up of—

Ms. Laura Savatteri: A team made up of pharmacists and also a team made up of pharmacists at Medbuy and with the knowledge that the admixtures are ultimately being dispensed to patients at a hospital level.

M^me^ France Gélinas: There would be pharmacists at Marchese dealing directly with pharmacists at Medbuy to make sure that they understand the specifications of the contract.

Ms. Laura Savatteri: Right.

M^me^ France Gélinas: The same thing with the way the labels are prepared: Who negotiates those—what they want, how they want the labels prepared?

Ms. Laura Savatteri: I was not involved in the RFP phase. My involvement with Marchese Hospital Solutions occurred after that. But what I do know is that Medbuy had requested, prior to start-up, that Marchese Hospital Solutions submit a final label set that would be used for all of the admixtures so that they could approve them and distribute them to all of the health care professionals at the hospital level for training and education purposes. If anybody had any questions at that time, Marchese was open to discussing and addressing them.

M^me^ France Gélinas: I'll let it go.

The Chair (Mr. Ernie Hardeman): Okay. Thank you very much. The government side: Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Ms. Savatteri, you are an accredited pharmacist, as you've told us. If you were presented with the request to provide four grams of gemcitabine in 100 millilitres, how would you do it?

Ms. Laura Savatteri: Are you referring to the preparation?

Ms. Helena Jaczek: I'm just asking you a general question. How would you prepare that four grams of gemcitabine in 100 millilitres of sodium chloride.

Ms. Laura Savatteri: Are you referring to the admixing of the product?

Ms. Helena Jaczek: Yes.

Ms. Laura Savatteri: Okay. I can walk you through that, although that is not my direct area of expertise; I've never actually mixed any of these myself. But if you wanted four grams in 100 millilitres of gemcitabine, typically what would happen is, you would get a two-gram gemcitabine vial. It needs to be reconstituted with 50 millilitres of normal saline. So we would have two two-gram gemcitabine vials and we would have a 100-millilitre pre-filled normal saline bag—

Ms. Helena Jaczek: When you say "pre-filled," could you specify? Do you mean pre-filled with 100 millilitres or with some other quantity?

Ms. Laura Savatteri: Pre-filled with 100 millilitres plus whatever the manufacturer's overfill is on that bag.

Ms. Helena Jaczek: Why would you include the overfill?

Ms. Laura Savatteri: It's a pharmacy standard that all pre-filled bags contain a certain amount of overfill. That's actually a manufacturer specification to take into account fluid evaporation over time.

Ms. Helena Jaczek: So that's the way you would prepare this product?

Ms. Laura Savatteri: Correct, if I was asked for four grams in 100 millilitres.

Ms. Helena Jaczek: So it wouldn't be 100 millilitres but—

Ms. Laura Savatteri: It's a nominal amount. Unless it was specified for it to be 40 milligrams per millilitre or 38 milligrams per millilitre.

Ms. Helena Jaczek: What's the difference between four grams per 100 millilitre and 40 milligrams per millilitre?

Ms. Laura Savatteri: Four grams in 100 millilitres does not specify a degree of specificity with regard to concentration. If a concentration is explicitly stated in the requirement of the product, what you would typically see was a greater level of specificity on the label and in the weight of the product, as prepared.

Ms. Helena Jaczek: I personally find that very puzzling. To me, four grams per 100 millilitres is a concentration. So I'm very, very surprised that you feel that way.

As you have probably heard if you've been consulting Hansard in this regard, since the hospitals have gone back to doing their own admixing, they are, in fact, ensuring that there are 100 millilitres of the diluent. That's how they're doing it.

When they saw this particular request through Medbuy, who was the pharmacist responsible for outlining how this product would be admixed?

Ms. Laura Savatteri: I don't know that I can answer that question, to be honest with you. I don't know the answer to that.

Ms. Helena Jaczek: Who was the pharmacist on site, then, at Marchese Hospital Solutions?

Ms. Laura Savatteri: The current pharmacist on site wasn't there at the time, so that wouldn't be—and to answer that question is not within my direct knowledge.

Ms. Helena Jaczek: Mr. Chair, I'll be requesting the name of that pharmacist.

The Chair (Mr. Ernie Hardeman): Yes, okay.

Ms. Helena Jaczek: In terms of your frustrations with Health Canada and the Ontario College of Pharmacists—I think we can understand, through your numerous tabs, that you did try to explain your situation and you were getting some conflicting answers, but I do have a question in relation to your inquiry under tab 5, "Inquiry: Marchese Hospital Solutions," in the second paragraph. This is presumably when you were involved as the pharmacist attempting to assist Marchese. At the end of the second paragraph, you say, "[W]e plan to prepare such admixtures pursuant to a prescription by the hospital pharmacist through our accredited pharmacy." Could you just explain that to us? Were you envisaging this on a per-patient basis? What exactly do you mean by that plan?

Ms. Laura Savatteri: What was meant by this is that any admixtures—actually, if you don't mind, I'd just like to reread this to make sure that I'm answering your question appropriately.

M^me^ France Gélinas: Remind me where we are.

Ms. Helena Jaczek: It's in the second paragraph; tab 5.

M^me^ France Gélinas: Okay.

Ms. Helena Jaczek: Towards the end of the second paragraph.

M^me^ France Gélinas: "We are currently working"—

Ms. Helena Jaczek: "In the interim 4-6 month period, we plan to prepare such admixtures pursuant to a prescription by the hospital pharmacist through our accredited pharmacy." I just want to get an understanding of what that actually meant, what was envisaged by this.

Ms. Laura Savatteri: Okay. At this point, a corporate decision was made to provide controlled substances and narcotics containing admixtures through an accredited pharmacy and to ensure safe tracking and inventory.

Ms. Helena Jaczek: And that would be on a per-patient basis?

Ms. Laura Savatteri: Not on a per-patient basis. The word here "prescription" is not a patient-specific prescription. It's a prescription written for a hospital by a hospital pharmacist.

Ms. Helena Jaczek: So there was no intention to provide chemotherapeutic agents in this way?

Ms. Laura Savatteri: No.

Ms. Helena Jaczek: Okay. Thank you.

Going back to the decision, can you explain the process to us a little bit? If you are not familiar with the name of the pharmacist who was responsible for initiating the process of admixing gemcitabine, perhaps you could explain to us: Presumably a pharmacist said, "You will take a Hospira bag of saline and you will add four grams of gemcitabine." Presumably somebody said that to some technician who would actually do the preparation. There's no thought that a pharmacist actually prepared the admix solution; correct?

Ms. Laura Savatteri: Correct.

Ms. Helena Jaczek: So there was some sort of direction given from a pharmacist: "This is the way you're going to do it." Would that be a correct assumption?

Ms. Laura Savatteri: All of the mixture breakdowns or formulae are prepared by pharmacists, and the actual execution of the mixing occurs by an infusion technician who is well trained.

Ms. Helena Jaczek: So presumably once that initial process was decided upon by the pharmacist, in that time it was done the same way and nobody questioned it at Marchese. It was just "the way we do gemcitabine."

Ms. Laura Savatteri: Right, and there was opportunity also for questions from Medbuy and from any of the hospitals as well.

Ms. Helena Jaczek: Why would they question it? They were assuming they were getting four grams per 100 millilitres.

Ms. Laura Savatteri: I can't speculate as to why they would question it, but they might because the labels looked a little bit different or whatever.

Ms. Helena Jaczek: I don't think they were particularly interested in that, but anyway—let's just go back in time. When did Marchese Hospital Solutions start providing the admixed compound to hospitals? What was the first batch that was sent out?

Ms. Laura Savatteri: Mid-February 2012.

Ms. Helena Jaczek: While you were doing all this negotiation between Health Canada and the Ontario College of Pharmacists trying to find out how to regulate, you were already sending this product out to hospitals?

Ms. Laura Savatteri: Actually, the communications began in November 2011, and that was not by me. That was another individual within Marchese. They continued, and mid-February is when we started to actually send out the admixtures. At that time, there had already been a lot of information gathered from the regulatory bodies, but there did come a point, yes, where a decision was made by the executive team on how to proceed.

Ms. Helena Jaczek: Thank you. That'll be all for now. We'll reserve our time.

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

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Mr. Jeff Yurek: Thank you, Chair. Thanks for coming in today. Just a few questions I have for you before I turn it over. Were you involved at all with the contract negotiations with Medbuy?

Ms. Laura Savatteri: No.

Mr. Jeff Yurek: Have you ever been involved with Medbuy?

Ms. Laura Savatteri: I've had some conversations with Medbuy, yes.

Mr. Jeff Yurek: In regard to?

Ms. Laura Savatteri: At the beginning of the transition, reaching out to some of the hospital members with regard to logistical activities, total quantity per case and things like that. Throughout the transition, there were many conversations that took place.

Mr. Jeff Yurek: Tell me about the transition. How did that proceed, as far as you were involved?

Ms. Laura Savatteri: The transition began, I believe, at beginning of January, and the start-up was—it was about mid-February. I'm not sure what—do you have any specific—

Mr. Jeff Yurek: What occurred between Marchese and the hospitals and Medbuy? Was there interaction amongst the three, or just the two?

Ms. Laura Savatteri: One of the things that happened was, all of the hospital directors were reached out to. It was an introductory phone call that took place to introduce who Marchese Hospital Solutions was, what we were going to do, that we would be the new contract provider and to ask what types of products they would be interested in, even though we had an idea. They were mostly logistical conversations: what days they would prefer to order etc. There were negotiations and things that occurred with Medbuy, and I wasn't involved in those.

Mr. Jeff Yurek: Was there ever a time where Medbuy, Marchese and the hospitals were on the same call or same meeting with this transition, or was it—

Ms. Laura Savatteri: Not during the transition.

Mr. Jeff Yurek: Where do you think the Ministry of Health should fall in this process? You've talked to Health Canada; you've talked to the College of Pharmacists. Where should the Ministry of Health have been in this, if at all?

Ms. Laura Savatteri: I'm not sure how to best answer that question, but I can tell you that there's definitely a need for more clarity in the process. Perhaps that's something that the Ministry of Health could help with.

Mr. Jeff Yurek: Were you shocked that they weren't involved at all?

Ms. Laura Savatteri: I can't say that I have an opinion on that, to be honest with you.

Mr. Jeff Yurek: You've looked at the contract given out. What are your thoughts on the details of the contract?

Ms. Laura Savatteri: I haven't really looked at the details of the contract, to be honest with you.

Mr. Jeff Yurek: How about the list of products available?

Ms. Laura Savatteri: Knowing now, with what's been happening lately, there could be more room for clarity in the future.

Mr. Jeff Yurek: Was there ever an opportunity for clarity on either Medbuy, hospitals or your part that you know of?

Ms. Laura Savatteri: If there was a question that needed to be asked, it would have been asked.

Mr. Jeff Yurek: You think there are just a lot of assumptions that went on?

Ms. Laura Savatteri: There could have been a lot of assumptions. I can tell you that there are questions that came up in general with certain products when something really stood out. But with respect to gemcitabine and cyclophosphamide, I don't know that there were any questions—at least, none to my knowledge.

Mr. Jeff Yurek: How would that be resolved if there was an issue? Would that be between Marchese and Medbuy, or Marchese and the hospital?

Ms. Laura Savatteri: It would depend on the situation. If a hospital had brought an issue to Marchese's attention, Marchese would have addressed it almost immediately but in collaboration with Medbuy. It could really work either way. It could be that a hospital brings it to the attention of Medbuy; Medbuy brings it to the attention of us. But there should always be that loop.

Mr. Jeff Yurek: Did Medbuy have a process laid out for the hospitals in order to facilitate questions or comments to Marchese?

Ms. Laura Savatteri: I don't have an in-depth knowledge about that.

Mr. Jeff Yurek: Thanks.

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

Ms. Elliott?

Mrs. Christine Elliott: Thank you very much, Ms. Savatteri, for appearing today. I just have a few questions. One is that you've given us copies of emails that went back and forth between yourself and Health Canada. There was an indication at tab 11 that there was going to be a face-to-face meeting in June between Health Canada and the Ontario College of Pharmacists. Do you know if such a meeting ever took place?

Ms. Laura Savatteri: The idea is that in June there was going to be a meeting between Health Canada and NAPRA and its registrars. Because at that meeting this Health Canada representative felt that jurisdictional decisions may be made, that was the reasoning for postponing a meeting between Marchese, Health Canada and the Ontario College of Pharmacists. I don't know the results of that meeting, to answer your question.

Mrs. Christine Elliott: Was there a specific decision made internally at Marchese as a result of that June 15 email that that was going to be the end of things, that there was no clear jurisdiction, that you were just going to carry on?

Ms. Laura Savatteri: At the end of May there was a pharmacy accredited in Mississauga, so that was part of a corporate decision that was made on how to move forward.

Mrs. Christine Elliott: You've indicated that you haven't read the contract between Marchese and Medbuy. Did you have anything at all to do with the implementation and the decisions that were made about the admixture preparation process?

Ms. Laura Savatteri: I was involved at some level with a group of pharmacists.

Mrs. Christine Elliott: Can you tell us what your involvement was?

Ms. Laura Savatteri: Sure. I'm trying to think right now; it just seems like so long ago. Basically there were lots of different activities. My main activity was to communicate about the regulatory jurisdiction aspect that I've talked about today, working with the pharmacists on some of the mixture breakdowns and asking questions to Medbuy when a question was had—that type of thing.

Mrs. Christine Elliott: Was there ever a discussion about the mixture process itself and whether you would use the standard bags or whether you would be drawing from the bags the specific amounts, the specific 100 millilitres that would be used? Any discussions regarding preparation?

Ms. Laura Savatteri: No.

Mrs. Christine Elliott: Or any discussion regarding proposed use, whether it would be single-use or multi-use?

Ms. Laura Savatteri: No.

Mrs. Christine Elliott: You indicated that there was a label set that was submitted to Medbuy as part of the process of receiving the contract. Do you know if that label set was the one that was actually used?

Ms. Laura Savatteri: To my knowledge, it was.

Mrs. Christine Elliott: So there were no changes made to the label set—

Ms. Laura Savatteri: Are you referring to the final label set that was sent prior to start-up?

Mrs. Christine Elliott: Yes.

Ms. Laura Savatteri: Yes. As far as I know, there were no changes.

Mrs. Christine Elliott: Thank you.

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

Mrs. Jane McKenna: Yes, I just have a couple of questions. Just to get clarification, you were the facilitator, the mediator, back and forth on these emails. Correct?

Ms. Laura Savatteri: Yes.

Mrs. Jane McKenna: Okay. What would have been your job description, to be able to have all that knowledge to go back and forth? Would you not have had to look at the contract and see exactly what you were—I'm just curious about how you would know this information if you didn't have all those facts in front of you.

Ms. Laura Savatteri: I'm definitely not a regulatory expert or a lawyer. I'm a pharmacist by background, and my job at the time was to be the pharmacy manager of our Kitchener location. I had infusion experience, but I don't know that that's necessarily what drove the role that was given to me. From a resource perspective, I was available, and I was told that I had strong communication skills and so I could carry out that function. I was not a decision-maker in the process; I was simply there to gather information.

Mrs. Jane McKenna: First of all, Marchese came to Medbuy because Medbuy—as far as they understood out there, Baxter was the only one that could facilitate what they needed, so they didn't put an RFP out there. I think if someone is giving you that role of a communicator—to communicate is great, but knowledge is wealth, so you have to be able to have both of those things. When you are the communicator back and forth, and being a brand new company that has never done this before, did you not feel it was your responsibility to have all of that knowledge? You were given that role for a reason; you would have had a job description of what that was. Would you have not, stepping out of it now, realized that maybe there was more knowledge that you should have had going into this process?

Ms. Laura Savatteri: To be honest with you, I don't know that reading the contract would have helped with any regulatory jurisdictional questions. I worked very closely in reporting back and forth to senior management and executive management, who had all of that knowledge. I was providing information, and it was a very open communication. I don't know that the words in the contract would have been specific to that.

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Mrs. Jane McKenna: Okay. So now that you're through the process—I mean, I'll say this over and over again: When I get out of a situation, I can digest what has usually happened and wish I had said things clearly at the time that sound great after it's over, which I would have really said. What do you feel could have been done differently at your end?

Ms. Laura Savatteri: Can you rephrase? Are you referring specifically to the regulatory—

Mrs. Jane McKenna: Yes.

Ms. Laura Savatteri: To be quite honest with you, I feel that Marchese—with all of the information and knowledge that we had at the time, I feel that we did our best to try to get the answers that we needed.

Mrs. Jane McKenna: Okay. I'm just saying this because we're going back and forth here. When you're first-hand on anything and you've never done any of this before, I would make sure that all the people who were dotting the i's and crossing the t's were being very specific of what—I wouldn't be speculating or guessing or maybe not enough communication or whatever that is. To me, I would have had everything in stone—who was asking what, specifically—so that there wouldn't be any overlap, any confusion at all.

Even speaking with you here today, I'm confused, as a person that is not a pharmacist, and by no means do I attest to be that at all. I just think that if I was in that position and there were so many grey areas and so many things that are clearly high-alert—how there weren't people being more specific that were in the situations that we are, like yourself, to ask those questions. If you don't have the knowledge to ask the questions, how are you going to know the questions to ask, I guess is what I'm saying.

Ms. Laura Savatteri: Sorry, I'm unclear. What knowledge are you referring to not having?

Mrs. Jane McKenna: When you were going back and forth in all the tabs here—at the end result, when you were finished with everything you were doing, getting to the point, I guess, of meeting whoever that was, on what tab that was—I apologize. Do you feel that all the questions and all the things that you did from tab 1 up to tab 16 was everything you possibly could have done with what you had?

Ms. Laura Savatteri: I honestly believe that we provided every detail of our operation. I do believe that we tried our best to try to understand what jurisdictional scope we might fall under.

Mrs. Jane McKenna: Okay.

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

M^me^ France Gélinas: I want to come back to some of the comments that you made regarding concentration. Am I right in thinking that if we had asked Medbuy to prepare gemcitabine at 40 milligrams per millilitre rather than 40 grams per 100 millilitres, that we wouldn't be here today?

Ms. Laura Savatteri: I would guess not.

M^me^ France Gélinas: And same thing goes for cyclophosphamide: Had we asked for 20 milligrams per millilitre rather than four grams per 200 millilitres, you and I would have never met?

Ms. Laura Savatteri: I would guess not.

M^me^ France Gélinas: All right. Marchese lost a big contract. All of those hospitals high-tailed it back to the security of their own pharmacies and are now mixing those drugs themselves. With this committee going on, and Dr. Thiessen going on, I cannot see the day where they will feel comfortable going out again. What is the learning that Medbuy is taking from this?

Ms. Laura Savatteri: I prefer not to speculate. I don't know what learning Medbuy would take from this.

M^me^ France Gélinas: No, I meant to say Marchese. I'm really sorry. I said Medbuy; I meant to say Marchese. I'm sorry.

Ms. Laura Savatteri: That's okay. I think the learning from Marchese, and probably the learning from everybody, is that there can be more clarity in the process. I think that one of the things that, really, we would need to answer your question more intelligently is to really see the results from the investigation of Dr. Thiessen. I'm really happy about the fact that he's getting to analyze every aspect of this drug supply chain. I do think that, ultimately, a national labelling standard would be paramount.

M^me^ France Gélinas: That makes sense.

On the label from Marchese that was shared with us—I don't know if it's because I don't know how to read it—we don't see a best-before date. Is it your understanding that it should always be there?

Ms. Laura Savatteri: Absolutely.

M^me^ France Gélinas: Is it because I don't know how to read those things?

Ms. Laura Savatteri: It's probably because it's blank, because it depends on the day that it's made. So, if it's 30 days from that day, it's written when it's prepared.

M^me^ France Gélinas: Oh, I see. So the labels that were copied to us were generic labels before a solution was actually made, and once a solution is made, it will be stamped with that date on it?

Ms. Laura Savatteri: I would presume so. I'd have to see it, but yes.

M^me^ France Gélinas: Okay. It sort of makes sense.

Every pharmacist who has stood in front of us talked to us about how basic concentration of medication is; that as soon as you start your training, you're taught—somebody teaches you about the importance of concentration versus total amount. It seems to vary greatly from one medication to the next, but it always seems to be something that you guys talk about. Am I right? Is it that basic that when you talk about medication, a flag would always go up as to, "Does this need to be concentration-specific or not," or is this something really out of the ordinary for you?

Ms. Laura Savatteri: Well, it's not out of the ordinary. "Concentration" is a commonly used term in pharmacy, and every pharmacist would have an understanding of concentration, I would presume. Of course, it depends on the situation, it depends on the information given on the drug in question etc.

M^me^ France Gélinas: Did you want to go with your questions?

Ms. Cindy Forster: I've asked this question, actually, of a number of people who have been here to present over the last couple of weeks. The fact that Marchese thought they were preparing a stock drug for one patient, a single-patient dose: Should a red flag have been raised, in particular with respect to the amount of drug in a 100-millilitre bag or in a 200-millilitre bag, having heard from a number of witnesses that the dosage in those bags actually exceeded any dose for any patient who had ever had those drugs administered?

Ms. Laura Savatteri: That's a good question. What I can tell you is that Marchese Hospital Solutions has prepared admixtures as specified in the contract. The role of Marchese Hospital Solutions staff is to ensure that we're providing a sterile and stable product according to specifications. If at any time there was a question asked from a hospital about a dose, we have the ability to look that up. But there is an expectation that these admixtures are going to be appropriately prescribed and dispensed, and administered by the appropriate health care professional to the appropriate patient in the hospital setting.

Ms. Cindy Forster: Someone—I think it was my colleague from Nickel Belt, Ms. Gélinas—asked what the role of the pharmacist was, and in your experience, you said that one of those roles was in fact checking the prescription for the appropriate dosage. Do you not think that Marchese, having had a pharmacist on site, it was part of his role to ensure, if the contract was for a one-patient dose order, that it was in fact an appropriate dose of medication in the minibags?

Ms. Laura Savatteri: That's also a great question. My answer is that prescriptions are patient-specific. Marchese Hospital Solutions is providing an admixture based on an admixing service to a hospital. It's a very unique type of situation, and in fact the pharmacist is working in a much different capacity; in a different role, a much more technical role. It is not necessarily a clinical role, because the pharmacist does not know the patient, does not know the prescriber and is not privy to any of the clinical parameters surrounding that particular patient.

What the pharmacist is doing in that regard is acting as an intermediary between Medbuy and the hospital, so we're not privy to how the drug will be administered ultimately.

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The Chair (Mr. Ernie Hardeman): Okay, that concludes the time for the third party. Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Ms. Savatteri, knowing as you did intimately that there was this regulatory grey zone, as we've heard, and following up a bit on what Ms. Forster has just asked you, would you not think, as a pharmacist, that there might be an extra burden, perhaps, on Marchese Hospital Solutions to be extra, extra careful that in fact the contract was being adhered to in the way that the purchaser—in this case, Medbuy—intended? It strikes me that you were aware there was a grey zone, so I would have wondered if you would not feel that perhaps you would want to be extra careful in a situation like this.

Ms. Laura Savatteri: I think the entire team wants to and continues to be extra careful. One of the things that Marchese Hospital Solutions does really well is just that. It's a state-of-the-art facility where there's a lot of compliance with what's called USP 797 practices. It's a highly sterile environment. There are a lot of quality control processes, from the minute an order is received to the minute it leaves the door, to ensure its sterility. Those are the types of technical quality assurance measures that take place. As you've mentioned, it is all in accordance with the contract.

One of the important things here is that because there are so many health care professionals involved in this practice, there's always an openness to communication. If an issue had been raised, Marchese Hospital Solutions, I believe, would have been happy to address it.

Ms. Helena Jaczek: As far as you know, did anyone from Marchese, perhaps the pharmacist that was responsible for the first admixture of these two chemotherapeutic agents—as far as you know, was there any phone call from Marchese back to Medbuy to say, "You haven't provided us with a specific concentration," in the way that you look at it per millilitre as opposed to per 100 millilitres? Was there any communication back to Medbuy to inquire as to what the meaning of that was?

Ms. Laura Savatteri: No. I have no knowledge of that.

Ms. Helena Jaczek: Okay. In terms of your role now as a pharmacist on staff at Marchese Hospital Solutions—

Ms. Laura Savatteri: Marchese Health Care.

Ms. Helena Jaczek: Marchese Health Care?

Ms. Laura Savatteri: Right. I'm not employed by Marchese Hospital Solutions. I had a limited involvement during that time.

Ms. Helena Jaczek: I see. Now you're at Marchese Health Care, which is an accredited pharmacist.

Ms. Laura Savatteri: Correct.

Ms. Helena Jaczek: In terms of what we've heard from other individuals in these hearings, there was a feeling that it was not reasonable that one patient would receive the entire 100-millilitre or 107-millilitre or 111-millilitre bag. As a pharmacist, do you have any opinion as to whether that was a reasonable dose?

Ms. Laura Savatteri: I have no opinion, but what I do know is that from my understanding, there was no information to indicate that multiple patients would be receiving one admixture.

Ms. Helena Jaczek: I see. And as far as you know, again, nobody went to a textbook and looked up what a reasonable dose was?

Ms. Laura Savatteri: I can't comment on that.

Ms. Helena Jaczek: Okay, thank you. In terms of your involvement when the phone call came in from Peterborough, were you one of the people who was at the end of the phone when Peterborough phoned?

Ms. Laura Savatteri: No.

Ms. Helena Jaczek: Who was?

Ms. Laura Savatteri: The pharmacist on site.

Ms. Helena Jaczek: Who is? What is the name? We're having so much trouble keeping—

Ms. Laura Savatteri: I can provide her name to the Clerk at a later date, if that's okay.

Ms. Helena Jaczek: Yes. This is the person at Marchese?

Ms. Laura Savatteri: Right.

Ms. Helena Jaczek: In terms of what has happened since, have you been involved in terms of Dr. Jake Thiessen's investigations?

Ms. Laura Savatteri: Yes. I've spoken to him on a couple of occasions.

Ms. Helena Jaczek: And you've explained the situation as you have to us: that it was your understanding that it was four grams in a 100, plus or minus, bag.

Ms. Laura Savatteri: The Marchese team had explained that to him.

Ms. Helena Jaczek: Okay. So your role, really, was very much on the side of this regulatory grey zone.

Ms. Laura Savatteri: Correct.

Ms. Helena Jaczek: What do you think about those particular regulations that have been put in place since this incident occurred? Do you have any opinion related to how this might safeguard the supply?

Ms. Laura Savatteri: I do think that we're heading in a positive direction. I think there may be an opportunity for more clarity. Depending on what these regulations entail, I don't know if they could possibly prevent an incident like this from happening. I think that it would have to be quite detailed to get to that level, but it's definitely a positive thing.

Ms. Helena Jaczek: Just to reiterate my colleague's question, if the RFP had said something like 40 milligrams per millilitre, there would have been no confusion, in your opinion.

Ms. Laura Savatteri: No question.

Ms. Helena Jaczek: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. The official opposition? Any further questions? Yes?

Mrs. Amrit Mangat: Thank you, Chair. Thank you, Ms. Savatteri, for your presentation. In your presentation, you said that you were in conversation with an OCP pharmacy inspector who—on page 9—you said "confirmed her intention of attending for an opening inspection before May 30, 2012." Was that inspection conducted?

Ms. Laura Savatteri: Yes.

Mrs. Amrit Mangat: Can you share with us what was discussed during that inspection? Were you a part of that inspection?

Ms. Laura Savatteri: Yes.

Mrs. Amrit Mangat: Okay. What was discussed during that inspection?

Ms. Laura Savatteri: I don't recall the specifics, but it was mainly related to some of the products that would be dispensed at that location. Typically, what they do in an opening inspection is they take a look at your computer software; the drug references that the pharmacy has made available; the procedures in place to ensure no access from the public; the procedures in place to ensure safe tracking and storage of controlled substances and narcotics; refrigeration and temperature control—those types of things.

Mrs. Amrit Mangat: Have you spoken with the college inspectors since the issue arose?

Ms. Laura Savatteri: I'm sorry, can you repeat that, please?

Mrs. Amrit Mangat: Have you spoken with the college inspectors since this issue arose?

Ms. Laura Savatteri: I have, but not with regard to this.

Mrs. Amrit Mangat: Okay. What have you spoken with them about?

Ms. Laura Savatteri: Well, there happened to be an inspection in Hamilton on a day when I was working, and nobody else was around. So it wasn't really into the Mississauga facility, but it happened to be the same inspector, yes.

Mrs. Amrit Mangat: Has anyone from your facility spoken to them?

Ms. Laura Savatteri: I believe so.

Mrs. Amrit Mangat: Thank you.

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

Thank you very much for your presentation—much appreciated. We look forward to digesting your well-prepared report. Thank you very much.

Ms. Laura Savatteri: Thank you.

The Chair (Mr. Ernie Hardeman): That concludes our delegations today, so we will go in camera to discuss about future direction for the committee.

The committee continued in closed session at 1628.

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