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Oversight of pharmaceutical companies

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Mardi 4 juin 2013

Comité permanent de la politique sociale

La surveillance, le contrôle et la réglementation des entreprises pharmaceutiques

Chair: Ernie Hardeman Clerk: William Short Président : Ernie Hardeman Greffier : William Short

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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON SOCIAL POLICY

Tuesday 4 June 2013

COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Mardi 4 juin 2013

The committee met at 1614 in committee room 1.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

The Chair (Mr. Ernie Hardeman): The orders of the day have completed, so we will call the meeting of the Standing Committee on Social Policy to order. It's the June 4 meeting. We're here on a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

BAXTER CORP. CANADA

The Chair (Mr. Ernie Hardeman): We have with us a delegation from Baxter Corp. Canada and they're already at the table. Before we start the meeting, we're doing this all under sworn testimony, so we will ask each one to swear an oath or affirm an oath. The Clerk will do that. We'll do all the people at the table and that way anyone can speak as we proceed with the process.

The Clerk of the Committee (Mr. William Short): I'll just start from my left to right. So it's Ms. Bentley?

Ms. Carol Bentley: Yes.

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

Ms. Carol Bentley: Affirmed, please.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please. Ms. Bentley, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Carol Bentley: I will.

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

Ms. Anne Miao: Yes.

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

Ms. Anne Miao: Affirmed, please.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please. Ms. Miao, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Anne Miao: I do.

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

Mr. Mike Oliver: Affirmed, please.

The Clerk of the Committee (Mr. William Short): Okay. If you could raise your right hand. Mr. Oliver, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Mike Oliver: I do.

The Clerk of the Committee (Mr. William Short): Thank you. And Mr. Lynch, same thing?

Mr. Phil Lynch: Yes.

The Clerk of the Committee (Mr. William Short): Do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Phil Lynch: I do.

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

The Chair (Mr. Ernie Hardeman): Thank you all very much. While we went through that, we now have almost a full committee, so we're prepared to start. We will give you 20 minutes to make a presentation to the committee. Then, at the end of the 20 minutes, we will have 20 minutes from each caucus to ask questions or make statements to your presentation. The process will start with the government side when you're through with your 20 minutes. With that, the floor is yours. Again, thank you for being here.

Mr. Mike Oliver: Good afternoon, committee. My name is Mike Oliver. I'm the general manager of Baxter Corp. Today I'm joined by Anne Miao, our director of pharmacy for Baxter Corp., to my right; to my left, Phil Lynch, director of quality for Baxter Corp; to my far right, Carol Bentley, regional director of sales at Baxter Corp.

First, we want to acknowledge the very challenging circumstances that have given rise to the committee's review of the matters at hand. Our thoughts are with the affected patients and their families. We also applaud the efforts and leadership of hospitals and pharmacy teams who have been working tirelessly to support patients. We also thank you for the opportunity to provide to the committee an overview of Baxter and its long-standing partnership with Canadian health care.

As the Canadian subsidiary of Baxter International, Baxter Corp. provides life-saving and life-sustaining therapies for patients with hemophilia, immune disorders, infectious diseases, kidney disease, trauma and other acute and chronic medical conditions.

Part of Baxter's diversified scope of therapies for patients also includes a drug delivery platform for intravenous molecules. These include intravenous-based solutions and administration sets, premixed drugs and drug reconstitution systems, IV nutrition products, infusion pumps and inhalation anesthetics.

As a global leader in ready-to-administer medication, Baxter also provides intravenous admixing services to hospitals' customers in nine countries around the world, including Canada. These are services that we'll focus on today, which Baxter delivers through Baxter centralized intravenous admixture pharmacy services, otherwise known as CIVA.

In a moment, I will provide some history about why the CIVA arm of Baxter's operation was created. IV admixing is and remains a critical service that is essential to hospital practice and patient care. First, let's focus on IV admixing and why it is a service that has been outsourced to Baxter's CIVA facility.

IV admixing has changed over the years. For example, it was initially done by nurses at the bedside for individual patient dosing of pharmaceuticals. Changes in pharmacy practice recommended by bodies such as the American society of hospital pharmacists and the Canadian Society of Hospital Pharmacists created a movement to centralize preparation of IV admixtures by pharmacists in hospital pharmacies. This created a very heavy workload for hospital pharmacies, many of which lack the appropriate technical infrastructure, personnel, time and facility of space to assume the responsibilities to handle the biohazard risks associated with and posed by oncology drugs.

To provide an alternative solution for hospital pharmacies, Baxter partnered with hospitals enabling them to outsource admixing activities. This helped to relieve the pressure on operations, freeing hospital pharmacies to focus on direct patient care and clinical activities while ensuring patient safety, quality and supply. CIVA has been providing admixing services for Canadian hospitals for 27 years.

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I would now like to take a few minutes and have Anne Miao, our director of pharmacy, provide you with some context regarding where CIVA has started and how and why it has evolved to where it is today.

Anne?

Ms. Anne Miao: Thank you. Good afternoon. My name is Anne Miao. I'm the director of pharmacy at Baxter Corp. Part of my responsibilities includes the CIVA admixing centre. I have been in my current role for two and a half years, and prior to that, I had been practising in hospital pharmacy for over 13 years. Part of my experience in hospital pharmacy included implementation of a unit dose distribution system in hospitals. I am currently a licensed pharmacist with the Ontario College of Pharmacists, category A.

With an aim to help to improve the efficiency of medication preparation, in 1986, Baxter entered into a partnership with one of the Toronto teaching hospitals to operate an admixing centre on hospital premises. The hospital partnered with Baxter to build a clean room, where the admixing activity safely took place.

Initially, all the doses were patient-specific. However, over time, it was mutually agreed upon that, to become more efficient and effective, hospitals would be better served by CIVA if they adopted a system of batched admixtures.

Admixing is not specific to individual patients. Rather, non-patient-specific batches are ordered by the hospital to meet the hospital pharmacy's short-term needs. Appropriate processes were established to permit this to be done safely, with a focus on high-quality standards.

In 2005, Baxter opened a dedicated admixing CIVA facility in Mississauga to service an expanding customer base. The opening of a stand-alone facility was driven by a number of factors, including space constraints, operational dependencies and ensuring continuity of supply.

Today, CIVA Pharmacy Services provides an admixing service, customized and just-in-time, in accordance with the specific needs of the hospital. CIVA aseptically admixes a range of commercially available medications for just over 100 hospitals across Canada. Operating 365 days a year, CIVA provides multiple therapeutic categories, including oncology, anti-infectives, analgesics, nutrition, critical care and cardiology. Every year, CIVA develops between 20 to 40 new admixing codes to better service their pharmacy customers. The development of these codes is a direct result of specific customer requests, and they were developed in consultation with our hospital pharmacists.

CIVA also has an extensive database of drug stability stemming from internal Baxter stability studies, third-party stability studies and recognized literature, as well as the ability to customize labels to meet various industry labelling requirements—for example, Cancer Care Ontario and ISMP.

My colleague Phil Lynch would now provide an overall around our quality procedures and policies.

Mr. Phil Lynch: Good afternoon. My name is Phil Lynch and I'm the director of quality for Baxter Corp. Canada.

At Baxter, we have an uncompromising commitment to the quality and safety of the therapies and services we deliver to clinicians and patients. CIVA is licensed by Health Canada's Office of Controlled Substances for the sale and distribution of narcotics and controlled substances, and is audited by them to ensure adequate controls are in place.

Pharmacists who oversee operations are licensed by the Ontario College of Pharmacists. Each admixture produced at Baxter CIVA Pharmacy Services undergoes rigorous quality processes to ensure aseptic technique, accuracy and applicable good manufacturing practices, or GMP, requirements are followed. The admixing service is operated under the direction of licensed pharmacists and certified technicians and a quality assurance team that ensures safe and precise processes. We reconstitute medications per the product monograph provided by the pharmaceutical manufacturer. Further, we track, package and label all admixed medications to ensure identification and full traceability.

As part of our commitment to ensure safety and quality, CIVA relies on stringent internal corporate protocols, voluntary standards and best practices Baxter has derived globally from the company's experience with regulatory requirements established in other countries. The CIVA facility adheres to Baxter's global internal quality processes and applicable elements of GMP issued by Health Canada. These systems are regularly assessed through robust audits by Baxter's global compliance group and are continually improved to ensure safety, identity, accuracy, quality and traceability of the service provided.

The CIVA facility has a classified clean room consisting of standards that meet the ISO, so the International Organization for Standardization or ISO 7 requirements, and is equipped with primary engineering controls including Laminar airflow hoods and biosafety cabinets meeting ISO 5 standards. With these in place, CIVA's processes and procedures are designed to meet or exceed the applicable sections of GMP, ISO 14644, and applicable sections of the pharmacy practice guidelines, including United States Pharmacopeia chapter 797.

Mr. Mike Oliver: Thank you, Phil.

You may get some sense as to why hospitals have chosen to outsource admixing services: to achieve a high degree of patient safety and to ensure confidence in the quality of the services being provided. In our view, outsourcing is not done primarily for financial reasons but as a result of the complexity of providing these services in an efficient and effective way. This underscores the criticality of ensuring a strong partnership between Baxter and its customers.

Baxter works hand in hand with each new hospital customer to determine their specific admixing requirements. As a part of the up front needs analysis, Baxter works with each customer to analyze their drug utilization data, identify which drugs could be provided in a batch and develop specific service codes. Once each unique service code has been created, the Baxter CIVA team works with the customer to determine order frequency, minimum order quantities, delivery days and special handling and administrative requirements, including labelling and alerts. A service agreement is drawn up, including a statement of work which outlines responsibilities and accountabilities for both Baxter and the customer. Service codes are not a product. Understanding a service code requires knowledge of how the code was developed and how it will be used clinically.

Baxter appreciates the opportunity to appear here before the committee today. We have highlighted the Baxter-hospital customer partnership and how this relationship is critical to ensuring that the right treatment is provided to the right patient at the right time.

In closing, in addition to recent regulatory changes introduced by the provincial Ministry of Health and Long-Term Care and the Ontario College of Pharmacists, Baxter would also welcome national standards and guidelines and federal oversight to harmonize admixing standards across the provinces and nationally affirm patient safety.

In addition, as the health system and patient needs evolve, Baxter is committed to partnering with key stakeholders to develop standards that drive patient safety and high-quality outcomes across all levels of health care delivery, including the appropriate procurement process.

We would be happy to answer any questions you have at this time.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation, and we will now start the 20-minute rotation. Mrs. Mangat.

Mrs. Amrit Mangat: Thank you, Mr. Oliver, for your presentation, and welcome to Queen's Park.

Mr. Mike Oliver: Thank you.

Mrs. Amrit Mangat: My question is, for how long has your company been providing these medications through Medbuy?

Ms. Carol Bentley: Hi. I'm Carol, and I can answer that question for you. Baxter and Medbuy had a contractual relationship from November 2008 through to September 2011. As we approached September 2011, that contract was extended for three months so that Medbuy could complete their RFP process.

Mrs. Amrit Mangat: I'm sure that there has been a great deal of discussion about the labelling of these medications. Can you share with committee members how labelling by your company was different, if it was different, from Marchese, to identify concentration?

Ms. Carol Bentley: I think I'm going to ask Anne to talk about labelling.

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Ms. Anne Miao: So thank you for the question. I can only speak from our labelling. I have not seen the Marchese label. I am just passing around, circulating, a sample label of our cyclophosphamide codes, as well as our gemcitabine codes. As you can see on the label, we have both the concentration as well as instructions for administration.

The Chair (Mr. Ernie Hardeman): For the rest of the committee, we'll get a copy made of the page that you have there so they can all—

Mrs. Amrit Mangat: So in order to ensure that what happened doesn't happen again, what measures do you think should be taken?

Ms. Anne Miao: With the permission of the panel, I think it may be helpful if I walk you through a process of how Baxter CIVA prepares a gemcitabine code for a customer. Would that be all right?

Mrs. Amrit Mangat: Chair, is it okay if she walks us through the process?

The Chair (Mr. Ernie Hardeman): Yes, that'd be fine.

Ms. Anne Miao: I'm just going to refer to my notes to make sure that I have everything correct.

When we admix any codes for hospital customers, first and foremost, we work and collaborate with our hospital pharmacists to understand exactly what their needs are and how they will be administering the medication. I'm using an example of gemcitabine four grams in this process. Let's start at the point that gemcitabine comes in two-gram vials, and each vial requires 50 millilitres of normal saline to reconstitute. In working with Baxter's hospital customers, we have determined that it would be ideal if we can put two vials of two grams together to make a four-gram code because it would be easiest for the hospital pharmacists to draw down from the bags.

Originally, when we were discussing the challenges that the hospital pharmacists had, they were indicating that the most critical pinch point for them was the reconstitution process because it takes them about four hours to reconstitute. Because we understand that we cannot standardize oncology dosing, we can derive a process whereby we mitigate the reconstitution portion of the process for them.

At the CIVA centre, we would withdraw 50 millilitres of normal saline and administer it into each two-gram vial to reconstitute. Once it's in solution format, we withdraw the entire contents of each vial and inject it into an empty non-DHB bag. The rationale for that is because once we reconstitute the vials, the vials are not tamperproof anymore, and we did not feel that it was safe to transport the reconstituted vials as such back to the hospital. So we proposed that we inject it in a closedsystem empty bag whereby we can then transport it back to the hospital. The hospital pharmacists would then wait to receive a prescription from an oncologist with the prescribed dose for each individual patient. They will look on our label and use the concentration listed there to calculate the exact dose required as per the prescription from the oncologist.

Usually, the way each dose is calculated is based on height and weight and using a formulation to determine the body surface area. Based on the calculation from the body surface area, each dose would be determined. They would then withdraw the appropriate amount from the four-gram bag. Then they would further dilute it in a vehicle, be it saline or dextrose, depending on the prescription. Then they would put individual patient labels on it and then have it double-checked and sent up to the floor for administration.

So I hope that sort of helps illustrate the processes.

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

Mrs. Amrit Mangat: Thank you.

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

Ms. Helena Jaczek: Thank you for that very clear description of the process.

You were quite clear in your own mind then, when you were the recipient of the Medbuy contract, that the admixed compound was not going to be used for a single patient? You mentioned that and it's clear from your description that you fully understood it was not going to be the whole bag for one patient. Is that correct?

Ms. Anne Miao: Yes, that's correct.

Ms. Helena Jaczek: Were you clear, from your Medbuy contract, that a specific concentration was required to be admixed to a specific concentration?

Ms. Anne Miao: If I may just point to the 10 steps. We developed that admixture code with the customers and, as a result, we know that what they really wanted was to have us do the reconstitution as per product monograph. So the final concentration of the reconstituted solution, as per product monograph, is what they required and that's how we prepared the admixture for them.

Ms. Helena Jaczek: So when you received the contract from Medbuy, which, as we have seen at least on the most recent RFP process, when it came to gemcitabine, four grams per 100 millilitres, you felt that you needed to go to the hospital pharmacist and have a further clarification. Is that correct? Or was the RFP clear to you, that you would know what to do?

Ms. Carol Bentley: Maybe I can help with this. The contract that Baxter and Medbuy had between 2008 and 2011 formalized a relationship that had been going on before that for quite some time between Baxter and Medbuy's member hospitals. In the way we work with hospitals, we have a number of sales representatives who actually work with the hospitals to develop whatever admix codes they require. So Medbuy, in conjunction with their members—and this is back in 2006-07—basically asked their committee about formalizing a contract with Baxter for admix services, and that was done in 2008.

Ms. Helena Jaczek: So your relationship kind of predated, with the hospitals—

Mr. Mike Oliver: Yes.

Ms. Carol Bentley: It did, yes.

Ms. Helena Jaczek: When you looked at the RFP that you bid on, I guess early 2012, when you saw the requirements in the schedule from Medbuy, how maybe—again, to the pharmacist, how would you have interpreted that?

Ms. Anne Miao: Just for clarity, the RFP was out in 2011. We looked at the listing, as they have indicated in the RFP, and we were required to submit label samples for each code. As you can see, our label samples actually include the displaced volume of the drug. So it actually says 105.26 millilitres for gemcitabine for four grams.

Ms. Helena Jaczek: Did you get any feedback on whether your labels were acceptable?

Ms. Carol Bentley: No. We were the incumbent at the time. Do you mean, did we get feedback in the debrief from the RFP?

Ms. Helena Jaczek: Yes, exactly.

Ms. Carol Bentley: Yes. When we were not awarded the business—we were notified in December 2011 that

we were not getting the business again for another term—we requested a debrief meeting, which you're allowed to do in the procurement rules. In the debrief meeting, they did mention, as they marked our answers to criteria, that one of the issues was labelling.

Ms. Helena Jaczek: It was one of the issues?

Ms. Carol Bentley: It was called out, yes, in terms of—however, there was no specificity in terms of—

Ms. Helena Jaczek: Of why? Ms. Carol Bentley: Of why.

Ms. Helena Jaczek: Okay. Perhaps we'll turn to this grey zone that we've heard about. With its long experience in this particular line of work, was Baxter aware about the lack of regulation specifically related to admixing?

Mr. Phil Lynch: Yes, we were aware of that. We have been partnering with Health Canada in all of our businesses for a number of years, so we were aware that we were in a grey zone.

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Ms. Helena Jaczek: We heard yesterday from Marchese that they made a tremendous effort to try to find out how they perhaps could be regulated. Was that a conversation that Baxter had also had with Health Canada or the College of Pharmacists?

Mr. Phil Lynch: During my tenure here at Baxter, I have had a conversation—or two conversations—with Health Canada regarding CIVA.

Ms. Helena Jaczek: How many years ago would that have—

Mr. Phil Lynch: Within the last two years.

Ms. Helena Jaczek: In the last two years.

Our government has introduced a number of measures, as you're no doubt aware, and Health Canada is involved. Do you feel that it is a step forward that we are attempting to put more oversight into the admixing business?

Mr. Mike Oliver: I think we would agree that anything that ultimately has patient safety as the cornerstone of any regulation, whether that is provincial or whether that is federal—we very much would welcome that

Ms. Helena Jaczek: Baxter has a number of different divisions. Perhaps you could explain to us your various businesses and what type of oversight there is existing in some of these other areas that were involved.

Mr. Mike Oliver: Sure. I'll talk a little bit about our organization, and then I'll ask Phil, maybe, to talk about the quality standards that exist.

Baxter is divided into two global businesses: One is biosciences, and one is medical products. Within medical products, you have a number of what we call internal franchises. With those franchises, there would be IV therapy, fluid systems, and then we have a big renal portfolio.

In Canada, we're one of the few medical device manufacturers that still manufacture in Alliston, Ontario. We provide and manufacture on an annual basis about 67 million IV bags or renal bags, 97% of which are provided for Canadians.

We have a very rigorous quality system in place, and I'll ask Phil to make some comments on the manufacturing processes associated with that. The plants that sit outside of Canada would all be subject to a similar level of internal and external scrutiny related to manufacturing practices. But specific to the Alliston facility—Phil?

Mr. Phil Lynch: Thanks, Mike. Our Alliston facility falls under GMP, so it is under Health Canada licence, as is our general office. That would cover off all of our medical devices, as well as drug products that we import from various facilities in Baxter.

We are also covered by the medical device regulations, as Mike has noted, so SOR/98-2. We have a technical service centre where we would repair some of our medical devices, as well as a third party warehouse facility where we perform release of our products to the Canadian market.

Mr. Mike Oliver: I would just add, in addition to Phil's comments, there are a number of devices and instruments that require pre-approval from Health Canada. In order for you to be able to sell the product in Canada, it has to be licensed under Health Canada. It's a formal submission process, and they review those technologies, typically in a reasonable time—and then launch them in the marketplace. But you cannot sell them in Canada until Health Canada has officially approved them.

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

The Chair (Mr. Ernie Hardeman): To the official opposition. Mrs. Elliott.

Mrs. Christine Elliott: Thank you very much for appearing before the committee today. We really appreciate it.

If I could just go back to 2008, when you first started negotiating the contracts with Medbuy—and I believe the first was on behalf of the London Health Sciences Centre. Is that correct? Was London the first one?

Ms. Carol Bentley: London Health Sciences was one of the members that belonged to Medbuy, yes.

Mrs. Christine Elliott: Okay. But that was done before Windsor or before Lakeridge, so that was—

Ms. Carol Bentley: I'm not exactly sure when it was done. I wasn't with Baxter then.

Mrs. Christine Elliott: Oh, okay. Well, in any event, in the first instance, you've indicated that the contract was just the culmination of your discussions that happened before that. Could you just let us know exactly—step us through the process of what would happen. You would have received the RFP, and then you would have gone and had discussions with them. Could you please tell us a little bit about that background?

Ms. Carol Bentley: The CIVA business has been here for 27 years, and it's basically us meeting with pharmacists—who are one of the people who we call in most of the time—and discussing that we did have this service, and developing products that met their needs. So this evolved over many, many, many years with many different hospitals in the marketplace.

The list of codes that we developed might have been hospital specific, or if one hospital was using them and that was of value to another hospital, then we would have that discussion with the pharmacist as well. Medbuy's contract with us in 2008 basically just formalized a process that had already started and predated that in the years before with their member hospitals.

Mrs. Christine Elliott: So as far as Baxter was concerned, there was no question about what product was going to be produced and what it was going to be used for.

Ms. Carol Bentley: That's right, because we were involved with the hospital pharmacist every step of the way in terms of determining what the requirements are and how we could meet those requirements.

Mrs. Christine Elliott: And would your contract have been that specific to reflect that, the specific needs of what was to be produced?

Ms. Carol Bentley: The contract reflected the codes that were in scope of the contract for all the members that belonged to Medbuy, but we had that basic understanding of the history of how those codes got produced and what they were. We had that understanding as we entered into that contract, yes.

Mrs. Christine Elliott: And the first contract, was that the same contract that you used in further discussions? Did it form the template for all of your other admixing contracts with the other health corporations or hospitals that were involved?

Ms. Carol Bentley: Contracting has evolved over the last couple of years—

Mrs. Christine Elliott: I'm specifically speaking about the contracts involving London, Windsor and Lakeridge.

Ms. Carol Bentley: Okay. London, Windsor and Lakeridge were all part of the Medbuy contract, and we worked with those member hospitals within the scope of that contract that we had from 2008 to 2011.

Mrs. Christine Elliott: Would you be able to provide us with a copy of that contract?

Ms. Carol Bentley: I don't see why not.

Mrs. Christine Elliott: I think it's important because there seems to be a discrepancy in terms of the specificity of the contract that was between Medbuy and Marchese. I think it's important for us to understand the differences, if any, between the two contracts because that seems to be the basis of some discussion, so that would be very helpful if you could provide us with a copy of that.

Mr. Mike Oliver: It's important, too, that prior to the admixing contract with Medbuy, Baxter would have already had a number of already pre-existing contracts with Medbuy. I think this was—Carol can correct me if I am mistaken—the first time Medbuy had gone into the admixing space. Typically they would be procuring a lot of our other devices on multi-year contracts. Likewise, there are other GPOs in the country that do the same thing, some based in Ontario.

Mrs. Christine Elliott: You were dealing with the hospital pharmacists. What involvement did you have with Medbuy specifically?

Ms. Carol Bentley: In the period that we had the contract we formalized the contract and the codes there. But also, during that time, if their member hospitals required additional admix codes for additional items, we would work with the hospitals to develop those codes, as Anne described, and then we would add those codes to the contract

Mrs. Christine Elliott: Thank you.

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

Mr. Jeff Yurek: How was your relationship with Medbuy over the years? Were they easy to work with? Did they have a process outlined so if there was a problem with your product they could follow up with you, or their member hospitals could follow the process and bring their questions or concerns to Baxter?

Ms. Carol Bentley: Yes. We have a good working relationship with Medbuy. And, yes, if there were issues as they related to products or anything else, they have a procurement team that would contact the supplier and articulate what those concerns are.

Mr. Jeff Yurek: And that was from Medbuy, the procurement team?

Ms. Carol Bentley: Yes, Medbuy has a procurement team.

Mr. Jeff Yurek: Now, did you know of any process they hadn't placed in the hospital setting or pharmacy setting where they could start a process to say, "I'm not happy with this product"? Do you know of any?

Ms. Anne Miao: Yes. Typically if there is a concern with any products directly received in the hospital pharmacy they would contact the CIVA centre. There's a coordinator at the CIVA centre which will take down their concern and address it appropriately with the entire CIVA team. As well, each hospital has a sales representative that is liaised with that hospital. They may reach out to the sales team, as well, directly, who in turn will bring it in to the CIVA centre.

Mr. Phil Lynch: I might just add to that: That would flow into our quality system through the complaints and adverse event reporting systems as well.

Mr. Jeff Yurek: Now, with regards to the RFP that was released in 2011, what are your thoughts on the RFP? Was it clear? Was it definitely laying out what exactly the winner of the RFP would have to provide? **1650**

Ms. Carol Bentley: Since we had been the incumbent before, we were very clear in terms of what the obligations would be in the next contract period.

Mr. Jeff Yurek: You were clear.

Ms. Carol Bentley: Yes.

Mr. Jeff Yurek: But was the contract clear that they were asking in the RFP—was that clear? You did the work beforehand, so obviously you knew what was going forward, but was the document that Medbuy provided to you clear—

Ms. Carol Bentley: Yes, it was clear.

Mr. Jeff Yurek: —on understanding?

Ms. Carol Bentley: Yes.

Mr. Jeff Yurek: Did you help create the RFP contract with Medbuy?

Ms. Carol Bentley: They asked us in the RFP process—so that precedes the RFP process—for a list of items that their member hospitals were purchasing from us, and we provided that information to Medbuy.

Mr. Jeff Yurek: Just with regard to oversight, you didn't have a pharmacist on site, so the college of pharmacy had nothing to do with your business.

Ms. Anne Miao: We do have registered and licensed pharmacists on site, more than one.

Mr. Jeff Yurek: At CIVA?

Ms. Anne Miao: Yes, at CIVA.

Mr. Jeff Yurek: Okay. I didn't realize that. Did you have any dealings with the college of pharmacy at all?

Ms. Anne Miao: Other than through the normal licensing channel for the pharmacists?

Mr. Jeff Yurek: Yes.

Ms. Anne Miao: No.

Mr. Jeff Yurek: And Health Canada: I might have missed that. What role did Health Canada play with CIVA?

Mr. Phil Lynch: Over the last couple of years I've had conversations with the Ontario inspectorate, which reports up through Ottawa, around how we perform our activities at CIVA.

Mr. Jeff Yurek: Did they have inspections and such of the facility?

Mr. Phil Lynch: No. Health Canada, through the Office of Controlled Substances, would audit our facility because we're licensed to distribute narcotics. That was the only auditing.

Mr. Jeff Yurek: Did you ever think of working with the OCP and Health Canada to develop oversight or did you not think it was necessary?

Mr. Phil Lynch: We had had some conversations around that, but they were informal.

Mr. Jeff Yurek: Just my last question for now: Did you batch weekly, daily for the hospitals? How did you prepare the—in what quantities did you prepare the product or how often did you?

Ms. Anne Miao: It varies between the hospitals. As we mentioned all through, we work very closely with the hospitals to understand the quantity and the codes that are required. We do admix on a daily basis. Whether we ship to hospitals on a daily basis depends on their ordering schedule. We work with them, ensuring that there's appropriate inventory turnover.

Mr. Jeff Yurek: Jane, do you have any—

The Chair (Mr. Ernie Hardeman): Ms. McKenna? Mrs. Jane McKenna: Do you know who your competitors are?

Mr. Mike Oliver: In Canada, our primary competitor for the Medbuy contract was Marchese, which I think at the time we had some competitive information around. I wouldn't necessarily term it as a competitor, but we view the ability to improve patient safety and efficiency as

taking the volume of that service out of hospitals. Doing it in our facility, with the standards that we have, at the volume that we do it, adds tremendous efficiencies, and in some cases cost efficiencies as well.

Mrs. Jane McKenna: Just for myself, if you knew that was your competitor—when they came in here, Ms. Zaffiro said that Medbuy didn't put an RFP out because they didn't realize there was anyone to compete with you at all. Ms. Zaffiro came forward to say that she wanted to bid on this RFP.

When you asked what was the reason that you didn't get the project and they said that it was the label, are you not able to see that, to actually see what the reason was? Would you not want to know what the reason was? Because to be in business 27 years is a long time, and to have someone say, "You've got a label problem," and then you don't know exactly what the label problem is—

Ms. Carol Bentley: Yes. Maybe I can clarify a couple of things. In March 2011, Medbuy issued an ACAN. An ACAN is a statement to the marketplace saying that they would like to enter into a contract again with us for CIVA services. Basically, that process tells the marketplace, and if there are any challengers, then Medbuy is obligated, through the procurement process, to issue an RFP. That's what she was referring to.

At that time, we found out that there were challengers to the ACAN process and therefore they moved to the next step, which is an RFP. I think it was at that time that we formally found out that there were other entities in Canada that were interested in this space as well. So that's the answer to your first question.

The second part is, in the RFP document, it clearly outlines an RFP process. Within Medbuy's document, the process identified that the proponent who was not getting the business could go to a debrief meeting, which we did. We requested the debrief and we went in in January. At that time, we asked what were the—it was all done on scoring, so there were criteria that were developed by the committee, and then it was scored by the committee. There were areas where our scores were less than Marchese's. One of those things was labelling. There were other things, but labelling was one of the things that was called out, and bar-coding in particular.

Mrs. Jane McKenna: When you got that—and I'm assuming you sat there through that process to see what the reason was—you were okay walking away with that? You felt that there was a legitimate reason why you didn't get it?

Ms. Carol Bentley: Well, we were very disappointed that we didn't get it. Unfortunately, in the process that was outlined in the RFP, proponents were asked to honour the process, and there wasn't a way for us to dispute it.

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

The Chair (Mr. Ernie Hardeman): Thank you. To the third party: Ms. Gélinas.

M^{me} France Gélinas: I'll pick up exactly where she left off. You had been supplying those drugs to the

hospitals for years. All of a sudden, Medbuy happens and says, "Oh, we will do a formal contract of a business transaction that was already there." Then in 2011 came the RFP for a business transaction that had already been there for years, that you had continued under a new contract, but basically the work had not changed and everything was fine; you lose that contract and you're told that it's because the label is an issue.

Why wasn't the fact that your labelling was an issue brought forward to you in those 27 years of continuous talking between you, the pharmacies and the hospitals?

Ms. Carol Bentley: I don't know.

M^{me} France Gélinas: All right. We were also told that you lost the contract because of service issues. Do you know what those service issues were?

Ms. Carol Bentley: Yes.

M^{me} France Gélinas: What were they?

Ms. Carol Bentley: In the debriefing—I'll just talk a little bit about the scoring. In the RFP document, it is very clear to the proponents in terms of how your proposal will be scored: 25 points were for financial, 75 points were for other criteria. Those other criteria were pharmaceutical and technical criteria, labelling criteria and what they called business criteria. All of those criteria were developed by Medbuy in conjunction with their pharmacy committee.

When the proposals were sent back to Medbuy, those criteria were rated based on a scoring system that was determined by the committee. It was during those reduced scores that we got that I was led to believe that that contributed to us losing the business. We did ask for a debrief, but the information that was provided was very, very high level in terms of where we lost points in our scoring.

M^{me} **France Gélinas:** Did they talk to you about cost at all?

Ms. Carol Bentley: No. Never.

M^{me} **France Gélinas:** Never? Okay, well, I will talk to you about cost. We now know that your proposal for gemcitabine—I always want to pronounce those in French; it makes way more sense to me—for four grams, you came in at \$34 and Marchese came in at \$5.60.

Ms. Carol Bentley: Oh.

M^{me} **France Gélinas:** Any idea as to why it would cost you \$34 to do something that Marchese can do for \$5.60?

1700

Ms. Anne Miao: I cannot comment on the processes under Marchese's jurisdiction because I have no visibility to that. What we base our costing on is time-motion studies at our CIVA centre, as well as the cost for the ancillaries.

M^{me} **France Gélinas:** The cost of \$34 that you submitted, was it significantly different from the cost that you had been charging the hospitals before?

Ms. Anne Miao: No, it wasn't.

M^{me} **France Gélinas:** It was the same price that you had been charging since you had been doing admixture.

How often would you increase your prices for the admixture?

Ms. Anne Miao: It varies. As you know, sometimes the ancillary costs increase, and if we change certain processes—for example, automate certain processes—we can have more efficiency in the cost. So we can actually decrease prices as well.

M^{me} **France Gélinas:** When would you pass on those savings? How is that done? When do those changes in prices take place?

Ms. Carol Bentley: Within the contract, usually there are ongoing business meetings that we have with our business partners. With Medbuy, it would be quarterly or semi-annually, and we would discuss pricing or pricing changes at that time. Perhaps they would happen once a year. I wasn't here so I don't exactly know what happened in the previous contract.

M^{me} France Gélinas: When Medbuy came in with the RFP—we're now in 2011. They go to you, and in the RFI, they actually ask you to provide a list of products. You're the one who gives Medbuy, "Here's all our codes; here's everything that we're presently providing as a subcontractor to your member hospital."

Ms. Carol Bentley: Right.

M^{me} **France Gélinas:** When they put that back out as an RFP, did you pretty well recognize the stuff that you had already submitted to them?

Ms. Carol Bentley: Yes.

M^{me} **France Gélinas:** Okay. So they took your information and put it out there as an RFP. You knew exactly what it was because you had been doing the work. Had anything changed to make it clearer, or was it your stuff that got back out?

Ms. Carol Bentley: No, it was pretty much what we had been providing to the hospitals.

M^{me} France Gélinas: Okay. So when you responded to the RFP, you knew exactly what was required of you. You know that what was required of you was a concentration-specific admix.

Ms. Anne Miao: If I may take that, we know exactly the concentration required for each admixing code, and we also know which ones were dose specific and dose non-specific.

M^{me} **France Gélinas:** And you know that because?

Ms. Anne Miao: We work with our customers to develop the codes.

M^{me} France Gélinas: Okay. So I'm trying to look at where the knowledge transfer happened. The knowledge transfer did not happen through the work of Medbuy; it happened through the work that you had done directly with the hospital receiving your products.

So here again—I'm trying to understand the processes as good as I can—what value add to clinical pharmacy does Medbuy bring?

Ms. Anne Miao: I believe Medbuy's value is as a procurement expert.

Ms. Carol Bentley: That is their mandate.

M^{me} **France Gélinas:** They have very good lawyers who know how to negotiate numbers really well and write contracts really well?

Mr. Mike Oliver: I think the primary role of GPOs in this country is to consolidate volume. If you look at Medbuy in this situation—and it's not limited to this situation, and there are others in this country—they take the volume of not one hospital, but 10, 20, 30 or 100, consolidate it, and in doing so hope to achieve efficiencies in purchase price.

M^{me} France Gélinas: Okay. Why can't hospitals get together and do that themselves?

Mr. Mike Oliver: Some of them do.

M^{me} **France Gélinas:** Some of them do?

Mr. Mike Oliver: I've been around this business a long time. There are groups of hospitals that do the same. There are some in this province that have come together and formed alliances in various parts of the country.

There are only two national GPOs. Medbuy is one of them; HealthPRO is the other. They are the only two that I am aware of that do national procurement, and hospitals belong to one or the other.

M^{me} France Gélinas: I don't know if you read the testimony, but I have really brought a focus to every time there is a hand-off, there is a risk of error in health care. By Medbuy existing, they've just increased the hand-off three times. But because of your previous involvement, you basically bypassed this by going right back to the pharmacy, to the hospital, to make sure that the products you deliver are what are required. But was that required of you, through Medbuy, to do that?

Ms. Carol Bentley: There is an expectation from Medbuy to service their hospitals and to service and meet the requirements, so I think that was, yes, their expectation

M^{me} **France Gélinas:** So the expectation is that once you have the contract, you go back to the actual member hospital to see exactly what it is that you're to deliver?

Ms. Carol Bentley: In this particular instance, with this product, it's very important that you do that, yes.

M^{me} France Gélinas: Okay.

Ms. Anne Miao: If I may expand on Carol's response, it has always been Baxter's focus to work with health care professionals. Our focus is for patient quality of care and, hence, it is of our own volition, since the 27 years, to work collaboratively with health care professionals in the hospitals.

M^{me'} France Gélinas: Okay. But I'm trying to pinpoint, as in—so you've been doing this, without any issue that made the front page of the paper, for what would have been 24 years. Medbuy comes around, puts in a contract, something that's already there. Then in 2011, we go out with an RFP for the first time, which you will lose.

Where in this RFP does it say that what you bid on is actually maybe not the final products, that you will have to go back to the hospital to know what final products you are to deliver? I read the thing and I didn't see it, but I'm not a pharmacist.

Ms. Anne Miao: I can't comment on the interactions with Medbuy and the hospital nor with Medbuy and Marchese, because I have no visibility to that. I can only comment, and as we've stated before, that it is Baxter's focus to always work with the hospitals directly.

M^{me} **France Gélinas:** I guess you've answered: This is your focus. It is not a requirement of Medbuy that you go back.

Ms. Anne Miao: No.

M^{me} **France Gélinas:** It is because of the way you do business, to ensure quality and everything else that you've done. Okay. That answers my question.

Because, again, I'm not a pharmacist, would there be a great change in the price you would have quoted if you wouldn't have known that this thing had to be concentration-specific; if all you had to do was go from a powder form to a liquid form and not be concentration-specific, and just use a pre-filled bag, mix the thing and put it in a pre-filled bag? Would there have been a difference from your \$34 that you had quoted, had you not known that you had to be concentration-specific?

Ms. Anne Miao: That is not our process. Because this is an oncologic, we take specific process precautions to protect our staff as well as the patient, to ensure accurate dosing. So we would not have looked at that as a process.

M^{me} France Gélinas: Okay. So it was clear to you that this is an oncology product that will be used concentration-specific, based on the patient's body mass and all the rest of it. So it never entered the RFP process that you may have to supply this in a different way.

Ms. Anne Miao: No, and I just want to clarify: We understood that the admixing code was not dose-specific. **1710**

M^{me} **France Gélinas:** Okay. Would you be able to provide four grams of gemcitabine for \$5.60 in an admixture?

Ms. Anne Miao: I cannot comment on that because we will not be using that process.

M^{me} France Gélinas: Okay. Fair enough. I'll save time for the next round.

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

Ms. Helena Jaczek: Sorry to dwell on this concentration issue to such an extent, but the reason we're here is because a number—hundreds of people—received a product that was diluted to an extent that obviously was picked up by the Peterborough hospital and so on. When I look at the RFP, and since we're talking about gemcitabine, we'll just continue to talk about it, I see four grams in 0.9% sodium chloride injection bag, 100 millilitres per bag. To me, that is the same thing as 40 milligrams per millilitre. Would you agree?

Ms. Anne Miao: I would agree.

Ms. Helena Jaczek: When you were responding to this—I know you'd had your historical relationship with hospital pharmacists and you'd been admixing and so on—why didn't you just go with this particular concentration?

Ms. Anne Miao: Because it's not accounting for the displaced volume of the lyophilized powder.

Ms. Helena Jaczek: Do you feel that what you were proposing to do—I don't know if you know, if you continued to have your relationship with hospital pharmacists. They are now doing this themselves; they are mixing themselves. Are they taking account for the displaced volume? How are they doing it?

Ms. Anne Miao: I can't comment on it because I'm not privy to the process they use in the hospital.

Ms. Helena Jaczek: In other words, you wouldn't think that—notwithstanding you wanted to account for the displaced volume, but surely you could have actually produced a product that was 40 milligrams per millilitre?

Ms. Anne Miao: Correct.

Ms. Helena Jaczek: You could have, but since you'd always done it that way, you ended up with 38.

Ms. Anne Miao: We followed the product monograph directions.

Ms. Helena Jaczek: I see. At any point, then, when you were preparing your response to the RFP, was this an issue? Did you call Medbuy and say, "By the way, the product monograph says to do it this way, and it's not going to end up with 40 milligrams per millilitre"? Did that conversation take place?

Ms. Anne Miao: That wasn't part of the RFP request.

Ms. Helena Jaczek: Did you feel you might have wanted to clarify that? Or it just never came up?

Ms. Anne Miao: I believe there was a pharmacy expert panel within Medbuy that was evaluating the whole RFP.

Ms. Helena Jaczek: And then, again, when you were debriefed, other than that there was a labelling issue, there was no specificity: "We were worried about the concentration"?

Ms. Anne Miao: No.

Ms. Helena Jaczek: Okay. As we know, Dr. Jake Thiessen has been appointed by our government to look into the whole sequence of events. Has Dr. Thiessen been in touch with Baxter at all?

Ms. Anne Miao: Yes. Baxter had preliminary communication with Dr. Thiessen and he has a planned visit to our CIVA centre.

Ms. Helena Jaczek: I see. Then, going back to—I think it was Mr. Lynch: You were aware of this grey area of lack of regulation for some two years. Can you tell us a little bit about the safeguards that you have in terms of quality control? Being aware of this, I would assume a large company like Baxter would want to put in some guidelines and various quality control issues. Could you tell us a little bit about that?

Mr. Phil Lynch: Absolutely, and just let me clarify: I've been at Baxter for five years, so I've been aware of the CIVA operation for that time. It's been the last two years that I've personally had conversations with Health Canada.

Baxter, like I said, has partnered with Health Canada on a number of areas in all of our operations within Canada. We've taken the regulatory requirements for drugs—GMP manufacturing requirements—and applied them to our CIVA centre.

As Mike also spoke to, we have a number of similar operations globally. In many of the countries, they are regulated, so Baxter has incorporated these regulatory requirements as well as a lot of the established best demonstrated practices we have across the industry and put these into corporate quality procedures that govern how Baxter operates these facilities. So these are all implemented within the CIVA centre. They are evaluated by our corporate compliance group on an annual basis to ensure that they are effectively implemented, and we continuously improve them.

The Chair (Mr. Ernie Hardeman): Ms. Jaczek, that concludes your time. Thank you very much.

The opposition: Ms. Elliott.

Mrs. Christine Elliott: If I could just go back to the RFP of 2011 and the contract that subsequently resulted from that, you had been in contact with the pharmacists and you had already supplied the products, so you knew pretty much what was required and it was concentration specific. You did indicate that you thought the RFP was clear. Was that because you already knew what you were going to provide, rather than the wording of the RFP itself?

Ms. Anne Miao: May I take that?

Mrs. Christine Elliott: Yes.

Ms. Anne Miao: I just wanted to clarify again that to a pharmacist, concentration can be represented as the active ingredient over a total volume or over a unit volume. So concentration is concentration. I believe the difference is that we know that gemcitabine four grams was not going to be used as one single dose for a patient. Does that help?

Mrs. Christine Elliott: Yes. I guess what I'm really getting at is: Your knowledge of what was required was based more on your specific knowledge of what the hospital pharmacist wanted, rather than the specific wording of the RFP. Is that correct?

Ms. Anne Miao: Partially correct. As well, if you look at the product monograph dosing for gemcitabine, in order for a four-gram dose to be used as a single-patient dose using a standard five-foot-ten patient, you're looking at a patient over 900 pounds.

Mrs. Christine Elliott: So you knew that you needed to be very specific with this and that it would be used specifically for each patient, depending upon their height and weight.

Ms. Anne Miao: We know that the bag would be drawn down as per patient requirements from the prescription in the hospital.

Mrs. Christine Elliott: Do you recall ever having any specific discussions with Medbuy about that? You discussed it with the hospital pharmacists, but did you have any discussions with Medbuy about the requirements and the usage?

Ms. Anne Miao: No.

Mrs. Christine Elliott: So the contract that was drawn up was drawn up basically by Medbuy for signa-

ture, but you knew yourselves that what needed to be provided wasn't really based on any specific discussions you had with Medbuy.

Ms. Carol Bentley: Right, and Medbuy, don't forget, is in council with a pharmacy committee. Part of their operating procedure is that the pharmacy procurement group work with a panel of pharmacists who are represented by each of their member hospitals. That panel or that committee works very, very closely with Medbuy in the decisions on the contracts and clarity understanding. That's part of their business model.

Mrs. Christine Elliott: Did you have any discussions with the committee in this whole process around the 2011 RFP?

Ms. Carol Bentley: During the formal RFP process, no, we did not have formal discussions with the committee.

Mrs. Christine Elliott: Thank you.

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

Mr. Jeff Yurek: Just a quick question. The College of Pharmacists will now be inspecting Baxter's CIVA. Do you welcome that oversight?

Ms. Anne Miao: Yes, we fully support the college's regulation, and in fact we've received notification from the college inviting us to have input to the standards, working with them.

Mr. Jeff Yurek: Further to that, what are your thoughts—I guess this would be more an opinion question to you—on expanding the college into hospital pharmacies?

Mr. Mike Oliver: I think we would welcome any regulation that will ensure patient safety, whether that is provincial or federal, in whatever centre it's done. We're agnostic of where it's done, whether it's at our facility or in a hospital. Regulations that improve and drive patient safety—we welcome that.

1720

The Chair (Mr. Ernie Hardeman): You have about one minute left, if you want it.

Mr. Jeff Yurek: No.

The Chair (Mr. Ernie Hardeman): We can come back to you. Ms. Gélinas?

M^{me} France Gélinas: Okay, I'm back at gemcitabine and the stability data. You have a procurement process and a distribution process that allow you to get this admixture to the hospital within the four days that your stability data was telling you was the expiry date on this product.

Ms. Anne Miao: I thought it was longer than four days, but yes.

Ms. Carol Bentley: It's four days, but part of our quality process is understanding what the stability is of the admixed products, and then making sure that delivery and filling orders and so on, and how it's delivered, meet those requirements and within that stability data.

M^{me} **France Gélinas:** How do you ship things to New Brunswick in a way that they can use this within four days?

Ms. Carol Bentley: Is it four days or 30 days?

Ms. Anne Miao: I can't remember. Is it exactly four days?

M^{me} **France Gélinas:** That's what your own stability data tells us. We have access to the documents that you have supplied.

Mr. Mike Oliver: We would use the shipping protocol.

Ms. Anne Miao: Oh, sorry—

Mr. Mike Oliver: Yes, go ahead.

Ms. Anne Miao: Sorry, I remember now. When we submitted that stability, we had four days, but since then, we have extended stability based on literature and others that have extended it beyond four days.

M^{me} **France Gélinas:** Okay, so it was four days, and now it's longer.

Ms. Anne Miao: Right, and if you noticed, a lot of our faraway customers did not order gemcitabine from

M^{me} **France Gélinas:** Okay. Were you surprised to learn of the error when you saw the papers, when you read the news?

Ms. Carol Bentley: Yes, I was surprised.

M^{me} **France Gélinas:** I'd like to hear the pharmacist.

Ms. Anne Miao: Yes, I was surprised.

M^{me} **France Gélinas:** What other feeling came to mind besides surprise?

Ms. Anne Miao: I felt really bad for the patients and their families.

M^{me} **France Gélinas:** Do you feel that this could have been prevented?

Ms. Anne Miao: I believe Dr. Thiessen's report would enlighten us as to the root cause, and that would perhaps help me answer the question.

M^{me} **France Gélinas:** Do you figure that would have happened if Baxter had continued to provide the drug?

Ms. Anne Miao: I feel that our processes in place are of high standards and quality, that we would have continued the high level of service that we have been supplying our customers.

Mr. Mike Oliver: We don't believe that that would have happened at Baxter.

Mr. Phil Lynch: We feel that our quality processes and redundant operational processes are such that we're proactively able to identify issues and respond to them accordingly.

M^{me} France Gélinas: And this includes going back to the pharmacy of the hospital using your products to see how what you do can be useful to them?

Interjections.

M^{me} **France Gélinas:** Do you figure that it should be part of the requirement of Medbuy from now on that the quality and redundancy that you have put within your process be extended to everybody else who does the same thing you do?

Ms. Carol Bentley: Yes, I'll answer this one. In the procurement processes for very clinically sensitive and complex products and services, I think there needs to be a deep understanding of how the products are used and of

the business and what is to be provided. I think that including quality elements like that within the procurement processes would be helpful in the future.

M^{me} **France Gélinas:** Are you worried that hospitals are now doing it in-house?

Ms. Anne Miao: I feel that the Ontario College of Pharmacists has guidelines in place that allow pharmacists to practise, and this is well within their scope of practice.

M^{me} France Gélinas: Except that every pharmacist we've talked to who works in a hospital tells us that they have nothing to do with this; it's the technicians who handle it. But I take it that that goes to the technicians also?

Ms. Anne Miao: It's interesting that you should mention that because the whole evolution of the CIVA service is a result of migration of pharmacists to a more direct patient-care focus, for example, pharmaceutical care. Hence, these not direct patient care activities are deemed more effective when outsourced.

M^{me} France Gélinas: You lost a multi-million dollar contract when this went to Marchese. Had you had any intention of coming back into this business with Medbuy or had you closed the door on this?

Ms. Carol Bentley: I believe the contract was awarded to Marchese for multiple years and we were regrouping. It was a large contract; however, we do have other customers in other parts of the country, so we continued with our CIVA operations. It was just one contract of many that we have.

M^{me} France Gélinas: Did you—

The Chair (Mr. Ernie Hardeman): Just very quickly, if it's a short question. You have half a minute.

M^{me} France Gélinas: No, it's not.

The Chair (Mr. Ernie Hardeman): Okay. Well, then, that's the end of the questions. Thank you very much and—

Interjection.

The Chair (Mr. Ernie Hardeman): Are you finished? If you're finished, then thank you all very much for being here today and making your presentations. It's very much appreciated and it will be of great assistance as we further deliberate the issue here.

Mr. Mike Oliver: Thank you.

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

Nothing else required? Is everybody happy? *The committee adjourned at 1726.*

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