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 6 May 2013

Journal des débats (Hansard)

Lundi 6 mai 2013

Standing Committee on Social Policy

Oversight of pharmaceutical companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la réglementation des entreprises pharmaceutiques

Chair: Ernie Hardeman
Clerk: William Short

Président : Ernie Hardeman
Greffier : William Short

Hansard on the Internet

Hansard and other documents of the Legislative Assembly can be on your personal computer within hours after each sitting. The address is:

Le Journal des débats sur Internet

L'adresse pour faire paraître sur votre ordinateur personnel le Journal et d'autres documents de l'Assemblée législative en quelques heures seulement après la séance est :

http://www.ontla.on.ca/

Index inquiries

Reference to a cumulative index of previous issues may be obtained by calling the Hansard Reporting Service indexing staff at 416-325-7410 or 325-3708.

Renseignements sur l'index

Adressez vos questions portant sur des numéros précédents du Journal des débats au personnel de l'index, qui vous fourniront des références aux pages dans l'index cumulatif, en composant le 416-325-7410 ou le 325-3708.

Hansard Reporting and Interpretation Services
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 6 May 2013

Lundi 6 mai 2013

The committee met at 1400 in committee room 1.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

The Chair (Mr. Ernie Hardeman): I call the meeting of the social policy committee to order. We're meeting again today for a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies. The first is Medbuy today.

Just for the committee's information, we only have two delegations today; the third one was Health Canada, who were unable to make it today. They have sent in a letter answering a number of the concerns that they knew about, and we can have a discussion at some point after the committee has read the letter as to how they wish to proceed—if that's enough information for them, or if they would like us to continue working on trying to get a time set up to hear from Health Canada.

MEDBUY

The Chair (Mr. Ernie Hardeman): With that, we will start with Medbuy. We have them sitting at the table at the front. We thank you very much for being here this afternoon. Before we start the meeting, we will ask you to be sworn in or affirmed in giving testimony before the committee. We'll turn that over to the Clerk.

The Clerk of the Committee (Mr. William Short): I'll go left to right. Mr. Blanchard, if you'd just raise your right hand, please. 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. Michael Blanchard: Yes, I do.

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

Mr. Nicholson, same thing; thank you. Mr. Nicholson, 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. Kent Nicholson: Yes, 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, as we have done with other delegations, give you the opportunity for 20 minutes to make a presentation as to your involvement, shall we say, with the process. Then we will have questions from the three parties. This time, the questions will start with the third party, I believe. I stand to be corrected, but—

Interjection.

The Chair (Mr. Ernie Hardeman): Right again: The third party is first this time, and then we'll make the rotation on that.

With that, I turn the floor over to you to make your presentation.

Mr. Kent Nicholson: Great, thank you. Just by way of orientation, you should have a copy of our opening statement. Additionally, there is a document that is called "Key Documents," and we will in our opening statement draw attention to a number of tabs that are contained therein. We had sent out the information on Friday; I believe it got distributed this morning. So, unfortunately, you don't have the benefit of a lot of preparation, but we'll take our time in terms of describing our opening comments.

I'm going to read the opening statement. I've kind of broken it into four areas. Firstly, we'll touch on a little bit of background in terms of Medbuy: who we are, and the nature of the work that we do. Then we wanted to touch on the request-for-proposal process that supported this particular sourcing initiative. We'll touch on the contract specifically, and we'll also share our knowledge of the events leading up to the issue being identified.

Moving to the prepared statement: By way of background, my name is Kent Nicholson. I'm the president and chief executive officer of Medbuy Corp., and have been since October 2011. With me today is Michael Blanchard, who is our vice-president of pharmacy, clinical services and business development. Michael is a licensed pharmacist and joined us in February 2013. Though Michael just joined us in February, he has over 30 years of pharmacy experience in both hospital and group-purchasing settings.

We begin by expressing our sympathies to the patients and their families that have been affected by the recent news concerning chemotherapy medication in Ontario and New Brunswick. We're committed to assisting in the determination of why this medication error occurred.

We are a national health group purchasing organization, or GPO, that works on behalf of publicly funded and accountable health care organizations in Canada.

These health care organizations comprise the Medbuy membership—or "members"—and are also shareholders of Medbuy.

Medbuy has been in existence since 1989. As a GPO, we aggregate the purchasing power of our members to obtain the best value from suppliers for a wide range of medical supplies, services and pharmaceuticals. The nature of the work that we do tends to drive a higher level of standardization by the hospitals, cutting costs and reducing product variation.

Patient safety is always the focus of our work. We bring together clinical experts from among our members, who work with our staff to make determinations regarding products and services that members ultimately purchase. Our expert member committees are actively engaged and participate in all aspects of our sourcing initiatives.

Medbuy is a share capital corporation registered in Ontario. We operate similarly to a not-for-profit, in that we do not retain earnings. Any revenue that we generate is distributed to our member hospitals in proportion to their spend under Medbuy contracts. In 2012, members' spend against Medbuy contracts totalled $627 million. Since our inception in 1989, we have saved our members hundreds of millions of dollars that have been redirected to provide front-line patient care.

We are compliant to the Broader Public Sector Accountability Act, meaning that we are governed by the laws that apply to the purchase of goods and services using public funds, and aim to ensure fair, open and competitive procurement practices.

Turning to the request for proposal: In 2008, as part of our role as a GPO, we issued a request for proposal, or RFP, for pharmaceutical products. This RFP included, for the first time, sterile preparation compounding services, or compounding. Medbuy and its members had been considering seeking a compounding contract since 2005. We were encouraged by our members to include compounding in the 2008 RFP, since many member hospitals were already outsourcing their compounding services.

The central consideration when deciding whether it is best to perform compounding in-house or through a third party provider is patient and employee safety. We received only one submission in response to the compounding portion of our 2008 RFP from Baxter. Thus Baxter was awarded the contract, and provided compounding service to participating members from 2008 until 2011.

In early 2011, with the Baxter contract due to expire, we made a public posting announcing that we would be renewing our contract with Baxter for compounding services since, to our knowledge at that time, Baxter was the sole provider of this compounding service. Marchese Health Care, or Marchese, objected to this since it believed it could also provide compounding services. In order to determine whether Marchese did in fact have the facilities and expertise to provide compounding services, some of our staff attended a Marchese facility. After the visit, we reported back to our pharmacy committee, and together we were satisfied that Marchese could in fact provide compounding service.

As a result, we posted the RFP in 2011 for compounding services. Deadline for RFP submissions was November 9, 2011. We received submissions from three proponents: Baxter, Gentès and Bolduc, and Marchese. The RFP listed a mandatory criterion requiring proponents to warrant that all compounding services would be supervised by licensed pharmacists. This requirement and all other evaluation criteria were determined after a review of existing practices, regulations and policies by member committees and our staff.

In accordance with the Broader Public Sector Accountability Act, our RFP ensured a fair and transparent process that was free of bias. Proponents were scored against a predetermined set of criteria. All submissions were scored independently by subject matter experts from member hospitals, eliminating group bias. The scoring criteria were developed by a committee made up of clinical experts from member hospitals in conjunction with our own internal pharmacy experts.

Scoring criteria were based on four categories: pharmaceutical, label, financial and business. The pharmaceutical and label scores were each assigned a maximum of 30 points; the financial score was assigned a maximum of 25 points; and the business score was assigned a maximum of 15 points.

The contract award was made to the proponent with the highest overall score. Spreadsheets reflecting the scoring process for this particular procurement are found at tab 1 of the document brief we have provided. Even a brief review of these documents demonstrates the detail and exhaustive process of evaluating submissions.

Compounding by third party providers has been available in Canada for over 25 years. As I have noted, the central consideration when outsourcing compounding is patient and employee safety. For this reason, we have been particularly attentive to the requirements we included in both the RFPs we have issued for this service and the contracts we have executed with suppliers. The mandatory requirement that compounding services be performed under the supervision of a licensed pharmacist is of paramount importance to us and our members.

1410

Marchese satisfied this requirement and warranted that 100% of the pharmacists performing compounding services were licensed in Ontario. In addition, Marchese made the following representations in its RFP submission:

—that it was a pharmacy licensed by the Ontario College of Pharmacists, which enabled it to provide infusion services in compliance with the Ontario Drug and Pharmacies Regulation Act;

—that it provided training to pharmacists in addition to that they received in school, such as the in-house sterile preparation certification program which adheres to the Ontario College of Pharmacists' model standards of practice, the Canadian Intravenous Nurses Association's

standards for infusion therapy, the Canadian Society of Hospital Pharmacists' guidelines, and other professional Canadian and US standards;

—that all staff receive annual recertification of an in-house sterile preparation certificate program;

—that it met United States Pharmacopeia 797 standards for sterile admixing services;

—that it had consulted with Health Canada regarding whether any additional requirements were needed to meet Health Canada regulations; and

—that its infusion technicians had undergone the Chemochek training and certification program.

In addition, as part of their RFP submissions, proponents were required to submit copies of their proposed labels for scoring. Labels were scored against the precise label-scoring criteria shown at tab 2. The labels that Marchese submitted with its RFP were concentration-specific, meaning that they showed the concentration of the active ingredient, as required by the scoring criteria for labelling. These are found at tab 3A.

Marchese received the highest score on its RFP submission and was, therefore, awarded the contract. The RFP submission, signed by Marchese, is at tab 4. The signatures of Marchese are shown in appendix 1 of its submission.

Although Marchese started using the trade name Marchese Hospital Solutions on some occasions following the contract award, as can be seen on its labels in tab 3B, the name Marchese Health Care continued to appear on many of the communications to and from Medbuy. Our understanding was, and remains today, that the contract is with Marchese Health Care.

Turning to the contract itself, we signed the contract with Marchese for compounding services in February 2012, referred to going forward as "the contract." A copy of the contract can be found at tab 5. Attached to the contract was a product and pricing list, which lists all the medications that Marchese would be preparing at the request of member hospitals. The list contained the same specifications for the relevant chemotherapy medication that was used in the previous contract with Baxter in 2008. Both lists are attached to tab 6. Baxter never experienced any difficulty in understanding these specifications or in delivering products that matched them.

Even after the award of the contract, we undertook ongoing monitoring of Marchese's performance. In November 2012, a group of our staff and members visited Marchese's Mississauga facility to ensure quality control. Marchese followed this visit with a letter to Medbuy dated December 5. In that letter, Marchese ensured that, "Marchese has a current and valid certificate of accreditation from the Ontario College of Pharmacists." This letter can be found at tab 7.

Turning now to the discovery of the chemotherapy medication error: On Friday, March 22, 2013, at approximately 5 p.m., we were informed by the director of pharmacy at London Health Sciences Centre that a potential problem had been identified at Lakeridge Health with the concentration of two chemotherapy medications. We immediately initiated inquiries that afternoon.

On the morning of March 25, 2013, we followed up by contacting both Lakeridge and Marchese to further investigate this issue. Marchese agreed to notify all users of these two products and inform them of the potential problem. Marchese also agreed to develop a solution and circulate a communication to the affected hospitals, advising them both of the problem and of the solution.

On Wednesday, March 27, we were advised by Marchese that it had verbally notified all members who purchased these medications of the issue. A written communication, prepared by Marchese, was sent out to our member hospitals on March 28, 2013. Since this issue was first raised, we have been in frequent contact with our members and other interested stakeholders.

In conclusion, we are committed to assisting with any and all investigations regarding why this issue occurred and will co-operate to make sure all of the issues are addressed. We want to do everything that is necessary to ensure that this does not happen again.

The Chair (Mr. Ernie Hardeman): Thank you. Yes, sir? Did you want to speak too?

Mr. Michael Blanchard: No, I'm good. Thank you.

The Chair (Mr. Ernie Hardeman): Oh, okay. I just saw your microphone come on so I thought maybe I had missed something. With that, we will start the questioning with the third party and France Gélinas.

M^me^ France Gélinas: Thank you, Mr. Chair. Thank you for coming. My first question is just a technical one. Mr. Blanchard wasn't there when the contract was being put together. Who would have been the pharmacist from Medbuy at the time?

Mr. Kent Nicholson: Michael has replaced a gentleman by the name of Richard Jones. Richard is also a pharmacist by training. Richard is currently the director of pharmacy at the Vancouver Island Health Authority.

M^me^ France Gélinas: Very good. Another little clean-up issue is on page 2—I don't know if you have the same pages—request for proposal, paragraph number 10. You say that you sent some people: "some of our staff attended at a Marchese facility." Which facility did they attend, do you know?

Mr. Michael Blanchard: I believe, in my reading of the documents, that it was the facility in Mississauga—pardon, in Hamilton.

M^me^ France Gélinas: In Hamilton, so not the facility where the compounding was going to happen.

Mr. Michael Blanchard: There were a couple of visits. Are you referring to—

M^me^ France Gélinas: Paragraph 10. You go on to say: "Baxter was the sole provider of this compounding service. Marchese Health Care ('Marchese') objected to this since it believed it could also provide compounding services. In order to determine whether Marchese did, in fact, have the facilities and expertise to provide compounding services, some of our staff attended at a Marchese facility."

Mr. Michael Blanchard: If I recall correctly in my reading of the documents that I reviewed, Marchese has

several facilities. They did, at that time, visit a facility in Hamilton.

M^me^ France Gélinas: Hamilton, which is not the facility that would be doing the compounding.

Mr. Kent Nicholson: I'm not sure. If, at the point in time that we were—again, this was before we even launched the RFP—I'm not sure at that point in time if Marchese had determined where they would manufacture or undertake this admixing. The intention was to see a typical facility to give some assertion that, in fact, they were in the compounding business and to give us a sense as to the quality of their facilities and their operation.

M^me^ France Gélinas: Okay. Then I go to page 3, paragraph 17, talking about labels. Second sentence: "Labels were scored against the precise label scoring criteria shown at tab 2. The labels that Marchese submitted with its RFP were concentration-specific, meaning that they showed the concentration of the active ingredient, as required by the scoring criteria...." They had shown you a label that was concentration-specific when they bid on the RFP, but when they supplied the chemo drugs, it was not so. Where was this check supposed to be done, that what they had bid on was actually what they delivered?

Mr. Michael Blanchard: If I understand your question, you're asking about both sets of labels: the labels that they submitted for their RFP and the labels that they subsequently began using when they delivered the product to the customer. I believe both sets of labels have an accurate and specific expression of concentration on both.

M^me^ France Gélinas: That's not what we heard. We heard that the concentration was not specific, as in, it had the total milligrams of the active compound within the saline, not the percentage.

1420

Mr. Michael Blanchard: If you refer—and I can't remember the tab.

Interjection: Tab 3.

Mr. Michael Blanchard: Tab 3. If you'd take a look at tab 3, as an example, the cyclophosphamide—

Interjection.

Mr. Michael Blanchard: The first page on tab 3B. These are the labels that they utilized after they started providing the service. If you take a look at the cyclophosphamide, for example, which is approximately the third row of labels from the top, the two on the far right side of the page: "Cyclophosphamide 4 g in 200 mL." That is an expression of concentration: two grams in a specific volume. That is the—

Ms. Cindy Forster: What about the other drug, the—

Mr. Michael Blanchard: Gemcitabine?

Ms. Cindy Forster: Yes.

Mr. Michael Blanchard: The same situation. I can find the label for you. We should have it here. If you turn the page over, the first label on the third row from the top: "Gemcitabine 4 g/100mL"—an expression of concentration.

M^me^ France Gélinas: So from the get-go, when they submitted, they actually used the label that they would be using for the year where they supplied diluted chemo drug, and nobody noticed that if you are to label that way, you are not guaranteeing the concentration of the active ingredient.

Mr. Michael Blanchard: I'm not sure if I understand your question, but both the labels that we received for the submission and those that were changed—both sets of labels equally express the specific accurate concentration. I'm not sure if I'm answering your question. Can you maybe rephrase?

Ms. Cindy Forster: Well, my understanding from some of the other people we've heard from is that when Baxter supplied labels, it would say "gemcitabine, five milligrams per millilitre." So four grams in a 100 millilitres and that equals 25 milligrams per millilitre or whatever that calculation is.

Mr. Michael Blanchard: There are some hospitals or members that—you know, there is redundancy in terms of the expression on a label of concentration. So you may express it as two grams in 100 millilitres or 20 milligrams per millilitre, but they're both expressions of concentration of identical specificity.

Ms. Cindy Forster: But if you were actually using these bags of admix drugs for more than one patient, then someone has to do a calculation—

Mr. Michael Blanchard: Yes.

Ms. Cindy Forster: —if the drug is expressed in this way on the label. So whoever that is, the pharmacy technician or the—

Mr. Michael Blanchard: Well, again, a qualified pharmacist. Most oncology products—a specific dose for a patient varies from patient to patient. It may even vary from week to week for the same patient. So when the physician decides on a drug dose, there is always a calculation, no matter what the expression of concentration is. What is key is that you do need an expression of concentration. If the dose is 625 milligrams, if the expression is 20 milligrams per millilitre, you still need to make a calculation. If the expression is 2,000 milligrams per 100 millilitres, you still have to make a calculation. So qualified pharmacists, that's part of their job. It's part of the act of or the art of pharmacy.

Ms. Cindy Forster: Thank you.

M^me^ France Gélinas: Okay. So with this train of thought, were the drugs that were used diluted?

Mr. Michael Blanchard: The drugs in question, both the gemcitabine and the cyclophosphamide, are approved for sale in Canada. They're available in a vial in a powder form. So there is a reconstitution and dissolution of the powder in the vial, and that volume is then transferred into a bag. That's what you mean by diluted?

M^me^ France Gélinas: No, I mean: Why do you think you're here today?

Mr. Michael Blanchard: Why am I here today? Well, simply that the issue or problem is not the concentration or the expression of concentration; there is an expression

of concentration on the labels. The problem is that the labels do not accurately describe the contents of the bag.

M^me^ France Gélinas: The label did not accurately describe the contents of the bag when they responded to the RFP.

Mr. Kent Nicholson: I would suggest that all of the labels they submitted with the RFP and the labels that came subsequently are an exact expression of concentration. When you say it's four grams in 200 millilitres, that's an exact expression of concentration. Our member hospitals relied on that representation. They received the product, they assumed, understandably, that the contents in the bag matched the label. If, in fact, the contents in the bag had matched the label, we wouldn't be here today. It's an issue that the representation on the label is inaccurate, but it is an exact expression of concentration.

The four affected hospitals all independently reviewed the label, interpreted it as an exact expression of concentration and relied on the accuracy of the label to administer to patients.

M^me^ France Gélinas: So the fact that a 200-millilitre bag, once you add the diluted substance in it, no longer has 200 millilitres in it—that never occurred to anybody?

Mr. Michael Blanchard: I would defer that to Marchese. We essentially hosted any RP and requested a specific product to be manufactured according to our description and our specs, which are represented by these labels.

We engaged the services of qualified pharmacists, licensed pharmacists, in an accredited pharmacy. We relied on their expertise to produce a bag of product to meet the specifications. These are licensed pharmacists, essentially, who oversee the production of these products: admixing and transferring the appropriate amount of product into the bag, and labelling it accordingly.

M^me^ France Gélinas: Now we know that the label did not accurately describe the contents of the bag, using your words. I take it that Medbuy knows that every time there's a hand-off, there is a risk for error. In health care, it happens everywhere—in pharmacy certainly, but also every other aspect of health care. Every time there is a hand-off, there is a risk for error.

In this particular case, going from preparing those mixtures in-house, patient-specific, to a hand-off to Medbuy, a hand-off to Marchese, a hand-off from Marchese back to the hospital: We've just added three layers of hand-offs; three layers of risk. How do you manage that risk? By the simple fact that you exist, you multiply the amount of hand-offs.

Mr. Michael Blanchard: We manage the risk by facilitating—our function is, we don't handle the product; we don't manufacture or admix the product. We essentially review with our members what are the practices, the standards, that are required for a pharmacy or to hand off a product, as you mentioned, to outsource the production. There are standards that these facilities employ to minimize that risk. Our job was to ensure that Marchese essentially met—or they stated they met all these criteria.

M^me^ France Gélinas: So you leave it back to your members or the hospitals to check?

1430

Mr. Michael Blanchard: We essentially—the committee, members and Medbuy staff—approached Marchese. There was a very comprehensive RFP process to evaluate the proponents—whether or not they had the standards and the facilities to produce a product within the guidelines, within the acceptable standards in the community. We felt that our comprehensive review provided us with sufficient comfort that they were capable of producing a product that was appropriately labeled and accurately prepared. The hospitals relied on that labelling, that it accurately represented the content of the bag. If it did, then we wouldn't be here today.

M^me^ France Gélinas: Other pharmacists have testified before you that it's not uncommon, when you mix a drug in a pre-set bag of saline, that you don't end up with the exact concentration; you end up with a little bit less because you add it into a bag of saline. This is not news to you, I take it?

Mr. Michael Blanchard: The commercially available pre-filled bags—there is overfill in them, and that's common knowledge. A qualified pharmacist would take account for that overfill in the preparation of their products. The label, again, would reflect accurately whether or not they did take that into account.

M^me^ France Gélinas: So you're telling us that the pharmacists at Marchese missed something that was obvious?

Mr. Michael Blanchard: I can't comment on what speculation—

Mr. Kent Nicholson: I think we can comment—back to my opening comments—that the specification, as it existed in the 2008 contract with Baxter, is identical to the specification that we went out to RFP for in 2011. So, Baxter had no issues understanding the specification and understanding that exactness was necessary in the handling and administration of chemo drugs. Their label indicated an exact concentration, and there was an exact concentration in the bag. So, our expectation was the specification was clear, that a licensed pharmacist would understand the necessity for exactness of these particular products, and that the label on the finished product was an absolute, accurate representation—four milligrams in 200 millilitres, not in approximately 200 millilitres, not in the total bag's contents. It's an exact definition: Four grams in 200 millilitres is an exact expression of concentration, not an approximation.

Mr. Michael Blanchard: And if I may add, qualified pharmacists would take that into account—the overfill—in their formulation. We spec'd out exact concentrations—one gram in exactly 100 millilitres. Qualified pharmacists would take that into consideration in preparing their product. They label it as an accurate, specific concentration in that bag, and if there wasn't, they should have adjusted the label accordingly.

M^me^ France Gélinas: Who should have caught that and adjusted the label accordingly?

Mr. Michael Blanchard: Well, Marchese, the pharmacist responsible for the production of the—

M^me^ France Gélinas: —the drug that Marchese—did you know that Marchese was unregulated?

Mr. Michael Blanchard: The pharmacist, to our knowledge—when we reviewed the criteria for awarding, one of the mandatory criteria was to have licensed pharmacists overview and oversee and supervise the production. With Marchese, we did satisfy ourselves that they were licensed; they had had licensed pharmacists in the province of Ontario. Regulated: We are aware of the regulation, that this is an area where oversight was a grey zone in terms of who was going to provide oversight for this type of production. Yes, we were aware.

M^me^ France Gélinas: You were aware.

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

We will now go to Helena Jaczek.

Ms. Helena Jaczek: Thank you for coming today and for providing us with exhaustive documentation.

Like my colleague, I just want to concentrate on a few issues that your presentation today did—it gave rise to a few questions, from my point of view. On your first page, number 5, you talk about your members and "expert member committees" who are "actively engaged ... in all aspects of our sourcing initiatives."

Now, as I understand it, Medbuy is made up of members who are all from accredited health facilities, essentially—public hospitals and so on. So the individuals who are on your expert member committees are all individuals who have a job with a health facility and they have a specific expertise that could be valuable to Medbuy. Is that correct?

Mr. Kent Nicholson: Correct.

Ms. Helena Jaczek: Specifically, when it comes to pharmacy, could you describe who and how many people are on your pharmacy expert committee?

Mr. Kent Nicholson: Sure. I'll talk about the committee structure in general and then specific to pharmacies. We operate four portfolios. Those portfolios include operating room, materials management, medical imaging and pharmacy. Typically, every one of our member hospitals has a participant in each of those four portfolio committees.

Specifically to pharmacy, our pharmacy portfolio committee is represented by about 25 hospital members; it is often the director of pharmacy or a designate within their facility, so it's really a wealth of experience. Around our pharmacy table we have some recognized experts in the art of pharmacy. We lead that group also with licensed pharmacists who are employees of Medbuy.

So we do work very collaboratively with our membership, and our intention is to leverage the expertise that exists in our member hospitals to ensure if there's any unique requirements of their facility that their participating members are around the table to act as a voice for their particular facility.

Ms. Helena Jaczek: And these individuals do attend various facilities, various premises, where pharmacy preparation takes place, where compounding might take place. These would be the same people who would attend?

Mr. Kent Nicholson: Yes. We would typically not bring the entire committee. So in the instance that we described, at the outset when we posted our RFP and we were actually posting a sole-source validation, our intention was to renew the contract with Baxter. We didn't expect anybody would put their hand up, but in fact someone did put their hand up. So there was a visit. That particular visit was simply our staff, but our staff are also—we have the benefit of having licensed pharmacists as well.

We also reference in the document that in November 2012, we visited the Marchese Mississauga facility, again, as part of our normal course of in-contract vendor management that we would visit a facility. We visited that facility with representatives from our pharmacy committee—not the entire 25, but there were perhaps six or eight of our member hospital pharmacy directors, along with staff. We had a visit, and you'll find in the tab, post the visit, that Marchese, again, reinforced their capabilities and made reference to the fact that there's licensed pharmacist oversight. They even continued with a representation that they were an accredited pharmacy.

Ms. Helena Jaczek: So that type of inspection or visit does not include taking a sample of the product and testing it for validity—that the label is correct and that the concentration in the drug is there?

Mr. Kent Nicholson: It does not. Again, our expectation of a licensed pharmacist is when a label is stated as an exact concentration, that that is in fact the contents of the bag. That was our experience with the previous incumbent supplier for the five years that that particular contract was in place.

1440

Ms. Helena Jaczek: Well, it strikes me that that sort of visit is more of a paper chase. It's more just looking at the papers: "Is this an accredited pharmacy? Do they use sterile technique?" or a few things like that. There's no actual validation or objective assessment.

Mr. Michael Blanchard: No, there's no manufacturing validation of the drug content.

Ms. Helena Jaczek: Since we know that Marchese, apparently, was also contracted—as you have in tab 3A and 3B—for many other products: In light of what occurred and what you first learned of on March 22, what assurances do we have that these other products are at the correct concentration?

Mr. Michael Blanchard: Again, we rely on the quality and the skill set of a pharmacist to make sure that the drugs are reconstituted. You have to remember, the active ingredients are all approved from various vendors. They are approved by Health Canada. This is essentially the act of preparing a drug as prescribed by the directions from the various manufacturers and vendors. We have confidence that the non-oncology products are being transferred to the bags.

Ms. Helena Jaczek: Would you have any expectation that the hospital pharmacist would do any validation?

Mr. Michael Blanchard: No.

Ms. Helena Jaczek: Coming to your point 14: When you're assessing the various proponents' bids, you look at the pharmaceutical and label scores, and each can reach 30 points. I would assume, as a physician, that the labelling piece should be a no-brainer: You ask for a certain concentration and you stick it on the label. Am I missing something?

Mr. Michael Blanchard: You are correct.

Ms. Helena Jaczek: In terms of the pharmaceutical piece, could you describe a little bit more how a proponent might gather those 30 points?

Mr. Michael Blanchard: If you refer to—I believe it's tab 1A. Just to give you an example: In tab 1, A and B, essentially, are the criteria that the proponents—the vendors that responded to the bid. If you take a look at pharmaceuticals, for pharmaceuticals there are several criteria that address the quality: the qualifications of the staff, the environment, the production facility. Do they meet certain standards? Are there clean rooms? Do they have certification of the clean hoods that they're utilizing in preparing the production? Identifying the training of their staff, the recertification of their staff etc.

Ms. Helena Jaczek: So you look for the certification or the training, that these individuals have obtained this particular piece of accreditation? You look at the facility to see that there are fume hoods or there are negative-pressure rooms? You physically do look at that piece?

Mr. Michael Blanchard: When they visited—basically, when you're looking at these—yes, we do look at them.

Ms. Helena Jaczek: Yes. Okay. Well, that's reassuring.

For those 30 points on the pharmaceutical side, I guess I'm a little surprised that it wouldn't be an all-or-nothing. Before you look at finances, before you look at business scores, I would have thought that when you are trying to obtain a pharmaceutical product, it's so important to have that absolutely correct that there has to be at least some minimum that would be acceptable out of the 30. Frankly, I would have thought you'd want to see 30 every time, before you looked at the other two scores. Is it a stepwise type of process in terms of looking at the proponents bidding on the RFP, or is it a combined score?

Mr. Michael Blanchard: There is a mandatory, and in this case the mandatory was that they needed a licensed pharmacist. That was the mandatory, and once they qualified and met that mandatory requirement, then the other criteria—it would be a combined score, the best score of the remaining.

Mr. Kent Nicholson: It is not unusual for us—again, I don't have the information directly in front of us, but it's not unusual for us to have, for the area of clinical—and in the pharmacy world, it would be called pharmaceutical—a minimum score, that if somebody doesn't meet that minimum score, their bid is rejected. It's not unusual for us to run initiatives that do have a minimum clinical score to have you continue to be a qualified proponent.

Ms. Helena Jaczek: Okay. Now, obviously, your contract was signed with Marchese Health Care, which you were satisfied was accredited, licensed pharmacist etc. But you knew that the facility you visited was not currently compounding chemicals. When you started to see Marchese Hospital Solutions coming back on various documentation and so on, did that raise any further questions about was this a licensed, accredited facility?

Mr. Michael Blanchard: My recollection of some of the readings of the documents—there's evidence to support that the initial production did occur in a facility other than the Mississauga facility. They did inform us—they had demonstrated or introduced plans to us to move the production to a new facility, and they were awaiting accreditation from the college of pharmacy of Ontario. They did notify us in an email of the date that they had received accreditation and were moving the production for the hospital to that new facility. They also indicated at that time that they were introducing a new business name, Hospital Solutions, to clearly distinguish between their hospital division and their retail home care division.

Ms. Helena Jaczek: Am I understanding that the feeling at Medbuy was that, notwithstanding this name change—Marchese Hospital Solutions—it was an accredited facility by Health Canada?

Mr. Michael Blanchard: Not by Health Canada. It was an accredited facility. It was a licensed pharmacy—

Ms. Helena Jaczek: But it was a pharmacy.

Mr. Michael Blanchard: A pharmacy accredited by the Ontario College of Pharmacists.

Ms. Helena Jaczek: If you had known that it in fact fell into this grey zone and was not accredited by the College of Pharmacists, in that the College of Pharmacists cannot enter that premise—at least to date; we hope they will be able to, but not at this moment in time—would you have continued with the contract?

Mr. Kent Nicholson: At that point in time—and again, represented by what we deemed to be the mandatory requirement. The mandatory requirement that we specified was that the work needed to be supervised by a licensed pharmacist. If we had put in a requirement as mandatory that you also had to be an accredited pharmacy, the previous incumbent, Baxter, would not have qualified. They were not, and still are not, to our knowledge, an accredited pharmacy. It was not part of the scoring, it was not part of the consideration. They made a representation that they were an accredited pharmacy, but what was a mandatory requirement for us was that the work was supervised by a licensed pharmacist.

Ms. Helena Jaczek: So you really were not aware that there was this grey zone, as we've heard it described. Or you just felt if there was a pharmacist there who was accredited, licensed by the College of Pharmacists, that was enough.

Mr. Michael Blanchard: I refer you back to our opening statement. This is a practice hospitals outsourced to a third party for nearly three decades. We had at the

time I believe 14 hospitals with individual arrangements with Baxter, essentially. In order to attempt to streamline—it was an effort to consolidate these individual hospital agreements to one agreement, and that was sort of the motivation for the 2008 contract with Baxter. This was an acceptable practice in the community. Health Canada and the College of Pharmacists were well aware of this practice, and it's a practice that has been ongoing for—like I mentioned before, I think Baxter has been in business for nearly 27 years.

1450

Ms. Helena Jaczek: Obviously, in light of this incident, the Ministry of Health and Long-Term Care has become very involved. They've established a working group. Are you part of that working group?

Mr. Michael Blanchard: No, I'm not.

Ms. Helena Jaczek: Is Medbuy at all involved?

Mr. Kent Nicholson: We're not. We've been approached, obviously, by Dr. Thiessen, and we've been approached by the Ministry of Health. We have shared much of what we've shared today. Contract detail, specification detail: All of that has been shared. To date, we've not been asked to participate in a working committee, if that's the term that you used.

Ms. Helena Jaczek: Then have you heard about the potential of some regulatory oversight by the College of Pharmacists? Do you feel that this is a good idea?

Mr. Michael Blanchard: Yes, it is.

Ms. Helena Jaczek: So this little gap that you've known about for some time will be addressed by the regulation?

Mr. Michael Blanchard: Again, it doesn't mean that the standards are going to change. The proponents are stating that they're compliant with these standards that are published in the community: USP 797, for example, which is the gold standard for admixing.

What this will do is bring forth an oversight body that will ensure that these vendors, service providers, are working to that standard.

Ms. Helena Jaczek: How much time, Mr. Chair?

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

Ms. Helena Jaczek: Okay, we'll save that.

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

Mrs. Christine Elliott: Thank you, Mr. Chair. Thank you very much for joining us this afternoon and for answering our questions. Some of my questions—I'll hope you'll bear with me. I haven't had a chance to go through all of the documents in detail.

I would like to go back, if I might, to 2008, when you first decided to issue an RFP for admixing services. I recognize that probably neither of you was involved in that, but do you have any knowledge about what process was gone through in order to establish the basic standards in order to develop the RFP in the first place?

Mr. Kent Nicholson: I'll start off, and Michael may be able to contribute as well.

We've done a lot of source-document-looking and investigation to try to understand the history of our involvement. Our pharmacy committee actually first raised this as a potential contracting opportunity for Medbuy in 2005. It came up in 2005 at a pharmacy committee that Medbuy should undertake to evaluate going to market for this particular service, which, again, was driven by the fact that many of our member hospitals, even at that point, were already using a third party compounder.

When we finally did make the decision in 2008 to put it on an RFP—it was a large RFP. This was a component of a larger RFP. In the same way that we create specifications for everything we go to market on, we would engage our pharmacy committee as experts. In this particular instance, our pharmacy committee had direct experience in contracting for a compounding service. We, in collaboration with them, would have created the first specification that we took out to market in 2008.

Mrs. Christine Elliott: And the contract ultimately went to Baxter. Was the same RFP used in the second, in 2011, or was it—

Mr. Kent Nicholson: Same specifications. Again, we've included it in the documents. There is a tab that simply lists the products that were on the previous Baxter contract as well as the products that went into the RFP. These particular chemo drugs are described the same way.

Mr. Michael Blanchard: It would be tabs 6A and B.

Mrs. Christine Elliott: One of the issues that has arisen here is the issue of concentration-specific solutions versus non-concentration-specific. It appears that you had always intended the contract to be for concentration-specific solutions. Did you have any discussions, first of all, with Baxter about that? And secondly, with Marchese on the same issue?

Mr. Michael Blanchard: I can't recall seeing any evidence or documentation. I think Baxter prepared the product according to the specifications on the label, and I have no knowledge of any problems with Baxter products.

Mrs. Christine Elliott: So Baxter always complied with your requirement—

Mr. Michael Blanchard: To our knowledge.

Mrs. Christine Elliott:—for a concentration-specific solution.

Mr. Michael Blanchard: Yes, to our knowledge.

Mrs. Christine Elliott: In just taking a brief look at the contract, I see that you're contracting for sterile preparation compounding services, but it doesn't specifically state in the contract, at least in my reading, that you want concentration-specific solutions. Now, I see that there are drugs that are listed and there are concentration-specific solutions listed there, I believe, but is there anywhere in the contract that it specifically states that's what you're looking for?

Mr. Michael Blanchard: We—and again I'm not that familiar with all the terms in the contract, but certainly we would refer the proponents to the one of the schedules, which would be the list of products. On this list of

products, there's a drug name, a drug strength, in a specific volume. Then there's also labelling criteria, which I believe are in one of the tabs, that basically state, "This is what your labels will be scored against." Again, there is a specific requirement in that list of criteria; I believe there are 12 or 14 criteria. But one of them does specifically state concentration—you know, a certain strength of the drug, in a certain specific volume. That whole package is posted electronically, and it's all part of the information that is provided to the proponent.

Mrs. Christine Elliott: So really, it was the specific concentration you were looking for, and however they arrived at that, your expectation was that the concentration stated on the bag was exactly correct.

Mr. Michael Blanchard: Correct. There are no assumptions otherwise. I mean, a professional qualified pharmacist would ensure that. If that was not the case, they would have not labelled it that way.

Mrs. Christine Elliott: Was there ever any discussion about the means of preparing the solutions? I understand that there are many different ways that one can do that, from just withdrawing some of the solution, mixing it with the powdered medication and then adding it back, which would account for a non-specific solution, versus specifically filling an empty bag, for example.

Did you have any discussion with Marchese about the process that they used in order to complete these solutions and fill them?

Mr. Michael Blanchard: My understanding is that it was part of engaging a qualified pharmacist. There are many ways of addressing—you know, there might be two or three different methodologies to prepare a product, and it's up to the individual professional pharmacist to make that determination. But the end point is specific: The content of the bag should reflect accurately what is stated on the label.

Mrs. Christine Elliott: As you may know, the president of Marchese testified before the committee last week, and she indicated that what she contracted for with Medbuy was for non-specific concentration solutions. Do you have any idea where she would have gotten that notion?

Mr. Michael Blanchard: I don't know. I couldn't—you know, from all the documents I read and in my conversations with the staff, there doesn't seem to be any indication that we would have suggested that.

Mrs. Christine Elliott: But is it fair to say that Marchese did not prepare the product that you were expecting?

Mr. Michael Blanchard: That is a fair statement.

Mrs. Christine Elliott: Thank you.

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

Mr. Jeff Yurek: Thank you. Just going back to Medbuy: Who oversees Medbuy, how it operates? Who's the overseer of Medbuy? Or do you have one?

Mr. Kent Nicholson: Well, we have a governance model, so we have a board of directors that provides oversight to management, obviously. In terms of what we need to be compliant to: certainly the Broader Public Sector Accountability Act. We can be audited at any point in time.

1500

Mr. Jeff Yurek: Have you ever been audited?

Mr. Kent Nicholson: Not a full-blown audit, to my knowledge, but certainly we get inquiries from time to time. Typically it's from unsuccessful proponents who want to take issue with our process, so we get a number of issues that are very initiative-specific in terms of us having to defend—we provide some detailed documentation similar to this in terms of how we do scoring and how we publish criteria. Any proponent that replies to an RFP of ours does get to see the scoring criteria as part of the RFP that we put out, so we tell them the weighting and the scoring criteria and how each of the sections will be scored. We do face challenges periodically where the BPS secretariat will inquire about a specific initiative, and we'll provide documentation that supports that we took it out in a fair and transparent and compliant way.

Mr. Jeff Yurek: Has the Ministry of Health ever been involved in giving you any guidelines specifically on how to procure compounded medications or any types of medications, per se?

Mr. Kent Nicholson: Not to my knowledge.

Mr. Jeff Yurek: So you've never had any discussion with the Ministry of Health. How about the LHIN? Did the LHIN ever talk to you about procurement of any sort?

Mr. Kent Nicholson: We have had meetings with LHIN representatives, more from building an awareness of the work that we do. Again, as people come to understand the work that we do the way that we've described it today, I think it's reasonably self-evident how we operate. Those inquiries don't tend to come at us in terms of trying to give us advice around how to run a public procurement, but more in a spirit of understanding what we do and how we add value to the system.

Mr. Jeff Yurek: Do you think it would be helpful if the Ministry of Health was involved with these types of product procurements, giving you at least some standards to meet?

Mr. Kent Nicholson: Back to the conversation around a gap in oversight: I can't think of anything bad that would come from further oversight in this area. I think it has been recognized—and you've probably had a number of people come to the standing committee and speak about the fact that manufacturers are highly regulated—that pharmacies are highly regulated and that this particular service falls somewhere in the middle. I can't think of anything bad that would come from further oversight, inspections and standards. I think that we would welcome that, and I think the people who are in this particular line of business would welcome that kind of oversight.

Mr. Jeff Yurek: Earlier you testified that one of the hospitals was unhappy with the labels. Do you have a mechanism in place where the hospital can say, "I'm not happy with this product"? What do you do with regard to that? Perhaps you can table some documentation showing how you've dealt with an issue like that before.

Mr. Kent Nicholson: Sure. There are processes whereby a member hospital could exclude themselves from an initiative, either at the outset of the initiative or at any point in the contract. There's very specific language that says that if you believe that there's any negative impact to patient care, patient safety or employee safety—those kinds of considerations—you can, at any point in time, advise us and we'll evaluate that. If, in fact, we agree, then you're released from your commitment from the contract.

Mr. Jeff Yurek: What if you didn't agree?

Mr. Michael Blanchard: Just to add to that, we also do have efficient tracking processes in place. Where members have a concern with the product, they can use our website to report or email us. There is a process and staff dedicated to monitoring and managing product concerns and follow-up with the vendors to modify—it could be a label, shipping; any of these issues. If it's a quality issue, it becomes a priority. If the vendor or the producer or the supplier cannot modify or rectify the problem, then we take the necessary action to sever the agreement.

Mr. Jeff Yurek: What if the hospital called in and said, "We're not happy with this product"? You review it and you say, "Well, we don't agree with you, but"—

Mr. Kent Nicholson: To my knowledge, we've never done that. We don't put ourselves in the place of the clinician. If a member hospital comes to us with a well-thought-out rationale as to why this does not meet their needs or does not meet the needs of their patients or the demographics—to my knowledge, we have never not accepted a member being excluded.

Mr. Jeff Yurek: I'm just going to go back to the contract. I haven't had a chance to—it's on my desk. You were just briefly going through the contract here. On the list of meds here, you can't really tell what you would use as a single and what you would use as a concentration-specific bag. It's just not glaring at me right here that a supplier or manufacturer or compounder or whatever wouldn't—it's not spelled out to them that this bag is going to be used multi-use or this bag is going to be a one-time use.

Mr. Michael Blanchard: Again, the reason for having all of the products listed—the requirement is to have an expression of concentration on the label. The end user, the pharmacist or the nurse, can then determine if there is a dose adjustment required. For example, in oncology, several patients—as I mentioned earlier, dosing is patient-specific. So a pharmacist would then, if they wanted to use "a bag" as a stock bag, and if it's labelled as we required—our requirement, our specification, was that it be a specific concentration on the label; that the bag contains a specific amount of product.

Mr. Jeff Yurek: Is that spelled out in the contract?

Mr. Michael Blanchard: It's spelled out, as I mentioned, to Ms.—

Mr. Jeff Yurek: Ms. Elliott?

Mr. Michael Blanchard: Christine Elliott. Ms. Elliott.

One of the schedules of the contract is the list of drugs that we provided to you—

Mr. Jeff Yurek: But it doesn't say "concentration-specific," though.

Mr. Michael Blanchard: Well, it does. If you take a look: cyclophosphamide, two grams in 100 millilitres. That's concentration-specific.

Mr. Jeff Yurek: That would be—what?—20 milligrams per millilitre, would be the concentration.

Mr. Michael Blanchard: Correct.

Mr. Jeff Yurek: So that holds true for the cefazolin? Would you expect two grams in exactly 50 millilitres?

Mr. Michael Blanchard: Yes.

Mr. Jeff Yurek: With cefazolin, you get the whole bag anyway. Is it assumed that that's fine—

Mr. Michael Blanchard: Well, it is not as clinically sensitive, but our specs did require that.

Mr. Jeff Yurek: Is that written in here that that's what you're—

Mr. Michael Blanchard: The specifications for each product are listed in the schedule, which we indicated here in tab 6A and B. So 6A is the list for 2008. These lists are part and parcel of the contract. It includes the contract.

Mr. Jeff Yurek: This is 2008?

Mr. Michael Blanchard: So 6A is 2008, which was awarded to Baxter, and 6B are the specs that we went out to market with for the 2011 RFP. So it is essentially two grams in 100 millilitres of sodium chloride per bag.

Mr. Jeff Yurek: Was this spelled out to Baxter and the other two proponents when they bid on it?

Mr. Michael Blanchard: Yes.

Mr. Jeff Yurek: It was spelled out specifically—

Mr. Michael Blanchard: Yes.

Mr. Jeff Yurek: —that cefazolin is going to be two grams, and I expect it in 50 millilitres?

Mr. Michael Blanchard: Yes.

Mr. Jeff Yurek: Okay.

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

Mrs. Jane McKenna: When we had Ms. Zaffiro in here, she had said that she felt that the communication had broken down, and the relationship was with yourselves, because the contract was between you and her. Her number one thing that she had already said was that her understanding was that it was one full bag per person and that it was non-specific-concentrated. So where would she get that information from?

Mr. Michael Blanchard: I have no indication, in the documents that I've read at Medbuy and the conversation I've had with the staff, that we would have suggested that to her. We have evidence. It's surprising, since the doses of gemcitabine and cyclophosphamide that were in the two bags in question were significantly higher than what could be used on one patient, and any qualified pharmacist would know this.

1510

Mrs. Jane McKenna: If it was clear as ice, it wouldn't be taking a year for one person or three people to actually find the mistake in the first place. There seems

to be a lot of overlap or miscommunication somewhere along the board here, because it's confusing just sitting here. It seems to be that your specific of what you're saying is that it's as clear as ice, but clearly it wasn't, because Marchese was in here and she had clearly said that—she was very stern on the fact that it was one bag per person that she understood and that it was non-specific-concentrated. So somewhere in the contract or somewhere there was miscommunication somewhere. Do you feel that there was that?

Mr. Kent Nicholson: I actually don't. We've spent some time thinking about how we could be clearer. The specification of the product, in our mind, is very clear. The labels that Marchese placed on the bag are also very clear. Both are an exact expression of concentration. For it later to be viewed that these bags were not supposed to be concentration-specific—quite frankly I don't understand.

The other thing I don't understand is: In the case of four grams of gemcitabine, that would be a harmful dose to a single patient. So to make an assertion that there was a belief that the patient was going to receive the entire bag—that would be a harmful dose.

Mrs. Jane McKenna: Okay. I have one other question. We had London Health Sciences Centre in here, and Sandy Jansen, who was the director of pharmacy services, said that when they received the label in the RFP process, it was different when they actually received the product. So what was the difference?

Mr. Kent Nicholson: One of the differences—and again, the labels are included in the package, both sets of labels.

Mrs. Jane McKenna: Yes.

Mr. Kent Nicholson: So one of the differences clearly is the introduction of Marchese Health Solutions, or—excuse me—Marchese Hospital Solutions. At no point did we ever request that the label be changed. There was a change to the label. The most glaring change is, it used to be Marchese Health Care. It's now Marchese Hospital Solutions. When that change was made, there was also apparently some cleanup. So if you compare the two sets of labels, there was an attempt to make the concentration stand out more in the Hospital Solutions instance. The exact concentration is actually identified in a box. Some redundancy was taken off the label. The label would appear to have gone through some changes in a spirit of making it actually clearer and more specific in terms of the concentration, not the reverse.

The Chair (Mr. Ernie Hardeman): That concludes your time. We have two minutes left on the Liberal side. Ms. Jaczek.

Ms. Helena Jaczek: Yes. Thank you. Just to go back to the fact that you were reassured that Marchese Health Care was a pharmacy licensed by the Ontario College of Pharmacists, which enabled it to provide infusion services etc.: Definition of a pharmacy—it strikes me that how we normally think of pharmacies is, there's a prescription, there's a patient's name, there's a dose. Do pharmacies, currently licensed, make up stockpile solutions of certain concentrations from which they can draw as needed when the patient-specific prescription comes in, or do they make it up de novo per patient in a pharmacy?

Mr. Michael Blanchard: The latter statement is probably practised in a retail setting.

Ms. Helena Jaczek: So then, what I would say is: What comfort did you derive from this, knowing that this was a stockpile, a concentration, as you felt it should be, to be delivered to hospitals for multiple use?

Mr. Michael Blanchard: They're batching for several patients, is what you're trying to say.

Ms. Helena Jaczek: Right, but you derived comfort from the fact that this was a pharmacy?

Mr. Michael Blanchard: A pharmacy—the mandatory was the supervision of production by a licensed pharmacist.

Ms. Helena Jaczek: Even though it wasn't going to be patient-specific. It was clearly compounding for many patients, from your perspective. Is there some way—I guess we're trying to speculate how—Marchese misunderstood the fact that this batch would be used for one patient? Could it relate to the fact that—

Mr. Michael Blanchard: This is something that the pharmacists—if I may?

The Chair (Mr. Ernie Hardeman): You go ahead and finish answering.

Mr. Michael Blanchard: Okay; thank you. I was just simply going to state that Marchese has been in the business of servicing home care patients, and they would probably, I would think, prepare their production in batches also.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time. We thank you very much for coming in this afternoon and sharing your information with us.

Mr. Michael Blanchard: You're welcome. Thank you.

ONTARIO COLLEGE OF PHARMACISTS

The Chair (Mr. Ernie Hardeman): As you're packing up, the next delegation is the Ontario College of Pharmacists.

Interjections.

The Chair (Mr. Ernie Hardeman): If those wanting to do the scrums would please go outside the doors to do them.

Interjections.

Ms. Helena Jaczek: That's a novel approach.

The Chair (Mr. Ernie Hardeman): I can only speak so loud; I can whistle louder.

Okay. We'll get back to order in the court. As I said, our next delegation is the Ontario College of Pharmacists: Marshall Moleschi?

Mr. Marshall Moleschi: Yes.

The Chair (Mr. Ernie Hardeman): I think you were here at our previous meeting and you were sworn in, so with that, you will not have to go through that process

again. As we did that day, you will have 20 minutes to make a presentation, and then we will have—what shall we say?—an around-the-room for questions for 20 minutes each. This time, we'll start with the government caucus.

With that, Marshall, the floor is yours.

Mr. Marshall Moleschi: Thank you very much. I'd like to take this time to just remind the committee of the role and the mandate of the college, to recap some key information that was initially presented to this committee when I was before you on April 16, and give you an overview of some of the activities that the college has been involved in that have transpired since that time. Throughout my remarks, I'll give additional insight and clarity to some particular issues, and I'd be glad to answer your questions.

The Ontario College of Pharmacists is the regulatory body for the profession of pharmacy in Ontario. The college receives its authority through a variety of laws, including the Pharmacy Act, the Regulated Health Professions Act, which is the RHPA, and the Drug and Pharmacies Regulation Act, which is in short the DPRA. The specific objects of the college are set out in the health professions procedural code. In carrying out these objectives, the college's duty is to serve and protect the public interest.

To be a pharmacist or a pharmacy technician in Ontario, you need to be registered with the college. To operate a community pharmacy in Ontario, you need to be accredited by the college. Section 118 of the DPRA specifies that the college does not have jurisdiction over "drugs compounded, dispensed or supplied in and by a hospital," so there is an exemption there.

The activities of the college are subject to a number of oversight mechanisms, including both general and specific oversight by the Ministry of Health and Long-Term Care and specific oversight by the Health Professions Appeal and Review Board and the Health Professions Regulatory Advisory Council. As required by the Pharmacy Act, the college is overseen by a council of 17 pharmacists elected from the electoral districts of the province, two of whom are in hospital practice; two elected pharmacy technicians, one from a hospital practice; 16 public members appointed by the Lieutenant Governor in Council; and finally, the deans of the University of Toronto and University of Waterloo are also on council.

With respect to practitioners, the college has regulatory oversight for the competence and conduct of pharmacists and pharmacy technicians, regardless of where they practise, as outlined in the RHPA.

1520

The college is responsible for setting and maintaining entry-to-practice standards to ensure that practitioners have the knowledge and skills necessary to safely and effectively practise pharmacy when entering the profession.

Once in the profession, pharmacists and pharmacy technicians must adhere to the college's quality assurance program, which requires practitioners, on a regular basis, to demonstrate their ongoing competence throughout their careers. We hold practitioners accountable to practise within their scope of practice and in compliance with all relevant regulations, standards of practice and ethical conduct.

The college's authority over the place of practice is outlined in the DPRA and, as already mentioned, is currently restricted to community pharmacies. And that section 118 excludes jurisdiction over the hospital. The accreditation process for community pharmacies includes: the college setting and maintaining accreditation standards, inspecting pharmacies before they open and soon after opening to ensure they meet these standards, and conducting routine inspections approximately every three to five years, but if it's warranted, much more often than that.

Should there be a concern raised regarding an accredited pharmacy or an individual pharmacist or pharmacy technician, we have a complaints, inquiry and discipline process whereby any member of the public can file a written complaint with the college, or, as registrar, I can initiate an investigation into any relevant matter. All complaints are investigated in a timely way. Priorities are based on risk of harm to the public, and notice and findings of discipline cases are made public.

Public trust and confidence is maintained through our public register, which lists all pharmacists and pharmacy technicians currently in good standing, with notations regarding any disciplinary action that they may have. The college website also provides a list of all community pharmacies in good standing. As reported in the college's most recent annual report, as of December 31, 2012, there were 13,400 pharmacists and 1,023 pharmacy technicians registered with the college and 3,567 accredited community pharmacies.

During my April 16 testimony, my initial session before this committee, the focus of my opening remarks and your subsequent questions was specifically to the college's understanding and actions pertaining to the incident of chemotherapy under-dosing. During that testimony, I provided a chronology of the events that transpired since first learning of the incident on March 31. I reported that our initial focus was on ensuring that appropriate steps were in place to ensure public safety and to address patient concerns.

On April 3, the college, utilizing its authority under section 75(2) of the health professionals procedural code, appointed an investigator to look into the competence and professional conduct of identified members. On that day, together with two Health Canada inspectors, the college investigator visited the accredited pharmacy, Marchese Health Care pharmacy, and was given permission to visit Marchese Hospital Solutions.

On April 4, the college, with Health Canada, reviewed the respective memos of the joint visit to the premises from the day before and developed next steps, which included the development of specific questions for the identified members.

On April 8, having confirmed the distinction between Marchese Health Care pharmacy, which is the accredited facility by us, and Marchese Hospital Solutions, which was a federally incorporated company contracted to produce the medications in question, the college publicly acknowledged that Marchese Hospital Solutions was not an accredited pharmacy and was outside of our regulatory authority and our inspection process.

The college's investigation then proceeded into the specific situation, and this investigation is ongoing and could take a few more months to complete the whole process. The focus is on the member and the possible misconduct of the member. Once completed, the findings from the investigation will, as per the college's procedures, be referred to the college's constituted committee for disposition. The outcome could be a possibility of three things: a referral to discipline, something that could be in the neighbourhood of a caution or it could be determined that there's no further action that needs to take place. All matters referred to discipline are made public.

Also, in our initial session on April 16, I advised this committee that the college was an active member of the ministry's working group, providing support to Dr. Jake Thiessen's independent review of quality assurance in the province's cancer drug supply chain. Finally, I reported that we were working diligently with the ministry to identify opportunities to make enhancements to our jurisdiction to provide authority into the oversight of facilities that fall in these identified grey areas.

Since April 16, the college has been engaged in a significant amount of activity regarding this situation. Already mentioned, our work on the specific investigation relating to the activities of the identified individuals at Marchese Hospital Solutions is ongoing.

At this time, it might be helpful for this committee if I were to take a few moments to outline the college's process, which, of course, is outlined in legislation with respect to how the college conducts investigations.

In cases such as this, the process begins when I, as the registrar, become aware of a situation where there are reasonable and probable grounds to believe that a member may be incompetent or has committed an act or acts of professional misconduct. I then can appoint an investigator to essentially initiate an investigation by inquiring into and examining the practice of identified members. This is what happened on April 3.

During the course of an investigation, there may be a number of site visits conducted, ongoing interviews and dialogue, gathering of relevant materials and a comprehensive review of the policies and procedures. As of today, the college remains in this stage of the investigation.

Once the investigator is confident that they have gathered all the relevant information, a report of their findings is forwarded to the college's inquiries, complaints and reports committee—we call that ICRC—as well as to any member named in the investigation. It is currently anticipated that the report of this investigation will be completed toward the end of May.

Once the report is received, the member has 30 days to provide the ICRC with any written submissions they may have. This would bring us to the end of June. The ICRC will then review the report at their next scheduled meeting and provide their disposition, which will be one of three things: referral to discipline, something like a caution to a member, or require no further action be taken.

Given the timeline that's outlined above, it's anticipated that the earliest this matter could be brought before the ICRC is in their July meeting. Should the ICRC refer the matter to discipline, it would mean that there are allegations of professional misconduct.

In addition to our own investigation, we are also actively participating in the working group of Dr. Thiessen's independent review. To this end, Dr. Thiessen has visited the college, reviewing and interviewing myself and Anne Resnick, the director of professional practice. This was done on April 23. During that session, the college shared with Dr. Thiessen a full chronology, which has also been shared with the ministry, of all correspondence between the college and Marchese Hospital Solutions and Marchese Health Care's pharmacy.

These include acknowledgement of initial contact with representatives from the Marchese group in late 2011 or early 2012 where they asked the college for clarification on regulatory requirements for a start-up business providing non-traditional pharmacy services. Upon request, Marchese provided the college with detailed descriptions of the proposed operation. The document describes a business that would prepare admixtures to fill bulk orders for hospitals. The business was not intended to deal with the public or fill orders pursuant to individual prescriptions.

As such, the college concluded that the proposed business would not be functioning as a pharmacy and may be considered manufacturing, and the college directed Marchese to contact Health Canada. Marchese indicated that they were going to do so.

The college's next contact with the Marchese group was when the accredited pharmacy, Marchese Health Care, received a routine inspection in January 2013. Although the outcome of the routine inspection was that Marchese Health Care met accreditation standards, the inspector did make a note of questions relating to the bulk hospital preparation business being conducted by Marchese Hospital Solutions, which was adjacent to the accredited pharmacy.

1530

Notes reflected that the designated manager of the accredited pharmacy indicated that Marchese Hospital Solutions was not regulated or inspected by Health Canada at this time, but was operating under the Public Hospitals Act. The college inspector further noted a few potential areas of overlap, and instructed the designated manager to ensure that the orders being filled by Marchese Hospital Solutions were filled separately from the Marchese Health Care pharmacy, and that the supervision of the accredited pharmacy should not be

compromised while they were attending to Hospital Solutions business.

In short, the college clearly communicated to the accredited pharmacy that there needed to be clear separation between themselves and the Hospital Solutions business, and requested that the college know the outcome of their interaction with Health Canada regarding acquiring an establishment licence for Marchese Hospital Solutions. There was no further dialogue between the college and Marchese until the incident in question.

With respect to our ongoing work with the ministry on the development of additional authority to oversee these facilities, on April 26 the college posted, for circulation, draft regulations and bylaw amendments. Understanding the importance and timeliness of this, the college made a request to the ministry for approval to abridge the circulation period, in accordance with subsection 95(1.6) of the health professions procedural code, from 60 days to 10 days. This was approved by the ministry. The draft regulation and bylaw amendments were posted on our website and have been available for comment since April 26. Given the 10-day requirement, they will close today at 5 p.m.

For clarification, I thought it might also be helpful to briefly summarize the proposed regulation and associated bylaws. These will provide the college with regulatory oversight over drug preparation premises where pharmacists and pharmacy technicians practise. Because of the language limitations of the legislation, the college's authority is provided under the Regulated Health Professions Act and the Pharmacy Act, not under the Drug and Pharmacies Regulation Act, which governs accredited pharmacies that provide pharmacy services directly to the public.

As per the regulations, any pharmacist or pharmacy technician engaged in or supervising drug preparation activities at or in connection with a drug preparation premises will be required to notify the college. These identified drug preparation premises will then be inspected by the college.

The proposed bylaw amendments further specify that the outcome and/or status of the inspection of these drug preparation premises will be posted on the college's public register.

Additionally, on this specific point, the college has brought forward separate proposed bylaw amendments that would establish a distinct public register of accredited pharmacies that would also include the posting of the outcome and/or status of their inspections, so it would be both the pharmacies and the drug preparation premises.

It's important to note that the combination of the college's proposed regulation and the ministry's proposed regulatory change to the Public Hospitals Act will ensure that hospitals only purchase from accredited or licensed suppliers. That will close the identified gap in the regulatory oversight.

Although the college's proposed regulations and bylaws outline some timelines relating to the college's identification and inspection of these facilities, the college is working diligently to expedite these timelines. It is anticipated that the regulation would take effect in late August or early September, but we're working now on establishing all the necessary processes and inviting voluntary identification and, potentially, inspections prior to authority being received.

Although it's still not completely clear as to the number of drug preparation premises currently operating, information gathered by ourselves, the ministry, the Ontario Hospital Association and Health Canada is indicating that the number is going to be around half a dozen. Given this and the efforts made by the college in anticipation of receiving this new authority, we anticipate being able to inspect all of these facilities before the end of this year.

A special meeting of the college council has been called for this Friday, May 10. The final draft of the proposed regulations and bylaw amendments, which will reflect all the feedback that has been received during the circulation period, will be presented to council at that time for approval. Assuming that approval is given, the regulations will be forwarded to government for their consideration for filing. Should the government decide to file the regulation, it will take effect 90 days after the date of filing, which, as previously indicated, would bring us to late August, early September as a timeline for when the college's authority in this area would commence.

I hope these opening remarks have helped to provide you with a clearer understanding of the role and the mandate of the college, summarize our conversation from our initial meeting on April 16, and bring you up to date on the many activities that the college has, and continues to be engaged in, and provide some further insight and clarity along the way.

At this time, I'd be happy to answer any questions you may have.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We will start the questions with Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair, and thank you, Mr. Moleschi. You've certainly had a very, very busy time since March 31. Not only were those first couple of weeks obviously very busy for you, but since you came on April 16, you've taken a number of actions.

In terms of the College of Pharmacists, with the new regulation and the bylaws, you've sort of given us a little bit about how you're trained to expedite this. You've shortened this consultation period, I believe—

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: What happens from here on in so that the bylaws will be in place?

Mr. Marshall Moleschi: So as of 5 p.m. this afternoon, the consultation on both the bylaws and the regulations will be concluded. We'll take the information that we receive from the feedback and we'll go back to our lawyers to see what can be incorporated and what makes sense and what is on target toward what we're

delivering. Then by Friday, we'll have those—both the regulations and the bylaws—in front of the council. Council will take the time it needs to ensure that that's meeting the intent that is there. If the council passes that, then they will be sent to government, and the ministry will then present it to government for filing.

During that period of time, there will have to be 90 days after that before it comes into effect. But at the same time, we haven't stopped our activities; we're very much involved in things. As a matter of fact, tonight, someone is arriving from another province where they're—they're doing not exactly what this is, but they do inspect hospitals. They do, in that province, have some central fill type of capability where they do some bulk packaging, and they do look at that. It's all within the health authority. But that expert will help us not only with the evidence that we've gathered but also with some procedures, what the standards are that we need to meet. We've received already a copy of their rough inspection form—well, it's not the rough form; it's what they use for an inspection form—and we'll ask all the questions. So throughout this week, he'll be working with us to be able to put some of these processes in place.

We're not inventing everything from scratch; we're putting something in place that has worked in a similar—not exactly the same—environment in another province so that we can take advantage of that.

Those documents, those standards, refer to Canadian national standards and international standards; I think USP 797 was mentioned and it refers to that. It also refers to regular compounding, sterile compounding and high-risk type of compounding, and there are different standards for those. We'll have to get a better understanding of what those references are, but we are using the work that other provinces have done to be able to build on that.

Ms. Helena Jaczek: Are you getting quite a bit of feedback on the proposed regulation? You say it's closing at 5 p.m. today.

Mr. Marshall Moleschi: I think after a couple days, there were like 3,000 hits on our website. There was dozens of feedback—there's a way that you can easily comment on the regulations, and there were dozens of them, although I'm not up to date as to what has transpired throughout the day today. There's a significant number.

1540

Ms. Helena Jaczek: So, obviously, it will take a certain amount of time to sift through all that and potentially incorporate suggestions into the final product for this bylaw.

Mr. Marshall Moleschi: It's going to take a lot of work to be able to do that, but we will not take a lot of time to do that. In other words, we'll work very diligently to be able to provide that, simply because we have the council meeting on Friday and we'll have to work with our lawyers to make sure that it is lined up for that.

Ms. Helena Jaczek: Then, as you were describing, looking beyond at other provincial jurisdictions in terms of not just this incident but perhaps more oversight over pharmaceutical procedures in general—you mentioned, I think, when you were here last, that British Columbia has more oversight in terms of what the college does?

Mr. Marshall Moleschi: Sure. In Ontario, hospitals are specifically exempted, whereas, in six or seven of the other provinces, the colleges look after both the community pharmacy and the hospital pharmacy. They have oversight in both those areas and have developed standards.

British Columbia is one area. A consultant is coming from British Columbia with their knowledge to be able to do this. This person is also a past director of pharmacy and actually a director of pharmacy for a whole region, so he's got a significant amount of experience. We will value that experience to be able to do that.

Also, what we're talking about is one step, and there are other steps that are taking place. There are steps that are happening with Health Canada, for example. I've probably been on the phone almost daily with Health Canada, with key people, to be able to do that.

We've had one teleconference where all the registrars right across Canada had been on with key people with Health Canada to help understand what the grey area was—what isn't looked after—so that we can focus on those areas. On the 15th of May, we're actually hosting all the registrars coming together face to face and spending time with Health Canada to be able to look at that.

We will put our systems in place, and they will look after pharmacies, and then these new entities that, over the evolution of time, have sprung up—we need to be able to look at them. But there's also a role for Health Canada, especially to do with their establishment licences and those things, and we will work together to make sure that there isn't a grey area going forward.

That's going to take a little bit of time, and it will take coordination, but there is an effort to do that right across Canada.

Ms. Helena Jaczek: Just to clarify: When you say you don't have oversight over hospital pharmacies—obviously, the pharmacists employed by hospitals must be accredited by the College of Pharmacists, correct?

Mr. Marshall Moleschi: We accredit pharmacies that are community pharmacies, that fill prescriptions on a retail basis.

Ms. Helena Jaczek: Right.

Mr. Marshall Moleschi: The pharmacists are registrants of ours, whether they're in community or hospital practice.

Ms. Helena Jaczek: Right.

Mr. Marshall Moleschi: And the pharmacy technicians are registrants of ours. It's just that we don't yet, at this point in time, have the ability to go into a hospital and look at their processes like we can on a community pharmacy site.

We can look at misconduct of an individual who was a registrant of ours, to see—well, there are several things we can look at. Their entry to standard to practise: We

look at them when they enter into the practice. They need to demonstrate to us on a periodic basis that they've maintained their competency—

Ms. Helena Jaczek: Through continuing education, or how?

Mr. Marshall Moleschi: It's continuing education, and we have a process that's a little more sophisticated than just continuing education. There's a testing process and a sampling process. Hospital pharmacists fall into that category as well, so we have the ability to do that.

If there's any alleged misconduct by a registrant—whether they're a pharmacist or a technician—in any part of their practice, we would have the ability to go and investigate that.

What we don't have the ability, as the college, is to look at the processes that a hospital would have. That's what British Columbia and six other provinces have. They can go in, do an inspection of a hospital pharmacy, and see if their processes meet today's current standards. Do they have the policies and procedures there to be able to ensure, if something goes wrong, that things are notified? Do they meet standard 797? Do they have other standards that meet the Canadian Society of Hospital Pharmacists' best-practice standards as well? Those are the types of things that a college would do if we had authority on that side.

We'll use some of those things to be able to look at these premises. There's a lot of parallel between those hospital inspections and the drug preparation premises. The drug preparation premises just aren't doing it patient-specific, but a lot of their processes will be the same, and we'll look at those opportunities to be able to do that.

Ms. Helena Jaczek: Explain to me how you inspect a community pharmacy. Do you go in a surprise visit? Do you watch them compound a medication? Do you look at records?

I'm coming partly from a physician background where, obviously, the College of Physicians and Surgeons can come in and take your patient records and make sure everything is documented correctly. I'm also thinking of my public health inspectors, who literally watch how the chicken is cooked start to finish and measure temperatures and do testing along the way. Can you detail what exactly happens during a community pharmacy inspection?

Mr. Marshall Moleschi: Yes, I could. Before opening, there's an inspection that takes place to make sure that everything is there and they have everything lined up to do that. That's a scheduled type of inspection. Those sorts of things, before a community pharmacy opens, they need to go through that process. There's hundreds that open every year, so there's lots of those that take place.

Shortly afterwards, we'll be there to watch the operation and, yes, we do look at the patient interaction. We look at the records that they've kept. There's a checklist that they go through, and that checklist is a checklist to guide them through a process, but they're also trained to be able to look at if there are any issues around safety, sterility and those sorts of things.

We look to see if they're dealing with any speciality types of areas well. If there's methadone, we spend particular due diligence to make sure that those processes are in place to make sure they have narcotic reconciliation that takes place on a regular basis. We look at the interaction. Now that pharmacists are making decisions about refills of prescriptions and those sorts of things, we'll look at those processes and the documentation around those processes. If they're doing compounding, we'll see to what standards they're doing it and whether it's sterile compounding versus regular non-sterile compounding, where you put in ingredients to get the creams and the ointments and those sorts of things. We'll look at the types of expiry, those sorts of things that they have in process.

Those are looked at, and then recommendations could come out of that if there were those sorts of things needed.

Ms. Helena Jaczek: Well, it sounds very thorough. In a pharmacy—a community, retail pharmacy—how often is a solution made of a drug to a certain concentration in a batch that can then be withdrawn for an individual patient? Does that happen at all? Or is it always sort of patient-specific, a specific dose compounded?

Mr. Marshall Moleschi: Our standards would be that it would be patient-specific, so that is the way things would be prepared: patient-specific. That's how we would determine whether it was a pharmacy versus manufacturing process. We've used tools like—I think it's POL-0051—the federal government's compounding versus manufacturing standard to judge that. It lists criteria for that: Was it in a patient relationship? Was it patient-specific? Those sorts of things.

But I will tell you that sometimes there are grey areas, and there are times when it would be very safe and effective to anticipate that there is going to be a group of patients that come that day. It would be very, very confined, but it could be done for a certain day, to be able to prepare a preparation because you're in that business, and you know you're going to have that many patients coming in. I think if you're a physician and you're familiar with the allergy testing type of stuff, sometimes physicians will prepare it for a group of patients that are coming in that day because that's the way it's going to work.

That is the exception, and we do try to allow for those sorts of exceptions. We'll look to see to make sure there are policies and procedures in place to handle those. I won't say that there's never an exception to that, but it has to be either specific to that patient or the real exception would be specific to a small group of patients.

1550

Ms. Helena Jaczek: You mentioned about the communication with other jurisdictions—Health Canada and so on. Would you say there's a move to have some uniformity as it relates to this compounding grey area across the province?

Mr. Marshall Moleschi: There's absolutely a move for uniformity. There's absolute concern that there may be an area that we didn't realize was out there; that our health care system has evolved and maybe our practices, as colleges, need to make sure that we reflect that new evolution. Certainly, there's a concern and a huge desire. I was able to call this meeting next week on very short notice. As a matter of fact, the agenda hasn't even all been prepared, but there is a desire right across Canada to be able to make sure that this area—it's called a grey area, that we didn't realize was there—be addressed. So, yes, there is a desire to be able to do that. I sense that with my peers in colleges right across Canada and also with Health Canada and provincial governments as well.

Ms. Helena Jaczek: Your inspector that went out—I think it was in January of this year—was, I guess, very aware. Again, that was good that it was noticed that there were these two facilities—Marchese Health Care, the pharmacy, and Marchese Hospital Solutions adjacent. There was an inquiry made, I guess, of the manager of the accredited pharmacy that Marchese Hospital Solutions was operating under the Public Hospitals Act, she said. How would your inspector have interpreted that? What did that mean?

Mr. Marshall Moleschi: So, the inspector would be aware of 0051, which talks about compounding versus manufacturing and that compounding is done in hospital-specific—I'm sorry; the compounding is done patient-specific. On the hospital side of things, if it was done in bulk, it would fall under manufacturing. She was aware enough, even though she's a community pharmacy inspector—because we don't look after the people trained for the hospital side. We will train people and we do do these new areas. She was aware that there was some activity that didn't seem consistent with that pharmacy. That was the response, so she has recorded the response that she got from the staff. The response that she got from the pharmacy staff was that it was done under the hospital act. I don't think there's follow-up as to how that pertained at that time.

Ms. Helena Jaczek: I see. Would you have any insight as to what that might have meant or what Marchese Hospital Solutions thought it meant?

Mr. Marshall Moleschi: I wouldn't have any insight. There were further questions that that inspector did. What they said is that because they relayed to her, that inspector, that they are pursuing an established licence under Health Canada, the pharmacy should let them know of the progress of Marchese Hospital Solutions under their interaction with Health Canada.

Ms. Helena Jaczek: Did your inspector make a note of what was going on on the Hospital Solutions side, like which drugs were being compounded, was it concentration-specific or patient-specific? I know she really didn't have jurisdiction, but did that come up?

Mr. Marshall Moleschi: I only can read from her report. From her report, she just saw some activity and some paperwork that didn't seem consistent with the pharmacy activities that seem to be associated with another type of activity. So, that inspector did not go into—

Ms. Helena Jaczek: Which was not patient-specific?

Mr. Marshall Moleschi: It was not patient-specific, and asked the questions and came up with the responses that we've recorded. That person did not go into the Hospital Solutions side of the building, which was separated by doors and rooms before you got over to that area, I later found out.

Ms. Helena Jaczek: Thank you. We'll save whatever time we have left.

The Chair (Mr. Ernie Hardeman): You have one minute left. With that, Mr. Yurek?

Mr. Jeff Yurek: Thank you, Chair. How are you?

Mr. Marshall Moleschi: Fine.

Mr. Jeff Yurek: Good to see you. Just a few questions: When you talk about what was mentioned about the batching in the pharmacy if you knew all your patients were coming the one day, I've always known that the underlying principle from the college is to put the public protection ahead of anything else. As long as you've got that as a guidance, you should be fine. Is that pretty accurate?

Mr. Marshall Moleschi: That's an underlying principle of all the things that we're doing. When we develop rules and regulations, they should all support that underlying principle, as we're doing that in the patient's best interest for the best patient outcome. That's part of what I'm emphasizing when I go around talking to groups. There are rules and regulations and there are bylaws that we have, but to have that public protection is ultimate.

Mr. Jeff Yurek: Are all hospital pharmacists registered with the college now?

Mr. Marshall Moleschi: All hospital pharmacists are registrants with the college, yes. That's changed, and I don't know the year that that changed, but it changed maybe 10 or 15 years ago. There was a time in Ontario's past where they weren't registered with the college; the college just looked after community pharmacy. But the world has evolved.

When I graduated, probably 5% of all pharmacists were on the hospital side. Now, a full 20% of pharmacists that are registered with us are on the hospital—only 60% are on the community side and then there are pharmacists who are like me, or some consultants or maybe other people—and I'm not sure where you are, Jeff—

Mr. Jeff Yurek: I'm not there yet.

Mr. Marshall Moleschi: You're not there yet. They are not working in a community pharmacy or a hospital pharmacy, but they have a consulting business or they're on family health teams or areas like that.

Mr. Jeff Yurek: Speaking of the evolution of, I guess, pharmacy: Would the college be willing to take over regulation of hospital pharmacies?

Mr. Marshall Moleschi: If we were asked, we would be willing. We think that that's an important area for oversight. There's a need to have oversight over that area as well, and I think the hospitals would like that too. Even though accreditation of the entire hospital is a vol-

untary process, you see hospitals wanting to go through that process. I would say that they want to go through our process where their labs or pharmacies and those different types of areas would also have oversight. That's specific to that profession, and I think that's really important.

I can't speak for council because it hasn't been put to council, but as the registrar I would put that forward to council.

Mr. Jeff Yurek: Just to the grey area, you said there was that area that Marchese fell into; that there's really no oversight. Has the Ministry of Health ever contacted the College of Pharmacists and said, "Hey, we've got this problem here. Can you help us solve it? There's a bunch of unregulated activity going on out there"?

Mr. Marshall Moleschi: Not prior to this. I think we both realized it at about the same time. It was the same day, and I forget the day that—it was the 3rd or 2nd, I think, when I got back from vacation, and I made calls to the ministry. I made calls to Health Canada when I saw the reports that were out there. We then got together with Health Canada to do a joint visit to the accredited pharmacy and asked permission to go into Marchese Hospital Solutions. So, at that time, they realized it, but I think it was at the same time as I realized it.

Mr. Jeff Yurek: With regard to pharmacy registered technicians, can you explain to the committee how technicians have evolved over the last four or five years and why in a hospital some would be registered with the OCP and others wouldn't?

Mr. Marshall Moleschi: Sure. Pharmacy practice has evolved, and the profession has evolved, over the years. When I graduated, there weren't pharmacy assistants or pharmacy techs. Very few pharmacists were filling the prescriptions and giving advice about their medications. But with time, there was a need for pharmacists to focus more on the clinical aspects of things and some of the distribution things. We called them technicians at the very beginning, but they're really assistants. They were non-regulated people who came in—pharmacists could delegate a task to them, but they couldn't delegate any responsibility. There was a whole variety of training. There wasn't a standardized training for people who were in that assistant role.

About 10 or 15 years ago—and Ontario was a lead—Ontario identified that there was a need for a standardization for the education of these people and a need to have a scope of practice, that there be a fence around the types of things that they could do; so, identify what that could be.

1600

Then in 2005-06 British Columbia, Ontario and Alberta moved together toward developing a health care professional that was called a regulated pharmacy technician; now it's just a pharmacy technician because it's a reserved title. That person would be registered with the college. They would have attained a certain level of education and demonstrated a certain level of skills, knowledge and ability to practise to that level, and a commitment to ongoing learning, so they've become a health care professional.

There is a very defined scope that they can do, and it's to do with the distribution side. It has nothing to do with the clinical side. But that could free up the pharmacist to spend more time on the clinical side to do that.

At the same time that this has developed, there are people who have been assistants; they're not regulated. We have a pharmacist who's regulated, and now we have a pharmacy technician who's regulated. But there are people working in pharmacies who are not regulated, and they can be assigned certain tasks, and it's appropriate that they do that. But no one can delegate away the authority and the responsibility; it would still be the pharmacist's responsibility and authority. They could do some less technical tasks, and that takes place.

There's an evolution now to bridge from unregulated to regulated. Not only can you go through a two-year program to go through that, but people who have not been regulated and didn't go through the two-year program, if they've got experience, can actually bridge that by taking about a year and a half worth of courses to do that. That's in place in Ontario, British Columbia and Alberta, but it's something that's moving right across Canada. In the last few weeks, there were some meetings at the national level to standardize that and bring it under one umbrella that's national, so each one of the provinces has the same model.

Mr. Jeff Yurek: Just before I hand it off, do you guys have questions?

You've noted here that there are 3,567 community pharmacies. Over the past few years has that number stayed the same, increased or decreased?

Mr. Marshall Moleschi: The number has actually increased over the last years. Now, realize that there are pharmacies that close and pharmacies that open. There are hundreds that open and close. But on a net basis, every year—I think over the last five years—there's been a 100% to 150% net increase in the number of pharmacies.

Last year was a year where a major chain actually closed down, and there still was a net increase. The major chain was Zellers, but there still was a net increase in the number of pharmacies that were there. There's a large opening of a chain this year too, so it has been increasing.

Mr. Jeff Yurek: With the increase in pharmacies and now this regulation adding more for your college to do, will the college be able to handle all of its tasks?

Mr. Marshall Moleschi: We will do our best to fulfill our mandate to protect the public.

Mrs. Jane McKenna: I just have one question for you. Thank you so much for coming here today. We've had a handful of people who have come into this committee who have all sat down to acknowledge that there's a grey area. We had Ms. Zaffiro, who came in to say that when she found out she was getting the RFP, she phoned Health Canada and phoned you people as well to see if she needed to get regulated because it was a grey area.

I guess my question is, if all of these people seem to be talking about the same thing, how come both of you—

Health Canada and yourselves—didn't get this from anybody else?

Mr. Marshall Moleschi: It's the question that we're asking ourselves as well. We did receive an inquiry, and it was over a year ago, from that group, and I've got records of it. We've done a fairly comprehensive review, and we came up to say, "This is not patient-specific by 0051; it looks like it's manufacturing. You need to talk to Health Canada."

My understanding was that there were ongoing discussions with that, and we actually had not heard back from them since then, other than this one encounter when I went through the records. Looking back, this one inspector did find a reference to Marchese Hospital Solutions in the January 2013 inspection, and we asked more questions about that. Should we have been on it more quickly? I would have liked to have been on it more quickly. We are on it now.

Mrs. Jane McKenna: Yes, that's wonderful. I guess the bottom line, I think, is that when people are in the system, and they're trying to answer the questions that they figure they should be being asked themselves, it will be an unbelievable opportunity to see the overlap and the gaps that were there, because clearly there were red flags along the way numerous times, and somehow that gap was just missed.

Thank you for your answer for that.

Mr. Marshall Moleschi: Our meetings with Health Canada are to make sure that that's looked after. I think it has been mentioned earlier today that Baxter is also—their process needs oversight as well. But a while ago, I went to Health Canada's website and I looked up Baxter, and they had three establishment licences. I assumed, and I assumed incorrectly, that this type of activity was covered under those establishment licences. What we're learning in this next little while, why it's so important that we get together, is that we need to understand Health Canada's processes a little more clearly than just the 0051 that we're taking as the rules that would divide between compounding and manufacturing; that it is more complicated than that. That's why we're doing these face-to-face meetings right now: to make sure that those gaps are identified.

I guess the assurance that I'd like to give to you, as overseers of all systems, is that it's important not only to identify that but we have processes in place so that we continually look at any gaps that may—because the world's going to evolve with time as well.

Mrs. Jane McKenna: Thank you.

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

Mrs. Christine Elliott: Thank you, Mr. Moleschi, for coming back before the committee. I just have two quick questions. One relates to the initial contact by Marchese with the college in late 2011/early 2012, where they were providing you with a detailed description of the work that they were proposing to do. I'm assuming that was in writing and there was a back-and-forth between them and the college.

Mr. Marshall Moleschi: Yes, there is a back-and-forth.

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

Mr. Marshall Moleschi: I will.

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

Secondly, with respect to the routine inspection earlier this year, comments were made that there was some overlap between Marchese Hospital Solutions and Marchese Health Care. Would you be able to provide us with a copy of the report, if any, that was provided?

Mr. Marshall Moleschi: I will provide you with that interchange, yes. I will.

Mrs. Christine Elliott: All right. Thank you very much.

The Chair (Mr. Ernie Hardeman): Okay. We'll go on to the third party. Ms. Gélinas.

M^me^ France Gélinas: Thank you. While we are asking for documents—this is more for the Clerk so that I don't forget. Medbuy did not submit the two proposals that came from Baxter and from Gentès and Bolduc; they only gave us the one from Marchese. If you could do a follow-up on that.

Sorry; that had nothing to do with you.

Mr. Marshall Moleschi: No, that's fine.

M^me^ France Gélinas: It's nice to see you again. I listened to some of the answers you've given. Some of my questions will repeat a bit, but it's for clarification. The first one, just keeping on the track where my colleague was going: On page 3, you talk about, "On April 4, the college, with Health Canada, reviewed the respective memos of the joint visit to the premises from the day before and developed next steps which included the development of specific questions for the identified members." If you could please table those questions with the Clerk as well as the answers that you got, once you asked those questions.

Then you go on to say, "having confirmed the distinction between Marchese Health Care pharmacy ... and Marchese Hospital Solutions (the federal corporation contracted to produce the medications ...), the college publicly acknowledged that Marchese Hospital Solutions was not an accredited pharmacy."

You are the only one that can accredit a pharmacy. Health Canada can't do that.

Mr. Marshall Moleschi: No, we wouldn't be able to accredit the pharmacy; it would have to get an establishment licence from Health Canada.

To be clear, the activities that Marchese Hospital Solutions was doing were not activities of a pharmacy. One of the things we had to do in that time was to find out not only what it was that they were doing, but also to go through records to see if there's anything that was patient-specific, which would have put them as an unaccredited pharmacy doing a pharmacy type of work, and we wanted to make sure that that wasn't taking place. In that investigation, we did not find anything that was patient-specific that Marchese Hospital Solutions was doing.

1610

M^me^ France Gélinas: Okay. Did you find anything that was outside of what they had told you they were

going to do? Remember the letter that my colleague asked for in late 2011/early 2012? They asked the college for clarification on the regulation requirements for a start-up business providing non-traditional pharmacy services. Were they doing exactly what they had said they would do?

Mr. Marshall Moleschi: To my best recollection, it was what they said they were going to do.

M^me^ France Gélinas: Okay. And you will share the—

Mr. Marshall Moleschi: What they had proposed that they were going to do, I'll share that with you.

M^me^ France Gélinas: Okay. You also, just before this, you said, "During that session, the college shared with Dr. Thiessen a full chronology, which we had already shared with the ministry, of all correspondence between the college and Marchese Hospital Solutions and Marchese Health Care pharmacy." If you could please table those with the Clerk as well, that would be—

Mr. Marshall Moleschi: Those would be one and the same as to what this is, as well as my opening remarks with the chronology. So, I will, but I wouldn't expect a whole lot different than what you just asked for.

M^me^ France Gélinas: Okay. I just wanted to make it clear.

The next one is on page 5 of your opening statement, where you're talking about a routine inspection that was done in January 2013 of the health care side, Marchese Health Care. Then you said: "Notes reflect that the designated manager of the accredited pharmacy indicated that Marchese Hospital Solutions was not regulated or inspected by Health Canada at this time, but was operating under the Public Hospitals Act."

Mr. Marshall Moleschi: She wrote that down to reflect what she was told by the pharmacist.

M^me^ France Gélinas: Okay. Do you know this to be true?

Mr. Marshall Moleschi: I do not. That's a reflection of what she was told. She then said, "Report back to us on your discussions with Health Canada on getting an establishment licence."

M^me^ France Gélinas: Okay. You call it, in your report, the "designated manager." If you could share the name of the designated manager with the Clerk, that would be helpful also. I take it that it's a designated manager at Marchese Hospital Solutions who said that.

Mr. Marshall Moleschi: No, it would be the designated manager in the pharmacy that—

M^me^ France Gélinas: The pharmacy side. It gets complicated quickly, doesn't it?

Mr. Marshall Moleschi: It does get complicated. There isn't a designated manager on Hospital Solutions in our regulations because that wasn't something we regulated. Until it has gone through all the posting, we won't, until that time.

M^me^ France Gélinas: All right. So the ministry has now put a draft regulation, and you're going through the process of having them basically becoming regulations for your college to follow. I was quite surprised when you mentioned that you are inviting voluntary identification and, potentially, inspection prior to authority being received. Can you tell me more about that?

Mr. Marshall Moleschi: That's what I will be proposing to our council in the Friday meeting.

There are timelines that go out a long way, and I sensed an urgency to be able to act as quickly as we could, so we're putting as much in place ahead of the regulations. The regulations will have to have the time that's laid out in law, and that's 90 days, but I do anticipate that we should be able to get timelines—that we could ask people to voluntarily identify themselves before the regulations go into effect. That would give us a head start in doing this in a timely way so that when the regulations come into force—probably in September—we'll have already looked at some. I can't force them into that, but I could ask people to do it voluntarily, and I think a significant number of individuals who are pharmacists or pharmacy technicians would be able to do that.

We're also looking at putting our processes in place with our standards in place that we could also look at some facilities before the September deadline—maybe in August—to be able to get a head start on some of this, so that when it goes into place we would have a head start on a lot of this.

We're putting a lot of things in place now. While I can't force people to go through our process till the regulations are in place, I could ask them if they would participate. That's the idea behind those sentences.

M^me^ France Gélinas: So you feel that your college has the competence to do that oversight?

Mr. Marshall Moleschi: My college will contract with others to be able to make sure that we have that and build on the experience of others. I have a consultant who's coming on a plane tonight to spend tomorrow and the next few days, and I've got a commitment from the registrar from another province to share his expertise to be able to help us with that.

Will it be the answer, a panacea to everything? No, but it will give us a head start, and that's what I'm looking for right now.

M^me^ France Gélinas: So acquiring those competences is something that you're working on and that you feel you can acquire?

Mr. Marshall Moleschi: Absolutely, and we need training. We, up until now, had been focused on the community side, and I think we do a good job of that, but there is a different degree of competence and a different competency set that we need to be able to do this sort of facility on the hospital side, which are more alike than it is on the community side.

M^me^ France Gélinas: You say that you feel a certain amount of urgency to move on with this, which is why you're having voluntary identification—inviting people for that. Could you describe this? What kind of urgency?

Mr. Marshall Moleschi: I think the people of Ontario—and our society in general, right across Canada—deserve to have confidence in their health systems. If we're a part of that health care system, we as a college

have a role to assure them that there are things in place so—it's not that nothing can go wrong, because things do go wrong in the health care system, but that there is oversight, that they can learn from those things that do go wrong and that we have a way of continuously improving our systems.

It's not just that we get a solution for today, because the world will evolve with time. We need to find a way to continuously look at the way things are evolving and evolve our systems to be able to do that. That's our commitment. Our commitment is to restore public confidence in the system. Pharmacy and pharmacists are a very respected profession, and that's important to the profession.

We are the organization that assures the public that they do meet that standard, and that's what we're trying to do by oversight of this alleged gap or this grey area: to be able to put in a system so that we can assure the public that there will be a system to deal with this.

M^me^ France Gélinas: I agree; oversight brings reassurance.

Mr. Marshall Moleschi: Yes.

M^me^ France Gélinas: You explained to my colleague that you were under the impression that Marchese came to you—came to the college. The college checked—they were not a pharmacy—and therefore could not do accreditation for them. You sent them to Health Canada and were under the impression that there was no grey zone, that Health Canada would do their job. I guess that explains why that urgency did not come before.

Mr. Marshall Moleschi: We gave them an alternative, to be able to look at their business model, and I guess the assumption that we made is that they wouldn't go forward with the business model until they were regulated by one of the two.

M^me^ France Gélinas: Okay; but they did. The Ministry of Health, though, knew that there was that grey zone, and they've known this for quite some years. Have they ever gone to the college to have a discussion about the grey zone?

Mr. Marshall Moleschi: I don't know if the government knew or did not know. They had not come to me with that discussion before this had taken place. The discussions that have taken place have been with Health Canada. It wasn't particularly around this, but other areas in the interpretation of 0051, where we saw some issues with putting those things into—operations, I guess.

M^me^ France Gélinas: You're looking to the wrong person if you want help pronouncing a word here.

Mr. Marshall Moleschi: I'm sorry.

I think that's the right thing to do: have regular meetings to be able to see if there's a disconnect—whether we need to refine the way we're interpreting it.

Meetings did take place last spring around 0051, and there was a meeting in June that I didn't participate in, where it was on the agenda. But, certainly now it's the subject of whole meetings, not just one agenda item.

1620

M^me^ France Gélinas: Okay. So the subject had been discussed before, as one of many, on at least two occasions that you know of. But now, not only will we talk about it; action will follow.

Mr. Marshall Moleschi: Yes, and it wasn't in this context. It was to do with how we both could work with 0051, the difference between manufacturing and compounding, and different issues.

M^me^ France Gélinas: If we look specifically at the level of risk every time there is a hand-off—it used to be that the hospital prepared those chemo drugs patient-specific. They put it together; it was going to a patient. People knew exactly how the drugs were going to be used. They were part of a team. We now have four levels of hand-off: the hospital to Medbuy, Medbuy to Marchese, Marchese back to the hospital and then the hospital pharmacy to the actual patients.

When we look at some of the detailed policy that your college has done to ensure that safety and quality can be maintained in various settings, I'm kind of surprised that we didn't see any detailed policy as to: How should pharmacists handle that level of risk by those many, many hand-offs that a subcontracting-out of pharmacy work would bring?

Mr. Marshall Moleschi: The question is, because it is a several-step process, why weren't we involved in—the simple answer is that we have been focused, based on our acts and our regulation, on the community side. We weren't involved in the drug distribution side on the hospital side. That, in Ontario, has been part of the process. So it is there.

My experience in British Columbia—because I was a hospital pharmacist and a director of pharmacy in my past, as well as a hospital administrator. In almost all my career, which goes more than 30 years, there have been some products that have been prepared by Baxter or Abbott at one time. So that does go back a long time. Buying some things in mini-bags—cefazolin—was not unusual in British Columbia.

M^me^ France Gélinas: Or in Ontario. So because it had been done for a long time, nobody is blinking an eye?

Mr. Marshall Moleschi: I don't know.

M^me^ France Gélinas: As a pharmacist, could you ever see a clinical use for four grams of cyclophosphamide to a single client?

Mr. Marshall Moleschi: I'm not up to date on my clinical side of things, so it would be hard for me to answer that. I would look it up in a book if I was asked that question.

M^me^ France Gélinas: And quickly—I can give you my Google and you would quickly find out that it is not all right.

I'll let it go around once. Thank you.

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

Ms. Helena Jaczek: Thank you. Your involvement with Dr. Thiessen's report is considerable, I assume?

Mr. Marshall Moleschi: My involvement is to provide information. "Considerable" was one afternoon, but there are daily conference calls that go on, and I'm on those calls.

Ms. Helena Jaczek: And with the working group with the ministry?

Mr. Marshall Moleschi: That's the daily—

Ms. Helena Jaczek: That's the daily.

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: Yes. Actually, I just have one little question.

The Chair (Mr. Ernie Hardeman): And you only have time for one little question.

Ms. Helena Jaczek: Good. We have heard from Peterborough that a pharmacy assistant detected the error. Who is a pharmacy assistant? You've referenced pharmacists and pharmacy technicians.

Mr. Marshall Moleschi: Pharmacy assistants are people who are not regulated by the college. They have a job description where they do tasks in a pharmacy, but they have to be checked by someone who's regulated. That person would have had a certain amount of training, but they hadn't gone through the process to become a regulated pharmacy technician, which is graduating from either an accredited program or going through, for a temporary period of time, a bridging program. It's essentially going through an accredited program, writing national exams for a regulated technician, and then being accepted by us as a registrant or a health care professional in good standing. That person likely just hasn't gone through that process at this time. It doesn't mean that their work is less valuable; they would just have certain work to do, and it would be involved in preparation. That person seemed to be on the ball.

Ms. Helena Jaczek: Very much so.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time for the government side. The official opposition: Mr. Yurek.

Mr. Jeff Yurek: Do I have time for one—

The Chair (Mr. Ernie Hardeman): You have all kinds of time—you have seven minutes left.

Mr. Jeff Yurek: With regard to the college investigation into Marchese now: It's purely just pharmacist-specific because that's really all that you have jurisdiction over?

Mr. Marshall Moleschi: Yes. Our investigation is into members, so they're people, they're pharmacists. Two people are on that investigation. It will be to determine whether there's any professional misconduct that has taken place as they've exercised their scope of practice.

Mr. Jeff Yurek: So any member outside of a typical defined pharmacy working out in the community—you would be able to investigate their professional performance?

Mr. Marshall Moleschi: We could investigate any registrant of ours, which would be a pharmacist or pharmacy technician, to do with professional misconduct.

Mr. Jeff Yurek: That would most probably just be complaint-driven if they're not a typical pharmacist?

Mr. Marshall Moleschi: Yes, that would be very typical. It would be unusual to do what I did: initiate a registrar's investigation. Based on the seriousness of the issue, we wanted to discover as much as we could as quickly as we could, and that's why I initiated a registrar's investigation.

Mr. Jeff Yurek: You said you'd feel fine with overseeing hospital pharmacies. I'm throwing this out there for the committee. Would it be fine if you oversaw third party outsourcing, like Medbuy and such, and give them a little oversight?

Mr. Marshall Moleschi: I don't know.

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

The Chair (Mr. Ernie Hardeman): Any more? If not, we'll go to the third party. Ms. Gélinas?

M^me^ France Gélinas: Okay; thank you. I want to come back to—have you seen the label that Marchese had on the—I'll take the cyclophosphamide. Have you seen the label that they had put out?

Mr. Marshall Moleschi: I have not seen the label. Perhaps staff may have, but that investigation is separate from—because I'm involved in the Thiessen, we've tried to keep those roles very separate.

M^me^ France Gélinas: Okay. In your 30 years of working as a pharmacist, would you say that it is part of your job as a pharmacist to check if an IV drug is to be prepared as concentration-specific or not?

Mr. Marshall Moleschi: I think it's part of the pharmacist's job to know how that drug—whichever way you prepare it—is going to be used, and make sure that you're contributing to the best health outcomes of the patient. A pharmacist should know how that's going to be used down the road.

M^me^ France Gélinas: When Marchese came to committee and told us that they assume that the drug was going to be used for a single patient, there is an easy way to check that, is there not?

Mr. Marshall Moleschi: They had a business model, and there's a third party involved, like Medbuy. I don't know any of the diligence that was done during that time.

M^me^ France Gélinas: Who do you figure—I know that he just asked a question and you were noncommittal, but as we are seeing more and more—I now have a book full of those medications that are being subcontracted out. Lots of them are IV drugs; in that particular section here, they're all IV. All come with the same labelling where you have no idea if the overfill has been accounted for or not. The pharmacist's judgment will tell you that sometimes it matters and sometimes it doesn't, because you know how the drug is to be used for the benefit of the client.

Given that there is no oversight of that four-times-hands-off process—and you spoke so eloquently of what oversight does to our health care system. It brings reassurance—it doesn't catch it all—but it brings reassurance; it brings best practices; it brings value. Who should oversee?

Mr. Marshall Moleschi: We're going to do our best to oversee where we have responsibility as laid out in regulations and bylaws. We will work with others to help assure the whole system that everyone is working together, and we'll do our best to be able to do that. We

will be even more diligent going forward in the future that if we see any areas that need to be addressed—it will be an education process even for our staff, but if anything raises a flag, that we have a process to be able to bring that to an area where we can identify and take action amongst a group of different organizations, federally or provincially.

You see police forces working at different levels—local police and national police—on different issues. Perhaps—and I'm not going to say that we're police, because we're not. We're actually in a profession and doing that. But we could learn from that as well, to look at ways we can coordinate some of our activities, as society evolves and the health care system evolves—that we can be best positioned to reassure the public that their system is safe and effective.

The Chair (Mr. Ernie Hardeman): Thank you very much. That does conclude the time. We thank you very much for being with us again today to enlighten us even further about the pharmacists involved in the situation. Thank you again for coming.

There being no further business, and we have no further delegations today, we stand adjourned.

The committee adjourned at 1632.

CONTENTS

Monday 6 May 2013

STANDING COMMITTEE ON SOCIAL POLICY

Chair / Président
Mr. Ernie Hardeman (Oxford PC)

Vice-Chair / Vice-Président
Mr. Ted Chudleigh (Halton PC)

Mr. Lorenzo Berardinetti (Scarborough Southwest / Scarborough-Sud-Ouest L)
Ms. Margarett R. Best (Scarborough–Guildwood L)
Mr. Ted Chudleigh (Halton PC)
Ms. Cheri DiNovo (Parkdale–High Park ND)
Mr. Ernie Hardeman (Oxford PC)
Ms. Helena Jaczek (Oak Ridges–Markham L)
Mrs. Amrit Mangat (Mississauga–Brampton South / Mississauga–Brampton-Sud L)
Mr. Michael Mantha (Algoma–Manitoulin ND)
Ms. Jane McKenna (Burlington PC)

Substitutions / Membres remplaçants
Mr. Grant Crack (Glengarry–Prescott–Russell L)
Mrs. Christine Elliott (Whitby–Oshawa PC)
M^{me} France Gélinas (Nickel Belt ND)

Also taking part / Autres participants et participantes
Ms. Cindy Forster (Welland ND)
Mr. Jeff Yurek (Elgin–Middlesex–London PC)

Clerk / Greffier
Mr. William Short

Staff / Personnel
Ms. Elaine Campbell, research officer,
Legislative Research Service