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 23 September 2013

Journal des débats (Hansard)

Lundi 23 septembre 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 23 September 2013

Lundi 23 septembre 2013

The committee met at 1404 in committee room 1.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

The Chair (Mr. Ernie Hardeman): I call the Standing Committee on Social Policy to order for the meeting of Monday, September 23. We're here today to hear deputations on a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies. Dr. Jake Thiessen is here to make a presentation today.

Mrs. Jane McKenna: Point of order.

The Chair (Mr. Ernie Hardeman): Point of order.

Mrs. Jane McKenna: I'd like to do a motion today for the Standing Committee on Social Policy.

I move that the social policy committee support the PC caucus programming motion and proceed with the Local Food Act as programmed in that motion.

The Chair (Mr. Ernie Hardeman): Thank you very much for that motion, and you have every right and ability to table it with the Clerk, but this committee is structured today to hear deputations, and the schedule is full with deputations, so we will not be able to carry on with this motion or debate on the motion in any way. So table it with the Clerk.

Mrs. Jane McKenna: Thank you. I hope we have everyone's support in the House when we do.

The Chair (Mr. Ernie Hardeman): Any further? Okay.

DR. JAKE THIESSEN

The Chair (Mr. Ernie Hardeman): With that, Mr. Thiessen, the floor is yours. I should remind you, you have sworn the oath in your previous appearance, so you will not have to be sworn in again, but you are under oath as you're testifying.

Dr. Jake Thiessen: Thank you. I asked the Clerk—

The Chair (Mr. Ernie Hardeman): He already told you that.

Dr. Jake Thiessen: Yes. He told me that, but then I said I'm delighted to know that I've been under oath for the last several months.

The Chair (Mr. Ernie Hardeman): Yes. He's very thorough and he's not as confident of my abilities as I am, so he thought maybe I might forget.

Mrs. Jane McKenna: Chair, who is asking the questions first? If you said it, I'm sorry; I didn't hear you.

The Chair (Mr. Ernie Hardeman): It will start with the official opposition.

Dr. Jake Thiessen: More formally, good afternoon. Thank you for inviting me to come back. I trust that our time today will be helpful as I share with you the findings of the report and the information that is presented in it.

As you know, this report was delivered on time, may I say, which was July 12, 2013.

Interjection.

Dr. Jake Thiessen: Pardon?

Mr. Rob Leone: That's unusual.

Dr. Jake Thiessen: Well, thank you.

Ms. Helena Jaczek: Not from a health professional, I should say.

Dr. Jake Thiessen: I do come from a family of businesspeople, and I do also engage in this to some degree, so I know: on time, on budget—how important that is.

Interjections.

The Chair (Mr. Ernie Hardeman): I'm happy we're having a mutual admiration society meeting, but if we could just carry on with the appropriate presentation.

Dr. Jake Thiessen: With that, please: In my report to you, I have given this information that I'm going to refer to. I apologize, but I'll probably just read from most of it, although I may interject from time to time.

My opening remarks today will basically be those that I delivered at the time, on August 7, when the formal release of the report was made, at which time I gave these very comments. I also will not present my qualifications again. They were given to you on May 27 and they're also identified in appendix 1 of my review.

Just to help us with the overview, I've broken out the various sections of my report, as you will have it before you, I suspect.

Of course, there's the executive summary on pages 1 to 3.

There's the table of contents, which appears on page 4, so if I suddenly say "this and this," kindly refer to that.

The introduction paves the way; it includes some background information on how I was going to go about it, which is on pages 5 to 9.

The observations from the investigation appear on pages 10 to 22.

The recommendations are launched on page 23, ending on 39.

There's a very crisp, simple conclusion statement on page 40.

There are acknowledgements on page 41.

References appear on page 42.

Lastly, the appendices are on pages 43 to 53.

That gives you a breakdown of my report.

My report presents details regarding the independent investigation of gemcitabine and cyclophosphamide underdosing that affected, as you've all heard by now, 1,202 patients in Ontario and New Brunswick. My investigation schedule is presented in appendix 2, which is on page 44, and you can see the itinerary of various people that I visited.

I chose to begin with the hospitals in both provinces to understand precisely what had happened and why and how they had responded to the crisis. To gain further evidence, I probed what might be considered the primary, directly linked stakeholders. These included the group purchasing organization, namely Medbuy; the vendor, namely Marchese Hospital Solutions; the previous vendor, which was Baxter, which we might say was the incumbent or the historic one that really was the first to engage Medbuy in a contract; and the suppliers of the pharmaceutical materials and the diluents. Just to make sure we all understand, "diluents" is the term we use scientifically simply to identify the material that is used to dissolve the drug that was in the vials.

1410

The review also took in key professional, structural, regulatory and oversight stakeholders. These included organizations like Cancer Care Ontario, Health Canada, the Ontario College of Pharmacists, the Institute for Safe Medication Practices and the Canadian Society of Hospital Pharmacists. People sometimes wonder, "How far and wide did you go?" Actually, I formally interviewed about 100 individuals in the course of this investigation and informally spoke with many others. I sought to gain factual, substantiated evidence, collect information and determine the viewpoints on a variety of issues that surrounded the incident. Just in case you were not clear about this, this was truly independent. I was the only person working on this.

The major findings were as follows: 1,007 patients were underdosed with cyclophosphamide; 191 with gemcitabine; and four received both oncology medications. The largest fraction, which is 1,162, was adults, and 40 were pediatric cases. All but 30 patients were being treated for cancer—I've given you some information there on page 45 of appendix 3. Just to help a little bit, people often ask me, "Why would anybody get an anticancer drug and not be an oncology patient?" I'd say, "Well, in the case of cyclophosphamide, it is very good in knocking back the immune system, and so there were patients with lupus and rheumatoid arthritis who also received cyclophosphamide as part of their treatment."

As far as product preparation, I gave you some of that on May 27. Again, I've distilled the essence of the comparison in table 2 on page 16. The vendor used only Health Canada-approved materials from registered suppliers. It employed a bulk reconstitution process that used the correct amount of drug and pre-filled saline bags that had some overfill. The overfill, which was furnished to me by Hospira—which is the bags they used—is identified in table 3 on page 18, and you can see what the numbers were in all the lots that were actually used by Marchese in making their dilutions. For example, a bag labelled 100 ml saline—by the way, it says on there, "100 ml bag"; that's what it says on the bag from the supplier. The same thing happens with Baxter; it actually has that on there. So, a 100-millilitre saline by the supplier actually contained, on average, 107 millilitres of the diluent. That would translate into a 7% overfill.

Such overfill led to an excess in the final fluid volume that was not accounted for when the company labelled the product sent to the hospitals. As a synopsis, then, the resulting dilution factor was an average of 7% for gemcitabine and 10% for cyclophosphamide.

Moving on to the group purchasing organization—namely, Medbuy—it is an organization whose members are hospitals. They actually service all of those. They have amalgamated purchasing power, which we've talked to and that I think you've learned about before. They awarded the drug product preparation contract to Marchese on the basis of four objective factors. I've identified those factors on page 21. Of these, the cost of the contracted products only represented 25% of the final evaluation score.

I clarified at the press release that Marchese did not present the lowest price. Nonetheless, in defining the products to be prepared, only a simple statement of specifications was used; namely, the amount of active ingredient per bag of the product—for example, for gemcitabine, 4 grams in 0.9% of the diluent injection bag, 100 millilitres per bag. That's how it was written.

I'm going to interject here, just to help a little bit. When Marchese was considered for this contract, one of the things Medbuy did was investigate what the capabilities of this company were. I can tell you that at that point, which was in 2011 when they made the application, Marchese was producing 752 products. I believe that all of the requested products that Medbuy had, which was 117—I know that number for sure, and I'm not sure if Medbuy was now 118 versus 117, but all of those were identified in the 752 that Marchese had already been producing. I think that's important for you to understand. This wasn't that Marchese was now producing some new things that they hadn't been doing; they had already been doing these kind of things, and they, in fact, had been doing this for gemcitabine and cyclophosphamide.

So the amalgamated outcome, as I'm putting this story together, is the following: The simple statement of specifications led Marchese to use a process that failed to adjust for the overfill volumes.

Finally, the hospitals did not correct their patient-specific doses—because it's an amount that they need per patient—to factor in the overfill, because there was no

clarifying patient-related instructions from Marchese, and the hospitals were therefore unaware of the lower concentrations. This is how patients were underdosed an average of 7% with gemcitabine and 10% with cyclophosphamide.

In this story, there is no evidence of any harmful intent to provide diluted products and thus underdose patients. The problem boiled down to gaps in communication and its unintended consequences. I can tell you, everybody's embarrassed.

What was the impact of the dilution factor on the patients? At this point, the impact is unknown; however, due to the relatively low degree of underdosing, along with the high prevalence of combination oncology drug use, the probability is small that the shortfall had an overall serious effect.

For those of you who wonder, I went through the records of Cancer Care Ontario to find out what the approved programs of treatment were in patients—CCO basically sanctions the treatment protocols—and wherever gemcitabine was used, 74% of the instances of gemcitabine use would be combination. For cyclophosphamide, aside from those immune patients—the ones who were dealing with lupus or rheumatoid arthritis—96% of cyclophosphamide is used in conjunction with other treatments. So it's essentially never alone.

The conclusion, therefore, because of the high problems of combination and the 7% and 10% which I've referred to, is consistent with the clinical decisions made at the affected hospitals, wherein oncologists generally simply continued with their patients' treatments despite this incident.

Lastly, to the recommendations: The recommendations really flow in many ways from the observations, and so in some ways they are best understood if you bring those two together—the observations and the recommendations.

Sorry to remind you about this, but I was asked to try to provide recommendations that would prevent incidents of this nature; for me, this nature meant several things. One is, naturally, in the world of oncology and what one would encounter, but if one looks at this entire structure that exists as part of product development and distribution, there was a broader field that I felt I needed to address simply because of what I had observed and knew. So I fundamentally examined the entire area of sterile and non-sterile product preparation wherever it might occur; that is, licensed pharmacies and other enterprises. I've concluded that there is a need for greater vigilance in order to mitigate identifiable risks. Simply translated, I've sought to heighten the safeguards for patients to impose a higher, more rigid standard around product preparation quality, and to stipulate various checks and balances. In essence, it boils down to three things for me: product quality, patient safety, and checks and balances. Those need to be in place, so I made some fairly sweeping recommendations that are broadly captured by five entities.

1420

Recommendations 1 to 4 are all about group purchasing organizations, like Medbuy, which must engage in more rigorous risk-based procurement processes and provide greater specificity for drug product preparation services.

Recommendation 5 is directed at the vendor in this case, which is Marchese. They must review their practices and ensure alignment with my various product preparation recommendations. But many of the things for Marchese are also addressed in some of the previous recommendations for the GPO, the group purchasing organization.

Recommendations 6 to 9 and 12 are directed to the Ontario College of Pharmacists, and in many ways they're also directed to the broader regulatory colleges across Canada: that they shall, in conjunction with Health Canada, define objective, recognized standards for sterile and non-sterile drug product preparation within licensed pharmacies. Inspection criteria shall be collaboratively established.

In addition, I'm calling for—and I'm very forward-thinking on what could potentially happen; what I need to make sure is that the patients are protected—electronic records for materials prepared, along with specialized label requirements. We just need to move to areas that some places are using, and it would be a travesty if we didn't close this off.

I'm very firm on requiring credentials beyond education and licensing for personnel engaged in product preparation. To me, just because you have a pharmacy licence and graduate from a pharmacy institution recognized in Canada and are licensed by a college is no guarantee that in fact you know what to do in product preparation, because of the nature of the newer pharmacists that are coming along. I want a specialized designation for pharmacies preparing large volumes of prepared products, and inspection of such will be annual. Of course, I've mentioned the licensing of hospital pharmacies, which hasn't existed to date.

Recommendation 11 is addressed to the Ontario Hospital Association. I want them to review their hospital record systems for traceability and efficiency. We can discuss that further, if you like.

Lastly, I want Health Canada to regulate all drug preparation premises beyond the pharmacies that are licensed and regulated by the provincial colleges of pharmacists. If you have read the report, I'm even saying this: If any pharmacy is shipping medications across a border, I want Health Canada to license that, because in our case we actually had Ontario shipping to New Brunswick, right? If one of the other vendors had been secured, like the Quebec vendor, the product might have been prepared in Quebec and shipped to New Brunswick and Ontario. So you've got to have a way of ensuring that in fact only high-quality products enter the marketplace.

In closing, as I've said in the report, I commend administrators, physicians, pharmacists, nurses and other

personnel in the affected hospitals for their timely and innovative responses. Their actions clearly demonstrate that their primary concern was for patients. These professionals are a credit to our health care system.

Lastly, I wish to acknowledge and recognize in particular the numerous patients and caregivers who faced the emotional impact of this incident. I trust that my efforts in uncovering the cause of the underdosing, in exploring various particulars around this issue, and providing recommendations, will offer a measure of encouragement. May the outcome of this report, this investigation and the things that will follow be a fresh confidence that the future will bring improved safeguards for product preparation throughout the health care community. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation and all your hard work and thoroughness in preparing your report. With that, we will start the questions and comments from the official opposition. Ms. McKenna?

Mrs. Jane McKenna: Thank you so much, Dr. Thiessen, for coming back again. I'm going to reiterate what the Chair said: All your hard work and coming in on time was superior, and I really, really appreciate all that you've done here.

I have two questions. My first question is, because of my recollection of the depositions we have heard from all parties and in the notes prepared by the legislative research service, there was confusion around labelling. We also heard that the Institute for Safe Medication Practices, or ISMP, has identified the need for a national labelling standard. The Ontario Hospital Association has also said that national labelling standards are necessary, and we heard that Cancer Care Ontario's guidelines were not specifically designed for compounding facilities but were intended for individual patients and cancer centres. So could you outline, please, the reason for your recommendation that the National Association of Pharmacy Regulatory Authorities, NAPRA, should develop label requirements?

Dr. Jake Thiessen: Thank you. Yes, label requirements mean different things to people. But what I think ought to be absolutely clear is what's there, for who, how it's to be taken and, in our case, there was another important element, which was the end user. I've identified this in the report as the pharmacists at the hospitals.

There ought to be no uncertainty, absolutely none, about what's in that product—that's one thing—what's in there, what the concentration is, and because many of these people are getting these drugs as infusions, how the infusion pumps are to work with all of this, so that there is no uncertainty about the whole thing. We can fly wonderful jets, but we can't get this right? This doesn't make any sense, you know? We've got to have absolutely solid label requirements in that regard.

The other thing that I've mentioned even in my opening remarks is the whole thing about traceability. I've done everything I can to shore up this entire area. I think I can say that the stakeholders that are part of all of this are anxious to move this all ahead. Can things that weren't anticipated happen? I suppose the answer is that there's always this possibility. But I want traceability. You should be able to take a barcoded medication and, with an instant and time through your computer system, say, "I know that this patient was on it and I know that there were three times this patient got it." This is inexcusable if we can't do that.

I've been in enough places that I see what goes on. My own pharmacy where I go to has a barcode on it. My medications have barcodes on them, so I'm very satisfied with that. But I've been in hospitals, and I see that they just don't know. I've asked, even in the course of my investigation—I've said, "So you make this stuff in-house now?" Just because you make it in-house doesn't give you any guarantees. It's a closed system; hospitals are closed systems. So you have to make sure that you're not blinded by things like this. But I said, "Okay, so now you've made that. Tell me what's in there." "Well, it's this and this." I said, "Good. Do you know which lot number and which supplier it came from?" They couldn't tell me.

Mrs. Jane McKenna: That's pretty scary.

Dr. Jake Thiessen: This is why I'm saying, labels, electronic records of everything that's there—and it is only then that you can get traceability.

This is long-winded, I'm sorry—

Mrs. Jane McKenna: No, no, it's very good. Thank you.

Dr. Jake Thiessen: —but what we need to do is make sure that there's no doubt about what's in there and what's good for the patient and how to deliver it, and we need to be able to trace everything.

Mrs. Jane McKenna: That's phenomenal. Thank you for all that information. My next question is—that will save so many—clear, concise information of what you're getting there.

The most striking aspect of this committee hearing for me has been the role played by Medbuy and the group purchasing organization or broker to the hospitals. I understand there are efficiencies that come from volume purchasing, but the more players you have involved, the greater the opportunity for errors to occur.

Medbuy assumed that the product would be delivered the same way as Baxter had because the specifications were the same. Marchese didn't interpret them the same way, however. So my question is, I know you recommended improvements in GPO-based processes. Do you think the communications protocols between Medbuy and a new supplier were adequate? Or do you think that they needed to be more specific?

1430

Dr. Jake Thiessen: As I think I said when I was here in May, this issue of hand-off is exceedingly important. It's not only how a group purchasing organization hands off what has happened with, let's say, the previous vendor to a new vendor, but also how there's an engagement between all the parties. I must say, there were shortcomings with that in this particular case, but there was no

ill intent here. It was just that in the heat of the battle and so on, these things happened.

I have written in a number of things that need to be done, which range from specifying exactly what needs to be in the specification of a product that's being prepared—that includes the materials, how it is being made, what the label is like etc. I've called that they actually do this pre-emptively with the CSHP, the Canadian Society of Hospital Pharmacists, and ISMP, so that there is no uncertainty.

We go back to your first question: There should be no uncertainty, if and when any new contracts arise, depending upon how this all goes out. Even the end user needs to be engaged with all of this in great detail to make sure the patient is getting the right thing.

I hope I've answered your question. I've come down pretty hard on the kinds of things that are required.

Mrs. Jane McKenna: Yes, you have. Thank you very, very much.

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

Ms. Cindy Forster: Thank you, Dr. Thiessen, for being here and for all of the hours that you've spent connecting with various stakeholders across the province.

I just want to clarify something that you said. In the report, you talked about how Marchese was already preparing 752 products in a similar way, and those included the two drugs. Can you expand a little bit more on that issue? Who were they preparing them for?

Dr. Jake Thiessen: That is a question that I may need to ask Medbuy about. The point that I was trying to investigate was this: Was this simply a company that was making new products that they had never made before, or was there in fact a history of making products successfully, as far as Medbuy was concerned? This is when Medbuy informed me, yes, they had investigated all of this and that Marchese in fact had been making a variety of products. I learned it was 752. I also learned that essentially all of the products they were asking them to produce had already been made for other clients. Who those clients were, I do not know. That was not part of my investigation.

Ms. Cindy Forster: So you don't know that those were actually being made at their place of business in the same way that they were now being produced for these hospitals? Or was it their actual local pharmacies that were perhaps making chemotherapy drugs for the community of patients?

Dr. Jake Thiessen: I do not know what their intent was, so I'm sorry, I'll need to defer that to others.

Ms. Cindy Forster: Okay. On page 6 of your report, you discuss root cause analysis, and you say it's "designed to answer three basic questions following a critical incident or adverse event in health care: what happened, why it happened, and what can be done to reduce the likelihood of it recurring. However, RCA does not directly address a fourth question"—you spoke to it briefly: "has the risk of future event recurrence actually been reduced?"

Dr. Jake Thiessen: At this point, my report has made a variety of recommendations. The degree to which these recommendations have been implemented, I do not know at this point. I think that they're under way, from the best that I can gather. Therefore, the implementation of them is not yet complete. What I'm suggesting, then, if the intent was to actually eliminate these kinds of errors—I dare say it's going to take several years before we'll know whether there's any recurring incident of this type, based upon the changes that occurred in the system. With all due respect, I think we have to yet wait and see whether the recommendations actually make a change.

Ms. Cindy Forster: So if it is going to actually deal with the issue of reoccurrence with the recommendations that you've made, is this going to include other medication errors or simply just for oncology medications?

Dr. Jake Thiessen: In essence, it's really the broad area of what I call sterile and non-sterile product preparation. So it's not only oncology; it includes all the others as well.

Ms. Cindy Forster: On page 13 of your report, you stated that the Ministry of Health and Long-Term Care "sought to determine what outsourced suppliers were being used by hospitals," and that there was a request to ensure that only suppliers with predetermined qualifications would be servicing the hospitals. Do you know how onerous a process that was?

Dr. Jake Thiessen: It basically sought information through attestations, and I believe the date was April 19 when this was sent out to all the hospitals. In due course, they came back with information that, yes, they were only going to be using—if they hadn't—suppliers that were predetermined to have met the requirements. I understand that, in fact, all of the institutions conformed to the request and provided the assurance.

Ms. Cindy Forster: Do you know why the ministry was not previously collecting this type of information?

Dr. Jake Thiessen: I do not.

Ms. Cindy Forster: Or whether they'll continue to collect it on a go-forward basis?

Dr. Jake Thiessen: The outcome of my report really lies in the hands of the government, so what they do with it, I suppose, is in their hands. I would be surprised if government wasn't as keen to make sure this doesn't happen again as I am. That's the best I can answer.

Ms. Cindy Forster: On page 15 of your report, you state, "It is noteworthy that this stage of dissolving the drug powder in the vials may consume considerable time." We heard that from some of the witnesses along the way. "This is an important reason why outsourcing through vendors is used by the hospitals. In a busy oncology service where many doses are prepared daily for patients, waiting for a drug to dissolve is a substantial inconvenience." Was this something that you heard at the hospitals from pharmacists?

Dr. Jake Thiessen: That's correct. I heard it from pharmacists at hospitals. I wanted to know not only what Marchese had done and what Baxter had done; I wanted to know what was going on in the hospitals at that point,

because they had all reverted to kind of a backup plan of doing it inside. So I said, "How do you actually do it?" And they said, "Typically, we'll take those vials of gemcitabine and cyclophosphamide first thing in the morning. We'll decide, perhaps based upon the schedule that was planned for chemo administration that day, how many of those we will need, and then, early in the morning, when the first person comes in, we add diluent to each one of them and then we try to dissolve them." And I said, "How did you do that?" Well, what would happen is somebody would periodically come by and shake them up again, come back and shake them up again etc. Cyclophosphamide is the hardest to dissolve; gemcitabine is much easier.

You can imagine, when you're administering perhaps hundreds of doses in a particular day, this is really quite an inconvenience, so the idea of outsourcing this, having the products arrive dissolved in bags—and it wasn't just vials; it would be in a bag—was for many of them a great convenience.

Ms. Cindy Forster: When the hospitals appeared before this committee, they kind of contradicted that notion in most of the questions that we asked, that it was too time-consuming to prepare these drugs in-house—it wasn't a monetary or a workload issue. So why are we now hearing a different opinion?

Dr. Jake Thiessen: I guess that was because I asked—and each one of them actually had a series of questions that I posed at each one of the hospitals. I asked, "Why do you outsource this?" And the answer was, "One is the length of time that we sometimes have to engage in preparing the vials." I think that was uniformly mentioned, other than Peterborough, because they only had gemcitabine. The others told me a similar story.

1440

They identified too that this is also, then—it means extra labour, time, and there were people like technicians or whoever who would do some of these things; so there was a time investment in all of this, where these people could do other things. In the entire economics of all of this, it was viewed as a benefit, whether it was time, manpower, cost. I didn't ever inquire, "Well, what do you estimate the cost of dose preparation to be for these two products, for example?" I didn't go there.

Ms. Cindy Forster: Okay. I think I'm going to pass and save some of my time. Thank you.

The Chair (Mr. Ernie Hardeman): Okay. With that, Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair, and thank you, Dr. Thiessen, for such a comprehensive report. Thank you for the clear language in it and the nice, logical flow. I really enjoyed reading it.

Of course, I know the minister, Deb Matthews, who appointed you to conduct this review, is also extremely pleased with the report—to assure you that we will be introducing legislation this fall that, if passed, will allow the Ontario College of Pharmacists to license hospital pharmacies. I know that, as a committee, this was something that we had latched on to, and you obviously make that recommendation.

I have a number of areas where I'd like a little bit more clarification, perhaps, of what you actually heard during the course of your review. But first, there's a technical question which continues to intrigue me. The overfill that traditionally was provided in the Baxter formulation, which was adjusted for with a corrected concentration: Once that solution is created, do you not then have further evaporation which would lead to a change in concentration over time, or was there some way of an expiry date that would allow for that?

Dr. Jake Thiessen: I hope I understood clearly. The preparation of the reconstituted product by Baxter, just so that we make sure we speak the same language here, entailed really the same thing everybody did, which was reconstitute in the vials. Then they simply took that and put that solution into an empty bag.

Ms. Helena Jaczek: Yes.

Dr. Jake Thiessen: That meant there was a certain volume there. In the case of gemcitabine, actually, there was a slight volume increase because of the solid material. For some reason, in solution, it actually grew—the volume grew—slightly. I think the increase was something like 5%, so that what was thought to have been 100 millilitres of material was actually 105 and change. So there was a slight growth in all of that.

But to, I hope, address your question head-on, the supply of materials from Baxter, then, to the hospitals typically would be used relatively quickly. Therefore, any kind of fluid movement through the membrane would be inconsequential. So therefore this issue of, can I say, a decrease of volume really wasn't there, because typically, it takes quite some time for the water to pass through that membrane.

Ms. Helena Jaczek: Yes. Okay. I assumed there was a time relationship.

Dr. Jake Thiessen: That's correct.

Ms. Helena Jaczek: Okay. Fine.

In relation to your recommendation, I guess—well, it's somewhat related to summary finding number 4. This is the issue related to the group purchasing organization, in this case Medbuy, and its pharmacy committee. There was a failure to appreciate, potentially, the issue that in fact arose. Were you privy to or did Medbuy share with you the actual conversations that took place in the pharmacy committee in relation to these two products and how the RFP was going out and the requirements? Did they really look at cyclophosphamide and gemcitabine from the perspective of what the concentration is going to be?

Dr. Jake Thiessen: I didn't go to any particular conversations—I understand Medbuy is going to be with you. What I understood from Medbuy is this: They had an executive pharmacy group that had a particular role and they had the various pharmacy representatives of the member organizations, and collectively they became part of a pharmacy committee.

This wasn't, as far as Medbuy was concerned, only a gemcitabine and cyclophosphamide story. In the contract there were about 117 products. So it was a much bigger contract, and I think they were all treated in exactly the same way: There was a one-line description; there was no specification on exactly what was needed for every particular product.

I hope I've answered the question. First, I wasn't privy to any conversations, and I didn't even inquire about that. The second thing is that it wasn't only those two drugs; there was a much larger basket of products.

Ms. Helena Jaczek: Since the release of your report, have you had any feedback from group purchasing organizations, or Medbuy in particular, in reaction to some of your recommendations?

Dr. Jake Thiessen: I've remained sterile.

Laughter.

Dr. Jake Thiessen: Sorry for the quip.

I've remained clean. I've stayed out of this, and I said that, basically, I wanted to be completely released from the obligations of this contract before I would do anything anywhere.

Some of you may know that the Ontario Hospital Association is having a conference at the end of October, and I've been asked to speak at that. So there are some things that are coming. I have been approached, but I've said, "I'm sorry. I can't do anything until the government has released me from this responsibility."

Ms. Helena Jaczek: One of your recommendations relates to the Ontario College of Pharmacists, and you mentioned it today: "credentials beyond education and licensing for personnel engaged in ... product preparation...."

Now, you're making that recommendation to the College of Pharmacists. Would it not be better to ensure that this is part of the undergraduate preparation for pharmacists in general, and wouldn't you have a very persuasive voice with the academic community?

Dr. Jake Thiessen: Well, thank you. You're giving me more credit than perhaps I enjoy—not to make light of it.

The programs of study across our country are defined by the Canadian Council for the Accreditation of Pharmacy Programs. There's a fair bit of, can I say, instruction as to what is to be in a program. There is some latitude, but the entire area of product preparation has fallen by the wayside in most places, because there has been this increasing interest in patient care activities; as you know, things like injections are now available in a pharmacy and so on. That said, I can speak about what happened in Waterloo, because I was involved in that program and we've retained it. But that should not be on the record.

The issue here is that I believe that no matter what you do in life where others are affected, you'd better make sure you have the credentials that support that activity. You can't drive a bus or a truck—whatever it happens to be—with a general licence. You must have special qualifications. The same thing applies in this field. You need to understand how to do things—when you are not well, whether you should even be engaged in any of this; fume hoods or special facilities; what particles are all about and so on—so that you do the right things knowledgeably and with skill and confidence.

I've come down fairly strongly in saying it is not good enough just to have a licence; you've got to have credentials. I'm not alone in this viewpoint. Certainly, an agency that one might say is self-serving, the Professional Compounding Centers of America, which has a subsidiary in Canada, is very big on providing people with instructions as to how to do this. And there are other programs that are available. I think you must have that. I think the patient ought to be able to go in and have confidence that such-and-such—Jake Thiessen—has got these credentials and he is actually qualified to make these products.

1450

I've even come on further, as you'll see later on. I've said that when I get a prepared product, not something that's come from a pharmaceutical manufacturer, I think, personally, that there ought to be an identified person, a signature or something that identifies who did it, so that you can check and say, "Yes, it was Jake Thiessen, and yes, he has these credentials." I can be confident.

Ms. Helena Jaczek: Thank you. Recommendation 6 and recommendation 10 refer in some measure to Health Canada, and I presume your sterility is extended to them—you haven't necessarily had any communication—but you certainly do see a role for Health Canada, an expanded role as it relates to compounded products.

Dr. Jake Thiessen: Yes. Thank you. I see it in two areas particularly. One area is to license places to make sure that we have the right kind of facility, people, processes, backup plans, electricity—so many things that are important; it's part of GMP, really. That's one facet.

The other facet is that I feel that Health Canada needs to work with the colleges. If the colleges are going to actually inspect pharmacies around product preparation—it doesn't matter whether it's a small or a large enterprise—there needs to be a uniform standard across Canada for the inspection. I think the standards and the inspection process ought to be common, and who better to do this than Health Canada, which walks into pharmaceutical companies to do that? I hope that helps.

Ms. Helena Jaczek: Yes, it absolutely does. Now, you make quite a point in your report of saying that in reaction to the crisis the health care professionals involved acted expeditiously and appropriately in order to mitigate patient harm and to, obviously, deal with and talk to those patients who were affected. Would you say that the Ministry of Health and Long-Term Care also reacted in an appropriate way when they became aware of the situation?

Dr. Jake Thiessen: To somebody who kind of understands fairly large enterprises, I feel that there was a remarkable attempt to intervene as quickly as possible and, thereby, to try to mitigate any further risk. That ranged from assembling a working group—I was im-

pressed that such a big group could be assembled so quickly and that they could address things. From the very beginning, once I came on, which was after my appointment on April 15, I was able to listen in on what was going on in the working group, and I'll tell you, there were just regular meetings. They were scheduled, everybody came on, and I thought that, in the midst of all the things everybody needs to do, people found time to be there, because this was viewed as an—

Ms. Helena Jaczek: Including the Ministry of Health and Long-Term Care personnel.

Dr. Jake Thiessen: Absolutely. It was the ministry which was orchestrating the working group, right? I just felt that this was actually a wonderful template for how to do things.

Ms. Helena Jaczek: Do I have some time left?

The Chair (Mr. Ernie Hardeman): Yes.

Ms. Helena Jaczek: Dr. Thiessen, we as a group, as you know, had witnesses over a period of time, and we heard from Peterborough fairly well into the process. Of course, we recognized the very timely intervention of the personnel in the pharmacy there, and really acknowledged that, thank heavens, they were so diligent in their approach. I guess, in retrospect, should we not be a little surprised that, perhaps, Windsor and London did not come to the same sort of line of questioning as they did in Peterborough? How do you react to that?

Dr. Jake Thiessen: Well, I think you're absolutely correct. On the one hand it creates a virtuous umbrella over Peterborough because they, in fact, were the ones to discover it, I think to the embarrassment of people in other locations who did not. Yes, they should have. In fact, my report indicates what the hand-off ought to be when it comes to the end user. If people carry through on what I'm saying, there shall be a way that the end-user pharmacists in the hospitals actually get a trial sample to start with that they can check, that they can go back and ask questions about etc.

The intent here is to make sure that in the busyness of life, as happens in these hospitals, you actually have a procedure that you need to follow. It's like an SOP, standing operating practice, as to how in fact you change from one vendor to another one and receive those products. But I'm also suggesting that whenever a new batch comes in, that somebody checks to make sure, "Oh, yes, this is what the label should be. Yes, yes, yes"—it's a checkoff sheet. It's kind of like what happens in industry, part of GMP really; right?

Ms. Helena Jaczek: So an additional quality assurance measure.

Dr. Jake Thiessen: That's exactly right. Thank you. A perfect way of saying it. Quality assurance is job one.

Ms. Helena Jaczek: Okay. Thank you very much.

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

Mrs. Jane McKenna: A couple of questions. I think the problems, although not intentional, did demonstrate lack of due diligence with Medbuy. To me, there weren't enough specifications in the actual contract. Why do you think that was?

Dr. Jake Thiessen: I think that's something that only they can answer. Anything that I say is going to be conjectural. It seemed to have worked with Baxter, and they had seen what was going on with Marchese servicing CCACs or whatever else. The way Marchese identified the product seemed to be the same way that Baxter was identifying it, and putting one plus one together, they got three, and it was kind of left at that.

Mrs. Jane McKenna: Yes, because our interpretation—well, actually, facts in here—that what we saw was that Baxter had done this for years with them and had communication going right to the hospital pharmacy and back with them.

I guess I'm just wondering why that appeared that way, because if the broker is the one that's writing the contract and fully responsible for that—in my own mind I guess that's the answer to it: Why weren't they so specific if they were doing a brand new contract with a brand new company that had come to them that was going to be starting this?

Dr. Jake Thiessen: Well, that's a very good question. They were short-sighted in all of this.

Mrs. Jane McKenna: Sadly.

Dr. Jake Thiessen: I think you've put a very good point on the floor here, which is that Baxter gained its reputation on working directly with pharmacists and pharmacies in hospitals.

Mrs. Jane McKenna: Right.

Dr. Jake Thiessen: Their reputation wasn't built on a vendor—sorry—on an intermediary, a GPO. They had the distinguished reputation.

Mrs. Jane McKenna: My next question following with that is, I think the thing that frustrates me the most is that there are just so many dropped balls along the way. Obviously, it's at the expense of everybody else when you don't have an actual structure of what exactly you're doing. You can tick off checks and balances, on which you've done a phenomenal job of doing for us so this doesn't happen again, so thank you very much.

I don't have a lot of questions because you pretty much answered all that, but I guess my next question to you is: You're the aftermath of what's happened, right? You come in with all these recommendations, but France has mentioned numerous times that since 2001, the government has known about the problems with not regulating. So my question to you is, if you found all these recommendations in the aftermath, and yet maybe not as specific prior to the problems that occurred, do you think the government of Ontario's responsibility—they could have found some of these recommendations prior to having the problem afterwards?

1500

Dr. Jake Thiessen: A fair question. I guess the structure of our government is fundamentally—as I understand it, there are a lot of policy-related issues. But when it comes right down to servicing any particular area, they delegate—to a hospital association; Cancer Care Ontario;

colleges of medicine, pharmacy, dentistry etc.—and they're trusting that the people that they delegate it to are doing whatever is necessary.

I don't think, personally, with all due respect, that just because you put up a stop sign, you hire a cop. You trust, by and large, that people obey stop signs. It's like that with these agencies. You're trusting. That's why one of my comments in the quote is that there's so much trust that we all embrace in society, and this trust is basically that people are going to do the right thing.

So it's fair to ask the question. I'm not surprised they didn't know, and I'm not surprised that they didn't go after it, because there are so many things the government needs to do.

Mrs. Jane McKenna: It makes me sad that you're saying that. I trust that my husband is going to pick up my son after school. If someone's job description is to oversee exactly what has happened here—that's their job description. That's not a trust level; that's just something that it's part of their mandate to be able to do.

Where does the buck fall? Who is responsible? It's wonderful that you're here in the aftermath, and you've done a phenomenal job, but I just wonder if this has been going on since 2001—and they might not have had everything specifically, because this is obviously a specific case that happened. To me, in the end, the government is ultimately responsible because they are the ones that are making sure that everything goes through.

That's the only point that I wanted to make. Trust, to me, is very different than your job description.

Dr. Jake Thiessen: My litmus test is this: Who could have prevented it? I suppose one could say that government could have prevented it, but government doesn't really function at the level where all of this happened. In attributing any of this to government, I think, with all due respect, it goes beyond the oversight agency; it goes to the people that I feel are ultimately responsible. I could identify various places where it could have been stopped.

Mrs. Jane McKenna: Where?

Dr. Jake Thiessen: Well, obviously, if it hadn't been for the BPSA—it's the procurement act, really, or the requirements around procurement—that there was a successful relationship between Baxter and Medbuy. Do you think that if it hadn't been for the BPSA, that Marchese would have gotten the contract? Well, I don't think so. That's conjectural, because there was a successful relationship. Besides, Marchese wasn't the cheapest or the least costly. One could argue that it could have been stopped right there. It would have never happened.

Where else might it have been stopped? Well, obviously at the level of Medbuy. If they had, in fact, contractually done what I proposed here, with detail, it would have specified the product, and it would have been fine. They all use the same materials, so it's not a question of materials. Nobody was trying to save money by using cheap materials or anything like that.

The third place was at the level of Marchese, obviously—if somehow they had done the right thing. In my report, I've actually said exactly what they should have done: They should have filled the vials, emptied the rest of the bag and then put the materials back into the bags. That would have solved it, but they would have intuitively had to have done that. That's step number three.

Number four: Everybody should have functioned like Peterborough—somebody should have looked at it and said.

So when I look at it, I'm sorry, I see four participants that are key, and any one of them could have stopped this thing. They're on the ground. Those are the individuals or institutions that are designated to satisfy the best interests of people.

Mrs. Jane McKenna: I'm very grateful for that answer. I guess where I just want to finish off for myself—do I have time still?

The Chair (Mr. Ernie Hardeman): You've got lots of time.

Mrs. Jane McKenna: I guess what I want to say for myself is that ultimately, in the end, I'm not saying that those people weren't—because you're 100% right. You're right in there. You know all that. But if someone has come to me, and my job description is what it is and they've clearly been pointing out that there's a problem and it's been going on since 2001, I think at that point, personally, I would not be looking at everybody else to fix it. I would be trying to figure out what the problem was, because people don't come—it's 2013 now—with the same thing over and over again and you just keep dismissing it and passing it on as everybody else's problem, because there is a hierarchy that has the responsibility of that.

So I'm very grateful for your answer, and I'm not, by any means, not thinking that you're right in what you are saying. I'm just saying that, to me, the buck has to stop somewhere.

Dr. Jake Thiessen: Yes, and I suppose we could say that God created gravity; we've got a problem.

Mrs. Jane McKenna: Well, that's—

Dr. Jake Thiessen: Sorry.

Mrs. Jane McKenna: Okay, that's it for me. Jeff, do you have any questions? I know you just sat down. Do you want to just pass and we'll get our time when we come back?

Mr. Jeff Yurek: Sure. I just want to apologize for being late. I was at the committee next door that we just finished, the tanning bed legislation that's going back to the Legislature.

Welcome again.

Dr. Jake Thiessen: Thank you.

The Chair (Mr. Ernie Hardeman): The third party, Ms. Gélinas.

M^me^ France Gélinas: Chair, how long do I have?

The Chair (Mr. Ernie Hardeman): About 22 minutes.

M^me^ France Gélinas: Thank you.

My first line of questioning will kind of continue what MPP Jaczek had started. Basically, you've just gone through four areas where things could have gone better.

In your report, you talk about how there was a fundamental breakdown in communication. Had the hospital communicated to Medbuy more clearly, had Medbuy said the right thing to Marchese, none of this would have happened. Yet we know that they had an advisory committee of pharmacists that helped Medbuy with that procurement, that contracting out. I find your report is very silent on that. My first line of questioning is, how come the silence on the communication chain?

Dr. Jake Thiessen: Well, I'm not quite certain about "the silence." I felt that I was fairly strong with some of the statements so that, for example, the end user would actually define very clearly what is needed. That was there as one of the recommendations.

As far as the infrastructure that is needed at a GPO in order to make sure that every need of a hospital is supplied—that is, every need in terms of product quality and safety—that can best be answered, obviously, in this case, by the group purchasing organization. I don't need to defend them. I do need to say that they certainly had, as I indicated in your absence, really quite a large collection of pharmacy people from all the member institutions that were, I'd like to think, providing some advice. I do know that they would meet periodically. It wasn't every week, but they would meet periodically. So there was an attempt to gain information that would help Medbuy in making the right kind of decision here, but it boiled down to some details that were not well managed, and that is the essence of it. That's why, as you'll notice in the recommendations that have come down on the issue of specifications—what is the expression? The devil is in the details. Isn't that the expression we sometimes hear?

M^me^ France Gélinas: Yes.

Dr. Jake Thiessen: I'm afraid that without rigid and actually very clear specifications, lots of stuff can go south. Whether you do a renovation or whether you do travelling across the country or wherever, specifications are important. I've said that the future security of the patients in Ontario and elsewhere lies in making sure specifications are really clear.

1510

M^me^ France Gélinas: So jumping from this, the issue of whether an intravenous drug is concentration-specific or total amount-specific is something so basic to the health care system. Anybody who deals with IV drugs knows the difference between the two. Whether you talk to a pharmacy technician, a pharmacist, the nurses—they all know better. They all know that a drug either needs to be concentration-specific or quantity-specific, and they all know how to deal with this. How could we have a culture where health care professionals put their guard down? How could it be that when it came to London, the first one who saw that this was not concentration-specific did not automatically click on? When you talked to all of those people, what brought in a culture where a health care professional actually put their guard down as to the basics of what their professional responsibilities are?

Dr. Jake Thiessen: A very good question. It was obviously inadequate. I have to go back to the specifications simply because that is where one knows what one has. If you say that it is 100 grams per litre, and you have evidence for that, you have a formulation that actually shows what the weighings are, all those kinds of things—and I've identified this in the report about how the specifications are to be written—then you know what you've got. Short of that, you don't know, and so—

M^me^ France Gélinas: But they had reviewed the labels. They had lots of opportunities. We've heard from Marchese, who had really tried to go back to the hospital and get feedback. And yet none of that worked.

Dr. Jake Thiessen: Sadly. Very sadly. And I completely agree with you: It's a shortcoming in a system, in a culture, and one has to really say that, in many cases, the professionals overlooked something that shouldn't have been overlooked.

M^me^ France Gélinas: And you feel that by putting recommendations towards specifications, this won't happen again?

Dr. Jake Thiessen: Well, I think I've tried as best as possible to intervene in this whole system, at various places, and say, "This is what needs to be done." I've used my best experience and insight into all of this to create an inventory, a checklist of things that need to be there and how it's even developed. That's the best I can do.

M^me^ France Gélinas: When you open up—my colleagues told me that your first recommendations you figure are targeted at Medbuy, but really, the first four recommendations are targeted at hospitals. You have made a series of recommendations that would add oversight to an area that already has a ton of quality assurance on it. You have added, in your recommendation, oversight of a part of Marchese that needed oversight, that had none, but I don't get how the oversight of the GPO has improved. Those things, when I try to follow the administrative structure and the corporate structure of these things, make Alfred Apps and Mazza look like a walk in the park. Their administrative structures are really, to me, meant to distance themselves from the hospitals so that they don't fall under the oversight of the hospital.

So here we are, adding oversight to our hospital—I'm not against it, by the way; I'm all for it—but we're adding oversight to our hospitals that already have lots, and we leave those GPOs at arm's length from our hospitals. They have failed us royally, and we put no oversight in. By your report, you value oversight. You've added it to the hospital, you've added it to Marchese, but to the centre of who failed us in the communications chain, nothing will have changed. You are making suggestions to them, and we have no way of finding out if those suggestions will be carried out. I'm guessing that, in the short term, they will; in three years from now, when they will have forgotten those thousands of people who received diluted chemotherapy, it will be back to what it was before.

There is no oversight of those GPOs. There is nothing in your report that talks about governance, that talks about the corporate structures of those things, to make sure that the oversight is carried over. How come?

Dr. Jake Thiessen: All right. I guess quality assurance, in some ways, is a bottom-up program here rather than a top-down. As I understand it presently, there is no oversight-regulatory agency that governs group purchasing organizations. I think you've raised an interesting point, which is, should there be something that is, in fact, done to oversee all of this? I guess that, in the absence of anything before, as I was working through all of this—there is no infrastructure right now regarding all of this.

However, what I've said is that, at the very least, one needs to know who all the vendors are. I've asked for a listing of all the vendors from every GPO, whether it is a public institution or a private institution that is being serviced. I've called for that, so there will be an openness. In the absence of this sort of large infrastructure, it's the best thing that I could do.

But in many ways, I'm calling for kind of a bottom-up, which is that when it comes right down to it, at the level of the patient, which is where the end user engages product and patient, there needs to be an absolute assurance at that point that those products meet exactly what is required. So, moving back up through the chain, this really in some ways defines everything that needs to happen. Pharmacists ultimately need to have the assurance that the vendor has provided exactly what is needed, and the vendor needs to have assurance that it has filled the specifications of the GPO.

That's the procedure that I have proposed for you here. I'll admit I don't have the infrastructure from the top.

M^me^ France Gélinas: So, it begs the question: Why do we need a GPO?

Dr. Jake Thiessen: Well, I guess this is ultimately a question for the hospitals, because it is their service organization, this GPO. It is something that has been developed by them in order to gain a cost advantage in the purchase of a host of commodities.

M^me^ France Gélinas: Yes, but your report goes way further than this. Your report, in the recommendations as well as in the body of it, says that it is inevitable that it will continue, that they have a role to play, and yet they failed us, and we are still leaving the structure in place. We haven't done any recommendations as to how we can pull them into the quality assurance at either end. What am I missing here?

Dr. Jake Thiessen: We may need a government program to oversee the GPOs.

M^me^ France Gélinas: And why didn't you recommend that?

Dr. Jake Thiessen: Well, I suppose I should have. It was short-sighted on my part.

M^me^ France Gélinas: I'll let it—

Dr. Jake Thiessen: I'm willing to admit that that was something that I did not entertain in this report.

M^me^ France Gélinas: But you saw the role that they play?

1520

Dr. Jake Thiessen: Yes, absolutely. I saw the role that they play and the advantages that accrue from that—advantages, obviously, from the point of view of the institutions. They see this as an important thing. I can certainly imagine an even expanded role for GPOs for the future. The idea of some kind of an infrastructure—perhaps government infrastructure, even national infrastructure—which would lead to some oversight of GPOs is something that is worth considering.

M^me^ France Gélinas: Thank you. I'll let it go around.

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

Ms. Helena Jaczek: Thank you, Chair. I'd just like to pick up a little bit on Ms. McKenna's line of questioning.

Since you were, as you've told us, privy to all those conversations with the Ministry of Health and Long-Term Care's working group that they brought together, did you ever hear of any evidence within the ministry that there was some awareness of this regulatory gap, that they'd been aware of it for many years, that it was something that had been talked about since 2001 and had been ignored in some fashion?

Dr. Jake Thiessen: Could you help me here, please, with the regulatory gap? Which one are you referring to? This kind of oversight of GPOs, or are we talking about—

Ms. Helena Jaczek: The one that I believe Ms. McKenna was talking about, in terms of neither Health Canada nor the college of pharmacists were involved in oversight of compounding.

Dr. Jake Thiessen: Yes. Well, I don't want to draw this out unnecessarily, but one of the things that many people perhaps don't appreciate enough is kind of the historical feature. On page 30, I talk a little bit about the whole issue of manufacturing and compounding. If we talk about this regulatory gap, if we really need to call it that, allow me this perspective: The history is that pharmacists really furnished all products for patients, and that goes back to as late as the latter part of the 19th century. I think Eli Lilly was one of the first ones, in 1876, that actually formed a company to begin to produce some of these things. Before that, it was really that all products were actually produced by pharmacists—compounded, okay? So this was considered part of the professional responsibilities of a pharmacist.

That task of providing the products in their final form to patients has eroded and eroded with time, to the point where nowadays it's relatively minor, as I pointed out. This is not the story only in Canada; it's the story in the US.

What has happened, and I've seen this in various places—this is more at the national level, whether it's Health Canada or the Food and Drug Administration—is that because of the fact that there's this professional role that exists in history, and yet the primary agency overseeing medications is a national agency, there's naturally

a kind of careful attempt not to step on each other's toes. Gradually, the national agencies like Health Canada and the FDA have begun to take over more and more of this, but always cautiously, because they view the role of the professional as to be respected. This is not only true in pharmacy; this is true in dentistry and various other places.

What has happened here in this story, really, is that suddenly we see something here where it's almost like a regulatory oversight gap. I've never been enamoured with that concept—I'm sorry—because I've always viewed it in history as just part of the natural ebb and flow of a professional.

Ms. Helena Jaczek: So you would say there was no flagrant neglect on the part of any officials within the Ministry of Health and Long-Term Care in terms of what Ms. McKenna has pointed out and is calling a regulatory gap.

Dr. Jake Thiessen: Yes, I don't see any flagrant—absolutely. I see this as just falling into the accepted customs and practices of both.

Ms. Helena Jaczek: Thank you. I guess to just follow up a little bit on Ms. Gélinas's discussion related to the GPOs, when you're talking a little bit about perhaps the potential for some further oversight—notwithstanding that you didn't particularly recommend it—would you be thinking of this only related to compounded products? Would you see the need for something like that when you're just dealing with a standard compound that comes straight from the manufacturer—it isn't changed in any way? Would you see the need there?

Dr. Jake Thiessen: Well, when it comes from the manufacturer directly to the patient, through the pharmacist or dentist or whoever, then we would say that that's part of the accepted distribution system that Health Canada manages. In terms of these kinds of products, it might be just a little bit different than I proposed at various places where something like Health Canada needs to be involved. The idea, though, that a group purchasing organization needs to be held more accountable by somebody—that's worth exploring.

Ms. Helena Jaczek: In terms of quality assurance—we were talking about this in my first round—you suggested that perhaps when that first admixture arrives, that it be tested to ensure that in fact everything is correct. Would you see any potential—as you know, we just heard about a situation where various diagnostic imaging has been checked and been found to be faulty out of Lakeridge and so on. Would you see any need for quality assurance where another pharmacy comes in and checks that particular product or on a random basis—some sort of cross-pharmacy quality assurance as a check and balance?

Dr. Jake Thiessen: Well, in the various viewpoints that I've either sought or that came to me spontaneously, there was one company that said, "Why don't you recommend enlisting us to actually oversee some of these things?" So there are people, there are businesses that I think are following this entire story to see whether there is a new opportunity to provide quality assurance that doesn't exist. So I guess time will tell whether some of this will take place.

Ms. Helena Jaczek: Thank you. I'll save whatever I have left.

The Chair (Mr. Ernie Hardeman): Thank you. The official opposition: Mr. Yurek. You have 12 minutes left.

Mr. Jeff Yurek: Thank you very much.

Before I ask you any real questions, just to plug the profession of pharmacy: When something goes wrong, you can always call a pharmacist to come and fix up the problems. I've just got to add that in there.

Dr. Jake Thiessen: Thank you, Mr. Yurek. Whether they're an MPP or not?

Mr. Jeff Yurek: Exactly.

Just going over the infrastructure that isn't in place to oversee the GPOs, do your recommendations give a requirement for Medbuy to introduce their own standard operating procedures or a quality assurance program? Will your recommendations lead to that?

Dr. Jake Thiessen: In essence, that is it, because, as you'll notice in the report, I've recommended that they, in fact, connect with the Canadian Society of Hospital Pharmacists, because they serve the hospital community, and ISMP to make sure that they have the right kind of qualifications and standards there. So in essence, it is basically a definition of the standards that are necessary. I haven't actually specified SOPs formally, but I would like to think that that would be part of it.

Mr. Jeff Yurek: Is there a place in this process that you've undergone where you'll do a review in six months to see what they've done with your recommendations and—

Dr. Jake Thiessen: My wife would say no, but that is not in my hand; that is the hand of others. I have not been engaged on that.

1530

Mr. Jeff Yurek: You have not been engaged on that. Okay.

That was my concern coming forward that has been raised: There is no oversight of these GPOs—a chance—and you've thrown out some recommendations that possibly could lead to a quality assurance standard operating procedure policy to ensure that this never occurs again. However, beyond this committee reporting this and letting the government do what they should be doing, there's no follow-up to bring the trust back to the person getting that chemo drug product that we have not only implemented changes but we have verified that those changes are ensuring a safe product and there's a safe system now working at the hospital level.

Dr. Jake Thiessen: My mandate was such that—and I've delivered on the things that were requested of the mandate, but in terms of making sure that these things happen, I guess the only assurance I can offer at this point is that, immediately following the press release on August 7, there was a working group call and there was—what I heard, because I'm distinct from it; I can just listen in. But there was a mass assurance that, in fact,

they would carry through on every one of the things that were handed to them. This ranges from Health Canada down through the GPOs and so on. People were going to try to make this all happen.

That's the best I can do, Mr. Yurek, at this point. I do know, just in keeping my ear to the track, that there are things that are ongoing to support what was promised at that point.

Mr. Jeff Yurek: With regards to your process that you underwent, did you find any gaps in communication alone, in general, between Medbuy and front-line health care workers such as your pharmacy technicians and pharmacists? Are they able to access Medbuy at any time with their concerns?

Dr. Jake Thiessen: As far as I know, and I explained this a little bit before, Medbuy uses a system where they enlist the pharmacists from the representative institutions that are part of the Medbuy consortium to actually provide advice at various points in time. So there is certainly that engagement. How successful or unsuccessful that is at this point is difficult to say because I didn't really delve into all of that. But certainly there is a system in place for that.

I think what has happened is that, with the recommendations, there will be a new call for engagement, because you cannot institute these recommendations at the level of the GPO without having a whole lot of pharmacy input.

Mr. Jeff Yurek: Jane, did you want to ask something?

Mrs. Jane McKenna: Yes. I just want to go back to where we were just prior to going around again. Just so I'm clear on what you said, so I'm not saying anything that you haven't, while you were speaking, you said the responsibilities of the province and the federals have eroded over time and it's just become custom and accepted. Is that correct?

Dr. Jake Thiessen: The erosion was related to pharmacy and the fact that over time its preparation of products—what we would call compounding—has eroded from a point in, let's say, the middle 1800s, where they were basically doing absolutely everything, to now, where it's relatively little that they do on a comparative basis. What happened in the course of all of this is that something that was basically a professional jurisdiction—compounding—has increasingly become a national jurisdiction because Health Canada oversees manufacturers. It's kind of the shape of a curve that we can draw in the air about who oversees what. There has been, and I mentioned this before, this kind of respect that Health Canada or our food and drug administration has for the professions which allows them still to kind of oversee things that belong to their jurisdiction, and that's how it's been left. I don't think it's necessarily, with all due respect, a major snafu here regarding regulatory oversight. It represents something that's paved by decades of history and it's just an evolving thing.

Mrs. Jane McKenna: Okay, thank you.

Dr. Jake Thiessen: I'm not sure if I addressed your question right.

Mrs. Jane McKenna: Yes, you have.

The Chair (Mr. Ernie Hardeman): To the third party.

M^me^ France Gélinas: I'll open with something that you don't address much in your report either: the pediatric cases. I was wondering if you had found out more than what you have in your report as to what the outcome was on the dosage in the 30 pediatric cases.

Dr. Jake Thiessen: I have not, and I did not. For me, some of this came subsequent, as I was trying to—there were some uncertainties about total numbers, so I asked for an accounting of all patients. This was really, in some ways, after I had done all the visits. I wanted to get hard evidence because I was challenged by, "Well, you've said this number and these people have said this number," so I wanted to make sure I had the numbers right. I contacted them and I said that I want a full inventory. I want to know who got what, because it wasn't even clear whether some of them got gemcitabine and cyclophosphamide. I wanted to get all the information. That's presented in the appendix, where I've identified—as I said, at the outset, there were 30 individuals—I've just got to make sure I have my numbers correct here—who were in fact receiving cyclophosphamide for purposes of knocking down their immune system, which is 30, correct, in appendix 3. They only received cyclophosphamide. I only learned that later on.

As far as the pediatric cases, I tended to learn that later on as well. There was some smattering of information, because I asked, "What was the spectrum?" They said, "From young to older," but I didn't pursue that at that point. I'm sorry, I can't help you on what happened to the pediatric cases. I don't even know the regimen they were on.

M^me^ France Gélinas: Okay. That's fine.

Dr. Jake Thiessen: I'm sorry.

M^me^ France Gélinas: No, no, it was an aside, as in you mentioned it in your report. We've heard something about the pediatric cases, but not a whole lot. So I guess we will leave it at that.

I want to come back to comments that we have heard, where, after Marchese got the contract, they really tried to connect on a number of occasions with the pharmacy staff in the hospitals. It started with London because London was the first one. Although, from what we hear, when London needed to connect with Marchese, Marchese would comply; when Marchese needed to connect back with the end user, the doors were not open for them to do that. From your knowledge of the business, why did that happen?

Dr. Jake Thiessen: I cannot answer that; I'm sorry. I don't know the details of such problems, if they existed. I did ask, when I was at the hospitals, "Did you contact Medbuy or Marchese about this discovery?" and they said yes, that they had. So I knew there was communication. It was intriguing, I felt, that they would go to both Medbuy and Marchese to try to get answers to things. I

would like to think that in the infrastructure that exists around this there would have been clear lines of communication around such issues. They nonetheless did contact them, but the degree to which, the difficulty that you were alluding to, I do not know that.

M^me^ France Gélinas: Did they share that with you? Did you know that before you came here?

Dr. Jake Thiessen: That I came—

M^me^ France Gélinas: Before you and I had this conversation, had you been made aware?

Dr. Jake Thiessen: When I was at the hospitals, I said, "Did you contact Marchese?" and they said yes. I asked did they get any responses and they said they had some difficulties with the responses, but that was on the discovery of the incident. That was the extent of the communication I had with them over that.

1540

M^me^ France Gélinas: Because when you identified the four areas where—

Dr. Jake Thiessen: It could have been, yes.

M^me^ France Gélinas: —things could have been caught—in the recommendations that you made in your report toward specification, and the first batch will be tested by the pharmacists is one of the recommendations that you made—those are pretty basic principles that apply in health care all the time. Why is it that it didn't come to them without you having to put it on paper?

Dr. Jake Thiessen: Good question. Short-sightedness, too busy, maybe not caring enough.

M^me^ France Gélinas: All of the above?

Dr. Jake Thiessen: All of the above.

M^me^ France Gélinas: This is a little bit—

Dr. Jake Thiessen: I can't answer for them.

M^me^ France Gélinas: No.

Dr. Jake Thiessen: At best, it's conjecture. But I said near the beginning somewhere that I think everybody's embarrassed by this whole thing, embarrassed to the point of, in some cases, very despondent about why this happened and how it happened and who is responsible, and would love to rerun the tape and fix this up, but unfortunately, it happened.

M^me^ France Gélinas: Yes, it did. When you were talking, when you had your meeting with the pharmacy staff and the staff from the hospital—you gave us all of the information on those different meetings—I'm guessing: What was the tone of it? You started to talk about this. Do they realize that they could have caught that?

Dr. Jake Thiessen: They're very embarrassed. That's why I said moments ago that that is a reflection on individuals and institutions. When it comes to institutions, it's individuals, ultimately.

I obviously feel for them as well about what happened. If it was one of my sons or daughters as a pharmacist in those locations and had been responsible—I can imagine how people feel. They were devastated by this.

M^me^ France Gélinas: Go ahead.

Ms. Cindy Forster: Just one question: When we had Marchese Hospital Solutions here over, I think, two different periods, we asked each of the pharmacists who appeared before us about their experience around chemotherapy admixture-type programs, and none of them really had any, if a very small amount of, experience with chemotherapy agents. But you don't address that part in your report. Do you have any comments on that? I know you talked earlier about people having credentials as opposed to just licensing, but if you wouldn't mind speaking to that.

Dr. Jake Thiessen: Okay. The question you're asking, if I can translate, is: Should the vendor who is doing drug preparation have personnel who have experience in every therapeutic category?

Ms. Cindy Forster: Should the vendor and should the middleman—the GPO—perhaps make that one of the criteria?

Dr. Jake Thiessen: Okay. I would personally not be prepared to go there, and I'll tell you why. It's because, if you look at the array of products that are there, they range from what we would consider relatively low-risk to high-risk products in just a host of areas, from antibiotics through epidurals to TPN, chemo etc.

If the specification were that the one giving oversight at the level of the vendor had to have personal experience in each one of the areas, you wouldn't find people like that, or you would have to have so many employees that you couldn't afford to do any of this.

I think, when it comes right down to it, drug product preparation is fairly generic. My personal view is it doesn't require specialization in every one of the therapeutic categories in order to be successful and robust in delivering the required kinds of products. I think you have to be absolutely knowledgeable and experienced in product production, so that whatever the ticket says for the production is what you produce. That's GMP, good manufacturing practice. I don't want to toot my horn here, but that's why I've said it isn't adequate to have a pharmacy licence and be registered with the college. My personal view is that you have to have credentials in those areas, for the good of patients and the quality products that you—

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

We'll now go back to the government: Ms. Jaczek.

Ms. Helena Jaczek: Dr. Thiessen, obviously our focus is on looking forward and implementing your recommendations. I wonder if you could just lead us through how you see, in the future, a group purchasing organization putting out their requirements in terms of concentration and perhaps use of cyclophosphamide. And lead me through what you see as the ideal process in terms of obtaining that compounded product. In other words, who should be involved in the discussions? To what extent is the entire process of the compounding gone into? Could you lead me through how you envisage this? Also, scoring, the evaluation criteria—you've mentioned experience. Could you just go through some of that so that I have a really clear picture?

Dr. Jake Thiessen: When it comes to the entire matter of a product, the requirements are defined by, usually, a combination of medicine and pharmacy, ultimately. The dose that is requested is a decision that is made, typically, by medicine for a particular patient. Once you have the dose defined and you have the end user who is actually helping to deliver the dose to the patient—that's the role of the pharmacist, typically. Between the two of them, one can define what the dose is, how it's to be administered to patients, if it's in fact in a diluted state, as we talked about briefly before. That defines what the characteristics must be of the arrived product.

As far as the vendor is concerned, that vendor now knows what the expectations are for the arrived product. However, the way this entire system works, it all works through a GPO. In many ways, it is the GPO's responsibility, ultimately, to define the specifications very clearly. That GPO can't do that using individuals who, dare I say, have non-professional qualifications. They must be professionals, because it is the professionals that can best translate either the physician's orders or the product specifications to a GPO, who then passes it off to the vendor. That's the flow that is required.

In terms of the requirements around the way that a vendor actually produces it, there are things that need to be embraced, which I've indicated. It doesn't matter whether the vendor is a pharmacist who is actually producing it or an organization like Marchese that does it on a grand scale. There need to be specifications on how that is being produced. This is why I've been fairly adamant, in my report, that the agencies that oversee this must ensure a higher level of quality specification—I'm going to add the word "specification"—by embracing such a thing as USP 795 or 797, because these things are pretty clear when it comes to what is expected. That's our best standard.

By the way, the Canadian Society of Hospital Pharmacists has been working on a draft of all of this already. This was in the works. So there are things coming. They're going to be working with Health Canada to actually bring this forward. I was made aware of that. Okay?

1550

There's this flow that begins at the level of interest of the patients, works through product specifications in light of that, and while that's the instruction to the vendor, ultimately, because of the system here, that needs to be appropriately transcribed by the GPO to the vendor so that there is no miscommunication, no shortage of instructions. Maybe what it requires is, as has been suggested, that there be a national organization that oversees GPOs to make sure it really happens.

Ms. Helena Jaczek: So in terms of evaluation criteria, when the response to the RFP is examined by the GPO, what would you recommend as the evaluation criteria for these types of compounds?

Dr. Jake Thiessen: What I've suggested is that there in fact be—first of all, products shouldn't all be in one bucket, as it were, all considered equally. So I proposed that there actually be an assignment of a risk to a product that is being prepared. This is actually laid out very well in USP 797: what kind of risks are identifiable, whether it's low, medium or high. There are many factors that determine that. We don't have time to go into that, but that's where I think that needs to be done so that when an RFP is now issued, everybody knows that these and these products are in such a category, and there might be three categories potentially. Somebody who is going to be involved in preparation of high-risk materials—my view is that there be special criteria to allow such a manufacturer to actually deliver on those. I should call it a "vendor." I'm sorry: special requirements from a vendor who delivers on those.

Ms. Helena Jaczek: That would include their experience in providing this product previously or—

Dr. Jake Thiessen: Or they do a trial run. There are always things like beta versions. We know that in the software industry. There can be a way of testing them to find out whether they'd do the right job.

Ms. Helena Jaczek: Thank you.

The Chair (Mr. Ernie Hardeman): Okay, thank you very much. We have five minutes left for the official opposition.

Mr. Jeff Yurek: Thank you, Chair.

Dr. Thiessen, the CCACs currently have a system where they RFP out pharmacy services, and the end results of course are different. Off the top of your head, or maybe you've sought it out, is there oversight of the CCACs on this RFP process at all?

Dr. Jake Thiessen: There are requirements. Mr. Yurek, there are requirements. Is there oversight on the CCACs? I'm sorry, I can't answer that.

Mr. Jeff Yurek: I'm just trying to put this together because, right now, we're moving into—your requirements, hopefully, will not end up beside Dr. Drummond's report on a shelf somewhere, but they'll get implemented. But I'm hoping—after they're recommended, now we're finding out that it looks like there's still going to be an area that we need to look at to ensure that these organizations like Medbuy are performing to our qualities that we expect of them.

CCACs have been doing this for a while. I know they have their own committees; all the CCACs get together and they try to make the best possible process available. The LHIN directs some funding to the CCACs, and the LHIN directs some funding to the hospitals.

I'm just wondering if it's already invented somewhere else there of what's going on. Maybe it's going to fall back into the lap of the Minister of Health and her ministry to actually be the overseer of this itself instead of looking at some other national structure or using what we have in place. Your thoughts on what's available?

Dr. Jake Thiessen: Well, thank you. Again, my understanding with these GPOs is, they do not function only in one province. We saw that in this particular case. If we leave this in the hands of a province, I'm not sure whether that's the necessary safeguard. It's only a ques-

tion in view of the things that you came forward with, suggesting about the oversight.

I wonder whether what we need is national oversight on all of this. As surfaced in this particular case, the products flowed from Ontario to New Brunswick. So my concern in all of this for the well-being of Canadians—not Ontarians; Canadians—is that in fact what we are dealing with here is something that safeguards the interests, no matter where you are in this land and no matter how the products move.

Therefore, if a GPO is instrumental in allowing vendors to distribute products across the country, would it be wise to think about a national organization that oversees this—again, to safeguard everybody?

Mr. Jeff Yurek: Okay. Thanks for everything you've done.

Dr. Jake Thiessen: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. You held up very well under some gruelling questions. Thank you very much, Doctor, for being here this afternoon. I think your presentation has enlightened the committee considerably, and we very much appreciate that and all the work that you've done to bring the matter this far forward. Thank you very much.

We'll just hold on a minute. I believe our next deputation is out in the hallway, so we'll just wait for a moment while they come in.

Okay, we shall proceed with the meeting.

MEDBUY

The Chair (Mr. Ernie Hardeman): We want to thank our guests from Medbuy, who are going to make a presentation over the next while.

I understand that of the four people in the panel, there are two that have been sworn in and two that haven't. I just want to remind those that have been sworn in that you are still sworn in, and we'd ask the Clerk to swear in the other two, just in case you have something to say. Thank you.

The Clerk of the Committee (Mr. William Short): Ms. Kelterborn, I'll do you first. Did you want to be affirmed or swear an oath?

Ms. Ann Kelterborn: I'll swear an oath.

The Clerk of the Committee (Mr. William Short): If you'd just put your hand on the Bible, please. Thank you.

Ms. Kelterborn, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Ann Kelterborn: I do.

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

Mr. Swartz? The Bible as well? Okay. Thank you.

Mr. Swartz, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Ron Swartz: I do.

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

The Chair (Mr. Ernie Hardeman): Very good. Thank you very much. With that, we will turn the floor over to you, after a giant thank you for being here. We'll turn it over to you for your presentation, and then we will have questions. The available time will be split evenly between the three parties. In this deputation, we will start with the third party for the questioning.

With that, the floor is yours.

Mr. Kent Nicholson: Great. Thank you.

I believe our opening statement has been distributed, so I'll encourage you to read along with me.

I will start this afternoon by reintroducing myself and my colleague Michael Blanchard and by introducing two new team members from Medbuy who are here to assist the committee today.

1600

I am, as many of you will remember, Kent Nicholson, the president and chief executive officer of Medbuy. With me today is Michael Blanchard, who also attended with me on May 6, 2013, when we first appeared before this committee. Michael is our vice-president of pharmacy, clinical services and business development. He is a licensed pharmacist who joined Medbuy in February 2013.

Now let me introduce the two new members of our panel. Firstly, Ann Kelterborn is our director of strategic sourcing and member services, pharmacy, with Medbuy. Ann has 30 years of pharmacy experience, having worked in hospital, retail, industry and GPO settings. She is a licensed pharmacist and also received her MBA in 1995.

Also with us today is Ron Swartz. Ron is the manager, clinical services and patient safety, pharmacy, with Medbuy. He's a graduate of the faculty of pharmacy at the University of Toronto and has spent his entire career, prior to joining Medbuy in 2005, in a hospital pharmacy setting. He has worked in large and small community hospitals as the director of pharmacy and in a pediatric teaching hospital. He has a wide array of clinical experience, including pediatrics, pain management, palliative care and infectious diseases.

Recognizing that it has been some time since our first appearance, we thought it would be helpful to reiterate some background on Medbuy and the work that we do.

Medbuy is a national health care group-purchasing organization 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 and pharmaceuticals. The nature of the work that we do tends to drive a higher level of standardization by the hospitals, reducing costs and product

variation. Patient safety and product quality are always a focus of our work.

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

Specific to our pharmacy committee, the committee is comprised of senior licensed pharmacists from our member hospitals.

Medbuy operates like 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, member spend against Medbuy contracts totalled $627 million. Since our inception in 1989, we have saved our member hospitals hundreds of millions of dollars that have been redirected to provide front-line patient care.

Prior to this incident, we had a flawless record of providing on-spec products from approved suppliers to our member hospitals.

We welcome the opportunity to appear today as this will provide us with the chance to update the committee on certain developments that have occurred since we were last here, including the report that was released by Dr. Jake Thiessen in July.

The three specific areas that we'd like to address today are as follows: first of all, the regulatory environment; secondly, Medbuy's response to the recommendations of Dr. Thiessen; and lastly, the actions taken by Medbuy in connection with the existing Marchese contract.

Starting with the regulatory environment: As we discussed when we were before the committee on May 6, compounding and admixing by third parties is a service available to hospitals in Ontario for nearly three decades. It's well known both by industry participants and by regulators that this was an activity that did not directly fall within the jurisdiction of either Health Canada or the College of Pharmacists.

We fully support a higher degree of oversight, regulation and licensing. As we indicated previously, Medbuy's awareness of this lack of direct regulatory oversight for this particular activity led us to include certain steps or precautions in our RFP. This included requiring the activities to be carried out under the supervision of a licensed pharmacist and referencing the need that the third party compounder adhere to the USP 797 standard, which is considered the pharmacy gold standard for carrying out these activities.

Since Medbuy's RFP was conducted in the fall of 2011 and, indeed, even since we appeared before this committee on May 6, there have been some important changes in the regulatory environment that will have a bearing on the provision of compounding and admixing services by a third party, whether provided directly to a hospital or through a GPO such as Medbuy. These changes are as follows:

Firstly, there have been amendments made to regulation 965 under the Public Hospitals Act to now include directives to hospitals about the types of organizations—and the requirements those organizations must meet—which may supply products such as these to public hospitals.

Secondly, amendments have been made to the Pharmacy Act to now introduce the concept of a drug preparation premises or DPP, and there is now a requirement that a third party carrying on compounding and admixing services must have a DPP licence such that it will fall under the regulatory oversight of the Ontario College of Pharmacists, which will in turn provide the college with the ability to conduct inspections.

Thirdly, Health Canada has recently taken the position that third party providers of compounding and admixing services must obtain a narcotics dealer's licence under the Controlled Drugs and Substances Act. We are specifically aware that Health Canada has taken this position in relation to Marchese and that Marchese has in fact obtained such a licence.

Fourthly, the province has indicated that it will introduce legislation in the fall to address Dr. Thiessen's recommendation 12, which states, "The OCP shall license all pharmacies operating within Ontario's clinics or hospitals."

For future initiatives, Medbuy's RFP documents will clearly make compliance to these new federal and provincial regulations, where applicable, a mandatory requirement.

Turning to our response to the recommendations in Dr. Thiessen's report: As the committee is aware, Dr. Jake Thiessen was commissioned by the Ontario Ministry of Health and Long-Term Care to conduct an investigation into the oncology underdosing incident and to provide recommendations about how similar events or incidents could be avoided in the future. Dr. Thiessen completed his work and delivered his report in July of this year.

Medbuy completely supports all of his recommendations and specifically those that relate to GPOs such as Medbuy. I'd like to take this opportunity to advise the committee of what Medbuy has already started to do in order to implement the recommendations of Dr. Thiessen that pertain to GPOs.

First of all, recommendation 1—and these are direct quotes and lifts from his report:

"Notwithstanding the underdosing incident, the continued use of group purchasing organizations (GPOs) to negotiate vendor product preparation pharmaceutical services shall not be discouraged. However, improvements are needed in the GPO-based processes."

Medbuy is absolutely committed to continuous quality improvement and has in fact hired a consultant as an independent process expert to undertake a broad review of all of our contracting processes to identify specific ways in which they can be improved. In addition, Medbuy, in conjunction with the members of its pharmacy committee, has created a pharmacy subcommittee to

conduct an assessment specific to the contracting process for the sterile preparation compounding service. To supplement the subcommittee's expertise and to provide a degree of impartiality, we have engaged an expert consultant from the Institute for Safe Medication Practices to work with us through this review.

Recommendation 2: "Every GPO shall review its procurement process to ensure that risk for patients is considered an essential evaluation and adjudication criterion when considering proposals."

As we indicated in our testimony before this committee on May 6, Medbuy has always recognized our contribution to patient safety and care. In order to strengthen our existing risk management processes, we are now introducing enhanced risk assessment tools and mitigation strategies. We have begun our improvement efforts by risk rating every initiative and every product within each initiative that we plan to tender to assist in the development of the sourcing strategy. Risk rating means that you treat high-risk products—which would include chemotherapy medications—differently and apply an even greater degree of diligence to sourcing, procurement, delivery and education in relation to those products. Further enhancements may also come from the pharmacy subcommittee review and from other stakeholder groups.

Recommendation 3 stated: "Every GPO shall develop and adopt a standardized product and/or service specification description that outlines the requirements for contracted sterile or non-sterile pharmaceutical preparation services."

1610

Medbuy is committed to working collaboratively with all stakeholders, including our pharmacy committee members, the Institute for Safe Medication Practices and the Canadian Society of Hospital Pharmacists, to develop standardized product and service specifications for contracted sterile and non-sterile pharmaceutical preparations. In the interim, as part of our current contract remediation process, Medbuy's pharmacy team, with the assistance of the pharmacy committee, has reviewed the current contract specifications, has prescribed clarification of compounding procedures related to end-user requirements and has ensured that all labels represent the final products precisely.

Finally, recommendation 4: "Annually in January, each GPO shall publicize information regarding the contracted pharmaceutical services provided by all its vendors."

Medbuy will comply with this recommendation, and in fact, this information is currently available. The Medbuy contract with Marchese is the only contract for pharmacy service that Medbuy currently has.

Thirdly, I'd like to transition to a short discussion around the actions we've taken in connection to the existing Marchese contract. Since the discovery in March of this year of the chemotherapy underdosing incident, Medbuy has requested Marchese to make certain changes to their practices that are required in order to ensure this type of incident is not repeated. Those changes include: To ensure that end-user requirements are understood and met, Marchese has undertaken to review with each participating hospital the compounding formula and label requirements for each item supplied. Marchese will obtain sign-off from the hospital attesting that the items supplied meet their requirements.

Secondly, specific to chemotherapy products, all hospitals have moved this activity in-house. With no further demand for these products, our plans are to remove them from the contract. Should demand for these products appear at some point in the future, the sign-off process that I described above will be utilized.

Thirdly, specific to narcotic products, the requirement that these products be concentration-specific has been reinforced. An improvement implemented by Marchese in August, as a result of our discussions, is the use of sterile empty bags instead of pre-filled commercial bags in the preparation of narcotic items.

Lastly, in the case of antimicrobial products, the use of commercially filled bags has been accepted. Labels for these products must contain the name and total amount of active ingredient in the bag and designate it is a single-dose bag and the nominal volume of the bag expressed as a range.

We feel confident that these improvements in the practices of Marchese under the terms of the current contract will address and remediate any factors that contributed to the underdosing incident that arose earlier this year.

The current contract expires December 31, 2013. At the present time, we have not made a decision regarding a future contract for compounding services. Consideration will include identifying the needs of our membership as well as changes in the regulatory environment.

In conclusion, we have spent a great deal of time reflecting on what went wrong in this situation. What is now apparent to us is that all stakeholders involved in this incident relied on assumptions. Some of these assumptions ultimately proved to be incorrect. The actions that we've highlighted, both related to responding to Dr. Thiessen's report and in remediating the existing contract, are focused on detailing facts and removing any reliance on assumptions or interpretations.

We remain deeply aware of the impact this incident has had on patients and their families. To them we again express our sympathies and pledge our commitment to do everything we can to avoid a reoccurrence of such an incident.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We will have about 35 minutes per caucus for the questions, and we will start again with the third party. Ms. Gélinas.

M^me^ France Gélinas: Welcome back to Queen's Park. I will start with some of the information that you shared with us in your opening and that is still not clear to me.

The corporate structure of Medbuy: You act like a not-for-profit but you are not, under the law, a not-for-profit corporation. What exactly are you?

Mr. Kent Nicholson: We are a corporation, but the intention in describing our operating model was to be clear that we generate no profits. Any profit or any revenue that is in excess of our operating expenses is returned to our membership 100%. We, in fact, operate similar to a co-operative, if that helps people understand the nature of the work that we do.

M^me^ France Gélinas: What would keep a hospital purchasing department from doing the exact same thing you are doing for a number of hospitals in and out of province? The purchasing department at UHN is huge. They could get deals similar to what you're getting by purchasing for a number of hospitals. What's the difference?

Mr. Kent Nicholson: I'm not sure there's any particular difference, other than the fact that we already exist; we already have the infrastructure and we already have the knowledge base.

I think I shared with the committee the first time I was here that we're not a large team; we're 50 or 60 people. Roughly 20% of our team are licensed health care practitioners: we have registered nurses; we have a physician on staff; we have licensed pharmacists; we have pharmacist technicians.

We started from very humble beginnings. We were three hospitals in 1989, and it was a simple concept: that they had similar needs. The ability to aggregate their volume would tend to get attention in the marketplace, drive better pricing, and that continued for a significant period of time.

Our membership has grown now to include about 25 full members and probably 75 hospitals, so some of our members represent more than a single facility. We continue to aggregate volume and generate savings in taking that to market.

But additional to that, we help foster the ability to drive standardization, so it's really in the way that we work. We have our committees—and I think the first time I was here, I also described our committee structure. We have four committees, and the pharmacy committee is one of those committees. Every one of our member hospitals has a representative on our pharmacy committee. We work in a uniquely collaborative fashion.

We very much are, I think, an extension of our hospitals. We're an extension of the purchasing departments of the hospitals. There's a clear delineation for things that they are buying in common. They tend to rely on our process and expertise for things that are unique to the hospital, and there are hundreds or thousands of those items. Their purchasing department is working hard to kind of keep ahead of the BPS requirements of all of their purchasing activities.

M^me^ France Gélinas: I'm sure you've read Dr. Thiessen's report, like we all have.

Mr. Kent Nicholson: Yes, we have.

M^me^ France Gélinas: He puts a lot of emphasis on oversight. He makes recommendations that the pharmacies in hospitals—although hospitals are heavily regulated and have many layers of oversight, he has added a level of oversight. He looked at Marchese and basically did the same thing: He said that we have to put in place oversight, and this has been put in place through the college etc. But because of your structure, you don't fall under the many layers of oversight that appear for the hospitals, and here you are with no oversight. Any comments about that?

Mr. Kent Nicholson: I'd make a couple of comments. Certainly we don't operate under direct oversight, but we have regulations that we're under an obligation to follow, the Broader Public Sector Accountability Act being one of those in terms of how we run our initiatives.

M^me^ France Gélinas: Which Dr. Thiessen identified as one of the problems that led to where we're at now.

Mr. Kent Nicholson: We are fully transparent with our membership, so our membership has the opportunity at any point in time to review any of the work that we do. That's not necessarily a common practice, but we have had a hospital member's internal audit department request a review of a number of contracts of ours to assess compliance and understand the process, which we were happy to carry out, and the hospital was very pleased with the outcome of the exercise.

1620

More broadly, would we take issue or exception with oversight? I don't think we can talk out of both sides of our mouths. I was clear in my opening statements that a number of areas of oversight, be they in a hospital setting or be they in the compounding environment with third parties—I have no objection to the work that we do coming under some oversight. I'm not quite sure what that would look like, who would do that or how that would manifest itself, recognizing that we have membership that crosses the provincial boundary. But, again, we are a fully transparent organization, and I would have no issue or objection to some form of oversight that we would come under.

M^me^ France Gélinas: You have made a number of comments about things that have changed. You made reference to the changes to the Public Hospitals Act, to the Pharmacy Act, to the narcotic dealers' licences, and the fourth one is what will be coming regarding the college looking after hospital pharmacies. But this is not where the problem arose. All of this could have been in place, but we still would have ended up with a failure in communication as to what was needed.

Mr. Kent Nicholson: I'm not sure why you say that. Our feelings have always been that increased regulation and increased oversight related to all of the stakeholders had the potential to avoid this situation.

M^me^ France Gélinas: Are you surprised, then, that there was no increased oversight recommended for GPOs?

Mr. Kent Nicholson: To be quite frank, I'm not sure that I thought about it before arriving today. That's my honest answer. My honest reaction is the same: I don't have any opposition that we would come under some form of oversight.

Mr. Michael Blanchard: The regulatory oversight for the clinical component of what we do is covered under the hospital. A lot of our decisions and clinical reviews come from our hospital members' various committees.

Certainly, having this additional oversight that Dr. Thiessen has recommended—the specifications may have been standardized for this type of activity. There's no guarantee, but it may have assisted in mitigating this risk.

M^me^ France Gélinas: The idea of concentration-specific medication is such basic knowledge for any professional who works with IV drugs. Whether it's a pharmacy assistant or a nursing assistant, they all know the difference between a drug that is concentration-specific rather than amount-specific. Yet you had a committee in place, Medbuy reviewed, Marchese showed you the label of what they were going to do, it went to the hospital and, all throughout, nobody caught it.

If it had only happened in London, you'd say, "Human error; they did not catch it," but it happened in more. It happened in three. The fourth one finally caught it. That leads one to believe that it is a systemic problem, yet Dr. Thiessen does not talk about the failure in communication. When you talk about what you are doing to improve so that it never happens again—and I believe you when you state on the record that you don't want it to happen again—none of you address that.

I don't know who to address my question to, so I'll go to you.

Mr. Michael Blanchard: Your question is, Dr. Thiessen did not address the failure in communication, or the gap in communication?

M^me^ France Gélinas: And neither did you today when you came and told us about what you have done so that it never happens again.

Mr. Michael Blanchard: I believe we may have mentioned that—or Kent, here, did address that. But we certainly have given serious thought to the whole process and how we could prevent it. Certainly, we acknowledge that there were some assumptions in our methodology that we're certainly taking steps to—the knowledge that we had was based on certain assumptions, and that was a gap in our communications.

Mr. Kent Nicholson: I'll make one comment with respect to—again, in reading an opening statement, sometimes it's difficult to add context for what we have here. But the concept of risk rating and the concept of not only risk rating the overall initiative but risk rating down to a product level, I think, have a real and impactful impact in a situation such as this.

We took 117 products out to market. We did assess risks. From an overall initiative perspective, we assessed risks—things like stability, vendors' ability to supply, and those types of things. We wrote a specification that way.

Had we risk-rated the individual products, I think we would have started to see some groupings. We very likely would have placed at the very top of the list the chemo products in question as being the highest risk, both in terms of handling but also in terms of sensitivity to dosing. As soon as you identify something as high-risk and do something as basic or fundamental as put it in your RFP in that way, it starts to turn your mind to a different way of taking things to market. That's what we were trying to get to.

If we had identified these four products—two gram and four gram of gemcitabine and cyclophosphamide—as high-risk, and maybe the highest-risk products, we would combine that with the fact that the overall spend on these products was less than $10,000 on a contract worth $2.6 million. It may have started to take us in a number of different directions. One is, we could have more clearly articulated the specifications. We could have told the compounder how to compound the product. We could have taken these four products out of this RFP altogether and tendered them very separately. There are a number of things.

Our response to the recommendation was, "We are going to risk-rate every product in every initiative that we take to market." Inherent in that—we take some very large initiatives to market; 117 products would be not a large initiative by our standard. We have initiatives that have hundreds or thousands of line items. Going through a process of risk-rating every one of those products to identify and start to stratify, "What are the highest-risk products within this initiative?", just intuitively and naturally takes your mind to a different way of handling those products. How you do that in each instance is unique to that initiative, but what has unlocked it for us is this concept of risk rating at a product level.

M^me^ France Gélinas: If I come—sorry.

Mr. Michael Blanchard: I was just going to add to your question. We have, in our remediation plan, addressed—Marchese has undertaken to ensure that the communication—to review, with each hospital, the label and the procedure and the formula for preparing the product, and obtaining a sign-off. That's something that we've introduced in the current contract and that we plan in future contracts. This will address that communication gap and ensure that the clinical end user is aware of exactly what they're receiving, and the label. We stated that in our opening.

M^me^ France Gélinas: Okay. Coming back to my opening comments, what would happen if we were to bring you back under a hospital corporation umbrella?

Mr. Kent Nicholson: I'm not sure exactly what—under a hospital? What does that model look like in your mind? Is that part of the provincial government? Is it connected to one hospital?

1630

M^me^ France Gélinas: You are connected to one hospital corporation.

Mr. Kent Nicholson: Again, if the mandate of that organization is to standardize and group buy and aggregate, I'm not sure how they operate any differently than we do today. They sound like the same thing. It's just that you're resident or connected or tied to one hospital as opposed to the way that we are structured, that all hospi-

tals are equal members and equal voices around our table.

M^me^ France Gélinas: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. We'll go to the government side: Ms. Jaczek?

Ms. Helena Jaczek: Thank you. I'd like to go into a little bit more of your structure. You said that Medbuy has 25 members. There are other GPOs out there. How does a hospital decide if they wish to be involved in group purchasing? How do they decide which GPO to become a member of? What do you offer? Is this a competitive environment?

Mr. Kent Nicholson: Ourselves and our main competitor operate both as not-for-profit organizations. I see Medbuy as a service organization, and our interest is to serve our members well.

How an individual member decides whether they'd like to be a member of Medbuy or a member of HealthPRO is very personal for them. They—

Ms. Helena Jaczek: Well, "personal" usually relates to some sort of business advantage.

Mr. Kent Nicholson: Well, again, the challenge of comparing and contrasting two GPOs—you could request from ourselves and HealthPRO a basket of goods and compare the price of that basket of goods. How big you want to make that basket—we carry more than 100,000 SKUs under contract. The comparison between ourselves and HealthPRO is not a straightforward exercise in terms of what the cost of that basket is, but that would be a consideration. People would do a value assessment.

I think our membership would say that one of the uniquenesses of Medbuy is, we are a little more intimate in our membership. The fact that we've got 25 members—that is a significantly fewer number than our competitor. By virtue of that, I think our membership feels more inclusive and more engaged. Every one of our committees is represented by every one of our membership. That is not the case with our competitor.

Again, the intention of today is for me not to get into a pluses and minuses of—but certainly those are some of the considerations that people might go through in evaluating a GPO.

Ms. Helena Jaczek: Okay. We'll come back to engagement of the membership in a minute.

Just reading from the second page of your presentation today, you say, "Medbuy operates like 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."

What revenue do you generate?

Mr. Kent Nicholson: It's generally rebate revenue. Many of our contracts have a rebate structure connected to them, usually based in meeting certain volume thresholds. If our members meet certain volume thresholds, there are additional rebates that are secured on their behalf. All of those rebate dollars come to Medbuy. We take that pool of money, we offset our operating expenses and we distribute 100% of the remainder.

Ms. Helena Jaczek: Explain to me a little bit more about rebates. What are these rebates?

Mr. Kent Nicholson: The total value that we secure from vendors, and again, it's very optional for—a vendor can propose to a proposal any way they want, but it is not unusual for a vendor to—when we aggregate volume, we do better for our membership on the off-invoice price than they can do themselves. Immediately, off the invoice, they get a more attractive price. Then, very often, vendors will put in place some form of rebate structure that incents compliance to the contract and volume aggregation. So if you meet certain volume thresholds, then a rebate kicks in and a rebate applies to all the volume that all of our membership has purchased against that contract.

Ms. Helena Jaczek: So if you purchase a much larger amount of a product, they will say, "We will give you a rebate"? Is it as simple as that?

Mr. Kent Nicholson: What they're targeting is commitment and compliance to the agreement, so if we aggregate all of our volume our members spend and it's $10 million or it's $20 million, conceivably they will create—and this is their structure, not ours.

Ms. Helena Jaczek: This is what they put in the response to the RFP.

Mr. Kent Nicholson: This is what they put in their proposal. So they'll give you an invoice price and they may say, "If you hit a threshold of $15 million, which represents 75% of your spend, we will give you a rebate that equals this. If you go to 80%, it equals this. If you go to 90%, it equals this." Clearly, we're not encouraging members to spend more than 100% of their requirement. That's generally the nature of a rebate structure. It ensures that the vendor gets the volume, and in return for the volume, it gives us further recognition on the price.

Ms. Helena Jaczek: I seem to recall when you came before you referred to value added, that this was a component. Can you explain to us again what that was all about, that some companies offered some financial incentive? I don't remember the rebate issue. It was more some additional funding that was an incentive to choose them.

Mr. Kent Nicholson: I would not consider a rebate related to value-added discussions at all. It's purely part of the financial consideration, and we calculate it in the way that we evaluate the attractiveness of their financial proposal.

Ms. Helena Jaczek: When you're scoring the vendor's applications or proposals, is there a category that refers to value added?

Mr. Kent Nicholson: There was at one point. There is no longer, and that's probably been the practice for two or three years. We do not have a separate category of value add. Within value add, that could be anything from extended warranties to in-service training to attendance at training events, so there's a variety of value-added incentives that used to be part of our structure. What we've now done is, if we can't quantify it financially, if you can't actually translate it into dollars and cents, then

we don't consider it. If we can translate it into dollars and cents, then we include it in the financial evaluation.

Ms. Helena Jaczek: Thank you. Now, in terms of what happened, you explained to us the previous way that Medbuy was operating. You stated, "This included requiring the activities to be carried out under the supervision of a licensed pharmacist and referencing the need that the third party compounder adhered to the USP 797 standard, which is considered the pharmacy gold standard for carrying out these activities." So what went wrong?

Mr. Kent Nicholson: Well, again, in my opening remarks and at the end of my opening remarks, in a heartfelt way—and I don't like to simplify things or trivialize things. There were assumptions that all of the stakeholders made. We made assumptions; Marchese made assumptions; the hospitals made assumptions. Unfortunately, those assumptions, in some instances, were incorrect.

Ms. Helena Jaczek: Okay, so you talked about engagement of your membership. Who was on the committee that reviewed Marchese's proposal and the others that submitted proposals? Who was physically at the table with the proposals in front of them?

Mr. Kent Nicholson: I think I'll turn it over to you, Ann, maybe to talk about how the RFP is scored and that process.

Ms. Ann Kelterborn: For the RFP scoring, we have a representative from each member, as Kent was saying, and those—

Ms. Helena Jaczek: Each of the 25—

Ms. Ann Kelterborn: Each of the 25 belong to our pharmacy committee. In general, their expertise is senior-level pharmacy. They're generally the directors or managers of pharmacy who are, in a sense, still connected to their internal experts. When we develop the criteria, we develop that criteria with them up front at the table and review that. We have biannual meetings with them as well as monthly conference calls.

In the case of when the proposals are received, those are sent out along with the criteria, and the members score those independently, so we eliminate that bias or that group. We're not all in a room together scoring something at the same time. Everybody is independently scoring it. Those are collected, collated and the final result is established.

1640

At the same time, from the financial part of it—because the members score the non-financial, along with ourselves, components of that. Financial is done corporately, as it is with all of our initiatives, and that's done separately. So you are doing your non-financial and your financial. Those come together, and they roll up to produce a total score.

Ms. Helena Jaczek: Did any of those 25 members make a note of the issue related to concentration and specificity? Did they recall anything about the previous contract with Baxter? Was there any—

Ms. Ann Kelterborn: Not to my recollection. When our scoring is done, it's done according to a template that is established with criteria. There are scores of zero to three. Which place you land in that scoring grid depends on your answer, and your answers that we are looking for, from a zero to a three—they could be binary answers or judgment-call answers, and that's how it's put forward, and the members will score according to what the responses were in the RFP.

Ms. Helena Jaczek: And then these—

Interjection.

Ms. Helena Jaczek: Sorry. Did you want to say something?

Mr. Ron Swartz: Yes, I think I'll just supplement a bit. It's that all these criteria—I mean, we generated the first draft of the criteria in terms of looking at the literatures and standards that are available of the day. These criteria then go to the committee, and they're thoroughly discussed at the committee and approved by the committee. I think 10 members of our committee contain regional cancer centres inside their facilities, so whether in a committee or in their staff, there is very large amount of oncology expertise.

Ms. Helena Jaczek: So in reviewing the minutes of the pharmacy committee—I presume you have minutes and so on—there were no questions raised related to labelling concentration, how the product was going to be produced?

Mr. Ron Swartz: No. Our view still is that all the products listed there were concentration-specific. We asked for a specific strength of a drug, amount of a drug and a specific volume of fluid in there. It's the same item list that we'd used before. Many members have been buying some of these products for years without incident.

Truly the standards, at the time, did not address this in any real away in terms of labelling. I guess they, like us, didn't envision this type of error happening, and so they had not addressed it.

Ms. Helena Jaczek: And the USP 797 standard would not have specified how the admixture was to be produced?

Mr. Ron Swartz: No. It's a technical standard that really looks at the room and airflow in the room and changes like that. It looks at staff training, staff testing, how often they change their gloves, what sort of testing should happen in terms of, if I were doing microbiological testing of the hood, am I going to do end product testing or not?

Ms. Helena Jaczek: But it doesn't actually talk about how you mix the stuff?

Mr. Ron Swartz: No. Well, it talks to it in terms of the process of putting in sterile, in terms of keeping a clear airflow in—because they use laminar flow hoods. These are devices that create sterile air—not quite sterile air, but very close to sterile air. It blows out parallel to you, so they talk about ways of positioning products in there so as you're not contaminating from one product to another in different production and things like that.

Ms. Helena Jaczek: So the—

Interjection.

Ms. Helena Jaczek: Yes.

Mr. Michael Blanchard: The drug monograph itself outlines specifically how to prepare the product, and the pharmacist would have relied on that information.

Ms. Helena Jaczek: So the expectation, presumably, in the case of awarding the contract to Marchese, was that the compound would be mixed and the end result would be the four grams per—

Mr. Michael Blanchard: Yes. That the overflow would have been taken into account, as per the instructions.

Ms. Helena Jaczek: So that as you've reviewed all your notes, that was, presumably, the assumption of the people of that time.

As you move forward, explain to me again—and you have, to a certain extent—exactly how this will look in the future, should you choose to continue to use a compounding process or purchase these types of products.

Mr. Kent Nicholson: I'll start and maybe the team can jump in. But, as I've described, if I were to restart this process, I would take a look at the basket and I would risk-rate every product.

Inherent in that, I would start to stratify: What are the highest-risk products in this RFP? In all likelihood, for those products that are highest-risk, we would have a more detailed specification, at minimum, that we would write.

We did not feel it was our role to tell the compounder how to compound product, but our experience recently and what we've gone through would indicate, for those high-risk products, that we probably would take the step to say, "This is what you do: You start with an empty bag. You do this, you do this, you do this, you do this."

As I said, we may include that particular activity within this larger RFP or we may break it separately and award it separately, if we felt that that was in the best interests of patients and our membership.

Ms. Helena Jaczek: I guess I'm a little puzzled. You've been around since 1989. You have all this expertise from the membership. That this concept of risk, in terms of compounding being really a different thing than just supplying tablets of a certain type, wouldn't have come to the fore—just help me with that.

Mr. Kent Nicholson: Well, we've tried to describe that we have always considered risk when we undertake our work. If I jump to the med-surgery portfolio, we will identify initiatives that have high clinical sensitivity, and those are initiatives that we engage fully with our expert committee. We also assign an ad hoc committee, experts beyond even our committee. We have an operating room committee, and no one sitting on the operating room committee is an expert in everything. So if it's a highly clinically sensitive product, we will develop a specific ad hoc that supports that particular initiative.

In our legacy, in our history, I indicated that we've had a flawless record. We've never had an incident such as this. We do attribute it to bringing subject matter experts around the table to help us in the work that we do.

In this particular instance, we relate it to compounding service. We certainly focused on risk, and I think Ron has touched on some of the risks that we thought were inherent. We never thought the risk was that somebody would compound to the incorrect concentration, or overlook or overfill or disregard that, or that a package would leave a plant with a very clear label on it and the product not match exactly the expression that was on the label.

We did spend a lot of time thinking about aspects of sterility and stability. We did run this initiative with the same diligence that we've always employed. Unfortunately, we ran into a situation that we've never had occur.

Certainly, most of the products that we acquire, 99.5% of the products we acquire, are licensed by Health Canada for sale in the business that we do. As it relates to the med-surgery portfolio, we are not buying a service or product that is not approved for sale by Health Canada, so that gives you a level of comfort that only those that carry a licence can put their hand up and operate in this area.

Ms. Helena Jaczek: Thank you. Just again, explain to me the role of the subcommittee. You mentioned you're going to put in place a new pharmacy subcommittee. What's the purpose and who is on that?

Mr. Michael Blanchard: First of all, this is standard practice, that whenever an initiative is reviewed, prior to going out to renew a contract for any particular product or group of products, the pharmacy committee members strike a working group to review the process, to identify opportunities to improve the exercise.

In this case, the committee is focusing on Dr. Thiessen's report. He identified four areas that we're going to be specifically looking at. We've engaged a facilitator to help us through this exercise. We've also engaged an independent expert consultant from the Institute for Safe Medication Practices. The scope they're going to be looking at is essentially four areas: the specifications, the transition, the clinical sign-off—the end-user validation—and the fourth was—I can't remember.

1650

Ms. Ann Kelterborn: The risk rating.

Mr. Michael Blanchard: The risk rating, yes, which we've already started.

Ms. Helena Jaczek: So before any future RFP goes out—

Mr. Michael Blanchard: Yes, the decision to renew or not renew this contract or to continue participating will be pending the recommendation from the subgroup. The subgroup is made up of expert members from various hospitals. I believe there are eight hospitals. All four affected hospitals will be participating, and some non-affected hospitals. One of the hospitals, I think, never used the service, but they will. So we have a broad spectrum of participants.

Ms. Helena Jaczek: In case you do go out again, they put that together, the RFP goes out, and then you will return to the same model of evaluation, I presume, with your entire pharmacy committee, with each hospital member—

Mr. Michael Blanchard: This committee will put forth recommendations to the main committee, report back, and then a decision will be made. If they do move forward, then I'm sure the recommendations to implement some additional safeguards and checkpoints and introduce more checks and balances in the system have force functions to ensure that certain quality control checkpoints are documented.

Ms. Helena Jaczek: Thank you. I'll just reserve—

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

The official opposition: Ms. McKenna.

Mrs. Jane McKenna: The first question I have is, isn't it the responsibility of the broker to take the risk value out?

Mr. Kent Nicholson: Could you help me understand that?

Mrs. Jane McKenna: Just going back a few minutes ago, you were speaking about how there was a lot of assuming and assumption. But there shouldn't be any interpretation when you have a contract that you've put together. It should be very specific what you're expecting from the person who assigned that contract. I always want to figure out, where does the buck fall? I understand that everybody has, maybe, some ownership in it. But if I get a contract from somebody and it's specific in there what my expectations are in that contract, there should be no interpretation or any assumption at all. To me, as a broker, that's your responsibility. I could be wrong. That's why I'm asking you that. Is it not your responsibility as a broker to have clear and concise information in there so there's no interpretation anywhere; nobody's assuming anything?

Mr. Kent Nicholson: I would agree. We accept that responsibility. Again, the way that we exercise that responsibility and have always exercised that responsibility is to engage our member hospitals, who are experts, front-line patient caregivers who use the products. This particular initiative was no different than that. We had the pharmacy directors around the table reviewing the specification, reviewing the clinical scoring, reviewing the proposals that were submitted.

Again, I think the step that we've highlighted two or three times that may make a difference going forward will be to risk-rate individual products and identify products within large RFPs that are higher-risk, and inherently, they will get a further level of detail, specification, discussion.

This unfortunate incident came down to someone asking a question. Somebody in Peterborough said, "Is this an exact concentration?" That's all it took. We could have asked that question; Marchese could have asked that question; the hospital could have asked that question; anybody could have asked that question, all the way along.

Trying to utilize this exercise of risk-rating products to identify the highest-risk products, to eliminate, going forward, any need for assumptions or an interpretation, is exactly what we're recommending that we do.

Mrs. Jane McKenna: I'm just reading through what you have here. Sorry, the page isn't marked. You're going to now be changing your contract with these specific things in here. Just going through this whole process, when Baxter was in here, when they started back—and I don't remember the actual time, but their relationship was a relationship that was built with the pharmacists, back and forth, open communication. So whenever there was a question, there was open communication. They didn't go through anybody else to get those answers.

You having to write a contract on something that is very tactorial, that's very hands on from another company, would be very hard to do, as far as I'm concerned. So when you were doing this contract, you can clearly see in it, right—and I'm not saying it wasn't done intentionally or any of those things, so please, that's not what I'm trying to say. What I'm trying to say, though, is that there weren't specifics in the contract clearly or we wouldn't have the problems that we're having. Why is that? I'm just wondering, if you had the actual model—and I realize that there are differences—why is it that one company was so clear on what that process was and yet this company was not?

Mr. Kent Nicholson: I think there is probably something to the fact that they had a legacy relationship. Baxter's relationship for this particular service predates our involvement in any contracting. The first time we were here to the committee, we indicated the very first contract we ever put in place was in 2008. Prior to 2008, many hospitals already had a relationship with Baxter. So our membership came to us, saying, "Could you aggregate this? Could you standardize this? We're all using Baxter. Could you go out on our behalf for a contract?", which we agreed to do on the condition that they're going to be participative in the construction of that specification, the evaluation of the proposals, and we did that in 2008.

At that point in time, the only proponent was Baxter and so that specification carried forward from that point forward. It was a list of products. Every one of those products was intended to be an exact concentration, and we utilized that list when we went to market a second time. Our intention was to continue a relationship with Baxter, but the process of declaring that this is something we wanted to tender, we believed it was sole-source. We had an objection to that. We reviewed the objector, their capabilities. We thought it was a valid objection and we put it out to market and received three bids. So I think there was, based on a legacy relationship, more intimacy that Baxter had with the hospitals.

One of our recommendations very specific to the current Marchese contract is for this service in particular, because it is—you're not manufacturing a product, but you are compounding. You're not buying a pacemaker

that's assembled. You are taking components and you're putting it together and you're providing it to the hospital for use. So our recommendation with Marchese has been, "You must meet with every hospital member, and you must describe your process for formulation. You must describe the label you're going to put on this product." There will be a sign-off between the hospital and Marchese confirming that both parties understand the requirements and they match the way the product is used in that particular hospital.

Mrs. Jane McKenna: Okay. So my next question is—Ms. Gélinas asked if you would be open to oversight. I didn't really get your full answer of yes, 100% you would be. I'm just saying, for me, it would just alleviate if someone else was overseeing exactly what you were doing, and I would welcome that. I'm just saying myself, just because of the situation that we've all been in here. So did you say that you 100% wanted oversight?

Mr. Kent Nicholson: It wasn't clear to me who that is and how that works but—

Mrs. Jane McKenna: Well, it would be ministry oversight. It would be the ministry ultimately in the end; right?

Mr. Kent Nicholson: But again, we cross provincial boundaries. If there was some form of oversight that was struck to say, "Let's review periodically the work of GPO, how they do that work, how they execute," we would welcome that. I can think of nothing bad that can come out of that and only good could come out of it, to have somebody independently take a look at the work that you're doing with a fresh set of eyes and a new perspective. Sometimes we're too close to the work that we do and so I have no issue. I don't know how to do it, but I would have no issue with that form of oversight.

Mrs. Jane McKenna: Okay.

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

Mr. Jeff Yurek: Thanks for coming out again. Does Medbuy have a quality assurance program in place?

1700

Mr. Kent Nicholson: Certainly, we are asked by our membership to attest that the work that we do is compliant. We do review the execution of our work, that it follows steps that are prescribed.

Do we have a separate quality committee? No, we don't, but we are asked by our membership on an annual basis to attest that we are compliant.

Mr. Jeff Yurek: So you have no—

Mr. Michael Blanchard: Well, the work of our committees in terms of our business processes, as Kent mentioned—there's that aspect of quality: Do we comply with the guidelines and the procurement directives and so on? There's that aspect.

I assume you're looking at whether we have a quality program in place to ensure that the products that are put under contract meet those quality standards.

Mr. Jeff Yurek: Just in general, I would have assumed that a $627-million corporation would have quality in place. I'm quite shocked—I was expecting you'd say, "Yes, we do."

Obviously, I hope you've learned from this, that without a quality system in place in your corporation, you have communication gaps, and you have assumptions that occur, that lead to people not getting the right chemo drug at the end of the day.

Mr. Michael Blanchard: Well, that's part of our exercise where we hired that external process expert.

Mr. Jeff Yurek: Further to that, what has come up through committee—I asked each of the hospitals when they did attend—the front-line health care workers: Is there a complaints process that the front-line health care workers can send to Medbuy and say, "I have a problem with X product"?

Mr. Michael Blanchard: Yes, they do.

Mr. Jeff Yurek: Each one said no.

Mr. Michael Blanchard: Ann, maybe you can address that. We do have a web-based reporting system.

Mr. Jeff Yurek: And front-line health care workers can access that, or do they have to go through their manager or somebody's manager?

Mr. Michael Blanchard: Yes, the buyer and—well, Ann, I'll let you—

Ms. Ann Kelterborn: They would access that through our e-catalogue. Those who do have access—

Mr. Jeff Yurek: Front-line health care workers don't all have access to that.

Ms. Ann Kelterborn: They don't, but they can always have access to it. It's just an application process to us through their committee representatives.

I'm saying that in a number of hospitals, there are a number of folks, from pharmacists to technicians to buyers, who may touch or be involved in products, who can actually go online or contact their representatives from the committee and have those people post online or contact us.

Mr. Michael Blanchard: There is a structured process within the hospital and within Medbuy. If a front-line nurse, for example, has a product problem, within most hospitals there's a reporting system and mechanism. They would report back to the pharmacy buyer, who would then report to us, and that is structured.

Mr. Jeff Yurek: Okay, but that's broken, because the front-line health care workers who testified at this committee do not know of that process. I'd recommend to you to write that down too, in your reviews. I would assume that, going forward, you would head towards a quality assurance program but in that fact, that you would be open to expanding the ability of those complaints to get to Medbuy.

Mr. Michael Blanchard: That's surprising, because we usually review those complaints, and they're documented and reported to the committee on a monthly basis for discussion.

Mr. Jeff Yurek: But if they don't reach you, you don't get them.

Mr. Michael Blanchard: Well, it will be interesting to find out which front-line hospital—

Mr. Jeff Yurek: All of them.

Mr. Michael Blanchard: All of them?

Mr. Jeff Yurek: All of them.

Mr. Michael Blanchard: That's—

Interjection: I think the question—

Mr. Jeff Yurek: I hope that you're just not going to be defensive.

Mr. Michael Blanchard: No, but it's—

Mr. Jeff Yurek: We're trying to make sure that this does not occur again, right?

Mr. Michael Blanchard: I understand what you're saying.

Mr. Jeff Yurek: Okay.

Mr. Michael Blanchard: But I'm just plainly surprised, because I've only been at Medbuy for a few months, and the documentation that I've reviewed, and so on, would indicate otherwise.

Mr. Jeff Yurek: Going to the RFP procedure, this was the first time to send out a request for proposal for admixed products, correct?

Ms. Ann Kelterborn: Yes.

Mr. Jeff Yurek: How did you create the RFP? What resources did you use then to develop that RFP?

Mr. Ron Swartz: We looked at the standards of the day that were available. I had actually attended a US conference where one of the sessions was on the outsourcing of sterile compounding, so I got information from there. There is a set of guidelines or a process for outsourcing from the American Society of Health-System Pharmacists, so we had that. We looked at USP 797, really specifically around the processes. Specifically, I was looking at that around the training and testing of staff and what's going on. I looked at GMP, Canadian Good Manufacturing Processes, for the same thing, to try to draw all these standards in. It's well recognized, and this has been discussed very early on in the committee, that there was no oversight for this group; therefore, we have to be very sure about the process that we're doing to do this.

As well, as you may know, there have been many problems in the US with unsterile products getting into the marketplace from these compounding agencies—a number of deaths reported down there. If you see the FDA warning list now, they're regularly doing recalls on products from this. We're very aware of the sterility issues. That's really what the focus became, because that was the focus of pharmacists at that time, both in the US and in Canada, because these are the issues that have been identified. So we used those.

Then the rest of it just came from the committee in terms of, "Do you want pharmacist oversight?" "Yes." We don't have to license pharmacist oversight. So they would make those kinds of recommendations to that. So we spent virtually a full afternoon at a committee meeting with the committee going line by line over all these criteria and reviewing it.

Mr. Jeff Yurek: Did anybody on the committee have experience with contract preparation and RFPs in general, or was it just the health care professionals?

Mr. Ron Swartz: They're all just health care professionals, but they're all directors of pharmacies, so many have done RFPs. If they've been part of the pharmacy committee for a time, and many have, then they've got the experience of being involved in the development of other RFPs.

Mr. Jeff Yurek: How long did it take to develop the RFP?

Mr. Ron Swartz: Well, we started talking about it in 2010 at some point, so really we started working on that from there. Actually, I think the conference was in 2009, mid-year. I went to that conference. We had been thinking about it for a while, and there was considerable time spent in looking at the literature and drafting the criteria.

Mr. Jeff Yurek: Do you have—

Mr. Michael Blanchard: I was just going to say that in reviewing the minutes and so on, they spent well over a year, almost on a monthly basis, in discussions around developing the RFP and the criteria.

Mr. Jeff Yurek: Did it ever come across to perhaps use Baxter in your creation of the RFP since they were already providing this service?

Mr. Ron Swartz: No. We had regular business meetings with Baxter. Many of us had site visits to Baxter, so we were somewhat familiar with their process. We had seen it. But they were going to be one of the competitors in this RFP, so we weren't necessarily asking them to write the RFP to give them the most favourable outcome. We were looking at the standards and criteria of the day and trying to develop those into measurable criteria from which we could be comfortable with the outcome.

Mr. Jeff Yurek: Was there ever a thought to contacting the CCAC, since they've been working on RFPs for various items for years on end and keep re-evaluating their RFP process in building upon it?

Mr. Ron Swartz: No, there had been members who actually had CCAC contracts or hospitals outside our membership who had CCAC contracts, so that expertise was there. The CCAC focus is very different. It's home care. It's patient-specific. It's for the individual prescription through a licensed pharmacy. It's quite a different process from the batch compounding process. It's a sterile process in terms of putting the drug in the bag—yes, it's exactly the same—but in the general process there would be significant differences.

1710

Mr. Jeff Yurek: Do you have a committee that is reviewing your RFP program and continually monitoring and updating the RFP processes, contracts?

Mr. Ron Swartz: We regularly would look at lessons learned from our past documents. In terms of our major RFP cycle which are going out next year, we already had developed our strategy committee and we have a task force or a project force on general RFP criteria. So they have looked at this; it's gone out to the committee. We gather the comments from the committee after the last award and bring that into this process. So we have what we identify as a "lessons learned" document, which we use to correct faults going forward.

Mr. Jeff Yurek: Now, with regard to the changeover from Baxter to Marchese, we also learned in committee that it was rocky. Have you looked at your changeover procedures for when you do switch a supplier, have you reviewed with staff what went wrong, and are you implementing changes in that?

Mr. Ron Swartz: I can start this and you can go from there.

Ms. Ann Kelterborn: Sure.

Mr. Ron Swartz: Yes. I mean, we would argue that it was rushed, and whether it was rocky—I think that the handover process or the change in management process wasn't much different than it would have been for many RFPs. I think the fly in the ointment, as it were, was the unwillingness of certain suppliers to sell direct to Marchese, and it was this process—which we weren't aware of until we made the award either. I think that process contributed more to issues in transition than really the product-to-product transition, because in the end there was a sterile drug in a bag, and that's what they'd been getting and that's what they would be getting.

Mr. Jeff Yurek: Did you want to add something?

Ms. Ann Kelterborn: I just wanted to mention the subcommittee that has now been struck. According to Dr. Thiessen's recommendations, that will be one of the areas that they will be looking at and reviewing on a go-forward basis for what would need to be in place if we do this initiative in the future.

Mr. Jeff Yurek: Just a couple more questions for your comment, because this also came up during committee. I was reviewing my notes, and during Marchese's deputation they stated that Medbuy and Marchese did have a conversation about overfill during the contract negotiations. Can you comment on that?

Mr. Ron Swartz: We did. The conversation was with respect to antibiotic bags. So if they came to us and said, for instance, "With a Cefazolin one-gram bag, where we know for certain it's a single-use, is the overfill an issue?", our answer was, "No, it's not chemically because you're administering the whole bag." That then got applied to a broader range of products as being single-use bags, and that was never in the conversation.

Mr. Jeff Yurek: It also was brought up that—it was noted that their labelling was superior. Nobody said it was unclear, yet some of the hospitals did not like the labelling. Any comments on that?

Mr. Ron Swartz: Labelling is always—there's always a judgment to this. They were superior in two ways; there were really two sets of superiority we saw from Marchese. One was just customer service, which we felt was superior to what Baxter was offering. The second, with respect to the labels—the biggest component was bar-coding. There's a very large movement in hospitals to bar-coding to the bedside. It's a well-documented, well-recognized patient safety measure. A number of hospitals are bar-coding products now, so the availability of a bar-coded product was a significant advantage to many of our members.

Mr. Jeff Yurek: I'll put my time to the next—

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

M^me^ France Gélinas: How long do I have left?

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

M^me^ France Gélinas: I'll start with this. You have put into place a series of very good quality improvement steps that you read in your opening statement: the risk assessment of individual products; the sign-off back to the end users; the clarity of the label with single dose; the range of volume; that kind of stuff. To me, those are all good quality improvement steps.

If it wasn't for this committee, how would we have found out and who knows that you're doing this?

Mr. Michael Blanchard: Our members are. Certainly the committee members, yes, this whole—what we refer to as a remediation plan has certainly been developed with input, and we've got our pharmacist members on the committee. All the hospitals that are utilizing this product and some that continue to use the services from Marchese have been involved and are kept up to date.

M^me^ France Gélinas: Do you know if any of the other GPOs are also learning from what happened?

Mr. Kent Nicholson: I don't know first-hand. I would expect that everybody in health care procurement has followed this and has followed the incident. It's not only GPOs, but there are regional shared services organizations that also act on behalf of hospitals to acquire product. So I believe everyone is well aware of the situation and is well aware of Dr. Thiessen's report. I can't comment as to what actions they are taking.

M^me^ France Gélinas: Okay. Let's say you would stop using one of the new quality steps that you've put in place. How would we find out and who would know?

Mr. Michael Blanchard: If we stopped?

M^me^ France Gélinas: Yes.

Mr. Michael Blanchard: I have no intention of stopping any of this.

M^me^ France Gélinas: Okay.

Mr. Michael Blanchard: But to make sure, as our pharmacist friend here, Mr. Yurek, has stated, we certainly have started some quality assurance. We've introduced quality assurance components in our processes, and we will continue to enhance that whole—and turn it into a formal program with reporting. My intention is to develop a set of quality control metrics.

Mr. Kent Nicholson: Just further, this is not the first time that we have talked about our response to Dr. Thiessen's report. We have communicated these action steps just as they are to our complete hospital membership—to the CEOs, to the CFOs and to all of our board members: "Here is our response; here is our action plan as it relates to Dr. Thiessen's report." So we've been very visible and very transparent, in the spirit of, we're fine to be held to account. I would fully expect that some of those or all of those CEOs—certainly, my board, who are representative of hospital executives as well—are going to consistently test for our follow-through on the work that we've started.

M^me^ France Gélinas: So, talking of reporting, I take it you do yearly financial statements. Do you have your financial statements audited?

Mr. Kent Nicholson: Yes, we do.

M^me^ France Gélinas: And who has access to those audited financial statements?

Mr. Kent Nicholson: The board.

M^me^ France Gélinas: Okay. Are they available? If anybody was to ask you for a copy, are they available, or solely to your membership and your board?

Mr. Kent Nicholson: Certainly making them available to the standing committee, I have no issue with, but making them broadly, publicly available, I just need to double-check in terms of whether there is any competitor or confidential information that is contained in there.

M^me^ France Gélinas: But it hasn't been your practice to make those broadly available? You report to your members and to your board, then?

Mr. Kent Nicholson: Correct.

M^me^ France Gélinas: That's where it ends? The people that work for you: Would they be on the sunshine list if they make more than $100,000? Are you covered by the sunshine list?

Mr. Kent Nicholson: No.

M^me^ France Gélinas: No? Do you do it voluntarily just to show transparency?

Mr. Kent Nicholson: We don't.

M^me^ France Gélinas: No? And do you have employees, within the 60 that you talked about, that make over $100,000?

Mr. Kent Nicholson: Yes, we do.

M^me^ France Gélinas: And out of 60, how many would you put to that?

Mr. Kent Nicholson: Perhaps five.

M^me^ France Gélinas: Okay. Do you know if any other group purchasing organizations do admixtures purchasing?

Mr. Michael Blanchard: Come again, please?

M^me^ France Gélinas: We know that Medbuy did put out a request for admixtures. Do you know if any other GPO has done the same?

1720

Mr. Michael Blanchard: I can't speak for all of them. I'm not aware of any. It might be—

Mr. Kent Nicholson: I think it in part speaks to what your definition of a GPO is. My suspicion—again, I don't have the absolute facts, but we have some provinces that have provincial shared services organizations, where participation with that shared service organization is mandated. I believe some of those provincial shared services organizations outsource their compounding service.

Mr. Michael Blanchard: It might be a few across the country, but I can't—it's speculating.

M^me^ France Gélinas: Okay. That was the first time for you?

Mr. Kent Nicholson: It was 2008; 2008 was the first contract we ever put in place, and again, it was at the request of our membership, because they already were outsourcing this activity. They were all using Baxter, so they asked us to do this on their behalf, which we did.

M^me^ France Gélinas: Okay. How much sharing of best practices exists between GPOs?

Mr. Kent Nicholson: It depends on what you refer to as "best practice." I think that there's some level of competition—we are competitors at some level—but we do come together on issues of commonality. In drug shortage issues, there's a working committee where all of the GPOs and a number of the provincial shared services organizations are represented—so issues that have large-scale impacts on the health care system, where it makes sense for us to be part of a collaborative working group, we do so willingly. Sharing a best practice in terms of how I undertake the contracting process and so on: That would be viewed in some respects as competitive.

Mr. Michael Blanchard: Another example would be bar-coding, where there's been a collaborative effort, developing bar-coding to the patient.

M^me^ France Gélinas: Okay. So the industry does not meet to share best practices, or you don't belong to an association together or anything like that?

Mr. Kent Nicholson: I sit on the GS1 CareNET board, and so does my colleague with HealthPRO. Again, GS1 is a standards organization which is attempting to drive unique identifiers for all health care products—not only pharmacy products, but all health care products—to have a unique identifier to be able to track and recognize and recall anything related to the hospital sector in the same way that bar-coding is universally accepted in the grocery industry; it's universally accepted in the retail industry. It has not evolved in health care, which is quite counter. You would think it's more important in health care than in selling a can of peas, but it's the opposite.

Again, making bar-coding an important part of the label criteria was our effort and our committee's effort to move that initiative along for something that makes absolute sense.

M^me^ France Gélinas: My colleague will ask a question now, and I'll come back.

Mr. Kent Nicholson: Sure.

Ms. Cindy Forster: Good afternoon. When Dr. Thiessen was here earlier today, he indicated that when you went out with the RFP for 752 products—

Mr. Kent Nicholson: It was 117.

Ms. Cindy Forster: —117 products, Marchese was already dealing with 752 products, and those included the two chemotherapy agents in question. Then when I asked to clarify that after the fact, he wasn't sure whether or not, in fact, Marchese was already dealing with those products before your RFP within their facility or whether they were doing it, perhaps, in the community, based in their local pharmacies. Can you shed some light on that? They said that it was a question that perhaps Medbuy would better answer.

Mr. Ron Swartz: I don't know for sure what products on that list they were making. The gemcitabine and cyclophosphamide that are on there seem to be our identifications for those, so they may have just been

added. But certainly, when I saw their facility in Kitchener, they did have a chemotherapy preparation area. That was one of the things that we had looked for: "Do you have that?" Yes, they do. "Do you have staff trained to get all the different stuff needed to go in there?" Yes, they have. All the requirements were there. They were certainly prepared to make some. I would assume—again, without knowledge—that having the space prepared and functional would say to me that they must have been using it for something.

Mr. Kent Nicholson: It came to us as part of the validation process. When we went out with a single-source validation, we were expecting to renew our contract with Baxter. In their objection, they gave us back a product listing. If it totalled 752, you might know—

Ms. Cindy Forster: Right.

Mr. Kent Nicholson: I was worried about our list. So this is what they represented. "Here is the justification of why we're absolutely in the compounding business, and we actually have a more extensive list of products that we compound currently than you're going out for RFP on."

Ms. Cindy Forster: Well, that's interesting, because when the pharmacists were actually here from Marchese—there were a number of them—we asked a question of each one of them with respect to their experience around admixtures or compounding of chemotherapy agents, and all of them indicated minimal or no experience in that area. That's why I asked the question. Do you have any insight into that?

Mr. Michael Blanchard: From what I've seen and read, essentially, the question was asked and they objected. Our initial intent was to single-award or sole-award to Baxter and renew the contract with Baxter. They objected and provided us with an extensive list of products that they prepare currently. In that list were oncology items, and, as Ron stated, at our site visit we observed an oncology preparation facility.

Ms. Cindy Forster: Thank you.

M^me^ France Gélinas: There was a breakdown in communication, Dr. Thiessen told us, at every level. The hospital didn't tell Medbuy; Medbuy didn't tell Marchese; Marchese sent it back to the hospital; nobody knew that the bag we were dealing with was not concentration-specific and the underdosing arose.

The mere fact that you exist means that there are more handoffs. I take it that you all have a health care background. Every time there is a handoff, there is a risk of error. How do you compose with this, because you have become a middle person in between, that the fact that you exist brings a level of risk to health care that was not there before?

Mr. Kent Nicholson: Maybe I haven't been effective in terms of trying to describe how our committees work and the degree of engagement and interaction.

We are owned by our members. We are them and they are us. We don't make decisions without their involvement. Do we create additional handoffs? In that model where we work so collaboratively, I'm not sure we do, but if we acknowledge that there were handoffs, the alternative to us existing would be that each individual member hospital would have to write their own RFP, would have to take it to market independently and would have to write their own specifications. Very likely, we would have a number of different suppliers, potentially, with a number of different labels and with a number of different scoring criteria.

In that model of 75 individual hospitals contracting for this service independently—I'm not quite sure which of those two models introduces more risk. I might say that 75 independent events as opposed to a single event where we bring together subject-matter experts to build a standard specification and standard criteria is actually a method of reducing risk, but that's a subject for debate.

1730

M^me^ France Gélinas: I'm guessing it would be more like 25, because you have 25 members, some of them having many sites.

The legacy relationship between Baxter and the hospitals is basically what assured quality. We've just severed that relationship, and yet there was no attention being given to quality. You were about to sever something that assured quality, and you did not replace it by anything else. How could that be?

Mr. Kent Nicholson: We took what we thought were appropriate steps to ensure quality. The fact that we severed a relationship with Baxter—I'm not sure I would categorize it that way.

These hospitals, again, do not have the latitude to just continue a relationship without assessing the potential for other competitors to compete for this business. So, by virtue of the fact that we existed, we didn't create a requirement to take this out for competitive RFP.

As Ron described, in terms of spending a number of months building the criteria, building the specification, engaging our members, we felt we were doing all the steps that we could contemplate to have a quality outcome.

The Chair (Mr. Ernie Hardeman): Thank you very much. We now go back to the government side: Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. One of the issues that I think we've all wrestled with is, Marchese Hospital Solutions assumed that the entire bag was going to be used for one patient. They apparently did have some communication, because there was some idea that they were going to provide an IV connection out of the bag. Did they communicate that proposal at any time to Medbuy, and if so, to whom?

Mr. Ron Swartz: Yes, they did. They asked me whether or not I thought that the members would want IV lines attached to any of their bags. I said they did not, because various hospitals have various practices on that, and the hospitals are going to label it anyway.

To me, it was a straightforward answer to a straightforward question: "Do you want the set attached?" "No, I do not."

I didn't say or didn't imply in that—in my mind, anyway—that that meant that it was a single-use bag.

Ms. Helena Jaczek: It didn't? I mean, surely if it's an IV connection, it's for one person? You're so concerned about sterility. That would have been an obvious conclusion to their inquiry.

Mr. Ron Swartz: Well, then, all the more reason why we wouldn't want a bag set on there. If we'd said yes, then it's a greater inference than if I'd said no.

Ms. Helena Jaczek: But why wouldn't you say, "Are you assuming that this is to be used for one patient?"

Mr. Ron Swartz: Because the question was, "Do I want a set attached?" and my answer was no.

Mr. Michael Blanchard: It was a question that came from them and that applied to all of the products, just not the—

Ms. Helena Jaczek: But including chemotherapeutic agents. You, of course, were aware yourself that the bag was going to be used for multiple patients.

Mr. Ron Swartz: I'm aware that oncology doses are calculated individually by patient size and protocols, so that a one-size-fits-all product is not going to work in oncology treatment, yes.

Ms. Helena Jaczek: I think your answer is yes, you knew the bag was to be used for multiple patients.

Mr. Ron Swartz: Yes.

Ms. Helena Jaczek: In relation to the fact that when you went to Marchese Hospital Solutions, they were preparing chemotherapeutic agents; they were admixing—you observed this process?

Mr. Ron Swartz: I observed them admixing some products. I don't think they were necessarily chemotherapeutic products. But they did have a space that was functional and certainly appeared to be used—the responses in the RFP with respect to oncology products in terms of special packaging, shipping and handling—they certainly were aware of that, because they answered those quite well.

Ms. Helena Jaczek: Did you ask them if they were supplying admixed chemotherapeutic agents to any facilities?

Mr. Ron Swartz: No.

Ms. Helena Jaczek: When you talk about bar-coding—I can understand the utility of bar-coding when you're relating a specific product to a specific patient. You've got a wonderful way of tracking the product and ensuring that a particular patient has received that product.

In a case where bar-coding is used for a bag to be used for multiple patients—this was considered useful? Can you just explain that to me?

Mr. Ron Swartz: Well, the bar-coding would still transfer into their system, and so it would give you a sense of serialization, so you'd know exactly what bag was used to prepare which products. So if a patient issue arose after, I would know which bag that came from, because that would get transferred in the information onto the patient-specific bar code by the hospital.

Ms. Helena Jaczek: So you would know that a number of patients had received that particular product from that particular bag.

Mr. Ron Swartz: They would be able to know that.

Ms. Helena Jaczek: But it wasn't patient-specific. Okay. I understand.

Overall, I guess through the course of our inquiries—and you've heard from my colleague Ms. Gélinas, I guess we're trying to understand the value that you add to the system other than sort of a cost. You've got bulk, you've got volume, so the manufacturer is going to lower the cost and provide that, and that's a flow-through savings to hospitals. But how much does it cost to run your organization? You talked about, I think, 60 employees. What kind of budget are we talking about?

Mr. Kent Nicholson: It's in the range of about $7 million annually. In my opening statement, I made reference that we have saved hospitals hundreds of millions of dollars, and that's a real number. Last year alone, we took to market about $300 million of spend and saved our membership about $36 million against what they were previously paying, which would have been a contract that we also put in place.

Ms. Helena Jaczek: So net of your expenses there's a considerable value as a business case for group purchasing.

Mr. Kent Nicholson: Absolutely.

Ms. Helena Jaczek: Thank you. I'll reserve any time.

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

Mrs. Christine Elliott: Good afternoon. Thank you again for joining us at committee. My questions primarily relate to your response to Dr. Thiessen's recommendations. I'm specifically referring to your response to recommendation number 3, which indicates that you're going to be working with partners to develop standardized product and service specifications. I'm just trying to understand the scope of that work. Is that for all of the products that you currently have contracts with, the companies for all of the products that are out there now?

Mr. Kent Nicholson: No, the recommendation was specifically targeted at sterile pharmaceutical preparation services, so the 117 products that are under that contract, we would drive to a potentially standard specification: a standard way of preparing those products, a standard way of labelling those products. We felt that we could not wait until all the partners and all the stakeholders rallied around this issue, so we have taken some steps within our own control, between ourselves and Marchese, with our pharmacy committee. But if and when a larger scope, which might include ISMP and the college, wanted to undertake more specificity around compounding activities, of course we would be at the table.

Mrs. Christine Elliott: I'm just trying to understand: Are they 117 different specifications for each product, or is it one standard that will apply to all that you're talking about?

Mr. Michael Blanchard: There's a series of specifications for this type of product. The number that

Kent is referring to is the 117 items that were on this contract, so sterile IV admix products. We're working on developing a set of award criteria.

Mrs. Christine Elliott: Okay. And you also mentioned that in the meantime, until it's all been developed, you've looked at current contracts and you've ensured that all the labels represent the final products precisely. Could you just explain what kind of a process you've gone through to ensure that?

Mr. Michael Blanchard: Well, working with Marchese, several discussions and meeting with them. We've worked collaboratively using Dr. Thiessen's report as a baseline for activity, so reviewing the shelf life, for example; validating, doing a literature search and ensuring that there is evidence to support the shelf life for all these products. Marchese has agreed to visit all the hospitals, bringing in with them their admixing formulas, sitting down with the clinical manager for that particular area, reviewing and obtaining a sign-off from that hospital, acknowledging and attesting that, "Yes, this is the label, the process, in which you're manufacturing the product or putting the product together." I agree with it and I'm aware of it. That's just a couple of examples that we've worked our way through.

1740

Mrs. Christine Elliott: Has that process been completed for all of your current contracts?

Mr. Michael Blanchard: It's certainly completed by hospitals. They've been making appointments and reviewing. We've also decided to come to some agreement on how Marchese is going to manage and address the overfill issue, for example, on the antimicrobials. The proposed label changes have been agreed to; they have reviewed them—Marchese is actually asking ISMP to review the labels. So we're hoping to get that final feedback from them in the next week or two and implement those changes for the antibiotics.

Mrs. Christine Elliott: You also mentioned—and this is under "Actions taken by Medbuy in connection with the Marchese contract"—speaking about going to the hospitals and meeting with their personnel to make sure that they understand the use of the products that they currently have under those contracts through Medbuy. Who do you typically meet with at the hospital? Is there a—

Mr. Michael Blanchard: Basically we facilitated those meetings by identifying, through our pharmacy committee, the expert pharmacist responsible for delivering that care in the hospital. Marchese's clinical pharmacist and business manager will meet with that pharmacist from that hospital to review.

Mrs. Christine Elliott: Then, I guess, it would be up to the individual hospital, the pharmacy representative there, to disseminate that information to all of the front-line staff. Is that your understanding of the situation?

Mr. Michael Blanchard: Yes—if there's any changes, of course. But to date, there have been no issues that I'm aware of with the current products. If there are any changes to labelling and so on, there is a communication tool that's prepared and disseminated to all the hospitals. Within the hospitals, there's distribution and communication out to the front-line staff.

Mrs. Christine Elliott: One of Dr. Thiessen's recommendations that I know isn't strictly under your purview was to recommend that the Ontario Hospital Association conduct a formal review to determine the efficiency and traceability of computer-based clinic and hospital records. I'm just wondering about your observations as to how things stand now. What recommendations would you make to that, and what do you think the OHA's recommendations would be in that respect? Is there anything in particular that stands out in your mind that they should be looking for?

Mr. Michael Blanchard: That's one of the recommendations that I needed some clarification on. So I couldn't really comment on it, unless—

Mr. Kent Nicholson: Again, I think we would be working on assumptions. I think Dr. Thiessen saw things in his review at individual hospitals and I think it involved traceability, the ability to actually pinpoint the patients that were impacted. It took varying degrees of time, and that all points to a system that perhaps traceability within the hospital requires a view. I think that's what Dr. Thiessen's recommendation 11 was highlighting.

Mrs. Christine Elliott: It would certainly seem that if we had a working system of electronic medical records, that would certainly facilitate that work and would eliminate a lot of the assumptions that we're working on. We would have that information available in real time. Would you agree with that?

Mr. Kent Nicholson: Yeah. We've spent a lot of time today—actually, a surprising amount of time—talking about barcoding. Again, that is directly linked to traceability within the hospital system. So our committee members who highlighted having a barcode on the label were well placed in their thinking in terms of making this an important criteria. It was a distinguishing factor in terms of why we made the award. Baxter was not in a position to provide products barcoded; Marchese were already there. So it was one of those points of differentiation that had a significant impact on the outcome.

Mrs. Christine Elliott: Thank you. I believe my colleague has another question.

Mr. Jeff Yurek: Reviewing the notes, during the RFP review of the request that came in, there was a huge discrepancy in the price on one of the products, where Baxter was five times the price of what Marchese came in at. Did that raise any red flags? Did any of you call up—either company—and say, "You're way out of whack on your pricing here. Is there an explanation?"

Mr. Kent Nicholson: I think I've heard that you've received some testimony from, perhaps, Marchese and, perhaps, Baxter as well. We are awarding the contract on a total financial submission basis. In this particular case, the two bids in question were very close. Nothing in the overall submission highlighted any type of issue.

We tend not to assess individual line item pricing because we have no basis of understanding how individual companies decide to break down their overall price into individual line item. So, as an example, one company might break down their pricing, really based on a time and motion study and in a very factual way. Somebody else might break down their pricing in a much simpler way—size of bag, as an example. So trying to conclude something from line item pricing is really impossible for us to do.

I think I've highlighted that the two products in question represented less than $10,000 out of the $2.6 million that members drew against this contract. Identifying the financial difference in line item pricing at that level was really impossible for us to identify or draw any conclusion.

Mr. Jeff Yurek: With regard to your financials that you give to your members, does that get filtered up to the Ministry of Health?

Mr. Kent Nicholson: Get filtered up?

Mr. Jeff Yurek: To the Ministry of Health.

Mr. Kent Nicholson: I'm not aware whether our—some of our financial information is available in our annual report, which is available online. Again, as an organization, we are uniquely transparent. Our audited financial statements are not found in our annual report. The nature of what we do, because we're not involved in the transaction itself—so the $627 million you referenced: I'm not party to any of those transactions. I don't order product. I don't receive product. I don't pay an invoice. So, quite frankly, our financial statements are rather boring. Again, it accounts for our operating expenses, and that's about the detail that's contained in our financial statement.

Mr. Jeff Yurek: Do the rebates flow through Medbuy or do they go directly to the hospitals?

Mr. Kent Nicholson: The rebates flow through us. We offset our operating expense. The remainder is distributed 100% to our members.

Mr. Jeff Yurek: So that would—

The Chair (Mr. Ernie Hardeman): Thank you very much, Mr. Yurek. Your time is up.

We have one minute left for the government side.

Ms. Helena Jaczek: Yes, thank you. Just to follow up a little bit on the savings that accrue to hospitals, what do you compare your price to? Is it the price that an individual pharmacy would have to pay for the product if they ordered one dose? Or how do you come to those savings numbers?

Mr. Kent Nicholson: So the reference that I made to what we took out last year and the savings that we generated were against the previous contract, so against what those hospitals were previously paying. Same volumes, same—

Ms. Helena Jaczek: How would you reckon your savings the time you put out your first contract? How would you calculate savings there?

Mr. Kent Nicholson: Well, again, generally if it's an entirely new service never acquired by the hospital before, we would have no basis to benchmark. The issue of compounding—they, historically, were compounding prior to us being involved in that activity at all, so we would have had a basis of comparison in 2008. We would have had another basis of comparison in 2011, when it went back to market.

Ms. Helena Jaczek: But there's no sort of absolute price that you compare to. It's all based on previous contracts?

Mr. Kent Nicholson: Yes.

Ms. Helena Jaczek: Okay, fine. I want to understand the whole picture.

Now, since you have so many pharmacists, obviously, 25 members, hospitals and so on, one of the recommendations in Dr. Thiessen's report, of course, is to have the Ontario College of Pharmacists have the power to license hospital pharmacies. Have you had any feedback from your membership as to how they're reacting to that?

Mr. Kent Nicholson: I've got a couple here, former hospital pharmacists.

Mr. Michael Blanchard: It's something that the hospital pharmacist community in general are embracing.

Ms. Helena Jaczek: Good. Thank you. No further questions.

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

M^me^ France Gélinas: Chair?

The Chair (Mr. Ernie Hardeman): Yes?

Ms. Cindy Forster: I'd like to move a motion before we recess at 6.

The Chair (Mr. Ernie Hardeman): Let's finish this one first.

We thank you again very much for being here for a repeat performance. Obviously, in most cycles, a repeat performance is that if you did a good job the first time, you get an encore. We'll have to judge to see as to how the rating of the second performance turns out. But thank you very much for being here again today.

With that, I do have a couple—and we'll get to your motion. We were contacted by Dr. Thiessen, our previous presenter. He would like confirming that he has now concluded performing here, and as he mentioned in his presentation, he wants complete—what shall we say?—clearance so he can do other things, that he's no longer involved in dealing with this report. I told the Clerk to contact him and say that, in my mind, he was complete, but if that wasn't so, we would let him know. Is everyone here happy with that? Okay, thank you very much. We can do that.

Now we have a motion.

Ms. Cindy Forster: Thank you.

I move that, pursuant to standing order 111(a), the Standing Committee on Social Policy study and report all matters related to the mandate, management, organization and operation—

The Chair (Mr. Ernie Hardeman): Excuse me. We can table the motion, but you can't really put the motion. As we ruled on the other one, this meeting was set up for

something else. You can table it with the Clerk to be dealt with at the next convenient time.

Ms. Cindy Forster: Well, I'd like to request that that be the first order of business tomorrow at social policy.

The Chair (Mr. Ernie Hardeman): We'll have to see what—the social policy is set up tomorrow for a closed meeting for report writing. We'll have to make a decision at that time as to what we do with it at that time. We cannot make a motion today to tell what this committee must do tomorrow.

Ms. Cindy Forster: Well, in fact—

The Chair (Mr. Ernie Hardeman): Okay, thank you. That concludes the debate.

Now, is there anything else for the betterment of Rotary? If not, this meeting stands adjourned.

The committee adjourned at 1752.

CONTENTS

Monday 23 September 2013

STANDING COMMITTEE ON SOCIAL POLICY

Chair / Président
Mr. Ernie Hardeman (Oxford PC)

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

Mr. Bas Balkissoon (Scarborough–Rouge River L)
Mr. Ted Chudleigh (Halton PC)
Mr. Mike Colle (Eglinton–Lawrence L)
Mr. Vic Dhillon (Brampton West / Brampton-Ouest L)
Ms. Cheri DiNovo (Parkdale–High Park ND)
Mr. Ernie Hardeman (Oxford PC)
Ms. Helena Jaczek (Oak Ridges–Markham L)
Ms. Jane McKenna (Burlington PC)
Mr. Paul Miller (Hamilton East–Stoney Creek / Hamilton-Est–Stoney Creek ND)

Substitutions / Membres remplaçants
Ms. Cindy Forster (Welland ND)
M^{me} France Gélinas (Nickel Belt ND)
Mr. Rob Leone (Cambridge PC)

Also taking part / Autres participants et participantes
Mrs. Christine Elliott (Whitby–Oshawa PC)
Mr. Jeff Yurek (Elgin–Middlesex–London PC)

Clerk / Greffier
Mr. William Short

Staff / Personnel
Ms. Elaine Campbell, research officer,
Research Services