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# Official Report of Debates (Hansard)

**Monday 27 May 2013**

# Journal des débats (Hansard)

**Lundi 27 mai 2013**

## Standing Committee on Social Policy

Oversight of pharmaceutical companies

## Comité permanent de la politique sociale

La surveillance, le contrôle et la réglementation des entreprises pharmaceutiques

Chair: Ernie Hardeman
Clerk: William Short

Président : Ernie Hardeman
Greffier : William Short

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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

# STANDING COMMITTEE ON SOCIAL POLICY

# COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Monday 27 May 2013

Lundi 27 mai 2013

*The committee met at 1409 in committee room 1.*

## OVERSIGHT OF PHARMACEUTICAL COMPANIES

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

## DR. JAKE THIESSEN

**The Chair (Mr. Ernie Hardeman):** Our first deputation this afternoon is Dr. Jake Thiessen. Before we do that, we will point out that, first of all, after today's—we only have two delegations we will be hearing, and hopefully we'll have an issue of a report that we'd like to discuss after that. Hopefully the committee will be able to stay after the two to hear that.

Secondly, I just want to point out that as with all delegations, we will present you with 20 minutes to make your presentation. At the end of the presentation, we will have 20 minutes of questions from all three parties to ask any questions about your presentation that they may have. We will start the questioning this time with the government caucus.

With that, Doctor, thank you very much for coming in and sharing your knowledge and your successes or failures with us. We do have to swear an oath to this committee at this time, so with that, we'll turn it over to the Clerk for the swearing of the oath, or affirming your oath.

**The Clerk of the Committee (Mr. William Short):** Dr. Thiessen, do you prefer to do an oath or an affirmation?

**Dr. Jake Thiessen:** Oath.

**The Clerk of the Committee (Mr. William Short):** Oath? Okay. If you just want to grab the Bible, please. Thank you.

Dr. Thiessen, 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?

**Dr. Jake Thiessen:** I do.

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

**The Chair (Mr. Ernie Hardeman):** Thank you very much for that. Now we will turn the floor over to you for your presentation.

**Dr. Jake Thiessen:** Thank you. Good afternoon. I've come to inform you a bit about the work that I've been doing as an appointed independent reviewer for the entire oncology medication issue.

I thought perhaps I'd give you a little bit of background about myself. I'm originally from Manitoba. My first degree in pharmacy was from that university. Ultimately, I went to the University of California, where I obtained a PhD, particularly in medicinal chemistry. I'm a former professor, associate dean and current professor emeritus at the Leslie Dan Faculty of Pharmacy. In fact, I used to walk across in front of Queen's Park on a regular basis.

Following 33 years at the University of Toronto, I spent six years at the University of Waterloo, where I had strategic responsibility for the development of a new health sciences campus and Canada's 10th school of pharmacy. Education, research and administrative leadership have been central to my academic career for about 40 years.

I am specialized in an area that—the words may be foreign to you—pharmacokinetics and pharmacodynamics, which basically describe quantitatively those forces that affect how the body disposes of or handles medicines and how, in turn, medicines affect the body. The dynamic of these two areas influences strategies around patient treatment in all disease states.

I've spent some years working with medical oncologists and basic scientists at Princess Margaret Hospital. In recent years, my University of Waterloo research collaborations explored a special region of light and its illuminating benefits in the pharmaceutical and medical fields. I can tell you that we have a start-up company that was formed called Verisanté, which is traded on the ventures exchange. Our first product, called Aura, is a revolutionary technology allowing skin irregularities to be scanned and thereby assist in the early diagnosis of skin cancer.

My broad experience includes international projects in countries like Taiwan, Saudi Arabia, Sudan, Nigeria and others, actually. I've been the president of the Canadian Council for Accreditation of Pharmacy Programs. In a past life, I chaired the Ontario Ministry of Health's Drug Quality and Therapeutics Committee. I chaired the Health Canada Scientific Advisory Committee on Bioavailability and Bioequivalence. Presently, I serve Health Canada in the capacity as chair of the Scientific Advisory

Committee on Pharmaceutical Sciences and Clinical Pharmacology.

I suppose, on the basis of my qualifications and experience, I would be considered seasoned with a broad understanding of professional education, research methodologies, pharmaceuticals, the industry surrounding all of that—supply chain, patient care etc.

On a more personal note, my interests in cancer include not only the areas that I've mentioned, but my own father passed away prematurely from the illness. My mother also had a severe bout of it, and my wife's two sisters have died of cancer.

When I was asked whether I would take on this role of independent reviewer, I was reminded of Martin Luther's comment, which was, "Our lives begin to end the day we become silent about the things that matter." This kind of riveting idea was what actually helped, in some ways, in agreeing to do this.

My official appointment date is identified there as April 15, and this is some three and a half weeks following the first discovery of the questionable products. Regarding the details of the appointment, I suppose you're familiar with them, and so I'll pass over those in the interest of time.

As I approached all of this, I thought that trustworthy insights are gained through evidence-based information and validation. So I was very keen to make sure that whatever information I gathered was not just hearsay but evidence-based. I have approached this incident without a preconceived bias regarding stakeholder guilt or innocence.

In terms of methodology, I put this down as the combination of the Kipling method and root cause analysis. Kipling is what we widely know as what, why, when, how, where and who—those kinds of things. This is a fundamental kind of research approach. Research that involves root cause analysis also has a similar kind of flavour to it.

To assist with informing you today, I thought it might be helpful to present two figures that encompass this incident and the stakeholders. So on page 3 of the handout, I present first what I call kind of the directly linked stakeholders around the incident. They, of course, are the vendor and the group purchasing organization, which in this case is Medbuy. There are materials I will refer to later on that really link the vendor and the GPO. There are, of course, the hospitals, and ultimately there are the patients.

On the following page, page 4, I am presenting to you what I call an enlarged group of key professional, structural, regulatory and oversight stakeholders. You can see that this encompasses the Ministry of Health for Ontario, Health Canada, the Ontario College of Pharmacists, Cancer Care Ontario and the Ontario Hospital Association, and then there are a series of others that one might say certainly have strong professional interest in this entire development. As I speak to this later on, I will refer to these two figures.

As a caveat, I want to alert you to the fact that my work is still not complete. You've asked me to appear as I approach the midpoint of the 13.5-week allotted investigation time. Some aspects remain to be explored, and the final recommendations are not yet formulated. Nonetheless, I seek to distill for you in a short period of time some of the key things that I feel have emerged as part of this six-week journey I have been making.

In view of the dire implications for patients—and I can tell you that that was the heartbeat for why I got into this. It was all about trying to figure out—given my own experiences in my own family, it was all about patients. I even told the minister directly that the only reason I was interested in this was to pursue the patient care issue. I was simply wanting to somehow try to gather information about the incident and substantiate the evidence and its outcomes. It was important, I felt, to learn how the episode had been dealt with, as this incident was not only about materials—it's not only about chemotherapeutic agents—it's about people who had been affected.

To begin with, as I've indicated there, I felt it was necessary to begin at ground zero, which in this case is the Peterborough hospital where the discovery was made on March 20. Remember, I was appointed officially as of April 15, so I launched very quickly into the work before me, which was to try to gather the information. As you'll see here, April 17 was the date for the visit to Peterborough, and Lakeridge was actually included at that same time.

The New Brunswick institutions were eventually contacted as well, and I did that via telephone. Thereafter, the search expanded to stakeholders like the vendor, Marchese, followed by those that would be considered as part of what I've already referred to as the professional or regulatory involvement.

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Beginning at the level of patients, I want to highlight first what happened at the level of the hospitals and then the enlarged group of stakeholders. I'm calling this the "response to the incident" regarding the affected group.

I want to remind you of the numbers which you undoubtedly have heard before, but the best count that I have is 1,202 patients, ranging from only one in Peterborough through the largest number, which is in London, and then ultimately 183 in New Brunswick. That represents the entire count.

One of the quotes that I use in a variety of presentations that I make both nationally and internationally is the one that I picked off a website entitled Finest Quotes. It goes like this: "We eat food prepared by others, drive on roads built by others; we rely, every day, [on] actions of others, and we are relied upon in turn. Where trust fails chaos closes in. Our entire civilization relies on a singular faith that we can count on others." I thought to help you a little bit, on the positive side, maybe an overarching outcome that I've observed is to say, "Okay, let's just review this from the point of view of: Was the trust in the institutions that are involved here real and legitimate?" So I thought I would quickly walk you through some of the responses that I've observed.

To begin with, I must tell you that there were absolutely valiant efforts to find the identities of the patients,

sometimes combing through three computer records. You don't know the kinds of efforts some people made in trying to identify the patients. Then I want to tell you that pharmacy—and there's no nepotism here—pharmacy in those institutions took decisive action in removing the questionable items from the supply system. They played a responsible and responsive role here in contacting potential users—and there is no formal structure to this. This is an informal system of passing information on. I actually searched for all of these items that they said had been taken out of the supply system. I wanted to know: Were the counts supported when I saw the quarantined items in the total counts of things that they had purchased or had obtained? So I walked through all of that and I can tell you, every one of them is accounted for.

Not only that, they had an immediate backup plan where they began making in-house both the cyclophosphamide and gemcitabine doses—a terrific story, I feel.

I feel that there was mobilized action on a grand scale. Diligence by administration, risk management personnel etc., was absolutely exemplary. There was uncommon commitment to trying to connect with patients—and you can imagine physicians in their busy role, medical oncologists, who are not only burdened with the customary role of seeing patients, who now were reaching out to the patients who had been affected, trying to talk to them. They had mailings, registered mailings; they had town hall meetings; they had all kinds of things that were done in order to connect with people. I give them high marks for this.

I can tell you that the present infrastructure and collection of personnel within each hospital has met and largely overcome a major challenge. Evidence supports the view that the hospitals performed well in this crisis. Many laudable untold actions by administrators, physicians, pharmacists, nurses etc. have been observed.

This was trust illustrated. You can't legislate such action. The health care system would quickly become dysfunctional with such people. I can tell you, although I'm not finished with all of this, I hope to actually have a chronological record of all of these things in the ultimate report that I'm going to assemble.

As far as the other stakeholders are concerned, with that March 20 discovery, eventually, Cancer Care Ontario notified the ministry on the 28th. There were many things that fell out as a result of all of that.

On April 11, to the best of my knowledge, the ministry assembled a working group of all kinds of people to try to deal, on a daily basis, with whatever information surfaced and to see how they could actually contribute to the resolution of the matter.

On April 2, Cancer Care Ontario and the Ontario Hospital Association provided rapid media announcements.

The Ontario Hospital Association, on the 17th, actually sent out a questionnaire to make sure that everything was going to be taken care of, mitigating any kind of further risk.

The Ministry of Health, on the 19th, announced regulatory changes under the Public Hospitals Act, allowing 17 days of questioning, and there were a number of things that were stipulated as part of that regulation, including the role that pharmacy would play, who was licensed to do these things and so on.

On May 10, the Ontario College of Pharmacists announced an amendment to Ontario regulation 202/94, by adding part IX, "Inspection of drug preparation premises." This provided the college with the authority to inspect these DPPs, as we call them, where pharmacists and pharmacy technicians work or at least are proposing to work. There were also things in that regulation change outlining the parameters, including timelines, of how a member is to notify the college of any current or intended employment, and there are many other things that are part of that. They also made a change to some of the accompanying bylaws.

Health Canada also stepped up to the plate. They provided regulatory direction on the 19th of April involving some stipulated constraints around compounding and admixing of medications. Specifically, there must be three conditions prevailing: It must be done within a hospital; if it's outside a hospital, it must be under the supervision of a provincially licensed pharmacist; and if not that, then functionally, it must fall under the licensing and manufacturing requirements as found in the Food and Drugs Act.

If I step back for a moment and just recollect all the things that happened, I have to say that decisive actions were taken, whether in hospitals or through provincial or national agencies, and featured commendable crisis-stemming leadership. There was a concerted resolve to address the issues squarely and urgently and to avoid any similar incident and therefore safeguard patients' care. Again, in keeping with what I said before, I hope to be able to actually provide a chronological record of what took place.

Let me shift to more of the cold analytical side here, which is about the materials that are part of all of this. To help you, based upon the discoveries that I made, I would like to compare for you what actually happened during the days when the vendor, Marchese, was playing its role versus what happened once Marchese was no longer in the picture so that you could clearly see what's the same and what's different.

In front of you, in step 1, as I've called it, are the two medications in question. There's the cyclophosphamide picture on the left, which is a two-gram vial. Then on the right is the gemcitabine vial, which is also containing two grams of the drug. The first step that is required and is followed by both the hospitals now and Marchese then, is to reconstitute the powder. They use the identical Health Canada-approved drugs in those vials. Those medications were contractually obtained by the group purchasing organization; that's part of the group buy. It didn't matter whether it was Marchese doing it or a hospital subsequently. It's exactly the same material. They used exactly the same technique in reconstituting—and I'll say a little bit more about that in a few moments. And they used the exact volume of the same diluent, which is normal saline,

so exactly the same thing was happening at Marchese as was happening subsequently at the hospitals.

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Let's pick up step number 2. They've reconstituted; they've dissolved the medication that's in those vials. The next step is what happens now at the hospital. At the hospital, a particular dose is prescribed for a patient that's individualized and a required amount of drug is drawn up from the vial. That required volume matches the amount that's required for the ultimate administration to the patient.

What happens is, that amount, that volume, is now diluted into approved normal saline. This is a dilution step for the convenience of administration for the patient, and very often, of course, what happens practically is that these medications are administered via an infusion pump, so that's all part of the system of administering.

What happened when Marchese was doing it is this: They also drew up the entire contents of the same vial and they placed them in the bags. These were saline bags from the GPO's—this is the group purchasing organization—approved supply, which was Hospira, and what they actually did was they took two vials in each case. In the case of cyclophosphamide, they used 100 millilitres for each of the two vials. So they had two vials, 100 millilitres each, and they returned those volumes to those bags. In the case of gemcitabine, they used a 100-millilitre supply of approved normal saline and they would take 50 millilitres of that saline, put it into one of the vials of gemcitabine and 50 into the other one—just like what the hospitals do—and then they would take the dissolved material and put it into the bag again.

So are you with me? What the hospital is doing now was in essence what Marchese was doing at that point, but there are a few differences I want you to be aware of.

First, in terms of the gemcitabine, the story is very simple: It was a nominal 100-millilitre saline bag from which they were drawing. When they had withdrawn the 50 millilitres for each of those vials, in essence the bag should be empty, right? Now they put the dissolved drug back into the bag, so basically the bag now contains the equivalent of two vials, or four grams. The concentration, in theory: four grams per 100 millilitres. We can explore this a little bit more.

For the cyclophosphamide it was a little different, in that there is no 200-millilitre bag of normal saline. There's a 250-millilitre bag. That's the nominal quantity in the 250-millilitre bag. What they did first is they withdrew 50 millilitres from the 250-millilitre bag and discarded it. Now they were left with 200. They took 100 out, dissolved the contents of one cyclophosphamide vial and did the same for the second one. The dissolved contents were now returned to the bag. That's what they did.

Step 3: With Marchese in the supply chain, they basically took those bags that had been furnished by Marchese and they then drew out what was considered to be the dose, just like what they're doing now, a certain volume, and diluted it at the hospital into normal saline for administration to the patient.

I hope that clarifies what's the same and what's different between the two situations.

Further clarification I want to present: Only quality, approved pharmaceutical products and diluents were used. It's best to understand these things in terms of what I'm going to call nominal content, accuracy in content and precision in content. We can explore that later on. There is no evidence of any malicious or deliberate drug-sparing dilution in preparing the bags of cyclophosphamide or gemcitabine by Marchese. But I must tell you, diluent overfill is the issue that is critical in all of this.

In closing, let me just add one more thing here. I want to return to the patients, because that was what I was interested in. I believe there is some work that remains to be done, and I'm going to give you just a snapshot of what I'm interested in: the degree to which there is some variance from what is expected in delivery of the amount of either of those two chemo agents. The big question is, so what? What was the implication for patients? That's the key question.

While I have experience in this field, having worked in it to some degree, I think that the best would be for us to take and get an outside opinion about this, in fact, outside of Ontario—not, can I say, part of the Ontario system. So I'm working with Cancer Care Ontario to actually create an objective, exterior-to-Ontario evaluation of what the implication would be of this kind of underdosing that has been presented. I feel that that would do us all a world of good. I think it would provide the best assurance and confidence for patients that the incident is understood, first of all, and to undergird and perhaps restore some damaged trust that is there.

Ladies and gentleman, those are my opening remarks. Thank you.

**The Chair (Mr. Ernie Hardeman):** Thank you very much for your presentation—very thorough and helpful, I think, in our deliberations. With that, we will start with Ms. Jaczek.

**Ms. Helena Jaczek:** Welcome to Queen's Park, Dr. Thiessen. You were talking about walking in front of it, and I recalled my days as a medical student on the fourth floor of the medical sciences building. I spent some summers in the department of pharmacology, so it was just a bit of a flashback for me as well.

I'm going to start where you ended. You do have experience, as you've told us, in pharmacokinetics and pharmacodynamics. You are talking about an external review of the impact on the patients, and I think, from the word go, this is obviously the prime concern, certainly, for those of us in the government. We have heard reassuring words to date from Cancer Care Ontario in terms of their opinion of the impact on patients. Could you just elaborate a little bit on the kind of individual responses there are to medications in terms of pharmacokinetics and metabolism by different individuals? Just to sort of give us a general picture of that.

**Dr. Jake Thiessen:** Okay, thank you very much. Yes, there's certainly a fairly broad spectrum of responses that

you might expect in people. If you look back at the history of even chemo agents, which we're going to talk about specifically, for quite some time, the idea was that perhaps the use of the largest possible dose would be the way to go. Increasingly, over the last number of years, and particularly, I would say, in the last 10 years, what has emerged is something called personalized medicine. Functionally, there's an increasing interest in finding out what a patient is most sensitive to when it comes to the particular cancer. That sensitivity then serves, among other things, to identify the most logical drugs to use.

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But there's more to the story than that. The cancers are embedded in the body. What is needed, if in fact—and depending upon how that chemo agent is used, the drug has to get to that particular cancer site, and that's not necessarily an automatic, depending upon where it is. So part of the goal is to find a dose that would be most suitable in getting the bloodstream to deliver to that particular site. The individual is then dosed upon some metrics, we commonly call them. One of the metrics that sometimes is used is simple body weight, but in Ontario it's more appropriate to use body surface area as kind of a surrogate of the best estimate as to what the dose is that is going to be needed in a particular patient. So that is typically what is done.

The response can vary rather dramatically. There's a fair bit of variability that is encountered in that. One of that areas that I studied particularly was the myelosuppression and whether there would be more science that could be brought to myelosuppression in order to figure out when the next dose ought to be given. There's a kind of a juggling between art and science in all of this. Ultimately, there are factors like the recovery from myelosuppression, for example, or mucositis or whatever it happens to be, but also there are issues around age that are factored into it. There are issues sometimes over organ function, like kidney and liver and so on. So there's always this kind of modification of science, which is the ideal best, with what is known, to serve the patient. There are variables, frankly, that are important in all of it. I hope that helps to clarify—

**Ms. Helena Jaczek:** Yes. I think what is hopefully reassuring to the public in general is that while this was an underdosing, the actual critical dose for each individual patient is a best estimate, in essence, of what is appropriate. As some of my constituents have said to me in the last week or so during constituency week, thank heavens it wasn't an overdose, that that potentially could have led to more severe side effects as well. So I think this individual response is a very fascinating area, and I think the idea of following up with that investigation is very interesting.

Now, coming back to the way Marchese interpreted the specifications given to them by Medbuy: I presume you've looked at the way Medbuy had their schedule and how it was described, how they wished the medication to be provided to the hospitals. Do you feel that the way Medbuy put those specs out was a reasonable way of asking for this product?

**Dr. Jake Thiessen:** Thank you. Can I say that I've yet to visit Medbuy? I'm scheduled to visit them in the beginning of June. That's a very critical visit. There's more to an agreement between a group purchasing organization and a vendor like Marchese than meets the eye. There are specifications that at this point I do not know about, that I have not been able to identify. I certainly know about things that Marchese has told me, but if you recall, one of the things I want to do is validate information. So I want to hear it from Medbuy's side.

Ingredients that fall into this are a clear understanding about nominal content, how it was to be packaged, what was to be on the label—a very critical part, what was to be on the label—what storage conditions should have been and so on. This is a bit of an unusual case because there was a prior vendor, namely Baxter, that had served this community for quite some time, and now there's a hand-off that is taking place, a hand-off from an older vendor to a newer vendor. There are a lot of questions about how that hand-off should have been made, and I'm interested in exploring exactly what the clarifications were.

The real hand-off needs to occur to the end user, which in this case is the pharmacy at the hospitals. The pharmacies are dependent upon a clear understanding of what that product is about. As I'm going to explore that with Medbuy, there are a number of questions that I want to be ironclad about, and that will help me understand a lot of things, not the least of which is, what was the overfill factor in all of this?

**Ms. Helena Jaczek:** I understand that you have yet to visit Medbuy, but would you have expected Marchese to bring to the attention of the receiving pharmacy at the hospital that there was overfill in the bags?

**Dr. Jake Thiessen:** I think that's a logical question. Marchese's been very careful to indicate that they were delivering on a required, contractually agreed upon product. That's what they were doing. Their interaction with the hospitals was only as a service agency for those contracted products. Would it have been logical? That's something that I want to explore with Medbuy. Because I think there's a triumvirate that's here, and I need to understand much better what the roles of each should have been.

It's easy for us to blame at this point, but it's important first to understand. I need to understand that from Medbuy's side.

**Ms. Helena Jaczek:** In terms of the rapid response you have outlined to us, it sounds like you were really quite impressed with the individual hospitals, Cancer Care Ontario and the Ministry of Health. Is that a fair summary?

**Dr. Jake Thiessen:** That's a very fair summary, thank you.

**Ms. Helena Jaczek:** In terms of the regulations that the Ministry of Health has enacted, do you feel that this is in some measure addressing this gap in oversight that has previously existed?

**Dr. Jake Thiessen:** Okay. Can I say that I've termed both the steps that have been taken by the ministry and

the activities by the Ontario college as remedial clarification. That's how I've coined it. I think, given everything that unfolded, the importance of making sure that there was no doubt as to who was in charge to make sure that any other vendor or outsource supplier was issuing or providing products that were safe was the right thing to do, these kinds of announcements.

Will there be a broader look at all of this? That's my responsibility. I personally feel that there are some areas here that warrant some further attention.

**Ms. Helena Jaczek:** With your experience in pharmacy, as you've detailed to us, were you aware of this grey area, grey zone that we've heard about in terms of this lack of oversight of compounded medications?

**Dr. Jake Thiessen:** You know, I know that's the terminology that is used, a "grey zone." This area of what I would call broadly the professional area of a profession's life is something that is common in many areas. It's not only pharmacy; it's in medicine and dentistry. The United States has also grappled similarly with this whole thing. There is this sense of entrusting to the professionals things that the professionals know most about.

I have never felt this is particularly grey—this is a personal opinion. I felt this is part of the customary evolution of service that professionals provide. Does that necessarily offer the security that we all would like? Well, perhaps not. But you know what? We can fix some of these things and hopefully embed them for future generations.

**Ms. Helena Jaczek:** You're undertaking the study here in Ontario. Are you aware of differences, province to province, in terms of oversight of hospital pharmacy or of this type of compounding facility? Further to that, would you ideally see a national system so that your findings could potentially affect other provinces?

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**Dr. Jake Thiessen:** First of all, to your latter point: Yes, I think there are areas of all of this that are of national interest. I mean, it so happened—can we step back for a moment? It so happened that this was Ontario-centric, and New Brunswick was in some ways the recipient of all of this, right? It could have easily been done in New Brunswick, and then, "So how would this look in Ontario," right? I personally feel that there are some national things that need to be looked at.

We have done some work to try to find out what the best practices are in other areas—not only in Canada, but south of the border—and those will be part of the quest as I try to provide the best advice in the future. Thank you.

**Ms. Helena Jaczek:** We'll reserve any time we have for the next round.

**The Chair (Mr. Ernie Hardeman):** Thank you. The official opposition: Ms. McKenna.

**Mrs. Jane McKenna:** Thank you again, Dr. Thiessen, for coming in. Just because we've obviously been sitting here through all of the people that have come in, I'll be anxious after you speak to Medbuy as to what your—hopefully you'll be able to come back and tell us that.

I have a few questions. When we had Ms. Zaffiro in here, she said that she did exactly what the contract told her to do. When I'm looking at Medbuy, which is a broker—I'm assuming that if somebody is a broker, they understand the product that they are getting and understand the product that they're handing off to somebody else. So I guess my biggest confusion—maybe you can't answer because you haven't spoken to them, but they explained to us that they didn't think that there was anybody else there who did what Baxter did, which was the admixing, so they didn't even put an RFP out. Marchese actually came to them and told them that they could do the job, so nevertheless, they went out to see Marchese's facilities and whatever.

When they had Baxter, they had a contract that they did themselves. We asked if anybody else overlooked that contract that was done, and they said no; they were fully responsible for the contract between them and Marchese and them and Baxter. So I guess my question is, if you're doing the exact same thing with the exact same contract, how can it be different?

**Dr. Jake Thiessen:** In terms of this, one of the places that I am still to visit is Baxter. I want to understand, also, exactly what happened while they were still offering their services prior to Marchese. There are some elements of that that need to be understood, and you've got to remember that cyclophosphamide is actually coming from Baxter. So ironically, the agency, the vendor, that was both providing a service and a product also now was providing some things to Marchese, so there are some things in that that I am going to be exploring.

Why isn't it exactly the same? If we can use that as the jump-off point. I understand—but this remains to be tested with Medbuy—that in fact Marchese was not privy to the methods and the formulation, if I can call it that, the admixture formulation that Baxter was using.

**Mrs. Jane McKenna:** Okay. Now that we all realize that, and thank you so much for that, I guess the bottom line is that if you don't know of any other company out there that is doing this, to have them come in and take over this position to do this—I was just overwhelmed, I guess, at the fact that there was nobody overseeing anything, considering that this was a brand new contract with a company that had never done it before.

I'll be grateful, when you do actually go, to see how that fell apart from one company to the next, because clearly—Baxter had that position three years ago in 2010, and they understood exactly what they had to do. So I'm kind of confused with that.

My next question is, should the hospital not at any time notice the extra in each bag after they withdrew the portion from it for over a year? They were doing the same thing.

**Dr. Jake Thiessen:** I'm sorry, at the level of the hospital?

**Mrs. Jane McKenna:** Yes.

**Dr. Jake Thiessen:** Correct. The events that take place inside a hospital—and I've reviewed all of this,

because I've visited them all. I know exactly what happens at every one of the hospital pharmacies. I know how the patients are linked into it all. There are places—especially somebody like London, which is a very busy location—that are preparing hundreds of doses every day. When those bags are there and they are drawing out a certain volume, the idea of them not noticing that in fact there was some residual volume left and so on is entirely obvious to me. Because you've got to remember that there is now in every one of those bags four grams. Well, four grams is not an amount ever given, I don't think, to a single patient. It represents something for a variety of patients. And you get different sizes, as we were talking about a few moments ago. They'll take out several—perhaps 50, 60, 80 millilitres or whatever it happens to be—and there's some left, and it's easily possible not to notice that in fact there's a volume differential. I actually did a test on myself. What I did was I thought, "Okay, everybody thinks that they can tell volume differences." So I had an independent person—this is the scientist in me; sorry—making up 210 and 220 millilitres of saline in a bag. Let me tell you that these bags are irregular. They're squishy. It is very difficult to tell which bags have a variance in the volume that's there. I'm just giving you a practicality of life.

Combining the two things—that is, the nature of bags and the fact that only partial volumes would be drawn out, especially if there were children involved that were being treated etc.—it's entirely possible that they wouldn't notice.

**Mrs. Jane McKenna:** Just one more thing: Now that everything is back in the hospital and they're doing all the premixing there, each place that came in told us that it was all running smoothly, and there weren't any bumps or hurdles or anything at all. I guess my question would be, what would have been the reason for sending that out, then, if nobody has noticed anything at all by now doing it in-house?

**Dr. Jake Thiessen:** There are, I think, two reasons for it. One is that it takes a while, particularly for cyclophosphamide, to dissolve. How long does it take? Well, if you were to have an automatic shaker, you could probably get it to dissolve in something like five to 10 minutes. But the way they actually do it is, in the morning, they will decide, during a slow time, to actually create so many vials of cyclophosphamide, for example, and they will add the diluent to it. And then while they're doing other things, somebody comes by and shakes it. Then they'll do something and they'll come by and shake it. So I said, "Well, using your technique, how long does it take?" They said, "About four hours." So if you're a fairly busy place and you're trying to, as that stuff dissolves—to have an agency come along and actually provide you with the dissolved material is a big advantage to them.

The other thing is, they're also working with chemo agents that are noxious under the best of circumstances. To have somebody doing it under what is called USP 797, which is fairly tightly controlled, really nice facilities, makes some sense. But you're asking an important question: Should it have stayed in-hospital? There are hospitals that do it; they do it regularly. But there was a feeling that it might benefit them in their operation, and that's why they did it.

**Mrs. Jane McKenna:** That's it for me. Thank you. Go ahead, Jeff.

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

**Mr. Jeff Yurek:** Good afternoon.

**Dr. Jake Thiessen:** Good to see you.

**Mr. Jeff Yurek:** Good to see you. Sorry I was a little late. I was doing a tour with some constituents and we got hung up on the third floor.

I was doing a calculation: It's been 18 years since I sat in your class, so thanks very much. Thanks for doing what you're doing.

**Ms. Cindy Forster:** You haven't aged at all.

**Mr. Jeff Yurek:** Oh, thanks.

**Dr. Jake Thiessen:** He looks younger now than then.

**Mr. Jeff Yurek:** But thanks very much for leading this study and for the education you've done for all the pharmacists through all the years, both at Toronto and at Waterloo—although I was pro-Toronto, I will say good for Waterloo.

**Dr. Jake Thiessen:** Oh, that's fine.

**Mr. Jeff Yurek:** I wanted to ask a lot of questions about Medbuy, but that's fine; I can throw in a few of those. I'll get back to the Medbuy issues.

Just to go off of Jane's question with regard to the hospital, have there been any chemo spills at all since they've taken over? Have there been any issues of that sort?

**Dr. Jake Thiessen:** To my knowledge, no. That's the best I can tell you.

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**Mr. Jeff Yurek:** Another question we had: Do you have the stability data? Have you looked at the stability data—

**Dr. Jake Thiessen:** Yes.

**Mr. Jeff Yurek:** —because we're having trouble finding data that actually would cover both Baxter and Marchese with supplying the drug for the long term.

**Dr. Jake Thiessen:** Of the two agents, I would say that cyclophosphamide is the most unstable. At room temperature, of those reconstituted vials, the shelf life is thought to be only four days at most. There's the view that perhaps that ought to be narrowed a bit, depending upon the temperature of these rooms. But if it's refrigerated, then in fact it's something in the order of approaching a month. It's like 27, 28 days for both of them.

One of the things that the people at Peterborough noticed was not only the difference in the label but also the storage conditions. I know that there's been some concern about that whole issue. The view, as you know, Mr. Yurek, is that any time you can prolong shelf life, the better, and simply refrigerating things is the logical thing. So there is no issue for me about the difference in storage conditions. It's that when you refrigerate it, it's better for everything.

**Mr. Jeff Yurek:** Okay. I liked your point about the hand-off of the contract; that's something that definitely needs to be looked at, to ensure that—continuity of care, I guess, for the patient at the end of the day is what needs to be looked at.

The other question I have is with regard to the College of Pharmacists. You've talked to them. They've been here talking a few times and I've mentioned to them extending the college's powers to oversee and regulate hospital pharmacies, in-house pharmacies. Do you have any thoughts on that?

**Dr. Jake Thiessen:** Well, you know very well that there is this issue about what the college actually oversees. Hospitals have typically been the jurisdiction of the Ontario Hospital Association, the entire Accreditation Canada matter. I would say that, by and large, pharmacists in these hospitals of course are licensed with the college in their respective locations, and I think—is it right?—something like five out of the 13 areas in Canada do have licensing requirements of their hospital pharmacies by the colleges. So I think that leaves eight that do not have that.

Am I sensitive to that? Personally not, but I could see a standardization as being important, and if it goes that direction, I would support it. Do I feel that it's absolutely necessary? The answer is no, I think it has functioned well outside of that.

**Mr. Jeff Yurek:** Okay. I'm just going to reorganize my Medbuy thoughts, so I'll pass it on.

**The Chair (Mr. Ernie Hardeman):** Okay, very good. The third party: Ms. Forster?

**Ms. Cindy Forster:** Thank you, Dr. Thiessen, for being here today and for your opening remarks about the reasons that you actually undertook this investigation, that the main reason, of course, was for patient care.

My first question is, how was it that you were contacted, recommended, and by whom, to actually undertake this investigation?

**Dr. Jake Thiessen:** Thank you. I don't know.

**Ms. Cindy Forster:** You don't know. Okay.

**Dr. Jake Thiessen:** Very simple. I don't know, and I haven't asked.

**Ms. Cindy Forster:** So that's a question for someone else.

I'm just going to ask you a couple of specific questions, and then I'm actually going to turn it over to my colleague, because she has a long list of questions and wasn't here for part of your presentation.

With respect to the issue of the stability, you spoke to four days of stability on the cyclophosphamide, but what about the other drug if it's not refrigerated?

**Dr. Jake Thiessen:** Yes. I guess the standards that have been adopted for gemcitabine is that refrigeration is there, as needed. Is it that there's exaggerated degradation if left at room temperature? I haven't been able to get that information myself, to be honest, but what we know about thermodynamics—and sorry to be technical about it—is that any time you leave it at room temperature, it goes off much more quickly. It's like our butter.

**Ms. Cindy Forster:** So is that going to be part of the next few weeks when you're actually consulting experts in other provinces with respect to the report you're going to do? Are you going to be delving into that a little further?

**Dr. Jake Thiessen:** Well, it would be a side issue. But it isn't—dare I say—central to my concerns, because typically, when these things are reconstituted, they tend to be used fairly quickly anyhow; if for no other reason, those vials, reconstituted, serve an immediate need for the patients in the particular unit. With all due respect, it's probably not a primary issue.

**Ms. Cindy Forster:** Okay. Do you think that a red flag should have been raised at Marchese with respect to the specific concentration versus just mixing this bag as a one-dose, one-patient in light of the fact that it was four grams, and we're hearing from you, and we've heard from others over the past few weeks, that a four-gram dose would not be a usual dose for any cancer patient?

**Dr. Jake Thiessen:** That's a very reasonable question. It remains for me, and I ask you to accept this, that I need to understand the contractual agreement. That is so critical in all of this. I'm just going to give you some ifs, okay? If in fact there was contentment at the group purchasing agency to leave it at nominal content—and there's a difference between nominal content and accuracy and all these kinds of things—then that makes good sense why they just left it at that. If, on the other hand, there was carelessness or whatever, then that needs to be addressed. At this point, I simply don't know.

**Ms. Cindy Forster:** Okay, thank you. There was just one more thing. When you were going through your comparison between what happens in hospitals and what happened at Marchese, you talked about the cyclophosphamide being in the 200-millilitre bag, but the bag starts out being a 250-millilitre bag, so they were withdrawing 50 millilitres, discarding that, I guess, and then reconstituting 100 millilitres in each of the two vials. After they discarded the 50 millilitres, would they not have seen that there were still millilitres left, overfill, in that 250-millilitre bag?

**Dr. Jake Thiessen:** Yes. I mean, that makes good sense, in terms of these vials don't necessarily only allow you to add 100 millilitres.

**Ms. Cindy Forster:** Right.

**Dr. Jake Thiessen:** And it would have been rather easy for them, because they're reconstituting what they think is 200 millilitres left, to simply kind of take out enough to reconstitute in the vial and so on. Remember, what they're doing is returning the drug to the bag, right? I asked them specifically about that. They said, "Yes, we did notice always some additional amount or volume left in the bags, but it was never anything severe or exaggerated." To that point, one of the things I've wanted to know is specifically what kind of limits there were for the manufacturers of the normal saline for those bags.

I've got back data from Hospira, which was the supplier in this case to Marchese through the Medbuy agreement. Their US division—let me add one more piece. I

asked for the very lots that I know Marchese was using, so I could actually find the batches and I could now ask their division. What I got back from them is that for the 250-millilitre bag, which is the one that's primarily in question, it was around 8.2%. Their finished product testing was 8.2%, which was, in a 250-millilitre bag, about 20 millilitres more. So that is the error that is there due to overfill, or—can I say—that is the additional amount that's there. Those are the numbers that they were willing to give me back on all of that. I'm discovering that Baxter has the same kind of issue with their bags. Everybody seems to be overfilling.

The question is, should this be, was this, considered in the contract? I don't know at this point.

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**Ms. Cindy Forster:** You may not know the answer to this either. When Baxter was preparing their medication, though, were they estimating that there was an 8% overfill, or were they actually drawing up the fluid in that bag and basing their 38 milligrams per millilitre on an accurate amount of solution?

**Dr. Jake Thiessen:** Good question. I will find out when I visit Baxter.

**Ms. Cindy Forster:** Okay. My last question is, is there anyone else working with you on a team for this investigation. If there is, who are they?

**Dr. Jake Thiessen:** I am largely independent, resolutely independent. There is some support I get through the ministry with some scheduling and a little bit of literature search, but basically this is a one-man operation.

**Ms. Cindy Forster:** Thank you very much.

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

**M^me^ France Gélinas:** It's a pleasure to meet you, Dr. Thiessen. I'm sorry that I was late. You may have covered this, but just in case: You made it clear that you're halfway through your investigation; 13 and a half weeks is what you were referring to. How long after the 13 and a half weeks have passed do you expect your report to be ready?

**Dr. Jake Thiessen:** I like delivering on time. July 12 is D-Day.

**M^me^ France Gélinas:** Okay. So this is what you're going for?

**Dr. Jake Thiessen:** Yes.

**M^me^ France Gélinas:** Okay. Good to hear.

I also wanted to know, in the document you gave us, on page 8, you talk about nominal content, accuracy in content and precision in content. I take it that this is the type of terminology that is taught and used in pharmacy?

**Dr. Jake Thiessen:** Yes, those are rather critical terms. Nominal content is what a manufacturer declares as the target for content for a particular product. If you go into your pharmacy and buy some ibuprofen, it will say 200 milligrams on it, for example. That is the target amount in that particular container. But what actually happens is, when they do finished product testing, that content may not be exactly 200 milligrams, on average. It may be less or more by a certain amount. But more importantly, there will also be a certain amount of variability that is observed, so not all tablets are necessarily 200 milligrams. They range through a permitted spectrum. The standard for most pharmaceutical products in Canada is plus or minus 10%, which means that while most of the medications will have an amount near the nominal statement that's on the container, there can be some variability around all of that—

**M^me^ France Gélinas:** Sorry; does the 10% also apply to chemotherapy drugs?

**Dr. Jake Thiessen:** Okay, I'm coming to that. That's exactly correct: This also applies to cyclophosphamide and gemcitabine. Those vials that are received from the manufacturer are said to have a nominal content—two grams, let's say. What they actually contain is some variation on the theme. Yes, they tend to be around that, but they don't necessarily have exactly 2,000 milligrams, or two grams, in there. There is some spread that is recognized or permitted.

That helps us to understand the idea of accuracy. The precision is how much spread there tends to be. Nominal is what is said to be the target.

Now, let's go to the bags. For the bags, the target on the bag is what the manufacturer says is supposed to be there. In the case of a 250-millilitre bag, it says, "250 millilitres normal saline." The interesting thing is that the permitted accuracy allows it to be higher, and there is still a variability around all of that.

Going to the chemo agents in those vials, at this point, I know about gemcitabine because it comes through a distributor in Canada, but it is actually made off-shore; that drug comes from off-shore. I do not yet know about cyclophosphamide. It is actually distributed by Baxter, and I'm going to try to find out exactly what their specifications are. For the other one, I kind of know what they are. But if one follows what is called the United States Pharmacopeia for both of these, cyclophosphamide is allowed a plus or minus 10% for those vials; for gemcitabine, the USP standard is plus or minus 5%.

**M^me^ France Gélinas:** So when we're told that Baxter put the concentration amount on their label, is this what you would call precision in content? I'm trying to relate the two.

**Dr. Jake Thiessen:** The four grams per 100 millilitres is the target; it's the nominal amount. What Baxter did was they actually indicated that in the reconstitution, there was a volume enlargement due to the presence of the drug, which expanded the volume from 100 to 105. They used a bit of a different technique in creating their dosage forms than Marchese did. My understanding, to be affirmed when I visit Baxter, is that they actually started with empty bags.

**M^me^ France Gélinas:** And built it up from—

**Dr. Jake Thiessen:** And then filled into them, correct.

**M^me^ France Gélinas:** Okay. Something that is outside of the purview of what we do, but I was hoping maybe you would look at, is when the technician came and alerted us that he used to get the cyclo drug at room temperature, and his first surprise was that he had to get

it out of the fridge when it came from the new supplier. It kind of raised alarm bells a little bit that, given the short lifespan of those drugs, was there a mistake there from before? How can we guarantee that Baxter was delivering and being used, given that their supply chain was at room temperature, within the four days? It has nothing to do with what we're looking at, but it still worries me.

**Dr. Jake Thiessen:** Thank you. Good point, something I'm going to be asking Baxter about, because I want to know the full details of their specifications.

In terms of the Marchese side of this, I asked them about this. Why? Because I knew the same kind of issue over room temperature versus refrigeration. Their statement to me was, "When we shipped these things and so on, we felt that a constant environment for both of them was the best way to make sure the right thing was being done." So they basically were asking for refrigeration for both of them, and it was more almost a quality control consistency than it was trying to somehow signal a differentiation. That's the point that they were making. But like I said, to return to the issue, is there something here that needs to be understood from the Baxter side?

**M^me^ France Gélinas:** So you will be looking at the time lapse between the drug being prepared at Baxter and the drug being used in Ontario cancer treatment centres. You will be looking at that timeline?

**Dr. Jake Thiessen:** I simply want to know what their specifications are and what the evidence around that is, yes. So if they're saying that four days at room temperature is acceptable, I want to know what their evidence is for that.

**M^me^ France Gélinas:** Okay. Sounds good.

I want to go away a little bit from the technical nature of what you do more to the human side of what you do. So far, of the people that you've mentioned you've talked to, how did it go?

**Dr. Jake Thiessen:** How did it go with these people?

**M^me^ France Gélinas:** Yes.

**Dr. Jake Thiessen:** It was always a very collegial, open kind of event. Let me just give you a glimpse—can I give you a glimpse into a hospital visit, for example, just to help you understand?

**M^me^ France Gélinas:** Sure.

**Dr. Jack Thiessen:** Typically, the arrangements would be made to visit. The first part of the visit would typically be Q&A—question and answer—around a variety of issues. I had a whole battery of questions for everybody in those hospitals, and the people that would be present would be like the president and CEO, risk management people, oncology heads; there would be the pharmacy people, nursing and so on. So the room would generally be filled. It would be a number not unlike this, for example.

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I would pursue everything from infrastructure through how they actually dealt with the news and what the evidence was. Sometimes somebody would say, "Well, this," and I'd say, "Okay, would you please let me know what your take on all of this was?" So it was kind of, dare I call it, an inquest into the events there.

When all my questioning would be finished, which would be in the hour-and-a-half range, typically, as what we've seen here, I would then make a visit to the places that might have been touched by the medication. Certainly I visited the pharmacies and looked at everything there.

My technique in these places—and it was there or Marchese whatever—was to use a chaser technology, or chaser technique, I should call it, where I would simply say, "Okay, now, I want to know exactly this. Suppose the order comes in here. What do you actually do?" So I'd track everything that was happening, and I could see where there would be areas, issues in hospitals that ought to be addressed, ultimately.

I've been doing this kind of thing with every single visit, so I have a swath of information. That just gives you an idea.

**The Chair (Mr. Ernie Hardeman):** Just one little question left, and your time is up.

**M^me^ France Gélinas:** Okay. On a scale of things, you talked about how hard it was to dissolve cyclophosphamide: If you have a shaker, 10 minutes; if you don't—if you know cancer drugs in general that are being mixed in Ontario hospitals, on a scale of 0 to 10 or whatever makes sense to you, how complicated was it to mix those drugs compared to the other arsenals of drugs that are being prepared every day?

**Dr. Jake Thiessen:** I would say cyclophosphamide is somewhat of an exception. Most of them are used as what we would call salts; gemcitabine is a hydrochloride salt. They dissolve very quickly; they dissolve willingly. But cyclophosphamide is an exception.

**M^me^ France Gélinas:** Harder?

**Dr. Jake Thiessen:** Yes.

**M^me^ France Gélinas:** All right.

**The Chair (Mr. Ernie Hardeman):** Very good. Thank you very much. Back to the government side: Ms. Jaczek.

**Ms. Helena Jaczek:** I just wanted to go into the whole concept of group purchasing of these compounded facilities a bit, because my colleague from the NDP has talked through these hearings a little bit about how every extra step and every other organization involved is, in fact, sort of increasing the risk for something to go wrong.

I know you haven't visited Medbuy yet, but in theory, if the concentration is clearly on the specification, if the compound is very clearly labelled as to the concentration, would there be any additional risk?

**Dr. Jake Thiessen:** Additional risk, please? In—

**Ms. Helena Jaczek:** In potentially an error occurring. It sounds like there was sort of a bit of a lack of communication that was going on between what Marchese was doing, because they weren't alerting anyone to the overfill in the bag. If they had done what we think Baxter did, which was label according to concentration, where's the extra risk?

**Dr. Jake Thiessen:** Okay. In terms of the risk, yes, I agree with you completely that every time you add a step, in theory you add risk. On the counter side, the one thing that happens with a group purchasing agreement like this and a vendor like this is you tend to create uniformity, a uniformity in production of something. It's no different than a pharmaceutical company or whatever: Uniformity has some advantages. This is part of what has been widely recognized in hospitals, that when you have many hands doing many things, you also have a risk of some kind.

The other thing is that if you have—and we could perhaps disagree on risk here when it comes to an agency like Baxter or Marchese, but they have the finest facilities. All I can tell you is, in visiting Marchese—I still have to visit Baxter—there is no hospital that I've ever seen in all the visits I've made that has a facility that matches this. It is splendid in its configuration, in all the things that they have as checks and balances. They have some very detailed requirements around how things are produced.

There's a risk in adding a layer, which is a vendor, but there are also some benefits potentially. So one has to weigh this. I think this is a decision that a group purchasing agent needs to make. Sorry.

**Ms. Helena Jaczek:** Thank you for that.

**The Chair (Mr. Ernie Hardeman):** Thank you very much. The official opposition, Mr. Yurek.

**Mr. Jeff Yurek:** A question that just came up, before I go back to my Medbuy questions: When you were visiting the hospital, did you come across any process that staff could undertake if they were unhappy with a product that Medbuy had procured for them?

**Dr. Jake Thiessen:** Help me again, please, here.

**Mr. Jeff Yurek:** The London Health Sciences pharmacists said they weren't happy with the label. Is there any process in place at the hospital level to say, "I'm not happy with this product. How do I get a hold of Medbuy and let them know that I'm unhappy with it?"

**Dr. Jake Thiessen:** You know what? That's an exceedingly good point. In fact I think this speaks to the whole GPO issue, how this unfolds and how hand-off is done and how servicing occurs. This is one of the things, frankly, Mr. Yurek, that I want to investigate with all of them. Was there a way of people declaring some concerns about things? At this point I haven't found it yet.

I understand that one of the reasons why this particular vendor gained the contract was, in fact, the label. They liked the label, ironically—this is the team that was doing the evaluation—so were there some issues over the label at some of the hospitals? There were primarily over the lack of concentration identified and the storage differences. Those were the two things. Was that something that they gave feedback on? I don't know.

**Mr. Jeff Yurek:** Some of my concerns have been the fact that admixed products are kind of a step up from your average products you procure for the hospital, and my fear is it has just been swept into the big realm of their BPS policy—I guess that's the right name, broader public sector policy. I feel like a lot of these mixed drugs are now being treated much like ordering masks or brooms or whatever for the hospital. I've looked at the contract from Medbuy, and I know you will; I don't know if you have or not. But looking at risk prevention—and there's a lot of people out there who are a lot smarter and getting paid a lot more at the hospital level than I'll ever be—wouldn't you think it would be easy to limit the amount of risk so that it would actually be specific on the product you want to procure? For instance, we all know there's extra fluid in all IV bags; that's common knowledge in the industry. Wouldn't it be easier just to say we want cyclophosphamide 40 milligrams per millilitre, instead of four grams in 100 millilitres? That way it takes the whole error of overdilution or underdilution—either way—out of the mix.

**Dr. Jake Thiessen:** I completely agree with you.

**Mr. Jeff Yurek:** I just hope you take a look at this. Hopefully, you're going to review the RFP process. I think they were new at this for admixtures. There might have been steps. The vagueness of the contract—I think there were a lot of assumptions that were built into the contract, and those assumptions could add failure to every level of any organization or government.

**Dr. Jake Thiessen:** As we say, Mr. Yurek, the devil is in the details.

**Mr. Jeff Yurek:** Those are just my two cents I wanted to throw at you as you go forward to Medbuy. Again, I appreciate what you're doing for this province.

**Dr. Jake Thiessen:** Thank you so much.

**The Chair (Mr. Ernie Hardeman):** Thank you. Does that conclude the—

**Mr. Jeff Yurek:** I'm finished.

**The Chair (Mr. Ernie Hardeman):** If you're done, everyone's done. Thank you very much for your participation in this hearing this afternoon and taking the time out of your busy schedule. I want to say, since we're somewhat in the same exercise, we wish you well in your endeavours.

**Dr. Jake Thiessen:** Thank you.

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## MS. SARAH HICKEY

**The Chair (Mr. Ernie Hardeman):** Our next delegation is Sarah Hickey.

*Interjection.*

**The Chair (Mr. Ernie Hardeman):** If we could ask the people who want to have a conference at the back to please take it out into the hall, particularly Mr. Yurek.

Thank you very much, Ms. Hickey, for being here this afternoon to help us with our process here. As we did with the previous delegations, we will provide you with the opportunity to make a presentation for 20 minutes, and at the conclusion of the presentation we will have questions from each caucus for 20 minutes. This time the questioning will start with the official opposition. With that, thank you very much again for being here, and the floor is yours.

*Interjection.*

**The Chair (Mr. Ernie Hardeman):** Oh, excuse me. I almost missed it. We do ask if you would swear the oath. We are doing the testimony under oath, so the Clerk will either administer the oath or have you affirm.

**The Clerk of the Committee (Mr. William Short):** Ms. Hickey, would you prefer an oath or an affirmation?

**Ms. Sarah Hickey:** An oath, please.

**The Clerk of the Committee (Mr. William Short):** The Bible is in front of you there. Ms. Hickey, 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. Sarah Hickey:** I do.

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

**The Chair (Mr. Ernie Hardeman):** Thank you very much for that, and with that, the floor is now yours.

**Ms. Sarah Hickey:** Good afternoon, and thank you for inviting me to appear before this committee. I appreciate being given the opportunity to participate in the work this committee is doing.

I'd like to begin by telling you a little about me, and then I will outline my involvement around the events of March 20 and the discovery of the situation involving two chemotherapy medications.

I am a graduate of Dalhousie University, where I obtained a bachelor of science in pharmacy in 1996. Following that, I moved to Toronto where I did a hospital pharmacy residency at Mount Sinai Hospital. I then worked for four years as a pharmacist at what was then called the Greater Niagara General Hospital in Niagara Falls. It is now part of the Niagara Health System.

In 2001, I moved back to Nova Scotia, where I worked as a pharmacist for Annapolis Valley Health from 2001 to 2007. I was also a member of the occupational health and safety committee and the Baby-Friendly committee while I was there.

In 2007, my family moved to Peterborough, and I began work as a hospital pharmacist at the Peterborough Regional Health Centre. I was a member of the medication reconciliation implementation team at PRHC, and I am currently a member of the ISMP ambulatory care medication reconciliation working group representing ambulatory oncology.

In 2010, I became a casual part-time employee of Peterborough Regional Health Centre and took a full-time position as an oncology pharmacist for the R.S. McLaughlin Durham Regional Cancer Centre, which is part of Lakeridge Health in Oshawa.

I have received specialized training in quality improvement implementation, and I am a member of the Cancer Care Ontario regional systemic therapy program safety collaborative. I am a preceptor for the University of Toronto faculty of pharmacy and have been a preceptor for Dalhousie University College of Pharmacy.

I am a member of the Canadian association of pharmacists in oncology and the Ontario Pharmacists' Association, and I am registered with the Ontario College of Pharmacists in good standing.

Although I am an employee of Lakeridge Health, I work at the Peterborough Regional Health Centre in the cancer clinic. That clinic is a partner of the Central East Regional Cancer Program. I work in the multidisciplinary room, alongside oncologists, nurses and other health professionals. I do some patient counselling and also work with the interdisciplinary team on processing chemotherapy orders. I review the physician's orders to double-check that it's the right drug, the right dose, and whether any modifications should be made based on the patient's individual status, blood work, organ function etc.

I am also asked to research drug information questions for the health care team and check to make sure a patient's home medications do not interact with their chemotherapy.

So that's a little bit about me and my qualifications and experience. Now I would like to address the events of March 20, 2013.

You have heard from Craig Woudsma and Judy Turner, two of my colleagues in Peterborough. As they outlined in their appearance earlier this month, Craig had questions about the label on the Marchese-supplied gemcitabine product.

That afternoon, Craig called me to say there is a new product that looks different than the product that had been in use before. He outlined that the labelling was different. He thought, according to the labelling, that the concentration may be different than what the worksheet indicated.

After speaking with Craig, I called my colleagues at Lakeridge Health to see what they were doing about this difference. We had a discussion and it was concluded that the pharmacy team there would investigate the difference.

I then went to the Peterborough pharmacy and spoke with Judy. As she outlined in her appearance earlier this month, she called Marchese, and I was present for that call.

At first, we spoke with a Marchese representative who did not understand what our concerns were. As Judy noted, he then transferred us to another Marchese representative whose name I cannot recall. She explained how Marchese prepared the product, which was different than how our previous supplier prepared the product. We asked if Marchese had taken into account the overfill in the bag, and she said that they had not.

We concluded that they did not seem to have an appreciation for how we were using the bag or why the concentration was important.

Following that discussion, I did a calculation of the concentration based on our estimate of the contents of the bag. We knew the gemcitabine was mixed in a Hospira bag. We also knew that with a 100-millilitre Hospira bag, there is an approximate overfill of seven millilitres. Based on that, the approximate concentration would have been around 37.4 milligrams per millilitre, compared to 38 milligrams per millilitre, the concentration that was used to calculate the dose indicated on the worksheet.

In that moment, we had to make a decision. We had a patient who was there and needed medication. Based on my experience, I concluded the difference between 37.4 milligrams per millilitre and 38 milligrams per millilitre was not clinically significant.

When dealing with chemotherapy, there are a number of factors that go into the determination of a dose. Factors include weight change, managing side effects etc. For example, if a person's weight does not change by more than 10% between treatments, then it would be acceptable not to alter the dose of medication.

In this specific situation, we did not have any doubt as to the safety of the product. We knew it was the correct drug and we knew it was not a stronger concentration of medication in the product. While I would not normally make a change to the dose, even that small, I believe in the circumstances it was the appropriate clinical decision.

I advised to go ahead with this dose for the specific patient. The alternative would have been to send the patient home without treatment, which would have interrupted that individual's treatment cycle and, in my opinion, been of greater clinical significance.

Later that afternoon, we did receive a call back from the Lakeridge Health pharmacy, and they advised us not to use the Marchese products any further.

I became a pharmacist because I've always had an interest in the sciences, and I wanted to be in a profession that helps people. I grew up volunteering in my local hospital and was always inspired by the health care professionals I met. I chose hospital-based practice because I loved the multidisciplinary team approach, as well as the opportunity to give back to the public system.

I pursued the oncology field because, like a lot of us, someone in my life was affected by cancer. I was always very impressed with the quality of service offered by the cancer clinic and the team of professionals that dedicate themselves to patients with this terrible disease.

I take great pride in my work because I know what can happen when errors are made.

**1540**

I am a mom of five children, ranging from my oldest, who is 12, to my youngest, twins who are almost two. Every time I make a decision, I have in my mind that the person receiving the medication is someone's child, someone's parent, someone's family. I am motivated by the fact that we can keep making safety improvements to guard against human error. It is extremely rewarding to use your passion, knowledge and skills every day to help people.

I would also like to state how proud I am of the pharmacy assistants at the Peterborough cancer clinic and what a privilege it is to work with them.

Thank you again for the opportunity to be here today, and I am happy to answer any of your questions to the best of my ability.

**The Chair (Mr. Ernie Hardeman):** Thank you very much for your presentation. With that, we'll start the questions with the official opposition. Ms. McKenna.

**Mrs. Jane McKenna:** Thank you so much for coming in here today. I know it can be a bit overwhelming coming in here with everybody speaking and asking you questions. Your presentation was very well put together, so thank you for that. I'm very impressed that you're a mother of five and you look this great, with 12 and under to twins.

Anyway, my first question is, now that you're doing it in-house, have you had any chemo spills?

**Ms. Sarah Hickey:** No.

**Mrs. Jane McKenna:** No. Okay. Do you know if there is a process out there at all where people can complain about the Medbuy process?

**Ms. Sarah Hickey:** I'm not aware of a process, no.

**Mrs. Jane McKenna:** Okay. On page 3 here—I guess what I'm curious with is, how did you know—what was the difference that you saw or, pardon me, Judy saw from the one product, the Baxter product I'm guessing, to the Marchese product? What was the difference she saw?

**Ms. Sarah Hickey:** The Baxter product was clearly labelled 38 milligrams per millilitre concentration. On the Marchese label, it said four grams in 100 millilitres.

**Mrs. Jane McKenna:** I guess we're trying to figure that out, that if it was the exact same contract and there was nothing changing at all—I think we're still trying to figure out how the labels weren't exactly the same from one product to the next, if it was the exact same contract going in the RFP.

When you asked Marchese if they had taken into account the overfill in the bag, she said that they had not?

**Ms. Sarah Hickey:** Right. She went over the process of how they prepared the bag, and it didn't account for the overfill. Their assumption was we would be using the full bag, so the exact concentration wouldn't have mattered.

**Mrs. Jane McKenna:** Yes, we had Ms. Zaffiro in here who stated the exact same thing, that a lot of assumptions—you know, if you have a contract, it pretty much stipulates from line to line what exactly the expectations are, from the broker, obviously, getting the product, and then selling that off. They should have known that themselves.

My next question is, later in that afternoon, you said that Lakeridge Health pharmacy advised not to use Marchese products any further. How did they come to that assumption? How did they come up with that to say that, then?

**Ms. Sarah Hickey:** I'm not sure how they came to that conclusion.

**Mrs. Jane McKenna:** So you stopped from there?

**Ms. Sarah Hickey:** Yes.

**Mrs. Jane McKenna:** Okay. That's it for me right now.

**The Chair (Mr. Ernie Hardeman):** Thank you. Ms. Gélinas.

**M$^{me}$ France Gélinas:** Thank you so much for coming. I understand that your colleagues came as a pair. It's always a little bit easier. Thank you for being here on your own.

I will go ahead with, first, some of the questions that came from the presentation you just gave. First you said—I'm on page 2, if that helps—"After speaking with Craig, I called my colleagues at Lakeridge Health to see what they were doing about this difference." Who did you talk to at Lakeridge?

**Ms. Sarah Hickey:** Is it possible that I could give that name to the Clerk?

**M^me^ France Gélinas:** Why would you want to do that?

**Ms. Sarah Hickey:** I guess I didn't speak to her about saying her name here, and I don't know if I'm comfortable with that or not. Is it possible to do that?

**M^me^ France Gélinas:** I think her name has already been shared. We're just double-checking, but I'll respect your wishes.

**Ms. Sarah Hickey:** Okay.

**M^me^ France Gélinas:** You will give it to the Clerk after? Okay.

**Ms. Sarah Hickey:** Sure.

**M^me^ France Gélinas:** Okay. You went on to say that you spoke with Judy: "As she outlined in her appearance earlier this month, she called Marchese, and I was present for that call," and that particular person "did not understand what our concerns were." Who were you talking to at Marchese at the time?

**Ms. Sarah Hickey:** I'm not sure what that individual's name was.

**M^me^ France Gélinas:** Was it a pharmacist?

**Ms. Sarah Hickey:** I don't think so, but I don't know.

**M^me^ France Gélinas:** Is there a way you could find out who you talked to?

**Ms. Sarah Hickey:** Yes, I can find out.

**M^me^ France Gélinas:** And you'll let us know?

**Ms. Sarah Hickey:** Yes.

**M^me^ France Gélinas:** Then you went on to say that you talked to a different representative—the name you don't recall. I wouldn't mind, while you do your research, if you'd try to find out who that person was as well. "She explained how Marchese prepared the product, which was different than how our previous supplier prepared the product." How did you know how Baxter, which was your previous supplier, prepared the product?

**Ms. Sarah Hickey:** The difference was the Baxter product came in what we call a Viaflex bag, an empty bag that had fluid added to it, and the Marchese product came in a bag that was prepared by Hospira, so it already had a volume in the bag.

**M^me^ France Gélinas:** So it's not necessarily because you had spoken with Baxter; it's just because you recognized that by the mere fact that they were using a Viaflex bag that they had filled up.

**Ms. Sarah Hickey:** Right. It was just an observation that there was a difference. I hadn't spoken to anyone at Baxter.

**M^me^ France Gélinas:** Okay. You go on to say, "We concluded that they did not seem to have an appreciation for how we were using the bag, or why the concentration was important." I want to hear it in your words: Why was the concentration important?

**Ms. Sarah Hickey:** It's important because we need to know what the concentration is, because the dose is individualized for each patient. Their assumption was, we were using the entire bag, so the full four grams would be given to one patient, which isn't the case. We use it as a stock solution and we take an individual dose out of that bag for each patient.

**M^me^ France Gélinas:** Were you surprised when you heard that?

**Ms. Sarah Hickey:** I was concerned, I guess.

**M^me^ France Gélinas:** Sorry. I didn't hear you.

**Ms. Sarah Hickey:** Surprised, I guess. I was just trying to think through the situation. I wasn't interjecting emotion into it.

**M^me^ France Gélinas:** Okay. I think I follow your train of thought. So here you are on the phone being told by a pharmacist that a pharmacist thinks that a patient would get four grams of that chemo drug. That would have been common knowledge—not to me, but to pharmacists—that this is not a single dose.

**Ms. Sarah Hickey:** I wasn't sure if that individual that we were speaking to was a technician or a pharmacist. But if a pharmacist had experience in oncology, then they would know that that dose would be too high.

**M^me^ France Gélinas:** Then you go on to say you made a clinical decision for that one patient, taking into account who they were and everything else. In your clinical decision, you say, "And we knew it was not a stronger concentration of medication...." Why was this a relevant factor in your decision-making?

**Ms. Sarah Hickey:** It was just part of my thought process, what I knew about the product. It may have been more clinically significant had it been in a higher concentration.

**1550**

**M^me^ France Gélinas:** How so?

**Ms. Sarah Hickey:** You're potentially giving more drug and increasing the risk of side effects. Again, had it been an overconcentration, I would have had to think about the whole clinical situation, depending on how significant the difference was.

**M^me^ France Gélinas:** I take it that you know the patient who was there that day. You know the thought process and the decision process that you used to make the decisions to say, "Go ahead and use it." I'm sure you've had many nights to think over that decision. Are you still comfortable with it?

**Ms. Sarah Hickey:** Yes, I still am comfortable with that decision.

**M^me^ France Gélinas:** Okay. Then you go on to say that later that afternoon, we received a call from Lakeridge that advised us not to use the Marchese product. Who was it who called you?

**Ms. Sarah Hickey:** It was the same pharmacist who I had spoken to earlier in the afternoon.

**M^me^ France Gélinas:** Okay. Did they give any details as to why that was so, what you were to do with it—anything else?

**Ms. Sarah Hickey:** No.

**M^me^ France Gélinas:** How long was that conversation?

**Ms. Sarah Hickey:** A few moments.

**M^me^ France Gélinas:** Did they call you directly?

**Ms. Sarah Hickey:** Yes.

**M^me^ France Gélinas:** Anybody else?

**Ms. Sarah Hickey:** I don't know.

**M^me^ France Gélinas:** So you took the call and what did they say?

**Ms. Sarah Hickey:** They just said, "Do not use the Marchese cyclophosphamide or gemcitabine products."

**M^me^ France Gélinas:** I'm guessing you knew that you had patients who would have needed that drug the next day or the day after. What goes through your mind when all of a sudden, a needed drug is shelved like that?

**Ms. Sarah Hickey:** I left that work up to our pharmacy assistants, who are primarily responsible for procuring the drugs they need for the clinic the next day.

**M^me^ France Gélinas:** So once you received that information, what did you do with it? Who did you call? Who did you talk to?

**Ms. Sarah Hickey:** Oh yes, I did—I sent an email to the pharmacy assistants. They had already gone for the day at this point.

**M^me^ France Gélinas:** Did you hear back after work the next day or something?

**Ms. Sarah Hickey:** Yes, I think we spoke about it the next day.

**M^me^ France Gélinas:** And when you say "we," who is that?

**Ms. Sarah Hickey:** Me and the other—the pharmacy assistants who were working.

**M^me^ France Gélinas:** That's Judy and Craig?

**Ms. Sarah Hickey:** Yes.

**M^me^ France Gélinas:** And what did they have to say?

**Ms. Sarah Hickey:** That they had removed the product from the clinic.

**M^me^ France Gélinas:** And they never mentioned as to, "It's going to take us longer to prepare this," or—

**Ms. Sarah Hickey:** No, they didn't.

**M^me^ France Gélinas:** Did you know that they were to start preparing it in-house?

**Ms. Sarah Hickey:** Yes. They would have to use vials to prepare, and I knew that, yes.

**M^me^ France Gélinas:** And did you feel they were ready, equipped and knowledgeable to do that?

**Ms. Sarah Hickey:** Oh, yes.

**M^me^ France Gélinas:** What made you so sure?

**Ms. Sarah Hickey:** Well, I work with these assistants every day and they're very competent at their job.

**M^me^ France Gélinas:** And you knew that you had the drug in-house to dilute it yourself?

**Ms. Sarah Hickey:** I didn't ask them and they didn't express any concerns about that.

**M^me^ France Gélinas:** The next time you had to check that the right drug, the right dosage was being given to the right patient, did you follow up at all to see where it was coming from, how it had happened to be there for you to check?

**Ms. Sarah Hickey:** I don't actually physically check the product. The product is prepared in the chemo pharmacy and the pharmacy assistants check one another's preparations.

**M^me^ France Gélinas:** Does your hospital use a lot of admixed drugs in chemotherapy?

**Ms. Sarah Hickey:** I don't know if they use a lot of them, no. I don't know that.

**M^me^ France Gélinas:** Do they use any other ones except for the two that we're dealing with today?

**Ms. Sarah Hickey:** Do you mean buy products that come partially prepared, or prepared from a manufacturer, that they don't—for example, there are some other products that they use that come premixed. There would be a fluorouracil infuser bottle or a pamidronate infusion that comes in an ambulatory infusion device. In that case, they would check to make sure it's the right drug, and they would put a label on it and not have to mix it. Is that what you are asking?

**M^me^ France Gélinas:** Yes.

I'll let it go around.

**The Chair (Mr. Ernie Hardeman):** Okay, thank you very much. We'll then go to Ms. Jaczek.

**Ms. Helena Jaczek:** Yes, thank you. Thank you for your presentation, Ms. Hickey. First of all, on behalf of the government, I'd like to congratulate you and your team, Craig and Judy, for acting so expeditiously and doing the follow-up with Marchese and, obviously, doing the very best you could in trying to get to the bottom of the difference in the new product that was received.

You came to the conclusion that the difference between the 37.4 milligrams per millilitre that you had calculated, based on the Hospira bag, compared to the 38 milligrams per millilitre, was probably not clinically significant. I think most people could—as a physician, I can see that that was a very small difference, and I would respect your professional opinion. I'm just wondering: Did you check with the oncologist? Did you go to anybody else to talk about the discrepancy and to sort of have a conversation about this?

**Ms. Sarah Hickey:** In this situation, because the difference was very small, I felt it was within my scope of practice to continue using the product for that patient.

**Ms. Helena Jaczek:** Fair enough. Actually, I'd like to talk a little bit about the college oversight of pharmacists, sort of in general. Obviously, you've told us that you're a registered pharmacist with the Ontario College of Pharmacists and in good standing, and a member of the Canadian Association of Pharmacy in Oncology. What type of oversight does the College of Pharmacists have over you? You're working in a hospital setting. Just describe what maintaining your certification means.

**Ms. Sarah Hickey:** To be a member of the Ontario College of Pharmacists, I have to maintain a learning

portfolio, where I've demonstrated that I've maintained my knowledge. I have to work a certain amount of hours within a certain time frame to maintain my competency. Then I'm—

**Ms. Helena Jaczek:** And you report this on an annual basis?

**Ms. Sarah Hickey:** Yes. Annually, we declare if we've worked the appropriate hours. The learning portfolio is an audit process, so within five years, every member is asked to provide their learning portfolio to the college, in a randomly selected time frame.

**Ms. Helena Jaczek:** What would be the difference if you were working at an independent pharmacy, a community pharmacy? How would that differ, that oversight?

**Ms. Sarah Hickey:** As far as individual pharmacists—we are all expected to conform to the laws and regulations. But in hospital pharmacy practice, the pharmacy itself is not accredited by the Ontario College of Pharmacists, whereas a drugstore or a community pharmacy is.

**Ms. Helena Jaczek:** Do you have any opinion as to whether that should change? We've heard that in some jurisdictions, there is the ability of the College of Pharmacists—I believe it was in BC—to come into a hospital and actually do some on-site inspection.

**1600**

**Ms. Sarah Hickey:** No, I don't really have an opinion on that. Sorry.

**Ms. Helena Jaczek:** But you wouldn't have any objection?

**Ms. Sarah Hickey:** No.

**Ms. Helena Jaczek:** Okay. There have been some changes to regulations the College of Pharmacists has brought in here to respond to the concerns related to off-site drug compounding. Are you aware of that?

**Ms. Sarah Hickey:** Yes.

**Ms. Helena Jaczek:** Do you feel that that's appropriate? Does that give you some measure of comfort in the fact that you might be receiving compounded drugs from another source?

**Ms. Sarah Hickey:** I feel that if that's what the experts involved in the process have decided is best so that an outsourced product that has a problem with it isn't discovered by front-line workers moments before administering the drug—if that's part of a solution—then yes, I'm in favour of that.

**Ms. Helena Jaczek:** In terms of other compounded drugs—of course, we know about cyclophosphamide and gemcitabine, but what other compounded drugs does the Peterborough site of Lakeridge receive?

**Ms. Sarah Hickey:** I know that they have received fluorouracil, which is another chemotherapy agent, in a premixed infuser bottle. So an ambulatory infusion pump that's pre-made to various common doses is something that we've used, as well as another drug called pamidronate that also comes in an ambulatory infusion.

**Ms. Helena Jaczek:** And are you confident about the use of those prepared products that arrive in your pharmacy?

**Ms. Sarah Hickey:** Yes.

**Ms. Helena Jaczek:** And that's because you've had the experience of using them over time?

**Ms. Sarah Hickey:** Since I began working in oncology they've been used, so yes.

**Ms. Helena Jaczek:** And the concentration or the dose is very clear?

**Ms. Sarah Hickey:** I've never had any concerns about them, no.

**Ms. Helena Jaczek:** Okay. I think that's all for now, Mr. Chair.

**The Chair (Mr. Ernie Hardeman):** Okay, thank you very much. The official opposition, Ms. McKenna.

**Mrs. Jane McKenna:** I just have one question for you. Usually after something has happened you can sit back and look and think, "Gee, what would I have done differently?" Is there anything you would have done differently now that it's passed and you can sit back and digest everything that's gone on?

**Ms. Sarah Hickey:** I feel strongly that we made the right decision for the patient at that moment. It wasn't ideal, the situation, but we are asked to make difficult decisions at times for patient care, and in that case it was the best decision for the patient.

**Mrs. Jane McKenna:** Okay. Anybody else that was around you—do you feel that anybody let you down for having to make that decision solely by yourself? Do you feel anybody else could have done anything to have taken some of that weight off of your shoulders?

**Ms. Sarah Hickey:** No, I think we all do our very best.

**Mrs. Jane McKenna:** And the communication was very fluent through the whole process that was going on. Considering it was something that you had never dealt with before, did you feel that the open lines of communication were just that?

**Ms. Sarah Hickey:** Yes.

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

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

**M^me^ France Gélinas:** How long would you say you have been working with cyclophosphamide?

**Ms. Sarah Hickey:** I've had some experience with it previous to working full-time in oncology, but most of my experience has been in the last four years.

**M^me^ France Gélinas:** And did you know what the stability data was for that drug?

**Ms. Sarah Hickey:** Cyclophosphamide in particular?

**M^me^ France Gélinas:** Cyclophosphamide, yes.

**Ms. Sarah Hickey:** I know where to find the information about stability.

**M^me^ France Gélinas:** Okay. When you were getting it from Baxter it was not through a cold chain; it was room temperature. One of the things that alerted, I want to call him Greg—I forgot his name—was that he now got it out of the fridge. Did the fact that it was not refrigerated and the stability data was rather short for room temperature—I'm curious to see how this drug was delivered to you and used within such a short time frame.

**Ms. Sarah Hickey:** I just want to clarify: Are you referring to gemcitabine or cyclophosphamide?

**M^me^ France Gélinas:** Cyclophosphamide.

**Ms. Sarah Hickey:** I had no conversations about cyclophosphamide with the pharmacy assistants about any concerns at storage.

**M^me^ France Gélinas:** He told us that one of the things that alerted him that he was dealing with a different product was that when he got it from Baxter he got it from the fridge, and before it never used to be in the fridge.

**Ms. Sarah Hickey:** That wasn't a concern he discussed with me.

**M^me^ France Gélinas:** So you don't know how long your hospital would have had this product before?

**Ms. Sarah Hickey:** No.

**M^me^ France Gélinas:** You don't know when the drug comes in and when it gets used?

**Ms. Sarah Hickey:** No, I don't.

**M^me^ France Gélinas:** How do you ensure that you're using the products within the allotted stability time?

**Ms. Sarah Hickey:** That would be the role of the pharmacy assistants.

**M^me^ France Gélinas:** This is not something that a pharmacist would ever advise on?

**Ms. Sarah Hickey:** If they had concerns with stability information, I would gladly help them, but I'm quite removed from the pharmacy itself and work with a team of physicians and nurses.

**M^me^ France Gélinas:** Right now, are you handling those drugs any different than before March 20?

**Ms. Sarah Hickey:** I don't physically handle any of the drugs. I just review the orders.

**M^me^ France Gélinas:** Do you know if the staff complement in oncology pharmacy has changed at your hospital since March 20?

**Ms. Sarah Hickey:** No, it hasn't.

**M^me^ France Gélinas:** Has the work that you do changed at all?

**Ms. Sarah Hickey:** No, it hasn't.

**M^me^ France Gélinas:** The government has new regulations coming out where hospitals will be responsible to find out if the drugs they're purchasing are coming from an accredited source. Who do you think will be responsible for that check?

**Ms. Sarah Hickey:** I'm not sure.

**M^me^ France Gélinas:** Do you figure it would come to a pharmacist?

**Ms. Sarah Hickey:** I suppose it would be different in every hospital, but I'm not really sure.

**M^me^ France Gélinas:** Do you figure this is information that a pharmacist would have?

**Ms. Sarah Hickey:** Information of where the product was purchased, whether from—

**M^me^ France Gélinas:** An accredited source or not.

**Ms. Sarah Hickey:** It could be important, but from my perspective, where I do my work, it wouldn't be a question that I would ask while I'm reviewing the orders.

**M^me^ France Gélinas:** Dr. Thiessen was there just before you. Had you met him before?

**Ms. Sarah Hickey:** Yes.

**M^me^ France Gélinas:** In what circumstances?

**Ms. Sarah Hickey:** When he came to our hospital, we had a meeting.

**M^me^ France Gélinas:** When was that?

**Ms. Sarah Hickey:** I don't know the exact date, but it was concerning the events of March 20.

**M^me^ France Gélinas:** Have you had more than one meeting with Dr. Thiessen?

**Ms. Sarah Hickey:** Just one.

**M^me^ France Gélinas:** Who else was present when you were there?

**Ms. Sarah Hickey:** My director was there. The manager of the cancer clinic, the pharmacy assistants—

**M^me^ France Gélinas:** How many pharmacy assistants were there?

**Ms. Sarah Hickey:** There were three.

**M^me^ France Gélinas:** Aside from the two that we've talked to, who's the third one?

**Ms. Sarah Hickey:** Can I give her name to the Clerk?

**M^me^ France Gélinas:** Why do we have to go through this again, remind me?

**1600**

**Ms. Sarah Hickey:** I didn't have a chance to speak to her—because she was away on vacation—that I would mention her name here today, so if it would be okay with you, I'd like to leave it with the Clerk instead.

**M^me^ France Gélinas:** Okay. And the third assistant took a place in the meeting?

**Ms. Sarah Hickey:** Yes.

**M^me^ France Gélinas:** Why was she invited?

**Ms. Sarah Hickey:** Because she was working in the clinic on that day.

**M^me^ France Gélinas:** And who else?

**Ms. Sarah Hickey:** Judy Turner and Craig Woudsma.

**M^me^ France Gélinas:** Who else was at the meeting?

**Ms. Sarah Hickey:** Oh, at the meeting?

**M^me^ France Gélinas:** You said your director, manager of cancer—the three technicians, yourself—

**Ms. Sarah Hickey:** Yes, and Kate Crawford, our lawyer. That's all I can remember who was there that day.

**M^me^ France Gélinas:** Do you remember how long the meeting lasted?

**Ms. Sarah Hickey:** It was about an hour.

**M^me^ France Gélinas:** About an hour. Did you have a chance to talk during that meeting?

**Ms. Sarah Hickey:** Yes, I did.

**M^me^ France Gélinas:** What were some of the questions that were directed at you?

**Ms. Sarah Hickey:** Dr. Thiessen just asked for us to explain in our own words our involvement, and he asked—I don't remember the specific questions, but just questions to help direct our thoughts.

**M^me^ France Gélinas:** Do you remember what you said?

**Ms. Sarah Hickey:** Yes. I said the same things that were in my opening statement.

**M^me^ France Gélinas:** When was that opening statement prepared for you?

**Ms. Sarah Hickey:** I prepared it myself, but I did have help with it from someone in our communications department. It was on Friday and over the weekend I worked on it.

**M^me^ France Gélinas:** Did you prepare any notes for when you met with Dr. Thiessen?

**Ms. Sarah Hickey:** No.

**M^me^ France Gélinas:** Did anybody else?

**Ms. Sarah Hickey:** I'm not sure.

**M^me^ France Gélinas:** Not that you could see?

**Ms. Sarah Hickey:** No.

**The Chair (Mr. Ernie Hardeman):** We're just about to finish, so if you have one more question, you can go ahead.

**M^me^ France Gélinas:** The question of concentration is something that Dr. Thiessen has raised with us, the nominal content versus the accuracy in content and the precision in content. To you, are those concepts basic to a pharmacist, or is this something that is novel to you?

**Ms. Sarah Hickey:** No. That's common knowledge.

**M^me^ France Gélinas:** Thank you.

**The Chair (Mr. Ernie Hardeman):** Thank you very much for your presentation.

The government side: Ms. Jaczek.

**Ms. Helena Jaczek:** I just want to understand the relationship between the Peterborough site and Lakeridge. When the pharmacist phoned you from Lakeridge to say, "Don't use the product anymore; quarantine the Marchese product," is that pharmacist sort of the senior pharmacist? I mean, do you report to that pharmacist at all? How does this hierarchy work between the two sites?

**Ms. Sarah Hickey:** No, they weren't my supervisor. We work collaboratively. I don't—

**Ms. Helena Jaczek:** When you got the phone call, did you question why this decision was being made? Because you had decided, at least for the individual patient, that it wasn't going to make much difference. So what was that conversation about?

**Ms. Sarah Hickey:** At the time, no, I didn't question their decision.

**Ms. Helena Jaczek:** I see. So she just said it's quarantined, and that was it. Was there conversation within your unit in Peterborough about the situation, then, subsequent to that phone call?

**Ms. Sarah Hickey:** Just that communication about the directive from Lakeridge, what we were to do with the product.

**Ms. Helena Jaczek:** Okay. Thank you. That's all.

**The Chair (Mr. Ernie Hardeman):** Thank you very much. Are there any further questions from—

**Mrs. Jane McKenna:** Yes.

**The Chair (Mr. Ernie Hardeman):** Oh, you've used all your time. I shouldn't say "from anyone," then, should I?

That does conclude the presentation this afternoon. We want to thank you very much for coming in.

**Ms. Sarah Hickey:** Thank you.

**The Chair (Mr. Ernie Hardeman):** Thank you. Now, with the committee's indulgence, if we could have a few minutes in an in-camera session, we have an issue we need to discuss for evidence.

*The committee continued in closed session at 1616.*

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## STANDING COMMITTEE ON SOCIAL POLICY

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