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Official Report of Debates (Hansard)

Tuesday 16 April 2013

Journal des débats (Hansard)

Mardi 16 avril 2013

Standing Committee on Social Policy

Subcommittee report

Oversight of pharmaceutical companies

Comité permanent de la politique sociale

Rapport du sous-comité

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

STANDING COMMITTEE ON SOCIAL POLICY

Tuesday 16 April 2013

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Mardi 16 avril 2013

The committee met at 1600 in committee room 1.

The Chair (Mr. Ernie Hardeman): I call the committee on social policy to order. We are today starting the first day of drilling into the study related to recent reports where diluted chemotherapy drugs were administered to patients in Ontario, and whether or not the Ministry of Health and Long-Term Care effectively exercised its role into the oversight, monitoring and regulation of non-accredited pharmaceutical companies. That's the purpose of our committee as we move forward.

SUBCOMMITTEE REPORT

The Chair (Mr. Ernie Hardeman): The first item of business that we must deal with is to welcome our guests, but we do have to do a little business first. We have to have the report from the subcommittee to the committee to structure today's meeting. Ms. Elliott.

Mrs. Christine Elliott: I'm pleased to read the subcommittee report.

Your subcommittee met on Monday, April 15, 2013, to consider the method of proceeding on the standing order 111(a) study and investigation regarding recent reports where diluted chemotherapy drugs were administered to patients in Ontario; and, whether the Ministry of Health and Long-Term Care effectively exercised its role into the oversight, monitoring and regulating of non-accredited pharmaceutical companies, and recommends the following:

(1) That the Clerk of the Committee schedule the Ministry of Health and Long-Term Care for one hour and 30 minutes on Tuesday, April 16, 2013. That the time allotted for the ministry briefing be 30 minutes and the remaining hour be evenly split by the three political parties.

(2) That each party provides the committee Clerk with a list of potential witnesses by noon on Thursday, April 18, 2013.

(3) That witnesses be scheduled in one-hour-and-20-minute intervals.

(4) That witnesses be offered up to 20 minutes for their opening remarks, and the remaining hour be used by each political party for questioning on a rotating basis.

(5) That the committee Clerk, in consultation with the Chair, be authorized prior to the adoption of the report of the subcommittee to commence making any preliminary arrangements necessary to facilitate the committee's proceedings.

The Chair (Mr. Ernie Hardeman): You've heard the motion. Any discussion? If not, I'll call the vote.

All those in favour? Opposed? The motion is carried.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

MINISTRY OF HEALTH AND LONG-TERM CARE

The Chair (Mr. Ernie Hardeman): The next item on the agenda, of course, is to have a deputation from the Ministry of Health and Long-Term Care. As our guests at the table will know, as they just listened to the subcommittee report, number 1 was to call the Ministry of Health and Long-Term Care to make a presentation, to give us an overview as we start the meeting.

The second item, of course, on the list was that each party provides the committee Clerk with a list of potential witnesses by noon on Thursday, April 18, 2013. The reason I mention that, of course, is that I wouldn't be surprised that some of the people who are here helping us, giving an overview, may very well be in the list to be called back as witnesses in the future. I just put that out there, to make sure we understand, as we're going through, that that may very well happen. There seems to be a broader representation here today than how maybe just the overview was envisioned. We're happy to have you here, but we just want to leave it with that.

With that, I'll turn it over to the Clerk to start appropriately with the affirming or the swearing of the oaths.

The Clerk of the Committee (Mr. William Short): Mr. Rafi, we'll start with you. You prefer to swear an affirmation?

Mr. Saäd Rafi: Yes, I do. Affirmation.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please.

Mr. Rafi, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Saäd Rafi: I affirm that, yes.

The Clerk of the Committee (Mr. William Short): Thank you. Ms. Brown, affirmation as well?

Ms. Catherine Brown: Yes.

The Clerk of the Committee (Mr. William Short): Ms. Brown, do you solemnly affirm that the evidence

you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Catherine Brown: Yes, I affirm.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. Sherar, did you want to swear an oath?

Mr. Michael Sherar: Yes.

The Clerk of the Committee (Mr. William Short): The Bible is there. Mr. Sherar, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Michael Sherar: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. Moleschi, did you want to swear an oath as well?

Mr. Marshall Moleschi: Yes.

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

Mr. Marshall Moleschi: I do.

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

The Chair (Mr. Ernie Hardeman): Thank you all very much for being here. Again, going back to the subcommittee report, as it pointed out, we have allotted half an hour for the presentation for the deputants to speak about what they wish to tell us. Then we'll have 20 minutes for each party to ask any questions they may have. We would ask that as you start your presentation you give your name, for the record, to the speaker system so it can be put into Hansard. With that, we'll turn the meeting over to you to make your presentation. Deputy, we'll let you—

Mr. Saäd Rafi: Thank you very much. Saäd Rafi. Good afternoon. I'd like to thank you for the opportunity for us to provide you with a briefing on this matter.

As I mentioned, my name is Saäd Rafi. I am the Deputy Minister of Health and Long-Term Care. Joining me this afternoon, on my right, from the ministry is Catherine Brown, who is an assistant deputy minister. On my immediate left in addition, from Cancer Care Ontario, is the CEO, Michael Sherar. To his left, from the Ontario College of Pharmacists, is the registrar, Marshall Moleschi.

We will be providing details about the chronology of events as information about what happened began to surface and the various steps that were taken along the way. Before we do that, though, let me first express our concern for the many patients and their families who have been affected by this incident. At the best of times, dealing with cancer and chemotherapy is a very stressful and difficult experience.

Our task in uncovering what happened is complicated somewhat by the complex nature of our health care system, which operates on a number of levels and, in this case, involves several different players, but we are determined to find all those facts.

Let me tell you more about who is involved and who is committed to working with the province to find out what happened so that it does not happen again.

Cancer Care Ontario is charged with steering and coordinating this province's cancer services and prevention efforts. Cancer Care Ontario leads systems planning, establishes guidelines and standards, and tracks performance targets to ensure system-wide improvements in cancer care.

The Ontario College of Pharmacists is the regulatory body for the practice of pharmacy in Ontario. It's important to know that no person may establish or operate a pharmacy in Ontario unless a certificate of accreditation has been issued by the college for the pharmacy. The college is here today and they will take you through their role in the system as a regulator and outline the work they have undertaken to investigate this incident.

Public hospitals also have a key role in caring for patients and, in that role, administering treatment, including pharmaceutical products. Ontario hospitals are not-for-profit, community-based corporations that are approved by the Ministry of Health and Long-Term Care under the Public Hospitals Act.

Among our many responsibilities at the Ministry of Health and Long-Term Care, we develop legislation, regulations, standards, policies and directives for Ontario's health care system.

Another key partner in the Ontario health care system is Health Canada, the federal body responsible for considerable oversight, including those who manufacture and prepare pharmaceuticals in non-pharmacy settings.

We all have an important role to play in ensuring quality of care and safety for patients.

We know that on April 2, Cancer Care Ontario publicly reported that a number of patients at four Ontario hospitals who underwent chemotherapy treatment within the last year received lower-than-intended doses of two cancer drugs, cyclophosphamide and gemcitabine. We don't yet know what specific effect this diluted treatment might have had, but the fact that this situation came about is unacceptable. We need to understand all of the information about how this happened so that we can ensure it does not happen again.

We know that the four Ontario hospitals—London Health Sciences Centre, Windsor Regional, Lakeridge Health and Peterborough Regional Health Centre—immediately stopped using the under-dosed chemotherapy drugs and took the necessary precautions to ensure proper doses of the drugs were administered.

All affected patients and/or their families have been notified by the hospitals and have either met with their oncologist or have made arrangements to do so. Mr. Sherar, from Cancer Care Ontario, will provide more information about the steps that have been taken to notify and meet with patients.

As you know, on April 9, the government selected Dr. Jake Thiessen, the founding director of the University of

Waterloo's School of Pharmacy, to conduct an independent review of the province's cancer drug supply chain. His review will focus on the under-dosing of chemotherapy drugs at the four hospitals here and also one in New Brunswick. His job is to find out how it happened and why, and then to provide recommendations on how to prevent it happening again.

To support Dr. Thiessen's review and co-ordinate the response to this incident, we have convened a working group with representation from the affected hospitals, the Ontario Hospital Association, Cancer Care Ontario, the Ontario College of Pharmacists, the province of New Brunswick, Health Canada and others, as necessary.

We have discovered that there are clear limitations on what the Ontario College of Pharmacists can do in ensuring the safety of these drugs. As I mentioned earlier, they can inspect pharmacies and regulate members of the college, but not manufacturers.

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We don't know how these manufacturers or this company, which prepares products, fell through a gap, but we need to learn how and why, and jurisdictions like the provinces and the federal government need to continue to work together so we can make sure there is no gap in oversight in the future. Dr. Thiessen and the working group will help find the answers, and the various organizations involved in the delivery of cancer drugs will come together to act on those answers.

As I mentioned at the outset, two of these organizations, Cancer Care Ontario and the Ontario College of Pharmacists, are here today and will provide their perspective on that situation. After that, we will be pleased to answer your questions, so I'll immediately turn it over to Michael Sherar, and then Marshall Moleschi will follow. Thank you.

Mr. Michael Sherar: Thank you, Saäd. If it's the pleasure of the Chair, I'll continue. Again, at the pleasure of the committee, what I had proposed to do was just give a brief background on myself, the role of Cancer Care Ontario generally with respect to chemotherapy, and then I'll talk about chemotherapy safety and then go on to a chronology of events that occurred subsequent to the discovery of this error, if it pleases the committee.

Just briefly: I am the president and CEO of Cancer Care Ontario. I'm a medical physicist and research scientist by professional background. I've actually worked in the Ontario cancer system since 1985, when I started my PhD. From 2006 until 2011, I was CCO's vice-president for planning and regional programs and had the responsibility of developing regional cancer programs, including capital planning for cancer services across the province.

Prior to my role as CCO's vice-president, I was in fact regional vice-president for cancer services in London for Cancer Care Ontario and vice-president of the London regional cancer program at London Health Sciences Centre.

At the start of my comments, I just want to echo Saäd's comments with respect to our concern for patients and their families impacted, and as you'll see in my comments in the chronology of the events, of course that was our first priority in working with hospitals around notification and support of patients who were affected by this error.

Before I get into the chronology of events, I thought it may be worthwhile for the committee just to talk a little bit about the role of Cancer Care Ontario and who we are. We are an operational service agency of the Ministry of Health and Long-Term Care and we're governed by the Cancer Act. Our board of directors is appointed by the Lieutenant Governor in Council, and we have accountability to the Ministry of Health and Long-Term Care, primarily through a memorandum of understanding; the current one is dated 2009. This includes a number of responsibilities, including a protocol with respect to information exchange, communication and issues management. We're also accountable to the government through a series of Management Board of Cabinet directives.

With respect to the cancer system, we are the Ontario government's chief adviser on cancer control services and the system through which those services are provided. Our mandate is to drive quality and continuous improvement in disease prevention, screening, the delivery of care, and patient experience for cancer. As you may be aware, we're doing additional work now in the area of chronic kidney disease in the province.

We don't operate or manage the hospitals that provide cancer control services, but we do have funding agreements, now in excess of over $800 million, with those hospitals and other cancer care providers which link that funding to a framework of accountability, delivery of data and continuous quality improvement in the system as a whole. We do that primarily through the development and implementation—we do this with partners across the province—of a multi-year Ontario cancer plan. The way in which we work is through a series of regional networks, each led by a regional vice-president for cancer in each of the 14 local health integration networks.

With respect to systemic treatment, or chemotherapy—this is the modality of treatment that uses drugs to slow or stop cancer cells from multiplying or spreading—again, we work with the Ministry of Health and Long-Term Care, our regional cancer programs and health care providers on the organization and delivery of chemotherapy across the province. Through that, we're responsible for developing and implementing an agenda of quality improvement for systemic therapy, and that leverage is on regional cancer programs and our partnerships with clinical networks throughout the province. That includes monitoring and facilitating access to treatment and enhancing the quality and efficiency of systemic treatment, including development of evidence-based guidelines, and that's through our program in evidence-based care. We develop organizational standards and performance measures, and we coordinate and share information with health care providers and hospital administrators across the province to continually improve

the design and delivery of our systemic treatment system in the province.

As it relates to chemotherapy safety, we have produced several guidelines focused on safety issues for chemotherapy; as examples, in August 2009, we issued key components of chemotherapy labelling, so these guidelines focused on what are the necessary components and formatting of chemotherapy labels to maximize safe delivery and minimize errors. Those guidelines—and this is the way in which we work with our providers across the province—are supported by education programs concordant to those guidelines, and we measure concordance with those guidelines across the province. It's important to note that these guidelines are directed at hospital pharmacies, not compounding companies.

Earlier to these guidelines, we have issued guidelines for regional models of the care for systemic treatment standards for organizations that provide the delivery of systemic treatment across the province and also safe handling from the perspective of providers of chemotherapy within those organizations.

That's just a summary of some of the work that we do generally with respect to chemotherapy, and specifically with respect to chemotherapy safety.

What I would like to do now is just to go on to a chronology of the events subsequent to the discovery of this error. I'll start when Cancer Care Ontario was first notified of the issue, which was on Wednesday, March 27, and this came through email and subsequent telephone discussion, actually from Neil Johnson, who's the regional vice-president in London and for the southwest region. At that time, in discussion with Neil, it was decided, following this outreach and understanding the work that had already gone on between hospitals, to convene a conference call with what we knew then were the affected hospitals—and at that time, we knew it was Windsor, Lakeridge and London—and organized a call the next day, in the afternoon. That was to give time for the hospitals to have their own incident management meetings earlier.

So we held that conference call the next day on March 28. In accordance with our protocol for notifying the Ministry of Health, we did also the next day—it was around 2 p.m.—notify the Ministry of Health with respect to the issue and what we knew at the time about the issue, and that was through the communications and information branch at the ministry.

We had the conference call with the affected hospitals, and they included not only the regional vice-president but leaders within the cancer program—pharmacy staff, oncology leads and communication leads—so that we could, together with Cancer Care Ontario and the hospitals, get a fuller understanding about the issue and establish appropriate next steps that we might be able to coordinate across the hospitals.

It was during that call that we really learned the early perspectives on the nature of the error and the approximate number of patients that were affected, and each of the hospitals undertook to disclose their plans with respect to notifying patients. We also learned that there was another jurisdiction that was impacted, and that was, of course, Horizon Health Network in New Brunswick. The focus of the call, though, was primarily on the patient notification plans at the hospitals.

We worked with the hospitals on that call and understood that—of course, as you'll know—there were quite different numbers of patients affected at the different hospitals. The largest number was in London, and they had the biggest task of assembling all of the information and getting the plans ready so that they could notify patients. They were looking to a little later date than the other hospitals to start notification of patients, and I'll talk a little bit about the subsequent actions with respect to that.

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We did at the time want to immediately understand whether there was any issue in the other hospitals that deliver chemotherapy in the province—there are 77 of them—so we undertook to develop quickly an issues briefing note that we would be able to provide through our network of regional vice-presidents to those 77 treatment hospitals.

I would say that across Good Friday and Saturday of the Easter weekend, all of the parties worked to develop that comprehensive issues briefing that we could rapidly get out to other hospitals to ensure that what we thought was known about the hospitals affected—just those hospitals—that there weren't other hospitals affected.

In addition, on March 30, CCO was contacted by LHIN CEOs and hospital CEOs from the regions affected, with a request that we hold a meeting to update them on the issue—and their desire to brief the minister directly. We recommended at that time that we would hold a joint call with all the LHIN CEOs from the regions affected, and the hospital CEOs, on Easter Monday, so that was scheduled.

On Easter Sunday, we did provide another issues briefing notice to the Ministry of Health through the communications and information branch, again summarizing all the knowledge that we had gathered to date at that point.

It was that afternoon, on the Easter Sunday, that we contacted all of the regional vice-presidents in the cancer programs, calling their attention to the issue and asking them, with a briefing note, to confirm that this specific issue didn't involve any other systemic treatment hospitals within their regions, so that we could cover the entire province. The issues briefing note that was completed was shared with all of the regions at that time.

We continued to work with the specific hospitals affected on the plans for notification. We understood at that point that Windsor was more ready to start their activities with respect to patient notification and—legitimately, I think—was eager to start that as soon as possible.

We did understand that London, because of the larger volume of patients, was not quite ready. So we agreed, after a call that we had on the Sunday, that we would

defer that decision together until the Monday call that I was going to have with the LHIN CEOs and the hospital CEOs together.

We did, on that call, look at the issues around patient notification and agree together that Windsor would start the next day, on the Tuesday. We understood that London was working as hard as they possibly could to be ready to start their patient notification and had indicated that they likely would be ready by Wednesday evening or Thursday, but we agreed together that we would do this in a staggered way. It was going to take some time to notify all patients anyway. Windsor indicated to us that because some of the patients were in active treatment, they had a duty to notify patients when they were coming in for appointments that were actually scheduled on that Monday. So the notification, I think, actually started on the Monday and then continued through the rest of the week. It was the next day that we issued the press release.

I'm almost finished.

With respect to the press release, I think, since then our work has been working with hospitals to help them in terms of their own patient notification efforts, getting feedback from hospitals across the province that this wasn't an issue in any other hospital with respect to this specific error. But we also checked with them with respect to the general issue, what we knew about the nature of the error, that they were checking with respect to all of our guidelines and the issues of preparation of chemotherapy drugs following those guidelines and checking with their pharmacy staff. We have got check-back from all of the hospitals both on the specific issue and the general issue of preparation of chemotherapy, that they have checked and double-checked those processes.

That work is now complete, and we're now in the process of supporting the work of Dr. Thiessen, of course, who's leading the third party review, and happy to work with all of the organizations involved in supporting that work, to really understand what happened with respect to this error and what we can learn in terms of improving the system for the future.

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

Mr. Marshall Moleschi: Thank you, Michael. My name is Marshall Moleschi. I'm the registrar at the Ontario College of Pharmacists.

A little bit about my background: I have been a community pharmacist a long time ago, a hospital pharmacist—I did have some experience in cancer chemotherapy—a hospital administrator, and I have a little bit of experience in introducing a northern British Columbia cancer centre. I've been registrar in the province of British Columbia for the college of pharmacists and I have been registrar here in Ontario for about the past year and a half.

My political experience goes back to the last century as a pharmacist, so it's been some time ago.

A little bit about the college of pharmacists: We're the regulatory body for profession of pharmacy in Ontario. Our mandate is public protection with regard to the conduct of pharmacy health care professionals and the operation of community pharmacies. The college receives its authority from a variety of laws, including the Pharmacy Act, the Regulated Health Professions Act and the Drug and Pharmacies Regulation Act.

To be a pharmacist or a pharmacy technician in Ontario you need to be registered with us, with the college, and to operate a community pharmacy in Ontario you need to be accredited by the college

Section 118 of the DPRA, or the Drug and Pharmacies Regulation Act, specifies that the college does not have jurisdiction over "drugs compounded, dispensed or supplied in and by a hospital." Therefore, until now the college has not been focused on the hospital drug distribution system.

With respect to community pharmacies, we set and maintain accreditation standards. We inspect pharmacies before they first open and soon after opening to ensure that they meet our standards. We also conduct routine inspections every three to five years approximately, and we will also do it more often it's warranted or if they're engaged in something that we think is a little bit more risky type of an activity.

Several years ago, we introduced the point-ofcare symbol, which is displayed in all registered community pharmacies to provide some assurance to the public or to provide the assurance to the public that they've successfully passed the accreditation process.

With respect to our practitioners, we set and maintain entry-to-practice standards to ensure they have the knowledge and skills when entering practice. We have a quality assurance program which requires practitioners to demonstrate on an ongoing basis their competency throughout their career. We hold practitioners accountable to practise within their scope of practice, to all relevant regulations, standards of practice and ethical conduct. We provide guidelines and policies to practitioners to support them in their practice as they go about the scope of their practice and upholding the standards of practice.

Should there be any concerns about their practice, we have a complaints inquiry and discipline process, so any member of the public can file a written complaint with the college and I, as registrar, can initiate an investigation. All complaints that are received are investigated in a timely manner and their priority is based on their risk of harm to the public. Notice and findings of our discipline cases are made public

The public trust and confidence is maintained through our public register, which lists all pharmacists and technicians currently in good standing. That can be found on our website. Any notations regarding disciplinary actions are also noted there. The college website also provides a list of all community pharmacies in good standing with this accreditation.

I'd like to go to the facts regarding this current situation. We take matters such as this—

The Chair (Mr. Ernie Hardeman): Just wrap up in a couple of minutes.

1630

Mr. Marshall Moleschi: A couple of minutes, yes—extremely seriously. We're committed to our mandate of public protection. I'll give you a brief overview of what has transpired.

March 31: The college first became aware of the issue of underdosing of chemotherapy medications when I received a phone call at Easter dinner while I was on vacation in Vancouver. I immediately notified my senior staff, and I returned to Toronto the following day. I confirmed that appropriate steps were taking place to ensure public safety—so there's withdrawal of product, that sort of thing that has just been talked about. We contacted Health Canada to establish a plan to jointly and immediately look into the situation. The college has a long and positive relationship of collaboration with Health Canada in dealing with these types of issues, and that continues.

The college, on April 3, appointed an investigator with two Health Canada inspectors, and we visited the premises. From April 3 to the present, we have had an ongoing investigation into this matter. We're continuing to work in partnership with Health Canada, and we do have stages to our investigation. If there are any questions, I can explain what that is.

In addition to our specific investigation, the college is actively a member of the ministry's working group and will provide support to Dr. Jake Thiessen's independent review of the quality assurance in this province around the cancer drug supply chain. We're continuing to work closely with the ministry to identify opportunities to make enhancements to our jurisdiction to provide the authority and oversight of facilities such as this that may fall outside our community pharmacy practice.

I just wanted to state that there has been excellent cooperation from all parties involved.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. That does conclude the obligation on you to present yourself. With that, we'll start the questions. We'll start with the official opposition. Ms. Elliott.

Mrs. Christine Elliott: Thank you very much for your presentations. I think at this point, we'll have some fairly general questions, but we may ask—well, I'm sure we will ask you to come back to speak more specifically about what has been going on.

Mr. Moleschi, you indicated that the matter is under active investigation right now within the college. Can you give us more particulars about what's going on with your investigation, separate and apart from the investigation that's going on through the ministry?

Mr. Marshall Moleschi: Our investigation is very specific to the situation. We have identified some pharmacists to people. It's a registrar's investigation; I've initiated a registrar's investigation. We have asked them some questions. They have a period of time, 14 days, to reply. We will then review the responses that take place.

I must emphasize that we're really early in this investigation. We gather that information. We also may come back to those people who we have identified and ask further questions. We go to other people who we think are involved in this investigation, and then we produce an investigation report, which goes to a committee. That report will go to an internal committee that looks at disposition of that matter. The disposition could be a possibility of three things: Those people could be referred to discipline, they could go to a caution, or the committee may find that there's no further action to take place. That's the way the process would work.

Mrs. Christine Elliott: I'm sorry, could you just give us some guidelines as to the time that you're looking at? You've mentioned something about 14 days. I'm just a little bit confused about when you expect that this report will be ready.

Mr. Marshall Moleschi: It will take some time. The normal process would take in the period of a few months to be able to complete. There are some timelines that are laid out in the act, and we follow the timelines that are consistent with other health care professions. That's the time frame that we're working to. But we're continuing to gather questions and investigate. With Health Canada, we've added some more questions. It's a joint investigation, and we'll probably, within a very short period of time, also go in with Health Canada to ask some more questions and visit the site.

Mrs. Christine Elliott: So this is a registrar's investigation that you've initiated, but you're working with Health Canada on it. Can you give us a bit more specifics about that relationship and how that will unfold within the course of your investigation?

Mr. Marshall Moleschi: We are dealing with an entity that isn't a pharmacy. It was not compounding direct, specific to patients, on orders from a prescriber, like a physician, and it wasn't registered with us. We do want to investigate to see what relations it had and what it was doing, so that's really important. We need to understand, also, when we go into the investigation—because we deal with compounding; Health Canada generally deals with manufacturing, so they have a role in that—we want to work jointly so that we can make sure that the public is safe and we can investigate. Whichever area the information is going to go, we can use our tools in each organization to be able to investigate this matter fully.

Mrs. Christine Elliott: Okay. So, will they be doing their own separate investigation, or do you have—in terms of how it actually operates, could you give us some indication of who will be doing what?

Mr. Marshall Moleschi: We're jointly gathering information. We're gathering information at this stage. If that information leads us down our path—our investigation is going to continue into the conduct of the members who are registrants, the pharmacists involved. When Health Canada finds more information, it can pursue its investigation based on what it has, and its rules and its laws that it has. We are working together in gathering the information, and we'll each use our processes to move that further.

Mrs. Christine Elliott: Would it be fair to say it's more information-sharing, really, at this point that you're doing, rather than a joint investigation?

Mr. Marshall Moleschi: We are using this information to do our investigation. Yes, we are sharing information, but we will use it appropriately to exercise our authorities as we gather that information.

Mr. Saäd Rafi: Can I just supplement that? I don't want to run afoul of the word "investigation," because it may have differing definitions under differing pieces of legislation, but Health Canada is doing a review, asking questions of Marchese, the company that is involved, as they have regulatory and legislative tools to do so, and, we think, some jurisdiction.

You've heard Marshall's responsibilities in his investigation, and the province has asked Dr. Thiessen to take a look at the supply chain. He has been appointed under the Public Hospitals Act, so certainly he can enter hospitals, have that conversation and determine what their role in the handling of product was. He has requested access and to have questions of Marchese, and to this point they have been quite co-operative in doing so. So there are three reviews/investigations.

Mrs. Christine Elliott: Okay, thank you. And you mentioned that your investigation will be coming before an internal committee. Will you be sharing that information with others?

Mr. Marshall Moleschi: We'll need to put it through our processes, and then if it goes to that committee to discipline, then the notice of that discipline is out there and the results of that discipline are published to the public.

Mrs. Christine Elliott: But will the information that you get through the investigation be shared with Cancer Care Ontario, the Ministry of Health or, perhaps, the members of this committee? Is it possible that that information can come forward to us?

Mr. Marshall Moleschi: There are some limitations in legislation, but outside that we would share the information. Without any of those limitations, we would share. I think this committee has the ability to request information.

Mrs. Christine Elliott: Okay, thank you.

If I could, Mr. Sherar: You mentioned the guidelines that you have published on various matters with respect to chemotherapy drugs and the administration of them.

Mr. Michael Sherar: Yes.

Mrs. Christine Elliott: Would you be able to provide the committee with copies of those guidelines?

Mr. Michael Sherar: Yes. They're all public on my website, but we will provide copies of those guidelines.

Mrs. Christine Elliott: All right, thank you.

To Mr. Rafi: Would you be able to provide us with a complete list of all of the members of the team that's taking a look at this, that are working with Mr. Thiessen?

Mr. Saäd Rafi: Yes. We have a working group, and we'll get you the associations and their names.

Mrs. Christine Elliott: Thank you. Those are all my questions. My colleagues may have some.

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

Mr. Jeff Yurek: Sure. Thanks, Chair.

Thanks for coming out. Mr. Sherar, just in addition to supplying the guidelines for cancer care, would you also be able to supply the policy you have in awarding contracts to companies outside the hospital for providing drugs to the hospital?

Mr. Michael Sherar: Maybe Mr. Rafi can speak to this, but we don't have a policy with respect to contracts that hospitals have with suppliers. We don't manage the procurement process for hospitals or have policies around their procurement.

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Mr. Jeff Yurek: Would it be based on each individual hospital, or would it be a Ministry of Health—

Mr. Michael Sherar: That's correct.

Mr. Jeff Yurek: Okay. Are there any other providers in the system providing manufactured or compounded chemotherapy medications to hospitals, or is Marchese the only one?

Mr. Michael Sherar: No, there are others.

Mr. Jeff Yurek: There are others?

Mr. Michael Sherar: There are others, yes.

Mr. Jeff Yurek: Would we be able to get a list of those providers?

Mr. Michael Sherar: I'm not sure. We have a complete list of those providers. We can try to assemble that list as best we know.

Saäd, you might want to speak to that.

Mr. Saäd Rafi: We are trying to find out who's in the industry, because the unregulated aspects—in other words, who are not pharmacies. It's hard to know who else is out there.

But we are trying to work with the Ontario Hospital Association to see who of their members has a supply relationship for cancer drugs. I think that CCO branched out to all hospitals—I believe there are 77 sites that are cancer sites—and asked them who are using various third party suppliers—sorry, who are using Marchese as a third party supplier, and it was narrowed down to these four hospitals. We'll have to go to that next level of questioning, if I understand your question correctly.

Mr. Jeff Yurek: Yes, that would be great. And in regard to the contract with Marchese, who negotiated the contract? Was it the individual hospitals? Was it Cancer Care Ontario? Was it the Ministry of Health?

Mr. Michael Sherar: Again, Saäd, you may want to speak to this. Cancer Care Ontario doesn't negotiate these contracts. Either the hospitals do or there are organizations that work for the hospitals to negotiate these contracts.

Mr. Saäd Rafi: Hospitals are their own duly constituted organizations with a board of directors under the Public Hospitals Act and, I believe, the Ontario Business Corporations Act as well, so they have their own purchasing approach. Some use third party purchasers, outsourcers, to provide all manner of products.

In this world, we are learning that some hospitals receive the material themselves and compound; some

receive compounded material. We don't dictate who they buy from or how they go about procuring, except for the directives and guidelines on procurement that they are obligated to follow, set out by the Ministry of Government Services.

Mr. Jeff Yurek: Can we get a copy of those guidelines from government services, please?

Mr. Saäd Rafi: Procurement guidelines? Certainly.

Mr. Jeff Yurek: And in reference to the cancer patients, what is the wait time currently for those patients who have been affected to actually see an oncologist and have a discussion?

Mr. Michael Sherar: As Saäd said in his comments, the arrangements for patients to either see their oncologist or schedule an appointment, if they would like, or use some other mechanism to have their questions answered—that process is largely complete with respect to the hospitals' outreach to all of the patients who are affected by this.

Mr. Jeff Yurek: Okay. Marshall, just a quick question, just for clarification: The Ontario College of Pharmacists' investigation on their part of the incident is only focused on the health care professionals who were pharmacists at the time. Is that correct? It's not on Marchese as a whole or the hospitals as a whole? It's just on the health care—

Mr. Marshall Moleschi: The investigations are on the health care professionals who are involved in this, to see if there was any misconduct or any incompetence. That's sort of the investigation that's taking place.

We're also looking because different organizations have the name Marchese in there, so we were looking to see if there was any relationship between Marchese Hospital Solutions, which is a federal corporation, and the relationship with Marchese Health Care pharmacies that are out there as well.

Mr. Jeff Yurek: Okay. So you have no jurisdiction over manufacturing? There's that area between compounding and manufacturing that you—

Mr. Marshall Moleschi: That's correct. Unless it's patient-specific, and that could only be done in a pharmacy—the admixture is not within our jurisdiction right now. We're engaged in conversation with the ministry to see whether our powers can be increased.

Mr. Jeff Yurek: And just one last question. I guess the Ministry of Health would be the question: Is the LHIN involved at all in this whole issue, or situation?

Mr. Saäd Rafi: Yes, they have been. I don't know if Michael had a chance to mention that in his chronology, but they were informed early on in the chronology of events. It would be the Erie St. Clair LHIN, so the Windsor area, and then what we call the South West LHIN, which would be the London area—

Interjection.

Mr. Saäd Rafi: Oh, and the South East LHIN too—sorry; Central East.

Mr. Michael Sherar: Which covers Lakeridge and Peterborough.

Mr. Jeff Yurek: Thanks. That's all for me now, Chair.

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

Mr. Jeff Yurek: Jane?

Mrs. Jane McKenna: Thank you so much for coming in today. I know we all have the best interests of the cancer patients and their families. My daughter lives in Windsor, and one of her very dear friends is one of these victims in this situation.

When I'm actually listening to Ms. Elliott speak right now, I understand the confusion because it's very difficult. If you knew the questions to ask, we wouldn't be in the position we are in right now. So ultimately, us asking you these questions—we wouldn't be sitting here if we had those questions answered.

I just wonder, how are we going to get a clear plan of what we're actually trying to do? Because it seems that we're not really sure what we're actually putting forward. I guess my question is—for example, you're saying right there that you're going to find out, Marshall, if there's any action to be taken—who hasn't done the proper protocol—but how do you know if they don't know what their job description was? How are you going to know that?

Mr. Marshall Moleschi: So we will be looking at information that we can get from the processes that were in place, so using this tool to be able to find information. We're trying to find out as much information as to the policies and procedures that they have, their job description—all those sorts of things—and gather any relevant information, what their training programs are and that sort of thing.

There are some colleges across Canada that do have some responsibility on the hospital side. British Columbia was one of those. There are standards that you need to look at, and those standards are well laid out. When the college would go in, they would look at the policies and procedures, the training, if they're meeting the modern standards of the day. So those sorts of things are what we would be reviewing.

We're going to try to get that information as well through this mechanism. Even though we don't have that direct responsibility, we're going to use our tools to be able to find that information.

Mrs. Jane McKenna: That's not something that you do on a regular basis right now. We're just doing this because of this situation or—

Mr. Marshall Moleschi: So this college does not have the authority because of an exemption under 118 of an act—

Mrs. Jane McKenna: Right.

Mr. Marshall Moleschi: —to be able to look at the supply. We didn't do that on a regular basis. We have not done that. In the future, the discussions that are taking place right now with the ministry is, is that needed in this province and can we have those sorts of authority? That's part of the discussion that's going on. So we are finding that information.

Mrs. Jane McKenna: So if you don't, who does have the authority?

Mr. Saäd Rafi: If I might. Through the course of this in a very compressed period of time, we've learned that where these drugs were being combined is not considered a pharmacy. So the existing legislative framework that the college has has created this gap.

We are working with Health Canada, I would say, hand in glove, because we feel that they have legislative authority, but it's, again, a unique circumstance, how this company has structured itself to combine or prepare these drugs. Health Canada is going through a very rigorous assessment of questions of the company as to how you do your business, and then they're looking at their legislation, how to apply it.

In addition to that, since we have the authority of the Public Hospitals Act, we've asked Dr. Thiessen to come in and say, "Okay. This is a supply chain"—I think to the questions Mr. Yurek was asking—"matter as well, so what happened from a quality assurance point of view on the supply chain?"

We have this working group that meets now on a daily basis, and putting those three components together, we hope to then have that coordinated approach and understanding of the situation as well as the remedies. In some cases, I think it's been well chronicled that there is a bit of a regulatory gap, and that's why we're trying to work with Health Canada to fill it.

Mrs. Jane McKenna: So—

The Chair (Mr. Ernie Hardeman): You're out of time. Thank you very much.

Before we go to the third party, I just want to point out that Mr. Yurek is not a subbed-in member of the committee, and he made a request for a number of documents. So on behalf of Mr. Yurek, I would ask that they be presented.

Interjection: Of course.

The Chair (Mr. Ernie Hardeman): We have to have it officially asked for, so we just wanted to make sure that was done.

With that, we'll go to Ms. Gélinas.

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M^me^ France Gélinas: My first question will be for Mr. Moleschi. In the notes that you have given us, on page 4 you talk about, "On April 3, the college appointed an investigator and with two Health Canada inspectors visited the premises." Could you describe which of the premises you visited and does that include premises that are considered a pharmacy and the premises that are presently in the grey zone of not being covered by you because they're not compounding drugs and not being covered by Health Canada because they're not manufacturing? Did you go there?

Mr. Marshall Moleschi: Yes. These two entities are—one is an accredited pharmacy. They occupy a building. It looks like an industrial type of building. There's a pharmacy area available to the public, and we entered that premises with Health Canada and we were looking to ask where the manufacturing was taking place, so the admixture mixing of the other company. It was not adjacent, but it was close by in the same building, so we were given permission to be able to go into that area and investigate.

M^me^ France Gélinas: Okay. Then that brings me to Deputy Minister Rafi. There is a federal policy document, that I'm sure by now everybody has read and reread, by Health Canada called Policy on Manufacturing and Compounding Drug Products in Canada, and it deals specifically with grey areas. This policy was last updated in 2009, but it dates back to 1997. Do you know what I'm talking about?

Mr. Saäd Rafi: Yes. I've not read the entire policy, but I know what you're talking about.

M^me^ France Gélinas: Okay. Basically, the document lays out a strategy and criteria for determining whether federal or provincial regulators have oversight. It notes that, "discussions may take place between the two jurisdictions for final determination of whether an activity is considered to be compounding or manufacturing." It goes on to note that these decisions are made on a "case-by-case basis."

I take it that the ministry is aware of this policy? We know that there's this grey area. We've living it now, so now we all know, but I'm assuming you knew before I did.

Mr. Saäd Rafi: Well, I don't know when you knew, but we have learned of it recently, yes, certainly in discussions with Health Canada.

M^me^ France Gélinas: Is there someone within the ministry that has responsibility for ensuring compliance with this policy and in making those case-by-case decisions?

Mr. Saäd Rafi: Well, I think that the ultimate answer is yes, because we work—when these situations arise, it's a fairly specific policy that if one doesn't find themselves in this unfortunate circumstance, we may not have been alive to it and its existence.

This is part of our conversation with Health Canada, along with conversations we've had with them on the Food and Drug Act and what we believe to be considerable powers of investigation. As Marshall Moleschi has indicated, they have been, I think, very co-operative in working with us, as has Marchese, the company itself.

M^me^ France Gélinas: Okay. So if we don't look at this particular pharmacy/compounding because I don't know how to call them anymore—

Mr. Saäd Rafi: Yes, exactly.

M^me^ France Gélinas: Can you give me another example where the ministry worked with Health Canada and said, "Okay, we're solid on the pharmacy side. You guys are solid on the compounding side. There's a grey area here. Let's settle it"? Has this happened in Ontario before this case?

Mr. Saäd Rafi: Well, I'm not aware of it, and I'm just saying "recent history." We certainly have worked closely with Health Canada and all other provinces and territories on a particular pharmaceutical-related issue with Sandoz and drug supply, but that was a different

circumstance, but in my three-and-a-little-bit years of tenure in the ministry that's the only example I can recall.

M^me^ France Gélinas: Can you reassure this committee that Marchese, being the facility in question, has never made contact with the ministry to let them know, "We have this new corporate structure. Part of our corporate structure is a pharmacy; part of our corporate structure is manufacturing. But we have this corporate structure that falls in between"? Have they ever flagged that to you and informed the ministry of their new corporate structure and what that corporation was doing?

Mr. Saäd Rafi: I can't answer that right now, but I will get you that answer.

M^me^ France Gélinas: Okay.

Mr. Saäd Rafi: My suspicion is that they did not—what's the word?—proactively come to us and say, "Listen, we've just federally incorporated ourselves"—I think in early 2012—"and we do the following things on the following premises, and this is our corporate structure"—I can't even pronounce the corporate holding company structure; Mezentco or something—"and we have this company underneath that company." I don't think that has happened, but I also don't believe that they have an obligation to do that, just like any other federally incorporated company doesn't have an obligation to come and report in.

M^me^ France Gélinas: Okay. And maybe that would be—back to Mr. Moleschi, then. When, through the press, which is where I got most of my information on this—it took quite a bit of time before we realized that we were all calling them a pharmacy. I've been in the system long enough to know that if it's a pharmacy, it falls under your college. I felt pretty confident about it all. Then, almost a week later, we realized that, no, although the hospital was buying from what we thought was a pharmacy, they were actually buying from a federally incorporated corporation that had no oversight. How come it took so long for that piece of it to be discovered?

Mr. Marshall Moleschi: It's the clarity on what they were. We did want to find out what it was that they were doing and under what authority they were doing that. So we did send an investigator in—I think it was the Wednesday; it's in the notes there. We had to get some information. We also wanted to do a company search to understand what that company was. It takes some time, I guess. By Monday, we were confident that they were acting independently and not doing any patient-specific type of compounding, but they were actually doing admixtures. We had to gather that information and then we could announce that it wasn't behaving as a pharmacy, and it was separate from the Marchese Health Care pharmacy. It was Marchese Hospital Solutions that was doing that enterprise. We also wanted to investigate to find out if Marchese Health Care pharmacy was doing any of that as well.

So we did have to do our due diligence, and it did take, I guess, three working days to do that.

M^me^ France Gélinas: Okay. Now that it has been found that we have this grey area, I'm sure the field is talking. Do you figure there are more of those corporate entities in Ontario?

Mr. Marshall Moleschi: To me?

M^me^ France Gélinas: To you.

Mr. Marshall Moleschi: We are quite concerned, and we do want to know if there are any areas that may not fall under one jurisdiction or the other. We're very concerned about that. We're working with Health Canada to discover that. What we're talking about here are agencies that have contracted with hospitals, and there are other organizations that are looking into that so that we can get a fairly defined group.

We also want to look at the behaviours of the pharmacies that we're looking at, to make sure that they are compounding patient-specific. There are a number of pharmacies that have compounding listed as some of their activities, and we're reviewing all those records to make sure that they're doing what is appropriate in the legislation. So we're doing our due diligence, and we're reviewing all our records as well.

We're taking efforts to be able to do that, and what we're talking about specifically here is something that is between a group of people so that it can be easily identified by those who are looking at it.

M^me^ France Gélinas: Back to you, Deputy: The minister looked quite surprised when she was told—well, she announced to us—that there was this grey area. Was it a surprise to you and your ministry that there was now a corporate structure out there that fell in the grey area of oversight?

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Mr. Saäd Rafi: I think the word "surprise" is less the word for me than, there's frustration and disappointment that it's difficult to pinpoint the problem and then the solution.

My own experience on the economic side of things tells me that companies incorporate and structure themselves in a multitude of different ways for a multitude of different purposes. It's impossible to predict the future by effective regulation or legislation, but we're working very hard to figure out how to close those gaps and, as I mentioned to the earlier question, with Health Canada's support as well, because—I think you've already identified it—there's the combining; there's the manufacturing; what is "preparing"? Is that a Food and Drugs Act issue? Is that an improvement to the regulatory and legislative structure for the college?

M^me^ France Gélinas: I guess I spent enough time looking at Ornge's corporate structure to know now that corporations can take very many different forms, none of them for the betterment of the patient. Am I looking at the same thing here? Am I looking at a legitimate health care provider that goes and gets creative with their corporate structure in order to avoid accountability?

Mr. Saäd Rafi: I can't respond to that. I don't know what motivated them to structure themselves the way they did and to go after business for supplying and combining drugs. That's a question that I think should be put to them.

M^me^ France Gélinas: I will. I just wanted to have your take on it before we go.

I think we got from Mr. Sherar that you will be asking the 77 hospitals that provide chemotherapy treatment if they procure their chemotherapy drugs from—where they're procuring from, if they're not compounding it in-house.

Mr. Michael Sherar: Our questions of the hospitals were specifically aimed at the issues of safety right now with respect to this issue. We had questions initially through our regional vice-presidents around this specific issue of these drug products that we understood from the hospitals had led to the underdosing of patients, making sure that that wasn't an issue in any other hospital across the province. We confirmed that.

We did send out—and this was on April 2—a more general advisory with respect to what we understood about the nature of the issue, the error that had been made and the checking of procedures and policies with respect to guidelines that were in place for the administration of chemotherapy to patients—understanding that issue. They all responded to us, again to our satisfaction, that they had in fact indeed done those checks.

That issue was more around the general nature of preparing chemotherapy in adherence to guidelines that were in place. That was the nature of our questions.

M^me^ France Gélinas: That's good.

Deputy, again, please: Knowing the little bit that we know now, is the ministry, in its role of oversight of the health care system—are you interested in finding out if there are other such corporations providing services to our health care system, and are steps being taken to identify them?

Mr. Saäd Rafi: As I mentioned, in the working group, the hospitals affected are part of that group, but so is the Ontario Hospital Association. We have been talking with them at some length, but priority one was the patients. The next priority moved to, "Okay, so what do we know? What are we able to gather? Who has regulatory authority?" Now we're looking at how to deal with that regulatory authority and where the gaps exist. Then, yes, I think we have to turn our minds to the types of things that you're asking, but that is on our list of things. Of those 77 hospitals that provide cancer treatment—and I think that was the nature of that question earlier from Mr. Yurek—how are they procuring various drugs? Are third parties used in this regard? And then what are the quality assurance aspects? How do you receive the product? Do you receive it already combined but in a—I'm conscious of the experts in the room—sort of a bulk stock that you then break down to individual various doses to the nature of the patient? If you do that, do you do that in your hospital, and what are the quality assurance steps that you undertake? What are the mathematical applications you apply to that bulk stock? Do you get the vial instead as the product, and who do you get that from—through an outsourcer or direct from the supplier? And that's part of Dr. Thiessen's work as well.

The Chair (Mr. Ernie Hardeman): Two minutes left.

M^me^ France Gélinas: Okay, two minutes left. I'll use them wisely.

We all know that more and more hospitals are outsourcing more and more services, not only in drugs but in rehab, in patient transfer, in lots of services that used to be done and provided—services and programs that used to be within the hospital confines under their accreditation etc. are now being contracted out. I see the responsibility for the ministry to make sure that those programs and services are contracted out with accountability. Who within your ministry follows that? As more and more hospitals contract out more and more services and programs, who makes sure that those contracted-out programs and services have oversight, have accountability?

Mr. Saäd Rafi: Well, the hospitals themselves—that's a very broad question, and I don't want to short-change your answer.

M^me^ France Gélinas: I realize. Use your 45 seconds wisely.

Mr. Saäd Rafi: Well, I'm sure I'll be back, so I can embellish further.

Look, there's a legislative structure; they have their own corporate responsibilities; they have officers of their organizations; they have legislative accountability; they have procurement rules to follow. There are 154 organizations, $17 billion.

I don't know that all the examples you used, either, were provided by hospitals in the past. Patient transfer was an ambulance-based service. Non-emergent transfer has been done for many, many years. I want to be careful that we're not indicting the hospital sector, writ large for this unfortunate and terrible circumstance, on many other things.

M^me^ France Gélinas: I have no intention of doing that.

Mr. Saäd Rafi: We do monitor the hospital activities. They have quality improvement plans. They report publicly. We have relationships with the hospital sector through the Ontario Hospital Association, and they have a legislative framework.

M^me^ France Gélinas: I'm more interested that once the service is in the community, and it is out of the hospital's responsibility, does it fall under yours, given that you have oversight of the health care system?

Mr. Saäd Rafi: Sorry, it's not our sole responsibility. Hospitals have to take a great deal of responsibility for every activity that takes place in the hospital. The Public Hospitals Act, as well as several other pieces of legislation, oversee their responsibilities as well. The ministry can't be expected in this—in the hospital circumstance, for every patient interaction, they have legislative responsibilities for their patients.

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

The government side: Ms. Jaczek.

Ms. Helena Jaczek: I'd like to go back to the chronology, because I think, in this very unfortunate incident, what is really important and one of the aspects we want

to look at is the response time in which the ministry took the actions that they did.

Mr. Sherar, as I understood it, the first notification to the Ministry of Health and Long-Term Care was March 29, I believe; the Good Friday. Would that have been correct?

Mr. Michael Sherar: March 28.

Ms. Helena Jaczek: Actually, it's March 28.

Mr. Michael Sherar: Which was the Thursday, I think, just before Good Friday.

Ms. Helena Jaczek: Thursday. Deputy, to you, in terms of this of this notification: At what point—perhaps we should even ask you—were you personally notified of this situation?

Mr. Saäd Rafi: Easter Monday.

Ms. Helena Jaczek: Easter Monday. If we could just follow a little bit of what would have occurred with that notification to the ministry. Cancer Care Ontario, obviously, was engaging in a certain process. Was there discussion regarding patient notification and so on?

Mr. Saäd Rafi: I think it's important to point out that prior to the 27th, when Cancer Care Ontario was officially brought in by the hospitals, these two particular hospitals had started to communicate with each other. Lakeridge/Peterborough—Peterborough is within the Lakeridge family—where the particular pharmaceutical technician—I don't wish to shortchange the individual, but this very clever individual realized a particular problem because they had just made a recent move over to this supplier—through a supplier.

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This individual, as I understand it, noticed a difference in the weight of the product. Again, I'm out of my depth, but I understand saline has a different weight than the actual combining chemotherapy drug. He decided to check, contacted his superiors and they reached out to London. I'm not entirely sure why London; I think they knew that they had a supply relationship through Medbuy. Then the other people using that outsourcing company got together and over the next six calendar days, as Mr. Sherar has pointed out, they started to examine, amongst their patient records, who would have had these drugs, when they would have started these drugs and what the impacts were. That became a very complex and operationally intense exercise.

So then Cancer Care Ontario was involved. I had a particularly challenging weekend on a personal matter. I was informed on the Monday. We started working with Cancer Care Ontario in earnest, although we had heard about this on the 28th or the 29th, every day for the remainder of that week. They issued a notice, I believe, on the 2nd—

Mr. Michael Sherar: A press release.

Mr. Saäd Rafi: A press release notice on the 2nd with the number of patients, the affected hospitals, and then—I can go on for the rest of that week into this week, if you wish.

Ms. Helena Jaczek: Through that period, then, you feel confident that every step was taken with as much speed as possible in terms of looking at the patients first, and that the process was—from your position as deputy, that Cancer Care Ontario and those individual hospitals were taking their responsibilities very seriously and they were working as fast as they can? Is that fair to say?

Mr. Saäd Rafi: It is, and I say that because, of course, I was not witnessing the actual procedures put in place, but I know the CEOs of these facilities and I have come to know the integrity of the VPs of Cancer Care Ontario; I've worked with Michael since he was instituted—actually, just prior to him being instituted as CEO. These are all very, I would say, high-integrity, high-sincerity individuals who put the care of the patients of their facilities first, just like every hospital in Ontario does. I think they acted as swiftly as they could and at varying paces—I think that's already been chronicled—based on the complexity of the patient cohort they had.

Ms. Helena Jaczek: Thank you. So now, the actions that the ministry has taken since then: the appointment of Dr. Jake Thiessen—he's the third party expert reviewer—then you have the working group as well. I'm just trying to understand how the working group relates to Dr. Thiessen.

Mr. Saäd Rafi: I would think of the working group as a resource to the ministry and, predominantly, Dr. Thiessen, in that he has the ability to ask very pointed and deliberate questions, because they happen to coalesce every day virtually on a daily conference call. He is using that first line of inquiry to then go out and do his visits. He's starting, I believe, with hospital visits this week. Then he'll have some preliminary assessment. As he says, drugs are his life. He has over 40 years of pharmaceutical experience, so he understands both the hospital environment as well as the combining and manufacturing end of this supply chain.

They're there as a resource. They're also there as a resource to us as we were trying to discuss and explain the various regulatory approaches, so that we come to a common set of understanding and conclusions to hopefully prevent this from ever happening again.

Ms. Helena Jaczek: I think somebody else may have touched on it, but the independent review will be made public, I am assuming?

Mr. Saäd Rafi: I don't see why it couldn't be.

Ms. Helena Jaczek: Okay. Mr. Moleschi, just again trying to understand the jurisdiction here in Ontario—which I understand is maybe different from others, and we'll get to that—did Marchese Hospital Solutions have a pharmacist on staff within that corporate entity?

Mr. Marshall Moleschi: We were going in to discover that. They did have a pharmacist who was working there. They weren't listed with us, but when we went in to discover, there was a pharmacist involved.

Ms. Helena Jaczek: But would that pharmacist be someone in good standing? Their licence and—

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: Yes.

Mr. Marshall Moleschi: And that's why we have someone to do the investigation with.

Ms. Helena Jaczek: Okay. So with that knowledge, you and Health Canada are collaborating on this investigation.

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: And because of the grey area, you've both decided—

Mr. Marshall Moleschi: We wanted to see what was there—

Ms. Helena Jaczek: You wanted to see—

Mr. Marshall Moleschi: —gather the information and use our processes to make sure that the public could be assured that the system is safe, and we would do what is needed to be able to improve it.

Ms. Helena Jaczek: Right. Now, you made a point in your presentation that this section 118 of the DPRA specifies that the college does not have jurisdiction over "drugs compounded, dispensed or supplied in and by a hospital." You were in BC. Are there other jurisdictions that have that ability to go into a hospital?

Mr. Marshall Moleschi: Yes, they do. They would be able to look at the processes in a hospital. They would look at the policies and procedures, the methods they have for detecting any errors, their quality assurance programs, the types of hoods they were using for the type of activity they were doing, because there are different levels for the different types. Chemotherapy requires a little more extensive—quite a bit more extensive—process than sterile compounding. Sterile compounding has higher standards than general compounding.

Ms. Helena Jaczek: Let's put it this way: Would you be advocating to have that section changed so that the College of Pharmacists here in Ontario would have jurisdiction in hospitals?

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: So I guess my question now, back to the deputy, is: How can we be assured of the safety, the quality assurance of hospital pharmacy now?

Mr. Saäd Rafi: Well, I think that's some of the work that Dr. Thiessen is going to help us better understand: give us an informed and expert judgment on whether the QA, quality assurance, practices were being adhered to, I guess. I say "I guess" because I don't want to say something that limits his activities.

In addition to that, he will look at, I would imagine, the contractual relationships and whether—if a company says, "We fulfilled our contractual relationships," was the contract robust enough for ensuring quality? Because not every hospital is receiving these combined drugs in the same way, I'm led to understand.

That's part of the path of discovery that we're on. I think, as the registrar has said, this may take a few months. We want to be thorough, but we don't want to be so slow as to continue to have patients unduly worried—so trying to find that right balance to make sure that the right changes are proposed, be they regulatory, be they directives, by they legislative.

I think the registrar has indicated his interest in one specific area of the existing legislation, the Drug and Pharmacies Regulation Act, but there may be other areas. In addition to that, we are asking the federal government to determine what it can do and what it should be doing with respect to the aspects of the Food and Drugs Act, where it has jurisdiction over manufacturing and preparing, amongst other things.

Ms. Helena Jaczek: Thank you. Now, my colleague, Ms. Gélinas, made reference to the Health Canada document that details their oversight of drug compounding. May I ask, Chair, that we have that document tabled so we can all have an opportunity to review that?

The Chair (Mr. Ernie Hardeman): Yes.

Mr. Saäd Rafi: Sure.

Ms. Helena Jaczek: I guess, if I have some time left—

The Chair (Mr. Ernie Hardeman): Oh, yes. You have, yes.

Ms. Helena Jaczek: Oh, good.

Mr. Sherar, obviously you have very broad experience with Cancer Care Ontario and elsewhere. Can you talk a little bit about the potential risk to these individuals? Just try and give us a picture of how the products may have been used. I know we all—obviously, when we hear "cancer," everybody is totally, understandably very concerned. Could you perhaps, in the discussions that Cancer Care Ontario has had with its clinicians and so on, give us a picture of what this actually means?

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Mr. Michael Sherar: Yes. You know, I really appreciate the concern of patients and their families. Of course, we want to provide accurate information, not unduly alarming patients but giving a balanced view of the picture. This is a particularly difficult issue to kind of make conclusive statements on.

As you'll appreciate, there's very little or very sparse literature or evidence around under-dosing, so actually quantifying in terms of all of the patients who have been affected in the province—the impact on their particular outcomes, or as a group—is very, very difficult to do. That's why, I think, our focus with the hospitals has been that the issues around the effect that individual patients might have are best discussed with their oncologist. I think the hospitals have done a very good job of making sure that patients have the ability to have those discussions and have those questions answered.

I think researchers and Cancer Care Ontario and others will, of course, learn everything we can from this incident, to understand what the outcome may have been for these patients, whether it has been affected. I don't know the extent of how much we'll know in the future with respect to the outcome on individual patients.

As you're aware, probably from the press, these drugs are used in a variety of ways, for a variety of different cancers, for a variety of different intents: from a curative intent, where it's used in addition to, for example, surgery, to prevention of recurrence, to palliative care for treatments of patients who have advanced disease. Even though there's obviously a significant number of patients that we're very concerned about, the ability to make conclusive statements about the impact on patients across

all of those different uses of the drugs, the different stages of disease, is really very difficult to make.

I completely understand the difficulty that oncologists and others have in trying to reassure patients of what the impact may be. That's why I think our focus with hospitals has been, as I say, to make sure that they have those individual conversations. They can understand the likelihood of impact in a much better way. Whether there might be any increased monitoring of those patients or changes to treatment is really best discussed at the individual level.

Ms. Helena Jaczek: When was this product from Marchese Hospital Solutions first used? Do you know how far back we're going?

Mr. Michael Sherar: Yes. I probably don't know the exact date, but it was approximately just over a year ago, in early 2012. I believe both Windsor and London, early in 2012, started using this product. Lakeridge were much later, in the last month or so, and that's why there's a much smaller number of patients. As Deputy Rafi has indicated, Peterborough had just switched over. They work very closely with Lakeridge in the delivery of their systemic treatment program—and only one patient there, of course, as they have just switched to this product.

Ms. Helena Jaczek: So during that year or so, there haven't been any unexpected clinical things? People obviously didn't know about the situation. But there was nothing that was brought to Cancer Care Ontario as about, "Somehow things are not working the way they should"? There was no apparent change in outcomes that was alarming during that time? I'm thinking of things that might be a little more reassuring for people, if that's at all possible.

Mr. Michael Sherar: No, we didn't receive any indication from hospitals prior to March 27 that there was an issue. No.

Ms. Helena Jaczek: Thank you. I'm not sure if my colleagues have any other questions. Otherwise, I think we're good. Thank you.

The Chair (Mr. Ernie Hardeman): I was going to say: You just can't sell that last two minutes, can you?

Well, thank you very much. That does conclude the time for today. As we said, we hope that you will be available again if the committee decides they need more information. Ms. Brown, I'm sure that they saved all the questions for you for next time.

Thank you again very much for being here today and enlightening us somewhat on the scope of the challenge that we're facing over the next number of weeks or months to come to some kind of recommendation as to how we can all make sure that this never happens again. Thank you very much for being here.

As for the committee, I just want to remind the committee that we need the names of the delegates that we wish to be asked to report by Thursday—the names that you wish to interview in future meetings.

With that, we're concluded until Monday at 2, same time, same place, to repeat today's events. The meeting stands adjourned.

The committee adjourned at 1726.

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Also taking part / Autres participants et participantes
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Clerk / Greffier
Mr. William Short

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Ms. Elaine Campbell, research officer,
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