ISSN 1710-9477

Legislative Assembly of Ontario

Second Session, 40th Parliament

Assemblée législative de l'Ontario

Deuxième session, 40e législature

Official Report of Debates (Hansard)

Monday 21 October 2013

Journal des débats (Hansard)

Lundi 21 octobre 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
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Room 500, West Wing, Legislative Building
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Telephone 416-325-7400; fax 416-325-7430
Published by the Legislative Assembly of Ontario

Service du Journal des débats et d'interprétation
Salle 500, aile ouest, Édifice du Parlement
111, rue Wellesley ouest, Queen's Park
Toronto ON M7A 1A2
Téléphone, 416-325-7400; télécopieur, 416-325-7430
Publié par l'Assemblée législative de l'Ontario

LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON SOCIAL POLICY

COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Monday 21 October 2013

Lundi 21 octobre 2013

The committee met at 1405 in committee room 1.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

The Chair (Mr. Ernie Hardeman): We'll call the Standing Committee on Social Policy to order for the committee hearing for October 21, on the study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies. I welcome everyone.

Before we hear our presenter today, I think you have a motion, Ms. Jaczek.

Ms. Helena Jaczek: Yes. I move that Rod Jackson replaces Jane McKenna on the subcommittee for committee business.

The Chair (Mr. Ernie Hardeman): You've heard the motion. All those in favour? Opposed? I didn't hear any nays, so I'm going to take it as carried.

HEALTH CANADA

The Chair (Mr. Ernie Hardeman): For delegations today, we have Health Canada here: Dr. Supriya Sharma.

We thank you very much for coming today. We'll give you 20 minutes for an opening statement—you can use any or all of that—and then we will have questions from the three parties. We will start with the third party in this round, and hopefully address this all in about an hour and a half, if we can get it all in.

We have an oath; we're doing all of the hearings under oath. The Clerk will issue the oath or the affirmation.

The Clerk of the Committee (Mr. William Short): Dr. Sharma, if you could just raise your right hand. 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?

Dr. Supriya Sharma: I do.

The Chair (Mr. Ernie Hardeman): With that, the floor is yours.

Interruption.

Dr. Supriya Sharma: I thought there was—did you have housekeeping? Done? Okay. Thank you very much.

Good afternoon, Mr. Chair and members of the committee. I would like to thank you for inviting me to appear today. I look forward to outlining the actions Health Canada has taken relating to the important oncology medication issue that the committee is studying.

Firstly, I thought I'd share a bit of my background with you. I'm currently the senior medical adviser of the health products and food branch in Health Canada. I'll speak in more detail about the role of the organization a bit later, but overall it's the authority that is responsible, among other things, for regulating the manufacture and sale of pharmaceuticals in Canada.

I'm trained as a pediatrician. I earned my MD from the University of Ottawa, and completed my pediatrics residency in Calgary and in Australia. I then earned a hematology/oncology research fellowship at the Hospital for Sick Children and the Toronto General Hospital. I also have a master's degree in public health from Harvard University. Following my master's, I did a project writing a Harvard business case on how large-scale health care institutions incorporate patient safety initiatives into their organizations. I've worked at Health Canada since 2002, in a variety of management positions.

Mr. Chair, I'd like to share my initial personal reaction when I first heard about the reported underdosing of chemotherapy drugs. First and foremost, I thought of my own friends and family. Patients and loved ones always invest tremendous trust in the quality of care being received. This is even more so in the case of potentially life-threatening diseases such as cancer.

Like so many Canadians, I too have had people very dear to me who have suffered from cancer and have relied on chemotherapy drugs for life-saving treatment, so my feelings were no different than those of concerned family members that were reported in the media or conveyed to the committee. I was worried and uncertain as to whether my loved ones had received lower-than-intended doses and, if so, what it would have meant to their overall care and prognoses.

As a trained health care professional, my thoughts also went out to the first-line health care providers who were treating the affected patients. We're all in this field to help people. Having studied medication errors and incidents, and how health care institutions deal with patient safety issues, I'm well aware of how devastating it can be for health care providers to learn that anything they might have done may have adversely affected patient outcomes.

Then I thought of the mandate of Health Canada, and what role we would need to play in determining what had

happened, as well as what role we could best play in achieving a solution to the problem.

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Health Canada, and more specifically, the health products and food branch, was contacted by the Ontario Ministry of Health and Long-Term Care on the evening of April 1, 2013, and informed of the public communication that was to go out regarding the reported underdosing of certain chemotherapy drugs.

Mr. Chair, from the moment we first heard about the incident from the ministry, I and my colleagues have taken the situation very seriously. Working with provincial and territorial partners, our actions have taken two tracks:

—in the short term, identifying the circumstances and practices at the Marchese Hospital Solutions facility where the underdosing was reported to have occurred; and,

—in the longer term, understanding the extent and scope of these compounding-like activities across Canada and working toward longer-term solutions to provide clarity regarding appropriate safety oversight.

Together with colleagues from the Ontario College of Pharmacists, Health Canada sent inspectors into the Marchese facility for a fact-finding visit to better understand what activities were taking place in the facility and under what oversight. Letters outlining a series of questions based upon what we found were then sent to Marchese under the joint signature of Health Canada, the Ontario Ministry of Health and Long-Term Care, and the Ontario College of Pharmacists. The responses to those letters and the materials provided further delineated the details of the processes and procedures of procurement, as well as the preparation of the medications supplied to hospitals.

During that same time period, Dr. Jake Thiessen was appointed by the Ontario Minister of Health to provide an independent assessment of the circumstances surrounding the situation. Health Canada was pleased to sit as a member of the working group brought together by the ministry to share information and to support his painstaking work.

As the facts surrounding the underdosing incident in Ontario emerged, Health Canada and all provincial and territorial regulators developed a more detailed understanding of how the practice of pharmacy has changed and evolved to adapt to a new drug preparation and purchasing model. We were able to clarify the complexity and diversity of practices that existed even within a single organization.

Mr. Chair, our understanding and regulation of traditional drug compounding has been premised on the issuance of a prescription or a hospital order by a health care practitioner for the delivery of a single drug to a single patient. Indeed, it is for this reason that compounding as traditionally understood has been covered by provincial and territorial physician and pharmacy regulations. It has been explicitly exempted from the relevant federal regulations, which have focused on drug manufacturing processes.

Today, compounding-like activities are being conducted in dedicated facilities by third parties, outside a health care setting and for many patients at once, often without a specific prescription. As a practical matter, it has come to look like a kind of hybrid of compounding and manufacturing. This type of activity challenges existing federal and PT regulatory definitions and regimes, which were not explicitly designed to capture these types of activities in a manner that is proportional to the potential risk to patients.

While we were working collaboratively to assess longer-term approaches to ensure appropriate oversight of these activities, we also felt that Canadians needed to know how existing frameworks were being applied to protect their safety. To this end, on April 19, 2013, Health Canada issued an interim direction to facilities undertaking admixing/compounding activities and outlined the conditions under which they could be allowed to continue providing services:

(1) They are done within a hospital, meeting provincial regulatory requirements;

(2) They are done outside a hospital, as a service under the supervision of a provincially licensed pharmacist; or

(3) They are done in a manner that meets the licensing and manufacturing requirements of the federal Food and Drugs Act and regulations.

Canadians could be reassured that organizations following these directions would have the active oversight in place to help ensure the safety and effectiveness of health products prepared in this way. As a follow-up to the issuance of the directive, we surveyed all companies that were performing compounding/admixing activities and asked them to report to us whether or not they were conducting the activities, and if so, to declare what category they fell under.

On the same day, the Ontario Minister of Health announced new regulations to allow the Ontario College of Pharmacists to inspect drug preparation premises in Ontario and to require hospitals to purchase products only from facilities that had passed such inspections.

With that level of certainty in place in Ontario and across Canada, Health Canada then took on a leadership role in facilitating the development of a longer-term solution. We brought together provinces and territories through an assistant deputy minister-level task group. This group focused first on understanding the extent and scope of these activities in the various jurisdictions.

Provinces and territories collected information on facilities undertaking these activities, their oversight and on the drivers for the expansion of this model. The information collected showed a variety of practices and oversight frameworks that are in place.

The information from the provinces and territories augmented Health Canada's outreach to companies. Overall, companies were identified that were conducting compounding/admixing services, the vast majority of which are in Ontario and Quebec.

In parallel, Health Canada reached out to the Council of Pharmacy Registrars of Canada. This group, along with representatives of the National Association of Pharmacy Regulatory Authorities, provided a great deal of information on regulatory oversight, capacity and pharmacy practices both at the hospital and the community level in the provinces and territories.

In broad terms, the task groups supported a national approach to oversight, as well as a strong desire to help move a framework forward. Caution was expressed, however, about what that solution should be, and that it be implemented in a measured, methodical way, given the complexity of existing practices across the country. We were cautioned against moving too rapidly towards a solution, without fully examining all the intended and unintended consequences. We do not, for example, want to find ourselves in a drug shortage situation because new regulations require a significant retooling of existing facilities.

In fact, it was the collaboration at these tables that provided the necessary information to fully understand the scope of practice at the national level. As Dr. Thiessen has reported to the committee, he felt that the manner in which all parties came together around the circumstances was exemplary.

What emerged from these discussions was a lack of clarity regarding the actual activities being undertaken by companies and the need to more clearly delineate what would most appropriately be regulated at the provincial/territorial level as opposed to at the federal level.

To this end, a subgroup was brought together by Health Canada that included representatives from the provincial/territorial committee, three representatives appointed by the National Association of Pharmacy Regulatory Authorities, the Canadian Society of Hospital Pharmacists, the Canadian Pharmacists Association and Accreditation Canada. This group met over the summer and parsed out the necessary detail to better map out the practices of compounding, manufacturing, as well as more clearly define this new practice of compounding-like activities.

Mr. Chair, as our Minister of Health has said, Health Canada accepts Dr. Thiessen's findings. These compounding-like activities require more effective regulatory oversight. Health Canada will play a leadership role in the oversight of these activities. Indeed, such work is really just a continuation of the leadership role we have taken since first learning of the reported underdosing in Ontario last spring.

However, as mentioned previously, we have learned throughout this process that there is a significant variation in approach and capacity across Canadian provinces and territories to oversee these activities. Therefore, it's very important that we continue our collaborative, thoughtful approach to the issue to avoid unintended consequences, including impacts on the supply of needed medications for Canadians. Dr. Thiessen's report of what occurred here in Ontario is a pillar of this work. At the federal level, we need to find a way to give it practical expression in a way that respects the varying provincial and territorial approaches.

Mr. Chair, although we are still assessing how best to implement a fair, reasonable approach to oversight that improves patient safety across the country, we feel that we have a fairly clear understanding of where we will be heading. Coming out of the collaborative efforts to date, we feel that we have come to ground on a good working definition for these new activities. The definitions and associated criteria provide precision to distinguish the type of activity being conducted, by whom, according to what standard or standards and to what end. On this basis, regulatory oversight can be more clearly applied.

From a federal perspective, we would continue to exempt "traditional" compounding from federal requirements, and focus our attention on those other activities that appear to be a hybrid between compounding and manufacturing. Such an approach would continue to balance the complementary roles of Health Canada for the safety, quality and efficacy of drugs with the benefits gained from the knowledge and expertise of health care professionals in an established patient-practitioner relationship.

Given the unique nature of these activities, Health Canada will be looking to develop a risk-based approach that focuses on the safety and quality of these activities and products. We will also be looking to integrate other key elements in this approach, including labelling and reporting requirements.

We will continue our work in this regard and hope to have something to share more broadly with Ontario and all provinces and territories in the coming months.

Mr. Chair, I would again like to thank you for listening to my presentation, and I would now be happy to take questions.

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The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we'll start with the questions from the third party. Ms. Gélinas.

M^me^ France Gélinas: Thank you for being here. You have put together this committee. You're trying to move forward in a way that does more good than harm. Your example clearly shows we wouldn't want to put something forward that would lead to drug shortages or whatever else. You're looking at a hybrid between compounding and manufacturing, which is basically—the work that Marchese had done could be defined in that way. Did you look at all at the group purchasing organizations, which also had a role to play in bringing the diluted chemo drugs?

Dr. Supriya Sharma: Well, certainly we've been following the work of the committee. In our fact-finding discussions with Marchese, we had to go through and sort out what their business model was like. That's when we had more information in terms of the role that the group purchasing organization plays.

Certainly in the regulation of the actual products, the group purchasing organization is in a unique position

because they don't actually prepare or take possession or fabricate or treat the actual products themselves; they're actually an intermediary in the contracting process. So what we're focusing on are the actual activities near the products, the premises, the people, the processes that are in place, and we haven't been specifically looking at any particular oversight of the group purchasing organizations as such because of the nature of their place in the system.

M^me^ France Gélinas: After Dr. Thiessen finished his report, he came and presented to the committee. One of the questions I asked him was basically along the same lines of what I just asked you as to the value oversight. We realize that because pharmacists, pharmacies have oversight, because a hospital has oversight, it increases the quality of drugs, as well as everything else that they do. But such oversight does not exist for the group purchasing organizations, although they kind of were at the genesis of why. Had their request for proposal said that this preparation had to be concentration-specific, none of us would have ever come here, 1,000 Ontarians wouldn't have had to live through what they lived through. So to completely ignore them was not the way to go.

Dr. Thiessen, in his testimony in front of this committee, sort of said yes, it was something that should have gone. He said, "The idea of some kind of an infrastructure—perhaps government infrastructure, even national infrastructure—which would lead to some oversight of" the group purchasing organization "is something that is worth considering." I'm quoting Dr. Thiessen. Because those group purchasing organizations don't only work in Ontario—in this particular case, some of the drugs were shipped to New Brunswick—he saw a role for the federal government to play. I wanted to have your feel as to, is this feasible or unthinkable?

Dr. Supriya Sharma: Of course, we're following the work of the committee very closely, and I read the same comments in terms of the testimony. We sit on the membership of the implementation working group, and that was brought together by the Ministry of Health in Ontario to look at Dr. Thiessen's recommendations. Dr. Thiessen did direct a number of his recommendations towards the group purchasing organization, but as he said in front of committee, this was something that didn't actually make it into his report. Through that group and our work with Ontario, we're willing to look at the issue as a separate issue in addition to the comments that Dr. Thiessen has made. We haven't turned our minds to that at this point in time, but we're willing to take a look at that as an option.

M^me^ France Gélinas: And that would be done at the level of the same committee that you make reference to in the presentation you've just given us today?

Dr. Supriya Sharma: There are a number of different committees. The one that I was just referring to is called the implementation working group. We used to have a group that was there as a working group to share information at the time that the issue came about and to support Dr. Thiessen's work. That committee has been sort of sunsetted, and now a separate group has been brought together to look at the actual report, and then moving forward on implementing the recommendations. That's probably a good venue at least to start the discussions around a broader look at the group purchasing organizations.

M^me^ France Gélinas: How will we find out what was decided from that group if it's decided to leave things as is? If there's no action, specifically for group purchasing organizations, how do we find out the reason why and basically what went on at your committee?

Dr. Supriya Sharma: My understanding, and I think this is probably a question better placed at the ministry, is that there will be at least a report or something else that will come out of that group that we're working with to be able to show progress in terms of the recommendations. I think that's probably the best place to have any sort of report coming out from the work of that group that's been brought together.

M^me^ France Gélinas: Okay. I would ask the Clerk to follow up—when you do have a final report, if it could be shared with this committee.

Dr. Supriya Sharma: Absolutely.

M^me^ France Gélinas: My second series of questions: Your committee does its work, does the implementation, and we put in some kind of an oversight structure for the hybrid between compounding and manufacturing. Looking back, it seems like that was an issue that had been raised quite some time ago. Copies of emails were shared with us that showed that as early as 2001 and 2003, this area of new work had been identified that fell between two areas of oversight, where Health Canada did manufacturing and Ontario, in this case, did the oversight. How could you explain to the committee why this work was not done sooner? Everybody knew that that hybrid, compounding and manufacturing, was happening in more than one province, in quite a few facilities, and it was not done before.

Dr. Supriya Sharma: It's a really good question. As Dr. Thiessen has said, when we're hearing about how the overall situation has been characterized, people have been referring to things like a gap. In reality, there's no gap. For me, a gap is a space between two sets of regulations, so there's a place where an activity is not covered off at all. I don't think that was the case. If you look at the regulations that are in place at the provincial/territorial level of compounding, those were in place. Then we have regulations at the manufacturing side of things. There was no light in between those. There was, I think, a need for clarity to say, "Given how you're structuring your activities, you would fall under one or the other."

It actually goes back to even before 2000. Back in 1997 was when you first started having discussions around compounding and manufacturing and being able to tell the difference between the two of those. We had workshops and we had discussions, and that actually gave rise to our first policy, which is now policy 51, talking about compounding and manufacturing. I know

the committee has referred to that policy before. So that was first published in 2000. Then, continuing practices—they kept evolving, and we brought people together again, because there was a need for more clarity and more guidance as to how one would fall into one or the other. So that guidance was updated in 2004, and then it was updated again in 2009.

Throughout this period, we've been aware that there have been changes. What we've been doing is strengthening our documentation to be able to give guidance to industry to say, "Depending on how you're structuring your business"—and it really does depend on how you're structuring your business—"you would fall into one category or another." We were actually in the process of revising that document again when this situation came to pass. And if you look at that document, under compounding alone, there are I believe 14 different categories of things that you need to consider that would help put you in one category or another.

So it has been a long time coming, but we have been trying to give as much guidance as possible. To a large extent, people and companies have been following that guidance, and then have been electing to go into one category or another, or not. Frankly, we've had companies that have come to us and sought guidance, and we've outlined, "If you follow a certain business plan, you would be regulated by the province, and these are the regulations you would have to abide by. And if you are not, then you would fall under manufacturing, and this is what you would do under Health Canada's regulations." Some companies have either decided not to go into that line of business, or they've structured themselves either as manufacturers or as compounders and have gone into business. This was, I think, a different situation.

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M^me^ France Gélinas: Okay. So do you think that through the implementation committee this will continue, as in they will have to basically do their homework and identify themselves as falling within one oversight or the other, or do you foresee new categories of oversight being created?

Dr. Supriya Sharma: We're looking at putting together a new category. I think we're looking at leaving the definition of manufacturing as it is. Certainly, it's a global industry that we deal with, and we have other international standards and requirements and harmonization initiatives that we're party to, so disturbing that or changing that would have, I think, a bigger impact.

Then we're looking at strengthening what we're putting in the traditional compounding category. That has been interesting as well, because different provinces have different definitions of compounding. So we're looking at harmonizing that definition and having one broad, overarching definition of compounding.

Then we're looking at what is falling in between and looking at creating a new category, and we're still working through what that will be called. Our working definition is called commercial compounding-manufacturing, and the pivot point in terms of defining those activities really is the patient-practitioner relationship. We're looking at the evidence of a prescription or a hospital order as defining that as a pivot point, and then we are looking at expanding that definition to make sure that we are giving as much clarity to it as possible.

But also, we don't want to then create another category that would then be used to potentially circumvent other regulations. For example, if we have manufacturing regulations in place, we don't want people to then go into another category that potentially has a slightly different or potentially lighter regulatory touch to avoid going through the full set of manufacturing standards and regulations. The developing of that middle category is exactly what we're doing now, so looking at, as we said, products, personnel, premises, procedures, labelling, reporting, standards. All of that work is ongoing.

M^me^ France Gélinas: Would you see this falling under the federal government, this new category?

Dr. Supriya Sharma: Yes.

M^me^ France Gélinas: Okay. Thank you. It has been some time now since we found out about the diluted chemo drugs. I can see that you have spent a whole lot of time, brainpower, effort and energy trying to move us forward. Do you feel confident that this new category, as you call it, would be able to catch something like this and prevent it from happening? The people who have received this awful phone call telling them, "By the way, you received the diluted chemo drug" are also following what this committee is doing. They see a group of hospitals wanting to do the right thing, with 11 pharmacists reviewing a request for proposals that all missed the fact that this drug had to be concentration-specific. Medbuy missed that. It then went to Marchese, which had four fully licensed pharmacists who compounded the drugs and completely missed that this drug had to be concentration-specific. It then went back to pharmacists in cancer treatment centres, who know those drugs and who deal with them and who are oncology pharmacists, who missed the fact that this drug had to be concentration-specific. How do we assure those people that the good work that you're doing will prevent this from happening?

Dr. Supriya Sharma: In my opening remarks I talked a bit about personally having the same thoughts as the patients and the families. My family is from southern Ontario, and yesterday I saw my cousin who had gone through chemotherapy in this past year in Ontario and had cyclophosphamide. So I know exactly how they felt when they actually got the news. I have to say that bringing Dr. Thiessen in to take a look at the issue—I have a great deal of personal and professional respect for him, and he outlined a number of recommendations specific to this situation. We're all working together to move ahead on those recommendations.

When we're looking at the Health Canada portion of it, in terms of licensing these facilities, of course we're looking at the situation that happened, but we're also building a system not only for today but for tomorrow as well. When we had the SARS outbreak, I was part of the group that did the lessons learned, and the line that we

were talking about was that the next SARS is not going to be SARS.

I have the utmost confidence that when we're looking at the situation, when we're working with people, that we're looking at everything that has happened in this case and we are looking at the regulatory framework set in place, how products are used and everything that we've learned from this situation to make sure that when we're putting in oversight, we are putting in patient safety measures that will ensure that it doesn't happen again.

The health system is a complicated system. I could spend the entire hour and a half going on just about the regulations at the federal level, but those are details, and, frankly, patients don't need to know those details. Families don't really care about details. That's what they pay us to look for and look at and go through, and that's what we're doing. We're looking at what we have and what we can put in place to make sure that the appropriate oversight exists.

There still is that aspect of patient care, health care professional activities, that also has to come in, and that's a very personalized sort of activity. We need to take account of that as well.

If you'll indulge me, my history is in patient safety and medication errors and incidents. James Reason published a model back in 2000 called the Swiss cheese model of medical error. Basically, I've heard comments at the committee saying that every time you put a layer in, you're introducing an aspect of error. But what the model actually says is that, absolutely, each layer has a hole in it or may have multiple holes in it, but each layer also has the ability to be a defence, and a defence that would stop an error from actually going through. So when you get a catastrophic error or something that actually reaches patients, it's because all the holes line up, and what you try to do in a system is make sure that you have as few holes as possible, they're as small as possible, and that when you're putting in layers, each of them can act as a defence, a place or something that can get caught. That's not just oversight, but I think that's all the way through the system.

So we're working with our partners on the federal aspect. We're working with our National Association of Pharmacy Regulatory Authorities. They're putting standards in place for community and hospital pharmacies. We're working with our colleagues in the Canadian Society of Hospital Pharmacists. Wherever this activity is taking place, whether it's something that is regulated federally or is something that is regulated provincially—that we have the same standards in place for the same types of activities that have the same levels of risks associated with them.

M^me^ France Gélinas: I'll save my time.

The Chair (Mr. Ernie Hardeman): Okay. Thank you very much. The government side: Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair, and thank you, Dr. Sharma, for your presentation.

I would like to have a little bit more clarification on a couple of points, and it's picking up a little bit on my colleague's questions. On April 19, 2013, Health Canada issued an interim direction made up of three requirements: that what we have called admixing here basically be done within a hospital, meeting provincial regulatory requirements; done, outside a hospital, as a service under the supervision of a provincially licensed pharmacist—which Marchese Solutions did have; and three, done in a manner that meets the licensing and manufacturing requirements of the federal Food and Drugs Act.

So my question is, how would these conditions actually prevent what happened in this situation, which essentially was a miscommunication related to the need for a concentration-specific product? I'm missing how this would have prevented the situation.

Dr. Supriya Sharma: I think the interim direction was really designed to say that this is actually what is the situation now, in that if you're providing these services, you should have appropriate oversight. That interim direction was in concert with the activities that Ontario had put forward. So Ontario really stepped up to say that they were putting in measures so that drug preparation premises could be inspected and they would have that oversight.

In this case, if we're speaking specifically from Marchese, we would have that pharmacist there and they would be supervising the activities, but that was also coupled with the fact that you would have inspectors from the Ontario College of Pharmacists that would go and inspect the facilities.

Speaking specifically with the incident, I do have to defer to Dr. Thiessen's report. He really pointed out, as you've said, the four areas where the error sort of could have been picked up, and I do acknowledge that the oversight part of it wasn't directly impacting that specific situation, which is why, when he did his report, there were 12 recommendations. The one that was directed at Health Canada in terms of the licensing was just one of those.

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In speaking with us, he basically has said that he wanted to address the issue, but that from his public service side, he wanted to make sure that other aspects of what he had seen that he felt that he wanted to comment on—he wanted to make sure that he did incorporate that into his report, and I think that's what he did with the recommendation for Health Canada.

Ms. Helena Jaczek: Thank you. Health Canada has obviously been very busy since this incident occurred, and you've been looking nationally at companies that are involved with compounding or admixing services, the vast majority of which are in Ontario or Quebec, as you've said. Did you get any sense of how many hospitals are actually acquiring their chemotherapeutic admixed compounds from these companies? Has this now become basically the norm? How big is this across the country?

Dr. Supriya Sharma: We did ask in general terms about the business model and we did get information from provinces and territories to talk a bit about scope,

and it really is very variable. There are some provinces where they have either very limited types of products that they outsource or very limited companies that they deal with, and then different provinces have taken different approaches.

For example, in British Columbia, there's a centre called the Lower Mainland Consolidation centre. That is a free-standing structure where three health regions have come together and have put up a facility for centralized pharmacy admixing types of activities and other pharmacy activities. It looks very much like a Marchese would look or another company would look, but it is fully owned by the hospitals. That's one model, for example.

In Alberta, they actually have a special designation for what they call compounding and repackaging pharmacies, so the one facility that fell into the category that we were serving that was in Alberta actually has a licence with the Alberta provincial government.

In Quebec, we certainly have seen that there is a fair amount of outsourcing that's happening. The Ordre des pharmaciens du Québec has standards, both for sterile and non-sterile admixing, that they inspect against.

So it's really variable, and I have to say, there's also variability among the sizes of hospitals as well. We have those in broad brush strokes.

The most detailed look, I think, was the survey that was done by the Ontario Hospital Association, and I believe that's been provided to the committee. That really gives the best picture for Ontario specifically.

Ms. Helena Jaczek: As an example, that facility in the Lower Mainland doesn't have any kind of licence from Health Canada. They are provincially monitored in some fashion.

Dr. Supriya Sharma: That's right. They actually fall under the hospital. They're fully owned by the hospital, and the registrars in British Columbia have the authority to inspect hospital pharmacies in practice.

Now, if they were preparing—for example, if they're using narcotics or controlled substances and they're doing that in a non-patient-specific manner, there would be a role for Health Canada from that aspect. But currently, no, we don't have oversight over that facility because of how the province and territory regulate them.

Ms. Helena Jaczek: It's your expectation as a physician, perhaps, that an inspection by a college of pharmacists, going into one of these premises that is admixing compounds, would talk about admixtures that can be administered to multiple patients. You would expect that to be part and parcel of the inspection, that that be a special category.

Dr. Supriya Sharma: Yes. Definitely, in terms of whether the inspection is happening at a federal level or at a provincial level, you look at the spectrum of activities that are taking place and then make sure that the appropriate standards are being applied.

In the case of both sterile and non-sterile admixtures, it would either be the USP 797 and 795; I know those standards have been discussed here at the committee. Those are the ones that are the most commonly applied and then expanded, so each province may have additional requirements where they may bring in other elements that they would be looking at as well in terms of recording and record keeping etc., and then they would apply those standards. But absolutely, it would be something that would be inspected against.

Ms. Helena Jaczek: So you would expect, if we hadn't had this situation at Marchese, with the type of inspection that would be done through the College of Pharmacists, that they would go in and they would specifically talk about some of these types of admixtures and really drill down how you are going to prepare it, with the volume versus the therapeutic agent being specifically talked about.

Dr. Supriya Sharma: Yes, and beyond that, to the point of your laminar airflow through the facilities, how you're labelling even your intermediaries. So if you're doing admixing, there are some requirements on what the final product would look like and what that label would say. But even along the process, the requirements on which vials are there, who signs off on them—it's a very detailed set of standards that they would be inspecting against.

Ms. Helena Jaczek: Okay. Just another thing from your presentation: You talk about, "From a federal perspective, we would continue to exempt 'traditional' compounding." What exactly do you mean by "'traditional' compounding"?

Dr. Supriya Sharma: And you'll notice that "traditional" is in quotes in there, because part of the discussion that we've had is, really, what is traditional compounding? As I had mentioned, compounding as a definition can be different from province to province. The National Association of Pharmacy Regulatory Authorities has actually put together a national definition and people can choose to adopt that.

But when we think of traditional compounding, it really is making a specific dose for a specific patient to meet a specific need. And there are some other circumstances around that. So, for example, it can't duplicate a commercially available product. We don't want people compounding products that should otherwise be—you know, have a drug product identification number, unless it's a shortage situation. There are other parameters in terms of patient safety etc., but really it focuses on: Somebody is coming in and there is a product that I need to provide to meet those patient needs. It is not otherwise available, so I need to compound for that specific person.

Ms. Helena Jaczek: So would you say that, from your perspective, with all the work that Health Canada has been doing subsequent to this very unfortunate event, you've had good co-operation with all the provinces, that the dialogue has really been very, very helpful, and you see your way forward to national oversight, with agreement with provinces as appropriate, that will really drill down and make sure something like this will not happen in the future?

Dr. Supriya Sharma: Absolutely. I was looking back, in preparation for the committee, through the notes, and

as I was looking back, I thought, this is actually a model I would replicate in terms of how people came together, how we worked collaboratively, how we were on teleconferences at 10 o'clock at night. Maybe I would move those times around a little bit, but certainly we worked very, very well together, and brought people together, I think, around key issues. We had high-level discussions, and then, when we found we got to a place where we needed more technical discussion and needed to drill down deeper, we brought a subgroup together.

We're still in that process, so I think I can't declare victory at this point in time, but I think we really have accomplished a lot in a short period of time, and we do have a path forward that will get us to a place where we will hopefully have a proposal fairly shortly. Then, of course, it will have to go out for consultation and will benefit from the input of all the stakeholders in finalizing that and then implementing it.

Ms. Helena Jaczek: Were you aware of what has been called this grey area of lack of oversight prior to this incident?

Dr. Supriya Sharma: I was aware, as I mentioned, of needing to sort out what is compounding and what is manufacturing. In terms of the terminology that's been used around this, it wasn't something that I was familiar with. Because I wasn't at, of course, all the meetings going back through the years, I went back specifically looking for whether there was a place where somebody said, where there was a group that said, "We think that federally you need to create a new category because there is some confusion and it should be separate and you should regulate that." That wasn't the case. We didn't see that in the communications. We did see that there was a need, as I said, for more clarity around what is compounding, what is manufacturing, and there was discussion around admixing as an activity and where it should appropriately fall.

So in that situation, yes, I think there was some discussion about what is now being referred to as something different in the press and by other people. But, no, it wasn't the way that I think it's been characterized.

Ms. Helena Jaczek: Had any other compounders, like Marchese, approached Health Canada prior to this event? Did you find any correspondence from other companies providing this service?

Dr. Supriya Sharma: Yes, we have. As recently as March, we had another company that came in and provided a detailed presentation, and we walked through what would be the different requirements under the different regulatory frameworks. That company actually decided to wait and said that instead of going one way or the other, they would wait till a proposal was put forth and a separate category was created before they would come into business. Other companies have made those decisions. We've had companies that have come in and asked questions and they are accredited pharmacies, and the activities they were doing—they were regulated under provinces and territories. There's been a mix, but certainly we've had companies come to us.

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Ms. Helena Jaczek: Thank you. We'll reserve our time.

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

Mrs. Jane McKenna: Thank you so much for coming. I have a couple of questions. There are so many papers that we've looked at, but anyway, just the stack here: It came to our attention, and it was in the paper in the London press, that it goes back as far as 1997 and that these companies that prepare mixtures and compounds of drugs weren't being inspected by either federal officials who inspected drug manufacturers or provincial regulators who supervised drug dispensary. And then there's a quote back here by Ms. Matthews saying that she admitted there was a grey area in oversight that had been eliminated. "It became clear pretty quickly that we needed to ensure that drugs are purchased from an accredited facility. We could have waited (for Thiessen's report)," which obviously was before that, "but I just did not want to wait," she was saying.

I guess my question to you is that if so many people knew there was a grey area, because clearly there is—I mean, we have documentation of people saying it, from the minister down to—you know, for 15 years they've been asking this question. Why is it that it's so grey, even with people like yourself, who are in the situation yourself? I'm so confused with that, that it's so grey and we're still talking about how grey it is when there are so many people, including the minister, who realized there was a problem.

Dr. Supriya Sharma: Again, I don't think it was a gap. The question is, where would these activities fall? So if you look at drug manufacturing—taking a molecule and making it into a tablet or a capsule or whatever it is—there's a whole spectrum of activities, everything from using sterile processes to making the intravenous fluids it goes through to making an ointment, potentially, and there are risks associated with it.

If we're looking at admixing, it's at that lower end. You're taking approved products that have quality oversight and safety oversight, they're approved by Health Canada and you're mixing them together, a relatively low-risk activity. If you look at it from the pharmacy side of things—I don't know if we have a pharmacist in the room who'll call me out. Remington is the bible of pharmacy practice and when it talks about admixing, it talks about it as being one of the highest-risk activities that take place. So that's in the spectrum.

There are these activities and if you look at where they're taking place, they're taking place—if you're just looking at the activities, they're taking place in community pharmacies, in hospital pharmacies, at the bedside and in private facilities.

I think the question is—it's an activity and it's changed and it's evolved and it's taking place in a number of different places. Depending on how you structure your business or your practice, you could fall under one regime or another. I think that's where the con-

fusion was lying. It wasn't that there was a zone where you should be in business and no one should be seeing you. It's that you need to come under one umbrella or another.

When we issued the interim direction, my first reaction was that we shouldn't have to tell people that they need to be regulated. I think Ontarians and Canadians would say that if you're going into business and you are providing needed medications for patients, part of the responsibility is that you're meeting the appropriate safety and quality standards. I think the confusion or the difficulty in this situation is that based on those details, and based on how you structure yourself, you could fall under one or the other. We knew about that and that's why, when we're moving forward with guidance documents or anything that's available for industry or we're giving advice to industry, we're trying to lead them through that process. But it still really is on a case-by-case basis.

When we were going forward, I think it got to the point where we were saying, "We've clarified, we've reclarified, we've reissued, we're doing it again. It seems like there still is this category that doesn't naturally fit into one or the other, so let's create a special category for it and we'll regulate it to that point." I think that's the tipping point that we're at at this point in time.

Mrs. Jane McKenna: I guess anybody here can speak for this as well, because we've had so many people in here, but Ms. Zaffiro, when she came, said that she called numerous times because she was totally new to this process, she had never done this before. She phoned over to the federal, phoned over to the province numerous times to say, "How do I get regulated? I am now in this process." She was totally in the dark of trying to get someone to call her back, someone to get answers from, and couldn't get any answers from it at all. So that to me is a red flag, red bells: that this woman is now trying to get answers from the federal, trying to get answers from the province on how she can become regulated, and she couldn't get any response back from that. To me, if I'm at the other end of that call and I've got someone who clearly is in a grey area and doesn't know what to do, but she's out trying to figure out that information and still can't get an answer from either of you—how do you fix that, then? That person actually was trying to get things in motion and couldn't, so how do you fix that?

Dr. Supriya Sharma: When I heard that testimony, I had the same reaction as you did—absolutely. I looked through it, and then I went through our records. I don't have all of the emails, because I know you've got—

Mrs. Jane McKenna: There's lots of stuff.

Dr. Supriya Sharma: There's lots of paper, but maybe just to use one example: For example, we got a call—actually, it was a call from an administrative assistant—into Health Canada on January 10. Between January and February, there are about 12 or 13 back-and-forths in terms of emails that were not submitted to the committee. I'm happy to provide those to the committee, but they weren't discussed. So the question that came into our group on the controlled substances side was—the email was asking, "We would like to have a dealer's licence for a controlled substance," because Health Canada also regulates on the narcotics side any risks in terms of diversion of the product. So on January 10, that comes in. The next day or the day after, a message went back to Marchese to say, "Absolutely. Here's a dealer's licence. Here's the package." Then a message comes in on January 16 from an email, saying, "Okay, we need a dealer's licence. Can we get more information on it?" We said, "Yes, absolutely. Here's the package. Here's your dealer's licence application"—January 18. And there was a call, and we went through those.

The first email that came in was, "We need a dealer's licence. We need it by February 1." To get a dealer's licence for controlled substances takes, on average, four to six months. If we have to do a criminal record check, that in and of itself takes 75 days. So you also have to sort of say, "If you don't know what you're getting into, you need to educate yourself." So all of that information was provided, and there wasn't an application that came in.

We can go through it again. It was back and forth. I think we sent the application on three separate occasions. There were at least 12 or 13 times where we confirmed that we need the dealer's licence, and we didn't see that. We didn't see that coming in.

So I totally respect that somebody wants to be regulated, but it's not good enough to want to be regulated; you have to be regulated. I have to say that at no point in time did the Ontario College of Pharmacists nor Health Canada ever decline to regulate. What we didn't do a good job of—and I have to fully admit this—is that we didn't do a good job in saying exactly what framework the company would fall under.

But in the call—I think it was on February 7, 2012—when one of our GMP compliance specialists spoke to Ms. Savatteri, she said that for your admixtures, you would need DINs, which are drug identification numbers, and you would need an establishment licence. If you're going through that level of regulation, that process, from the time that you start to the time that you get your establishment licence and all your products through the process, can take 500 days. It's not reasonable to come to Health Canada in February with a business case and expect to be shipping product at the end of that month.

I think there are a lot of details in terms of how that communication took place that weren't completely reflected in the testimony that was given. But as I said, we are fully cognizant of the fact that we should have done a better job in terms of saying more directly that this is how you should be regulated.

Mrs. Jane McKenna: So I guess my thing is, just because I've sat through all of this whole process myself—the thing that I find extremely frustrating is, how is she supposed to know all that? You're clearly saying all of those things are exactly what's supposed to happen, but if I have an insurance fellow and he's telling me how to do my insurance, I don't know the questions to ask

him. That's this job, to be able to educate me on what I need to know and not know. So I just find it a bit patronizing when you say—because I'm not saying that it's not true. But to sit here and say, "Well, she should have known that you can't have it in 500 days" or whatever—the woman sat here, and there's absolutely no way she would have known that in the first place, because she was brand new to it. So if the fact is that she shouldn't have been able to get this in the first place, where was the ball dropped? I guess that's where I'm confused, because the ball has dropped somewhere. This woman has been given this contract. A broker has gone in and given it to her. There's clearly miscommunication, because Baxter was one on one with the hospital. There was no middleman. The contract was written totally differently than how Baxter understood it. But my point is, to me, the frustrating thing sitting in here—I won't speak for anybody else—is that everybody just keeps saying what everybody else should have assumed to know, but how in God's name is anybody supposed to know that when they've never been in this process before?

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We have all the information of everybody sitting in here. We've all sat through it. I know you watched it and listened to it, and you've definitely educated yourself on it. The ball was dropped, period. So who's owning the ball that was dropped? You can't expect somebody to know all of those things—and to say, "How would you expect to do that by February," when she had no knowledge of any of that herself?

So do we go back to the contract at the very beginning from Medbuy to her, that she shouldn't have been able to have that? I mean, I'm just curious.

Let me just quickly say this. When one of the recommendations from Thiessen, number 10—he was very specific when he said, "Health Canada shall license all enterprises that function beyond the product preparation permitted within a licensed pharmacy; that is, all product preparation enterprises not within a licensed pharmacy shall be licensed." So he was very clear that that needed to be done.

I don't know. I guess I'm just frustrated sitting in here, because we're not here to finger-point and to say whatever. I'm just saying, clearly, when you have a process that doesn't work—we have sat through people over and over again. When you say that you're having these committees and you're going to have the end result, we would really like to see that end result, because unless you're prepared to implement whatever you're doing, it's null and void for me. There's just no point to it, for myself.

Dr. Supriya Sharma: No, absolutely. So in terms of Dr. Thiessen's recommendation number 10—I think I have it committed to memory—we made the commitment to do that. When we're talking about the committees and all their work, they're really all directed in doing that: licensing the pharmacies that are not otherwise accredited. Then, we're working through the logistics of all of those processes to put together a framework to be able to do that and are committed to implementation. So I can say that with 100% certainty.

My objective in illustrating, just on the controlled drugs and substances side, was not to sort of be defensive or not to say anything about what we couldn't do better—but in that case, exactly, you're not expected to know it before you ask the question. Once you've asked the question and you've got a direct response, then the responsibility does go back to the company to say, "Okay, I've been given this direction. If I want to be able to say that I want to be regulated, then I need to take the steps." When we did get to a place with Marchese where they do have a dealer's licence, we sent them the application again. We did teleconferences. We answered all the questions and helped them through the process of doing the inspection. But that is all premised on them actually giving us an application and taking that step forward as well.

Mrs. Jane McKenna: Could we ask to see all that, to get all that? Because we don't have that, do we?

M^me^ France Gélinas: We've got bits and pieces.

Mrs. Jane McKenna: We have bits and pieces. So I'd like to actually see exactly what physically those email back-and-forths were so that we can actually—not that it's hearsay, it's just that we don't have all that. We've got bits and pieces of that.

Dr. Supriya Sharma: Absolutely, and we would want you to have the complete records.

Mrs. Jane McKenna: The other thing is that while Dr. Thiessen was here, he said that over time—now, this is what I wrote in my scribble here—the responsibilities of the province and federals have eroded over time and it has become accepted that things have kind of just become convoluted, because there has been such grey area everywhere. Would you agree with that, with what he said there, that it has kind of eroded over time?

Dr. Supriya Sharma: I don't have the transcript in front of me, but I think he went on to kind of clarify a little bit about what he was talking about. But in terms of our relationship when we're talking about pharmaceuticals, we actually have a very good working relationship in terms of the federal, provincial and territorial levels because—I know this is going to sound like a bit of irony—the roles and responsibilities are quite clearly delineated. We don't have a lot of situations where there's confusion about who does what. We have areas where we definitely need to co-operate, because it is a continuum of health care. In terms of patients getting medications, there's a whole life cycle that's involved. We've had a really good working relationship. We do have discussions. We look at the risks and benefits of products. Obviously, the province has to look at cost-effectiveness; they have different issues that they deal with in terms of the delivery of health care. I think that that relationship has been very good, and we continue to work together with them.

Mrs. Jane McKenna: He can ask some questions next, but I'm just hoping, in the end of all of this, that it

becomes clear as ice, that everybody knows exactly what they're doing, because when you have companies that are out there and it's not written down that everybody understands the role of what to do, the people that are affected are the people that—obviously, the 1,000 chemotherapy people that are affected by this, right? If it was so clear, we sure as heck wouldn't be sitting here today or going through the process that we've gone through.

Anyway, I want to thank you very much from my side of it. Do you have any questions?

Mr. Rick Nicholls: I've got a couple.

Mrs. Jane McKenna: Okay. Go ahead.

Mr. Rick Nicholls: Thank you very much. Good afternoon, Doctor. Just a couple of things, as I'm relatively new to this particular committee. Not that we want to be pointing fingers, but again, I guess one of the questions that I would have to ask is: What's being done to those individuals or companies who erred in the mixing itself? I have a little saying that when you mess up, you fess up, but in this particular case, when we think about the patients who have been affected—what is being done in this particular case?

Dr. Supriya Sharma: Just to clarify, what has been done in terms of Marchese as a company or—

Mr. Rick Nicholls: Yes.

Dr. Supriya Sharma: Obviously, we found out on April 1 that this happened. We went in with the Ontario College of Pharmacists and talked to them on the 2nd, went in on the 3rd and got more information about the company. I think the immediate thing that happened was that the hospitals that were getting chemotherapy admixtures all took that activity and brought it in-house. I think that was the immediate concern: For the products that were affected, let's deal with things immediately. Then we went through the process with the Ministry of Health and the Ontario College of Pharmacists to get a sense of the company and how the company was structured.

I think a number of things have happened. I think the most significant part of it, though, is that when Ontario moved forward to put forward their recommendations and regulations on the drug preparation premises, it meant that Marchese as an institution has been inspected, so that there were standards that were put in place. They were inspected against those standards, and then they have since passed those standards. So they've been brought into a regulatory framework, and they are now, for all intents and purposes, regulated at the provincial level. As we move to our new framework, we'll have to see how that then plays out with respect to how they're conducting their activities in the future.

Mr. Rick Nicholls: Well, recognizing that the errors had been identified, I guess an obvious question I would have is, are there any repercussions because of it? I know that new standards have been put in place and you're following maybe some new processes and/or procedures, but something happened that caused all of this. Good is coming out of it, but again, when you look at the company that is doing the mixing and so on—I look at the qualifications of those people, and obviously the ball was dropped somewhere along the line. I guess I'm concerned about repercussions—not so much standards that are being put in place so this wouldn't happen again, but the repercussions that would be put in place as a result of the error—human error, I suspect.

Dr. Supriya Sharma: I'm not sure in terms of what you were referring to when you were saying repercussions. Do you mean legal—

Mr. Rick Nicholls: Well, again, somebody is ultimately responsible—the overseer. Who would that overseer be at this particular place? Not that I need names; I don't need that. But my point being is that somebody—

The Chair (Mr. Ernie Hardeman): If I could just stop you there for a moment. I mean, you can ask any questions you like, but I think it's fair to assume that the presenter was thinking of questions that relate to her presentation. The overall picture of who's going to be liable or what went wrong—I think we leave that to the committee's discussion after the fact.

Mr. Rick Nicholls: Okay.

The Chair (Mr. Ernie Hardeman): So stay with the questions to the witness that would pertain to the witness's expertise.

Mr. Rick Nicholls: That's fair. Okay. Well, then, looking at the other questions that I have here, I have no further questions at this point in time.

The Chair (Mr. Ernie Hardeman): Well, thank you for giving me that opportunity to speak once.

Ms. Gélinas?

M^me^ France Gélinas: Just so that I use my time wisely, how much?

1510

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

M^me^ France Gélinas: I have four minutes? Okay. The first one will be very quick. It's a comment that you made to Helena when she was asking about how many different purchasing organizations exist out there. You talked about what happened in BC and what happened in Alberta and that the Ontario Hospital Association had done something that describes what happens in Ontario. Have you see this document?

Dr. Supriya Sharma: Yes. I was referring to the Ontario Hospital Association survey. They actually surveyed all their hospitals to look at what products were being outsourced, what categories of products and the drivers for that outsourcing. My understanding was that was something that was tabled with the committee.

M^me^ France Gélinas: Okay. Somehow this does not ring a bell with me that we have seen this. Clerk, if you could make sure that we have a copy of this because it does not ring a bell with me, but I would sure like to have a look at it.

Dr. Supriya Sharma: It's publicly available, so I can resend the link as well.

M^me^ France Gélinas: Okay. Thank you. That was one thing.

Then my question has to do with how Marchese had just been awarded a multi-million dollar contract from

Medbuy. They reached out to you and—well, first, they reached out to the College of Pharmacists and realized they could not be licensed there, so they reached out to you and told you that they have a deadline that is completely unattainable. You have now been made aware that there is a company that is not licensed under the College of Pharmacists, because they've told you this, and that asked to be licensed on a deadline that is not feasible. Nobody looks beyond that as to making sure they don't go on and do something they're not licensed for?

Dr. Supriya Sharma: That's a really good question. When Marchese first came to Health Canada, their first documentation was saying—basically they came as Marchese Health Care and they said, "We are an accredited pharmacy and we are thinking about going into business, providing this type"—well, it was a type of service. They didn't talk about the type of service, but they had a series of questions that they wanted answered. They've subsequently come back to us and have said, "We are not going to be an accredited pharmacy," and then a third occasion they came back and said, "We would like to be a hybrid facility, a combination between an accredited pharmacy and having a good manufacturing practice and manufacturing facility."

So during the course of the discussions, it was shifting a bit in terms of their business model. Our understanding was that they were still exploring options, and as late as February 2012, that was the first time we actually saw on paper what a business plan might look like. Again, it was sort of just in general terms. Again, all of that was in the future tense. We weren't aware—and I think in retrospect, we should have been aware—that they were already shipping product out the door. We weren't aware, when they came to us in November 2011, that they were bidding on a request for proposal. If we have to go back and look at things, it's that communication that was missing, and I think we can do a better job of that.

I have to say that's all in the context of the fact that we're not used to companies going into business and supplying medications, especially something like chemotherapy to adults and children, without being regulated. Even on the controlled drugs and substance side, when we were looking at the dealer's licence part of it, when we were talking to them, they were putting together approaches and they said, "Well, we can either take this approach or we can take that approach." So the question was, "Well, what would you normally do in a situation where you have a company that's providing necessary medications and they don't have a dealer's licence and you have to do something about it?" They said, "We've never had that situation before. If we've had to do compliance and enforcement, it's always been in a company that has been regulated, then there's been an issue and then we've had to step in."

It was a very unusual circumstance. Should we have known about it? Yes, but the way that the system is working, you have companies that seek to be regulated. There are processes by which they submit applications to be regulated. We didn't ever get those applications. We have correspondence from the company that says they were seeking to be regulated by the Ontario College of Pharmacists. When we spoke to the Ontario College of Pharmacists, they were hearing that they were seeking to be regulated by Health Canada. I think that's where we've needed to be able to make sure that we have those communications, and we do now.

Marshall Moleschi, who has testified in front of committee—I think he and I have each other on speed-dial. As we moved forward on the Marchese file, there were a number of situations where companies were coming to us and saying something, and then when we talked to the Ontario College of Pharmacists there was a slightly different representation of facts. It served us really well to work together and to decide how we were going to approach it together. Then when we sent letters to companies, we sent them either under a joint signature or we sent them with the other organization c.c.'d, so that companies knew that we were talking to each other. In terms of moving forward, that's a really good model of how to address it, to make sure we're aware of what's out there.

As I mentioned, we have companies that come and seek advice on business proposals, and they may go into business a year from now, five years from now, 10 years from now, or they may not go into business at all. I think we have to think about how we follow up with those companies as well.

M^me^ France Gélinas: You mentioned that you are presently creating a new category—

The Chair (Mr. Ernie Hardeman): Thank you. You can finish that one question and then that's it.

M^me^ France Gélinas: You are presently working on this new category for what you call commercial compounding etc. How many businesses do you figure would fall under this new category that you're working on?

Dr. Supriya Sharma: We can look at estimates. I think it's really difficult to know that. When we were talking with the Ontario college around their drug preparation premises, they were saying that they expected five or six companies to come in under that category; there have only been two. I think what will happen is that we need to put the proposal out. We need to do consultations on what it would look like, and then when we move forward to finalizing that and implementing that—the industry landscape shifts, and we've seen that. When you put regulations forward, it shifts. So companies will decide that they would like to be in that category and may structure their business to be in that category. Other companies may decide that they don't, and they want to go another route. So I think it's really difficult to predict.

When we did our survey and our outreach to companies, we had 14 of them that came forward and said, "We are conducting these types of activities." We expect there would be at least a subsection of those that would come forward in this new category, but I think in terms of the future, we'd have to see where the industry goes, and that really depends on the drivers within the health

care system, what kind of services are being provided and where the health system feels there is a need for those services.

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

Ms. Helena Jaczek: Thank you, Chair. I think the Ontario Hospital Association survey is something that was referenced in Elaine Campbell's memo of October 9. So I'm sure we're going to be able to get hold of that.

The fundamental problem in this whole tragedy was that Marchese Hospital Solutions assumed that the cytotoxic agent was going to be delivered to one patient. The entire bag was going to be delivered to one patient, and they did, as we know, try and reach out to Medbuy to clarify in some fashion, and they never got a clarification. They in fact were told that there didn't seem to be "any clinical impact from changing the volume." I'm quoting now from an email from Ron Swartz that we have on our desks today.

Anyway, that fundamental error of not understanding how the product was to be used at the end of the day was what caused all of this. Are you confident that the type of oversight by Health Canada, the work that you're doing with the provinces, the work that the College of Pharmacists is going to be doing here in Ontario, could or will prevent this kind of miscommunication?

Dr. Supriya Sharma: The hope and the intent is that when we're putting together the framework, part of that framework will concern itself with labelling. We're in the process of taking a look at what requirements are already there for labelling. So whether it's the USP labelling, whether it's what provinces are using, whether it's British Columbia or Quebec, we're working internationally with our counterparts to see if they have systems or ideas for us that we can incorporate into our thinking. So what we'll be doing on the labelling is putting together our best representation of what a label should look like, and the hope is that standardizing that labelling will go a long way in terms of making sure that it's an accurate representation of what that product is. It'll give people guidance on how it's supposed to be used.

Having said that, it can't replace that point-of-care assessment of what the product is, what the dose is and how that should be delivered to the patient. When we're looking at these products that are prepared in a facility, if they're being used as more bulk preparations or stock preparations, the product that actually reaches the patient won't have the label that we're working on; it won't have the drug information number that we've authorized as Health Canada, because it has now been subject to another process and that has a label. But then, within the hospital system, once that bulk product is used for an individual patient, there's an individual patient label that's put on it as well. So I think what is really the lesson learned through all of this—and again, it's not specific to Health Canada—is to make sure that everyone along the way has a really good understanding of what the product is and how it's supposed to be used.

In summary, I think the Health Canada requirements that we're putting in will go a certain way, and then we still have to have respect in terms of the practice of pharmacy and the practice of medicine in that they will look after the part where it actually talks about the dispensing and the prescribing and the medications actually reaching the patient.

Ms. Helena Jaczek: Wouldn't it be fairly easy to just have on the label, "For multiple patient use"?

Dr. Supriya Sharma: That's actually one of the things that we're looking at: How do you express that? One of the things we're looking at is, we would either say, "For multiple patient use," or put it in the negative. So for the ones that are designed for single use, we would put, "For single use only"—something like that. But certainly those are things that we're exploring, as to how to best do that, and we have to do it for products across the spectrum. We're talking about this as one category, but we're looking at sterile preparations, and within sterile preparations there's going to be risk stratification and non-sterile preparations, and they have different risks associated with them. So we want to make sure that we have requirements that are fit for the purpose for the different levels of risk.

Ms. Helena Jaczek: As you've said, you, as Health Canada, accept Dr. Jake Thiessen's recommendations—as do we, of course—and you are drilling down even further, as you've described, with this national strategy and various subgroups looking at these particular areas, such as labelling and so on. I find that very reassuring. Thank you, Mr. Chair.

The Chair (Mr. Ernie Hardeman): Any further questions from the official opposition? That concludes the questions, then. We thank you very much for coming in and making a presentation and for making yourself available to the committee for that information.

That concludes the presentation part of the meeting today. We will go in camera to discuss the writing of the report. We'll just take a couple of minutes to, as they say, clear the galleries.

The committee continued in closed session at 1523.

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