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**Monday 1 December 2014**

**Journal  
des débats  
(Hansard)**

**Lundi 1<sup>er</sup> décembre 2014**

**Standing Committee on  
Social Policy**

Safeguarding Health Care  
Integrity Act, 2014

**Comité permanent de  
la politique sociale**

Loi de 2014 de sauvegarde  
de l'intégrité des soins de santé

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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

## STANDING COMMITTEE ON SOCIAL POLICY

## COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Monday 1 December 2014

Lundi 1<sup>er</sup> décembre 2014

*The committee met at 1401 in committee room 1.*

### SAFEGUARDING HEALTH CARE INTEGRITY ACT, 2014 LOI DE 2014 DE SAUVEGARDE DE L'INTÉGRITÉ DES SOINS DE SANTÉ

Consideration of the following bill:

Bill 21, An Act to safeguard health care integrity by enacting the Voluntary Blood Donations Act, 2014 and by amending certain statutes with respect to the regulation of pharmacies and other matters concerning regulated health professions / Projet de loi 21, Loi visant à sauvegarder l'intégrité des soins de santé par l'édiction de la Loi de 2014 sur le don de sang volontaire et la modification de certaines lois en ce qui concerne la réglementation des pharmacies et d'autres questions relatives aux professions de la santé réglementées.

**The Chair (Mr. Peter Tabuns):** Good afternoon. The Standing Committee on Social Policy will now come to order. We are here for public hearings on Bill 21, An Act to safeguard health care integrity by enacting the Voluntary Blood Donations Act, 2014 and by amending certain statutes with respect to the regulation of pharmacies and other matters concerning regulated health professions.

Please note, members of the committee, that written submissions received on this bill are on your desks.

For those who are presenting, each presenter will have up to five minutes for their presentation and up to nine minutes for questions from committee members, which will be divided equally among the three recognized parties. Presenters, when you have one minute left for your presentation, I will state that and remind you that your time is running out.

I will propose that we start the rotation with the official opposition for the first presenter, then to the third party, then to the government. I gather you're all right with that? Great.

MS. KAT LANTEIGNE

**The Chair (Mr. Peter Tabuns):** Our first presenter is Kat Lanteigne. If you would introduce yourself for Hansard.

**Ms. Kat Lanteigne:** Hi. I'm Kat Lanteigne. It's an honour to present today, and especially profound since it

is World AIDS Day. My uncle died of AIDS in 2001, and an extended family member was deeply impacted because of tainted blood.

Over the past few years, I have been able to meet hundreds of tainted-blood survivors and their family members across Canada. They shared their painful stories of how our country turned its back on them when they desperately needed it to stand up for them.

I have spent the better part of my life trying to understand why and how AIDS and the tainted blood crisis were allowed to happen. I can unequivocally assure you that the tainted blood crisis was allowed to happen and that it did not happen because of bad science. Hubris, profit motives, homophobia and denial replaced competent health care strategy. Your predecessors lacked the understanding that to be an effective leader, one must have a deep sense of humanity and justice. While lives were being stolen and the trust in our blood system was broken, Canadian families were fighting to make sure the truth was told, through impossible obstacles. But they did it. We are indebted to these brave Canadians. All that they fought for cannot be abandoned because the pharmaceutical industry wants to commodify our blood.

Bill 21 is not a simplistic answer to "paid or unpaid donors." It is enshrining in our law the main principles of how to manage our public blood system. Every piece of legislation has a story, and Bill 21 will carry with it the lessons we have learned from our shared tragic past of the worst preventable health care crisis our country has endured.

I was encouraged when you unanimously voted Bill 21 to committee, and I am hopeful that the propagandized scripts provided to you by the pharmaceutical industry have not swayed you as we move forward. We are our own people, we have our own unique history, and we do not have to employ private health care models in our country that we know do not work: 30,000 people were infected with HIV and hepatitis C; we spent \$17 million on an exhaustive federal inquiry; \$5 billion has been paid in compensation; thousands have died. Claiming ignorance on the validity of Justice Krever's findings or whether they apply today is an inexcusable argument for not understanding our own Canadian story.

Our domestic blood system cannot sustain any competition regardless of what private companies want to use it for, whether it is research or for export to make medications. It is the sole responsibility of Canadian Blood Services to collect blood and plasma in our country.

Exploiting the vulnerable is not a shared Canadian value and we must make great efforts to stop commodifying human tissue.

I commend the provincial government for bringing in this legislation but more questions need to be asked. Why did Health Canada and Canadian Blood Services allow these private clinics to get so far in their planning process without the public knowing?

It is my understanding that EXApharma is now attempting to set up shop in our western provinces.

**The Chair (Mr. Peter Tabuns):** One minute left.

**Ms. Kat Lanteigne:** Clearly they underestimate Canadians. I can guarantee they will be met with similar opposition. There are legions of us who have not forgotten and we will be an unstoppable force.

To tell us “never again” is an empty promise unless you actually take measures to make it so. Your vote on the Voluntary Blood Donations Act will be the ultimate statement on the tainted blood crisis. You have the chance to do what your predecessors chose not to do. You get to stand up and say “No way, never again, not on our watch.”

Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you, Ms. Lanteigne. To the official opposition, Mr. Walker.

**Ms. Kat Lanteigne:** Can I have a tissue? Does anybody have a tissue? Thank you. Sorry to interrupt for a moment. Thank you.

**The Chair (Mr. Peter Tabuns):** Fair enough.

**Mr. Bill Walker:** Thank you very much, Ms. Lanteigne. Just a couple of questions, if I can. One that I have is, in the Krever inquiry, it said that Canada should be self-sufficient in blood. When we spoke in the House last week, one of the questions I asked was kind of that balanced question in regard to are we able, are we truly capable of—and one of the reasons I asked that is it seems they’re using blood protein more and more for things like Alzheimer’s and dementia, which I believe is a huge cohort that’s coming through our system. Are we going to be able to have the supplies we need? Can you give me unequivocal evidence that suggests that that is able to be done through a voluntary system?

**Ms. Kat Lanteigne:** Well, Bill, I’ve watched you in the House, and it’s been fascinating, because you have been one of the people who has supported and been reading the script provided to you by the pharmaceutical industry. I’ve paid very close attention to that.

I would give you an example of what’s happened within the hemophilia community. Hemophiliacs, most of them, took the plasma-based medication. Today, after almost all of their clients have been killed, 90% of hemophiliacs now take a synthetic product. Those advancements in science have helped ensure that they’re not exposed to blood-borne viruses that can show up in that kind of medication.

In your information package, you will see that all plasma-based medication has warnings on it. Although we have better testing today, it is not perfect. Science isn’t perfect. We don’t know what the next blood-borne

pathogen will be. There are also many opportunities to move forward.

**Mr. Bill Walker:** I would like to comment back. I take a little bit of offence that you tell me that I’m reading from a script from the pharmaceutical industry. I’m not certain how you know where I got my information or what I’ve read. I ask this because I truly do believe there needs to be a balanced approach to this. If you did listen to me in the House, one of the things I said is if it’s my son or my wife or a family member or a friend lying in a hospital needing a blood transfusion or they need research capabilities to be able to stop some of these horrific resources, then we need a blood supply that absolutely is there.

You did not answer my question. Can you unequivocally prove to me that there will be a supply available when it’s needed? That’s what I think we need to look at.

A friend of mine—on the weekend, I had a good chat with her. She travelled through Europe in the early 1980s and she actually participated in giving her blood for compensation—

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Mr. Bill Walker:** —and she saw absolutely no concern with doing that. Again, with the same mindset, if I’m helping someone and it’s for pay—do people really care whether it’s paid or unpaid as long as the blood is there when they need it?

**Ms. Kat Lanteigne:** Well, I would have to say to you that I’m very fortunate to have a lot of shared advocacy in our country and in the province of Ontario.

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I have seen a letter that you have written back to co-infected hemophiliac Andrew Cumming stating that you would absolutely back this bill unequivocally—

**The Chair (Mr. Peter Tabuns):** I’m sorry to say you’ve used your time. We’ll go to Madame Gélinas.

**M<sup>me</sup> France Gélinas:** Thank you, Ms. Lanteigne, and I thank you for coming to Queen’s Park. I have seen your play, a reading of your play, and it is very powerful. I would certainly encourage everybody to take the time to go and listen and see when it’s next on. It’s a worthwhile experience.

So let’s say we started to allow this in Ontario. Let’s say we allow companies to pay people for plasma. What kind of damage do you see happening?

**Ms. Kat Lanteigne:** Well, one of the things that has been promoted to people, a line of argument for private plasma companies, is that it’s not a problem in other countries, which is not true. It is a problem in Germany. The head of transfusion medicine has stated on multiple occasions that it is impacting their whole blood donorship. They can’t win donors back because they are being cultured to be paid for their blood, for that plasma, regardless of what it is being used for. So when you create a competitive model like that, you commodify a public resource, and you lose control over how and where and what is happening with it. That’s one of the major issues.

It happened here in Canada. We can't sustain it. If you read the Krever inquiry in total and the subsequent documentation that comes with it, it is very clear that that model here is absolutely not sustainable. We cannot do it. It doesn't work in Canada. It was a failure the first time. That is one of the large pieces that we really need to understand.

**M<sup>me</sup> France Gélinas:** What do you make of the service that already exists in northern Alberta where they do pay people for donations?

**Ms. Kat Lanteigne:** That's a facility called Cangene in Winnipeg. It was acknowledged by Justice Horace Krever as a rare circumstance. They collect types of rare blood. It's not what we're talking about here. We can't be collecting plasma en masse.

**M<sup>me</sup> France Gélinas:** Sorry; I said "Alberta." I meant to say—

**Ms. Kat Lanteigne:** That's okay.

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**M<sup>me</sup> France Gélinas:** —but you know what I was talking about. Any other words of wisdom that you have to share with us as to the danger of going down this path?

**Ms. Kat Lanteigne:** Well, I think one of the most important things to understand is that this is not the first time that companies have tried to come in and set up shop. I have all these articles here that I can post for you or that you can look around and see. This is in 1994, right at the beginning of Krever. The title is *Bad Blood: Why is a Proposed Red Cross Plasma Clinic so Controversial*—

**The Chair (Mr. Peter Tabuns):** Your time is up, I'm afraid, with this questioner. We'll go to the government. Mrs. McGarry.

**Mrs. Kathryn McGarry:** Thank you very much for your very emotional presentation. I understand that's straight from the heart. As you know, we as a government have a number one priority, and that's making sure that, in the health care sector, our blood system is safe. We've learned important lessons from the heartbreaking consequences that happened in the 1980s, such as your uncle who died of AIDS.

I could have had a very similar story. I had a stepson who was in hospital for four years and had blood transfusions, and in the mid-to-late 1980s we got a letter suggesting that he too could have a disease that was passed by tainted blood. So not only as a care provider, as a nurse—because I've given lots of those—but also as a parent, I felt that fear. We were very fortunate: We had our son tested, and he fortunately did not pick up one of those things. So this is very important to myself as well.

Based on the recommendations from the Krever commission—it investigated how we can stop that tragedy happening again—and that our blood supply is based on the voluntary supply order, I'm very happy to see this bill because I think it would strengthen the government's enforcement power in the case of violations.

I know that, back in March 2013, Minister Matthews wrote to the federal Minister of Health because she had those serious concerns about preserving the integrity of

our national blood system. In May 2013, we informed the CPR that they needed a licence to operate. We expected them to apply. We sent in inspectors this past March to recognize that they hadn't applied and were already operating. We're moving ahead, as you know, to ensure that this legislation keeps our blood supply voluntary.

I know you've thought an awful lot about this, and my first question to you is, can you explain why you think it's so important to have a single operator perform the core functions of the national blood supply system?

**Ms. Kat Lanteigne:** One of the biggest reasons for that—there are a few—is because it was Justice Horace Krever's main recommendation, that we have a single operator. It is their responsibility to do so. It's a fundamental principle within Canadian Blood Services, for our donors, to protect the donor. When you are exploiting people and commodifying their blood, that is not protecting the donor. There is a huge history—

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Ms. Kat Lanteigne:** —and that is very clear throughout Krever. We can't provide a competitive model in our country. It is the responsibility—the sole responsibility, outside of Quebec—for Canadian Blood Services to collect blood and plasma in our country, regardless of what it is used for. That is what our tax dollars are for.

**Mrs. Kathryn McGarry:** Are you worried about the supply, that we wouldn't have enough if we weren't able to—

**The Chair (Mr. Peter Tabuns):** Ms. McGarry, Ms. Lanteigne, I'm sorry, you've used up your time.

Thank you very much for your presentation.

**Ms. Kat Lanteigne:** Thank you.

## PLASMA PROTEIN THERAPEUTICS ASSOCIATION

**The Chair (Mr. Peter Tabuns):** Our next presenter, then, is Plasma Protein Therapeutics Association: Mr. Penrod. If you would introduce yourself for Hansard, and I think you know the drill.

**Mr. Joshua Penrod:** Hopefully. I can be a slow learner from time to time.

My name is Joshua Penrod. Good afternoon, everyone. I am vice-president of the Plasma Protein Therapeutics Association.

PPTA is a global trade association consisting of the collectors of source plasma, and the manufacturers of plasma protein therapeutics made from source plasma. These therapeutics treat a variety of rare, serious, often chronic and genetic diseases such as primary immune deficiency, genetic emphysema and bleeding disorders. In addition, PPTA members have operations all over the world, including Canada. Thank you for inviting our participation in this important proceeding today.

Canada, as a nation, is a world leader in the treatment of rare disease through diagnosis and effective intervention for patients in need of plasma protein therapies.

My brief comments today will give you the global industry's overview on Bill 21. Our concerns are quite

basic and involve the proposed ban on compensated donation.

First, I have to say at the beginning that what we do—collecting plasma for manufacturing—is far different from what CBS or other blood collection systems do. They collect products for transfusion; our companies do not. It is as simple as that, so the concern about paying for blood isn't really accurate, because that's not what we do.

Last year, however, we did collect more than 30 million source plasma donations in the United States and Europe, which is the vast majority of the world supply. This plasma was further manufactured into millions of units of life-saving therapies for people with rare diseases.

When you donate source plasma for further manufacture, you go through a thorough screening and testing process. In addition, the actual process of donation can take more than an hour, because you are connected to an automated machine that removes your plasma and returns your red blood cells and other components back to you. It takes a long time, a lot longer than what you would normally see for a blood donation.

Our industry and the patients rely on higher volumes and a greater number of donations. To make enough product for one patient for one year requires hundreds of donations, sometimes over a thousand.

Compensation acts as a way of saluting the commitment that people have to donate, and to respect the time it takes to donate plasma. Our industry has many safety standards in place as well, which means that, unlike transfusion components, plasma from one-time donors is never used until that donor comes back again to donate and, hopefully, will continue to donate for a long time. This makes sure that the donor is committed to making plasma donation a part of their life.

A complete ban on compensated donation makes little sense when considering the need for plasma and the system that's used to collect it. Non-compensated models work well for transfusion components; we don't think there's any question about that. However, non-compensated models for source plasma collection simply do not work at all. Experience around that world has shown that, time and again, and the top four collecting countries possess both compensated and non-compensated systems.

As a result, we would recommend a couple of proposed solutions to this:

(1) Our first solution would be to not ban compensation for source plasma. This highlights a concern that we would share with policy-makers in that transfusion components are far different from plasma for further manufacture. We understand the concerns there, and we think that such a distinction is readily workable.

(2) A system like Germany's can be used, where there is a hard limit on the amount of compensation. In Germany, there is a limit of €25, which is viewed as making a donor whole for time, effort, travel and so on, although the German system does differ from that of the US.

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Another alternative to explore is to delegate authority to Canadian Blood Services. This would give greater authority to a trusted resource within Canada, would allow flexibility of supply chains, and would, in essence, be a far more pragmatic approach than an outright ban, which would have no benefit on safety or availability of plasma-derived products.

The world is far better now than it was when the Krever commission issued its report years ago. Most of the greatest leaps forward in technology, safety and efficacy have been effected since that time. The vast majority—over 90%—of hemophilia patients in Canada today use recombinant constituents that have virtually eliminated human plasma. Major plasma protein patient groups today—those with primary immune deficiency or alpha-1 antitrypsin deficiency, for example—did not have any therapies available at the time of the Krever report.

**The Chair (Mr. Peter Tabuns):** You have one minute left.

**Mr. Joshua Penrod:** Thank you.

It is a far different world now. We have offered some solutions to address concerns about donor compensation and we stress our deep unease about a lack of clarity and a willingness to rush headlong into a solution for no purpose.

Thank you for your attention to these important issues. We are certainly willing to participate in any further dialogue to further enhance understanding about the issues and about our industry. We again thank you for your consideration in inviting our participation. Canada is a world leader in treating patients with a need for plasma protein therapeutics and this issue is of extraordinary importance to them, the patients, and to the industry supplying their life-saving therapies. Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you. Madame Gélinas.

**M<sup>me</sup> France Gélinas:** Thank you for coming. I would like to have your take on a question very similar to one I asked, and you were in the room. What do you figure would happen to our voluntary system if we started paying people for collecting source plasma and not paying them for collecting plasma for donation?

**Mr. Joshua Penrod:** I hesitate to predict what would happen in any certain circumstance, but what I can tell you is that we do have empirical data from countries in Europe, particularly the Czech Republic, that show that compensating for plasma actually raised donations for both compensated and non-compensated sectors because of an increased awareness of the need for both the transfusable components and the components for further manufacture.

I think you have seen the same thing happen in the US, where we have had national blood utilization surveys that have shown, basically, that the factors that contribute to the need for transfusable components or the need for plasma for further manufacture are, in fact, independent and de-linked.

We do have some experience as well in that we have our own International Plasma Awareness Week, sort of an industry-wide awareness campaign that basically increases awareness across the board. We know that advertising for certain plasma centres actually increases donation in others, including blood centres, as well. So there is a variety and a wide spectrum of approaches that have been taken and solutions that have been arrived at. But I don't want to predict anything.

**M<sup>me</sup> France Gélinas:** You give us the example of what happened in Czechoslovakia. Do you have any example where starting to pay, to compensate for donation of source plasma, had a negative effect on a voluntary system?

**Mr. Joshua Penrod:** We have no evidence to suggest that.

**M<sup>me</sup> France Gélinas:** And where have you looked?

**Mr. Joshua Penrod:** The US, Czech Republic, Germany, Austria—the countries, basically, where we're operating.

**M<sup>me</sup> France Gélinas:** Did any of them previously have a voluntary-only-based system?

**Mr. Joshua Penrod:** There is a different approach depending on the country because you have different policy frameworks in place.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Joshua Penrod:** In the US, for example, there have been parallel systems for many, many years. I confess that I don't know the entire history of the development of the German system. I do know that compensation in Germany is also offered for transfusable components in addition to plasma for further manufacture. Austria has just celebrated 50 years of having the industry in place, which is essentially as long as the industry has existed. So the picture is actually quite complex.

**The Chair (Mr. Peter Tabuns):** Your time is up. We go to the government: Mr. Fraser.

**Mr. John Fraser:** Thank you very much for joining us this afternoon, Mr. Penrod, and for your presentation. I just wanted to mention that we did revise the bill to ensure that bulk purchases or bulk transactions of blood or blood products are okay.

I want to go back to what our earlier witness was speaking about in terms of the Krever commission. In terms of the basic principles that were brought out for the blood system in Canada one was that blood is a public resource. The second one is that donors should not be paid. The other really strong recommendation that came out of that is that we should have a single operator for the blood system in Canada.

So in terms of these exemptions that you've raised today, have you discussed this with Canadian Blood Services, patient groups or other organizations? This amendment that you're bringing forward, is that something that you've—

**Mr. Joshua Penrod:** Sure. Yes, we have discussed it. I don't want to speak on their behalf; I know that CBS is speaking later, as are a number of patient groups.

We believe that the general direction—first of all, let me back up and say that the big concern from what happened in the spring, as you've pointed out, was the potential to interpret that finished products would not be allowed into Ontario from the US and elsewhere. That was a big change and a big relief for us, because that way we knew that the patients would still have access to the care.

In terms of the current statutory language and the way it would be addressed, at least at PPTA, we were looking at it sort of as a convention of legal interpretation, where you have a statute that would basically—the policy that's being affected is to eliminate compensated donation. Our view on it was that if CBS is this trusted resource, and if they are indeed the one that is being put in the driver's seat, as it were, to make this policy manifest, I think it's important to recognize that they need flexibility—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Joshua Penrod:**—accorded to them in addition to the needs of the patients, because they are the ones who are responsible for addressing those needs.

The language of the statute itself is such that that exemption—it can't just be interpreted into it. I think it has to be frank and forthright in the language, according to the plain language of the proposal.

**Mr. John Fraser:** I'm just asking you this. The message we get from CBS is, "This is what we want: a single operator, no paid-for donations." That's what we get from them, so I just want to know what they say in response to you—

**The Chair (Mr. Peter Tabuns):** Mr. Fraser, I'm sorry to say, but your time is up.

We go to the opposition: Ms. Martow.

**Mrs. Gila Martow:** Thank you very much. I noticed that the National Hemophilia Foundation is one of your endorsers, so I thought that was interesting to note.

I think the discussion here comes down to calculated risks. There are risks even if people donate blood; there is no perfect guarantee. Companies follow the regulations and regulations are in place. I believe that whether people donate or pay, we can have a safe blood and plasma supply.

What I wanted to ask is, do you see it as hypocritical if we're buying plasma products from the States—I think we're buying 70% of our products from the States—where people are remunerated in some fashion for their donation? Are we being hypocritical to not follow suit here while we're still importing those supplies?

**Mr. Joshua Penrod:** I think that different jurisdictions have different policy goals in mind. I certainly wouldn't want to come in here as an outsider and label it as such. I think that those are questions that have to be resolved within policy-making in the province and certainly within Canada. But it is a bit puzzling.

It should also be noted too that the Krever commission's report was an extremely important document, with very, very, very intensive, important findings based on an exhaustive review.

I think it's also important to recognize the changes in safety, efficacy and technology that have evolved in the past two decades since the Krever commission report has been published. Most of the major advances in safety occurred in the late 1980s, and again with testing technology in the late 1990s, which applies equally to both compensated and non-compensated models.

As a whole, we are very, very confident in the safety profile of compensated and non-compensated donations alike. Those donations made by donors in our industry system, using compensated donation—we have not seen any viral transmission in more than two decades. That's a pretty impressive safety record globally overall.

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**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mrs. Gila Martow:** I think that's what it comes down to—public safety—and also people feeling comfortable with our blood supply and our plasma supply. I think that the difference shouldn't be focused on compensated or not compensated; I think that the difference should be focused on the fact that we're doing everything scientifically possible to ensure that the blood supply is safe, so I want to thank you for your time. It was a great presentation.

**Mr. Joshua Penrod:** Thank you.

**The Chair (Mr. Peter Tabuns):** Excellent timing. Thank you, Mr. Penrod.

**Mr. Joshua Penrod:** Thank you.

#### REGISTERED NURSES' ASSOCIATION OF ONTARIO

**The Chair (Mr. Peter Tabuns):** The next presenter is the Registered Nurses' Association of Ontario. Good afternoon. If you would introduce yourself for Hansard, Doris. You have five minutes. I'll give you a one-minute warning.

**Ms. Doris Grinspun:** I'd be happy to do that. Thank you very much. My name is Doris Grinspun, and I'm the CEO of the Registered Nurses' Association of Ontario, RNAO. With me today is our senior policy analyst, Dr. Lynn Anne Mulrooney. RNAO is the professional association for registered nurses, registered practical—oh, nurse practitioners and nursing students—I almost took another group—who practise in all roles and sectors in Ontario. Our mandate is to advocate for healthy public policy and for the role of nurses in enhancing the health of Ontarians.

The RNAO appreciates this opportunity to provide feedback to the committee looking at Bill 21. We have provided each of you with a detailed written submission that analyzes each area of the bill: voluntary blood donations, regulation of pharmacies, and other matters concerning regulated health professions. This afternoon, we will focus only on blood donations. We can take questions on any areas of the bill, though.

To tell you the truth, as I was sitting there, I was questioning myself: Why do we need a committee for such a question? I was questioning myself if this is what

taxpayers will want us to be doing: spending their money in having this committee wasting our time on something that should be not be asked. Blood and money simply don't mix—at least not for nurses.

Blood is a precious public resource. Allowing the commercial plasma industry to harvest blood from vulnerable people in return for payment in Ontario is in direct opposition to the evidence-informed policies of the World Health Organization. It contravenes the findings of Justice Krever's commission of inquiry into the blood system in Canada that was necessitated by the public health calamity of thousands of infections and deaths caused by contaminated blood products collected from paid donors. Having a self-sufficient national blood system comprised of altruistic donors with strong Canadian regulatory enforcement will honour the precautionary principle.

RNAO is asking our political leaders from all parties to put safeguarding the public ahead of profit. There are strong economic forces at work, in Ontario and elsewhere in the country, that are seeking to generate revenue from a growing demand for body parts, including organs and blood. In a world of increasing economic inequality, those who are often invisible are those who are forced into selling their body parts because they are simply desperate. What we can learn from the organ trade is that those who sell their organs are left in worse health and with lower incomes, and their communities have a declining willingness to donate.

Donations of whole blood and blood components should be fully voluntary, like any invasive procedure. There is always a potential for harm. The overall incidence of complications directly related to blood donation is 1%. This may seem to be a small number, but it is worthy of concern given the large quantities of blood collected each day across the world. It is important to remember that the reason why many countries prohibit paying people for blood is the great harm done, not only to the recipients of contaminated blood products but to the donors.

Since the 1970s, into the 1990s, outbreaks of blood-borne diseases such as HIV, hepatitis B and hepatitis C have been attributed to commercial plasma centres in Austria, Mexico, India and China. While the science and technology on blood safety have advanced since then, it is still true that the most vulnerable people in our society are prone to selling their blood, and their health must be protected. So RNAO urges you to prohibit selling blood for money or paying for blood. Blood and money simply don't mix.

**The Chair (Mr. Peter Tabuns):** Thank you, Ms. Grinspun. To the government: Ms. McGarry.

**Mrs. Kathryn McGarry:** It's wonderful to see you again, Ms. Grinspun. As you know, I've been nursing for over 30 years, and I—

**Ms. Doris Grinspun:** I just tweeted about it.

**Mrs. Kathryn McGarry:** When I can look, I will. But thank you very much. I think we were at Mount Sinai together many years ago, which doesn't seem like that long ago.

I really appreciate the RNAO's position on this and the fact that the members are concerned about this particular issue. I just wanted to point out that I know you had sent a letter in July to Premier Wynne asking us to quickly move forward to prohibit paid plasma clinics. In fact that's one of the reasons why Bill 21 has come forward in this fall sitting and why we are here so quickly as a committee to make sure that we can move to get this legislation through. So I certainly appreciate that.

I just wanted to ask a couple of things of you on schedule 1. And I do have just a quick follow-up on schedule 2. But I just really wanted you to tell the committee again why upholding the voluntary blood donation and a single system under the Canadian blood supply is so critical.

**Ms. Doris Grinspun:** First of all, it ensures the precautionary principle in a much, much better way. Any time that money enters into the equation of health care—and specifically the issue of selling organs, including blood—there is cutting of corners, there is closing of eyes, there is closing of ears. We saw that. We saw that happening, and we have seen it happening in other countries. For those who say that it is happening in the US, well, the US has a multi-tier system. We don't, thankfully. And some of us actually left the US to come here for that same reason.

**Mrs. Kathryn McGarry:** Thank you. If I could just move quickly: I had a question about seeing if you think that improved information-sharing between the health regulatory colleges and other public institutions, like the hospitals and that kind of thing, would better protect the public if there were some issues between the registered members and the public institutions.

**Ms. Doris Grinspun:** We are in support of that aspect of the bill. We are seeking clarifications, though, so that for the nurse or the doctor who is undergoing investigation—

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Ms. Doris Grinspun:** —it is clear what the parameters are by which information is shared for really protecting the public and what that means.

**Mrs. Kathryn McGarry:** So you see more of a balanced approach, not only protecting the public but also protecting the members and maybe seeing the bill roll out so that it does both in the long run.

**Ms. Doris Grinspun:** Correct, and also to clarify some aspects of the bill—and it is in our submission—to ensure that it protects both.

**The Chair (Mr. Peter Tabuns):** Thank you. We'll go to the opposition. Mr. Walker.

**Mr. Bill Walker:** Just before you go—I want to say thank you to the last presenter. I didn't get a chance to speak, and I just wanted to thank him. I thought he brought four recommendations that are pretty balanced and worth consideration by the committee.

I wanted to preface—even in my first comments I didn't do this—that safety and availability are absolutely the key things that I'm looking at when I look at this bill, when I've spoken to it. It's trying to balance the need of

the greater good of all Ontarians at the end of the day. So that's why I made the comments, that's why I want to be in committee to see all of the different aspects.

Doris, do you think we can guarantee the supply of blood versus demand as we go forward with our aging demographic?

**Ms. Doris Grinspun:** Yes, I think we can. I think it's an issue of raising awareness, raising consciousness, educating people that today, you may need blood, and tomorrow, I may need the blood; and donating in good times, not waiting until a family member is very ill etc. I absolutely think we can.

**Mr. Bill Walker:** So if a company today was to come in and use the exact same process—the only difference being that they would implement a paid donor versus a volunteer—would you agree to that?

**Ms. Doris Grinspun:** No. Money and blood, and money and organs in general, do not mix. I come from a country where some of those things happen in terms of organs and the black market etc., and it simply doesn't work. So, no.

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**Mr. Bill Walker:** Do you have any difference of opinion if we were to separate research versus transfusion for patient purposes?

**Dr. Lynn Anne Mulrooney:** No, but the other point that I would just add on to what Doris was saying—I think there are many things that we can do, like look at why Canada is using more plasma than other countries. If we had some revisions to the way we organize the pharmaceutical industry, and brought in national pharmaceutical, for example, there could be savings that would be available for us to invest into our system.

There are lots of bright people. We could arrange a better way of doing things, I think, if we tried, rather than preying on vulnerable people.

**Mr. Bill Walker:** I guess I'm not suggesting that we're preying on vulnerable people. As I referenced in my earlier remarks, I have a good friend, who is certainly far from being a vulnerable person, who went to Europe and did this as part of their travelling and saw absolutely no concern with doing it.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Bill Walker:** My question, I guess, gets back to the ability—we're currently importing 70% of our plasma protein products. So if we're doing that, we're utilizing blood from those types of sources. Why can we not do it here if we're prepared to buy it?

**Dr. Lynn Anne Mulrooney:** I think, actually, if you look at the literature, sir, and the experiences, a lot of the people who donate are actually very vulnerable. That's why they are willing to go through the process of something that is—

**The Chair (Mr. Peter Tabuns):** Thank you. I'm afraid we have to go on to the third party: Madame Gélinas.

**M<sup>me</sup> France Gélinas:** I think you've stated your case pretty clearly to keep it the Canadian way—that is, volunteer donation.

I would like to take you to the other two parts of the bill, if you don't mind. I see that you make recommendations, and one of them has to do with what happened with the diluted chemo drugs: that recommendation number 2 from the committee be added. I was wondering why you made such a comment and how those particular recommendations—what would that mean?

**Dr. Lynn Anne Mulrooney:** We looked very carefully at the report that came from your committee. We thought you made a very compelling argument, from the testimony that you heard, in terms of the need for accountability and transparency in how pharmaceuticals are acquired and how public money is spent. I think the best rationale is to go back to your report. I think it's all very clearly outlined there. We think we have to be accountable.

**M<sup>me</sup> France Gélinas:** You feel that the recommendations from the committee will bring transparency and accountability? Do you figure they will be effective?

**Dr. Lynn Anne Mulrooney:** Yes, especially the second. The second one, we thought, particularly addressed the concerns that were raised about what was happening with money. It just seemed to be kind of going all over the place. It seemed very confusing.

**M<sup>me</sup> France Gélinas:** And it was, let me tell you.

My last question: You also make recommendations about some of the changes in reporting, specifically when it has to do with places of work. Could you give me ideas—except for hospitals, what did you have in mind?

**Ms. Doris Grinspun:** Any time that there is a complaint and an investigation, that positions the public at risk. That's the piece that needs to be then clarified, to protect both the health care professional and the public. That should be reportable, because not every time the person that is being investigated, even though it can place the public at risk—take, for example, the issue of abuse—that is actually conveyed to the employer.

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**M<sup>me</sup> France Gélinas:** The way the bill is written now does not include this?

**Ms. Doris Grinspun:** Some of that needs to be clarified further, and we made some recommendations in our submission.

**M<sup>me</sup> France Gélinas:** Okay. Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you very much.

#### Therapure Biopharma Inc.

**The Chair (Mr. Peter Tabuns):** Our next presenters, then: Therapure Biopharma Inc. Mr. Krause? When you're seated, if you could introduce yourself for Hansard. You'll have five minutes, and I'll give you a warning at the one-minute mark. Please proceed.

**Mr. Mark Krause:** Thank you very much. I appreciate you taking the opportunity today to be here and for us to present. My name is Mark Krause. I head up the plasma protein group at Therapure Biopharma Inc.

By way of background, Therapure is a contract manufacturing company. We're located in Mississauga,

Ontario. We manufacture, on behalf of third-party life science companies, complex biologics.

We were born, if you will, in 2008. We were bought by an investment company out of Toronto out of bankruptcy. We have grown, since that time, from 13 employees to almost 300 today. Arguably, we are a world leader in the field. We have spent, in that time, about \$150 million to build the business, and this is, we feel, very important for the life sciences sector in Ontario in particular.

For us, plasma proteins are a vital part of our business. We have significant contracts both with industry as well as—actually, we have a very large contract with the US Department of Defense around manufacturing a product for them, which is a nerve gas antidote based from plasma.

These are very important proteins, obviously. The only place that we can currently get them from is plasma proteins. One of the concerns that we have, and that we had discussed in the earlier version of the bill, is with respect to the importation of raw material from compensated donors—plasma protein from compensated donors from the US.

It appears that a change was made to the Trillium Gift of Life Network Act which addresses that primarily, but at the same time we really need to make sure, from our business perspective, that we can import plasma from compensated donors. Otherwise, we will severely impact our business.

What we're looking to see is a positive statement to the effect that we are allowed to import plasma from compensated donors. We do struggle from an investment perspective. We make long-term investment decisions, and anything from a legislative perspective that harms that certainly doesn't bode well from an investment perspective, both from a dollar perspective as well as, obviously, from an employment perspective. So hopefully we can see something from a positive-statement perspective that importation for manufacturing purposes is allowed.

Regarding the banning of compensation of donors, we are looking at, over the next three years, expanding the business and investing another \$200 million into the business. That is based purely on products from plasma proteins. Again, when we look at the long-term perspective of this, anything that jeopardizes our ability to do that is not good. But from our perspective as well, having the ability to use plasma from compensated donors in Ontario is actually not a bad thing.

Right now, if we're looking at manufacturing anything using plasma proteins, we're doing so by purchasing it from the US. They're the only country with a surplus in plasma proteins and they are also the only one that's recognized, from a safety perspective, as being a "gold" standard. That's because of the high levels of safety. We as a company are very comfortable with those safety standards—

**The Chair (Mr. Peter Tabuns):** One minute left.

**Mr. Mark Krause:** —both from a patient perspective as well as, quite frankly, from an employee perspective, because people are in contact with plasma as well.

From our perspective as an Ontario-based company, why wouldn't Ontario want to be in control of that supply and in control of the safety standards? We do, as has been said a couple of times, import over 70% of our products currently from the US and from compensated donors. Why would we not want to be in control of that?

**The Chair (Mr. Peter Tabuns):** Thank you very much. The first question to the opposition: Mr. Walker?

**Mr. Bill Walker:** Thank you very much. Just to reconfirm, I think I heard you say that you cannot sustain your current business without the ability to have paid donors, whether it be the importation and/or here in Canada, and thus research would be severely negated if you don't have that supply. Can you just expand on that a little bit to make sure I heard you correctly?

**Mr. Mark Krause:** Yes, you did hear correctly. I can't sit here and say that 100% of the business would be impacted, but we roughly have about 50% of our business that relies on plasma from compensated donors. Without that we obviously wouldn't be investing both in jobs as well as money into the facility in order to be able to do that. So we are heavily invested from that perspective, or heavily tied into plasma from compensated donors. It goes beyond just the business. It's also to the end of the day. We're manufacturing product for third-party companies; those third party companies are bringing those products to patients. At the end of the day, if we can't manufacture because we're not able to bring in that plasma, simply put, the patients don't have the product. It's not easy to transfer manufacturing processes. This is at least an 18- to 24-month process, and if that's a requirement, because we're unable to do so, there will be a gap to the patients at the end of the day.

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**Mr. Bill Walker:** Can you expand upon that? You did reference in your brief notes the Department of Defense in the United States for gas, that type of concern. I certainly know of the one for Alzheimer's and dementia, which I believe is going to be a significant issue that we're going to have to address as a society. It's already starting to mount; we can't wait too much longer until we find that cure, or at least something that can help. Can you just expand a little bit on the other types of research that are being done and the types of ailments that people are currently suffering from?

**Mr. Mark Krause:** I can speak directly to the Department of Defense one. It's called human butyrylcholinesterase; it's a very trace protein found in very small quantities. What that does is it provides an antidote, effectively, to being exposed to sarin gas. What the Department of Defense is looking at this for is that before troops go into the theatre, where they may be exposed to various nerve gas agents, sarin gas being one of those, that becomes available to the troops and they will then be immune from any adverse reactions, which is not insignificant given the nature of these nerve gases.

**Mr. Bill Walker:** Any other health ones?

**Mr. Mark Krause:** Pardon me?

**Mr. Bill Walker:** Any other health applications that you're aware of?

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Mr. Mark Krause:** There are. I hesitate a little bit because we don't disclose, typically, a lot of the clients that we're dealing with, but there are a significant number of other disease states that—

**Mr. Bill Walker:** That are in the research process?

**Mr. Mark Krause:** That are absolutely in the research process.

**Mr. Bill Walker:** Thank you very much.

**The Chair (Mr. Peter Tabuns):** Thank you, Mr. Walker. Madame Gélinas?

**M<sup>me</sup> France Gélinas:** I'm a little bit curious about your business model. Do you buy raw plasma right now from Canadian Blood Services?

**Mr. Mark Krause:** Typically, what we do from a business-model perspective is we always work with a third party. In the case of what we're looking at today, we work with the Department of Defense, and the Department of Defense purchases and sends plasma to us. In this case, it's a derivative of the plasma processing. We have other clients that we purchase plasma directly from, and typically we do not actually purchase it from Canadian Blood Services. Most, if not all—I'm sure that one of the next speakers from Canadian Blood Services will be able to clarify that—is used in order to manufacture product that gets sold back into the Canadian market, so that's not a source of plasma for us. Whenever we purchase plasma we need to go to the U.S. and purchase from—

**M<sup>me</sup> France Gélinas:** Where are the derivatives made? Where are those labs? Do we have one in Ontario?

**Mr. Mark Krause:** That's what we do. Our company is set up to manufacture on behalf of others. A good portion of the 300 employees that we have are working on purifying the plasma into the end product.

**M<sup>me</sup> France Gélinas:** For the contract that you willingly shared with us, the one with Defense in the States, they are one that purchased the plasma for you?

**Mr. Mark Krause:** The way that the contract is structured is that they purchase the plasma for us. Indirectly, we do purchase it and process it further in our facility, yes.

**M<sup>me</sup> France Gélinas:** Is there a reason why this arrangement is set up like that?

**Mr. Mark Krause:** Because it's not available any other way, I guess is the simplest way to put it. As I said, it's a derivative of the manufacturing process. We have no domestic manufacturers that are capable of manufacturing plasma products.

**M<sup>me</sup> France Gélinas:** Where are those manufacturers that are able to do this?

**Mr. Mark Krause:** They're all based out of the U.S., and they all use U.S. plasma from compensated donors.

**M<sup>me</sup> France Gélinas:** And who are those companies? Do you know some?

**Mr. Mark Krause:** I know some of the companies; I won't disclose who we use, but the larger companies—

CSL, Baxter and Grifols would be the three largest players.

**M<sup>me</sup> France Gélinas:** All the big ones that we already know.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**M<sup>me</sup> France Gélinas:** Okay. The way the system works right now, you are able to gain supply, and the way the bill is written right now, it's not going to shut down the doors to your business tomorrow; you would just like it to be clearer for your investors that there is a long, prosperous life for your business.

**Mr. Mark Krause:** That's right. Anything that puts question to that spooks long-term investment, whether it's our investors or others.

**M<sup>me</sup> France Gélinas:** But the bill—

**The Chair (Mr. Peter Tabuns):** Thank you. Your time is up. I'm afraid we have to go to the next party, the government: Mrs. Mangat.

**Mrs. Amrit Mangat:** Thank you, Mr. Krause, for presenting here at Queen's Park. In your statement, you said that your company is Mississauga-based.

**Mr. Mark Krause:** Yes.

**Mrs. Amrit Mangat:** Would you mind sharing with the residents of Mississauga, or Ontarians, what role your company is playing when it comes to the health care sector?

**Mr. Mark Krause:** Typically, a company that doesn't have the ability to manufacture a product will go through their own R&D. They will be able to articulate to us what type of product they would like to have manufactured. Rather than them building a large facility on their own, what they will do is come to us because we already have the facility.

I alluded to the \$150 million in investment that we've made. That's largely into the facility. The facility is very expensive, from a capital input perspective, and it's also very expensive to run the facility. So a lot of smaller, typically, companies choose to use us to manufacture their product, because it's more efficient, from their point of view.

**Mrs. Amrit Mangat:** I'm sure that you're aware that we revised the original text of the bill, and it wouldn't prohibit commercial transactions. So why do you feel that this change is important to you?

**Mr. Mark Krause:** There was a change to the original bill, which I think clarified it. We had an issue and we expressed what that issue was. I think, for the most part, it has been addressed. But as per most bills, having a clear statement with respect to the intent is more helpful.

I think there has been a carve-out, obviously, for Canadian Blood Services and bulk product, but not necessarily bulk input into the product, and we only have inputs into our product—so plasma directly, versus plasma products.

I'm personally less worried about—as Therapure, I'm less worried about product coming into the country than I am about raw material for us to manufacture product.

**Mrs. Amrit Mangat:** Thank you. Go ahead.

**Mr. John Fraser:** Thank you very much, Mr. Krause, for appearing today. I just want to make sure I heard you clearly. Did you say that the United States is a country that has a surplus in plasma protein? Did you say that?

**Mr. Mark Krause:** Yes.

**Mr. John Fraser:** Okay. That's all I wanted to clarify. I didn't quite get it. Thank you very much.

**The Chair (Mr. Peter Tabuns):** Further questions from the government? No?

Thank you very much.

## CANADIAN BLOOD SERVICES

**The Chair (Mr. Peter Tabuns):** Our next presenter: Canadian Blood Services. Good afternoon, sir. If you'd introduce yourself, and you know you'll have five minutes. I'll warn you at the one-minute mark.

**Dr. Graham Sher:** Thank you very much. Thank you, committee members. I'm Dr. Graham Sher. I'm the chief executive officer at Canadian Blood Services. I welcome the opportunity to speak to Bill 21.

I want to very briefly outline the scope of work that Canadian Blood Services does in this country—there has already been some discussion around that—and, importantly, clarify the collection practices for plasma in this country, and then present our organization's perspective on Bill 21 and the payment for donors.

As many of you probably know, we are responsible for operating Canada's national blood supply system across the entire country, with the exception of the province of Quebec. We provide safe, cost-effective and accessible supply to blood and blood products for all Canadians.

We are also responsible for bulk purchasing plasma protein products on the international market, and I'll come back to that in a moment.

We have responsibility for managing the country's stem cell program for patients awaiting stem cell and bone marrow transplantation. We're now operating Canada's national cord blood bank, and we are also involved in organ donation and transplantation. All of these programs are potentially implicated by Bill 21.

We are a not-for-profit, national organization and were created following Justice Krever's release of his report in 1997. I have been the CEO since 2001. My background is as a hematologist, and prior to joining the blood service, I ran the largest transfusion program in the country, treating many patients with HIV and hepatitis C from infected blood in the 1980s and 1990s.

Canada is 100% sufficient in blood for transfusion purposes: red blood cells, platelets to stop bleeding, and plasma for transfusion purposes. We do not need to import any of those, and that's not in the scope of discussion.

Like virtually every country in the world, however, Canada is not self-sufficient in plasma protein products derived from human plasma. We rely heavily on an importation model to support patient needs for these drugs.

To come to a question that Mr. Walker posed earlier, at the moment we are not sufficient in meeting patient

needs for a number of these drugs—not just the immunoglobulin drugs, but also albumin.

**1500**

Since 2003, Canadian Blood Services has been evolving a long-term national strategy to ensure a sufficient supply of plasma for plasma derivatives for Canadian patients, a supply that takes into account and balances security of supply, multiple vendors in the marketplace, product choices for patients, cost-effective delivery—important to governments—transparent procurement processes and complete stakeholder engagement in the procurement process.

To meet the high and growing demand for these plasma derivatives in Canada, we contract manufacture the plasma that we collect, and this goes to Ms. Gélinas's question. We send the plasma that we collect to two manufacturers, one in the United States and one in Europe, where the plasma is manufactured into these specialized drugs and then returned back to Canada for distribution to Canadian patients. That allows us to meet 30% of the need of all patients requiring immunoglobulins in this country. To meet the other 70% of the need, we then purchase drugs that are manufactured from paid commercial donors in the United States. These are drugs licensed by Health Canada, licensed for distribution in Canada.

This practice is not unique to Canada. Save and except for the United States, virtually every country in the world depends on the paid commercial industry to meet patient needs. Patient groups support this and you will hear from some of them later in your hearings.

What is my organization's position on paying donors? We believe that paying for plasma is a moral and ethical decision for governments and societies to determine, and we support the government of Ontario in passing this legislation—

**The Chair (Mr. Peter Tabuns):** One minute left.

**Dr. Graham Sher:** —for the citizens of Ontario. Paying donors is not an issue of safety. Decades of evidence have proven that drugs made from plasma derivatives today are inordinately safe and just as safe as those made from volunteer donors. This is not the 1980s; 20 years of advanced science and technical improvements have made these products extremely safe.

Without access to these products, a great percentage of Canadian patients would not get the care that they need. The demand for these drugs continues to rise and it will require enormous public expenditures for Canada to be 100% self-sufficient in plasma, and in fact that would be a risk strategy, putting all our eggs in a single basket.

We continue to work with not just the government of Ontario but all governments in this country to ensure the right balanced risk from a plasma sufficiency point of view to meet the needs of Canadians.

I thank you for your time and I thank you for allowing us the opportunity to provide input into this bill.

**The Chair (Mr. Peter Tabuns):** Thank you. You're on the button. Madame Gélinas.

**M<sup>me</sup> France Gélinas:** I'm interested in the business model behind—you end with the little sentence you've

given us: "... it is not economically feasible for Canada to be 100% sufficient in Canadian plasma collected for fractionation." How could it be that there are businesses that want to pay donors and make a business out of it, but Canadian Blood Services, which doesn't pay donors, cannot make a business out of it?

**Dr. Graham Sher:** A very good question. Currently, we collect about 200,000 litres of plasma in this country, which we send to these two manufacturers that I mentioned. In order to be 100% self-sufficient at today's rate of use of these drugs, we would need 800,000 to 850,000 litres. We would need to quadruple the size of the plasma collection program we have in Canada.

The commercial industry in the United States is collecting in excess of 24 million litres a year, an economy of scale that we simply can't achieve. So there is a cost differential between what we can do and what the large commercial industry is able to do in the United States.

That said, as I mentioned, we continue to work, not just with the government of Ontario but all the governments that are part of Canadian Blood Services, to see how we can increase the amount of plasma that we collect in this country in a cost-effective manner.

Equally importantly, we don't want to have 100% of the plasma come from Canadian donors. That was the situation in the United Kingdom a few years ago. Then mad cow disease hit that country and they had to cease all plasma collection in that country. So it's a notion of balancing risk and security of supply.

**M<sup>me</sup> France Gélinas:** I come from northern Ontario. I used to donate plasma in Sudbury; that closed. It went to Thunder Bay; Thunder Bay is now closed. Where do you collect plasma?

**Dr. Graham Sher:** The plasma that we send for fractionation is plasma that comes off the whole blood that we collect. We collect it right across the country in about 20,000 clinics that we run each year. The small facility that we closed in Thunder Bay was a facility not collecting plasma for fractionation purposes, but plasma for transfusion purposes. The demand for that plasma has gone down dramatically. We were only collecting 6,000 litres a year. There are 12,000 collections.

**M<sup>me</sup> France Gélinas:** So you don't do plasma. You only do whole blood and then you extract the plasma out?

**Dr. Graham Sher:** I apologize. We do small volumes of source plasma collection in four of our sites across the country.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**M<sup>me</sup> France Gélinas:** Okay. And this is part of the units that you send to the States and to Europe. But you don't see a business to be made for CBS in there?

**Dr. Graham Sher:** I absolutely do, and that's what I just mentioned: that we are currently in discussions with government to look at significantly increasing the volume of plasma that we collect in our volunteer non-remunerated system. There is a business case in development to that effect.

**M<sup>me</sup> France G  linas:** I look forward to seeing that.

**The Chair (Mr. Peter Tabuns):** Thank you. Now to the government: Mr. Anderson.

**Mr. Granville Anderson:** Thank you, Doctor, for appearing before this committee today. As you know, the royal Commission of Inquiry on the Blood System in Canada, more commonly referred to as the Krever commission, recommended that the Canadian blood supply system be governed by five basic principles, one of which is that “Donors of blood and plasma should not be paid for their donations except in rare circumstances.” Can you elaborate as to why this principle is so important to Canadian Blood Services?

**Dr. Graham Sher:** It is a principle that is important to us, Mr. Anderson, and a principle we continue to aspire to. Canadian Blood Services does not, and will not, pay its donors.

The issue that we have really brought to light with the complexity of the question that this bill speaks to is that the products we purchase come into this country from commercial donors, and we need to recognize that the patients whom we serve in this country are receiving products from paid donors, which today, in the current day and age, are extremely safe products.

That said, the voluntary blood sector, of which Canadian Blood Services is a part, has held to this principle of non-remuneration for the better part of 40 years now, and we see no reason to change that principle. At the same time, we have to recognize that a safe, successful and necessary commercial plasma industry coexists with the voluntary blood industry side by side, and we really do need to recognize that patients depend on both systems in order to provide products for their care. We are not talking about paying blood donors.

**Mr. Granville Anderson:** Okay. Thank you. As a follow-up, a number of organizations are concerned about the supply of PPPs for patients with blood disorders. Can you please explain why CBS ensures sufficient supply of PPPs as well as blood plasma for transfusion purposes? Why is it important to have a single operator perform the core functions of the national blood supply system?

**Dr. Graham Sher:** So as I mentioned when I described the functions of Canadian Blood Services, we are responsible for collecting all the blood for transfusion purposes. We also have sole responsibility for procuring the plasma protein products, PPPs, for patients who require these specialized drugs. That happens in one of two ways: either the plasma that we collect then gets manufactured in one of two facilities—one in Europe; one in the US—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Dr. Graham Sher:** —or we purchase these commercial products from the commercial market.

We have been given that sole responsibility by the provincial and territorial governments of Canada. All PT governments, including Ontario, are members of the Corporation of Canadian Blood Services, and we have the sole responsibility for meeting those patient need requirements.

**The Chair (Mr. Peter Tabuns):** Thank you. We go on to the opposition: Ms. Martow.

**Mrs. Gila Martow:** Thank you. My question is, if we’re shipping to countries to manufacture these plasma protein products and these are countries where they’re accepting plasma from centres that are remunerating people giving the plasma, is all the plasma being mixed together, or are there guarantees in place that our plasma is being treated separately and shipped back separately?

**Dr. Graham Sher:** A very good question. There is complete segregation of the process. When our plasma goes down to one of those two facilities in the US or Europe, our plasma is segregated, manufactured separately. The finished drugs are labelled “For Canadian Blood Services Use Only” and shipped back to us. Then the plant goes through a purification and cleaning process, following which any other provider’s plasma goes through.

There is no admixing of our plasma with the paid commercial plasma industry. That is true so that we can then assure ourselves that the product is coming from the plasma that we provide.

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**Mrs. Gila Martow:** Thank you. So in terms of sort of what you said, that there’s no safety concern as far as you’re concerned—it’s all a moral or ethical dilemma—and in a country as vast as Canada, where so many people live in such remote areas that it’s impossible—and I’m guessing that’s why the centres that Madame G  linas was donating at were shut down—do you feel that we have to take that sort of moral high ground and say, well, we’re able to collect enough blood products for blood, but in terms of plasma, in terms of manufacturing—and we are purchasing from countries where they take donations—that it would not be cost-effective to count on completely Canadian donations for all of our plasma protein products?

**Dr. Graham Sher:** Yes. I think that is well said. You used the word in an earlier question to another presenter, whether this is a hypocritical situation. I don’t think it’s hypocritical. It is the reality and the complexity of the multinational industry that we are required to depend on. I do not think it is cost-effective, or sensible from a risk management point of view, for us necessarily to collect 100% of plasma in our market. I think there are risks associated with this strategy too, and we really need to have a very carefully risk-managed strategy to support the needs of all Canadian patients.

**Mr. Bill Walker:** Thank you very much, Doctor. I have a couple of questions. You’ve shared with us in the documentation provided that Canada, like many other countries, is not self-sufficient in plasma for fractionation, that the demand for these products is increasing as new therapies are identified, and that for some patients, these products are life-saving treatments for which there are no alternatives.

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Mr. Bill Walker:** You’ve suggested that there is going to be increased demand, risk strategy is a big issue

that needs to be balanced, and that they are as safe for paid as non-paid. I'm suggesting that you might say that you could go down the road for plasma protein donations to be paid, but not for transfusion. Is that a fair assessment?

**Dr. Graham Sher:** Yes, and that is the current situation today. We purchase drugs made from paid plasma donors. We do not pay our blood donors. In fact, neither do they pay blood donors in the United States. That is the complexity of the sort of industry in which we exist today.

**Mr. Bill Walker:** Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you very much for your presentation today.

**Dr. Graham Sher:** Thank you, Mr. Chairman.

#### CANADIAN IMMUNODEFICIENCIES PATIENT ORGANIZATION

**The Chair (Mr. Peter Tabuns):** Our next presenter: Canadian Immunodeficiencies Patient Organization. Welcome. If you would identify yourself for Hansard, and then please begin.

**Ms. Whitney Goulstone:** I'm Whitney Goulstone. I'm the communications director for the Canadian Immunodeficiencies Patient Organization, CIPO. I'd like to thank the committee, especially on World AIDS Day and Epilepsy Action Day. Nice ribbons.

I'm sorry, but my colleague Dr. Stephen Betschel, who is our medical advisory doctor, is not here today, so I'm going to try to answer any questions you have. But patience, please: I don't really have a medical background.

The WHA currently recognizes 300 primary immunodeficiencies, with 900 patients in Ontario currently receiving plasma-derived therapy, either by IV or home therapy. For the majority of these patients, the only treatment option available is plasma-derived products.

Over the last 20 years, the plasma industry has developed very well-documented and effective procedures to collect and process plasma safely for both the donors and the recipients.

I, myself, along with 900 other Ontarians, have CVID, which is common variable immunodeficiency. I do not produce my own antibodies. This puts our bodies at greater risk of infection. Common colds can be terrifying. Colds quickly turn into pneumonia, which becomes life-threatening. We depend on plasma collected from healthy donors in order to keep our levels normal and stay out of hospital. Canada is the largest user of IV plasma, with the vast majority of our product coming from paid US donors.

The one thing a mother never wants is to cause unwanted distress to her children. That happened to me. Before I started treatment, a pneumonia took me to the ICU, where my husband was told to bring our children to say goodbye to their mother. That's something I never want to have happen again.

Since I started treatment, my quality of life has improved, and my stays in hospitals have decreased, along

with antibiotic use. My son, however, is currently undergoing testing on his own immune system and, one day, there is a large chance that he will need plasma therapy himself.

At CIPO, we understand the history, but we ask this government to please not close the door on this lifeline and its possibilities. CIPO will continue to work with CBS, the national rare blood disorder organizations, and the manufacturers of products to ensure ongoing product safety for our patients.

**The Chair (Mr. Peter Tabuns):** Thank you. Questions, to the government: Mr. Fraser.

**Mr. John Fraser:** Thank you very much, Ms. Goulstone, for presenting today. I appreciate what you had to say in terms of working with CBS. Earlier today, CBS stated that there are no issues with supply with respect to PPPs in Canada. Also, we heard from Mr. Krause, who is from—

**Ms. Whitney Goulstone:** PPTA.

**Mr. John Fraser:** Pardon me?

**Ms. Whitney Goulstone:** Oh, Mark Krause.

**Mr. John Fraser:** —Mark Krause, yes; Mr. Krause, yes—that in respect to the United States right now, they currently have a surplus in plasma protein. We also heard from Mr. Sher with regard to what occurred in the United Kingdom. They had a unique blood supply where they met all their needs and then found themselves in a very serious situation where they would have a very serious problem with supply. I guess what I'm trying to say is that having a mixed market for doing these things is a good thing. I know, for instance—

**Ms. Whitney Goulstone:** Yes, it is.

**Mr. John Fraser:** —Nordion, which is in Ottawa, supplies a huge portion of the medical isotopes for cancer.

Can you tell me what you discussed with CBS in terms of going forward for the concerns that you raised here today?

**Ms. Whitney Goulstone:** I'm not our representative on the national liaison committee. I'm starting in March. But we have had a sitting member on the national liaison committee.

It is good to have a mixed group in your blood supply. You never want to have one pool, so it is good to have a mixed group. It is nice to have a large donation base, even when it comes to plasma, especially when you're treating patients who have a lowered immune system, which is what you're having here. You're having patients who need a large pool of healthy antibodies, so it is good to have a large, diverse base.

**Mr. John Fraser:** I take it from those remarks that you believe that having a single operator is key to our blood system.

**Ms. Whitney Goulstone:** A mixed base. We want as large a pool as you can get.

**Mr. John Fraser:** Okay. That's all the questions that I have.

**The Chair (Mr. Peter Tabuns):** You have about 30 seconds. Mrs. McGarry?

**Mrs. Kathryn McGarry:** A quick question for you—thank you very much. Do you believe that there is any safety risk with using other supplies rather than the Canadian blood supply? The reason it was actually started was because of the tainted blood scandal in the 1980s. I think the PPS that we went in to see if they had applied hadn't even actually agreed to doing something like that, that they were asked to do, so it makes me a little suspicious that they're not—

**Ms. Whitney Goulstone:** Given the regulations that are going right now, that are set in place, I don't have any concerns.

**The Chair (Mr. Peter Tabuns):** I'm sorry to say that your time is up. We'll go to the next party, the opposition: Mr. Walker.

**Mr. Bill Walker:** Thank you very much. It's a pleasure to speak. I empathize, first and foremost, with the predicament that you found yourself in, the situation you had to deal with, and I share, certainly, that I don't want any other mother or dad or any sibling or friend or family to have to go through that.

I believe Dr. Sher shared with us that currently, there are about 200,000 litres annually produced, and that's not enough. We're still buying it from the States. Either projected demand or the actual reality is that 800,000 to 850,000 units are needed.

I take particular note with your document that you shared with us, that "there have been no problems or issues with these products and the safety regulations in place are considered safe by blood system regulators around the world."

**Ms. Whitney Goulstone:** That's true.

**Mr. Bill Walker:** "Currently, our patients feel safe with their product. We want them to continue in this regard." Your concern number 2 is that "not allowing paid plasma donations in Canada will encourage Canada's overreliance on the US for plasma. We are concerned that only three of some 30 plasma-derived products used by Canadians are manufactured in whole or in part by plasma collected from unpaid donors by CBS and Héma-Québec."

I think what you're saying is, there is an ability to do more here, right in Canada, right with our own product, our own fellow citizens, and why would we not do that? Certainly, some concern—"over the last 20 years the plasma industry has developed very well-documented and effective procedures to collect and process..." So again, you're feeling safe, you're feeling comfortable, and let's base this "on science and ethics rather than history and politics"—I couldn't agree more—and not cut off your patient's life.

When we're talking about this, that's the whole balance we're trying to find: What is the reality of what we can provide? Is there a risk at all to any single Ontarian that they won't have that product when they need it? Again, Dr. Sher said that many of them are life-saving realities. We can't play with something that's a life-saving reality. We need to make sure it's there, not say, "Oh, we wish we would have," or, "We could have,"

or, "We could do better." We need to ensure that we have the balance in place from that risk management strategy.

I'll turn it over to my colleague.

**Mrs. Gila Martow:** I think we all share your concerns, and I think that what has become very clear today is that in as large a country as Canada we can't collect and manufacture just from volunteers. It's just not cost-feasible unless we're going to be flying planes all over the country to collect.

Have you ever felt concern that there wouldn't be product available for you in the future should you need it? Is that something that worries you?

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**Ms. Whitney Goulstone:** Not yet.

**Mrs. Gila Martow:** Not yet?

**Ms. Whitney Goulstone:** Not yet. Relying solely on one country is a little daunting, but, I mean, the US is a large country. It does have enough product for itself. It's supplying a large population, though, as well as supplying the world, so it's a little scary, I think. Overreliance on one country—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Ms. Whitney Goulstone:** —can always have its faults.

**Mrs. Gila Martow:** What I think is also a concern, as I'm doing my research, is that there are these big manufacturing centres. What if there's a problem at one of the manufacturing centres, either some kind of infection or—

**Ms. Whitney Goulstone:** Exactly.

**Mrs. Gila Martow:** Just like we saw in Japan, where there was an earthquake. We need to ensure that we're not putting all our eggs in one basket. I think that it's all about risk management and it's about looking at the big picture here.

**Ms. Whitney Goulstone:** Exactly.

**Mrs. Gila Martow:** Thank you very much for coming in.

**The Chair (Mr. Peter Tabuns):** Your time is up. Madame Gélinas?

**M<sup>me</sup> France Gélinas:** Thank you so much for coming, and thank you for sharing your very personal story with us. So if you were in our shoes, if you had your druthers and you got to make the final decisions, would you say yes today to paying for plasma?

**Ms. Whitney Goulstone:** Yes.

**M<sup>me</sup> France Gélinas:** You would?

**Ms. Whitney Goulstone:** Yes.

**M<sup>me</sup> France Gélinas:** If you were there in the room and you listened to what Dr. Sher had to say about Canadian Blood Services, he left us with the assurance that we meet the needs, we have business deals in place; we deal with Europe and the United States. They are looking at a business model to make us even more robust in meeting the needs, but you still have fears?

**Ms. Whitney Goulstone:** I don't have any fears, no.

**M<sup>me</sup> France Gélinas:** Okay. You don't have any fears, but you don't want to stay with Canadian Blood Services and the volunteer model that we have?

**Ms. Whitney Goulstone:** I'm sorry; I don't think I understand your question completely.

**M<sup>me</sup> France Gélinas:** The question is, we have a volunteer-based model right now—

**Ms. Whitney Goulstone:** Right. I think that both models can coexist side by side.

**M<sup>me</sup> France Gélinas:** And you were there when other people explained to you that there are risks in bringing the side-by-side in a society like ours where we've had the volunteers for a long time. There is a risk. You don't see that risk?

**Ms. Whitney Goulstone:** I think that Dr. Sher agrees with—I didn't hear him saying that there was a risk. Economically, it would cost a lot, but I think most patient organizations think that paid donations are okay.

**M<sup>me</sup> France Gélinas:** And they don't see a risk to the system as a whole?

**Ms. Whitney Goulstone:** I think that, even if there were paid donations, the people who volunteer for blood product would continue to volunteer for blood product.

**M<sup>me</sup> France Gélinas:** Okay. Thank you.

**The Chair (Mr. Peter Tabuns):** Okay. Thank you very much.

**Ms. Whitney Goulstone:** Thank you.

#### ONTARIO HOSPITAL ASSOCIATION

**The Chair (Mr. Peter Tabuns):** Our next presenter, then, is the Ontario Hospital Association. Welcome. If you would introduce yourselves for Hansard. You have five minutes to speak. I'll give you a warning at the one-minute mark.

**Ms. Elizabeth Carlton:** Thank you very much. Good afternoon. My name is Elizabeth Carlton, and I'm vice-president of policy and public affairs at the Ontario Hospital Association. With me is Emily Musing, who is the executive director of pharmacy, clinical risk and quality at the University Health Network.

The OHA is pleased to have the opportunity to provide comments on Bill 21 on behalf of its members. To help inform our position, we consulted with nearly 100 hospital pharmacy professionals, as well as hospital leaders.

As you may know, the hospital has been supportive of Dr. Jake Thiessen's recommendations and the proposed legislation. In particular, we would like to reiterate our support for a number of proposed amendments to the Drug and Pharmacies Regulation Act, or the DPRA, as in many respects they acknowledge the need to tailor the application of the act to hospital pharmacies. Nonetheless, we believe that further clarification is warranted.

I'll now ask Emily to speak to some of those issues.

**Ms. Emily Musing:** Thank you. We'd like to highlight that hospital drug supply chains, and subsequently hospital pharmacies, are already subject to a number of rigorous oversight mechanisms, including Accreditation Canada, the Public Hospitals Act and the Excellent Care for All Act. As well, pharmacists and pharmacy technicians throughout Ontario are regulated by the Ontario College of Pharmacists, or OCP.

The OHA believes that OCP oversight should enhance the existing oversight processes over hospital pharmacies, rather than unnecessarily duplicating the existing mechanisms. Any new standards need to also account for the potential infrastructure costs of compliance. It will be important to consider appropriate timelines for requiring compliance with these new standards, especially where infrastructure upgrades are necessary.

We are committed to supporting the successful implementation of OCP's oversight of hospital pharmacies but we are concerned that, like some components of the DPRA itself, current regulations may be inappropriate for hospitals as they were not developed with hospital pharmacies in mind, but rather were targeted at regulating commercial practices in retail pharmacies. In particular, we are concerned with the broad applications of the general regulation 58/11 under the DPRA to hospital pharmacies. As such, we recommend that there be specific amendments made to explicitly exempt hospital pharmacies from these regulations.

Also, as presently drafted, Bill 21 provides the OCP with the full spectrum of regulation-making powers designated for retail pharmacies. The OHA recommends that Bill 21 be amended to specify that the OCP regulation-making powers are limited to those necessary to set standards for hospital pharmacies, and to inspect and accredit hospital pharmacies. We believe that this specification will allow OCP to set up the appropriate safeguards while at the same time limiting duplication of existing oversight mechanisms and preventing conflicting requirements moving forward.

This new oversight model will have profound implications for hospitals in terms of meeting new standards. The OHA is concerned that without a staged approach to implementation or the inclusion of transition provisions, hospital pharmacies may be in violation of the DPRA if Bill 21 were to be proclaimed immediately upon passage of the bill. As the OCP is currently in the process of developing standards, they will have had neither the opportunity to finalize these standards nor the opportunity to inspect and accredit hospital pharmacies prior to proclamation. As currently drafted, there would be a prohibition on the operation of existing hospital pharmacies without valid certifications of accreditation which could cause them to shut down. Once inspected, hospitals may also need time to update their practices and upgrade their infrastructure.

The OHA recommends that the coming-into-force provisions be more clearly articulated so as to avoid the complications mentioned.

**The Chair (Mr. Peter Tabuns):** You have one minute left.

**Ms. Emily Musing:** An alternative to this recommendation would be to allow hospital pharmacies to operate for a period of time that would permit the OCP to inspect and accredit them, and provide hospitals with a sufficient time frame in which to meet the new standards. This would offer all parties involved the ability to better anticipate how the processes would unfold and create

time frames that would respect the significant amount of work that would be required for implementation. The OHA recommends a period of two years.

**Ms. Elizabeth Carlton:** In closing, we also wish to speak briefly to the information-sharing provisions by regulatory colleges in the act. The OHA has advocated for an increased ability for regulatory colleges to share information with hospitals and we are supportive of this aspect of the legislation. But we do have a number of drafting suggestions for the committee's consideration, which we will be providing by way of our written submission.

The OHA and its member hospitals are pleased to have had the opportunity to speak today and we're pleased to answer any questions.

**The Chair (Mr. Peter Tabuns):** Thank you very much. Questions, to the opposition: Ms. Martow.

**Mrs. Gila Martow:** I just wanted to ask if you were consulted, because you raised some very valid concerns about transition, about increased infrastructure costs. Were you consulted in this aspect of the legislation?

**Ms. Elizabeth Carlton:** We were consulted in the very early stages of the drafting, and I have to say we do appreciate that. I think there were a number of provisions that reflect that nature, the collaborative process that was undertaken. But, as I think you can appreciate, there are still some areas for improvement and some measures that we would feel comforted if they were adopted.

**Mrs. Gila Martow:** And do you feel that the new infrastructure that will be needed and the upgrades—do you feel confident that this will make the supply safer? I know you want to comply with the regulation, but do you see a huge benefit in terms of the cost?

**Ms. Emily Musing:** Perhaps I can speak to that. There are very good standards in place that are available for us to measure ourselves against, which OCP is using. Those are best-practice standards. They're not minimum standards; they're best-practice standards. We, as hospitals, want to reach those best practices. For us to do that, however, it requires increased space; it requires capital funding to make that happen. It takes time, even when there is that commitment, to make it happen.

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Our concern at this point is more that—I think everyone wants to make things as safe as possible for patients. We want to reach that best practice, rather than just even minimum practice. But the question in our minds is, how do we set up a system, a process, that's sustainable so that we can get to that point in a safe and sustainable way?

**Mr. Bill Walker:** It seems that once again, a one-size approach does not fit all, and had they done proper consultation with your industry and really listened, you could have amended and not duplicated.

I took quite particular interest in your concern that if they put this in very expeditiously, you may have to shut down, which to me would perhaps jeopardize patient safety, which I think is one of our prominent concerns that all of us should be concerned with.

I think you've proposed some practical and rational thought processes. How about we come in and look at what we're doing already? Maybe we're meeting all of the criteria and best practices as it is, and we don't need to be overregulated.

**The Chair (Mr. Peter Tabuns):** You have 30 seconds.

**Mr. Bill Walker:** I think you've done really good homework. I look forward to further recommendations from you. I think what we all need to be doing is looking at that rash—"rational," not "rash"; I wanted to clarify to make sure people were listening—that rational, practical approach and we wouldn't have to revisit these things so often. Thank you very much.

**The Chair (Mr. Peter Tabuns):** Thank you. Madame Gélinas?

**M<sup>me</sup> France Gélinas:** Thank you for your presentation. I was one of the lucky MPPs—the diluted chemo drugs—and at no place during our review did we see that hospital accreditation would have saved the day. Even if the College of Pharmacists had accredited every single one of those pharmacy departments, we would still have had the diluted chemo drugs. The two are not related.

Did I miss some place? Is there some place that I have missed, where asking the Ontario College of Pharmacists to accredit you would have saved the day?

**Ms. Elizabeth Carlton:** First and foremost, our members appreciated that what this incident did was highlight, maybe, areas where they could be improved in terms of quality and safety. Whether this is sort of the be-all and the end-all, I think, is another question.

I think there are a series of things that enhance safety. As you heard Emily stating, that is uppermost in our members' minds, their interest to do that and to meet new standards, to ensure that there is the highest level within our system.

**Ms. Emily Musing:** I would say the other thing is, to have the college more involved and engaged in inspections and audits and in setting standards, I think, allows for a province-wide standard approach to how we're setting our expectations for safety. I think that can only be a good thing.

I want to just state that even before all this happened, within the hospitals we've had certification processes for individuals to ensure that they knew what they were doing with IV preparation. We have inspections that we make within the hospitals with regard to our sterile compounding rooms. We take samples that get tested each time when we make product. So we've shared a lot of these best practices with OCPS; we've moved forward so that, hopefully, it can be spread throughout all hospitals and to other sectors as well, as we look forward to what needs to be done to ensure that things are safe for our patients.

**Ms. Elizabeth Carlton:** Just to add to that, in our conversations with the OCP—which, again, have been very collaborative and very open—our interest is in ensuring that there's not duplication, so there's alignment between the various standards and we're not trying to

reinvent the wheel. I think they've heard that message, but we want to ensure that moves forward.

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**M<sup>me</sup> France Gélinas:** As you know, the bill has been time-allocated. You have until noon Wednesday to bring us your recommendations for amendments. Fully understood—

**The Chair (Mr. Peter Tabuns):** Actually, public submissions are until 6 p.m. tomorrow, and your amendments by noon on Wednesday.

**M<sup>me</sup> France Gélinas:** Oh. You have until tomorrow to bring us your amendments.

We brought this so that it would make it safer. If we end up with hospital pharmacies closing, we've done the exact opposite of what we're trying to do. Bring your recommendations—before tomorrow—so that we can meet the government time allocation schedule.

**The Chair (Mr. Peter Tabuns):** Thank you. The government: Ms. McGarry.

**Mrs. Kathryn McGarry:** Thank you very much for your submission. I just wanted to reiterate that we, too, agreed that we needed to get a better understanding and strengthen our cancer care, so we appointed Dr. Jake Thiessen, and he did come forward with recommendations, many of which are in the report. We endorsed all of his recommendations. I know that Bill 21, if passed, would authorize the College of Pharmacists to inspect, license and set standards for hospital pharmacies. That's to do with patient safety as well. I know that as soon as an underdosing error was found in the past, immediate steps were taken to correct it. So thank you very much for the work that you do as well.

I know that you're generally supportive and looking at recommendations. I understand they're probably already written. You did say that you thought you would need two years to bring in some of the recommendations. Can you just identify what would need to be done to bring that in?

**Ms. Emily Musing:** Perhaps I can start. Hospitals already have in place within the strategic plan and capital planning process a whole variety of priorities that have already been put into place and discussed from the front line to managers to their administration to their boards. So if something is identified through this process, then we would need to figure out a way to give sufficient time so that whatever changes are needed, from an infrastructure or capital planning perspective, can actually be embedded into that process, so that we are not just arbitrarily now taking operating dollars from one area to place into this area without having a full assessment about how that then impacts patient care.

That two-year time gap really is to ensure that things are done in a very thoughtful way so that when we say we need to build a new area for sterile compounding, that is done while we're taking into account what other priorities have already been identified in the hospital.

**Mrs. Kathryn McGarry:** Thank you. My colleague has a question.

**The Chair (Mr. Peter Tabuns):** Mr. Fraser.

**Mr. John Fraser:** Thank you very much for your presentation. My question goes to group buying as it relates to hospital pharmacy. I think that group buying is a good thing. We can find cost savings in it. There were concerns raised about transparency in group buying, and I think some of those will be addressed by Bill 8, which is before the Legislature right now. But as an organization, can you speak to the transparency—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. John Fraser:** —any measures you've taken for transparency in terms of group buying?

**Ms. Elizabeth Carlton:** What we observed from Dr. Thiessen's report was that he found that processes could be improved but that their use should not be discouraged. I think our hospitals rely on them in terms of getting what they need, critical supplies, and stretching their dollars. So for obvious reasons, we focused our examination and our submission on the things that were in the bill that really impact our members, and those were the OCP oversight preventions.

**The Chair (Mr. Peter Tabuns):** Thank you very much. Your time is up.

**Ms. Elizabeth Carlton:** Thank you.

#### COLLEGE OF PHYSIOTHERAPISTS OF ONTARIO

**The Chair (Mr. Peter Tabuns):** The next presentation is the College of Physiotherapists of Ontario. When you're seated, if you could introduce yourselves for Hansard. You have five minutes to speak. I'll give you a warning when you have one minute left.

**Mr. Peter Ruttan:** Thank you. Good afternoon. My name is Peter Ruttan. I am a physiotherapist and the president of the College of Physiotherapists of Ontario. I'm also chair of the college's inquiries, complaints and reports committee. I'm joined by Rod Hamilton, associate registrar of policy, who is a staff person at the college.

I'm pleased to join you here today and express my college's support for the objectives of Bill 21. I should begin by pointing out two important things. First, not all of the changes that Bill 21 would make to the Regulated Health Professions Act have an impact on our college. So while we support the whole bill in principle, I will only mention the changes that will have a direct impact on us or our members.

I would like to point out that you have not received a written submission from our college. We submitted our written comments to the government as a member of the Federation of Regulatory Health Colleges of Ontario. Copies of that submission, dated December 1, 2014, and addressed to Dr. Eric Hoskins, Minister of Health and Long-Term Care, have been provided to you.

Our college has a proven track record for being leaders in transparency. By that, I mean that we have made significant efforts to provide to the public as much information as possible about the processes at our college and about our physiotherapists. Bill 21 goes some distance

towards supporting our efforts in this regard but also falls short in some areas.

Sections 10 and 11 of schedule 2 of the bill, additional exceptions to the confidentiality duty, are an example.

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For example, right now, we are not permitted to share information about our investigations of physiotherapists with these members' employers. This means that even if we know that an individual physiotherapist may be incompetent or incapacitated, we can't inform the place where they work. This puts us in a position of knowingly standing by while patients may be at risk.

Bill 21 makes changes that attempt to fix this problem, but it leaves some important things out. The proposed changes will allow colleges to disclose information to hospitals that employ or provide privileges; however, our members work in settings outside of hospitals and often work as contractors. So even with the revisions included in the bill, we would still not be able to disclose information to a long-term-care facility or home care operator about a high-risk physiotherapist. The patients in these settings are among the most vulnerable of all, yet we would remain unable to help protect them in a timely way.

Mandatory reporting, anti-avoidance measures, sections 8 and 17 of schedule 2 of the bill: Another college concern relates to the way the mandatory reporting requirements for employment or privileges can be circumvented. The college believes that employers should be required to make a report to the college whenever a physiotherapist quits or is fired in connection with an investigation. However, at the moment, the proposed changes in the bill will leave the decision about whether to report up to the individual employer.

We think that it would better protect the public if the employer was not required to filter the information in this way. If employers were required to report all such situations to us, we could then investigate and determine whether there is any reason to be concerned. After all, our statute mandate requires us to be experts in investigation as well as guardians of the public interest.

We are aware of situations where physiotherapists have been let go from hospitals, but because of concerns related to employment law issues or their unions, we do not receive a report. We only find out later when these physiotherapists turn up as problems in a new institution.

If employers were held to a high level of transparency and required to make reports in any kind of problematic situation, we could possibly intervene to make certain—

**The Chair (Mr. Peter Tabuns):** One minute left.

**Mr. Peter Ruttan:** —that these physiotherapists got the additional training they needed to ensure the problem was not repeated.

Our proposed amendments: The federation's submission makes detailed suggestions about how to ensure that these small but important barriers to transparency can be addressed. On behalf of the Ontario physiotherapists, I hope you will consider making these amendments to better protect Ontario's public. Thank you.

**The Chair (Mr. Peter Tabuns):** Questions? Madame Gélinas.

**M<sup>me</sup> France Gélinas:** Yes. Thank you so much for coming, Mr. Ruttan, and thank you, Mr. Hamilton. The first question I have is—thank you for your letter dated December 1. If you were here before, you know that you have until tomorrow to give us your recommendations. Are all of the recommendations from the Federation of Health Regulatory Colleges of Ontario supported by your college in the way that they are written there?

**Mr. Peter Ruttan:** Yes, that's correct.

**M<sup>me</sup> France Gélinas:** What would happen if we did not? What would happen if we put those amendments forward and they were defeated? You can take them one at a time. Let's say the regulation about anti-avoidance measures: What do you see happening if we don't make those changes?

**Mr. Rod Hamilton:** As Peter indicated, there's the potential that employers and the people who contract physiotherapists will use their discretion instead of being required to make the reports that we think are necessary. We think that that limits the possibility in some circumstances where we would be aware of people who probably should have been reported. So that discretionary component, we think, is the problem.

**M<sup>me</sup> France Gélinas:** In the language that you have given us, it covers the self-employed, because physiotherapists can be self-employed and become a corporation. So really, the long-term-care home hires the corporation that is—does your language cover this? The physiotherapist is not being employed by the long-term-care home; they are being contracted through a corporation to the long-term-care home.

**Mr. Rod Hamilton:** Our legal counsel suggests that it does capture that.

**M<sup>me</sup> France Gélinas:** It does, eh? To me, it didn't look like it did. Very good.

For the second series of recommendations that you have, what would happen if those amendments were defeated?

**Mr. Rod Hamilton:** If they were defeated?

**M<sup>me</sup> France Gélinas:** Yes.

**Mr. Rod Hamilton:** Again, the concern is simply that we would not receive as many reports as we should, and in those circumstances, the people who are subject to those reports may continue to be able to do things that are inappropriate in their employment situations without us knowing about it.

**M<sup>me</sup> France Gélinas:** Okay, very good. If you want to make any changes, you have until tomorrow. Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you. To the government: Ms. McGarry.

**Mrs. Kathryn McGarry:** Thank you very much. I understand that you do have a series of amendments. If the bill passed now without the amendments, would that allow the College of Physiotherapists to protect the public, the way it stands now?

**Mr. Rod Hamilton:** Our concern is about circumstances over and above the reports that we will get. We

will get reports as a result of the bill's changes. We are concerned that we may miss reports and we feel that is an unfortunate circumstance, where there is an opportunity for us to get additional reports and to be able to deal with them.

**Mrs. Kathryn McGarry:** Okay. So some of the recommendations that you've been looking at, then, if they were to pass now, would that allow you to protect the member when need be as well as the public safety and find that balance?

**Mr. Rod Hamilton:** The member is always subject to the provisions in the bill that provide them with a fair deal in any kind of discussion of their problems. However, we believe that in this circumstance, it's wise to take an opportunity to look at the options that are there to protect the public still further.

**Mrs. Kathryn McGarry:** Okay. If the bill were passed right now with all the recommendations that you've got, again—

**Mr. Rod Hamilton:** We would be very pleased.

**Mrs. Kathryn McGarry:** Yes. It would protect the physiotherapists as well as the public?

**Mr. Rod Hamilton:** We believe it would.

**Mrs. Kathryn McGarry:** How would it impact the physiotherapists, and would you be able to bring those recommendations forward right away or would you need a time between the passage of the bill and rolling out the new regulations for your profession?

**Mr. Rod Hamilton:** To touch on the process briefly, if we become aware, if we receive a report, then the registrar has the responsibility to make a decision as to whether those concerns are at the level to conduct an immediate investigation, and if they are, then we would be able to conduct an investigation on the basis of that information. We would not need a great deal of time. We already conduct those kinds of investigations. It's a matter of the existing registrar's authority to investigate those kinds of concerns.

**Mrs. Kathryn McGarry:** The way it stands right now, then, if there was a problem with one of the members, what is your reporting procedure like right now to, let's say, the institution—I'll just pick a public hospital. What would—

**Mr. Rod Hamilton:** Right now there isn't. That's the problem.

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Mr. Rod Hamilton:** There is no opportunity for us to make reports to the facility. We don't have the authority to disclose information.

**Mrs. Kathryn McGarry:** Would you recommend that you do have the ability to disclose if that particular member would be putting public safety at risk?

**Mr. Rod Hamilton:** We think that would be much safer for patients.

**Mrs. Kathryn McGarry:** Okay. I appreciate that. Thank you very much.

**The Chair (Mr. Peter Tabuns):** Thank you. To the opposition: Mr. Walker.

**Mr. Bill Walker:** Thank you. I note that you also wrote a letter on May 2 to the former bill, Bill 117. The same recommendations applied?

**Mr. Rod Hamilton:** Yes.

**Mr. Bill Walker:** Can you share with us if any of those were accepted by the minister of the day?

**Mr. Rod Hamilton:** I'm afraid that I don't know that because that bill never moved forward, as far as I know.

**Mr. Bill Walker:** Okay. Did you receive feedback? Did you receive a reply to that letter?

**Mr. Rod Hamilton:** The federation actually wrote the letter. We did not ourselves write that letter.

**Mr. Bill Walker:** And are you aware if the federation received a reply from the minister at that time?

**Mr. Rod Hamilton:** I am not aware that they did.

**Mr. Bill Walker:** Thank you very much. It seems one of the first points that you made—there is a period currently of 150 days, and this will now extend the process if it actually becomes legislation. Is there any evidence suggesting the current timeline does not work sufficiently?

**Mr. Rod Hamilton:** I think that if you looked at the colleges as a whole, some colleges do find it challenging, and again this letter is from the colleges as a whole. I think some colleges do find it challenging to meet the statutory timelines because of the intervals that are required by the statute.

**Mr. Bill Walker:** So you're in favour of extending it?

**Mr. Rod Hamilton:** I think that, yes, we are.

**Mr. Bill Walker:** Okay, thank you. I just wanted to clarify.

The other point in here is that a lot of the mandatory reporting and anti-avoidance measures you've referenced and a lot of the provisions rely on subjective belief of the hospital administrator rather than also relying on objective events. Obviously that's very discerning. If we're leaving this up to interpretation, one of the things that I think we should all be striving for is to ensure that there is black and white in our regulations so it's not open to interpretation. Then we don't have to go through a lot of frivolous exercise to go back and forth of he said, she said, my interpretation. I certainly value that input and your recommendation for that item.

The other one you talk about is in relation to exceptions 36(1)(d.1) and 36(1)(d.2) that directly permit colleges to disclose otherwise confidential information to public hospitals that employ or provide privilege to a member of a college.

**1550**

Why do you believe or can you just share with me a little bit why this would not be consistent? Why would they not stick with the exact same language they would use in other regulations?

**Mr. Rod Hamilton:** I'm sorry, I don't quite understand your question.

**Mr. Bill Walker:** You're saying you are concerned that those new exemptions permit colleges to disclose otherwise. Why would they not use—I mean, there must be—

**Mr. Rod Hamilton:** We're not concerned about the implementation of the new exemptions. We're concerned that they don't quite go far enough in terms of capturing other facilities beyond hospitals themselves.

**Mr. Bill Walker:** Okay. Thank you for the point of clarification.

**The Chair (Mr. Peter Tabuns):** Thirty seconds remaining.

**Mrs. Gila Martow:** What centres are you concerned about it not covering? Seniors' centres or—

**Mr. Rod Hamilton:** For example, in physiotherapy, long-term-care facilities and long-term-care providers who work in the community wouldn't be covered by the existing requirements.

**Mrs. Gila Martow:** Okay. Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you very much.

#### NETWORK OF RARE BLOOD DISORDER ORGANIZATIONS

**The Chair (Mr. Peter Tabuns):** Our next presenter, then: Network of Rare Blood Disorder Organizations. Welcome, sir.

**Dr. Tom Alloway:** Thank you for inviting me.

**The Chair (Mr. Peter Tabuns):** A pleasure. If you could introduce yourself for Hansard, you'll have five minutes to speak. I'll warn you when you have a minute left.

**Dr. Tom Alloway:** I'm Tom Alloway. I'm the spokesperson for the Network of Rare Blood Disorder Organizations for the purpose of coming here today.

The Network of Rare Blood Disorder Organizations is a coalition of organizations that represent patients who are living with several different blood disorders. A list of those organizations is in the information I handed to you. These organizations seek to develop and advocate for best practices in health care delivery for people with blood disorders, many of which require treatment with blood, blood products or their alternatives. The member organizations believe that their voices can be more effectively heard if they coordinate their work and advocacy to secure and maintain patient access to the kind of medical care that empowers patients to live lives that are as normal as possible.

At the present time, thousands of Canadians with chronic hematologic and immune-system disorders rely on plasma-derived products to maintain their health and keep them alive, and most of the plasma used to manufacture these products comes from paid donors in the United States. A list of the plasma-derived medical products that are from paid donors is in your handout. Of the 30 plasma-derived products distributed by Canadian Blood Services, only one is produced wholly from unpaid donors; 27 are produced solely from plasma from paid US donors; two—immune globulin and albumin—are produced from a combination of both sources. Some 70% of the plasma required for these two products is produced from compensated US donors.

We submit that paying Ontarians is no more or less ethical than paying Americans, as we do today for most of the plasma-derived products used in Ontario and across Canada.

The members of the NRBDO have paid close attention to blood safety and supply issues over the last decade. In 2010 and 2011, the NRBDO endorsed the Dublin Consensus Statements, which are attached, which recognized the use of payment for blood and plasma donation and acknowledged valid roles for both paid and unpaid donation systems. In 2014, the member organizations of the NRBDO supported a background document and a policy developed by the Canadian Hemophilia Society—those are also attached—that similarly acknowledge the role of both paid and unpaid donation systems for producing an adequate supply of plasma for the manufacture of medicinal products. The NRBDO, therefore, believes that Bill 21, by forbidding payment for plasma donation, fails to promote the best interests of patients who need plasma-derived medical products.

Decisions on licensing individual plasma collection centres are the responsibility of Health Canada, based on the strictest industry and regulatory standards. While the collection and provision of fresh blood components is a national problem, the manufacture and provision of plasma-derived medicinal products is a global issue. Decisions on such an issue must be made based on up-to-date safety and supply data, not misconceptions that date from the 1970s and 1980s.

Those who oppose paying donors do so, we think, mainly on the basis of two arguments. First, blood from paid donors was an important source of products contaminated with HIV and other viruses and led to the tainted blood scandal of the 1980s, and second, payment for blood donation might endanger the viability of our current system of unpaid donations.

**The Chair (Mr. Peter Tabuns):** One minute left.

**Dr. Tom Alloway:** With respect to the first argument, we note that a number of important changes have occurred, and the safety issues that were raised by Justice Krever are, to a large extent, no longer applicable.

With respect to the second argument, we note that implementation of a paid-donor system in the United States and other countries has not prevented the maintenance of unpaid donor systems. We don't think it would interfere with CBS's unpaid-donor system in Canada, but it would have to be closely watched if a paid-donor system was introduced in Canada.

For the reasons outlined, the NRBDO opposes, I should say, those portions of Bill 21 that forbid the payment of donors in Ontario. Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you very much, sir. Mr. Fraser.

**Mr. John Fraser:** Thank you very much, Mr. Chair, and thank you, Mr. Alloway, for your presentation. My first question relates to this: One of the recommendations from the Krever commission was a single operator for Canada's blood system, as well as a voluntary blood system. Can you comment on whether you support a single operator for Canada's blood system?

**Dr. Tom Alloway:** A single operator, we support. But a single operator would not be, in our estimation, compromised if we also had a paid-donor system that produced products that that single operator then purchased, as they now purchase the products from the United States.

**Mr. John Fraser:** Okay. We heard earlier today from Mr. Sher from Canadian Blood Services that there are no issues with regard to the supply of plasma protein products. We also heard from Mr. Krause from Therapure that the US is in a surplus of plasma protein. We also heard from Mr. Sher about the situation in the UK where their blood system, which was unique to the UK, became compromised because of a blood-borne disease and put them in a position of from self-sufficiency to not self-sufficiency.

My question relates directly to whether you think the right thing to do is to have mixed suppliers in a blood system that is managed by a single operator.

**Dr. Tom Alloway:** The short answer to that is yes.

**Mr. John Fraser:** All right. Thank you very much. Anybody else have any questions?

**The Chair (Mr. Peter Tabuns):** Mrs. McGarry?

**Mrs. Kathryn McGarry:** I've been a nurse for many, many years and have always needed to give transfusions and plasma products in the course of my work, both in pediatrics, emergency and intensive care units. None of the times that I needed those products were we short. It may be that we needed to wait a little longer for some of the blood that was of a special type or antibodies, but we've never had a situation that I've been working in that there was a shortage.

The Krever commission was very clear that we go to one company or one agency that does all the blood supply in Canada. I'm just wondering why you think it's still a good idea to have a second paid agency.

**Dr. Tom Alloway:** A couple of reasons: One of them is, we are already using a lot of products from paid donors in the United States and—

**The Chair (Mr. Peter Tabuns):** Thirty seconds remaining.

**Dr. Tom Alloway:** —very frankly, we don't see why we should be paying Americans to donate blood when we could be paying Canadians.

The second thing is, we don't think that the CBS system of unpaid donation is going to be seriously compromised by having a mixed system. We certainly are not proposing that a second supplier of products to people be introduced. CBS should continue—

**The Chair (Mr. Peter Tabuns):** Thank you, Mr. Alloway. We need to go to the opposition: Ms. Martow.

**Mrs. Gila Martow:** Thank you very much for your presentation. I like the fact that you're hammering home the hypocrisy that we are purchasing some products from the United States, where they are paying people. I found it very interesting that you said that you don't think that—

**Dr. Tom Alloway:** I don't necessarily think it's hypocrisy; more like sanctimoniousness. Sanctimoniousness rather than hypocrisy—we are practising what we preach.

**Mrs. Gila Martow:** Well, in a way we are and in a way, we aren't. When you said that you don't believe that having the two systems existing side by side would—what I'm hearing from some people in the room is that, somehow, if we start to pay people for plasma product specifically, all of a sudden people will stop donating. That's like suggesting that when the government steps in with social services agencies, charities will not be feasible anymore, and we know that's not true.

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Do you feel that there's a lack of public awareness of the difference between donating blood and then donating for plasma purposes?

**Dr. Tom Alloway:** Yes, I think there is serious ignorance about that. There's a lot of ignorance about the blood system, but I think that's a very serious one, yes.

**Mrs. Gila Martow:** Yes, that's what I'm feeling from all of this: that it's really two very separate issues that are being thrown in together.

**Dr. Tom Alloway:** Yes.

**Mr. Bill Walker:** Thank you very much. I just want to expand a little bit. You referenced the Dublin Consensus Statements. For those who may be listening at home or reading this later, I just want to clarify that there were some pretty interesting people at that conference: the International Federation of Blood Donor Organizations, the National Blood Authority of Australia, the International Plasma Fractionation Association and the International Society of Blood Transfusion. They're all suggesting that there is no evidence that proves that paid or unpaid will have any harm to our voluntary system.

**Dr. Tom Alloway:** That's right, sir.

**Mr. Bill Walker:** So it really is interesting. "The NRBDO, therefore, believes that Bill 21, by forbidding payment for plasma donation, fails to promote the best interests of patients"—whom we're all here to serve—"who need plasma-derived medical products."

We're hearing that fairly consistently. Dr. Sher, from Canadian Blood Services, certainly pointed that out. I think there is an ability for them to coexist. My colleague Mrs. McGarry just made a reference that, in her experience, it's never happened that they haven't had that blood. I'm certain that she doesn't want to be the person on the floor the first time that ever happens. Why would we not look at regulation that's going to allow us to be prepared—

**The Chair (Mr. Peter Tabuns):** Thirty seconds

**Mr. Bill Walker:** —for the eventuality? We know that there's looming concern coming. We know that the trend is going upward of the amount that we need. We have to pay at times now to get it through the States. So I support your opposition to this bill.

**Dr. Tom Alloway:** Thank you.

**The Chair (Mr. Peter Tabuns):** Madame Gélinas.

**M<sup>me</sup> France Gélinas:** Thank you for coming to Queen's Park. My first question: What is the relationship of your organization with Canadian Blood Services, if any?

**Dr. Tom Alloway:** Well, Canadian Blood Services operates liaison committees. Many of the organizations that belong to NRBDO send representatives to the national and regional liaison committees of CBS. I'm a member of the national liaison committee. I'm certainly a supporter of CBS. I don't think we are proposing to harm CBS in any way, or, for that matter, Héma-Québec.

**M<sup>me</sup> France Gélinas:** Thank you. You were here earlier on when the CEO of Canadian Blood Services was telling us that they're looking at new business models moving forward to be more self-sufficient. Are you confident that Canadian Blood Services can carry this out?

**Dr. Tom Alloway:** We don't know what that new business model is. I will be very interested to see it. I can't comment on a model I've never seen.

**M<sup>me</sup> France Gélinas:** But from the relationship that you have with Canadian Blood Services, do you find them competent? Do you find that they need to do things better?

**Dr. Tom Alloway:** Oh, yes. Yes, absolutely. They are among the good guys of this world for sure.

**M<sup>me</sup> France Gélinas:** Good to know. Is there a list of naughty guys on the other side?

**Dr. Tom Alloway:** Dr. Sher, I'm sure, is happy to hear.

**The Chair (Mr. Peter Tabuns):** He was very happy to hear.

**M<sup>me</sup> France Gélinas:** So from what you're telling me, if we give Canadian Blood Services the time to put forward a new business model that I haven't seen either—I told them that I'm looking forward to seeing it. But your experience working with them is that they could be competent moving forward with a new business model that would change things and change the number of donations, the security—and I would throw in supportability—

**Dr. Tom Alloway:** Frankly, I would be surprised if they will be able to collect enough blood and blood product and plasma through the voluntary system to meet the complete plasma needs for manufacturing products in Canada, in a cost-effective way.

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Dr. Tom Alloway:** Maybe they will. We'll see.

**M<sup>me</sup> France Gélinas:** Do you know of a company that would be able to do that?

**Dr. Tom Alloway:** Well, there certainly was a company that was proposing to set up some paid plasma centres in Ontario, but I gather from what I read in the papers that they've decided to take their business elsewhere.

**M<sup>me</sup> France Gélinas:** What did that company have that CBS does not have?

**The Chair (Mr. Peter Tabuns):** I'm afraid you may never get to answer that question in this format because your time—

**Dr. Tom Alloway:** Yes, I think you're right. I wouldn't know.

**The Chair (Mr. Peter Tabuns):** We have to go to the next presenter. Thank you very much, Mr. Alloway.

**Dr. Tom Alloway:** Thank you.

MR. GEOFF KETTEL

**The Chair (Mr. Peter Tabuns):** Geoff Kettel: Geoff, come on down. If you would introduce yourself for Hansard. You have five minutes. I will give you a one-minute warning.

**Mr. Geoff Kettel:** Greetings from Don Valley West, Peter.

**The Chair (Mr. Peter Tabuns):** Thank you very much, Geoff. Good to see you here.

**Mr. Geoff Kettel:** My name is Geoff Kettel. It's good to be here, Mr. Tabuns—Chair—and members of the committee. I am honoured to speak in support of the Voluntary Blood Donations Act under Bill 21—just that piece of the whole thing.

Why am I here? What's my background on this file? I'm not a consumer; I'm a donor. I am a regular blood donor, having donated 166 units to date over the past 48 years.

But I also have some experience in blood administration. I am a former senior manager in the Ontario public service with over 30 years' service, retiring from the Ministry of Health and Long-Term Care in 2008.

From 1998 to 2002, I was responsible for liaison with CBS. I was responsible for Ontario's blood and hepatitis C policy and oversaw a budget of about \$1 billion. I was the Ontario government representative at the Canadian Blood Services in the period immediately following its establishment as a provincial/territorial funded organization with a mandate to manage blood donation, processing and distribution in Canada, except in Quebec.

I am therefore very aware of the tainted blood crisis. People around the ministry at that time were involved. I'm aware of the personal suffering of so many families touched by this preventable crisis. I agree with the thousands of victims that this cannot be allowed to happen again.

Why am I in support of Bill 21? I feel strongly that nothing should be allowed to undermine the viability of Canada's voluntary blood supply. The operation of for-profit plasma clinics in Ontario and payment for blood donation risks affecting the voluntary donor base. In addition, it clearly runs counter to the key findings and recommendations of the Krever report, which was written in response to the tainted blood crisis.

In his report, Justice Horace Krever was very specific in outlining the key principles by which the Canadian blood supply should be managed:

—blood is a public resource;

—donors should not be paid;

—sufficient blood should be collected so that importation from other countries is unnecessary;

—access to blood and blood products should be free and universal; and

—the safety of the blood supply is paramount.

I believe it is critical that you as legislators do your utmost to uphold Ontario's precautionary-principle-based

policy in this area and take all necessary and appropriate legislative and policy steps, including not granting licences for for-profit plasma clinics, to ensure that the long-term viability and security of Ontario's blood supply is safeguarded for future generations.

I would be happy to address any questions.

**The Chair (Mr. Peter Tabuns):** Thank you very much. The questions go first to the opposition. Mr. Walker.

**Mr. Bill Walker:** Thank you for your submission. Again, I relate back to the Dublin commission that the last speaker provided information on. Can you provide any evidence-based research to prove a paid system will jeopardize the voluntary system?

**Mr. Geoff Kettel:** The whole structure of the blood collection system is based on trying to minimize risks. That's why there's an exhaustive system of questions. You come in and your identity is checked. You go through an exhaustive list of very personal, intimidating questions, and then you go through that with the nurse. The whole thing is around trying to protect the supply.

I was walking around downtown a few months ago on Adelaide Street. Canadian Plasma Resources was right there next to Sherbourne Street. I was horrified. It's pretty obvious what the game is here. Precaution means that you don't try to collect blood from those who are most at risk of having issues.

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**Mr. Bill Walker:** So I'm asking you again: Is there any evidence, other than your own personal conjecture, that this will result in a program that will be jeopardized?

**Mr. Geoff Kettel:** What I'm talking about is, we should, as government, be operating on a precautionary-based principle. Sure, I'm not the expert. Bring the experts into the room. My background is in public policy, and I'm telling you that from a public policy perspective, we should be operating from a precautionary-based principle.

**Mr. Bill Walker:** Canadian Blood Services' Dr. Sher suggested that he believes two systems can coexist and that will serve the people best. We certainly have the Dublin commission. We have a group, the Canadian Immunodeficiencies Patient Organization, that has strongly suggested they can coexist. So from a public policy perspective, I think what we're hearing today is that we need both, to be able to continually serve the best interests of our patients and our people across this great province.

I guess I'd want to ask you—you're very passionate and I respect that fully. As a consumer, would you decline blood or medicine that has utilized paid plasma protein donations to create that—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Geoff Kettel:** I'm not a consumer.

**Mr. Bill Walker:** Well, you may be. Okay, I'll go the other way. If a loved one has dementia, for which we're using blood protein plasma now to try to create a cure, would you turn that down?

**Mr. Geoff Kettel:** No, I'll go back to your original point. The point is, I agree: It is, frankly, an unbalanced

system. I think I heard Dr. Sher say it was still 30% based on source and blood plasma. But I also heard him say that he was willing to entertain a business case to raise that percentage, to have plasma clinics which are stand-alone clinics—

**The Chair (Mr. Peter Tabuns):** Your three minutes are up, I'm afraid. We go to the next: Madame Gélinas?

**Mr. Geoff Kettel:** —and clearly, that's the way we should be going. It may never reach 100%, but we heard the point about—

**The Chair (Mr. Peter Tabuns):** Geoff, I'm afraid your time was up for that question. We have to go to the next question.

**M<sup>me</sup> France Gélinas:** It goes in three-minute blocks. My first question to you is, you were in a pretty interesting position to look at the relationship between the Ontario government and Canadian Blood Services. Would you say, now that you don't work for them anymore, that Ontario is getting value for money for the \$1 billion or so that we invest in Canadian Blood Services?

**Mr. Geoff Kettel:** I can't comment on value for money. The comment before was that these are the good guys; I would certainly agree with that. I've always had high admiration for Canadian Blood Services, ever since I started working with them.

**M<sup>me</sup> France Gélinas:** Earlier in the day, I talked about some of the collection centres that had closed, and some of the changes. Were those things that you were aware of and that you supported at the time?

**Mr. Geoff Kettel:** They're very recent. I believe the Thunder Bay one was very recent. I can't recall now the details, but there was some experimentation. I certainly hope that we can go back and increase the number of plasmapheresis clinics, stand-alone or as part of a regular whole-blood system.

I read an article in the New York Times a couple of months ago that said that the need for whole blood is actually decreasing, because of keyhole surgery and improvements in the surgery system. So maybe we need a more complex blood system: We already have platelets and whole blood, and let's expand in the plasma area.

**M<sup>me</sup> France Gélinas:** You've worked in hepatitis C policy and blood. From all those years of working, have you ever come up to someone who can guarantee you that our blood system is going to be safe forever?

**Mr. Geoff Kettel:** No, clearly not.

**M<sup>me</sup> France Gélinas:** So how do you ensure safety? How do you build safety?

**Mr. Geoff Kettel:** As I said before, you build safety based on the precautionary principle, by starting off with as clean a person as possible, and then by going through the stages of analysis. Then, of course, you have the mechanical systems—

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Mr. Geoff Kettel:** —of the actual process itself, the fractionation and so on, and the testing of the blood.

**M<sup>me</sup> France Gélinas:** Did Ontario ever consider having some of this mechanical fractionation further here

in Ontario, or will we forever send it to the States and to Europe?

**Mr. Geoff Kettel:** That question has been raised on many occasions. I believe that CBS has always responded that it wasn't practical. Clearly, from a made-in-Ontario, made-in-Canada position, we want to see that.

**The Chair (Mr. Peter Tabuns):** I'm afraid to say your three minutes with this questioner have ended, and I go to the next. The government: Mr. Anderson.

**Mr. Granville Anderson:** Thank you, Mr. Kettel, for coming forward and for your support and ongoing advocacy on this issue. I can hear from the passion in your voice that you are very, very committed to this. I wish more people would be like you.

You have been a champion of voluntary blood donation. In your opinion, what is the value of having a single national body responsible for blood collection in Canada?

**Mr. Geoff Kettel:** What Canada did back in the 1990s was absolutely appropriate and the right thing.

**Mr. Granville Anderson:** Can you explain to us why it is so important to safeguard the integrity of the voluntary blood donation system in Canada and why this legislation is so important to pass quickly?

**Mr. Geoff Kettel:** I think I've kind of already answered that. I think it's the precautionary principle that applies here. We want to increase the use of blood plasma from source and avoid the use of plasma which is derived from a payment system.

**Mr. Granville Anderson:** I believe you've answered this somehow: Why is the passage of Bill 21 so important to you? I know you have elaborated considerably on this, but I know you're speaking from a relative position of the safety of the blood.

**Mr. Geoff Kettel:** Frankly, there has been a lot of ambiguity. As I said, during the summer, walking downtown, I was quite surprised to see this clinic. I investigated and found out that there was this move afoot. In fact, I wrote to my MPP, who is the Premier, and said that I had concerns about this and would hope to see movement on this file. I'm very pleased to see that the legislation was reintroduced, and I do hope it's passed with proper review. But I would like to see it passed as soon as possible.

**Mr. Granville Anderson:** I believe my colleague, Ms. McGarry, has a follow-up question for you.

**Mrs. Kathryn McGarry:** As a nurse in the old days, 30 years ago, before universal precautions came in, we as nurses were also a little afraid of what our practice used to be like in terms of giving and administering possibly contaminated blood products.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mrs. Kathryn McGarry:** The safety of not only the staff but also the patients was certainly of utmost value to us, looking back. I had a child who had received blood products there.

I just want you to comment again about the source and the concern that you had with this clinic next door to the Sherbourne Street area.

**The Chair (Mr. Peter Tabuns):** I'm sorry to say this, but you've hit your 30 seconds.

Geoff, thank you very much; good to have you here today.

**Mr. Geoff Kettel:** Thanks, Peter.

#### MEDAVAIL TECHNOLOGIES INC.

**The Chair (Mr. Peter Tabuns):** Our next presenter: MedAvail Technologies Inc. Sir, if you would introduce yourself. You will have five minutes to speak, and then we will have three minutes, in rotation, with each party for questions.

**Mr. Sunny Lalli:** I'm Sunny Lalli. I am the director of pharmacy and regulatory affairs at MedAvail Technologies.

Mr. Chairman, members of the Standing Committee on Social Policy, good afternoon, everyone. My name is Sunny Lalli. I am the director of pharmacy and regulatory affairs for MedAvail Technologies Inc. I am also a member of the College of Pharmacists of Ontario. I would like to take this opportunity to thank the committee for the opportunity to comment today on Bill 21, the Safeguarding Health Care Integrity Act, 2014.

MedAvail Technologies is an Ontario-based privately funded health care technology solution provider that is commercializing a patient-facing, pharmacist-controlled automated remote dispensing system that can be deployed by any pharmacy in multiple patient care scenarios both in the province of Ontario and elsewhere. MedAvail is headquartered in Mississauga, Ontario, and currently employs over 100 Ontarians in its Mississauga headquarters. We also have a smaller team in the US.

MedAvail's patient-facing automated pharmacy system allows a patient to connect live via a two-way audio-video connection to a pharmacist who will review the patient's prescription and use their judgment and accountability to dispense medications directly to the patient at the point of prescribing—think hospital or doctor's clinic—or various other deployment scenarios such as northern Ontario and also underserved communities closer to home. We could service the homeless. We could service community health centres, subsidized housing, shelters or retirement homes—anywhere access to a trained professional pharmacist can improve the outcomes for people.

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In 2010, MedAvail's predecessor, PCAS, Patient Care Automation Services, worked closely with the Ministry of Health and Long-Term Care in helping to shape the current regulations under part IV of the general regulation to the Drug and Pharmacies Regulation Act that governs remote dispensing locations today. The current regulations prohibit the dispensing of narcotic or controlled medications from a remote dispensing location, which is inconsistent with the desire of the government to see the widest deployment of remote dispensing locations across the province where appropriate security is in place.

MedAvail believes that this remote dispensing solution is key to providing timely and expanded access to pharmacy services, which will lead to increased utilization of pharmacy and ultimately better health outcomes for patients, resulting in lower costs to the health care system overall.

I'd now like to comment on the aspect of how the proposed amendments to the Drug and Pharmacies Regulation Act that are in schedule 2 of the bill have the potential to impact adversely the deployment of a remote dispensing solution offered by MedAvail or other providers of automated pharmacy systems.

To begin with, MedAvail supports the objective of bringing unified oversight of hospital, health and custodial institutions, and community pharmacy practice under the Ontario College of Pharmacists. As a member of the college, I have first-hand experience with the high standards that the college has established for the practice of pharmacy in Ontario. In my experience as director of pharmacy and regulatory affairs for MedAvail, I have found the college to be helpful and responsive when I have had questions regarding current requirements for remote dispensing locations or have needed to discuss matters with them.

However, we are here this afternoon to draw your attention to an issue that will need to be addressed by way of legislative amendment or regulation changes once the proposed amendments in Bill 21 of the DPRA are passed into law. Currently, as you know, pharmacy practice in hospital, health and custodial institutions is exempt from the application of certain provisions of the DPRA and therefore not subject to oversight by the college. As a result, the current DPRA regulations that govern remote dispensing locations do not currently apply to pharmacy practice in hospital, health and custodial institutions.

Once Bill 21 is passed into law, the regulations regarding remote dispensing will also apply to pharmacy practice in hospital, health and custodial institutions, including the prohibition against dispensing narcotics and controlled medications from a remote dispensing location.

While a prohibition against the dispensing of narcotics and controlled medications from a remote dispensing location outside of a hospital, health or custodial institution is perhaps justified by security and other related concerns, there's no such rationale for extending this prohibition to remote dispensing locations in hospitals—for example, emergency rooms or surgical sites—

**The Chair (Mr. Peter Tabuns):** You have one minute left.

**Mr. Sunny Lalli:** Right—for example, emergency rooms or surgical sites, where the use of narcotics or controlled medications is an essential requirement of care.

I'd also like to point out that similar remote dispensing technologies, such as the MedCenter, have been used to dispense narcotics and controlled substances to patients in emergency rooms and an orthopedic surgery site for close to three years without issue or error.

MedAvail is here today to draw the attention of the committee and seek their support in the company's efforts to ensure that either legislatively or ultimately by way of regulation change, remote dispensing locations in hospitals continue to be able to dispense narcotic and controlled medications while still meeting all of the requirements that are currently in place for community pharmacies, such as the presentation of identification.

MedAvail looks forward to continuing to work with the Ministry of Health and Long-Term Care, the OCP and the Legislature as Bill 21 moves forward. Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you. We go to Madame Gélinas.

**M<sup>me</sup> France Gélinas:** I take it you had a look at Bill 21. Did you see any opportunity in Bill 21 to bring such changes forward?

**Mr. Sunny Lalli:** Our current concern is that the regulations would apply, similar to hospital pharmacies and similar to the concerns that the OHA had: that the community regulation, 58/11, would apply to all hospital, health and custodial institutions as well. Our concern there was that, in the 58/11 rules, there isn't an opportunity to dispense narcotic and controlled medications to patients who need it. In particular, we're concerned about that specifically being applied to remote dispensing locations in controlled and secure environments like a hospital, health or custodial institution.

**M<sup>me</sup> France Gélinas:** Okay. So, in Bill 21, the only reference to pharmacy or dispensing has to do with: They will now be subject to the College of Pharmacists regulations. Is there a link between what Bill 21 is trying to achieve—will it have an impact on your dispensing machine?

**Mr. Sunny Lalli:** Yes, it certainly will. In the Ontario College of Pharmacists regulation 58/11, which governs community pharmacy, there is a prohibition on dispensing narcotic and controlled substances from a remote dispensing location. So our argument is that because we were operating in hospitals or there were remote dispensing systems in hospitals before, dispensing narcotics to patients safely and effectively and in a controlled manner, that prohibition not be extended to hospital, health and custodial institutions. So it's specifically stated, yes.

**M<sup>me</sup> France Gélinas:** So you're afraid that a practice that is taking place in Ontario right now in a safe way is going to have to cease and desist if we pass Bill 21?

**Mr. Sunny Lalli:** That is a concern of ours.

**M<sup>me</sup> France Gélinas:** What would need to be amended in the bill in order for this not to happen?

**Mr. Sunny Lalli:** We could provide our specific amendments by tomorrow at 6 p.m., as was clarified earlier, but it would specifically be about an amendment saying it does not apply in a hospital, health or custodial institution. It's a specific part of the regulation that states that narcotic and controlled substances cannot be dispensed at a remote dispensing location.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**M<sup>me</sup> France Gélinas:** You said hospitals. What are the other two?

**Mr. Sunny Lalli:** Health or custodial institutions.

**M<sup>me</sup> France Gélinas:** What are those?

**Mr. Sunny Lalli:** Think of a community care centre, a long-term health care centre, centres like that, government-run.

**M<sup>me</sup> France Gélinas:** Okay. I would have issues with any centres that do not operate 24/7; I mean, a nurse practitioner-led clinic or nursing station and those kinds don't have security 24/7—

**The Chair (Mr. Peter Tabuns):** Your time is up, I'm afraid.

**M<sup>me</sup> France Gélinas:** Okay.

**The Chair (Mr. John Fraser):** To the government. Mr. Fraser.

**Mr. John Fraser:** Thank you very much for your presentation. Just in the way of background, how many locations do you have in terms of—

**Mr. Sunny Lalli:** Currently, MedAvail is a technology company. Our predecessor, PCAS Patient Care Automation Services, had about 16 sites out in the community, and they had a few in hospital emergency rooms as well as a surgical centre. Those systems were taken out of the market, and then MedAvail basically formed and took over the IP and all the assets of PCAS Patient Care Automation Services. They are now looking to deploy in Ontario with pharmacy partners.

**Mr. John Fraser:** Okay. That's great. I can see the remote applications and also the concerns with narcotics in those and that security is a fairly significant and serious concern. Do you think that the Ontario College of Pharmacists should be regulating hospital pharmacies?

**Mr. Sunny Lalli:** Just as a general statement, and not specifically talking about—

**Mr. John Fraser:** Yes.

**Mr. Sunny Lalli:** As we said in the statement, we are really supportive of the college and their oversight. I've worked closely with them in terms of the deployment of the remote dispensing locations, and I find them to be very fair and very even-handed. I believe I do agree with the OCP having oversight over hospital pharmacies. We just see this as an unintended consequence of the regulation. We did dispense narcotics and controlled medications to patients who needed them directly in the locations where they needed them in a timely manner.

**Mr. John Fraser:** Now, this is something that can be done by regulation. So the Ontario College of Pharmacists will be responsible for bringing regulations directly related to hospital pharmacies. Have you had any discussions with them? Have you brought forward this concern directly to the OCP?

**Mr. Sunny Lalli:** We plan to do that. We were working with members of the Legislature, and as soon as we're done with that, we will be speaking to the Ontario College of Pharmacists as well.

**Mr. John Fraser:** Thank you very much.

**The Chair (Mr. Peter Tabuns):** Other questions from the government? Mrs. McGarry?

**Mrs. Kathryn McGarry:** Just a quick question regarding part of—I think it's schedule 2. Just looking at

the different reporting mechanisms that we're looking at from both the regulated health colleges and some of the public institutions, such as hospitals, do you feel that increased oversight would assist in protecting public safety?

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Sunny Lalli:** I certainly do. I think the key is communication. The key is being very, very open in the way it's implemented with respect to the specific remote dispensing locations as well. I absolutely think that oversight is important. I absolutely think that working in a regulated environment is key, but I also wanted to raise concerns that our focus and the entire focus of remote dispensing technology—

**The Chair (Mr. Peter Tabuns):** Thank you. Your three minutes with the government are finished.

**Mr. Sunny Lalli:** Sure.

**The Chair (Mr. Peter Tabuns):** We'll go to the opposition.

**1630**

**Mrs. Gila Martow:** Thank you. I hope that what you're saying is that you have been consulted on possible problems. Is that what you said? Have you been speaking to the government about your concerns?

**Mr. Sunny Lalli:** We've raised our concerns. Have we specifically been approached? No, but we have done the approaching.

**Mrs. Gila Martow:** Okay, great. You keep bringing up "remote," and I think it's hard for us, when we're sitting here in downtown Toronto, to realize how spread out this province is and how difficult it is to offer perfect service everywhere in the far corners. So it becomes a balance, a little bit, and I think that's the challenge.

What do you sort of see as amendments that would have to take place for you to feel comfortable?

**Mr. Sunny Lalli:** We are very comfortable with the way the college regulates the remote dispensing locations today. As I was alluding to earlier, there was a specific amendment that prohibits the dispensing of narcotic and controlled medications in community settings, for example. But, in a hospital, health or custodial institution—a hospital, for example—I would like those sites to be able to dispense narcotic and controlled medications. It's very simple.

We do talk about access being a remote issue only, but there are populations closer to home. Think after-hours; think stigmatized populations. Access is an issue that's not limited to geography, and I just want to raise that as well.

**Mrs. Gila Martow:** Okay. I agree that access is very important and it isn't just geography. You're absolutely correct.

**Mr. Sunny Lalli:** Thank you.

**Mr. Bill Walker:** I don't think you really have to go to northern Ontario, necessarily, to see the concerns that would be there. In the great riding of Bruce-Grey-Owen Sound, which is only a couple of hours north of Toronto, we've already had two snow days that closed roads. Some of this would allow those patients to receive their

meds in a timely, convenient manner. I certainly applaud you for that, and I find it interesting that we currently prohibit that. We need to move forward.

The other question I wanted to ask: Are you able to share with us any other type of jurisdiction, whether it be in Canada or the States or across the world, that has this type of technology that's being used currently?

**Mr. Sunny Lalli:** Absolutely. Our specific technology is deployed in Illinois right now. In the US, there are some states that have regulations friendly to remote dispensing. It's typically regulated as telepharmacy. In British Columbia they do have telepharmacy rules on the books—nothing that allows an automated pharmacy system yet, but we're hoping that the British Columbia government will come around, or the college.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Bill Walker:** Well, I'd like to suggest to you that I'd prefer that Ontario be the first to do that, so that we're actually leading the curve rather than always chasing another province that can deem it to be good enough for their residents.

**Mr. Sunny Lalli:** Absolutely, and they have been the leader in Ontario and certainly in North America, in a lot of ways. There are other jurisdictions in the US that by waiver or variance with the specific pharmacy boards—

**Mr. Bill Walker:** Any issues with Illinois? Have they had any real negative implications?

**Mr. Sunny Lalli:** None at all. It has been very positive. We're in a hospital there as well as a remote employer site and a health clinic.

**Mr. Bill Walker:** Thank you very much.

**Mr. Sunny Lalli:** Thank you.

DR. ANTONIA SWANN

**The Chair (Mr. Peter Tabuns):** Our next presenter is Antonia Swann. Welcome. If you'd introduce yourself—I think you've seen a few cycles of this.

**Dr. Antonia Swann:** I have. Thank you very much. Hi, I'm Dr. Antonia Swann—I'm otherwise known as Smudge.

Good afternoon, ladies and gentlemen. This is World AIDS Day, and AIDS is a disease with which I am familiar in a bad way. I'm a tainted blood widow. My husband, James, passed away five years ago from tainted blood. I lived in a tainted blood household for 20 years, watching healthy, vibrant people who contributed positively to society get sick and die, partly because we allowed private blood donations in this country.

I fully support Bill 21, and I believe it should become law as soon as possible. There are many patient groups, I would like to point out, which are not necessarily affiliated with one particular organization, that are fully supportive of this bill, and I stand behind those people and with those people. For example, three provincial hemophilia chapters—Ontario, BC and Alberta—all support this bill.

A bit of background: My late husband, James Kreppner, was a lawyer and hemophiliac. He died of

AIDs and hepatitis C, which he received through tainted blood in the 1980s. He was one of this country's leading treatment activists. In fact, James served on the Canadian Blood Services board as one of their 12 board members helping run our new, safer blood system—Graham Sher and James knew each other quite well—and he served almost right up to his death five years ago.

When I testified 20 years ago today at the four-year, \$17-million Krever inquiry on the blood system, the risks from running that system could have been lowered at the time—that's what I said—and here we are again, 20 years later, at a crossroads regarding some of the very same issues that Krever tackled a generation ago. That was the largest public health disaster so far.

One of the things I want to drive home today is that the issues haven't changed. It wasn't an accident. We learned several things from Krever. The risk could have been lowered, given the knowledge at the time. Part of the reason Krever happened was due to private, paid donations. In light of the Krever inquiry—you have to understand that this was based on solid scientific evidence at the time, and that solid scientific evidence stands today.

What I want to tell you is that we are not immune to another disease like AIDS, the next AIDS, coming down nature's pipeline of diseases. That is an ongoing threat. I very much applaud the precautionary principle that was outlined a couple of speakers ago.

What I want to say is something James used to say. He used to joke about it; there was a lot of black humour. He used to say that if he had claimed in the early 1980s, before we knew about AIDS or hepatitis C or could even test for AIDS or knew what it was, that a green monkey virus would come from Africa, enter our blood system and end up killing and injuring thousands of Canadians, they would have put James in a straitjacket.

The point is that AIDS sounded unimaginable; it was from out of this world. What I'm telling you today is that I think it is arrogant and, more importantly, dangerous to assume that another as-yet-unknown blood-borne pathogen can't still come into the blood system. What we do test for, and what CBS does a great job of testing for, is current blood-borne pathogens like AIDS and hep C.

But the other issue I want to point out is that a generation ago, AIDS was new. It was something we couldn't even imagine. To imply that there isn't going to be another one coming down the pipeline is not being precautionary on the safety front. Safety was first and foremost for Krever.

What I also want to add is that using a private system is dangerous because there are numerous scientific and clinical trials demonstrating clearly that relying on private blood donations or paying people to give blood is going to encourage a less safe donor population to donate relative to an altruistic donor population. For example, high-risk practices, such as needle-sharing, are going to be more prevalent in a private system than a public altruistic one.

**The Chair (Mr. Peter Tabuns):** You have one minute.

**Dr. Antonia Swann:** Can I keep—one minute?

**The Chair (Mr. Peter Tabuns):** Yes, you have one minute.

**Dr. Antonia Swann:** My reason for coming here today is to stress one point: that you have to screen out less safe donors at the front door when you collect blood and/or blood products. The most simple and obvious way to minimize the risk of future blood-borne pathogens, to reduce the inevitable and invisible threats to our blood system, is to rely on an altruistic rather than a private system, which scientific studies show is less safe. I would rather have blood coming from a safer source—altruistic donors—than a private system, which is more likely to be higher risk and have future blood-borne pathogens inside that blood.

I don't want to bury my friends. As James once said, I'm tired of burying my friends. That's exactly how I feel today. I don't want to bury any more Canadians from something that should be avoidable, that we learned 20 years ago and that Krever clearly states—and we have not outgrown Krever. We still cannot be arrogant. There are future blood-borne pathogens coming and we can't test for them yet by definition.

**The Chair (Mr. Peter Tabuns):** Thank you, Dr. Swann. I'll go to the government: Ms. McGarry.

**Mrs. Kathryn McGarry:** We could talk forever. I so hear you not only as a health care provider, but also as a parent who could have lost her child amongst the same thing. I know you've been hearing those stories.

I'd like you to just continue to outline for us the importance of passing Bill 21. I think you have more to say on the issue.

**Dr. Antonia Swann:** I do, and thank you for the opportunity. I appreciate that.

Yes, I do. There are so many issues here. Some of it is complicated scientifically in Krever; that's why it was four years and \$17 million. I guess the bottom line I want to drive home is that it is based on logic and science, the concerns that we have and the precautionary principle, that when you're searching for the safest system, you want to rely on the safest possible sub-population from which to get that blood and those blood products.

The bottom line is, if you're paying people, wherever it's coming from, if you're paying people to give blood, \$20 is going to mean a lot more to someone on the street, a vulnerable population. They're going to be encouraged to give blood. I'm an economist. I study incentives and I work for a public health organization doing this kind of stuff. You want to make sure that for the future diseases that can come up—we're always up against nature. I'm not saying CBS isn't doing a great job, but it's just nature versus technology. To think that, oh, 20 years ago, we couldn't keep up with new pathogens in the blood system and to assume that that isn't going to be the case in future is quite worrisome to me. You have to err on the side of caution.

Another thing I want to add is that, regarding supply, I don't think—well, let me just first say that we want to make sure that instead of increasing our reliance on

private donors, we should shift our energy and resources. If we don't have new resources, we should shift them into generating more altruistic donors. That's where our efforts should go. That's where our resources should be diverted.

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Another point I'd like to add is that, yes, we may rely in part or large part for some of our blood products on private donations from, say, America, but that doesn't mean we like that. In fact, we want to lower that reliance because of the scientific studies demonstrating that blood from private, paid people is probably less safe, all else equal.

Which blood would you guys want to give your kid or yourself or your grandparent or your parent? You've got to err on the side of caution, because we don't know what the next blood-borne pathogen is, and that's my key point.

**The Chair (Mr. Peter Tabuns):** You have 30 seconds.

**Mrs. Kathryn McGarry:** I think what I'm hearing from you too is that we went through a system that put our patients at risk. There was a huge human cost, but there was also a financial cost.

**Dr. Antonia Swann:** Yes, absolutely.

**Mrs. Kathryn McGarry:** If you had some dollars to spend, what would you spend them on in the future in terms of addressing this?

**Dr. Antonia Swann:** If I had future dollars, I would certainly put much more resources into encouraging people to donate altruistically, to maintain our public system.

**The Chair (Mr. Peter Tabuns):** Ms. Swann, I'm sorry to say that we've run out of the three minutes for the Liberals. To the opposition: Mrs. Martow.

**Mrs. Gila Martow:** Thanks so much for your presentation and for coming today. You'll be in all of our thoughts.

**Dr. Antonia Swann:** Thank you.

**Mrs. Gila Martow:** I just want to mention that it's becoming very clear today that there's a difference between donating blood and donating plasma products. We're hearing from some experts that it is possible for Canada to be self-sufficient through volunteers giving blood itself, but the problem becomes very pronounced when it comes to blood products. Right now, we are getting 70% of our blood products from the US, and we're sending all of the plasma out to be—I think the word was “fractionation.”

**Dr. Antonia Swann:** Right, fractionated. As we did with Connaught, yes.

**Mrs. Gila Martow:** That's not even being done in Canada. Even though we're getting assurances that the plasma that we're sending out to these centres in the US and Europe is coming back the same in blood products, I'm a little sceptical about that, unless we're sending our own regulators to see.

I think that if we cannot, through private donations—we're hearing from experts saying that it's just too big

and too difficult and not cost-effective, that it would cost us so much more to do it ourselves than import, and we are already importing the plasma blood products from the States. Can two systems coexist, in your mind, in terms of regular blood donations and plasma products?

**Dr. Antonia Swann:** Thanks for the question. I think that we currently, as you say, do have a dual system in terms of relying on private donations for blood and blood products, as Graham Sher pointed out. But that doesn't mean I condone that or that we want to continue on that route. I would much rather see, and feel much more comfortable for my kids or my friends and people around this table, a move to put all the resources we have, as I was saying, towards really pushing—for plasma products, for every kind of blood product—towards a public system and not paying.

The problem, as I studied when I did my PhD in economics, is that when you let private corporations take over, even for whatever type of blood product it is, they're not going to put the public's safety first and foremost. You've got to make sure because what happened in the 1980s could very well be repeated. What I'm worried about is, profits went over safety, and people died as a result of that.

**Mrs. Gila Martow:** What happened in the 1980s was in terms of oversight of regulations, from my understanding.

**Dr. Antonia Swann:** That was one of the problems.

**The Chair (Mr. Peter Tabuns):** We have 30 seconds.

**Dr. Antonia Swann:** The other problem was that people allowed private corporations to put profits over people's lives. The bottom line is that we're no further ahead today. We can test for AIDS and hepatitis C and even hepatitis G, which you've probably never heard about—I studied this stuff. The bottom line is, we can't test for the next things. So we want to minimize the private—

**Mrs. Gila Martow:** Right, but we're already getting 70% from—

**Dr. Antonia Swann:** Yes, but that doesn't mean we want to increase that reliance; that's number one. And number two, we want to decrease that reliance, in fact, and I think we would be heroes to do that.

**The Chair (Mr. Peter Tabuns):** I'm afraid that we've gone through the three minutes for the opposition. Madame Gélinas.

**M<sup>me</sup> France Gélinas:** Thank you so much for your passion. I'm sorry about your loss.

**Dr. Antonia Swann:** Thank you.

**M<sup>me</sup> France Gélinas:** The first question that I want to ask you is this. You were here when Canadian Blood Services' Dr. Sher presented. He talks about a new business model that would bring our system more independence and do things differently. Do those words give you confidence?

**Dr. Antonia Swann:** To be honest, I have confidence in the CBS doing a good job today.

Yes, I guess the bottom line is, I want a system—and tell me if this is answering your question. I think, as

Krever suggested and recommended, that safety should be paramount. It is not our job to supply the world with blood or blood products as well. I wanted to mention that. It should be safe blood and blood products for Canadians, and whatever gets that job done is the number one priority.

Given the fact that we cannot predict the future, we don't know what the next blood-borne pathogen is—the green monkey virus, or whatever strangeness that nature can bring. I'm not trying to be paranoid; I'm trying to be practical and precautionary.

Sorry. I'm not sure I answered you.

**M<sup>me</sup> France Gélinas:** No, that's good. You have looked at what happens in other markets.

**Dr. Antonia Swann:** Yes.

**M<sup>me</sup> France Gélinas:** Given the size of Canada, and given our challenges and everything else, what is the basis for a for-profit, paid donation system to be successful and make money when we have a not-for-profit, don't-pay-for-donations system that apparently cannot do that? What am I missing? What's the big divide? Why is it that there's money to be made by the for-profit system that cannot be made by the not-for-profit?

**Dr. Antonia Swann:** Right. We have to change the way we think about how it is structured. Currently, we should be examining why it is more profitable in terms of plasma, assuming that's the case, to be relying on paid donations.

You have to also be cautious that in our history, when we tried to, say, set up—we had some catastrophes with places like Connaught and trying to fractionate and be self-sufficient in Canada.

**The Chair (Mr. Peter Tabuns):** You have 30 seconds left.

**Dr. Antonia Swann:** I guess the bottom line is, you want to minimize your reliance on private donations. If you have to coexist, you want to not increase that reliance, because of safety and science behind us. I can give you all the clinical trials you need to show that a private system is less safe because of the type of donors it attracts, whether it's for plasma or whatnot, relative to an altruistic system. We are coexisting with both types of systems, but let's do our best and not increase our reliance on private. That's all I would ask.

**The Chair (Mr. Peter Tabuns):** Dr. Swann, thank you very much.

**Dr. Antonia Swann:** Thank you very much.

#### ONTARIO PUBLIC SERVICE EMPLOYEES UNION

**The Chair (Mr. Peter Tabuns):** Our next presenter is the Ontario Public Service Employees Union. Welcome. If you'll introduce yourself for Hansard. You'll have five minutes to speak. I'll give you a one-minute warning when you're getting to the end. Then there will be three minutes of questions from each party.

**Mr. Rick Janson:** Okay. I'm Rick Janson. I do health policy work for the Ontario Public Service Employees

Union. I also write the blog *Diablogue*, which is read by a number of people, I'm sure, in this room.

The Ontario Public Service Employees Union represents about 130,000 public sector workers in the province. OPSEU's membership includes most of the staff of Canadian Blood Services in Ontario.

It is OPSEU's view that the private clinics that Canadian Plasma Resources planned to establish in Ontario represent a major shift in policy around paid donation of blood and blood derivatives. That shift in policy could place Ontarians at risk both in the quality of and accessibility to blood products. It also raises ethical concerns.

We support the government's introduction of Bill 21 as a means to reinforce Ontario's commitment to a single coordinated blood system based on non-remunerated donation.

This afternoon, I'm only going to present on security of supply, although our detailed brief does discuss issues of safety and ethics raised by for-profit, paid plasma collection.

Despite CPR's announced departure from Ontario last week, the clear intention of CPR remains to set up a parallel private plasma system in Canada. Contrary to widespread misinformation, commercial plasma collection is limited to a few countries which allow both remunerated and non-remunerated donations. This contrasts with the impression left by CBS CEO Dr. Graham Sher and privatization advocates that somehow Canada is outside of the mainstream on this issue. We're not.

CPR made it clear that they plan to become the dominant player in Canada's blood system. Short-term plans include opening 10 collection centres, not just the three planned for Hamilton and Toronto. CPR says their long-term plans include operating Canada's first fractionation facility.

The attempt to make this appear normal casts doubt about the objectivity of key players in this debate, including Canadian Blood Services. Comparisons to the existing paid plasma collections by Winnipeg's Cangene bioPharma, for example, are completely disingenuous. Cangene is a small niche provider, and paid collections are limited to specific rare blood types. Therefore, it is not surprising that it has little impact on CBS's Winnipeg donations, an assertion CBS makes to suggest that the impact of a rival collection organization the size of CPR will be minimal.

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While CPR claims that their goal is to make Canada self-sufficient in its pharmaceutical-based plasma supply, they are a private company whose prime objective is to generate profit for its investors, not solve Canada's health care needs. Given that CPR is entirely private, we have no idea whose deep pockets have financed the \$7 million this company says it has spent to date, or the \$400 million they say would be invested in their expansion plans.

It is difficult for us to believe that, with growing international demand, CPR will not use its position to sell Canadian plasma on the open market at the highest price, rather than restrict its market to CBS and Héma-Québec only.

Given that CBS told us in 2012 that they have neither a business relationship with CPR nor any intention to create such a relationship in the short term, it would suggest that CPR's market for Canadian-generated plasma would initially be international, not domestic.

Health Canada and the province of Ontario should be more than familiar with this situation, having just gone through intravenous drug supply shortages in Canada after the US federal drug administration intervened in Swiss pharmaceutical giant Sandoz's production line in Boucherville, Quebec. The fact that reductions in that production line had a much greater impact on Canada than on the US should throw up warning flags about where Canada will stand in the event of critical shortages of needed health care products.

The 2011 Dublin Consensus specifically points to the risk in setting up parallel blood and plasma systems. The Dublin Consensus states: "The coexistence of two independent collection systems, one for blood and one for plasma, in the same region or country, could create a risk of shortage in the supply of blood components." I highlight that.

It is our view that CBS should stop making excuses about the impossibility of securing a Canadian-based plasma supply and get on with the job to meet Canada's obligations to the World Health Assembly to become self-sufficient in blood and blood products. Forty-one nations are already there or partly the way there. That doesn't sound like an impossible mission to us.

We should also point out that the same resolution, WHA63.12—

**The Chair (Mr. Peter Tabuns):** One minute left.

**Mr. Rick Janson:** —calls on countries to develop national blood systems based on voluntary, non-remunerated blood donation, as does the more recent Dublin Consensus, which states that its first priority is to "provide safe," sustainable, "and sufficient blood components in all countries through the development of national blood transfusion systems based on voluntary non-remunerated donors," and that such principles apply to the plasma industry, which collects plasma exclusively for subsequent fractionation into plasma-derived medicinal products, or PDMPs.

I'm going to just skip ahead. Basically, our main point is that CBS has been actually self-destructing its voluntary blood donation system. It closed down a facility in Thunder Bay in 2012, as it did another one in Saint John, New Brunswick. It has taken at least two mobile voluntary blood collection units off the road.

**The Chair (Mr. Peter Tabuns):** I'm sorry to say that you've used up your five minutes.

**Mr. Rick Janson:** Okay.

**The Chair (Mr. Peter Tabuns):** The first questions go to the opposition: Mr. Walker.

**Mr. Bill Walker:** You've referenced the Dublin information fairly significantly, but I note that one you leave out is: "Recognize that both private and public sectors are needed to meet the global demand for plasma-derived products, in line with the Dublin Consensus."

I think what we're trying to establish here is that they can coexist. Most of the people in the room today have suggested that. From the transfusion side, we get that, but from the other side, from the research-based, the potential innovative solutions that we're going to need as a society are there.

I've asked a number of the presenters today to give me actual research-based evidence of where one negates the other, and no one has been able to do that. Unless you can provide me with something today—I think we have to be balanced. We're stating right here again: We need to ensure there is a balance. We can't go down just with the thought process, because of emotion, that we can't do this. We need to think about who's in front of us and who may need those products and services, going down the road. That's how I'm trying to look at it: with a balance to what the needs are.

We're being told that even Canada can't provide for its own needs right now. We're buying 70% of that research-based side.

So if we can't do it, and we're not doing it today, why are we going to allow legislation to be implemented that would actually prohibit that from happening?

**Mr. Rick Janson:** Because we're not even trying today. That's our problem.

**Mr. Bill Walker:** Fair enough, but this legislation is not going to necessarily engage us in trying. It's actually prohibiting the option to have that ability. What I want to know is how we do that.

My sister had a blood transfusion. Sadly, she passed away after that transfusion. But at the end of the day, I don't think she was really concerned—because let's not go down to the nth degree that there's no safety being built into the system. We're not going to be collecting blood from people, if I'm sitting in government, without all of the safety regulations and all of the practices that are in place today with Canadian Blood Services, to ensure the safety of our residents. We have to be very pragmatic and balanced in our thought processes here.

If we're going to do that, and if we don't have supply to meet the need, then we have to look at other ways of doing business. We have to look outside. Every country other than the US, I believe I was told by Canadian Blood Services's Dr. Sher, has to have paid to meet their demand—

**Mr. Rick Janson:** That's not true.

**Mr. Bill Walker:** Well, then, give me the evidence-based fact. Where is it?

**Mr. Rick Janson:** Sure. If you read my full paper, which I invite you to, you'll find that that is simply not true; the head of the hemophilia society in Ireland, for example, talked about four developed countries that are doing paid plasma. The rest, no.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Bill Walker:** Hemophilia is also part of the Dublin commission statement, and they're saying that this will not meet the demand. We have to look at two systems.

**Mr. Rick Janson:** Not necessarily. It's an integrated system—

**Mr. Bill Walker:** That's what it said. I'm taking it from their statement; I'm not making this up.

**The Chair (Mr. Peter Tabuns):** Mr. Walker, if you'd let him answer.

**Mr. Rick Janson:** Yes—and it's quite clear that the Dublin Consensus particularly places emphasis on non-profit voluntary donation. That's quite clear. It's part of their mandate. It's kind of sad that Canada actually wasn't part of the Dublin Consensus—

**The Chair (Mr. Peter Tabuns):** Your three minutes are up with the opposition. We'll go to the third party: Madame Gélinas.

**M<sup>me</sup> France Gélinas:** We've talked a lot today about Canada not being self-sufficient, but what you're telling us is that even if we were to allow plasma paid-for donations, it's not going to make us any more or any less self-sufficient because they will sell this plasma on the open market, I'm guessing, to the highest bidder, which may very well not be us.

**Mr. Rick Janson:** That's correct.

**M<sup>me</sup> France Gélinas:** Okay. So when we're talking about how we need to become more self-sufficient, the path of paying for donations is not the path that brings us to self-sufficiency.

**Mr. Rick Janson:** No. In fact, if you look at studies done around the world in terms of the impact of having this second tier, actually, it makes very little difference in terms of the overall supply.

I think there was one study done in the UK that showed that the difference between paid and unpaid would be negligible in terms of your total volumes that you would raise. In fact, in New Zealand there was also a study done on this, and in New Zealand they found that actually the prospect of paid donation turned off a lot of people, and a lot of people said in particular—I believe it was over 40%—that they would not donate if there was profit involved, if the company they were donating to was making profit off of their blood. That's really significant.

We have no idea what would happen in Canada. There have been different responses in different countries. CBS has said that it would affect their collections by about 8%. CPR, which wants to do this, said it would be about 6.6%, which is what they estimate to be the impact of having a paid second-tier private player in the market. So we know that it would impact overall donations, not just for PDMPs.

**M<sup>me</sup> France Gélinas:** So if the path to self-reliance is not through paid-for plasma donations for all of the PDMP products, what is the path to self-sufficiency?

**Mr. Rick Janson:** I think we need to go back to CBS's original mandate. They say that the demand for blood in hospitals is going down because of less invasive surgeries, which is true, but why can't we be putting the surplus stock, then, into PDMPs, as opposed to just saying, "Oh, we don't need it. Let's just start closing down our facilities. Let's close down Thunder Bay. Let's close down St. John. Let's cut the hours of our clinics. Let's make it more difficult for people to get through to our call lines by not staffing up during crises"—

**The Chair (Mr. Peter Tabuns):** You have 30 seconds left with this.

**Mr. Rick Janson:** Okay. What we've seen is the deliberate scaling back of CBS's voluntary collections. I think that as Ontario is a major stakeholder, it needs to start probing CBS as to why they're doing this. Why is it that we can't put these stocks back into PDMPs as opposed to just shutting it down?

**M<sup>me</sup> France Gélinas:** Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you, and we'll go to the government. Ms. Mangat.

**Mrs. Amrit Mangat:** Thank you, Mr. Janson, for taking the time and coming to Queen's Park to share your story. A previous presenter before you, Dr. Swann, spoke very eloquently about patient safety. It's really heart-breaking to hear her story. No one should have to go through what she went through.

Having said that, would you mind sharing with us what the value is of having a single national body for blood collection?

**Mr. Rick Janson:** Well, \$5 billion to start with, which was the compensation last time out from the federal government to victims of the tainted blood scandal.

Certainly I think there are lots of quality issues that get raised by this for sure.

1700

We don't know what we don't know is one of the big problems, and you're always taking a risk. One of the biggest recalls of any pharmaceutical product is biologics, and within biologics, the product that gets the most recalls is IVIG, which is exactly what we're talking about today. The more risk you put into the system, the more likely you're going to have problems down the line. There are recalls all the time for IVIG, which is the end product in this. Do you really want to take the risk by putting it into a situation where it's not clear, in terms of where this blood is coming from?

The CPR, for example, set up from a methadone clinic in Hamilton and also next to a homeless shelter in Toronto. What does that tell you about who this clientele is? It's a very high-risk clientele. No matter what scrubbers you have and so forth—I mean, there are other diseases as well that you can't scrub out of the system, that are finding themselves to be very resistant. Whether they're carriers or not, we don't know entirely. There is no test, for example, for mad cow disease essentially.

**Mrs. Amrit Mangat:** And why is the passage of Bill 21 important to your members?

**Mr. Rick Janson:** Well, I think it's a first step. I don't think it's the end of the story. I think CBS needs to do its job, in terms of providing self-sufficient resources. There are many world bodies that have come out and called for self-sufficiency in blood systems. We're not there. We're far from being there for PDMPs. The question is, why aren't we even working towards it? We don't even try.

Last time there was a shortage, the US FDA basically was not happy with the process in terms of the manufacturing of immunoglobulins in the United States, so it basically halted service—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Rick Janson:**—and it made it very difficult in Canada, particularly, to access supply at that time. At that time, the deputy ministers of the provinces all got together and decided they were going to try and increase that percentage from what it was at that time, which was about 23%. They set a much higher target in terms of Canadian content so that we would be in a better position should there be a faltering of the system, and we didn't do it. Instead, the US turned the supply on again and we were happy just to take their content.

**The Chair (Mr. Peter Tabuns):** Thank you, Mr. Janson. I'm sorry to say you've run out of time. Thank you very much for your presentation.

**Mr. Rick Janson:** Thank you.

MR. DAVID HARVEY

**The Chair (Mr. Peter Tabuns):** Our next presenter is David Harvey. Mr. Harvey, I think you've seen us go through a number of cycles, but if you'd introduce yourself. You have five minutes. I'll give you warnings at the appropriate time.

**Mr. David Harvey:** Good afternoon, committee, and thank you very much for the opportunity to present this afternoon. My name is David Harvey. I'm a retired lawyer and I represented families and organizations touched by tainted blood for about 20 years. I argued blood-related cases in the Ontario Superior Court, the Federal Court, the Federal Court of Appeal, the Ontario Court of Appeal and twice at the Supreme Court of Canada. I represented patient groups at the Krever inquiry. But I'm here today, not in any professional capacity, but in a personal capacity, to share what I've learned over the years and to congratulate the government on bringing forward the legal implementation of one of Justice Krever's primary recommendations.

Now, the issue is also personal for me. In my practice—I'm sorry.

**The Chair (Mr. Peter Tabuns):** No, that's okay. Take a second.

**Mr. David Harvey:** I went to too many funerals. I got too many calls that clients died. I had to call an ambulance in the middle of examining a witness because he was too weak to continue. Ms. Swann's late husband was one of my best friends.

And closer to home, I have sat in a hospital room with my mother and my father and my wife, weakened from chemotherapy, watching blood products drip into their veins, and with my background, you can imagine the kinds of concerns I had. But I was proud to be able to say to them that Canada has learned its lessons. They've reformed the system, and it's as safe as it can be. I'm here today to try and make sure that I can continue to say that.

Now, this committee is going to hear from a number of witnesses today and tomorrow—two days of hearings. It would be foolish to assume that this committee can

approach anywhere near the detail that Justice Krever heard over four years.

Justice Krever received and reviewed 175,000 documents totalling over a million pages. He had hearings from February 1994 to December 1995, hearing from 474 witnesses—247 days of hearings, written submissions from 89 parties, 50,000 pages of transcript, 100,000 pages of exhibits. There were witnesses from across Canada and around the world, experts in transfusion medicine, internationally renowned panels, front-line workers. With respect, it's impossible for this committee to come to a different conclusion than Justice Krever in a responsible manner.

I won't take you through the specific recommendations in Justice Krever's final report, but there were at least five that dealt specifically with payment for plasma.

**The Chair (Mr. Peter Tabuns):** You have about one minute left.

**Mr. David Harvey:** All five times it was no, no, no, no, no.

With respect to the issue of shortages of product, we're not talking about that. We're not talking about it, because paying for plasma in Ontario means a private company can collect Ontario plasma—which Justice Krever referred to as a “public resource” in Canada—and send it abroad without any guarantee it ever comes back here. So if you're talking about securing Canadian supply, having private companies pay donors and sell on the international market does nothing for Canadian health care.

I want to talk about the importance of a single operator a little bit, because that's also a fundamental principle from Justice Krever's report. There are many reasons, and I'll give you just one. Having the information on every donor and tracing from vein to vein who gave the blood and who got the blood is essential, because if a donor comes in and later tests positive for an infectious disease, you want to be able to find every recipient of every prior donation from that donor.

**The Chair (Mr. Peter Tabuns):** Mr. Harvey, I'm sorry to say that your five minutes are up. We'll go to the first questioner: Madame Gélinas.

**M<sup>me</sup> France Gélinas:** My first question is a little bit broad, but you can answer it any way you see fit. What do you say to people who say, “That was 20 years ago. We've learned. We have safety precautions in place. All of the safety questionnaires that Canadian Blood Services uses will be used in the for-profit system”? What do you say?

**Mr. David Harvey:** I say to them, that's right. We are very well equipped to fight the last war. But we should be afraid. Afraid is good. Afraid leads to vigilance.

We need to be looking at the future, as Dr. Swann referred to. It's what's coming next that we have to be concerned with. So any change we're making in policy needs to be changing towards increased safety, not falling back on the same kind of scientific arrogance and complacency and denial that we had in the 1980s that led us to say, “There's not really a problem.”

**M<sup>me</sup> France Gélinas:** When there was a serious one.

Do you see a way forward where Canada would be self-sufficient in plasma products?

**Mr. David Harvey:** I do. I was heartened to hear Dr. Sher say that there is a business plan going forward. But I'm also concerned about this attitude that I seem to be hearing, that it's a binary thing, that you either have paid plasma or you have shortages and that there's nothing in between—no.

1710

I compare it to the Ontario electricity system. We didn't want coal plants, but we had them, and we had to rely on them for a while until we could phase them out. We're in the same situation here. We have a reliance on paid plasma products because we have no choice at the moment, but going forward we can shift resources. We can increase our reliance on Canadian, voluntarily donated plasma products. We may still have a percentage that we have to rely on from imported donor-paid products, but we can reduce it, and the more we reduce it the better.

**The Chair (Mr. Peter Tabuns):** You have 30 seconds left.

**M<sup>me</sup> France Gélinas:** So this 30% that goes out and comes back, you think, could grow and could—

**Mr. David Harvey:** Absolutely. There are going to be some products where the market in Canada is just too small. We can't buy enough because these are made in huge pools. For us to send 30,000 units down to be pooled to make a particular product that we only buy a handful of vials of doesn't work—

**The Chair (Mr. Peter Tabuns):** I'm sorry to say that we're going to have to go on to the next party. The government: Mr. Fraser?

**Mr. John Fraser:** Thank you very much, Mr. Harvey, for being here today, and thank you for your work. You've spent a lot of time working to help people, find justice and try to create a system that will be better for all Canadians. I want to say that I was really glad to hear you bring up that paid-for plasma does not necessarily mean products that remain in our country. It hasn't been brought up by anybody today. It does not ensure supply.

I also liked your analogy with regard to coal-fired plants. We need to take a balanced approach, just because that's the prudent thing to do. That doesn't mean that you don't continue to work towards what your ideal is. To work towards your ideal, you have to uphold certain principles.

I'd like you to, if you could, tell me why you think that the voluntary blood system is so important to Canadians and Ontarians.

**Mr. David Harvey:** Dr. Swann covered that to some extent. It is safer. It's universally acknowledged to be safer to take blood from people who are donating for altruistic purposes. They've got nothing to gain.

If you walk in and they ask you, “Have you been to Britain in the last five years?”, because there are CJD concerns—it's a valid question currently being asked—for the voluntary donor, they say, “Yes, actually, I went

last summer.” For the donor who is not voluntary but is there to make money, they’re going to think: You know what? I feel really well, and if I say I went last summer or five summers ago, I’m not going to get my \$20. So: “No, I’ve never been there.”

You can’t test for CJD. There’s no test, so your front-line defence against that disease is the honesty of the donor. If you don’t pay, you get a more honest answer.

**Mr. Granville Anderson:** That’s common sense, for those of us who have it. It’s logic. It’s human nature. It’s just a fact of life.

**Mr. John Fraser:** So why do you think it’s important for us to pass this legislation quickly?

**The Chair (Mr. Peter Tabuns):** You have 30 seconds.

**Mr. John Fraser:** Quickly.

**Mr. David Harvey:** Okay. It was important. This is a fundamental recommendation of Justice Krever’s. It wasn’t necessary up until this point to put it into law because there was nobody actually proposing to open clinics. As soon as that happened, it became necessary to deal with it quickly.

**Mr. John Fraser:** Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you very much. Now to the opposition: Mrs. Martow?

**Mrs. Gila Martow:** Thank you for your presentation. I think that everybody, whatever their presentation or their line of questioning is, agrees that we obviously want the blood supply, our blood products and our plasma products, to be as safe as they can be. We all know that, but, given the circumstance—which is that, as you said yourself, there are some products where it is not feasible—and given the fact that 70% of certain blood products are coming from the States, where people are being paid for the products, we just can’t ignore that. We have to accept that.

I agree that we want to encourage people to donate whenever they can. We have to make it easier, but it’s actually getting harder for people to donate. We’re having an aging population. We’re having a crisis in the GTA in terms of traffic; if people are spending more hours in traffic, they have less time to go donate blood. I’ve had people say to me that they used to donate regularly, but now that it’s taking them an extra hour a day, they’re not donating anymore, because that was the time that they would have used to donate.

On principle, don’t you feel that we’re better off not backing ourselves into a corner where we might not have the actual products that we need, versus looking at other options?

**Mr. David Harvey:** I don’t think we’re in that corner. I think there’s a lot of room for expansion within CBS to collect blood. Even if we were in a position where we had absolutely no choice but to pay, then the preferable procedure, for me, would be to have CBS pay.

**Mrs. Gila Martow:** I know, but if this legislation—

**Mr. David Harvey:** There’s an exemption in the legislation for CBS which would permit that. It prevents the fragmentation of the system. It prevents losing all of

those benefits of having a single operator, and it prevents blood from leaving Canada, never to return, except in the form of profits for a private corporation.

**Mrs. Gila Martow:** But right now, there are certain products that we’re not even able to manufacture here. So why do you feel that that’s acceptable?

**Mr. David Harvey:** We custom-manufacture them by sending our plasma to the factory and getting back our plasma. By doing that, we can choose from among the best manufacturers with the most advanced, safest processes in the world.

**The Chair (Mr. Peter Tabuns):** Thirty seconds left.

**Mr. David Harvey:** We’re not bound to one place. We’re not bound to political pressure to support the Canadian company and preserve the jobs. We saw what happened when we did that with Connaught. It was a disaster. It cost a fortune; it cost lives. We can’t put ourselves in a captive position like that again.

**Mrs. Gila Martow:** It’s about oversight and ensuring that the regulations are in place and, obviously, regulated.

**The Chair (Mr. Peter Tabuns):** Ms. Martow, thank you.

**Mrs. Gila Martow:** Thank you very much.

**The Chair (Mr. Peter Tabuns):** Thank you very much, Mr. Harvey. I appreciate it.

**Mr. David Harvey:** Thank you.

#### MR. MICHAEL DECTER

**The Chair (Mr. Peter Tabuns):** Michael Decter? Michael? If you’ll introduce yourself. I know you’re familiar with the environment we’re operating in. You have five minutes. I’ll give you a one-minute warning, and questions to the parties—

**Mr. Michael Decter:** Thank you. It has been a long time since I was in this room, but it’s an important occasion to be back.

My name is Michael Decter. I currently serve on the board of Patients Canada and as the chair of Medavie Blue Cross. However, today I’m here in my capacity as a private citizen and as a former Deputy Minister of Health for this province.

I asked to be heard by the committee. Why? I think the most eloquent answer to that question was given by Randy Shilts in his book *And The Band Played On*, when he wrote: “It is a tale that”—sorry, I will need my glasses. I’ve aged a little since the last appearance. “It is a tale that bears telling so that it will never happen again, to any people, anywhere.”

Memories fade. New experts and those with financial gains in mind tell you that this time, it will be safe; this time, it will be different. Old lessons are forgotten. As we age, we have a responsibility to speak our remembered truth to your democratically given power.

Albert Einstein commented that the true definition of insanity is doing the same thing over again and expecting different results.

The truth is that this bill is a sensible and necessary law to prevent a future blood-borne disease tragedy. It is

the legislative specification of the central tenet of public health: the precautionary principle. If an action or policy has potential to harm human health, precautionary measures should be taken, even if some cause-and-effect relationships are not fully established scientifically.

Collection of blood on a paid basis, in locations adjacent to facilities built specifically to house or serve at-risk populations, is a recipe for disaster and should not be permitted.

As early as December 1982, the US Food and Drug Administration recommended that blood fractionators refrain from collecting plasma from high-risk donors. They did not, with tragic consequences.

What tale do I have to tell? In the summer of 1993, I was appointed to chair a national committee of Deputy Ministers of Health. We had three tasks:

- determine and recommend to health ministers whether an inquiry should be held into the blood system;
- negotiate an agreement with the victims of tainted blood to financially assist them and their families; and
- recommend an interim written agreement with the Canadian Red Cross.

1720

What we found was shocking to me and to my fellow deputies. We interviewed people in the Bureau of Biologics who had been entirely negligent in taking steps to ensure blood safety. The bureau issued licences to blood collection centres without inspections. It was understaffed and it was complacent in its attitude.

This blood system manager, the Canadian Red Cross, had a leadership with an attitude of arrogance in the face of an unfolding tragedy that was astonishing. They had no written agreement with the governments that funded it.

We recommended an inquiry that Justice Krever was appointed to chair in October 1993. In my view, his report stands as a landmark of integrity and sound policy. He did not wait for his final report in 1997; he issued an interim report in 1995. Recommendation 10 of that report stated: “That blood services develop a policy for locating blood donor clinics so as to avoid areas known to have a significantly higher than normal prevalence, and thus a potentially higher incidence, of HIV or any other disease transmissible by blood.”

During the inquiry, Justice Krever issued 95 section 13 notices to those who caused the blood crisis, both companies and individuals. Only one of those notices was successfully appealed.

**The Chair (Mr. Peter Tabuns):** You have one minute left.

**Mr. Michael Decter:** One minute?

It is fair to say that all those entrusted with blood safety let us down with fatal consequences for thousands of Canadians.

Given the time, I will read only two of Justice Krever’s recommendations:

- Donated blood is a public resource—Canadian Blood Services must act as a trustee of this public resource for the benefit of all persons in Canada;

—Safety of the blood supply system is paramount—the principle of safety must transcend other principles and policies.

Lurking out there just beyond the periphery of our current knowledge is the next HIV/AIDS virus or prions or Ebola. Your challenge is to apply the precautionary principle. That is what Bill 21 does and that is why I strongly support its passage into law. Thank you.

**The Chair (Mr. Peter Tabuns):** Thank you, Mr. Decter. The first question is to the government.

**Mr. Granville Anderson:** Mr. Decter, thank you very much for coming this evening. In 2006, you were quoted as saying that “crises can lead to better institutions, but only when the changes made reflect lessons learned.” Can you tell us what that means with respect to Bill 21? Is CBS an example of a better institution?

**Mr. Michael Decter:** Yes, and I’m honoured to say I was invited by the CBS board to speak at their first meeting and to speak at their 10th anniversary meeting. I praised them for what they’ve achieved in 10 years. I told them they’d achieved more than I thought they could in a decade, but I also said to them, “You have more to do.” One of the more-to-dos is to move towards self-sufficiency and to take on that challenge. They’ve chosen to take on some other challenges that are not to do with blood and blood products; I would rather they stayed focused on blood.

**Mr. Granville Anderson:** Okay. Can you please explain to us why it is so important to safeguard the integrity of the voluntary blood donation system in Canada and why this legislation is so important to its quick passage?

**Mr. Michael Decter:** Yes. One of the qualities of blood is that it is something that we possess and that we can share to assist, maybe even save the lives of others. I think when you reduce it to a commodity and put it into a private for-profit system, then it loses that quality.

I know there have been lots of studies done, but I know that mixed systems have had not good outcomes in health generally in this country. There’s lots of evidence on point on that. I think it’s important to keep separate what we do as a public good, and blood products for me fall into that category of a public good.

**Mr. Granville Anderson:** Can you tell us what you would tell individuals who oppose this bill, especially those who indicated that 70% comes from the US, so what is there to worry about, basically? What can you tell us about that comment?

**Mr. Michael Decter:** Well, I think you have to look broader at Canada’s role in the world. We import a great many things to this country, some of them because we can’t provide them ourselves. We don’t grow bananas in Canada—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Michael Decter:** —we don’t do things of that sort. We often import things from countries with lower safety standards. We have had tragedies run the gamut from antifreeze in wine to all sorts of things, so it’s a second-best solution for us to import 70%.

I think this bill is an important bill, but I think it's also important that the Canadian Blood Services implement their business plan to move us towards greater self-reliance.

**The Chair (Mr. Peter Tabuns):** Thank you, Mr. Decter. To the opposition: Mr. Walker.

**Mr. Bill Walker:** Thank you very much. Thank you, Mr. Decter. In your opening remarks you related that we have to be very cautious—I don't think there's anyone in this room who won't agree—about the potential risk of a new disease, and what do we do and how do we protect that? Because what I'm trying to get my head around—and I have two young boys, so it's a concern I have, and obviously would, if my sons would ever have something like that happen.

Similarly, if you look at the fractionation and the need to have those life-saving treatments, what if we don't have the supply? Which one of those do we value more? Which factor do we bear over the other? Because what I'm reading in a lot of the information that's been given to us today is that a lot of those things are derived from paid donations, and they seem to be working quite well. I don't know how I put one risk over another risk. Can you help me?

**Mr. Michael Decter:** Well, I think it's a false choice. I don't think that, because they're paid donations in other countries—most of those countries have personally paid health services, which we as a country have been against, as I understand it, including our current Prime Minister, whom I've debated on the subject over the years.

I don't think we have to go down that route. The fact that we currently import blood products that may in some cases be made from paid plasma because the other systems are mixed—the 70% isn't a very good number; it's a “may contain paid plasma,” not “does contain.” That is something that I think that we should be trying to work our way away from, but not—and I'll say this—by trying to produce a fractionator in Canada, which we did do before with tragic consequences.

I think I would be with David Harvey's testimony, saying that if we send out product from CBS, have it fractionated, get it back and not commingle it, that is a better solution than either importing something that we may not know all the qualities of or trying to build something in Canada that may not actually work out from a safety point of view.

**Mr. Bill Walker:** You've already suggested, I believe, that we may not be able to produce enough in some cases, so are you open, then—and is that the ability of the exemption in the Krever report—to allow it to be paid if we cannot produce enough, and to keep it in that one stream?

**Mr. Michael Decter:** If CBS, having seriously tried—which, in my view, they haven't—to get to self-sufficiency in collection using plasma for research, then I would certainly see that as being an important exemption in the bill, but I don't think that the right answer is to have other entrants with mixed motivations enter a

system that should be run four-square on the precautionary principle.

**Mr. Bill Walker:** But you are willing to look at that if it can be proven that we can't produce enough?

**Mr. Michael Decter:** I would be willing to look at CBS being able to do something there. I know there are some very small, special situations—Cangene, for example—in which that has been done.

**The Chair (Mr. Peter Tabuns):** Your time is up. Madame Gélinas?

**M<sup>me</sup> France Gélinas:** Pleased to see you; long time no see.

How do we get to self-sufficiency through CBS? Can you see a way forward that brings us there?

**Mr. Michael Decter:** Yes. There are plenty of other countries that have been able to achieve self-sufficiency, and there's plenty of ability at CBS after a decade. I think ministers have to exert some political will and say to CBS, “Look, we know you want to get into tissue banking. We know you want to do all of these other things, but you haven't finished your work on blood. We're not self-sufficient, and we would like you to take the steps.”

They're not all on the supply side. Let's be clear about this. The one recommendation of Justice Krever that wasn't implemented was that the budget for blood products be transferred to the hospitals, so that they could buy product from the CBS. The reason he proposed that—and I will confess that I was an adviser to the Krever inquiry on some of those points—is that blood is frankly not always as valued as it should be in the system, because it's transferred from CBS to the users for free.

**1730**

I think, frankly, that there is wastage. Some hospitals do a spectacularly good job of managing blood; others, not so good. I think if there were transfer pricing, you might see better utilization.

So I don't think we solve this entirely on more supply. Part of it is taking advantage of getting to the best standard, which would let us use less whole blood in total.

**M<sup>me</sup> France Gélinas:** Interesting. You also mentioned that mixed systems have not had good outcomes in this country. This is a comment you made. What were you referring to?

**Mr. Michael Decter:** It's a more general comment about health care. I think some parts of the health system work really well in the private sector. Chain drugstores, for example, work very well. They're popular. They do a good job. Public hospitals do a good job. When we start to try and bring public and private elements together in the same health enterprise, I think we run some complicated risks. The most glaring example—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Michael Decter:** —in this jurisdiction would be the rather sad experience of Ornge, where I think the attempt to make money took it off its main task. I guess someday we'll hear the full story, but that wasn't a happy experience.

I think that what is public should be public, and I would put blood there. What is private should be private, and I would put the manufacture of pharmaceuticals and their distribution and sale there.

**The Chair (Mr. Peter Tabuns):** Thank you, Mr. Decter.

#### CANADIAN PLASMA RESOURCES

**The Chair (Mr. Peter Tabuns):** Okay, our last presenter today: Canadian Plasma Resources. If you would introduce yourself for Hansard, as you've probably seen. You have five minutes to speak, and I'll give you a warning when you have one minute left.

**Dr. Barzin Bahardoust:** Barzin Bahardoust, CEO of Canadian Plasma Resources. Thank you, Mr. Chairman.

For those who are not aware, Canadian Plasma Resources is the target of the first part of Bill 21. I'm going to very briefly outline our concerns.

Canada is one of the largest markets for drugs manufactured from plasma and will spend \$750 million next year to buy these from foreign private companies. We are merely seeking the opportunity to compete with these companies and provide these drugs across Ontario and Canada in exactly the same manner as our competitors do. All of these companies compensate their plasma donors.

Why do we need to compensate donors? We would prefer if people walked in and donated frequently without any compensation. It would have lowered our costs. But plasma donors on average spend 90 minutes, excluding travel time, for a single plasma donation, and qualified donors must be repeat donors. For a committed weekly donor, that means almost 80 hours, or two full work-weeks, per year.

In Ontario, we already compensate living organ donors for out-of-pocket costs and loss of income. Our proposal to compensate plasma donors is consistent with what is already happening here in Ontario. In fact, the compensation of plasma donors is the only type which is explicitly permitted under section 10 of the Trillium Gift of Life Network Act, a Liberal government bill. We relied on that exemption when we began operating. Now you are taking that away. This bill does not acknowledge the need for plasma for further manufacturing.

Canada is the only G8 country without the capacity to produce essential medicines derived from plasma. We are the single largest net importer of immunoglobulin worldwide. This unique overreliance that we have on US donors is a risk to the security of supply. What happens to Canadian patients if there is ever a shortage or an export ban in the United States? You heard what happened in the UK. The only way to remedy this problem is to start our own plasma industry and diversify supply. What is truly striking about this bill is that the government of Ontario is banning the creation of an industry that its own citizens need to survive. How is this ethical?

The bill is also bad for Ontario's economy. We were proposing to make a \$400-million investment in Ontario

to open 10 plasma collection centres and to build and operate a fractionation plant with our strategic partner Biotest AG. That would mean 2,000 new manufacturing jobs for skilled workers. Now the investment and jobs will go to those provinces where we have agreements to operate, beginning in western Canada. It is confusing to us that a government would actively chase high-skilled, high-paid jobs out when it's struggling to balance its books.

Concern has been expressed that compensating plasma donors for further manufacturing will erode the voluntary blood donor base. The experience in other jurisdictions has shown that this is not the case. In fact, the donor time commitment is very different and donor pools rarely overlap. Countries with a mature plasma industry, such as the US and Germany, have a much higher rate of voluntary whole blood donations compared to Canada.

In regard to safety concerns, I would point out that the World Health Organization has regarded Health Canada, the regulatory body which licenses us, along with CBS and Héma-Québec, as having developed the highest standards of blood safety.

While we will not be able to grow our business in this province, we are prepared to operate our Toronto collection centres on a purely voluntary basis and for research purposes. This would allow our current employees to keep their jobs. However, the provisions of this bill that amend the Laboratory and Specimen Collection Centre Licensing Act would make it very difficult for us to do so. If the committee is interested in exploring an amendment that would allow our centres to operate on that basis, we would be pleased to work with you.

Thank you all sincerely for your time, and I would be happy to take your questions.

**The Chair (Mr. Peter Tabuns):** Thank you. Questions start with the opposition: Mr. Walker.

**Mr. Bill Walker:** Thank you very much. We're talking a fair bit today about the standards. I trust, as an industry, you're prepared to meet whatever requirements that the government would put in place to ensure that we have the highest safety standards in the world?

**Dr. Barzin Bahardoust:** We have to do that to be able to operate. In Canada, the BGTD office at Health Canada is the body that regulates blood establishments and plasma collection centres. Even those that solely collect plasma for further manufacturing—that's what we do—need to get their authorization from them. Without that, we would not be able to operate.

**Mr. Bill Walker:** Some people today have alleged that only people who are doing it for the wrong reasons, who are not altruistic; they're just going to do it for the money—I'll use my colleague across the way, Mr. Fraser. If he was to walk into one of your clinics and be paid \$100 or whatever the dollar—\$20, whatever it would be—and agree to donate that back to Canadian Blood Services—so he's doing it for no personal gain; he's a man of upstanding character—would there be any reason why we wouldn't do that when we know that

there is a potential for a shortage of a certain type of blood or blood plasma protein?

**Dr. Barzin Bahardoust:** Compensation for plasma donors, as long as that plasma is for further manufacturing, does not compromise the safety of the product. That is proven scientifically.

This is different with whole blood or blood for transfusion or plasma for transfusion. There are certain risk mitigations in place that are not available or applicable to whole blood or fresh blood products for transfusion, such as filtration steps during manufacturing and the quarantine of the plasma of repeat donors, that further increase the safety of plasma for further manufacturing, as opposed to fresh blood products. There is no safety risk with compensation for plasma donors as long as regulations are followed.

**Mr. Bill Walker:** The government's role is to set those regulations and standards. We utilize the Canadian Nuclear Society for the exact same reason. We're not going to supersede—I think I just want to make sure, for the record: No one in this room—certainly I'll speak only for myself right now. We're not lowering any standards of safety. If this bill doesn't pass, we're not changing anything. We want to keep the highest standards absolutely possible. I think what I've heard from many groups in the room today is that we can separate the two. One is for transfusion, the other for products that are for research and training—

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Mr. Bill Walker:** We can separate the two of them, again maintaining the absolute highest standard, and it could be maintained in Canada rather than exporting \$750 million for the same resources we're currently using in our country.

**Dr. Barzin Bahardoust:** If anything, we will bring Canadian oversight on the production, while now we are relying on other regulators, specifically the FDA. So there is direct regulatory oversight if production happens in Canada.

**The Chair (Mr. Peter Tabuns):** And your three minutes are up. I'll go to Madame Gélinas.

**M<sup>me</sup> France Gélinas:** Thank you so much for coming. You mentioned that you had the intention of investing up to \$400 million, that you've already invested several million dollars for the sites that you have here in Ontario. Can I ask: How much have you invested in Ontario so far?

**Dr. Barzin Bahardoust:** We invested approximately \$8 million in the three plasma collection centres that we have right now. Two of them have gone through Health Canada audits. One has not: the one in Hamilton. We invested approximately \$40 million in industrial property for the future fractionation plant, which is now going to be used for development and we don't have that property anymore.

**M<sup>me</sup> France Gélinas:** What led you to believe that that was going to be a successful business? This is a lot of money. I am taking that you do due diligence before

you invest that kind of money. What led you to believe that you were going to be successful?

**1740**

**Dr. Barzin Bahardoust:** We are using the same model that our competitors do in the United States. We use technology from the fifth-largest manufacturer of plasma protein products worldwide, Biotest. They're not currently in the Canadian market. We will start the registration of finished products hopefully early next year.

This company, again, as I mentioned, is the fifth-largest producer and supplier of plasma protein products worldwide and has a presence in Western Europe, in the United States and generally in 70 countries.

We believe that, again, our model will work. It's the same model that is being used for the products that Canada is already purchasing. Costs are similar to the United States, so we think that we will be able to compete.

**M<sup>me</sup> France Gélinas:** So you did not see this coming in Ontario, that this bill was going to come forward and that your ability to have a successful business was going to be taken away from you?

**Dr. Barzin Bahardoust:** We met with the Ministry of Health and Long-Term Care, with the chief of staff, over a year ago—almost two years ago. We had told them at that time—and the Ministry of Economic Development, Trade and Employment.

**The Chair (Mr. Peter Tabuns):** Thirty seconds.

**Dr. Barzin Bahardoust:** We had indicated to them that if such a bill would be passed, our ability to work in Ontario will be diminished. Again, we will not be able to recruit donors without compensation—enough donors to make the business viable.

**M<sup>me</sup> France Gélinas:** And what was their response?

**Dr. Barzin Bahardoust:** They told us that this seems to be a good idea and they never contacted us back. We told them, if there were any concerns, to please get back to us.

**M<sup>me</sup> France Gélinas:** Which they didn't do.

**Dr. Barzin Bahardoust:** We never heard back.

**The Chair (Mr. Peter Tabuns):** Your three minutes are up. To the government: Mrs. McGarry?

**Mrs. Kathryn McGarry:** Thank you very much for coming today and providing your perspective today.

**Dr. Barzin Bahardoust:** Thank you.

**Mrs. Kathryn McGarry:** You may have been in the room when I talked about my long tenure as a nurse in the province, and a child who was given products at the time where there were a lot that suffered from the tainted blood scandal. So it does hit me directly, not only as a provider but as a family member that could have gone through this.

That particular situation led to the Krever commission. We've heard very eloquently from a previous delegation about the number of reports and the amount of time that Mr. Krever went through his submissions. He really did come up with a single operator being the best solution for a Canadian blood supply here.

I know that you've tried to open pay-for-plasma clinics here in Ontario, and you've been met with significant resistance from not only government and organizations but also individuals and health care practitioners who believe in the need to preserve our voluntary blood donation system that's overseen by a single operator.

Why do you think that upholding a voluntary blood donation system is important to these Ontarians?

**Dr. Barzin Bahardoust:** We agree that we need a voluntary blood donation system for fresh blood products. The reality is that the plasma industry cannot be viewed as or be part of a subset of the national blood organization anymore.

Canadian Blood Services is procuring all of the plasma protein products that it's currently purchasing from private pharmaceutical companies. There is not a single not-for-profit company that is supplying Canadian Blood Services at the moment. They are purchasing these products and distributing them.

We are, again, as I mentioned, merely seeking to do the same. There are currently eight pharmaceutical companies that supply Canadian Blood Services. We were planning or hoping to be another pharmaceutical company that does that.

Again, we do agree with voluntary blood donation when it comes to fresh blood products. We just believe that there should be a distinction between plasma for further manufacturing for pharmaceuticals as opposed to fresh blood products.

**Mrs. Kathryn McGarry:** Okay; thank you. Under the Laboratory and Specimen Collection Centre Licensing Act, it's required to have a licence to operate a specimen collection centre. I understand you didn't apply for such a licence. Why is that?

**Dr. Barzin Bahardoust:** The Laboratory and Specimen Collection Centre Licensing Act specifically says that a specimen collection centre licence is required if the

specimen is collected for diagnosis, prophylaxis or treatment. We do not do any of those. We collect the specimen for screening donors to collect plasma for the manufacturing of drugs.

**The Chair (Mr. Peter Tabuns):** Sir, your time is up.

**Mrs. Kathryn McGarry:** Thank you.

**The Chair (Mr. Peter Tabuns):** I thank you very much for your presentation.

I'd like to thank everyone who came today and made their presentations. I think it's been very helpful to the committee.

A reminder to committee members: The deadline for the public to send in written submissions is 6 p.m. tomorrow, December 2. The deadline for committee members to file amendments to the bill with the Clerk is 12 noon on Wednesday, December 3.

This committee stands adjourned until 9 a.m. tomorrow, December 2.

No?

*Interjection.*

**The Chair (Mr. Peter Tabuns):** Yes—a big hand movement.

**M<sup>me</sup> France Gélinas:** I raised my hand gently. What's this?

*Interjection.*

**The Chair (Mr. Peter Tabuns):** A submission.

**M<sup>me</sup> France Gélinas:** Okay. My second question is, do we know what we're doing next week, and if not, can we have a committee of the—

**The Chair (Mr. Peter Tabuns):** The subcommittee?

**M<sup>me</sup> France Gélinas:** Subcommittee.

**The Chair (Mr. Peter Tabuns):** I'll discuss that with the Clerk, and we can discuss that in the morning.

**M<sup>me</sup> France Gélinas:** Sounds good.

**The Chair (Mr. Peter Tabuns):** Okay. Adjourned till 9 a.m. tomorrow morning.

*The committee adjourned at 1746.*



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