Jukes, Shaina HLTH:EX

From:

Jim Pimblett < jim.pimblett@beaconsfieldgroup.com>

Sent:

Friday, October 24, 2014 8:27 AM

To:

Jukes, Shaina HLTH:EX

Cc:

Min Lee

Subject:

attendees for the Nov 6th Mtg with Minister Lake

Hi Shaina,

Thanks again for your help with this. At the meeting with Minister the lake, the following people will attend (including myself)

Dr. Barzin Bahardoust Phd, CEO Canadian Plasma Resources

Dr. Georg Flos, Board member Biotest AG

Dr. Michael Ramroth Board member Biotest AG

Please let me know if you need further info.

Best,

Jim

Jukes, Shaina HLTH:EX

From:

Jim Pimblett < jim.pimblett@beaconsfieldgroup.com>

Sent:

Monday, October 27, 2014 10:03 AM

To:

Jukes, Shaina HLTH:EX; Min Lee

Subject:

Re: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Hi Shaina,

Just one agenda item. The establishment of a plasma based pharmaceutical business in BC.

Thanks!

Sent from my BlackBerry 10 smartphone on the Rogers network.

From: Jukes, Shaina HLTH:EX

Sent: Monday, October 27, 2014 12:57 PM

To: Min Lee Cc: Jim Pimblett

Subject: RE: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Good afternoon Min I am just following up on receiving agenda topics for your November 6th meeting.

Thank you, Shaina

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2 Phone: 250-953-3547| Fax: 250-356-9587| <u>Hlth.Health@qov.bc.ca</u>

From: Min Lee [mailto:min.lee@beaconsfieldgroup.com]

Sent: Wednesday, October 22, 2014 3:59 PM

To: Jukes, Shaina HLTH:EX

Cc: Jim Pimblett

Subject: RE: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Thank you very much Shaina,

We will submit agenda topics and attendee names by Friday as requested.

Have a great day.

Best, Min

Min Lee

Executive Assistant, Beaconsfield Group 2 Bloor Street East, Suite 3500 Toronto, Ontario, M4W 1A8 T 1.416.915.4263 M 1.416-419-6297 F 1.416.915.6280

min.lee@beaconsfieldgroup.com

x	
_	

From: Jukes, Shaina HLTH: EX [mailto:Shaina.Jukes@gov.bc.ca]

Sent: October-22-14 6:55 PM

To: Min Lee Cc: Jim Pimblett

Subject: RE: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Good afternoon Min, Please see below confirmed details for the November 6th meeting. We request you provide agenda topics and additional attendee names by Friday, October 24th as due to the short notice we do not have much time to prepare.

Meeting w/ Canadian Plasma Resources

Participants:

Minister Lake Staff TBC Jim Pimblett

Additional Attendees TBC

Date:

Thursday, November 6th

Time:

3:15pm - 3:45pm

Location:

Minister's Office, Room 337 Parliament Buildings Victoria

All the best, Shaina

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2 Phone: 250-953-3547| Fax: 250-356-9587| <u>Hlth.Health@gov.bc.ca</u>

From: Min Lee [mailto:min.lee@beaconsfieldgroup.com]

Sent: Wednesday, October 22, 2014 3:33 PM

To: Jukes, Shaina HLTH:EX
Cc: Jim Pimblett; Min Lee

Subject: RE: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Good afternoon Shaina,

Jim would be pleased to meet with Minister Lake on November 6th at 3:15pm. Could you kindly confirm the meeting location?

Thank you very much for arranging.

Best, Min

Min Lee

Executive Assistant, Beaconsfield Group 2 Bloor Street East, Suite 3500 Toronto, Ontario, M4W 1A8 T 1.416.915.4263 M 1.416-419-6297 F 1.416.915.6280 min.lee@beaconsfieldgroup.com

1	

From: Jukes, Shaina HLTH:EX [mailto:Shaina.Jukes@gov.bc.ca]

Sent: October-22-14 6:12 PM

To: Jim Pimblett

Subject: FW: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Good afternoon Jim, Minister Lake has an opening in his schedule on November 6th from 3:15pm – 3:45pm here in Victoria. Please let me know if this time will work for you and I will go ahead and confirm details.

All the best,

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2 Phone: 250-953-3547 | Fax: 250-356-9587 | Htth.Health@gov.bc.ca

From: Jim Pimblett [mailto:jim.pimblett@beaconsfieldgroup.com]

Sent: October-21-14 1:40 PM **To:** Loiacono, Sabrina HLTH:EX **Subject:** meeting request

Hi Sabrina,

My client, Canadian Plasma Resources, and their investors will be in BC on November 6, 7, and would like to meet with Minister Lake briefly if that is possible. As you may be aware, their proposal is to establish a plasma based pharmaceutical business in BC employing over a thousand people.

Best, Jim From: Docs Processing HLTH:EX

To: HLTH Ministers Office; Jukes, Shaina HLTH:EX

Cc: Casanova, Tamara HLTH:EX; Foran, Grace E HLTH:EX; O"Callaghan, Jacqueline HLTH:EX; Murray, Wendy

HLTH:EX; Docs Processing HLTH:EX; Stearn, Anne HLTH:EX; Belanger, Matthew GCPE:EX; Jabs, Ryan GCPE:EX;

Anderson, Kristy GCPE:EX

Subject: 1022826 - Minister Meeting (Nov 6) with Canadian Plasma Resources re proposed BC plasma based

pharmaceutical business

Date: Thursday, October 30, 2014 4:07:27 PM

Attachments: 1022826 - Minister Meeting with Canadian Plasma Resources.docx

Hello,

Attached is information prepared by HSD for Minister's meeting with Canadian Plasma Resources on November 6, 2014. It has been approved by Doug Hughes and Manjit Sidhu, ADMs, and reviewed by Grace Foran.

Jessica King

Documents Processing Unit / Deputy Minister's Office / Ministry of Health PO Box 9639 STN PROV GOVT Victoria BC V8W 9P1 Telephone 250 952-2636

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From: Jukes, Shaina HLTH:EX

Sent: Wednesday, October 22, 2014 3:39 PM

To: Casanova, Tamara HLTH:EX

Cc: O'Callaghan, Jacqueline HLTH:EX; Docs Processing HLTH:EX

Subject: 1022826 - Minister Meeting (Nov 6) with Canadian Plasma Resources re proposed BC plasma based pharmaceutical business

This is now confirmed I have requested an agenda for Friday and we will require staff and materials.

BRIEFING re: Canadian Plasma Resources

Participants:

Minister Lake

Staff TBC

Jim Pimblett

Additional Attendees TBC

Date:

Thursday, November 6th

Time:

3:15pm - 3:45pm

Location:

Minister's Office, Room 337 Parliament Buildings Victoria

Thank you,

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake
Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2
Phone: 250-953-3547 | Fax: 250-356-9587 | Hlth.Health@gov.bc.ca

From: Casanova, Tamara HLTH:EX

Sent: Wednesday, October 22, 2014 3:00 PM

To: Jukes, Shaina HLTH:EX

Cc: O'Callaghan, Jacqueline HLTH:EX; Docs Processing HLTH:EX

Subject: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Thanks for the heads up Shaina. Please let Jacqui and DocsProcessing know if anything will be required.

Many thanks, Tamara

Tamara Casanova | Executive Operations

Office of the Deputy Minister Ministry of Health

P: 250.952.1908 | C: 250.217.3655 | email: tamara.casanova@gov.bc.ca

From: Jukes, Shaina HLTH:EX

Sent: Wednesday, October 22, 2014 11:35 AM

To: Casanova, Tamara HLTH:EX Subject: FW: meeting request

FYI

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake
Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2
Phone: 250-953-3547 | Fax: 250-356-9587 | Hlth.Health@gov.bc.ca

From: Loiacono, Sabrina HLTH:EX

Sent: Wednesday, October 22, 2014 9:41 AM

To: 'Jim Pimblett'

Cc: Jukes, Shaina HLTH:EX Subject: RE: meeting request

Hi Jim,

Shaina Jukes the Minister's Administrative Coordinator who I've cc'ed, will be in touch to confirm a time, date, and location for this meeting.

Kind regards,

Sabrina

Sabrina Loiacono

Chief of Staff Honourable Terry Lake Minister of Health 250-953-3547

Email: sabrina.loiacono@gov.bc.ca

Please consider the environment before printing this email.

From: Jim Pimblett [mailto:jim.pimblett@beaconsfieldgroup.com]

Sent: October-21-14 1:40 PM
To: Loiacono, Sabrina HLTH:EX
Subject: meeting request

Hi Sabrina,

My client, Canadian Plasma Resources, and their investors will be in BC on November 6, 7, and would like to meet with Minister Lake briefly if that is possible. As you may be aware, their proposal is to establish a plasma based pharmaceutical business in BC employing over a thousand people.

Best, Jim

MEETING MATERIAL

Cliff #: 1022826

PREPARED FOR: Honourable Terry Lake, Minister of Health

TITLE: Minister of Health Meeting with Canadian Plasma Resources

MEETING REQUEST/ISSUE:

Meeting requested by Canadian Plasma Resources to discuss a proposed BC-based plasma pharmaceutical business. Jim Pimblett, Partner, Beaconsfield Group (a strategic advisory firm), will be attending on behalf of Canadian Plasma Resources.

SHOULD MINISTRY STAFF ATTEND THIS MEETING:

Yes, Associate Deputy Minister, Lynn Stevenson, and Assistant Deputy Minister, Doug Hughes

BACKGROUND:

Canadian Plasma Resources

Canadian Plasma Resources (CPR) is a private company based in Ontario that has applied to Health Canada to establish a paid plasma collection business. CPR is a subsidiary of EXAPharma, a company owned and operated by the Riahi family of Toronto with plans to use paid plasma to manufacture plasma protein products (PPPs) by contract with fractionators and through its own fractionation plants that it intends to establish in Canada. PPPs are specialized products derived from human plasma used to treat bleeding disorders such as hemophilia.

In January 2013, CPR applied to Health Canada for a license to operate paid plasma collection centres in Toronto. On March 18, 2014, CPR opened its first clinic in Toronto to train staff and collect plasma for research purposes. On October 24, 2014, Health Canada told the BC Ministry of Health that CPR's application is in the final stages of review and is likely to be approved.

In April 2013, Health Canada held public consultations on the health and safety of paid plasma donations. A summary report of discussions with stakeholders was produced, with Health Canada highlighting the authority of provinces and territories "to allow or disallow the payment of donors for their blood, including plasma."

¹ www.giveplasma.ca.

www.exapharma.ca

³ Maclean's. "Should we pay for blood?". April 15, 2013. www.macleans.ca/news/canada/should-we-pay-for-blood.

⁴ The Toronto Star. "Plasma clinic plans to open in Toronto in defiance of promised Ontario ban". March 18, 2014.

www.thestar.com/news/queenspark/2014/03/18/plasma_clinic_plans_to_open_in_toronto_in_defiance_of_promised_ontario_ban.html.

⁵ Telephone communication October 24, 2014, between the Biologics and Genetic Therapies Directorate, Health Products and Food Branch of Health Canada and the Laboratory, Diagnostic and Blood Services Branch of the BC Ministry of Health.

⁶ www.hc-sc.gc.ca/dhp-mps/consultation/biolog/plasma-consult-eng.php

Representatives of CPR/EXAPharma met with Canadian Blood Services (CBS) in 2009 and 2011 to discuss becoming a supplier of PPPs distributed by CBS to provinces and territories. CBS Chief Executive Officer, Dr. Graham Sher, said at the time that no commitments have been made with the company and that CBS' business model requires it to source PPPs that are licensed for sale in Canada through a public tendering process that is based on safety, security of supply, and cost. 8

Canadian Blood Services

As per the 1997 Federal/Provincial/Territorial Memorandum of Understanding, CBS is the sole provider of blood and blood products for Canadians (excluding Quebec, which has its own blood system, Héma-Quebec). This includes both the collection of plasma from voluntary donations and the supply and distribution of plasma and PPPs to Canadian hospitals. BC does not directly work with, or entertain proposals from, alternate suppliers of plasma products.

Canada is self-sufficient in plasma for transfusion, but relies, via CBS, on plasma collected from non-Canadian, paid donors for manufacturing PPPs. Most of the world's supply of plasma to make PPPs comes from paid donors. Approximately 70 percent of the PPPs distributed by CBS are derived from paid plasma donations. BC's budget for PPPs for 2014/15 is \$66.68 million.

Legislation and other Jurisdictions

The government of Ontario has introduced legislation (Bill 21, the *Safeguarding Health Care Integrity Act*, 2014) to ban payment for plasma and blood donations. The legislation passed first reading on July 22, 2014, and is proceeding through the legislative process. The bill, once passed, will make payment for blood and plasma donations an offence under Ontario law and subject to fines of up to \$500,000 for each day the offence continues.

Paid plasma donation is not illegal under BC law. BC's *Human Tissue Gift Act* does not prohibit payment for blood and plasma donations. Should Bill 21 succeed in passing, Ontario would join Quebec as the only Canadian jurisdictions with legislation prohibiting payment for blood and plasma donations. However, these provinces, like all other Canadian provinces and territories, rely on PPPs that are made with plasma from paid foreign donors.

Business Model and Effect on Voluntary Donations

Manitoba's Cangene Plasma Resources, a biopharmaceutical company licensed by Health Canada, has operated a plasma collection centre in Winnipeg for over 30 years that offers compensation for specific plasma donation programs. Makers of WinRho® SDF, a product used to treat Rh negative women during pregnancy, Cangene's operation is highly specialized and targets a donor base of women with unique antibodies to produce hyperimmune plasma products.

8 Ibid

⁷ Ibid.

⁹ www.ontla.on.ca/web/bills/bills_detail.do?locale=en&BillID=3015&detailPage=bills_detail_status.

Media reports of CPR, its promotional materials and its website, appear to show a business model that is less focused and more broad-based than Cangene's.

It is currently unknown what effect widespread payment for plasma would have on donations collected by CBS for the purpose of manufacturing PPPs used by Canadians. Currently CBS does not collect enough blood in BC to supply our needs. As a national organization, CBS determines collection targets based on cost effectiveness, which means that BC relies on the national inventory to meet our needs. s.13,s.17 s.13,s.17

s.13,s.16,s.17

ADVICE:

s.13

Prepared by: HSD Date: October 30, 2014

From: <u>Jukes, Shaina HLTH:EX</u>

To: O"Callaghan, Jacqueline HLTH:EX; Casanova, Tamara HLTH:EX

Cc: Docs Processing HLTH:EX

Subject: 1022826 - Possible Nov 6 Minister meeting with Canadian Plasma Resources

Date: Monday, October 27, 2014 10:26:35 AM

Hi Jacqui in follow up to our November 6th meeting with this group they have confirmed they only have the one following agenda item to discuss.

The establishment of a plasma based pharmaceutical business in BC.

Thank you, Shaina

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake
Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2
Phone: 250-953-3547 | Fax: 250-356-9587 | Hlth.Health@gov.bc.ca

From: O'Callaghan, Jacqueline HLTH:EX Sent: Thursday, October 23, 2014 11:49 AM

To: Casanova, Tamara HLTH:EX; Jukes, Shaina HLTH:EX

Cc: Docs Processing HLTH:EX

Subject: RE: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Good morning Shaina,

The DM happens to have a phone call scheduled for this afternoon with Mr. Pimblett, he will update the Minister on that discussion.

Jacqui.

From: Casanova, Tamara HLTH:EX

Sent: Wednesday, October 22, 2014 3:47 PM

To: O'Callaghan, Jacqueline HLTH:EX

Cc: Docs Processing HLTH:EX

Subject: RE: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Jacqui - Leaving this request with you to handle/check with Steve's meeting.

Thanks.

Tamara Casanova | Executive Operations

Office of the Deputy Minister Ministry of Health

P: 250.952.1908 | C: 250.217.3655 | email: tamara.casanova@gov.bc.ca

From: Jukes, Shaina HLTH:EX

Sent: Wednesday, October 22, 2014 3:44 PM

To: Casanova, Tamara HLTH:EX

Cc: O'Callaghan, Jacqueline HLTH:EX; Docs Processing HLTH:EX

Subject: RE: Possible Nov 6 Minister meeting with Canadian Plasma Resources

In addition Sabrina has mentioned that Steve might be meeting with them while they are here can we check on that please.

Thank you, Shaina

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake
Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2
Phone: 250-953-3547 | Fax: 250-356-9587 | Hlth.Health@gov.bc.ca

From: Jukes, Shaina HLTH:EX

Sent: Wednesday, October 22, 2014 3:39 PM

To: Casanova, Tamara HLTH:EX

Cc: O'Callaghan, Jacqueline HLTH:EX; Docs Processing HLTH:EX

Subject: RE: Possible Nov 6 Minister meeting with Canadian Plasma Resources

This is now confirmed I have requested an agenda for Friday and we will require staff and materials.

BRIEFING re: Canadian Plasma Resources

Participants:

Minister Lake

Staff TBC

Jim Pimblett

Additional Attendees TBC

Date:

Thursday, November 6th

Time:

3:15pm – 3:45pm

Location:

Minister's Office, Room 337 Parliament Buildings Victoria

Thank you,

S.

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake
Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2

Phone: 250-953-3547 | Fax: 250-356-9587 | Hlth.Health@gov.bc.ca

From: Casanova, Tamara HLTH:EX

Sent: Wednesday, October 22, 2014 3:00 PM

To: Jukes, Shaina HLTH:EX

Cc: O'Callaghan, Jacqueline HLTH:EX; Docs Processing HLTH:EX

Subject: Possible Nov 6 Minister meeting with Canadian Plasma Resources

Thanks for the heads up Shaina. Please let Jacqui and DocsProcessing know if anything will be required.

Many thanks, Tamara

Tamara Casanova | Executive Operations

Office of the Deputy Minister Ministry of Health

P: 250.952.1908 | C: 250.217.3655 | email: tamara.casanova@gov.bc.ca

From: Jukes, Shaina HLTH:EX

Sent: Wednesday, October 22, 2014 11:35 AM

To: Casanova, Tamara HLTH:EX Subject: FW: meeting request

FYI

Shaina Jukes

Administrative Coordinator to the Honourable Terry Lake
Minister of Health | PO Box 9050 Stn Prov Govt Victoria, BC V8W 9E2
Phone: 250-953-3547 | Fax: 250-356-9587 | Hlth.Health@gov.bc.ca

From: Loiacono, Sabrina HLTH:EX

Sent: Wednesday, October 22, 2014 9:41 AM

To: 'Jim Pimblett'

Cc: Jukes, Shaina HLTH:EX Subject: RE: meeting request

Hi Jim,

Shaina Jukes the Minister's Administrative Coordinator who I've cc'ed, will be in touch to confirm a time, date, and location for this meeting.

Kind regards,

Sabrina

Sabrina Loiacono

Chief of Staff Honourable Terry Lake

Minister of Health 250-953-3547

Email: sabrina.loiacono@gov.bc.ca

Please consider the environment before printing this email.

From: Jim Pimblett [mailto:jim.pimblett@beaconsfieldgroup.com]

Sent: October-21-14 1:40 PM
To: Loiacono, Sabrina HLTH:EX
Subject: meeting request

Hi Sabrina,

My client, Canadian Plasma Resources, and their investors will be in BC on November 6, 7, and would like to meet with Minister Lake briefly if that is possible. As you may be aware, their proposal is to establish a plasma based pharmaceutical business in BC employing over a thousand people.

Best, Jim

Vowles, Wendy M HLTH:EX

From:

Crickmore, Jane HLTH:EX

Sent:

Friday, September 4, 2015 12:49 PM

To:

Shera, Deborah HLTH:EX

Cc:

Vowles, Wendy M HLTH:EX; Davidson, Philip HLTH:EX

Subject:

Plasma discussion

Hi Deborah – I spoke to Jim Pimblet this am re: Canadian Plasma Resources. He was waiting to hear back from the ministry re: any licensing or regulatory issues for the establishment of a plasma facility in BC. (I thought this info had been conveyed to them previously, but he advised no.)

I confirmed that there is no health legislation that applies (that is, related to a licence) and that they would need to confirm with the College of Physicians and Surgeons of BC if they were required to be accredited. I advised there we could not provide comment on any other regulatory requirements – such as a business license. I also confirmed that our phlebotomists are not regulated.

s.13,s.17

He stated that they were continuing to explore where to set up this business venture – BC, AB, MB or SK.

There is no further information/action required from us.

Jane Crickmore
Executive Director
Laboratory, Diagnostic and Blood Services Branch
Ministry of Health, 6th Floor, 1483 Douglas Street, Victoria, BC
Tel: (250) 356-1713; Email: jane.crickmore@gov.bc.ca

Mailing Address:

PO Box 9633 Stn Prov Govt, Victoria, BC V8W 9P1

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CLIFF# 1020382 - Honourable Terry Lake, Minister of Health - Paid Plasma Donation

REQUEST

Information on paid plasma donation and Ontario legislation to prohibit paid donation.

BACKGROUND

Plasma is a component of whole blood that can be used in two different ways: it can be transfused into patients or it can be manufactured into specialized products. The process of manufacturing plasma products is known as fractionation and the end result can be considered a pharmaceutical product rather than a component of fresh blood.

PLASMA FOR TRANSFUSION

In Canada, plasma for transfusion is collected from unpaid, volunteer donors. Canadian Blood Services (CBS) Chief Executive Officer, Dr. Graham Sher, has noted that the principle of not paying donors for blood and plasma donations used for transfusion is accepted widely internationally, and that there is no intention of doing differently in Canada. Canada is entirely self-sufficient in plasma for transfusion.

PLASMA FOR FRACTIONATION

Most of the world's supply of fractionated plasma products comes from paid donors. The demand for fractionated products in Canada, (prescribed to treat immune disorders, hemophilia and other blood disorders), exceeds our domestic supply. To meet Canadian demand for fractionated products, CBS collects plasma from Canadian voluntary donations and supplements this with plasma purchased from the United States. Approximately 70 percent of the fractionated products distributed by CBS are derived from paid donations.

Manufacturers of fractionated products must be licensed by and meet the stringent quality and safety standards of Health Canada. These products have a remarkable safety profile resulting from multi-layered production testing processes and procedures.

Health Canada – Health Canada is responsible for regulating the safety of Canada's blood system but have stated that the provincial and territorial governments have the authority to allow or disallow the payment of donors for their blood, including plasma. BC's *Human Tissue Gift Act* does not prohibit the payment for blood and blood products.

Ontario On July 22, 2014, Bill 21, the *Safeguarding Health Care Integrity Act, 2014*, received first reading in the Legislative Assembly of Ontario. Bill 21 combines two bills that were previously introduced but that did not pass before the dissolution of the Ontario legislature in the spring. The bill, if passed, would make payment for blood donations an offence under Ontario law and subject to fines of up to \$500,000 for each day the offence continues.

Manitoba - Cangene Plasma Resources has been operating a plasma collection centre in Winnipeg which compensates donors for plasma. Cangene's operation is specialized as it targets a certain donor base of women with unique antibodies to produce hyper-immune products. This company has been licensed by Health Canada for over 30 years.

Quebec - The Civil Code in Quebec prohibits the payment for any body part or product and is based on the principle that the body cannot be the object of commerce. However, as in the rest of the world, Quebec continues to import products made from plasma from paid commercial plasma donors.

The Canadian Hemophilia Society (CHS) – CHS has developed a policy on paid plasma donations. The policy states that plasma products derived from both paid and unpaid sources of plasma are essential to the health of thousands of Canadians, and that the collection of source plasma from paid donors in a properly regulated environment is not a patient safety issue. While the policy of the CHS national organization supports the fractionation of plasma products from paid sources of plasma, the BC and Ontario Chapters of the CHS remain adamantly opposed to this practice.

World Health Organization (WHO) – WHO's goal for all countries is to obtain all blood supplies from voluntary unpaid donors by 2020 because studies point to volunteers as the group with the lowest prevalence of blood-borne infections. However, the WHO also recognizes that access to the supply of blood products is critical for the health and wellbeing of many people and emphasizes that supply must take priority over the source of donor plasma.

KEY MESSAGES

- Most of the world's supply of manufactured plasma products comes from paid donors.
- Canada relies on plasma products derived from plasma collected in large part from non-Canadian, paid donors that are distributed by Canadian Blood Services.
- Health Canada regulates the safety of blood and plasma used for transfusion and for the manufacture of blood products through the Food and Drugs Act.
- British Columbia's *Human Tissue Gift Act* does not prohibit paid blood and plasma donations.

Program Area: HSD Date: October 7, 2014

Z:\LDBSB\Briefing Notes\Blood\2014\1020382 Info for Minister on Paid Plasma.docx

¹ Canadian Blood Services website, March 13, 2013 statement Canadian Blood Services clarifies its role in the national and international collection and use of plasma

 $[\]underline{\text{http://www.bloodservices.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/page/CanadianBloodServicesClarifiesItsRoleInTh}\underline{\text{eNationalAndInternationalCollectionAndUseOfPlasma?OpenDocument\&CloseMenu}}$

http://www.hemophilia.ca/files/Policy%20on%20Paid%20Plasma%20Donations%2029-05-2013.pdf Draft Policy on Paid Plasma Donations. May 26, 2013

Vowles, Wendy M HLTH:EX

From:

Vowles, Wendy M HLTH:EX

Sent:

Tuesday, October 7, 2014 11:36 AM

To:

Evernden, Erica HLTH:EX; Williams, Dianna HLTH:EX

Cc:

Richard, Pat HLTH:EX; HSD Documents Coordinator HLTH:EX

Subject:

RE: 1020382 - MO Info Request re Plasma donation information and legislation to ban

private clinics who pay individuals to donate

Tracking:

Recipient

Read

Evernden, Erica HLTH:EX

Williams, Dianna HLTH:EX

Read: 2014-10-07 11:38 AM

Richard, Pat HLTH:EX

HSD Documents Coordinator HLTH:EX

Read: 2014-10-07 11:37 AM

Hi Erica,

Drafting now. We had a due date of Oct 15 noted. Apologies. Will send out shortly.

W

From: Evernden, Erica HLTH:EX

Sent: Tuesday, October 7, 2014 11:24 AM

To: Williams, Dianna HLTH:EX

Cc: Vowles, Wendy M HLTH:EX; Richard, Pat HLTH:EX; HSD Documents Coordinator HLTH:EX

Subject: FW: 1020382 - MO Info Request re Plasma donation information and legislation to ban private clinics who pay

individuals to donate

Hi Dianna -

This is sitting with you in eapprovals. Please note this needs to be assigned and completed asap.

Sincerely,

Erica Evernden | Manager, Executive Operations

Assistant Deputy Minister's Office | Health Services Policy & Quality Assurance Division | Ministry of Health

Phone: 250.952.1125 | Fax: 250.952.1052

From: Docs Processing HLTH:EX

Sent: Tuesday, October 7, 2014 11:10 AM

To: HSD Documents Coordinator HLTH:EX; Evernden, Erica HLTH:EX

Cc: Docs Processing HLTH:EX; Casanova, Tamara HLTH:EX

Subject: 1020382 - MO Info Request re Plasma donation information and legislation to ban private clinics who pay

individuals to donate

Per DMO; I have adjusted due date in cliff & e-apps. This is now urgent and needs to go to the MO today (Oct 7).

Thanks so much,

Kathy Simonson
Program Coordinator / Documents Processing Unit / Deputy Minister's Office / Ministry of Health
5-2 1515 Blanshard St, Victoria BC V8W 3C8
Telephone 250 952-1811

kathy.simonson@gov.bc.ca

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From: O'Brien, Kellie HLTH:EX

Sent: Wednesday, October 1, 2014 3:52 PM

To: Docs Processing HLTH:EX **Cc:** Casanova, Tamara HLTH:EX

Subject: 1020382 - Mo Info Request re Plasma donation information and legislation to ban private clinics who pay

individuals to donate

Hi Docs,

Could staff please provide me with some information around plasma donation.

I understand that the Ontario government was moving towards legislation to ban private clinics who pay individuals to donate. They have since moved away from this.

Could I please receive some information on this, if possible.

Thanks, Kellie

Kellie O'Brien

Executive Assistant to the Hon. Terry Lake Minister of Health, Province of BC

D: 250-953-3547 C: 250-896-0685

Davidson, Philip HLTH:EX

From:

Crickmore, Jane HLTH:EX

Sent:

Friday, October 24, 2014 9:37 AM

To:

Vowles, Wendy M HLTH:EX

Cc:

Davidson, Philip HLTH:EX

Subject:

RE: Bullets on paid plasma collection centres

Thanks Wendy – I think this will be important to note these issues and the "competition" for donors if such a company sets up in BC.

Jane Crickmore

Executive Director

Laboratory, Diagnostic and Blood Services Branch Health Services Policy and Quality Assurance Division Ministry of Health, 6th Floor, 1483 Douglas Street, Victoria, BC

Tel: (250) 356-1713; Email: jane.crickmore@gov.bc.ca

Mailing Address:

PO Box 9633 Stn Prov Govt, Victoria, BC V8W 9P1

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From: Vowles, Wendy M HLTH:EX Sent: Friday, October 24, 2014 9:19 AM

To: Crickmore, Jane HLTH:EX **Cc:** Davidson, Philip HLTH:EX

Subject: RE: Bullets on paid plasma collection centres

Hi Jane,

Philip spoke with **Health Canada** this morning and CPR is expected to receive a license shortly. s.13,s.16,s.17

CBS gets three products from **Cangene:** WinRho SDF, HepaGam B and VariZIG. I believe the donors in Winnipeg are specifically for WinRho but we are confirming.

From: Crickmore, Jane HLTH:EX Sent: Friday, October 24, 2014 8:50 AM

To: Stevenson, Lynn HLTH:EX

Cc: Hughes, Doug J HLTH:EX; Vowles, Wendy M HLTH:EX **Subject:** RE: Bullets on paid plasma collection centres

Yes, that is correct – we pay CBS to provide this function (both collect plasma and provide the resulting products) and therefore, as a province, we would not be working with an alternate supplier. However, that does not negate the fact that there are no legislative provisions to prevent this company from independently setting up in BC, and paying people to provide their plasma (which I assume they would then ship out of province to be processed into products).

We will be fleshing out the information for the meeting more fully.

Jane Crickmore

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To: Crickmore, Jane HLTH:EX

Cc: Hughes, Doug J HLTH:EX; Vowles, Wendy M HLTH:EX **Subject:** Re: Bullets on paid plasma collection centres

thanks for this jane...appreciate the quick turn around..i think the couple of things that might be strengthened is that from what i understand we (as a province) already pay cbs to do this so what is your advice?

Sent from my iPad

On Oct 23, 2014, at 4:56 PM, Crickmore, Jane HLTH:EX < <u>Jane.Crickmore@gov.bc.ca</u>> wrote:

Hi Lynn – in response to your request re: information on paid plasma collection centres – staff have been asked to prepare information in relation to a meeting that is supposed to be taking place between the Minister, the DM and Jim Pimblett of Canadian Plasma Resources on November 6th.

Attached are some information bullets that they are working from to prepare information for the meeting.

In summary:

- There is no legislation in BC that would prevent a paid plasma centre from operating in this province
- ON is pursuing legislation to prohibit such facilities; Quebec's law prohibits payment

- The BC chapter of the Canadian Hemophilia Society does not support the concept (the national society does not object to it)
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- CBS collects and ships Canadian plasma collected from volunteers to the US, where it is pooled with plasma collected from "paid donors", and manufactured into plasma protein products that CBS then provides to hospitals
- Approx 70 percent of the plasma protein products distributed by CBS are derived from paid donations.
- Approx \$460M of the CBS national budget nearly 50% of their budget is directed to the purchase of plasma protein products.

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<2014 10 23 MINISTER MEETING OVERVIEW - Nov. 6, 2014 - Paid Plasma.docx>

Gallant, Roxanne HLTH:EX

From:

Stevenson, Lynn HLTH:EX

Sent:

Friday, October 24, 2014 8:52 AM

To:

Crickmore, Jane HLTH:EX

Cc:

Hughes, Doug J HLTH:EX; Vowles, Wendy M HLTH:EX

Subject:

RE: Bullets on paid plasma collection centres

Thx much..lynn

From: Crickmore, Jane HLTH:EX

Sent: Friday, October 24, 2014 8:50 AM

To: Stevenson, Lynn HLTH:EX

Cc: Hughes, Doug J HLTH:EX; Vowles, Wendy M HLTH:EX **Subject:** RE: Bullets on paid plasma collection centres

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To: Crickmore, Jane HLTH:EX

Cc: Hughes, Doug J HLTH:EX; Vowles, Wendy M HLTH:EX **Subject:** Re: Bullets on paid plasma collection centres

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MINISTER MEETING WITH CANADIAN PLASMA RESOURCES

November 6, 2014

- A meeting is scheduled for November 6, 2014, between the Honourable Terry Lake,
 Minister of Health, Stephen Brown, Deputy Minister of Health, and Jim Pimblett of Canadian Plasma Resources (CPR).
- Laboratory, Diagnostic and Blood Services Branch is preparing a brief overview for this meeting (1022826).
- CPR is a private plasma collection company based in Ontario, which is attempting to establish a
 paid plasma donation business in Ontario.
- Canada is self-sufficient in plasma for transfusion, but relies on plasma collected from non-Canadian, paid donors for manufacturing specialized plasma protein products used to treat bleeding disorders such as hemophilia.
- Most of the world's supply of manufactured plasma protein products comes from paid donors.

Legislation:

- Health Canada regulates the safety of plasma used for transfusion and for manufacturing plasma
 protein products under the Food and Drugs Act. Health Canada has stated that the provincial and
 territorial governments have the authority to allow or disallow the payment of donors for their
 blood, including plasma.
- British Columbia's Human Tissue Gift Act does not prohibit paid blood and plasma donations.
- The government of Ontario has tabled legislation (Bill 21, the *Safeguarding Health Care Integrity Act*, 2014) to ban payment for plasma and blood donations. The legislation passed first reading on July 22, 2014, and is proceeding through the legislative process.
- In Manitoba, Cangene Plasma Resources (licensed by Health Canada) has been operating a
 plasma collection centre in Winnipeg for over 30 years that compensates donors for plasma.
 Cangene's operation is specialized as it targets a certain donor base of women with unique
 antibodies to produce hyper-immune products.
- In Quebec, a Civil Code prohibits the payment for any body part of product and is based on the
 principle that the body cannot be the object of commerce. However, as in the rest of the world,
 Quebec continues to import products made from plasma from paid commercial plasma donors.

Canadian Blood Services (CBS):

- CBS is responsible for the provision of blood and blood products (plasma protein products) for Canadians (excluding Quebec, which has its own blood system, Héma-Quebec).
- The demand for plasma protein products in Canada exceeds our domestic supply. In order to meet
 Canadian demand CBS collects plasma from Canadian voluntary donations which is shipped to
 the United States, and then combined with plasma purchased in the United States and
 manufactured into plasma protein products. These products are then distributed by CBS to
 Canadian hospitals.

 Approximately 70 percent of the plasma protein products distributed by CBS are derived from paid donations.

Canadian Hemophilia Society (CHS):

- CHS has developed a policy on paid plasma donations which states that plasma products derived
 from both paid and unpaid sources of plasma are essential to the health of thousands of
 Canadians, and that the collection of source plasma from paid donors in a properly regulated
 environment is not a patient safety issue.
- It is important to note that both the BC and Ontario Chapters of the CHS <u>remain adamantly</u> opposed to the practice of fractionation of plasma products from paid sources of plasma.

World Health Organization (WHO):

- WHO's goal for all countries is to obtain all blood supplies from voluntary unpaid donors by 2020 because studies point to volunteers as the group with the lowest prevalence of blood-borne infections.
- WHO also recognizes that access to the supply of blood products is critical for the health and
 wellbeing of many people and emphasizes that <u>supply must take priority over the source</u> of donor
 plasma.

Davidson, Philip HLTH:EX

From:

Crickmore, Jane HLTH:EX

Sent:

Saturday, October 25, 2014 8:10 AM

To:

Vowles, Wendy M HLTH:EX; Davidson, Philip HLTH:EX

Subject:

FW: November 6 - Minister meeting with Canadian Plasma Resources

fyi

Jane Crickmore
Executive Director
Laboratory, Diagnostic and Blood Services Branch
Ministry of Health
6th Floor, 1483 Douglas Street
Victoria, BC V8W 3K4

Tel: (250) 356-1713 Fax: (250) 356-1679

Email: jane.crickmore@gov.bc.ca

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From: Evernden, Erica HLTH:EX
Sent: Friday, October 24, 2014 8:31 PM

To: Hughes, Doug J HLTH:EX; Crickmore, Jane HLTH:EX

Subject: Fw: November 6 - Minister meeting with Canadian Plasma Resources

Fyi

Thanks, Erica

Sent from my BlackBerry 10 smartphone on the Rogers network.

From: O'Callaghan, Jacqueline HLTH:EX < <u>Jacqueline.OCallaghan@gov.bc.ca</u>>

Sent: Friday, October 24, 2014 3:40 PM

To: Evernden, Erica HLTH:EX; Stearn, Anne HLTH:EX **Cc:** Docs Processing HLTH:EX; Casanova, Tamara HLTH:EX

Subject: November 6 - Minister meeting with Canadian Plasma Resources

Hi Erica/Anne:

The MO has confirmed the above noted Minister meeting with Canadian Plasma Resources. Details are below.

Date: Thursday, November 6th **Time:** 3:15pm – 3:45pm

Location: Minister's Office, Room 337 Victoria (Parliament Buildings)

Agenda Items:

TBC

Participants:

- Jim Pimblett
- Additional TBD

Calendar invites will be sent to Lynn Stevenson and Doug Hughes to attend. Please advise if any additional staff will need to be included.

 $\textbf{Materials:} \ \, \text{DocsProcessing will assign formally for materials as per usual process.} \ \, \text{Due date for final materials to the MO} \ \, \text{is Thursday October 30}^{th}$

Please don't hesitate to give me a call if there are any concerns.

Many thanks, Jacqui.

Davidson, Philip HLTH:EX

From:

Vowles, Wendy M HLTH:EX

Sent:

Saturday, October 25, 2014 2:06 PM

To:

Crickmore, Jane HLTH:EX

Cc:

Davidson, Philip HLTH:EX; Carter, Janet HLTH:EX

Subject:

1022826 - Minister Meeting with Canadian Plasma Resources

Attachments:

1022826 - Minister Meeting with Canadian Plasma Resources.docx

Hi Jane,

Here is a draft for your review. Philip is off Monday, FYI, but Janet will be here.

W

MEETING MATERIAL

Cliff #: 1022826

PREPARED FOR: Honourable Terry Lake, Minister of Health

TITLE: Minister of Health Meeting with Canadian Plasma Resources

MEETING REQUEST/ISSUE:

Meeting requested by Canadian Plasma Resources to discuss a proposed BC-based plasma pharmaceutical business

SHOULD MINISTRY STAFF ATTEND THIS MEETING: (If so, who?)

Yes, Associate Deputy Minister of Health, Lynn Stevenson, and Assistant Deputy Minister Doug Hughes.

BACKGROUND: What do you know about this organization? What information should the person attending the meeting/declining the meeting know?

Canadian Plasma Resources

Canadian Plasma Resources (CPR) is a private company based in Ontario that has applied to Health Canada to establish a paid plasma collection business. CPR is a subsidiary of EXAPharma, a company owned and operated by the Riahi family of Toronto with plans to use paid plasma to manufacture plasma protein products (PPPs) by contract with fractionators and through its own fractionation plants that it intends to establish in Canada. PPPs are specialized products derived from human plasma used to treat bleeding disorders such as hemophilia.

In January 2013, CPR applied to Health Canada for a license to operate paid plasma collection centres in Toronto. On March 18, 2014, CPR opened its first clinic in Toronto to train staff and collect plasma for research purposes. On October 24, 2014, Health Canada told the BC Ministry of Health that CPR's application is in the final stages of review and is likely to be approved.

In April 2013, Health Canada held public consultations on the health and safety of paid plasma donations. A summary report of discussions with stakeholders was produced, with Health Canada highlighting the authority of provinces and territories "to allow or disallow the payment of donors for their blood, including plasma."

www.giveplasma.ca.

www.exapharma.ca

Maclean's. "Should we pay for blood?". April 15, 2013. www.macleans.ca/news/canada/should-we-pay-for-blood.

⁴ The Toronto Star. "Plasma clinic plans to open in Toronto in defiance of promised Ontario ban". March 18, 2014. www.thestar.com/news/queenspark/2014/03/18/plasma clinic plans to open in toronto in defiance of promised ontario ban.html.

⁵ Telephone communication October 24, 2014, between the Biologics and Genetic Therapies Directorate, Health Products and Food Branch of Health Canada and the Laboratory, Diagnostic and Blood Services Branch of the BC Ministry of Health.

⁶ www.hc-sc.gc.ca/dhp-mps/consultation/biolog/plasma-consult-eng.php

Representatives of CPR/EXAPharma met with Canadian Blood Services (CBS) in 2009 and 2011 to discuss becoming a supplier of PPPs distributed by CBS to provinces and territories. CBS chief executive officer, Dr. Graham Sher, said at the time that no commitments have been made with the company and that CBS' business model requires it to source PPPs that are licensed for sale in Canada through a public tendering process that is based on safety, security of supply, and cost. 8

Canadian Blood Services

As per the 1997 Federal/Provincial/Territorial Memorandum of Understanding, CBS is the sole provider of blood and blood products for Canadians (excluding Quebec, which has its own blood system, Héma-Quebec). This includes both the collection of plasma from voluntary donations and the supply and distribution of plasma and PPPs to Canadian hospitals. BC does not directly work with or entertain proposals from alternate suppliers of plasma products.

Canada is self-sufficient in plasma for transfusion, but relies, via CBS, on plasma collected from non-Canadian, paid donors for manufacturing PPPs. Most of the world's supply of plasma to make PPPs comes from paid donors. Approximately 70 percent of the PPPs distributed by CBS are derived from paid plasma donations. BC's budget for PPPs for 2014/15 is \$66.68M.

Legislation and other Jurisdictions

The government of Ontario has introduced legislation (Bill 21, the *Safeguarding Health Care Integrity Act, 2014*) to ban payment for plasma and blood donations. The legislation passed first reading on July 22, 2014, and is proceeding through the legislative process. The bill, once passed, will make payment for blood and plasma donations an offence under Ontario law and subject to fines of up to \$500,000 for each day the offence continues.

Paid plasma donation is not illegal under BC law. BC's *Human Tissue Gift Act* does not prohibit payment for blood and plasma donations. Should Bill 21 succeed in passing, Ontario would join Quebec as the only Canadian jurisdictions with legislation prohibiting payment for blood and plasma donations. However, these provinces, like the all other Canadian provinces and territories, rely on PPPs that are made with plasma from paid foreign donors.

Business Model and Effect on Voluntary Donations

Manitoba's Cangene Plasma Resources, a biopharmaceutical company licensed by Health Canada, has operated a plasma collection centre in Winnipeg for over 30 years that offers compensation for specific plasma donation programs. Makers of WinRho® SDF, a product used to treat Rh negative women during pregnancy, Cangene's operation is highly specialized and targets a donor base of women with unique antibodies to produce hyperimmune plasma products.

Media reports of CPR, its promotional materials and its website, appear to show a business model that is less focused and more broad-based than Cangene's.

8 Ihid

⁷ Ibid.

⁹ www.ontla.on.ca/web/bills/bills detail.do?locale=en&BillID=3015&detailPage=bills detail status.

It is currently unknown what effect widespread payment for plasma would have on donations collected by CBS for the purpose of manufacturing PPPs used by Canadians. Currently CBS does not collect enough blood in BC to supply our needs. as a national organization CBS determines collection target based on cost effectiveness, which means that BC relies on the national invent to meet our needs. s.13,s.17 s.13,s.17

s.13,s.16,s.17

ADVICE: Should any topics be brought up/avoided? Should any materials be brought to the meeting? If so, what other materials?

Z:\LDBSB\Briefing Notes\Blood\2014\1022826 - Minister Meeting with Canadian Plasma Resources.docx

Vowles, Wendy M HLTH:EX

From:

Hughes, Doug J HLTH:EX

Sent:

Thursday, November 6, 2014 4:02 PM

To:

Crickmore, Jane HLTH:EX

Subject:

Re: Plasma

Tx. Mtg. Went well. No follow up.

Sent from my BlackBerry 10 smartphone on the TELUS network.

Original Message

From: Crickmore, Jane HLTH:EX

Sent: Thursday, November 6, 2014 3:43 PM

To: Hughes, Doug J HLTH:EX

Subject: RE: Plasma

Doug, they had an application into Health Canada for approval. When we checked last week with Health Canada, a decision had not been rendered at that time. There are no legal barriers in BC for them to establish a centre and collect plasma here.

Jane Crickmore

Executive Director

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----Original Message----

From: Hughes, Doug J HLTH:EX

Sent: Thursday, November 6, 2014 3:26 PM

To: Crickmore, Jane HLTH:EX

Subject: Plasma

They say the have Federal approval to collects plasma?

Sent from my iPad

Stearn, Anne HLTH:EX

From:

Stevenson, Lynn HLTH:EX

Sent:

Saturday, October 25, 2014 12:17 PM

To:

Brown, Stephen R HLTH:EX

Subject:

Fwd: Bullets on paid plasma collection centres

Attachments:

2014 10 23 MINISTER MEETING OVERVIEW - Nov. 6, 2014 - Paid Plasma.docx;

ATT00001.htm

Fyi they will refine for mtg. Bottom line no barrier from a reg leg point of view however we pay cbs to do this and in particular assure quality. Will send the final note when completed. Lynn

Sent from my iPad

Begin forwarded message:

From: "Crickmore, Jane HLTH:EX" < Jane.Crickmore@gov.bc.ca>

Date: October 23, 2014 at 4:56:19 PM PDT

To: "Stevenson, Lynn HLTH:EX" < Lynn. Stevenson@gov.bc.ca>

Cc: "Hughes, Doug J HLTH:EX" < Doug. Hughes@gov.bc.ca >, "Vowles, Wendy M HLTH:EX"

<Wendy.Vowles@gov.bc.ca>

Subject: Bullets on paid plasma collection centres

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