IN THE MATTER OF an appeal filed pursuant to the *Rules for Appeals* under the *Pre-1986/Post-1990 Hepatitis C Settlement Agreement* and its *Protocols*

CLAIM FILE: 07-04822

REASONS FOR DECISION

INTRODUCTION

[1] The HCV Personal Representative has appealed the decisions of the Administrator dated September 22, 2008 and December 10, 2008, in which the claim for compensation made in relation to the deceased HCV Infected Class Member under the *Pre-1986/Post-1990 Hepatitis C Settlement Agreement* ("*Settlement Agreement*") was denied on the basis that there was no proof of infection with the Hepatitis C virus.

FACTS

[2] On February 19, 2008, the HCV Personal Representative filed a claim for compensation under the *Settlement Agreement* and submitted information up to and including May 5, 2008 in order to complete the required forms. In the claim, she stated that the HCV Infected Class Member, her deceased husband, was a Primarily-Infected Person who was infected with the Hepatitis C virus through blood transfusions. The Blood Transfusion History Form referred to blood transfusions received at three different hospitals in 1979. In the Treating Physician Form, filed on May 5, 2008, the part entitled "Section C – HCV Antibody Test and /or PCR Test" indicated that the deceased HCV Infected Class Member was not tested for the HCV antibody or the Hepatitis C virus; the box stating "a diagnosis of cirrhosis in the absence of any other cause" was checked. The Treating Physician noted that the deceased HCV Infected Class Member was at Disease

Level 6 and checked the box for ascites. He indicated that an HCV infection had materially contributed to the Disease Level 6 condition and later noted that the HCV had materially contributed to the death by "cirrhosis of the liver with ascites". At various places on the Form, the Treating Physician and made the notation "see Autopsy findings". He also added the following note to the form:

> In 1978 he worked off and on but 1979 he could not work. His wife believes he was on sick leave until around June 1979 when he became worse and never worked again.

A further Blood Transfusion History Form was filed on May 5, 2008, indicating that the medical condition leading to the blood transfusions was rectal bleeding. The deceased HCV Infected Class Member had no risk factors for the Hepatitis C virus.

[3] In support of the claim, the HCV Personal Representative submitted a record entitled "Summary Sheet" concerning the admission of the deceased HCV Infected Class Member to the hospital from December 14 to December 17, 1979. The case history summary stated, in part, as follows:

> This man was admitted with a probable acute colic causing jaundice and epigastric pain radiating to the back. Amylase was normal, liver enzymes elevated, bilirubin 7.1. While in the hospital the pain remitted and he felt well enough to be discharged. [...]

[4] The next day, on December 17, 1979, the deceased HCV Infected Class Member was readmitted to the hospital. The notes from the examination stated, in part, as follows:

> Markedly jaundiced, is very lethargic and apathetic. [...]
> Abdomen: [...] there is an obvious ascitis present clinically. [...] There are epigastric scars from previous surgery. The liver edge is felt.

The provisional diagnosis stated "jaundice and probable liver failure".

[5] The HCV Infected Class Member died on January 14, 1980. The Autopsy Report

stated, in part as follows:

> FINAL DIAGNOSIS:
>
> 1. CIRRHOSIS OF LIVER (POST NECROTIC).
> 2. ASCITES (THREE LITRES OF STRAW YELLOW FLUID).
> 3. ACUTE PULONARY CONGESTION [...]
> 4. BRAIN EDEMA

The Autopsy Report noted that the skin showed multiple scars in the abdomen and deep jaundice. The examination of the gastro-intestinal system showed, among other things, varicosis in the lower end of the esophagus, but no evidence of rupture of the varicose vein. It stated as follows with respect to the liver:

> [...] The size is markedly shrunken with gross irregular large nodule. Cut section show [sic] marked increase in consistency. No hepatoma seen.

At the end of the Autopsy Report, the microscopic findings with respect to the liver were summarized as follows:

> Section of liver shows complete loss of normal architecture with pseudolobulation and thick band of fibrous trabeculum. The liver cells show marked bile statis with no active necrosis. Moderate degree of chronic inflammatory cell infiltration is seen. No fatty metamorphosis seen. No hepatoma present.

[6] The HCV Personal Representative also submitted documents relating to an application for compensation made to a provincial program. There were three provincial program forms filled out by each of the three hospitals where transfusions were given and by the Canadian Blood Services. The first form, stamped April 9, 2003, confirmed five transfusions at a hospital on various dates in 1979 and had copies of the hospital transfusion records attached. The second form, stamped May 28, 2003, related to a second hospital and stated that the medical chart for the deceased HCV Infected Class Member was destroyed on May 7, 2000 and that there were no blood bank records prior to 1982. The third form, stamped May 16, 2003, related to the hospital where 24 units

were transfused and indicated that the traceback would be continued. A Canadian Blood Services report dated March 8, 2005, confirmed that the traceback was conducted for those 24 units of blood, with the results confirming that 14 were negative, 1 donor refused testing or was deceased and 9 donors were untraceable.

[7] Also included with the documents from the provincial program were two hospital blood transfusion forms dated August 6 and 10, 1979. In blood transfusion form dated August 6, 1979, the space “Previous Transfusions” was left blank. In the part of the form that contained details concerning the blood transfusions, there were several numbers listed in the column entitled “Bottle Number”. In the column entitled “Checked By”, there were initials in each space that corresponded to each Bottle Number. However, in the columns entitled “Time” and “Date”, there were notations in relation to only four of the Bottle Number entries. In the blood transfusion form dated August 10, 1979, the word “yes” was written in the space beside “Previous Transfusions”. There was one number listed under “Bottle Number” and the columns entitled “Checked By”, “Time” and “Date” each bore an entry corresponding to the Bottle Number.

[8] By letter dated August 11, 2008, the Canadian Blood Services forwarded the Traceback report, entitled “Transfusion Summary”, that stated as follows:

> **Timeframe: 1979**
>
> **Comments:**
> **24 units transfused at [one hospital]**
> 14 donors negative for HCV
> 1 donor refused
> 9 donors unlocatable
>
> **5 products transfused [at a second hospital]**
> CBS site [...] does not have donor records for these products and thus we are unable to perform a traceback.

> **[A third hospital] indicated that they have no patient or blood bank records prior to 1982.**

[9] The HCV Personal Representative has applied for and received compensation under the *Red Cross Settlement* and a provincial plan.

DECISION OF THE ADMINISTRATOR DATED SEPTEMBER 22, 2008

[10] In a decision dated September 22, 2008, the Administrator denied the claim for compensation for the following reasons:

> **Reasons for Decision**
>
> The Settlement Agreement requires the Administrator to determine a person's eligibility for class membership. As you may already know, section 2.01(1)(b) of the Settlement Agreement provides that you must deliver an HCV Antibody Test, PCR Test or similar test report to the Administrator. You have not provided proof of HCV (the Hepatitis C virus).
>
> The Court Approved Protocol, "HCV Antibody and PCR Tests Protocol", defines which HCV test is acceptable. Note that in some cases, the Administrator must consult a microbiologist to obtain his or her expert opinion.
>
> An **acceptable HCV Antibody Test** includes the following:
>
> a. a First Generation ELISA or EIA (1989-1990) which is confirmed or supplemented by a RIBA performed in a Canadian laboratory which reveals the presence of antibodies;
>
> b. a Second Generation ELISA or EIA (1991-1996) which is confirmed or supplemented by a RIBA performed in a Canadian laboratory which reveals the presence of antibodies; or
>
> c. a Third Generation ELISA or EIA or RIBA (1997 and after) performed in a Canadian laboratory which reveals the presence of antibodies.
>
> Where any of these tests were performed in a laboratory outside Canada, that laboratory must be acceptable to the Administrator, in consultation with a microbiologist.
>
> An acceptable **PCR Test** includes the following:
>
> a. a PCR Test dated January 1, 1998, or later, performed at any Canadian laboratory which indicates the presence of the virus; or

b. a PCR Test which indicates the presence of the virus that has been performed by a laboratory acceptable to the Administrator, in consultation with a scientist with PCR expertise.

If the Primarily-Infected Class Member is deceased and was not tested for the HCV antibody or HCV, you may deliver, instead of the evidence referred to in Section 2.01(1)(b), evidence of any one of the following:

(a) a liver biopsy consistent with HCV in the absence of any other cause of chronic hepatitus;

(b) an episode of jaundice within three months of receiving Blood in the absence of any other cause;

(c) a diagnosis of cirrhosis in the absence of any other cause; or

(d) where the claimant is a Primarily-Infected Hemophiliac, that the Primarily-Infected Hemophiliac has tested positive for HIV prior to his or her death.

As you may already know, every claim for compensation is reviewed and approved based on our review of documentation confirming a series of different bur related proven facts. As soon as a claim submission fails to meet one of several approval criteria as set out in the Settlement Agreement, the claim must be denied. It is important to note that in some cases, the subsequent claim evaluation steps were not completed after determining the need to deny the claim. Should you opt to appeal our decision to deny your claim and should you succeed on appeal, any and all pending evaluation steps will have to be completed. [Administrator's Emphasis]

REQUEST FOR REVIEW

[11] On October 20, 2008, the HCV Personal Representative filed a Request for Review. In the reasons for appealing, her daughter noted that additional records, found in files at home, confirmed that the deceased HCV Infected Class Member "[...] did not have any serious problems until after he received blood". She further stated as follows:

> The two papers attached here show that there was no gall bladder disease and the autopsy report also shows no gall stones. Therefore I believe the liver caused the jaundice and not the gall bladder. I also enclosed a form that was in the [workers' compensation] files showing he also received blood on December 6/78 and he may have received blood even before that.

SUPPLEMENTARY EVIDENCE FILED ON OCTOBER 20, 2008

[12] The HCV Personal Representative filed the following supplementary evidence with the Request for Review, including some medical and hospital records, as well as two opinions prepared by a medical specialist.

[13] The earliest record is a hospital report dated July 1, 1976 concerning an examination of the colon of the deceased HCV Infected Member that revealed a "possible slight splenomegaly".

[14] In early 1977, the deceased HCV Infected Class Member underwent further tests at the hospital. A report dated January 10, 1977 indicated that a test on his kidneys revealed no problems, and a report dated January 11, 1977 concerning a further examination of the colon confirmed that the results were essentially unchanged from the test on July 1, 1976, as described in the preceding paragraph.

[15] In a letter dated January 27, 1977 to another doctor, a specialist in internal medicine reported on his examination of the deceased HCV Infected Class Member, whose main complaint was "pain in the right lower quadrant" that arose at "irregular times". He stated, in part, as follows:

> Abdominal examination reveals McBurney's point tender. No mass could be felt. No hepatomegaly. No splenomegaly. I came to the conclusion that this patient has chronic appendicular colic and I think this man needs to have an operation. [...] I also entertain in the way of differential diagnosis Chrons's [sic] disease [...].

[16] On the same date, January 27, 1977, a surgeon prepared a "Consultation Note", in which he noted that the deceased HCV Infected Class Member had experienced some weight loss over the past two months and had complained, for over a year, of a "sharp

pain in the right lower abdomen". In his clinical diagnosis, he indicated "abdominal pain [not yet determined]" and suggested further investigations to be conducted.

[17] A hospital report dated February 9, 1977 confirmed that the deceased HCV Infected Class Member had an oesophageal hiatus hernia with probable oesophageal varices. Further examinations were recommended.

[18] On February 12, 1977, the surgeon added a "Chart Note" that the deceased HCV Infected Class Member was diagnosed with an oesophageal hiatal hernia and that further tests would be required.

[19] A hospital Operative Report dated March 1, 1977, concerning a test that was conducted by the surgeon, resulted in a diagnosis of non-specific gastritis and a sliding hiatal hernia. In a letter dated March 8, 1977, the surgeon reported the results of the test to the other doctor and made reference, among other things, to the chronic gastritis of the deceased HCV Infected Class Member.

[20] One month later, on April 8, 1977, the surgeon wrote to the other doctor to report that a test had ruled out the gall bladder as the cause of the problems being experienced by the deceased HCV Infected Class Member, but had demonstrated "[...] the significance of the demonstrated chronic gastritis". He also confirmed that the deceased HCV Infected Class Member had no oesophageal varices, but did have a hiatal hernia.

[21] In a medical report dated October 13, 1977, a second surgeon stated, among other things, that he had examined the deceased HCV Infected Class Member who had a lump on the right side of his abdomen. He diagnosed a ventral hernia and scheduled surgery for October 18, 1977.

[22] An Operative Record dated October 18, 1977 described the surgery for ventral hernia repair and noted that the deceased HCV Infected Class Member tolerated the procedure well. There was no reference in the report to a blood transfusion.

[23] On November 23, 1978, an examination of the colon revealed a possible polyp that was not present in the two previous examinations. Further investigations were recommended.

[24] On or about November 28, 1978, the doctor referred the deceased HCV Infected Class Member to another surgeon. The next day, the deceased HCV Infected Class Member was admitted to the hospital for a surgical procedure to determine the nature of the colon polyp.

[25] On December 4, 1978, the deceased HCV Infected Class Member had the surgical procedure and the Report of Operation prepared by the surgeon confirmed that there was no evidence of a polyp in the colon. There was no reference in the report to a blood transfusion.

[26] A hospital blood transfusion record indicated that blood was ordered on December 6, 1978, and the diagnosis was stated to be “anterior resection”. The space after “Previous Transfusions” and “Date” was left blank, as were the sections of the form indicating why the blood was required. In the part of the form that provided the details concerning the blood, two identification numbers were recorded in the column entitled “Bottle Number”. However, the spaces entitled “Checked By”, “Time” and “Date” contained no entries. There is a handwritten note at the very top of the form that states “Received blood in 1978”. However, there is no indication as to who wrote the note and I

have therefore disregarded it on the basis that it has no probative value and also appears to contradict the form, as the spaces for the time and date for transfusions were left blank.

[27] On May 16, 1979, the deceased HCV Infected Class Member had surgery for a large left femoral hernia. The Report of the Operation indicated that he had tolerated the procedure well, and there was no indication of any blood transfusion.

[28] By letter dated October 14, 2008, a certified specialist in internal medicine and nephrology, who is involved, among other things, in the investigation and management of patients with various liver diseases, including Hepatitis C, provided the following opinion:

> I have been asked [...] to review the information related to the [deceased HCV Infected Class Member], who died in January 1980 and to determine if there was a reasonable probability that he might have had i) liver disease, and ii) possibly hepatitis.
>
> I have reviewed the limited information provided and would summarize the pertinent findings (the facts):
>
> 1. Between 1976-77 [the deceased HCV Infected Class Member] was suffering from vague lower abdominal discomfort for which he saw various specialists and underwent investigations, without a specific diagnosis.
>
> 2. A Barium enema in Jul76 was unremarkable and possibility of slight splenomegaly was raised.
>
> 3. A gastroscopy in Mar77 was reported to have mild non-specific gastritis. No comments were given to exclude or confirm esophageal varices, in the report.
>
> 4. An upper GI examination in Feb77 showed esophageal hiatus hernia and probable esophageal varices.
>
> 5. A discharge summary sheet dated 14Dec79 states, "… probable acute biliary colic causing jaundice and epigastric pain radiating to the back. Amylase was normal, liver enzymes elevated, bilinubin 7.1…"
>
> 6. A Traceback report from Canadian Blood Services dated 11Aug08, indicates that the deceased received 24 units of blood at [a hospital] and of these 9 donors HCV status is unlocatable. He also received 5 units of

blood products at [another] Hospital and donor records were not available on these.

7. The autopsy report dated 14Jan80 shows that the deceased had cirrhosis of liver (post-necrotic) with ascites. Deep jaundice of skin was noted. The liver was markedly shrunken with gross irregular large nodules, the esophagus showed varicosities at lower end of esophagus and peritoneal cavity was noted to have 3 litres of straw yellow fluid (ascites). The spleen weighed 430 grams. No gall stones were noted.

8. The microscopic examination of the liver showed complete loss of normal architecture with pseudolobulation and thick band of fibrous trabeculum with market bile stasis with no active necrosis. Moderate degree of chronic inflammatory cell infiltration was seen. No fatty metamorphosis was seen.

Based on the above facts,

There is no doubt that the [the deceased HCV Infected Class Member] suffered from advanced liver disease – cirrhosis, as noted on autopsy examination, and its complications (esophageal varices, ascites and possibly splenomgealy), and some these were likely present in 1977 (upper GI series report #4 above). There has been no clear finding(s) of a gall bladder stones or disease, before or after death. The note in the discharge summary (#5 above) remains speculative and the jaundice could very well had been secondary to advanced liver disease.

The cause of cirrhosis of liver, at present, remains speculative but favors inflammatory condition like hepatitis, whether viral or non-viral and less likely to be alcoholic liver disease or non-alcoholic steato-hepatitis (NASH).

Various conditions can cause advanced liver disease, like cirrhosis and the common causes being alcoholic liver disease, non-alcoholic liver disease, vital hepatitis (hepatitis B & C), autoimmune hepatitis, primary biliary cirrhosis, toxic or ischemic liver injury. Of these the likelihood of alcoholic liver disease and non-alcoholic steatohepatis was low in the deceased because of the absence of fatty metamorphosis (#8 above), and the likelihood of an inflammatory pathology was high based on the findings of chronic inflammatory cell infiltration on the microscopic examination of liver (#8 above) and the possibilities include viral hepatitis (hepatitis B or hepatitis C) or auto-immune hepatitis. Toxic or ischemic liver disease was less likely as there was no evidence of necrosis (#8 above).

As the blood test for hepatitis C (anti-HCV) was not available at the time, it would be impossible to exclude the possibility of hepatitis C, as the cause of cirrhosis in this man. In 1980, the term hepatitis C was not coined and then it was classified as non-A, non-B hepatitis. I do not have the results of hepatic transaminase levels to review. Other causes of inflammatory hepatitis (autoimmune) cannot be excluded based on the limited information available.

In conclusion, based on the above facts and to the best of my knowledge, the probability of an infectious or inflammatory hepatitis – whether viral or non-viral causing the cirrhosis is high and the likelihood of alcoholic or non-alcoholic liver

> disease is low. Toxic or ischemic liver disease was less likely as there was no evidence of necrosis.

[29] The specialist prepared a further letter dated November 6, 2008, in which he stated as follows:

> I would like state [sic] and try to make it as clear as possible based on the limited information that [the deceased HCV Infected Class Member], who died in January of 1980, had advanced liver disease, as documented by autopsy.
>
> In all probability, the cause of advanced liver disease was infectious or inflammatory hepatitis likely of viral etiology. Hepatitis C as the cause of hepatic dysfunction, cirrhosis and terminal jaundice can not be excluded based on limited information, 28-years after death.
>
> As hepatitis C testing was not available then, it would be impossible to exclude or establish a definitive diagnosis, however, associative information favors inflammatory pathology like hepatitis B or C.
>
> The likelihood of hepatitis (B or C), as evidenced by inflammatory cell infiltration and absence of fatty metamorphosis on autopsy examination, is higher based on limited information. This may have been related to blood transfusion, as he had received during his lifetime. It is highly unlikely that the advanced liver disease and terminal jaundice were secondary to any other cause.
>
> I hope this information is sufficient and further clarifies the association between blood transfusion and the terminal liver disease.

DECISION OF ADMINISTRATOR DATED DECEMBER 10, 2008 ON REVIEW OF CLAIM FOLLOWING RECEIPT OF SUPPLEMENTARY EVIDENCE

[30] In view of the supplementary evidence that was submitted by the HCV Personal Representative with the Request for Review, the Administrator reviewed the claim.

[31] On December 10, 2008, the Administrator concluded that the evidence was not sufficient to meet the eligibility criteria in the *Settlement Agreement*. In its decision, the Administrator stated as follows:

> **Facts**
>
> 2. Page 36 – Claimant passed away on January 14, 2000.
> 3. Page 47 – Summary of Autopsy – Final diagnosis includes “Cirrhosis of the liver” and “Ascites”
> 4. Page 48 – On autopsy report, “deep jaundice” is noted.

5. Page 50 – Autopsy report – “Shows varicosis in the lower end of the esophagus. No evidence of rupture of varicose vein”.
6. Page 60 – December 1979 – “…admitted with probable acute biliary colic causing jaundice and epigastric pain…”, “…liver enzymes elevated…” Final diagnosis: “Acute biliary colic. Severe cirrhosis. Hepatic failure.”
7. Page 67 – Form 5 – Wrote transfused in 1979 – reason not specified.
8. Page 69 – Traceback done in 2003 – Blood transfused in August 1979.
9. Page 73 – [A hospital] wrote that Health Records and transfusion records are available.
10. Page 91 – Physician who completed Form 2 indicated “a diagnosis of cirrhosis in the absence of any other cause”, Disease Level 6 due to HCV (decomposition of the liver, ascites).
11. Page 97 – Physician indicated the following under the question, *Indicate the date the HCV Infected Class member first had any extent of disability as a result of an impairment caused by his or her HCV infection:* “In 1978 he worked off and on but 1979 he could not work. His wife believes he was on sick leave until around June 1979 when he became worse and never worked again.” Note that this date is before the Blood transfused in August 1979.
12. Page 115 – Final traceback report.

Summary of Supplementary Evidence

13. Evidence submitted by the Claimant is as follows:
    a. Letter dated November 6, 2008 from [the specialist]. His review was done based on “the limited information”. [The specialist] wrote: “Hepatitis C as the cause of hepatic dysfunction, cirrhosis and terminal jaundice can not be excluded based on limited information…”. [The specialist] further added: “The likelihood of hepatitis (B or C), as evidenced by inflammatory cell infiltration and absence of fatty metamorphosis on autopsy on examination is higher based on limited information. This may have been related to blood transfusion, as he had received during his lifetime. It is highly unlikely that the advanced liver disease and terminal jaundice were secondary to any other cause”.
    b. Page 4 – Letter dated October 14, 2008 from [the specialist], in which he states that he was asked to review the information and to determine “if there was a reasonable probability that he might have had i) liver disease, and ii) possibly hepatitis. [The specialist] wrote: “There is no doubt that the [deceased HCV Infected Class Member]suffered from advanced liver disease – cirrhosis, as noted on autopsy examination, and its complications (esophageal varices, ascites and possibly splenomegaly), and some of these were likely present in 1977…”.
    c. Page 10 – A report noting the “possible slight spleno-megaly”.
    d. Page 16 – Another report noting the “probably oesophageal varices”.
    e. Page 21 – In Past History, it is noted that claimant had a hemorrhoidectomy around 1963

<u>Administrator's Decision</u>

14. The claimant has submitted no health records from 1979.
15. The reason for the transfusions in 1979 is unknown.
16. The complications of cirrhosis were present in 1977 as noted by [the specialist].This is prior to the Blood received in 1979.
17. The Administrator has an obligation to assess each claim and determine whether the required proof for compensation exists. The Administrator has no discretion to allow compensation where the required proof does not exist. After careful consideration of the supplementary evidence submitted, the Administrator concludes that the alternative proof of HCV (hepatitis C virus) as per section 3.01(2)) has not been met; [the deceased HCV Infected Class Member] had complications of cirrhosis prior to Blood transfusions in 1979 and therefore a diagnosis of cirrhosis without any other cause has not been established.
18. The decision to reject this claim for compensation remains unchanged.

SUPPLEMENTARY EVIDENCE FILED ON JANUARY 23, 2009 ON APPEAL

[32] In a letter dated January 10, 2009 and filed with the Administrator on January 23, 2009, the HCV Personal Representative and her daughter submitted what they stated was "further medical information" that was found in files at home. In their letter, they listed and described 16 items of additional evidence. I have reviewed carefully the documents that were submitted and have determined that at least eight of the listed items were duplicates of documents that were previously filed with the Administrator. As such, that evidence was already considered by the Administrator in making one or both of its earlier decisions. Out of the remaining items, the only relevant ones were numbers 9, 11 and 15 which are summarized in the three following paragraphs.

[33] On December 13, 1978, a blood test for the HCV Infected Class Member was negative for the Hepatitis B antigen.

[34] On August 6, 1979, the deceased HCV Infected Class Member was admitted to a hospital for pain and gastro-intestinal bleeding. The Nurses Bedside Notes contain entries revealing that he passed blood three times was transfused with the first unit of whole

blood, bearing number 21058, at 1830 hours. A second unit was transfused at 2045, but the number of the unit was not recorded in the nursing notes. The hospital blood transfusion form, described in paragraph 7 above, contains notations in the columns headed "Time" and "Date" that bottle number 21058 was transfused on August 6, 1979 at 1830 hours, and bottle number 21055 was also transfused on that date at 2045. In other words, the columns headed "Time" and "Date" on the blood transfusion form were used to record the time and date of the transfusions. No other Nurses Bedside Notes were delivered in evidence.

[35] On September 26, 1979, he was discharged from a hospital in another city.

[36] In their letter dated January 10, 2009, the HCV Personal Representative and her daughter also made the following comments, among others:

> In [the specialist's] letter dated October 14, 2008, he states that there were oesophageal varices and ascites and possible slight splenomegaly.[...] the endoscopic examination on March 1, 1977 says there definitely no varices. The only place showing varices is in the Autopsy report. In [the specialist's] letter dated November 6, 2008 – about hepatitis B or C, see enclosed XXX hepatitis B was negative. [...]

ISSUE

[37] The issue to be determined is whether the decision of the Administrator to deny the claim for compensation is reasonable on the basis of the evidence.

ANALYSIS

i) Applicable Compensation Provisions in Settlement Agreement

[38] In my Reasons for Decision on the appeal in Claim File 07-00542, I analysed the provisions in Article Three of the *Settlement Agreement* concerning the payment of compensation for a deceased HCV Infected Class Member. Since those provisions also apply in the present appeal, I have reproduced my analysis from that decision below, and

have modified it slightly, where necessary, to apply to the circumstances of the present appeal. In that decision, I stated as follows:

> [15] Article Three of the *Settlement Agreement* contains the framework governing the compensation process for HCV Infected Class Members who have died, including the eligibility requirements in section 3.01 and the provisions for the payment of compensation in sections 3.02, 3.03 and 3.04. The expression "HCV Infected Class Member" is defined, in part, in section 1.01 as meaning "... collectively Primarily-Infected Class Members and Secondarily-Infected Persons".
>
> [16] The eligibility requirements that must be met by an HCV Personal Representative for a claim to be approved are outlined in section 3.01 of the *Settlement Agreement*, which states as follows:
>
> > **3.01 Eligibility – HCV Infected Class Members Who Have Died**
> >
> > (1) A person claiming to be the HCV Personal Representative of an HCV Infected Class Member who has died must deliver to the Administrator, within three years after the death of such HCV Infected Class Member or within two years after the Implementation Date, whichever event is the last to occur, an application form prescribed by the Administrator together with:
> >
> > (a) an original or notarial copy of the death certificate of the HCV Infected Class Member; and
> >
> > (b) unless the required proof has already been previously delivered to the Administrator:
> >
> > > (i) if the deceased was a Primarily-Infected Class Member, the proof required by Sections 2.01 and 2.03; or
> > >
> > > (ii) if the deceased was a Secondarily-Infected Person, the proof required by Sections 2.02 and 2.03;
> >
> > (c) the original certificate of appointment of estate trustee, grant of probate or of letters of administration or notarial will (or a copy thereof certified to be a true copy by a lawyer or notary) or such other proof of the right of the claimant to act for the estate of the deceased as may be required by the Administrator;
> >
> > and
> >
> > (d) proof that the death of the HCV Infected Class Member was caused by his or her infection with HCV except as provided in Section 3.03(1)(ii).
> >
> > (2) Notwithstanding the provisions of Section 2.01(1)(b), if a deceased Primarily-Infected Class Member was not tested for the HCV

> antibody or HCV, the HCV Personal Representative of such deceased Primarily-Infected Class Member may deliver, instead of the evidence referred to in Section 2.01(1)(b), evidence of any one of the following:
>
> (a) a liver biopsy consistent with HCV in the absence of any other cause of chronic hepatitis;
>
> (b) an episode of jaundice within three months of receiving Blood in the absence of any other cause;
>
> (c) a diagnosis of cirrhosis in the absence of any other cause; or
>
> (d) where the claimant is a Primarily-Infected Hemophiliac, that the Primarily-Infected Hemophiliac has tested positive for HIV prior to his or her death.
>
> Nothing in Section 3.01 will relieve any claimant from the requirement to prove that the death of the Primarily-Infected Class Member who died prior to January 1, 1999 was caused by his or her infection with HCV. [Emphasis Added]

[17] In order to be eligible for compensation under either section 3.02 or 3.03, section 3.01(1) requires an HCV Personal Representative to deliver to the Administrator all of the elements of proof described in paragraphs (a) through (d), as reproduced above. For the purposes of the present appeal, it is important to emphasize that, by virtue of paragraph 3.01(1)(d), proof that the death of the HCV Infected Class Member was caused by an infection with HCV is mandatory to establish eligibility for compensation.

[18] In circumstances where the eligibility requirements specified in section 3.01 are met, the HCV Personal Representative becomes an "Approved HCV Personal Representative", which is defined in section 1.01 in the following terms:

> **"Approved HCV Personal Representative"** means an HCV Personal Representative whose claim made pursuant to Section 3.01 or Section 5.05 has been accepted by the Administrator.

[19] The compensation payable under Article Three for the claim of an HCV Infected Class Member who has died is governed either by section 3.02 or 3.03, depending upon the date of death. In particular, section 3.02 applies where the death occurred prior to January 1, 1999, and section 3.03 applies where the death occurred on or after January 1, 1999. In the present case, the HCV Infected Class Member died in 1980, and the provisions of section 3.02 therefore govern the compensation, if any, to be paid for the claim.

[20] As indicated in the preceding paragraph, section 3.02 of the *Settlement Agreement* dictates the compensation to be paid for an HCV Class Infected Member who died prior to January 1, 1999. Subsection 3.02(1) is the principal provision concerning such compensation and contains wording that must be considered for the purposes of the present appeal. Subsection 3.02(2) simply provides an alternative choice for Dependants and Family Members concerning

the method of compensation. None of the other parts of section 3.02 have any relevance in the circumstances of this case, save and except for subsection 3.02(5) which expressly prohibits the payment of compensation in the absence of proof that the death of the HCV Infected Class Member was caused by an infection with HCV. For the purposes of the present appeal, the relevant parts of section 3.02 state as follows:

> **3.02 Compensation if Deceased Prior to January 1, 1999**
>
> (1) If an HCV Infected Class Member died prior to January 1, 1999 and his or her HCV Personal Representative delivers to the Administrator the evidence required under Article Two, Section 3.01, 5.01 and 5.04 within the period set out in Section 3.01(1) or Section 5.01, the Approved HCV Personal Representative is entitled to be reimbursed for the uninsured funeral expenses incurred up to a maximum of 8/11ths of five thousand dollars ($5,000.00) and, subject to the provisions of Section 3.02(2), the Approved HCV Personal Representative will be paid the amount of 8/11ths of forty five thousand dollars ($45,000.00) in full satisfaction of any and all Claims that the HCV Infected Class Member would have had under this Agreement if he or she had been alive on or after January 1, 1999. This 8/11ths of forty five thousand dollars ($45,000.00) payment to the Approved HCV Personal Representative is in addition to the Claims of Dependants and other Family Members pursuant to Article Four and will not affect the personal Claim of someone who is also an HCV Infected Class Member.
>
> (2) Instead of the 8/11ths of forty five thousand dollars ($45,000.00) payable pursuant to Section 3.01(1), and the payment of the Claims of Dependants and other Family Members pursuant to Article Four, the Approved HCV Personal Representative of an HCV Infected Class Member who died prior to January 1, 1999 and all the deceased HCV Infected Class Member's Dependants and other Family Members having Claims under this Agreement may agree to be paid 8/11ths of one hundred and eight thousand dollars ($108,000.00) in full satisfaction of all their Claims pursuant to this Agreement (including all potential claims pursuant to Article Four), and such amount will be paid jointly to them, but such payment will not affect the personal Claim of someone who is also an HCV Infected Class Member.
>
> […]
>
> (5) Notwithstanding any other provision in this Agreement, no compensation is payable to any Class Member under this Agreement with respect to an HCV Infected Class Member who died prior to January 1, 1999 unless there is proof acceptable to the Administrator that the death of the HCV Infected Class Member was caused by his or her infection with HCV. [Emphasis Added]

[21] Subsection 3.02(1) repeats in its opening words the obligation of the HCV Personal Representative to deliver the evidence specified in certain sections of

the *Settlement Agreement*, including section 3.01, and makes compensation conditional upon compliance with the requirement to produce such evidence. In other words, if any of the evidence required under section 3.01 is not delivered to the Administrator, compensation cannot be granted under section 3.02. As indicated in paragraphs XX and XX above, paragraph 3.01(1)(d) requires proof that the death of the HCV Infected Class Member was caused by an infection with HCV in order to establish eligibility for compensation. Furthermore, the explicit statement in subsection 3.02(5) that "no compensation is payable" for an HCV Infected Class Member who died prior to January 1, 1999, "...unless there is proof acceptable to the Administrator that the death of the HCV Infected Class Member was caused by his or her infection with HCV", underscores the mandatory nature of the evidentiary requirement in paragraph 3.01(1)(d). The failure to produce evidence that the death of the HCV Infected Class Member was caused by an HCV infection must therefore necessarily result in the denial of the claim for compensation.

[...]

[23] In the present appeal, the related provisions in subsections 3.01(1), 3.02(1) and 3.02(5) of the *Settlement Agreement* must be read together. A textual reading of those sections in their context in the *Settlement Agreement* and in conjunction with one another confirms that no compensation can be paid under subsection 3.02(1) unless there is proof acceptable to the Administrator to demonstrate that the death of the HCV Infected Class Member was caused by an infection with HCV. Absent such proof, the claim must be denied.

iv) Burden of Proof

[37] Before proceeding further, it is important to determine the evidentiary burden of proof that must be met by an HCV Personal Representative to satisfy the requirements for eligibility and compensation under the provisions of Article Three with respect to an HCV Infected Class Member who died prior to January 1, 1999.

[38] As indicated in paragraph 34 above, subsection 3.02(5) expressly states that no compensation can be paid with respect to an HCV Infected Class Member who died prior to January 1, 1999 unless there is "proof acceptable to the Administrator" that the death was caused by an infection with HCV. The burden of proof to be applied in assessing evidence delivered in support of a claim for compensation under subsection 3.02(1) is therefore "proof acceptable to the Administrator".

[39] In determining the import of the expression "proof acceptable to the Administrator", it is important to recognize that, under the terms of the *Settlement Agreement*, other burdens of proof are specified for different provisions. For example, in many instances, a claimant may be required to establish certain requirements "on the balance of probabilities" or "to the satisfaction of the Administrator".

[40] When the expression "proof acceptable to the Administrator" is considered in this context, it is readily apparent that the standard is intended to accord a broad discretion and significant flexibility to the Administrator in receiving and assessing evidence. In addition, the words "proof acceptable to the Administrator" clearly denote a less rigorous standard than either of the

> expressions "on the balance of probabilities" or "to the satisfaction of the Administrator". Indeed, a burden of proof expressed simply as "proof acceptable" to a decision-maker would necessarily find itself at the lower end of any evidentiary scale.
>
> [41] It is also significant to note that the expression "proof acceptable to the Administrator" appears to be used in the *Settlement Agreement* only in subsection 3.02(5) and paragraph 4.03(1)(b), the latter provision relating to claims of dependants of deceased HCV Infected Class Members. Finally, the usage of the standard "proof acceptable to the Administrator" undoubtedly reflects the reality that, in cases involving deaths prior to January 1, 1999, a higher or more stringent burden of proof would make it virtually impossible to satisfy the requirement of proving that the death of an HCV Infected Class Member was caused by an infection with HCV.

ii) Was the decision of the Administrator reasonable on the basis of the evidence?

[39] Before considering whether the decision of the Administrator to deny the claim for compensation was reasonable on the basis of the evidence, there is one evidentiary matter that must be addressed. In particular, it is important to determine, on the basis of the evidence, the date on which the deceased HCV Infected Class Member first received a blood transfusion. This has become important in view of the blood test dated December 13, 1978, described in paragraph 33 above, confirming that the deceased HCV Infected Class Member was not infected with Hepatitis B on that date.

[40] The Blood Transfusion History, referred to in paragraph 2 above, specified blood transfusions received at three different hospitals in 1979. In addition, the documents submitted in support of the claim for compensation under a provincial program, which were described in paragraphs 6 and 7 above, confirmed blood transfusions on dates in 1979, as did the Canadian Blood Services Traceback report, dated August 11, 2008 and reproduced in paragraph 8 above.

[41] In the Request for Review dated October 20, 2008 and summarized in paragraph 11 above, the HCV Personal Representative stated that she was enclosing

"[...] a form [...] showing he also received blood on December 6/78 and he may have received blood even before that." The form referred to by the HCV Personal Representative is a hospital blood transfusion record, described in paragraph 34 above.

[42] In order to determine whether the deceased HCV Infected Class Member received a blood transfusion on December 6, 1978, as suggested by the HCV Personal Representative, the information recorded on the form on that date must be compared with the blood transfusion forms used for the transfusions on August 6 and 10, 1979, described in paragraph 7 above, as well as the Nurses Beside Notes from that time period, summarized in paragraph 34 above.

[43] The blood transfusion form dated December 6, 1978 confirms that blood was ordered in the name of the deceased HCV Infected Class Member and was made available for transfusion. However, there were no entries in the columns headed "Time" and "Date" to indicate that the deceased HCV Infected Class Member was transfused with that blood. By way of comparison, the two other blood transfusion forms that were filed in evidence and described in paragraph 7 above, both contain notations in the columns 'Time" and "Date" to confirm the time and date of the transfusions received by the deceased HCV Infected Class Member. Furthermore, the fact that the time and date of blood transfusions were intended to be recorded in those spaces on the form by hospital personnel is amply demonstrated by the comparison of the entries in the Nurses Bedside Notes with the blood transfusion form dated August 6, 1979. In short, the blood transfusion form dated December 6, 1978 does not indicate that the deceased HCV Infected Class Member received a blood transfusion on that date. Furthermore, there is no other evidence whatsoever to demonstrate that he received a blood transfusion on that

date. In the circumstances, the evidence in the file, when considered in its totality, establishes that the deceased HCV Infected Class Member did not receive a blood transfusion on December 6, 1978 or at any other time prior to August 1979.

[44] In its decision dated December 10, 2008, the Administrator reviewed its earlier decision to reject the claim in light of the supplementary evidence filed by the HCV Personal Representative with the Request for Review. In conducting the review, the Administrator considered the evidence in the file as a whole, including the evidence filed with the claim and the supplementary evidence. In its decision, the Administrator referred to some of the pertinent facts, provided a summary of the two letters from the specialist and noted certain reasons in support of its decision. In particular, in numbers 17 and 18 of the decision, it concluded that a "diagnosis of cirrhosis without any other cause" was not established and that the decision to reject the claim for compensation would remain unchanged. In other words, it reaffirmed its earlier decision on September 22, 2008 that the HCV Personal Representative had not delivered proof of infection with the Hepatitis C virus.

[45] Following the second decision of the Administrator, the HCV Personal Representative and her daughter referred, in their letter dated January 23, 2009, to the following statement made by the specialist in his report dated October 14, 2008:

> There is no doubt that the deceased [HCV Infected Class Member] suffered from advanced liver disease – cirrhosis, as noted on the autopsy examination, and its complications (esophageal varices, ascites and possibly splenomegaly), and some of these were likely present in 1977 [...]".

In attempting to cast doubt on the accuracy of the specialist's statement, they referred to "number 4" on their list of evidence. However, that evidence was not properly characterized as newly discovered evidence, as it was previously filed with the

Administrator by the HCV Personal Representative on October 20, 2008 as part of the supplementary evidence on appeal and is summarized in paragraph 20 above. In other words, that evidence formed part of the claim file before the specialist provided his opinion. Even if I were to assume that the specialist was not given a copy of that document prior to preparing his opinion and was unaware of it, the remaining portion of his letter dated October 14, 2008 nevertheless states unequivocally that several illnesses could have caused the advanced liver disease of the deceased HCV Infected Class Member, including "[...] viral hepatitis (hepatitis B & C), autoimmune hepatitis [...]". He also reiterated his earlier statement in the letter that autoimmune hepatitis could not be excluded based on the limited information available. In his second letter dated November 6, 2008, the specialist emphasized that the deceased HCV Infected Class Member had advanced liver disease and stated as follows:

> As hepatitis C testing was not available then, it would be impossible to exclude or establish a definitive diagnosis, however, associative information favors inflammatory pathology like hepatitis B or C.
>
> The likelihood of hepatitis (B or C), as evidenced by inflammatory cell infiltration and absence of fatty metamorphosis on autopsy examination, is higher based on limited information. This may have been related to blood transfusion, as he had received during his lifetime. It is highly unlikely that the advanced liver disease and terminal jaundice were secondary to any other cause. [Emphasis Added]

[46] In the words of the specialist, who twice affirmed the likelihood of a diagnosis of either Hepatitis B or Hepatitis C, it was unlikely "[...] that the advanced liver disease and terminal jaundice were secondary to any other cause". Furthermore, his statement that the advanced liver disease was not likely secondary to any other cause was made in the context that the illness suffered by the deceased HCV Infected Class Member was likely either Hepatitis B or Hepatitis C; in his opinion, either disease was likely. It is therefore

clear and unequivocal, on the basis of the evidence from the specialist, that it was equally as likely that the deceased HCV Infected Class Member was infected with either Hepatitis B or Hepatitis C. In the circumstances, the evidence of the specialist does not demonstrate "a diagnosis of cirrhosis in the absence of any other cause", within the meaning of paragraph 3.01(2)(b) of the *Settlement Agreement*, in that Hepatitis B was equally as likely as a diagnosis as Hepatitis C.

[47] I have considered the evidence in this matter carefully and have determined that it was reasonably open to the Administrator to conclude, on the basis of the evidence in the file, that the there was no acceptable proof that the death of the HCV Infected Class Member was caused by his infection with HCV, as required by paragraph 3.01(1)(d) and subsection 3.02(5) of the *Settlement Agreement*. In the circumstances, the claim for compensation regrettably cannot succeed.

v) Compensation under another program

[48] As indicated previously, the HCV Personal Representative had applied for and received compensation in relation to the loss of her husband under the terms of the *Red Cross Settlement* and a provincial plan. In the Reasons for Decision rendered in Claim File 07-00464, I commented on the perception of inequity that may arise when compensation is awarded under one plan or agreement and denied under another. In particular, I stated as follows in paragraph 41 of that decision:

> [41] I can appreciate the frustration and distress that this decision will cause to the Claimant, particularly given that the member of the provincial review committee found him to be eligible for a benefit under that program. It must be recognized that the framework governing eligibility for compensation under the terms of the *Settlement Agreement* is completely different from the one applied by the member of the review committee in the context of the provincial agreement.

Although I fully understand that it must be confusing and upsetting when compensation is granted under the auspices of one program or agreement and yet denied under another one, the terms of the *Settlement Agreement* govern the present claim and must be applied. It is also important to recognize that the terms of the *Settlement Agreement* are the result of an agreement between the Parties which was approved by the Courts; neither the Administrator nor the Appeals Officer has any power or discretion to alter those terms.

CONCLUSION

[49] The decision of the Administrator to deny the claim for compensation was reasonable on the basis of the evidence. Regrettably, the appeal must be dismissed.

[50] The appeal is dismissed.

"D. McGillis"

The Honourable D. McGillis, Q.C.
Appeals Officer

DATED April 9, 2009

TO: Claimant
Fund Counsel
Administrator