IN THE MATTER OF A REFERENCE PURSUANT TO THE PROVISIONS OF THE TRANSFUSED HCV PLAN ESTABLISHED BY VIRTUE OF THE HEPATITIS C, JANUARY 1, 1986 – JULY 1, 1990 CLASS ACTIONS SETTLEMENT

Claim Number: 13602
Date of In-Person Hearing: October 2, 2007
Date of Decision: November 28, 2007

DECISION

A. Introduction

[1] The Claimant resides in Saskatoon, Saskatchewan. She has submitted a claim pursuant to the Transfused HCV Plan ("the Plan"), which is Schedule A to the 1986 - 1990 Hepatitis C Settlement Agreement ("the Settlement Agreement"), as personal representative of the estate of R, her deceased sister. R was a former resident of Saskatchewan and Alberta who passed away at age 55 on December 12, 2000 as a result of a Methadone overdose. The Claimant applied for compensation as a family member of an HCV Infected Person who was alleged to have died infected through a Blood transfusion received in Canada during the Class Period.

[2] Pursuant to the terms of the Settlement Agreement and the Plan, the "Class Period" (January 1 1986 to and including July 1, 1990) is the only period of time in respect of which compensation may be available. Further, while there are many possible sources of infection with respect to the Hepatitis C Virus ("HCV"), the Plan only provides compensation for individuals who received transfusions during the Class period of defined blood products, generally, but with an exception, where the donors have been tested and found to be infected with the HCV.

[3] R received a blood transfusion at the time of the birth of her youngest son in 1974 at St. Paul's Hospital in Vancouver. Canadian Blood Services (CBS) has confirmed that there are no records available to investigate the 1974 transfusion. She received a further blood transfusion at Calgary General Hospital (CGH) in September 1989 during surgery to repair a lacerated liver. CBS confirmed that a total of 5 units of blood were transfused, on September 3 and 5, 1989. The Application for compensation under the Plan[1] was submitted on January 9, 2004. On November 18, 2004, CBS reported that a traceback had been carried out on these 5 units, revealing that 4 units had tested negative for HCV and that the donor of 1 unit was deceased and therefore untraceable. As this traceback was inconclusive, given the proof of transfusion during the Class Period, in the absence of any evidence of non-prescription intravenous (IV) drug use, the Administrator would have allowed the claim. However, in her application and elsewhere, the Claimant reported that R had engaged in certain non-prescription IV drug use.

[1] TRAN1, Exhibit 1, pp. 32-36.

[4] After the application was submitted, correspondence was exchanged between the Claimant, her counsel and the Plan. The Court Approved Protocol – CAP - Non-Prescription Drug Use appears to have been adopted in late February 2004. Ultimately, in a letter dated June 2, 2006[2], the Administrator provided the Claimant with the following reasons in support of its decision to deny the application for compensation:

> The Settlement Agreement requires the Administrator to determine a person's eligibility for class membership. The CAP for non-prescription IV drug use provides that the Administrator shall weigh the totality of evidence obtained from the additional investigations required by the provisions of the CAP and determine whether, on a balance of probabilities, the HCV Infected Person meets the eligibility criteria.
>
> The Administrator carefully reviewed all the material that you provided to support your claim. A Committee reviewed your claim and concluded as follows:
>
> Dr. O, the doctor who completed the Treating Physician Form indicated that the HCV infected person had a history of non-prescription IV drug use. The doctor further wrote, "treated with methadone for IV drug use." This information was confirmed in the Tran 3 declaration form and the Other Risk Factor Inquiry Form completed by the Claimant.
>
> On May 4, 2004, the Administrator notified you in writing that your claim would be rejected unless you returned the further evidence to establish on a balance of probabilities that the HCV infected person was infected for the first time with HCV by a Blood transfusion received in Canada between January 1, 1986 and July 1, 1990. You submitted complete medical records and an affidavit dated September 29, 2005.
>
> In accordance with the CAP, the Administrator has considered all of the evidence submitted, including the opinion of a medical specialist experienced in treating and diagnosing HCV and has determined that, on the balance of probabilities, your claim does not meet the eligibility criteria. The administrator cannot conclude that the HCV infected person was infected by HCV for the first time by a blood transfusion received in Canada in the Class Period; therefore, your claim is denied.

[5] Fund Counsel relies on Section 3.01 (1) (a) of the Plan text:

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[2] pp. 3-5

ARTICLE THREE
REQUIRED PROOF FOR COMPENSATION

3.01 Claim by Primarily-Infected Person

(1) A person claiming to be a Primarily Infected Person must deliver to the Administrator…
(a) medical, clinical, laboratory, hospital, The Canadian Red Cross Society, Canadian Blood Services or Hema-Quebec records demonstrating that the claimant received a Blood transfusion in Canada during the Class Period:

(b) an HCV Antibody Test report, PCR Test report or similar test report pertaining to the claimant;

(c) ***a statutory declaration of the claimant including a declaration* (i) *that …she has never used non-prescription intravenous drugs***, (ii) to the best of his… knowledge, information and belief, that … she was not infected with Hepatitis Non-A Non-B or HCV prior to 1 January, 1986, (iii) as to where the claimant first received the blood transfusion in Canada during the Class Period, and (iv) as to the place of residence of the claimant, both when … she first received a Blood transfusion in Canada during the Class Period and at the time of delivery of the application hereunder.
[emphasis added]

[6] It is agreed that in these circumstances, the Claimant has complied with the provisions of Article 3.01 (1) (a), (b) and (c) (ii), (iii) and (iv). However, in light of the Deceased's admitted non-prescription IV drug use, this case turns on the issue of whether or not the Claimant has met the "notwithstanding" provisions of Section 3.01 (3) of the Plan, which provides:

3.01(3) Notwithstanding the provisions of Section 3.01 (1) (c), ***if a claimant cannot comply with the provisions of Section 3.01(1)(c) because the Claimant used non-prescription intravenous drugs, then … she must deliver to the Administrator other evidence establishing on a balance of probabilities that … she was infected for the first time with HCV by a Blood transfusion in Canada during the Class Period..***
[emphasis added]

B. Facts, Summary of Evidence

[7] The Claimant sought a review of the Administrator's denial of her claim by a Referee and requested an "in-person" hearing. There were many delays while Claimant Counsel attempted to obtain instructions to retain an expert witness. Ultimately, those instructions were not received. There was further delay when Dr. Gary Garber, an Infectious Disease expert from Ottawa, was not able to testify on behalf of the Administrator and the hearing had to be re-scheduled. An "in-person" hearing was ultimately held in Saskatoon on October 2, 2007. The Claimant testified as did R's widower. Carol Miller, Appeals Coordinator of the Hepatitis C January 1, 1986 - July 1, 1990 Claims Centre (the "Claims Centre"), testified on behalf of the Administrator. Dr. Garber testified by speaker phone on behalf of the Administrator. The parties submitted written briefs. The matter will be adjudicated upon based on the written materials and testimony tendered by the parties.

(a) Documentary Evidence

[8] The following documentary evidence was tendered at the hearing:

Exhibit 1 - Claims Centre File (pages 1-464)
Exhibit 2 - Documents not sent to Medical Expert (pages 465-665)
Exhibit 3 - Medical file sent by Administrator to Dr. Garber (pages 1-405)

(b) V*iva voce* testimony

Claimant's Evidence

The Claimant

[9] R was 6 years older than the Claimant. They were especially close growing up in northern Saskatchewan as their parents were alcoholics and the older children were left to look after their younger siblings. It was a difficult life. R was subjected to physical abuse at home. Sometimes the Claimant and R lived with their grandmother. The Claimant attended residential school for 6 years and is not sure if she and R attended there at the same time, but believes that R finished her Grade 8 there. After residential school, R attended high school in St. Louis, Saskatchewan. The Claimant lost track of R when R moved away with her first boyfriend. R had 3 children with this boyfriend before they separated after he physically abused her. R ended up with a second boyfriend and had other children. The Claimant visited her from time to time. Eventually R had a total of 9 children. She ended up moving to Vancouver where their other sister lived, and the Claimant did not see her for many years later, until R had married again, this time to a truck driver who worked in Alberta and Saskatchewan. The Claimant did not know how many years R was in Vancouver. She had no communication with her over these years

and only saw her when she came back to Saskatchewan with her new husband. The Claimant does not remember when R married her husband or when they returned to Saskatchewan, although she thinks it could have been in the late 1980s. R lived with her new husband in quite a few places in Alberta, including Calgary, Olds and other places before they moved to Saskatchewan The Claimant moved to Swift Current for a time, likely in the '90s, and R and her new husband were also there, as well as at times in Prince Albert and Saskatoon. R had severe arthritis in her arms and legs. When the Claimant saw R in Saskatchewan, R was taking Tylenol, anti-depressants and other medication. R was also drinking at this time and took Nytol. She drank anything with alcohol in it that might help her ease her pain. So far as the Claimant saw or knew, R did not use needles and took her medications orally. She was asked about the Other Risk Factor (ORF) Inquiry Form[3] that she signed on April 5, 2004, which checks off the box on "Non Prescription Intravenous Drug Use, which identified drugs as "opiates", time period "unknown" and frequency "more than 10 times but unknown." The brief handwritten portions were not in her writing, but were completed from information given to an associate of the Claimant's lawyer, based on hearsay from a family member, as the Claimant had never seen R use IV drugs, did not know what type of drugs she may have used and had no knowledge on how often she had used them. She does not know for sure what "opiates" means and cannot clearly remember where she heard this information from. She did not see any needle marks on R's body. She was submitting this information, along with health records, as Administrator on behalf of R's estate and did not have specific knowledge about many of the matters recorded in those records either.

[10] In cross-examination, the Claimant acknowledged:

- R was about 21 when she moved away with her first boyfriend and lived in Big River for a period of time.
- The Claimant moved to Saskatoon in about 1975 – R was living in Saskatoon when the Claimant moved there.
- R then moved to BC – at first the Claimant testified that it was in was in the early '70s, but later thought it was 1978 or not later than the early '80s.
- The Claimant did not know whether R was using IV drugs or sharing needles in Vancouver or what she was doing there, because she had totally lost touch with R over that period. Likewise, she had no knowledge of whether R may have used IV drugs, and if so, the number of times she may have used them or whether she shared needles or used sterile needles.
- It was maybe her older sister who told the Claimant that R was using drugs in Vancouver, but she cannot remember exactly what she said or whether the Claimant assumed that. She does not really remember what was in her mind when she completed the ORF form.
- R came back to Saskatchewan some time in the '90s, with her new husband. The Claimant was living in Saskatoon at the time.

[3] Ex. 3, p. 32-33

- The Claimant has no knowledge of R's drug use habits between roughly 1978 and the '90s, when R returned to Saskatchewan. The Claimant really had no knowledge of R's drug use history.

Claimant's widower

[11] R's former spouse was born in 1948. He testified that he met R in Vancouver, and was not sure whether this was in the late '70s or early '80s. He worked as a long-distance truck driver. R often accompanied him on his trips throughout Canada and the States. At times they would not return home for 2 to 3 months. They had a trailer in Saskatoon that they did not see too much of, and a sleeper in the truck. He and R were together in this way for a couple of years before they were married. After they were married, he continued as a truck driver. Their nomadic lifestyle continued after they were married until R passed away. At times, they kept an apartment in Prince Albert where R lived while he worked and kept an apartment in Edmonton. He tried to get to Prince Albert as often as possible, which was not often. He was spending a lot of time in Vancouver and rented an apartment in Chiliwack, BC and had planned for R to move there. R was lonely and wanted to see him more. He had not seen R between September and December 2000 but spoke to her by telephone daily. In December 2000 they drove from Saskatchewan to British Columbia for this move. While en route, he pulled the truck over to sleep and when he awoke found R dead. Over the time they were together, R's health was up and down. She was epileptic and had bad arthritis and headaches. The only medications she took that he was aware of were aspirin, Elavil and Dilantin, all of which she took orally. When reminded, he stated that he knew that R went to the drug store daily to get liquid Methadone, which he saw her drink out of a paper cup. He was aware that she suffered a serious stab wound in 1989. She was hospitalized for a long time. After she got home, she was never the same and felt sick all the time. Her recovery took a long time. R did not have addictions that he knew of. Although she drank alcohol, which was a problem because of Dilantin and the other medications she was on, he did not think she was an alcoholic. She did not get hammered out of her mind to the point that she did not know what she was doing, but did take 2 to 3 drinks at a time, 2 or 3 times a month. He never saw her use or have drug paraphernalia. He would never be able to get across the border with that kind of material. He did not think it was possible that R could have taken IV drugs when he was not with her because he did not see needle marks and he knows that when she went to doctors, they had a hard time finding veins to draw blood from. He was not aware as to why R was being treated with Methadone. He swore an Affidavit on September 29, 2005[4] in which he deposed that R did not use non-prescription IV drugs, or use drug paraphernalia associated with non-prescription IV drugs either prior to her first blood transfusion during the Class Period or at any other time. She did not share needles. In cross-examination he acknowledged:

- The 1989 stabbing happened in the Calgary apartment that they had maintained for about 2-3 years beforehand. R sometimes went with him on the road and

[4] Ex. 3, pp. 38-39.

sometimes stayed in Calgary when he was on the road. At times she remained in this apartment for as long as 2 to 3 months when he was away. From the beginning of their relationship, she did not always go on the road with him. There were many periods when they did not see each other for 3 to 4 weeks at a stretch.

- He did not know what R was doing when he was not there and could not say whether or not she was using drugs during these periods.
- He knows he was in his 30s when they first met.
- He was not aware at the time that Methadone was used to treat drug addiction and was not aware of the hospital records that referred to a history of IV drug use. However, he does not have any reason to suggest that there are errors in the hospital and medical records submitted.
- It is possible that R took IV drugs when he was not around.

Administrator's Evidence

Dr. Gary Garber

[12] Dr. Garber is the head of and professor of Infectious Diseases at the University of Ottawa. He has specific interest in HIV and HCV, and has actively treated HCV patients for about 6 years. He was asked by the Claims Centre to provide an independent opinion on a balance of probabilities, where there is more than one possible source of infection, as to the most probable source of infection. He did not know this patient so any information he had came from the file materials provided to him. In this case the issue was receipt of blood products versus IV drug use. He is not a statistician or an expert in epidemiology. However, part of his work requires him to consider and interpret statistics on a regular basis. He has been involved with hundreds of patients who were either actively or in the past involved in drug seeking behavior. Part of his work requires him to identify all potential risk factors where one could have had exposure to the HC virus. Blood and body fluids are only a risk factor if they are infected and if another person comes into contact with them. He was qualified as an expert witness, to give opinion evidence on HCV, its causes, origins, diagnosis and treatment.

[13] Dr. Garber wrote a report dated May 15, 2006,[5] key extracts of which are:

> This is a complicated file of a woman who had a blood transfusion associated with one of her multiple pregnancies (approximately 13), where that blood from the 70s is untraceable. She subsequently had a … liver laceration in 1989 in Calgary where she received 5 units of blood. Four of these units… tested negative, the fifth unit cannot be traced because the donor is deceased. At the time of admission she had slightly elevated liver function tests however having a liver laceration alone could be the cause of that modest observation. There is a history of injection drug use… documented on several occasions…. it is documented in 1989 as approximately 10

[5] Ex. 3, pp. 456-457

years ago. In 1994[6] it is documented as 6 years in the past and several other times where it elicited that she used injection drugs. It is also documented that she has difficult venous access because of this history. Along with that she appeared to have drug seeking behaviour and there is (sic) investigations of her attending multiple physicians obtaining narcotic medications. She … was then put on Methadone in 1999 where the physician had documented that she had extensive injection drug use history. It is also documented that she had difficulty with her stabilization on Methadone and … that she was having withdrawal symptoms and her comment that she would have to consider getting drugs off the street. She had multiple admissions to the Emergency Department because of problems of decreased levels of consciousness, drug overdose and alcohol intakes. She … died in 2000 and the autopsy finding indicated that the principal cause of death was respiratory arrest caused by an overdose of Methadone.

In 1994 a doctor made a note that she had cirrhosis of the liver. It's not clear where that information came from and another time in 1994 when she had abdominal pain an (sic) observation was of hepatitis. Again there is no liver function test at that time to draw any conclusions. Nor is there any history of jaundice documented at that time. … HCV testing was performed in 1995 and antibodies were positive. We have no PCR results. Hepatitis B surface antigen was negative, there was no antibody or core antibody results which could help denote other risks contact.

Of note on the autopsy report, is that she had evidence of fatty changes in the liver along with periportal and bridging fibrosis. These changes could certainly be on the basis of her extensive alcohol intake but as well could be caused by hepatitis C or the combination. However, what is also germane is that she was found to have talc pneumoconiosis which based on the size of the talc particles seen in the lung was felt to be compatible with impurities in injection drug use. These changes are usually seen in people who have a chronic injection drug use history.

On the other hand her sister … indicated that she did use injection drugs more than 10 times but … did not share needles. Her husband said to his knowledge … she never used non-prescription injection drugs. Clearly based on the overwhelming evidence on the file (his) affidavit showed clear lack of knowledge…

Impressions and Recommendations:

It appears that this individual had a protracted period of injection drug use followed by a long period of narcotic use which continued even when on methadone treatment. The changes seen on autopsy would suggest hepatitis C infection for at least 15 years which would certainly fit within the period of time that injection drug

[6] In testimony, Dr. Garber clarified that this date was in error and should have been 1992 as per Exhibit 3, p. 145.

use was well documented. On the other hand, there is one unit of blood that was given during the period of time that cannot be tested.

On the balance of probabilities it is far more likely that this individual was infected through injection drug use than from a single unit of blood that has not been able to be traced. [emphasis added]

[14] In Dr. Garber's view the chart showed an extensive pattern of drug abuse where nurses and physicians note prior illicit drug use, street drug use, injection drug use, drug-seeking behaviours, hospitalization due to drug overdose and difficulties initiating intravenous lines due to lack of good veins. The specific points of entry in the chart material that Dr. Garber relied on in forming his conclusions are set out below:

1989 – Calgary General Hospital (CGH) ER nursing notes[7] on the admission for stab wound show "**history of IV drugs – 10 years ago**".

1990 – CGH Anaesthetic Record for neck surgery[8] – stating, "**Patient admits to IV drug use and has used all her veins, including neck**. Finally successful in start IV in an external line in her neck." Difficulties establishing an IV line can happen to people who are not IV drug users, for example those who are on chronic chemotherapy for cancer treatment.

1992 – CGH Admission assessment for back pain [9]– refers to "**History of injection drug use, ~ 6 years ago**.

1994 – history notes[10] - there is a reference to cirrhosis of liver and hepatitis B – this is the first reference to Hepatitis B – there is not sufficient information to show whether she had and then cleared Hepatitis B or whether HCV was mis-transcribed.

April 1995, laboratory report[11]- this shows Hepatitis B negative and anti-HCV as positive. This is the first reference to HCV in the chart materials

March 1999 initial methadone consult from Prince Albert Clinic[12] - this refers to "**long-term IV drug use**" , "epilepsy and depression", and that the patient "**has lost 30 pounds in past 6 months – heavy use**", and "good candidate for meth."

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[7] Ex. 3, pp. 107-109 – see also pp. 70-71
[8] Ex. 3, p. 124
[9] Ex. 3, p. 145 – see also p. 188, an August 1993 Nursing History, stating "veins poor peripherally pt states is from previous IV drug abuse"
[10] Ex. 3, p. 221
[11] Ex. 3, p. 233
[12] Ex. 3, p. 310 – see also The Treating Physician Form (TRAN2) completed by R's Prince Albert physician, which indicates that R had a history of non-prescription intravenous drug use (Ex. 1, p. 40, box 24) and further that R "was **treated with Methadone for IV drugs** (box 27, page 41).

Autopsy report – January 2, 2001[13] - This refers to **pneumoconiosis**, which in the past referred to "black lung" a condition associated with miners. "Talc" pneumoconiosis refers to particles in the lungs associated with impurities in injection drugs. The Autopsy report further states:[14]

> "The lungs showed extensive foreign material within the airways and interstitium. The foreign material was crystalline and measured on average 25 microns. This is most consistent with talc or similar material. This foreign material resulted in a foreign body inflammatory reaction throughout the lungs with interstitial fibrosis in some areas. This is most likely a result of impurities with intravenous injected drugs. There are some occupations where a large amount of talc can be inhaled, however, in these cases the talc particles tend to be smaller. Particles as large as the ones found in this case usually are filtered before they reach the lungs in cases due to inhalation." [emphasis added]

It also found chronic inflammation and periportal fibrosis of the liver that was "suggestive of chronic alcohol ingestion…although the possibility of chronic viral hepatitis cannot be ruled out". Death was determined to be due to a Methadone overdose.

[15] While the chart does not show an exact duration of IV drug abuse, a methadone program is usually used, not for occasional users, but for long-standing and extensive drug abusers, typically of illicit drugs. Methadone is used to reduce cravings and drug-seeking behaviours. It is a longer-acting narcotic that metabolizes slowly, which therefore assists with withdrawal symptoms and keeps people stable and more productive. Records showing 30 pounds of weight loss over 6 months strongly suggest someone whose drug-seeking behaviours were preoccupying her to the point of neglecting to eat. Methadone is not exclusively used for injection drug users. IV drugs work faster and their supply is not necessarily reliable. As a result, users often mix the two. Methadone can also be used for people that are exclusively abusing oral medications.

[16] In terms of disease progression, Dr. Garber testified that while this in an imperfect science, one does not see significant liver changes until at least 15 years after infection. It can show up earlier (closer to the 15 year mark but still over 15 years) in individuals whose livers are compromised, either from alcohol abuse, or multiple toxins such as HIV and HVC. Given the liver findings on autopsy, this would put the date of probable infection as about 1985, which fits in quite appropriately with the chart entries. This strongly suggests that the HCV infection pre-dated the transfusion in 1989. He concludes that it was far more likely that R was infected from multiple exposures to injection drug abuse which appears to have been over a prolonged period of time than it was that she was infected from the very small risk of a single exposure to one unit of blood that could not be tested. Statistically, the small risk that this one unit of blood may have

[13] Ex. 3, pp. 26-31
[14] p. 29

contained HCV was somewhere between 1/1000 and 1/100, as compared to greater than 50% risk that chronic IV drug abusers, over time, tend to be HCV positive. During the '80s, HCV was growing rapidly in Canada among injection drug users. Even if one took a very conservative rate of infection from IV drug use as 10%, the risk of contracting the virus from IV drug abuse was at least 10 times higher. No matter which way he analyzed the evidence, on a balance of probabilities, injection drug use was far more likely the source of infection here.

[17] In cross-examination, Dr. Garber testified as follows:

- His opinion that R was a drug abuser is based on the medical records.
- Although there are a number of references to drug use, only two specific entries in the health records[15] relate to IV drug use over a specific time period, both from CGH. One was in 1989 and referred to 10 years previous (1979) and the other was May 1992 (not 1994 as referred to in Dr. Garber's report), which referred to IV drug abuse, ~ 6 years ago (around 1986). Other references show "extensive" but not a time frame.
- He was asked whether the 1992 entry may have simply repeated the entry that was already on the chart from 1989. It would not surprise him if these two entries were independently arrived at. It says "old chart" and he suspects that the old records would not have been available in ER. There is no record in either entry as to the type of drugs used, the method or frequency of IV use. It appears that based on the limited information disclosed by R to her health care providers, there is perhaps a range of between 10 to 3 years before her transfusion in 1989 that she is shown to have last used IV drugs.
- There is one reference to R abusing pills, by double doctoring.
- Methadone treatment is designed to suppress the craving, and does not necessarily have anything to do with method of ingestion. It is possible to treat someone who is exclusively addicted to pills with Methadone, although this is unlikely as there are other methods of treating people who are just addicted to pills. The 1999 entries do not comment on whether R was using injection drugs at that time, or suggest specifically that she was using them after 1989.
- A consideration of the state of R's liver gives other information as to when the infection likely occurred. In this case, the most specific information is from direct tissue, which was analyzed on autopsy. In 1989, the liver tissue was also viewed during the surgery to repair the laceration, however, this was only superficial and not microscopic. He was asked to comment about the liver being shown as normal at that time in the Operative Report[16] and abdominal ultrasound.[17] This was 10 years after the reported IV drug abuse in 1979. It would be relatively unusual to see enough scarring in the liver to see anything on ultrasound after only 10 years.
- Alcohol use can accelerate the manifestation of the disease. However, if a person is not an alcoholic, it may take 20-25 years before any liver changes would be

[15] Ex. E, pp. 109 and 145.
[16] Ex. 3, p. 76
[17] Ex. 3, p. 99.

manifested. If R was an alcoholic, this could have accelerated the manifestation of the disease (versus 20-25 years) but it would be distinctly unusual to accelerate this earlier than the 15 year bench-mark.

- Dr. Garber disagreed with the assertion that one would not expect to see significant damage to the liver from HCV from on average as early as 10 to 15 years from the point of infection.[18] He did not develop the 15-year mark, which is rather, a well established early benchmark among experts in the field, pertaining to patients with risk factors. This benchmark assists professionals in assessing the urgency of the disease, the indication for liver biopsy and methods and timing of treatment. Doing a liver biopsy within 10 years is not medically indicated because changes would not be seen.
- There is no evidence to suggest that the use of Dilantin, aspirin and Tylenol, drugs used in this case, would have accelerated the disease progression. In fact, the majority of the patients he sees are on multiple medications and/or have histories of depression and mental illness. The disease pattern over time is relatively consistent.
- Here there was no testing for Hepatitis B antibodies. Records only showed that the surface antigen was negative, which suggests only that the patient did not have active infection. It does not tell him whether the patient may have had Hepatitis B at an earlier time. If she did have a resolved Hepatitis B infection, that would be another indication of at-risk behaviour that could lead to both HBV and HCV infection.
- The first reference to HCV infection in April 1995[19] simply states a positive result and does not state the date of infection.
- The Coroner's report[20] states: "In consultation with R's family doctor in (Sask), it was learned that she had a life long battle with substance abuse, alcohol, street drugs and prescription drugs". The autopsy report shows the liver as being enlarged and somewhat mottled in colour.[21] It does not refer to cirrhosis. Dr. Garber testified that there are lots of things that can produce changes in the look of the liver, including

[18] Claimant Counsel was directed to provide any written materials upon which he intended to cross-examine Dr. Garber to him in advance of his testimony. As he did not do so, he was not permitted to cross-examine Dr. Garber on testimony given by him in relation to Claim file no. 1400543 at paragraph 24, which reported that he testified that usually one would not expect to see significant damage to the liver from HCV for, on average, 10 to 15 years from the point of infection. I was the Referee in that case. In the present case, Dr. Garber testified that he believed there must have been an error in that decision as he would not have given evidence that significant liver damage would have manifested 10 to 15 years following the date of infection with HCV. The applicable time is **15 years**. Following the October 2, 2007 hearing in this case, I was invited by Counsel for the Administrator to check my notes from the hearing in Claim No. 1400543, as her notes indicated that Dr. Garber did not testify to 10-15 years, but rather did state 15 years. I have checked my notes. Although they do state 10-15 years, there was no recording kept of Dr. Garber's testimony from that case and I concede that my notes may not have been accurate. I have no reason to doubt Counsel's assertion in this regard, particularly when viewed in the context of Dr. Garber's testimony in the case before me that he has been consistent in his testimony in that regard. Dr. Garber was completely unshaken on cross-examination in his opinion that 15 years would be the earliest at which one could expect to see significant damage following HCV infection. In short, I am not sufficiently confident in the accuracy of my pervious notes to doubt Dr. Garber's testimony in any significant respect.

[19] Ex. 3, p. 233

[20] Ex. 3, p. 24

[21] Ex. 3, p. 28

terminal and pre-terminal events. Reduced circulation (R stopping breathing leading to her death) can cause this. This report does not really indicate what is going on within the liver. It indicates that it is consistent with chronic alcohol ingestion although the possibility of chronic viral hepatitis could not be ruled out. As this took place in 2000 and the transfusion took place in 1989, he was asked whether this could have pushed the 11 year mark, getting close to the 15 year mark. He replied that while one might expect to see inflammation at the 11 year mark with someone who is a heavy drinker and has HCV, one would not expect to see fibrosis at that time. Here the most significant body of evidence points to a more extensive duration of infection before changes are seen, greater than 15 years. The Coroner's Report does not indicate recent IV drug use, but is consistent with IV drug abuse in the 70s and 80s.

- The Coroner's Report is inconclusive as to whether the foreign material present in the lungs was talc or another substance. However, it is some evidence of IV drug use.
- It is considered unethical to request liver biopsies on healthy individuals. The body of evidence therefore relates to people with disease – they establish the benchmark. There are extremes on either end of the range that create the benchmarks, but the 15 year mark is the minimum, not a mid-point.
- Gender and age are not risk factors for exposure. Risk factors have to do with exposure to the virus through shared drugs, needles, spoons and mixing implements. It is much easier to spread HCV through blood than it is HIV, based on the concentration of virus in the blood.
- If a patient is transfused with an infected unit of blood, there is not a 100% certainty of contracting the virus. About 15% of people with HCV antibodies do not have infection. That could mean that a donor could have been positive and not have donated an infected unit of blood. Other people could be exposed and not infected. Some clear the virus or develop an immunity to the virus. The majority of people given an infected unit of blood would contract the virus. If the unit of blood that could not be traced back was found to contain the virus, that would not end the matter, because the person could already have been infected with HCV from injection drug use. Here, the evidence of drug-seeking over a period of time does not support the assertion that there was never sharing of needles or paraphernalia. If a habitual drug user needs a fix, the niceties of sterility are not necessarily observed. If someone who does not have peripheral veins tells a nurse she was a user in the past, this points strongly towards significant needle use. This factor among others tilts the balance of probabilities heavily in favour of the Administrator.
- The disease progression here supports HCV infection prior to 1989. It could potentially be consistent with infection in the early 1970s from blood transfusion. However, this is unlikely as there was not a lot of non-A non-B hepatitis going back to the early 1970s.

Carol Miller, RN, Appeal Coordinator

[18] Ms. Miller testified as to her broad background in most areas of hospital nursing as well as her experience with the Claims Centre since May 2000, including her current position as Appeals Coordinator. She described the lengthy process by which the

Claimant's application was considered and ultimately denied. Since 2001 she has also served on the committee that deals with all claims that are denied. There is a different process for people with a history of IV drug use. In these situations, the claimant must show on a balance of probabilities that he was *first infected by transfusion.* Pursuant to the CAP, all relevant medical and hospital records are obtained, reviewed and sent along with summaries of documents dealing with IV drug use or liver problems, to an expert, in this case, Dr. Garber, to provide an opinion on the most likely source of infection. In this case, the IDU Committee considered the evidence that was both supportive and not supportive of the Claimant's position, using the requirements of the CAP.[22] Following a review of Dr. Garber's report, together with the rest of the file materials, the committee found that a review of the evidence delivered to the Administrator did not establish on a balance of probabilities that the HCV infected person was infected for the first time with HCV by a Blood Transfusion in Canada during the Class period.

[19] In cross-examination, Ms. Miller acknowledged that the ORF form does not refer to personal representatives. The answers shown on the IDU Committee Form[23] were completed during the IDU Committee meeting. Based on the CAP, each question is separately addressed. The four-person Committee accepted Dr. Garber's opinion and was unanimous that the claim must be denied. The answer to each question was typed in afterwards by Ms. Miller, using her own words. A denial letter was then issued.

C. ANALYSIS

[20] The Plan Text [Article 3.01(3)] places an onerous burden upon a Claimant who has a history of IV drug use, to show that he was ***first infected*** by a Class Period Blood transfusion. At the same time, it is not an insurmountable burden. The framers of the Plan clearly did not intend to exclude an individual from the protection of the Plan solely by reason of the fact that he or she admitted to non-prescription IV drug use at some point in his or her life. Such an intention would have been clearly signaled.

[21] Individuals with risk factors other than IVDU, such as tattoos, body piercing, intra-nasal drug use, prison / incarceration, unprotected sex and other surgical procedures, need only prove transfusion of infected Blood to *prima facie* bring themselves within the purview of the Plan. In circumstances where an untraceable unit of blood is deemed to constitute an inconclusive traceback, the Plan extends the benefit of the doubt to such individuals. Despite having obvious risk factors, such individuals do not face the significant "reverse onus" burden that is placed upon those with an admitted history of IV drug use, to whom the benefit of the doubt is not similarly extended.

[22] Ex. 1, pp. 458-461

[22] Despite the high burden placed upon a claimant with a history of IV drug use, Article 3.01 (3) of the Plan clearly recognizes the possibility of first infection being proven to be transfusion-related. Article 10.01(1) of the Settlement Agreement provides for a broad on-going supervisory role of the Courts, which extends as far as determining, among other things,[24] (A) whether the restrictions on payments of amounts should be varied or removed in whole or in part, and (B) whether the terms of the Plans should be amended due to a financial insufficiency or anticipated financial sufficiency of the Trust Fund". Specifically, the Settlement Agreement confers jurisdiction upon the Courts to "issue judgments or orders in such form as is necessary to implement and enforce the provisions of this Agreement and … supervise the ongoing performance of this Agreement including the Plans" … including a statement that the Courts will: …

> (h) approve, rescind or amend the protocols submitted by the Joint Committee or by Class Action Counsel; …
>
> (l) on application of the Administrator, Fund Counsel, the Auditors, any Class Action Counsel, the Joint Committee or the Trustee, provide advice and direction.

[23] By virtue of Article 10(2) of the Settlement Agreement, CAPs and orders granting direction on such matters determined by the Courts will take effect only when the order becomes final. The CAP-Non-prescription IV drug use is an example of the type of document the Courts are empowered to issue by the provisions of the Settlement Agreement. This CAP sets out the procedures by which Article 3.01(3) of the Plan is to be interpreted and implemented, in conjunction with other provisions of the Plan. This CAP falls broadly within the supervisory powers of the Courts under Article 10 of the Settlement Agreement and is clearly binding upon the Administrator, Referees and Arbitrators. The CAP recognizes the unique challenges and burdens that are imposed upon claimants with a history of non-prescription IV drug use and in fact, unlike other areas of the Plan, even provides that in such circumstances, the Administrator "shall assist the Claimant by advising what types of evidence will be useful in meeting the burden of proof in accordance with this CAP".

[24] I begin my analysis of the evidence as applied to the Plan Text and CAP, by observing that the Administrator was not looking for ways to deny the claim in this case. Instead, it applied its responsibilities in interpreting and applying the CAP professionally and with an open mind. The same can be said about Dr. Garber. The Administrator and Dr. Garber both applied the provisions of the CAP appropriately. I find Dr. Garber's testimony to be not only persuasive but compelling. I accept his testimony without hesitation.

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[24] 10.01(1)(i)

[25] Significant issues of credibility inevitably arise when assessing the testimony of claimants with a proven history of substance abuse. These issues relate to the honesty of a claimant, but perhaps more importantly to his or her reliability, given the lack of clear memory and poor judgment that may be associated with substance abuse and drug-seeking behaviours. Those issues, however, do not automatically exclude an individual from qualification for Plan benefits and must be carefully weighed within the context of the individual circumstances of each case. Such credibility issues are difficult enough to assess in the context of living claimants, who can testify to their personal circumstances and perhaps explain discrepancies in records. However, they are compounded significantly in the case of deceased individuals, particularly where, as in these circumstances, the witnesses did not live continuously with the Claimant over the period of time in question.

[26] I find both the Claimant and R's widower to have been credible witnesses who did their best to testify fully and honestly. However, they both had great difficulty providing detailed or clear testimony as to R's whereabouts and activities over much of the relevant period of time. There are simply too many gaps in their testimony to rise to the level of establishing first infection from the 1989 transfusion. The Claimant was for many of these years living in a different province from R. Even during periods when they both lived in Saskatchewan, they often lived in different cities. R's widower spent a great deal of time on the road and was simply not able to testify to what was taking place in his absence. R was by numerous accounts in the health records a very vague historian. Not only did she not volunteer details of her drug abuse either to health professionals, evidently she did not do so to those that were closest to her. While Claimant Counsel did his best on the materials available to him to minimize R's history of IV drug abuse, the records summarized previously, particularly at paragraph [14] paint a graphic picture of the nature and extent of the problem. The Claimant recalled hearing rumours from family members about IV drug abuse but could not recall the precise source of the information that her sister had used IV drugs more than 10 times that she provided in the ORF Form.

[27] It is simply indisputable based on the records available that R had a significant and prolonged history of IV drug use spanning back to the late 1970s or early 1980s. There are multiple entry points in the materials with respect to non-prescription IV drug use. There is no evidence with respect to whether the equipment R used was non-sterile or shared. In Dr. Garber's opinion, given R's apparent drug-seeking behaviours and significant addiction, it is likely that non-sterile equipment was used.

[28] While there is some reference to hepatitis B in R's medical records, Dr. Garber testified that it was difficult to draw any concrete conclusions with respect to whether R was in fact ever infected with hepatitis B based on what is available in the records. There is no evidence with respect to prior blood donation. He explained that

if there was a history of infection with hepatitis B, this would provide some evidence of "at-risk" behaviours or lifestyle.

[29] In assessing the issue of ***probabilities***, it becomes necessary to consider both the 1989 transfusion and the admitted intravenous non-prescription drug use, which the evidence establishes occurred beforehand. While it indeed remains ***possible*** that R was infected by way of the 1989 blood transfusion, from a statistical perspective alone, I find that the ***probability*** is that she was not and that she was rather infected by way of prior non-prescription intravenous drug use. Dr. Garber's evidence on disease progression is compelling. There is unfortunately no testimony from R to explain the discrepancies in her reports of drug use. Further, while there is no suggestion of dishonesty on her part, R's *reliability* as a historian in this regard is certainly very much open to question, given her clear addictions and well-documented drug-seeking behaviours.

[30] Counsel for the Claimant has raised interesting and important issues for consideration. Unfortunately for the Claimant, on the facts before me, these issues merely raise possibilities and do not rise to the level of probabilities required by the Plan and the CAP. The Claimant has not discharged the burden imposed upon her by the Plan to establish on a balance of probabilities, that R was in fact first infected by a Blood transfusion received during the Class Period. That the burden of proof rests with the Claimant in cases involving a history of intravenous drug use has been accepted and applied in numerous precedent cases under the Settlement Agreement. The drafters of the Plan, which has received court approval, have incorporated special rules for claims made by or on behalf of IV drug users, requiring a stricter burden of proof than the burden of proof required of Claimants who are not IV Drug Users. The CAP gives further guidance to the Administrator in interpreting and applying the provisions of the Plan.

[31] In the circumstances, I am unable to find that the Administrator has failed to properly apply the terms of the Plan and the CAP to these facts. Further, I find that the Claimant has failed to meet the burden upon her to establish that R was probably infected with HCV for the first time as a result of a 1989 Blood transfusion.

[32] The appeal must therefore fail. The Claimant is not entitled to receive compensation. The Administrator has an obligation to assess each claim and determine whether or not the required proof for compensation exists. The Administrator has no discretion to allow compensation where the required proof does not exist. The financial sufficiency of the Fund depends upon the Administrator properly scrutinizing each claim and determining whether the Claimant qualifies. A Referee similarly has no jurisdiction to alter, enlarge or disregard the terms of the Settlement Agreement or Plan.

D. Decision

[33] Upon careful consideration of the Settlement Agreement, Plan, CAP and documentary evidence tendered, the Administrator's denial of the Claimant's application for compensation is hereby upheld.

[34] I would like to express my appreciation to Ms. Miller and Ms. Bain for their assistance and courtesy throughout. I would be remiss if I did not acknowledge the Herculean effort of Mr. Slusar in presenting this appeal in the best possible light, leaving no stone unturned, under very difficult circumstances. He went well above and beyond the call of duty and is to be commended for his efforts.

[35] Although R's life was exceptionally difficult and challenging, she was fortunate to have had people that cared about her. In that respect, I would like to acknowledge the Claimant and R's widower for respecting R's memory in the honourable way they have conducted themselves in advancing this appeal.

Dated at Saskatoon, Saskatchewan, this 28th day of November, 2007.

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Daniel Shapiro, Q.C., C. Arb., Referee