DECISION

Claim No. 17930

Province of Infection – Nova Scotia

1. The Claimant applied for compensation as a Primarily-Infected Person pursuant to the Transfused HCV Plan.

2. The Claimant's application disclosed that he had used non-prescription intravenous drugs prior to the Class Period.

3. By letter dated January 24, 2011, the Administrator denied the claim on the basis that the Claimant had not provided evidence to establish on a balance of probabilities that he was infected for the first time with HCV by a blood transfusion in Canada during the Class Period.

4. The Administrator's letter of January 24, 2011 denying the claim stated in part:

> "The Settlement Agreement requires the Administrator to determine a person's eligibility for class membership. The Court Approved Protocol ('CAP') for non-prescription intravenous 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. Hoare, the gastroenterologist who completed the Treating Physician form indicated that you had a history of non-prescription intravenous drug use. The doctor further wrote 'in late teens used IV drugs for a few years but nothing since 1975'. You confirmed this information in your Tran 3 Declaration Form and your Other Risk Factor Inquiry form.
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> On February 11, 2009, the Administrator notified you in writing that your claim would be rejected unless you returned the Further Evidence of First Infection Form in which you indicate whether you want to provide further evidence which establishes on the balance of probabilities that you were infected for the first time with HCV by a Blood transfusion received in Canada between January 1, 1986 and July 1, 1990. You submitted an Affidavit dated January 22, 2010 and your complete medical records.
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> In accordance with the Court Approved Protocol, 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, you do not meet the eligibility criteria. The Administrator cannot conclude that you were infected by HCV for the first time by a blood transfusion received in Canada in the Class Period; therefore, your claim is denied."

5. The Claimant requested that the Administrator's denial of his claim be reviewed by an arbitrator. The Request for Review sets out the following grounds:

> "1. In my youth, I admit I made a poor choice in experimenting briefly with intravenous drug use but as I clearly indicated to the Claims Administrator, I purchased the needle at a drug store and it was not shared.

> 2. Although I realize the virus can take a number of months or years to show any effects, I consider it more than coincidental that if I acquired the virus prior to 1975, I had no symptoms until the early 1990's, shortly after I received the tainted blood in 1989.
>
> 3. I believe it is fundamentally unfair to refuse my claim that contrary to leading medical opinion based on the balance of probabilities, the virus was more likely contracted from the tainted blood infusion as opposed to a brief, clean, intravenous drug experiment many years earlier."

6. An oral hearing was held on December 8, 2011 in Summerside, Prince Edward Island. The Claimant was assisted at the hearing by his personal representative, and the Administrator was represented by Fund Counsel, John Callaghan. Witnesses at the hearing were Dr. Connie Hoare, Dr. Gary Garber, the Claimant and Carol Miller, R.N. Dr. Garber and Ms. Miller testified by phone.

7. The following facts are not in dispute:

(i) The Claimant used non-prescription intravenous drugs during the period 1973 to 1975 (the extent of such usage and whether needles were shared is in dispute and I will deal with this later).

(ii) The Claimant was transfused with nine units of blood in May of 1989 at the Victoria General Hospital in Halifax, Nova Scotia after receiving multiple injuries in a motor vehicle accident.

(iii) The Claimant had a history of abusing alcohol but stopped drinking in 1989 following the accident.

(iv) The Claimant was diagnosed with Stage 3 Hepatitis C infection in April of 2006.

(v) By September 2009, follow-up testing showed that the infection had progressed to Stage 4 cirrhosis.

(vi) After the Claimant applied for compensation under the Transfused HCV Plan in 2009, Canadian Blood Services conducted a traceback on the nine units of blood he had received in 1989. Four of the units were confirmed as negative. However, the donors of the other five units could not be located and, consequently, Canadian Blood Services could not determine their status (i.e., positive or negative).

8. As indicated above, there is conflict in the evidence about the extent to which the Claimant used non-prescription intravenous drugs and whether he shared needles. When he first saw Dr. Hoare on March 10, 2006, he told her that he had used "street drugs 20 to 30 years ago" and specifically that he "used IV Methamphetamine once a week and LSD twice a month". The Claimant also told Dr. Hoare that he shared needles with others. However, when the Claimant completed the "Other Risk Factor Inquiry Form" on October 8, 2009, he indicated that he used "methamphine [sic] (speed)" three to four times between 1973 and 1975 and that he did not share needles.

9. Dr. Hoare testified that the Claimant advised her in August of 2009 that he had misunderstood her question about sharing needles and explained to her that he sometimes gave needles to others but did not use their needles. At a later time, the Claimant further advised Dr. Hoare that he only used speed three or four times over the 1973-75 period.

10. In his testimony at the hearing, the Claimant acknowledged that he "used a fair amount of drugs". He said he could not be 100% certain but that, as best he could recall, it "would not have been 104 times per year...maybe half that". He said that he worked five days a week and "messed around with that drug on the weekend". He also indicated that, while he usually used the drug in the company

of others, they did not share needles or spoons, although they sometimes used the same water. The Claimant stated that he would buy new needles in packages of seven and that he would sometimes give a clean needle to others. When the Claimant was asked to explain why he put in the "Other Risk Factor Inquiry Form" that he only used speed three or four times and later conveyed that same information to Dr. Hoare, he replied that he was not quite sure and that "something got screwed up".

11. On the balance of probabilities, I find that the Claimant used speed, a non-prescription intravenous drug, approximately once a week for two to three years between 1973 and 1975. This frequency of usage is consistent with what the Claimant initially told Dr. Hoare and with his evidence at the hearing. Given this level of usage, it is highly unlikely that sharing of needles and other related drug paraphernalia did not occur on occasion. This is particularly so since the risks of such sharing were not known at the time.

12. For purposes of the present reference to arbitration, the relevant provisions of the Transfused HCV Plan are sections 3.01(1)(c) and 3.01(3) as set out below:

> "**3.01 Claim by Primarily-Infected Person**
>
> (1) A person claiming to be a Primarily-Infected Person must deliver to the Administrator an application form prescribed by the Administrator together with:
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> (c) a statutory declaration of the claimant including a declaration (i) that he or she has never used non-prescription intravenous drugs...
>
> (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 he or she must deliver to the Administrator other evidence establishing on a balance of probabilities that he or she was infected for the first time with HCV by a Blood transfusion in Canada during the Class Period."

13. It is common ground that the Claimant could not comply with section 3.01(1)(c) because he used non-prescription intravenous drugs. Consequently, the onus falls on the Claimant, under section 3.01(3), to deliver other evidence to the Administrator to "establish on a balance of probabilities that he...was infected for the first time with HCV by a Blood transfusion in Canada during the Class Period".

14. The Court Approved Protocol ("CAP") provides additional guidance with respect to the application of section 3.01(3). In the present case, the following CAP provisions are particularly germane:

> "**Applicability of CAP**
>
> 1. This CAP applies where:

a. there is an admission that the HCV Infected Person used non-prescription intravenous drugs;

Eligibility Criteria Where This CAP Applies

2. The Administrator must be satisfied on the balance of probabilities that:

b. the HCV Infected Person was infected with HCV for the first time:

i. by a Blood transfusion received in Canada in the Class Period;

3. The burden to prove eligibility is on the claimant. 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.

Additional Investigations

8. If the claim is not rejected under the Traceback CAP, the Administrator shall perform the following additional investigations:

a. obtain such additional information and records pursuant to s. 3.03 as the Administrator in its complete discretion considers necessary to inform its decision; and

b. obtain the opinion of a medical specialist experienced in treating and diagnosing HCV as to whether the HCV infection and the disease history of the HCV Infected Person is more consistent with infection at the time of the receipt of Blood, the Class Period Blood transfusion(s) or the secondary infection or with infection at the time of the non-prescription intravenous drug use as indicated by the totality of the medical evidence.

9. The Administrator shall weigh the totality of evidence obtained including the evidence obtained from the additional investigations required by the provisions of this CAP and determine whether, on a balance of probabilities, the HCV Infected Person meets the eligibility criteria.

10. In weighing the evidence in accordance with the provisions of this CAP, the Administrator must be satisfied that

the body of evidence is sufficiently complete in all of the circumstances of the particular case to permit it to make a decision. If the Administrator is not satisfied that the body of evidence is sufficiently complete in all of the circumstances of the particular case to permit it to make a decision, the Administrator shall reject the claim.

Results of the Investigations

12. Although none of these factors may prove conclusive in any individual case because the Administrator must consider the totality of the evidence, the following factors are examples of evidence that would be supportive of a finding that the person claimed to be an HCV Infected Person is eligible:

a. identification of a Class Period Blood transfusion from an HCV antibody positive donor;

b. the HCV Infected Person was under the age of 18 at the time of the receipt of Blood for the Hemophiliac or the Class Period Blood transfusions;

c. reliable evidence establishes that the non-prescription intravenous drug use took place after July 1, 1990;

d. an HCV disease history which is more consistent with the time of:

ii. the Class Period Blood transfusion(s) for which an HCV antibody positive donor has been located or for which the status of the donor remains unknown;

than with the time of non-prescription intravenous drug use;

e. reasonably reliable evidence that the non-prescription intravenous drug use history is subsequent to the receipt of Blood for the Hemophiliac, or the date of Class Period Blood transfusion(s), or the date of alleged secondary infection;

f. reasonably reliable evidence that the non-prescription intravenous drug use was limited to

a single occasion and was done with sterile equipment which was not shared; and

g. no medical history of unspecified Hepatitis, Hepatitis B or Non-A, Non-B Hepatitis prior to the date of the receipt of Blood for the Hemophiliac, the Class Period Blood transfusion(s) or the date of alleged secondary infection.

13. Although none of these factors may prove conclusive in any individual case because the Administrator must consider the totality of the evidence, the following are examples of evidence that would not be supportive of a finding that the person claimed to be an HCV Infected Person is eligible:

a. failure to identify a Class Period Blood transfusion from an HCV antibody positive donor;

b. an HCV disease history which is more consistent with infection at the time of non-prescription intravenous drug use than with the time of:

ii. the Class Period Blood transfusion(s) for which an HCV antibody positive donor has been located or for which the status of the donor remains unknown;

c. reasonably reliable evidence that the non-prescription intravenous drug use took place on more than one occasion or was done with non-sterile or shared equipment;

d. a medical history of unspecified Hepatitis, Hepatitis B or Non-A Non-B Hepatitis prior to the date of the receipt of blood for the Hemophiliac, or the Class Period Blood transfusion(s) or the date of alleged secondary infection;

e. a refusal to permit the Administrator to interview any person the Administrator believes may have knowledge about the non-prescription intravenous drug use or disease history of the HCV Infected Person;

f. a CBS or Hema-Quebec donor file which indicates that the HCV Infected Person;

i. tested positive for the antibodies to Hepatitis B; or;

ii. had donated blood prior to the Class Period and the pre-Class Period blood donations or recipients of the pre-Class Period blood donations have subsequently tested positive for HCV antibodies; and

g. the file is in any other way consistent with infection with HCV by non-prescription intravenous drug use prior to the receipt of Blood for the Hemophiliac, or the Class Period Blood transfusion(s), or the date of alleged secondary infection."

15. The record shows that the Administrator made a concerted effort to follow the CAP guidelines in deciding the present claim. Of the seven supportive factors set out in section 12, the Administrator concluded that only one of those factors existed here – namely, that the Claimant had no medical history of unspecified Hepatitis, Hepatitis B or Non-A, Non-B Hepatitis prior to being transfused in May of 1989. With respect to the non-supportive factors set out in section 13, the Administrator was of the view that two of them applied – namely, failure to identify a Class Period Blood transfusion from an HCV antibody positive donor and reasonably reliable evidence that the non-prescription intravenous drug use took place on more than one occasion or was done with non-sterile or shared equipment. The Administrator also noted that two of the other five non-supportive

factors were not applicable because the Claimant had never donated blood and had never been asked for permission to interview anyone who might have knowledge about his drug use or disease history.

16. The Administrator also obtained the opinion of Dr. Garber as to whether the HCV infection and the disease history of the Claimant was more consistent with infection at the time of the receipt of the blood or with infection at the time of the non-prescription intravenous drug use as indicated by the totality of the medical evidence. Dr. Garber is an Infectious Disease specialist with twenty-seven years experience. He has served since 1990 as Head of the Infectious Diseases Division at the University of Ottawa and The Ottawa Hospital. He set up a Hepatitis C clinic at The Ottawa Hospital in 2000 and personally manages approximately 200 Hepatitis C patients at any given time.

17. The text of Dr. Garber's letter to the Administrator dated December 10, 2010 is reproduced in full below:

> "I have reviewed the file of the above named claimant as requested. Briefly, this is a 53-year old male who was diagnosed with hepatitis C infection in 2006 after a work-up for elevated liver function tests. He was both antibody and PCR positive. Liver biopsy at that time indicated moderately advanced disease with grade 2 inflammation and stage 3 fibrosis. Subsequent repeat biopsy in 2009 showed stage 4 fibrosis which is now cirrhosis. In 1989 he was in a motor vehicle accident as a pedestrian. He was hit by a car. At that

time it looks like he received 9 units of blood products of which only 4 were tested negative and 5 have been non-traceable. There is no question that five untested united [sic] of blood are certainly a risk factor of acquiring hepatitis C infection. However, he readily admits that between 1973 and 1975 he used injection drugs. The claimant states that he used methamphetamine three or four times but never shared needles. A note by Dr. Hoare in March 2006 documents that he used street drugs 20-30 years ago using IV methamphetamine once a week and LSD twice a month and that note says that he did share needles with others when he was in Toronto at that time. As well, he was a moderately heavy drinker and he stopped drinking in 1989. He also has several tattoos, three or four of which were home made.

In 1989 when he was admitted to hospital both his AST and ALT were elevated. The AST elevation came down substantially as did other muscle inflammatory markers. The ALT was relatively stable through this between 50 and 90 although above the normal range. It would have been nice to have had an ALT one month later. This is a test that is much more specific for liver abnormality and could indicate that he already had some early liver disease at that time. Of course even if this were the case, one could not say with certainty whether the elevation was due to prior hepatitis C infection or alcohol intake.

The key issue is that on the balance of probabilities what is the more likely cause of his infection. He does have a history of injection drug use and there is some discrepancy between the affidavit in terms of amount of use of drug compared to that which is documented in the medical history. Although the claimant states that he never shared needles, in the early 70's there really was very little in the medical or lay literature espousing the dangers of sharing needles. It certainly was not known until many years later that even if clean needles were used, that the sharing of diluents, drug or paraphernalia can all facilitate the acquisition of hepatitis C. It would be highly unlikely for a 16-year old to engage in injection drug use completely on his own and without any friends or helpers. As well if in fact he engaged in more regular injection drug use, the chances of having a slip up in technique or in the sharing of needle etc. would be substantially high and is clearly a high risk of acquiring infection. Similarly the use of home made tattoos is problematic because at that time needles were cleaned with alcohol which is now known to be insufficient. As well it is now well known that even if clean needles were used that the re-use of ink was a transmission of hepatitis C vehicle. Finally there is the issue of five units of blood that

> were not tested. In 1989 hepatitis C was well established in the Canadian blood supply. Even so, the risk of injection drug use would be statistically significantly higher.
>
> Finally the issue is that he had advanced liver disease in 2006 in someone who had stopped drinking in 1989. Ordinarily one would have an infection with HCV for at least 15 years before seeing significant disease. That would put the possibility of acquisition of disease at or around 1990 but certainly as well could be before that time. Therefore one cannot say with any precision whether he was infected in 1989 or prior to that date such as in the 1970's. On the balance of probabilities I think there is at least an equal balance of possibility of acquiring disease from injection drug use in the 1970's compared to five units of blood that were not tested in 1989.
>
> If you have any questions please feel free to contact me."
> [emphasis added]

18. In his evidence at the hearing, Dr. Garber said that about 60% of the Hepatitis C patients he sees were infected through the use of intravenous drugs and tattoos. He indicated that there was little or no knowledge of the risks associated with needle sharing until the early 1980's and it was following that when public education campaigns about needle sharing began. According to Dr. Garber, the amount of drug use is an important consideration when assessing risk. He stated that with multiple use, say 100 times, there is much more likely to be a breakdown in sterile precautions. For persons who frequently use intravenous drugs for a considerable period, Dr. Garber placed the risk of infection at 20% or so. He said the risk of exposure from five units of untested blood in the Class Period, while very real, would be in the order of .1 to 1%. With respect to timing, Dr. Garber

postulated that, having regard to the progression of the disease when the Claimant was first diagnosed in 2006 and the advancement to cirrhosis in 2009, it was possible, and perhaps more likely, that he had been infected prior to 1989 but, in the final analysis, he could not say that with any degree of precision. In his opinion, either event – that is to say, intravenous drug use from 1973 to 1975 or blood transfusion in 1989 – could be the source of the Claimant's infection. In other words, from his perspective, it was "a toss up" which is why he concluded in his letter of December 10, 2010 that there was "at least an equal balance of possibility" of the Claimant having acquired Hepatitis C from injection drug use in the 1970's than the five untested units of blood in 1989.

19. Dr. Hoare's opinion on the probable cause of the Claimant's infection differs from Dr. Garber's. Dr. Hoare is an Internal Medicine specialist with a sub-speciality in Gastroenterology. As previously noted, she first saw the Claimant on March 10, 2006 and she has been involved with his treatment since that time. Dr. Hoare's view on the cause of the Claimant's Hepatitis C infection is set out in her letter to the Administrator dated July 21, 2009, the relevant portion of which reads as follows:

> "[The Claimant] has been a patient of mine for several years. His liver biopsy of 2006 (attached) indicates bridging fibrous with chronic Hepatitis C infection. He is scheduled for another biopsy in August of 2009.

> Although [the Claimant] displays a tattoo he received as a teenager and he has indicated he experimented briefly with intravenous drug use over 30 years ago (in his late teens), he has no recent encounters with any other intravenous needle use since those incidents in the mid 1970's.
>
> As he did not appear to display any symptoms of the Hepatitis C virus or liver disease until several years after he received blood transfusion(s) as the result of a car accident in 1989, I would find it reasonable and highly probable that the primary cause of his Hepatitis C infection was due to receiving tainted blood in the 1986-1990 time frame."

20. Subsequently, after the Claimant's application had been denied, Dr. Hoare submitted the following letter dated March 3, 2011 at the request of the Claimant's personal representative:

> "March 3, 2011
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> To Whom It May Concern:
>
> RE: [The Claimant]
> DOB: 02-03-1957
>
> I saw [the Claimant] twice (March 2006 and June 2009) about his Hepatitis C, I wrote that he had used IV drugs remotely. He says that he used from 1973 to 1975 three times yearly and that he never shared needles. During his MVA in 1989 he was transfused 9 units of blood. I would say that statistically, he would most likely have acquired the Hepatitis C from the transfusions and should qualify for compensation.
>
> Respectfully yours,
>
> C. Hoare, MD, FRCP, Internal Medicine"

21. Dr. Hoare's evidence at the hearing was consistent with the opinion expressed in her letters. She acknowledged that there was a discrepancy between the information that the Claimant had given her in March of 2006 concerning the extent of his drug use and the sharing of needles as compared with the information he gave her later on the same subject as reflected in her March 3, 2011 letter. However, she said that inconsistency did not change her opinion. She also agreed that the word "statistically" which appears in her March 3, 2011 letter was not a good choice of terminology because her opinion was not really based on statistical analysis. Rather, she said it was based on the blood work done immediately prior to the Claimant's surgery in 1989 and the rapid progression of the disease between 2006 and 2009. She said that the 1989 blood work showed that the Claimant's AST and ALT levels were high and that his albumin was below the normal range. Both Dr. Hoare and Dr. Garber indicated that these results could be markers of Hepatitis C but could equally be attributable to alcohol use and the accident. However, Dr. Hoare considered it significant that when she saw the Claimant in March of 2006, his AST and ALT levels remained elevated, while his albumin result had returned to normal and remained so up to and including 2009. Based on this, Dr. Hoare concluded that his elevated AST and ALT levels in 1989 were due to the use of alcohol and the accident, and were not signs of pre-existing early liver disease. With respect to timing, Dr. Hoare agreed with Dr. Garber that it was not

really a factor in determining whether the source of the Claimant's infection was intravenous drug use in the 70's or the 1989 blood transfusions.

22. I am satisfied that Dr. Garber and Dr. Hoare have each exercised their best professional judgment in forming their respective opinions. The fact that they have reached different conclusions as to the probable cause of the Claimant's Hepatitis C is simply a reflection of the difficulties inherent in the case. It is a close call either way. Dr. Garber, applying his expertise and experience, is of the view that there is at least equal probability that the Claimant acquired the disease from injection drug use in the 1970's rather than the five untested units of blood with which he was transfused in 1989. Dr. Hoare, on the other hand, is of the view that, on the balance of probabilities, the Claimant more likely was infected by the transfusions.

23. By virtue of Section 3.01 of the Transfused HCV Plan, the onus is on a claimant who has used non-prescription intravenous drugs to produce evidence establishing, on the balance of probabilities, that he or she was infected for the first time with HCV by a blood transfusion in Canada during the Class Period. The CAP makes it clear that the Administrator must, in determining whether a claimant has met this onus, weigh the totality of the evidence. Since I have been called upon, in my capacity as arbitrator, to review the decision of the Administrator, I

too must consider the totality of the evidence. Likewise, I must consider the supportive factors listed in section 12 of the CAP and the non-supportive factors set out in section 13 thereof.

24. I can find no fault with the Administrator's analysis of the supportive and non-supportive factors. It is significant, in my judgment, the only factor supportive of a finding that the Claimant has met the burden in Section 3.01(3) is that he had no medical history of Hepatitis prior to being transfused in 1989. There has been no identification of a Class Period blood transfusion from an HCV antibody positive donor. The intravenous drug use took place prior to the blood transfusion. Moreover, it is clear that the Claimant used intravenous drugs on a fairly regular basis over a three-year period and was not able to produce "reasonably reliable evidence that the non-prescription intravenous drug use was limited to a single occasion and was done with sterile equipment which was not shared".

25. Weighing the totality of the evidence, and having regard to the extent of the Claimant's use of non-prescription intravenous drugs prior to the Class Period, the opinion of Dr. Garber and the factors set out in the CAP, I am not satisfied, on the balance of probabilities, that the Claimant was infected for the first time with HCV by the transfusions which he received in 1989. The probability

that the Claimant was infected with HCV as a result of intravenous drug use is at least as high, and perhaps higher, than the risk that he was infected by the blood transfusions. Accordingly, I find that there is no basis for overturning the Administrator's denial of the claim.

26. I recognize, of course, that the conclusion which I have reached is not consistent with Dr. Hoare's opinion on the ultimate issue of probable cause. While I respect Dr. Hoare's opinion and have given it careful consideration, I am not persuaded on the evidence before me that it is correct. I note, as well, that Dr. Hoare would not have been familiar with the CAP guidelines which, had she considered them, may have led her to a different conclusion.

DATED at Halifax, Nova Scotia, this 3rd day of January, 2012.

S. BRUCE OUTHOUSE, Q.C.
Arbitrator