CLAIM No. **1496**
Province of Infection: **Ontario**
Province of Residence: **Ontario**

IN THE MATTER OF AN ARBITRATION
TO REVIEW THE DECISION OF THE ADMINISTRATOR

Before: Tanja Wacyk

Heard: May 19, 2005, at Ottawa, Ontario

DECISION

BACKGROUND:

1. The estate of the deceased, represented by the deceased's daughter, ("personal representative") submitted an application for compensation under the Transfused HCV Plan (the "Plan"), as set out under the terms of the 1986-1990 Hepatitis C Settlement Agreement (the "Agreement").

2. By letter dated February 6, 2004, the Administrator denied the claim on the basis there was insufficient evidence that the deceased was infected by HCV.

3. The estate requested that a Referee review the decision of the Administrator.

4. An oral hearing in this matter was held in Ottawa, Ontario, on May 19, 2005.

APPLICABLE PROVISIONS:

5. In order for the state to be entitled to compensation, it must be established that the deceased was an HCV-infected person. An HCV-infected person is defined by the Plan as a Primarily-Infected Person or a Secondary-Infected Person.

6. Prior to the deceased's death there was no antibody test available. In such a situation, the Plan provides that one of three alternative types of evidence can be provided to establish that the deceased had HCV.

7. The applicable provision in this instance is section 3.05(3) which provides as follows:

> 3.05 (3) Notwithstanding the provisions of Section 3.01(1)(b), if a deceased Primarily-Infected Person was not tested for the HCV antibody or HCV the HCV Personal Representative of such deceased Primarily-Infected Person may deliver, instead of the evidence referred to in Section 3.01(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 a Blood transfusion in the absence of any other cause;
>
> (c) a diagnosis of cirrhosis in the absence of any other cause.

8. Furthermore, subsection 3.05 1.a. requires that the estate provide proof that the death of the HCV Infected Person was caused by his or her infection with HCV. The parties agreed to also address that issue in the hearing.

EVIDENCE:

9. The following facts were not in dispute:

- The deceased died on May 1, 1990 after a difficult and protracted battle with leukemia;

- During the course of her treatment for leukemia and the accompanying anemia, the deceased received numerous transfusions;

- A trace-back of donors determined that two of the transfused units, one received in November 1988 and the other in January 1989, were from a donor who was HCV positive;

- The death of the deceased was attributed to leukemia, and she was never tested for HCV. Nor was a liver biopsy ever performed.

10. Three physicians commented on the deceased's HCV status.

Dr. Beck

11. Dr. Beck, the deceased's treating physician, who knew the patient for four years prior to her death indicated as follows on the Tran 2 form:

> Pt had weakened immune system secondary to Hep C infection - viral load - multiple viral and bacterial infections general malaise/weakness anorexia/poor nutrition thrombocytopenia was exacerbated by pts Hep C infection worsening of her bleeding tendencies & haemorrhage when it did occur. Hepatitis C infection may have had a significant affect/in part on pts coming out of remission of AML.

12. Dr. Beck filled the Trans 2 form out in 2003, some 13 years following the deceased's death. At the hearing it was unclear what medical records Dr. Beck had to assist in the completion of the Trans 2 form, as the deceased's daughter testified that Dr. Beck's medical records regarding her mother had been destroyed years earlier. Subsequent to the hearing, counsel for the estate provided a copy of the correspondence sent to Dr. Beck by the deceased's daughter. The document indicated that Dr. Beck was provided with a summary prepared from

the deceased's hospital records from Ottawa and Blind River, as well as a copy of some hospital records.

Dr. Lacroix

13. A second Tran 2 form was completed by Dr. Lacroix, a haematologist. Dr. Lacroix had never treated the deceased but relied on the deceased's medical records, as compiled by Dr. Markman, the deceased's treating haematologist. Dr. Lacroix wrote that "patient died of acute myelogenus leukemia" but had received Hepatitis C positive transfusion. Dr. Lacroix also wrote "unknown" when asked whether the death was caused by Hepatitis C.

14. Dr. Lacroix also provided a written report, dated July 8, 2003, created with a view to determining whether the deceased met the criteria in 3.05(3). In that regard, Dr. Lacroix stated:

> The question now is whether the deceased primarily infected person had an episode of jaundice within three months of the transfusion and there are some statements in the consultation that her sclera were somewhat yellowish tint and the sclera was slightly icteric. This however is not an episode of jaundice because if one reviews the laboratory data from 1990 her bilirubin was normal as were her liver functions Now it is possible that she had a fleeting episode of jaundice in 1989 but unfortunately I do not have any laboratory parameters from that time to confirm jaundice. A slight abnormality of the sclera is not sufficient amount of information to confirm an episode of jaundice.
>
> …The patient died of acute leukemia but whether or not the Hepatitis C contributed to the death is a question that is not answerable at this time from the information I have available to me.

Dr. Garber

15. Dr. Garber is an infectious disease specialist and the Head of the Division of Infectious Diseases at the University of Ottawa and the Ottawa Hospital. Dr. Garber's opinion was as follows:

> In reviewing the documentations on one occasions (*sic*) the sclera was described as yellowish. This is a very typical description of patients particularly those who are very pale and are undergoing febrile illnesses. Because her liver function tests and total bilirubin were never recorded as elevated, that clearly would not have been indicative of an acute hepatitis episode. Similarly her low platelets was completely expected with her underlying disease of leukemia

and in fact prior to any blood transfusions were low and became ever lower – due to chemotherapy. The refractory thrombocytopenia at the end of her illness again would be typical of bone marrow failure related to leukemic infiltration of the bone marrow. As well, at no time was there any evidence of liver function test abnormalities.

In review of this dossier clearly this patient was exposed to hepatitis C, however, there is no evidence that the patient was infected with hepatitis C. More importantly she never had episodes that could even be construed as acute hepatitis. As the usual complications of hepatitis C do not occur until 15 to 20 years after exposure and in the presence of normal liver function tests, there is no evidence that she would have been suffering from cirrhosis or other serious hepatitis C related disease. As to the issue of cause of death in this case it was very clear this woman developed a life threatening severe illness, that being acute myelogenous leukemia. Her response to chemotherapy was unfortunately relatively transient and the complications that she suffered in the last six months of her life, including bone marrow failure, becoming transfusion dependent and recurrent infections were completely typical, unfortunately, of a patient with end-stage leukemia. There is absolutely no evidence to suggest that hepatitis C played any part in this patient's demise.

Despite the submission by Dr Beck, hepatitis C does not tend to be a cause of weakening immune system and inducing viral and bacterial infections, except under complete liver failure and all the signs and symptoms including nutritional issues, anorexia, weakness, malaise and intercurrent infections as noted above are very typical of leukemia complication or complications of the treatment of leukemia.. (*sic*)

In conclusion, there is no evidence to support an alternative to hepatitis C diagnosis in the absence of hepatitis C virus testing and similarly there is absolutely no evidence to suggest that hepatitis C virus materially contributed to the death of the patient who clearly died of acute myelogenous leukemia.

ARGUMENT:

16. The estate submitted that because two of the deceased's donors tested positive, there was a strong likelihood she was infected. In support of that supposition the estate submitted two papers.

17. The first was "Molecular Detection of Hepatitis C Virus: Impact of Detection Methodology on Clinical and Laboratory Correlations" written by Dr. Mel Krajden, Department of Microbiology, The Toronto Hospital, University Hospital (1995). That article stated, at page 48, that the development and application of anti-HCV antibody detection assays have partially clarified the risk of HCV transmission from anti-HCV positive donors. The article indicates that approximately 70% of donors found positive for anti-HCV antibodies and about 90% of donors tested by second-generation EIA were capable of transmitting HCV infection. The estate submitted this suggests a high rate of infection if exposed.

18. The second article was titled "Transfusion transmission of HCV infection before anti-HCV testing of blood donations in England: results of the national HCV lookback program" from the National Blood Service, Watford, England, (September 2002). That article stated, at page 1151, that the strongest observation from data collected was the association of HCV infection in recipients with positive HCV PCR of their donors. However, the article also went on to state that about 40 percent of recipients with known HCV status were not infected with HCV.

19. The estate maintained that Dr. Garber's report was clear that the deceased had been exposed to Hep C, but that it then noted there was no evidence that she had been infected. The estate maintained that comment indicated that Dr. Garber had engaged in the wrong inquiry, and that in keeping with subsection 3.05(3), the appropriate question was whether the deceased had any episode of jaundice. The estate submitted that Dr. Garber appears to read into the provision that in order for the estate to qualify for compensation, it must demonstrate that the deceased had an acute case of hepatitis – but pointed out that the subsection speaks only of an episode of jaundice.

20. The estate also submitted that Dr. Lacroix had been asked the wrong question by the administrator, as her opinion, set out above, was in response to the question of whether the notations in the deceased's records that "sclera has somewhat of a yellowish tint to them" and "sclera appeared slightly icteric" could be "an episode of jaundice within 3 months of a blood transfusion." Rather, the estate submitted that Dr. Lacroix should have been asked if those observations are "evidence" of an episode, and suggested that her answer would have been different had that been the case.

21. The estate submitted that the plan was formulated with a recognition that evidence of infection would be difficult to obtain for deceased persons who had not been tested. Consequently, in fairness to the estate, the agreement must be read strictly in this instance – and should not be read to require confirmation of an episode of jaundice, but rather to require evidence of such an episode. I understood this to mean essentially "some evidence" of such an episode. The estate maintained that to do otherwise would set the bar to qualify too high.

22. Regarding whether hepatitis C materially contributed to the deceased's death, the estate pointed out that Dr. Lacroix, an oncologist, indicated she was not in a position to answer that question.

23. The estate submitted that Dr. Garber, the infectious disease specialist, was clear that the inquiry in which he engaged was whether the deceased died of liver failure. The estate submitted that Dr. Garber was looking for the usual complications resulting from hepatitis C - specifically whether the hepatitis C caused liver failure which caused the deceased's death - which does not usually occur until 15-20 years after exposure.

24. The estate maintained that this again set the bar too high in light of the difficulty in determining that question definitely using old records.

25. The estate argued that the Trans 2 completed by Dr. Beck should be preferred. The estate pointed out that Dr. Beck knew the deceased for four years. While he had not been aware that he should focus on hepatitis C at the time, with the new knowledge that two donors tested positive for hepatitis C, he reviewed the situation again and opined that the hepatitis C may have had a significant effect on the leukemia. The estate submitted that in light of the lack of scientific certainty, this should be sufficient to meet the test.

ANALYSIS:

26. The studies relied on by the estate are of limited assistance, as they deal with general statistical observations, and cannot be determinative regarding what occurred in the deceased's case.

27. The estate suggests an interpretation of subsection 3.05 (3) (b) which would in effect, establish entitlement on the basis of only "some" evidence of jaundice. However, if that were the intention of the drafters, this could easily have been indicted in the language of this provision. In the absence of clear language indicating a lower standard, I am compelled to find that the correct standard of proof in these applications is that of a balance of probabilities. In other words, is it more likely than not that the deceased had an episode of jaundice within three months of her transfusion in the absence of any other cause?

28. In this instance, Dr. Lacroix has gone no further than commenting that "…it is possible that [the deceased] had a fleeting episode of jaundice in 1989 but unfortunately I do not have any laboratory parameters from that time to confirm jaundice." This does not satisfy the test of a balance of probabilities.

29. Furthermore, Dr. Garber was the only physician who turned his mind to alternative causes of the deceased's sclera being described as yellowish. In the absence of any evidence to the contrary, this is the best evidence on this issue and must be relied on. Dr. Garber found that this was a very typical description of patients, and particularly of those who are very pale and are undergoing febrile illnesses. He notes that the deceased's liver function tests and total bilirubin were never recorded as elevated, and concludes that clearly would not have been indicative of an acute hepatitis episode.

30. Consequently, I find that on a balance of probabilities, the deceased did not have an episode of jaundice within three months of a blood transfusion in the absence of any other cause, and consequently there is no evidence that she was infected with HCV.

31. While the estate urges me to rely on the opinion of Dr. Beck rather than that of Dr. Lacroix or Dr. Garber, even if I were to do so, this does not assist the estate in this regard. While Dr. Beck seems to assume that the deceased was infected with HCV, there is no indication of why he was of that view. Given that his own records regarding the deceased had been destroyed, and he had only the hospital records and summary provided by the deceased's daughter to refer to, it appears he had only the same information as did Dr. Lacroix and Dr. Garber – neither of whom were able to reach that conclusion.

32. I further find that in any event, even if I had found that the estate had demonstrated that the deceased was an HCV-infected person, there is no evidence on which I can conclude that, on a balance of probabilities, HCV materially contributed to the death of the deceased.

33. Dr. Beck states only that hepatitis C infection **may** have had a significant affect, in part, on the deceased having come out of remission. Dr. Lacoix indicates she is unable to answer that question, and Dr Garber states there is absolutely no evidence to suggest that hepatitis C virus materially contributed to the deceased's death. This does not satisfy the estate's onus to establish, on a balance of probabilities, that HCV materially contributed to the deceased's death.

34. Accordingly, I find that the Administrator correctly determined that the estate of the deceased is not entitled to compensation pursuant to the Agreement, as there is insufficient evidence to demonstrate that she was infected with HCV, or that

HCV materially contributed to her death.

DISPOSITION:

35. The decision of the Administrator to deny the estate of the deceased compensation pursuant to the Hepatitis C 1986-1990 Class Action Settlement Agreement is upheld.

DATED AT TORONTO, THIS 30TH DAY OF MAY, 2005.

Tanja Wacyk, Referee