Court File No. 98-CV-141369 CP00

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

DIANNA LOUISE PARSONS, MICHAEL HERBERT CRUICKSHANKS, DAVID TULL, MARTIN HENRY GRIFFEN, ANNA KARDISH, ELSIE KOTYK, Executrix of the Estate of Harry Kotyk, deceased and ELSIE KOTYK, personally

Plaintiffs

and

THE CANADIAN RED CROSS SOCIETY, HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO and THE ATTORNEY GENERAL OF CANADA

Defendants

and

HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF ALBERTA
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF SASKATCHEWAN,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF MANITOBA,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NEW BRUNSWICK
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF PRINCE EDWARD ISLAND,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NOVA SCOTIA
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NEWFOUNDLAND,
THE GOVERNMENT OF THE NORTHWEST TERRITORIES,
THE GOVERNMENT OF NUNAVUT and THE GOVERNMENT OF THE YUKON TERRITORY

Intervenors

Proceeding under the Class Proceedings Act, 1992

Court File No. 98-CV-146405

B E T W E E N:

JAMES KREPPNER, BARRY ISAAC, NORMAN LANDRY, as Executor of the Estate of the late SERGE LANDRY, PETER FELSING, DONALD MILLIGAN, ALLAN GRUHLKE, JIM LOVE and PAULINE FOURNIER as Executrix of the Estate of the late PIERRE FOURNIER

Plaintiffs

and

THE CANADIAN RED CROSS SOCIETY, THE ATTORNEY GENERAL OF CANADA and HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO

Defendants

and

HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF ALBERTA, HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF SASKATCHEWAN, HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF MANITOBA,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NEW BRUNSWICK, HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF PRINCE EDWARD ISLAND HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NOVA SCOTIA
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NEWFOUNDLAND,
THE GOVERNMENT OF THE NORTHWEST TERRITORIES,
THE GOVERNMENT OF NUNAVUT AND THE GOVERNMENT OF THE YUKON TERRITORY

Intervenors

Proceeding under the Class Proceedings Act, 1992

No. C965349
Vancouver Registry

In the Supreme Court of British Columbia

Between:

Anita Endean, as representative plaintiff

Plaintiff

and:

**The Canadian Red Cross Society
Her Majesty the Queen in Right of the Province of
British Columbia, and The Attorney General of Canada**

Defendants

and:

**Prince George Regional Hospital, Dr. William Galliford, Dr.
Robert Hart Dykes, Dr. Peter Houghton, Dr. John Doe,
Her Majesty the Queen in Right of Canada, and
Her Majesty the Queen in Right of the Province of British Columbia**

Third Parties

Proceeding under the Class Proceedings Act, R.S.B.C. 1996, C. 50

CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

NO : 500-06-000016-960

SUPERIOR COURT
Class action

DOMINIQUE HONHON

Plaintiff

-vs-

THE ATTORNEY GENERAL OF CANADA
THE ATTORNEY GENERAL OF QUÉBEC
THE CANADIAN RED CROSS SOCIETY

Defendants

-and-

MICHEL SAVONITTO, in the capacity of the Joint Committee member for the province of Québec

PETITIONER

-and-

FONDS D'AIDE AUX RECOURS COLLECTIFS

-and-

LE CURATEUR PUBLIC DU QUÉBEC

Mis-en-cause

CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

NO : 500-06-000068-987

SUPERIOR COURT
Class action

DAVID PAGE

Plaintiff

-vs-

THE ATTORNEY GENERAL OF CANADA
THE ATTORNEY GENERAL OF QUÉBEC
THE CANADIAN RED CROSS SOCIETY

Defendants

-and-

FONDS D'AIDE AUX RECOURS COLLECTIFS

-and-

LE CURATEUR PUBLIC DU QUÉBEC

Mis-en-cause

AFFIDAVIT OF ASVINI KRISHNAMOORTHY
(sworn January 29, 2016)

I, Asvini Krishnamoorthy, of the City of Toronto, in the Province of Ontario, MAKE OATH AND SAY AS FOLLOWS:

1. I am a Legal Assistant employed by the Department of Justice and in that capacity have knowledge of the matters to which hereinafter I depose.

2. Annexed hereto and marked as Exhibit A to this my affidavit is a copy of the Quebec judgment rendered on November 19, 1999 in Page v. The Attorney General of Canada. (*Page c. Canada (Procureur général),* [1999] J.Q. no 5325).

3. Annexed hereto and marked as Exhibit B to this my affidavit is a copy of the Plaintiff's Factum, dated August 9, 1999, filed in support of the settlement approval motion in the Parsons action.

4. Annexed hereto and marked as Exhibit C to this my affidavit is a copy of the Factum filed on behalf of the representative plaintiffs in the Ontario Hemophiliac (Kreppner) class action, dated August 9, 1999.

5. Annexed hereto and marked as Exhibit D to this my affidavit is a copy of the Plan d'argumentation des requérants (Quebec Honhon/Page), dated August 20, 1999, filed in support of the settlement approval motion.

6. Annexed hereto and marked as Exhibit E to this my affidavit is a copy of the Submissions of the Representative Plaintiff on Application for Approval of the Proposed Settlement in the Endean action dated August 15, 1999.

7. Annexed hereto and marked as Exhibit F to this my affidavit is a copy of the report of Murray Krahn et al (CASL) entitled "Estimating the prognosis of Hepatitis C patients infected by transfusion in Canada between 1986 and 1999" together with a letter from Dr. Krahn dated June 10, 1999.

8. Annexed hereto and marked as Exhibit G to this my affidavit is a copy of the report of Robert S. Remis et al. entitled "Estimating the Number of Blood Transfusion Recipients Infected by Hepatitis C Virus in Canada, 1960-1985 and 1990-1992" dated June 22, 1998.

9. Annexed hereto and marked as Exhibit H to this my affidavit is a copy of the report of Robert S. Remis et al., « Estimation du nombre de transfusés infectés par le virus de l'Hépatite C au Canada, 1960-1985 ET 1990-1992 », 22 Juin, 1998.

10. Annexed hereto and marked as Exhibit I to this my affidavit is a copy of the report of Robert S. Remis, "Estimating the Number of Potential Beneficiaries of the Canadian HVC Class Action Settlement for Persons Infected by Transfusions Received From January 1986 to July 1990", dated July 6, 1999.

11. Annexed hereto and marked as Exhibit J to this my affidavit is a copy of the report of Robert S. Remis, « Estimation du nombre de bénéficiaires potentiels dans le cadre du règlement intervenu dans le recours collectif canadien relatif à l'hépatite C chez les personnes infectées par voie de transfusion sanguine reçue entre janvier 1986 et juillet 1990 », 6 juillet 1999.

12. Annexed hereto and marked as Exhibit K to this my affidavit is a copy of the Eckler Partners Ltd., "Actuarial Report on 1986-90 Hepatitis C Settlement, dated July 9, 1999.

13. Annexed hereto and marked as Exhibit L to this my affidavit is a copy of the Eckler

Associés, "Rapport Actuariel Sur la Convention de Règlement Relative à l'Hépatite C 1986-90", 9 juillet 1999.

14. Annexed hereto and marked as Exhibit M to this my affidavit is a copy of the report of the Medical Modelling Working Group ("MMWG"), "Estimating the Prognosis of Canadians Infected with the Hepatitis C Virus through the Blood Supply, 1986-1990, Fourth Revision of HCV Prognostic Model Incorporating Data from the Compensation Claimant Cohort," April 2011.

15. Annexed hereto and marked as Exhibit N to this my affidavit is a copy of the report of the MMWG, "Estimating the Prognosis of Canadians Infected with the Hepatitis C Virus through the Blood Supply, 1986-1990, Fifth Revision of HCV Prognostic Model Incorporating Data from the Compensation Claimant Cohort," September 2014.

16. Annexed hereto and marked as Exhibit O to this my affidavit is a copy of the Affidavit of J.J. Camp, with Exhibits, sworn November 23, 1999 and filed in support of the fee approval motion.

17. Annexed hereto and marked as Exhibit P to this my affidavit is a copy of the report of the MMWG "Estimating the Prognosis of Canadians Infected With the Hepatitis C Virus Through the Blood Supply, 1986-1990, Third Revision of the Hepatitis C Prognostic Model Incorporating Data From the Compensation Cohort" dated January 2008.

SWORN before me at the City of Toronto, in the Province of Ontario, this 29th day of January, 2016.

A Commissioner for taking affidavits within the Province of Ontario

ASVINI KRISHNAMOORTHY

This is Exhibit "A" referred to in the
affidavit of Asvini Krishnamoorthy
sworn before me at Toronto, Ontario
this 29th day of January, 2016

William Kim Lts.

A Commissioner for taking affidavits
within the Province of Ontario

Répertorié:

Page c. Canada (Procureur général)

Entre
David Page, requérant, et
Procureur général du Canada, Procureur géneral du Québec et Société canadienne de la Croix-Rouge, intimés, et
Étienne Saumure, intervenant, et
Fonds d'aide aux recours collectifs et le Curateur public du Québec, mis en cause

[1999] J.Q. no 5325

No 500-06-000068-987

Cour supérieure du Québec (Recours collectif)
District de Montréal

La juge Nicole Morneau

le 19 novembre 1999.

(11 paras)

Avocats:

Jean Blaquière et Henri Petit (Petit Blaquière Dagenais), pour le requérant.
André Lespérance et Nathalie Drouin (Côté & Ouellet), pour le Procureur général du Canada.
Robert Monette et Dany Leduc (Berbard Roy & Ass.), pour le Procureur général du Québec.
Robert E. Charbonneau (McMaster, Gervais), pour la Société canadienne de la Croix-Rouge.
Claude Lapointe et Karyne Desjardins (Lapointe, Cayen, Morel), pour l'intervenant, Étienne Saumure.
Louise Ducharme, pour Fonds d'aide aux recours collectifs.
Hélène Laberge, pour le Curateur public du Québec.

MOTIFS DU JUGEMENT

1 **LA JUGE NICOLE MORNEAU**:-- LE TRIBUNAL est saisi d'une requête visant à obtenir une ordonnance additionnelle d'approbation d'une transaction présentée par le requérant, David Page;

2 CONSIDÉRANT que le Tribunal a rendu un jugement le 21 septembre 1999 accueillant la requête en approbation d'une transaction présentée par le requérant, David Page;

3 CONSIDÉRANT l'entente intervenue entre les parties modifiant la Convention relative à l'Hépatite C 1986-1990 et ses annexes A à E datée du 15 juin 1999, contenue à l'Annexe F [Note de l'éd.: Voir l'annexe F à la fin du jugement] desdites convention et annexes;

4 CONSIDÉRANT que les parties ont convenu que les gouvernements PT possèdent l'option de verser des montants périodiques en conformité avec les articles 4.02 et 4.04 de l'Accord de financement de telle sorte que dans cette éventualité, il ne restera dans le Fonds en Fiducie aucune somme d'argent ou actif des gouvernements PT qui ne serait alloué actuariellement;

5 CONSIDÉRANT la nature avantageuse des modifications contenues à l'Annexe F de la Convention relative a l'Hépatite C 1986-1990 et ses annexes A à E datée du 15 juin 1999;

6 CONSIDÉRANT que les modifications à la Convention relative à l'Hépatite C 1986-1990 et ses annexes A à E datée du 15 juin 1999, prévues à l'Annexe F, sont également soumises pour approbation dans les provinces de l'Ontario et de la Colombie-Britannique, avec les adaptations nécessaires pour respecter la spécificité de chacune des juridictions;

7 CONSIDÉRANT que le Tribunal a pris connaissance du projet de jugement à être rendu par l'honorable juge Warren K. Winkler sur une requête similaire présentable en Ontario;

8 CONSIDÉRANT que les modifications prévues à l'Annexe F tiennent compte de la spécificité du droit applicable dans la province de Québec;

9 CONSIDÉRANT qu'il est dans l'intérêt des membres et de la justice que le Tribunal entérine les modifications de la Convention relative à l'Hépatite C 1986-1990 et ses annexes A à E datée du 15 juin 1999, contenues à l'Annexe F desdites convention et annexes, lesquelles sont à l'avantage des membres;

10 CONSIDÉRANT que le requérant demande d'être dispensé de donner l'avis prévu à l'article 1025 du Code de procédure compte tenu de la nature avantageuse des modifications pour les membres et afin d'éviter d'imposer à ceux-ci tout délai additionnel;

11 PAR CES MOTIFS, LE TRIBUNAL :

ACCUEILLE la présente requête;

PREND ACTE du consentement des parties aux modifications à la Convention relative à l'Hépatite C 1986-1990 et ses annexes A à E datée du 15 juin 1999, contenues à l'Annexe F jointe aux présentes;

ENTÉRINE les modifications à la Convention relative à l'Hépatite C 1986-1990 et ses annexes A à E datée du 15 juin 1999, contenues à l'Annexe F jointe aux présentes;

DISPENSE le requérant de publier l'avis prévu à l'article 1025 du Code de procédure civile;

DÉCLARE que le groupe, dont les membres seront liés par le jugement, est défini comme suit :

Le "Groupe" est constitué :

i. des personnes atteintes de l'hémophilie qui ont reçu ou se sont administré, au Québec, du sang ou des produits sanguins, tel que ci-après défini, entre le 1er janvier 1986 et le 1er juillet 1990 inclusivement, et qui sont ou ont été infectées par le virus de l'Hépatite C;
ii. d'un époux ou d'un conjoint infecté indirectement par le virus de l'Hépatite C par un époux ou un conjoint qui est une personne décrite au paragraphe (i);
iii. d'un enfant infecté indirectement par le virus de l'Hépatite C par un parent qui est une personne décrite aux paragraphes (i), (ii); ou
iv. d'un membre de la famille d'une personne décrite aux paragraphes (i), (ii), ou (iii);

le sang étant défini comme suit :

"sang", le sang total et des produits sanguins, y compris les concentrés de globules rouges, les plaquettes, le plasma (frais congelé et stocké) et les globules et le cryoprécipité et les produits de facteur de coagulation, notamment le facteur VII, le facteur VIII, le facteur IX, fournis directement ou indirectement par la Société canadienne de la Croix-Rouge. Le sang ne comprend pas l'albumine à 5 %, l'albumine à 25 %, l'immunoglobuline anti-cytomégalovirus, l'immunoglobuline anti-hépatique B, l'immunoglobuline anti Rh, l'immunoglobuline antivaricelleuse-antizostérienne, l'immunoglobuline sérique, l'immunoglobuline antitétanique, l'immunoglobuline intraveineuse (IVIG) et l'antithrombine III (ATIII).

DÉCLARE que la Convention relative a l'Hépatite C 1986-1990 intervenue en date du 15 juin 1999 ainsi que ses annexes "A", "B", "C", "D", "E" et "F" ci-après décrites :

Annexe "A" : Régime à l'intention des transfusés infectés par le VHC;

. Annexe "B" : Régime à l'intention des hémophiles infectés par le VHC;

. Annexe "C" : Programme d'aide financière fédéral/ provincial/ territorial pour les personnes indirectement infectées par le VIH;

. Annexe "D" : Accord de financement;

. Annexe "E" : Législation sur les prestations sociales;

. Annexe "F" : Modifications numéro 1 à la Convention de règlement;

(ci-après appelées "Convention de règlement") sont justes, raisonnables et ont été conclus dans le meilleur intérêt des membres du recours collectif des hémophiles infectés par le VHC;

APPROUVE la Convention de règlement et ORDONNE aux parties et aux membres liés par la Convention de règlement de s'y conformer;

DÉCLARE que la Convention de règlement constitue une transaction au sens de l'article 2631 du Code civil du Québec liant toutes les parties et tous les membres liés par ce règlement;

DÉCLARE qu'à la date d'approbation, le gouvernement fédéral doit payer au fiduciaire, en vertu des paragraphes 4.01 (1) et 4.02 (1) de l'Accord de financement, le montant dû et échu en date du 30 septembre 1999, soit la somme de 846 327 527,00 $, plus les intérêts courus entre cette date et la date de paiement, conformément à l'Accord de financement plus ou moins de tout ajustement prévu par cet accord.

ORDONNE ET DÉCLARE que le présent jugement n'affectera en aucune façon la Société canadienne de la Croix-Rouge étant donné que les présentes procédures en recours collectif ont été suspendues contre celle-ci par un jugement de l'honorable juge Blair de la Cour supérieure de l'Ontario daté du 20 juillet 1998, rendu en vertu de la Loi sur les arrangements avec les créanciers des compagnies (S.R.C. 1985, ch. C-36) dans une action portant le numéro 98-CL-002970, pareille suspension ayant été prolongée par des ordonnances ultérieures de la même Cour et datées des 19 août 1998, 5 octobre 1998, 18 janvier 1999, 5 mai 1999 et du 28 juillet 1999;

DÉCLARE que la Cour procédera ultérieurement à la nomination des personnes appropriées aux postes décrits à la Convention de règlement;

ORDONNE que Me Bonnie Tough soit et est par les présentes, désignée membre du Comité conjoint à titre de conseiller légal pour les personnes atteintes d'hémophilie qui ont reçu ou se sont administré au Québec, du sang ou des produits sanguins;

DÉCLARE que les honoraires et déboursés des procureurs du requérant et de l'intervenant seront déterminés à une date ultérieure;

DÉCLARE que le mis en cause, le Curateur public du Québec, pourra, par requête pour directives et instructions, s'adresser à cette Cour, selon qu'il le juge approprié;

DISPENSE le mis en cause, le Curateur public du Québec, d'obtenir l'autorisation du Tribunal requise pour transiger en faveur de chacune des personnes qu'il représente, pour quelqu'indemnisation que ce soit en vertu de la Convention de règlement, nonobstant l'article 36 de la Loi sur le curateur public (L.R.Q., c. C-81) et DÉCLARE que le présent jugement équivaut à l'autorisation requise en vertu de l'article 36 de la Loi sur le curateur public;

ORDONNE ET DÉCLARE que soit donné aux membres des recours collectifs et les membres de leur famille un avis du présent jugement, de la manière à être déterminée par le Tribunal à une date ultérieure;

DÉCLARE que la date limite pour s'exclure du groupe visé par le règlement sera la date que fixera ultérieurement le Tribunal après avoir approuvé les avis à être publiés;

DÉCLARE que sous réserve de l'article 1008 du Code de procédure civile du Québec, tout membre du groupe ci-avant décrit qui ne s'est pas exclu en présentant au gestionnaire des réclamations une formule d'exclusion dûment remplie dans le délai d'exclusion, sera lié par la présente Convention de règlement et le présent jugement;

ORDONNE ET DÉCLARE, conditionnellement à l'approbation de la Convention de règlement par l'honorable juge Smith en Colombie-Britannique et l'honorable juge Winkler en Ontario, qu'à l'exception de ce qui est prévu ci-avant, le recours collectif institué par monsieur David Page est rejeté sans frais.

La soussignée demeurera saisie du présent dossier à moins de contre ordre du Juge en chef.

LE TOUT sans frais.

LA JUGE NICOLE MORNEAU

* * * * *

ANNEXE F MODIFICATION NUMÉRO 1 - 2
NOVEMBRE 1999

La Convention de règlement est modifiée comme suit :

1. Par l'ajout au paragraphe 10.01 de la Convention de règlement des alinéas suivants :

"p. 1) Dans le cadre du libre exercice de leur pouvoir discrétionnaire, ordonner, de temps à autre, sur demande de toute partie ou du Comité conjoint, que les fonds et les autres éléments d'actif détenus par le fiduciaire en vertu de la Convention de règlement et qui ne font pas l'objet d'une attribution actuarielle soient en tout ou en partie :

(i) attribués aux membres des recours collectifs et/ou aux membres de la famille;
(ii) attribués de toute manière dont on peut raisonnablement s'attendre qu'elle bénéficie aux membres des recours collectifs et/ou aux membres de la famille, même si l'attribution ne prévoit pas le versement d'une indemnité aux membres des recours collectifs et/ou aux membres de la famille;
(iii) payés, en tout ou en partie, aux gouvernements FPT, à certains ou à un seul d'entre eux, compte tenu de la source des fonds et des autres éléments d'actif que comprend le fonds en fiducie; et/ou
(iv) conservés, en tout ou en partie, dans le fonds en fiducie; de la manière que, dans le cadre du libre exercice de leur pouvoir discrétionnaire, les tribunaux estimeront raisonnable en tenant compte de toutes les circonstances, pourvu que, dans la distribution, aucune discrimination n'ait lieu selon l'endroit où le membre du recours collectif a reçu du sang ou selon l'endroit où il réside;

p. 2) Dans le cadre du libre exercice de leur pouvoir discrétionnaire qui leur est conféré par l'alinéa p. 1) ci-devant, les tribunaux peuvent prendre en considération, mais sans être liés par aucun d'entre eux, notamment les facteurs suivants :

(i) le nombre de membres des recours collectifs et de membres de la famille;
(ii) l'expérience du fonds en fiducie;

(iii) le fait que les indemnités prévues par les régimes peuvent, dans certains cas, ne pas refléter le régime de responsabilité en matière extra-contractuelle;
(iv) l'article 103 6 du Code de procédure civile du Québec;
(v) la question de savoir si l'intégrité de la Convention de règlement sera maintenue et si les versements des indemnités prévues dans les régimes seront assurés;
(vi) la question de savoir si la progression de la maladie est très différente de celle prévue dans le modèle médical utilisé dans le rapport actuariel Eckler;
(vii) le fait que les membres des recours collectifs et les membres de la famille assument le risque d'insuffisance du fonds en fiducie;
(viii) le fait que les contributions des gouvernements FPT sont limitées en vertu de la Convention de règlement;
(ix) la source des fonds et des autres éléments d'actif que comprend le fonds en fiducie;
(x) tout autre fait que les tribunaux estiment important."

2. Les paragraphes 11.02 de la Convention de règlement et 6.03 de l'Accord de financement sont abrogés et remplacés par ce qui suit :

"11.02 (1) Le montant à payer ou payable par les gouvernements FPT en vertu de la Convention de règlement et de l'Accord de financement doit être réduit de 10 533 000 $ en date du 30 septembre 1999; soit la somme de 10 000 000 $ représentant la valeur actualisée estimée du coût excédentaire pour le fonds en fiducie du règlement des actions intentées ou poursuivies par ceux qui s'excluent ou qui sont réputés s'exclure d'un recours collectif et par ceux qui intentent une action récursoire ou en garantie ou qui présentent une réclamation, une demande ou toute autre procédure contre un gouvernement FPT dont l'objet ou la cause est, de quelque manière que ce soit : (i) dans le cas d'un membre d'un recours collectif des transfusés ou d'un membre de la famille aux termes du Régime à l'intention des transfusés infectés par le VHC, l'infection d'une personne directement infectée par le VHC pendant la période visée par les recours collectifs; ou (à) dans le cas d'un membre d'un recours collectif des transfusés ou des hémophiles ou d'un membre de la famille des transfusés ou des hémophiles aux termes du Régime à l'intention des hémophiles infectés par le VHC, l'infection d'un

hémophile ou d'un transfusé directement infecté par le VHC provenant du sang (y compris, dans chaque cas, l'infection d'une personne indirectement infectée) (collectivement appelés les personnes qui s'excluent); et la somme de 533 000 $ représentant la valeur actualisée du tiers des coûts liés à la défense contre les actions poursuivies par les personnes qui s'excluent. Pour plus de certitude, toute personne qui est membre d'un recours collectif ci-avant défini peut participer aux régimes créés par la Convention de règlement.

11.02 (2) Sur remise au fiduciaire d'une copie d'un jugement final (tel que défini au paragraphe 1.07 de la Convention de règlement) obtenu par une personne qui s'exclut contre les gouvernements FPT, certains ou un seul d'entre eux, ou d'une transaction conclue par une personne qui s'exclut et les gouvernements FPT, certains ou un seul d'entre eux, et d'une copie de l'ordonnance finale d'un tribunal homologuant une transaction, les gouvernements FPT ou leurs mandataires doivent recevoir à partir du fond en fiducie :

(i) suivant la date de ce jugement ou de ce règlement, un montant égal au montant que la personne qui s'exclut aurait eu droit de recevoir du fonds en fiducie s'il avait été admissible à un régime; et

(ii) un versement forfaitaire, sur approbation de l'un des tribunaux, en vue de couvrir le montant que la personne qui s'exclut aurait pu être en droit de recevoir de temps à autre du fonds en fiducie s'il avait été admissible à un régime, ce montant devant être calculé conformément à un protocole devant être approuvé par les tribunaux;

pourvu, cependant, que dans aucun cas, le montant devant être versé à partir du fonds en fiducie aux gouvernements FPT, à certains ou à un seul d'entre eux n'excède le montant du jugement ou du règlement versé à la personne qui s'exclut par les gouvernements FPT, certains ou un seul d'entre eux, plus les intérêts courus sur ce montant.

"11.02 (3) Aucun autre montant ne doit être payé à partir du fonds en fiducie pour régler une action poursuivie par une personne qui s'exclut, pour satisfaire à un jugement obtenu sur une action intentée par une personne qui s'exclut ou pour indemniser les gouvernements FPT, certains ou un seul d'entre eux

de tout jugement ou de tout règlement intervenu par suite de toute action intentée ou poursuivie par une personne qui s'exclut."

Le Régime à l'intention des transfusés (Annexe A) est modifié comme suit :

3. Le sous-paragraphe a) de la définition de "Personne directement infectée" au paragraphe 1.01 est modifié comme suit :

- remplacer le ";" par un "." à la fin du sous-paragraphe a);

et

- ajouter la phrase suivante à la fui dudit sous-paragraphe a) :

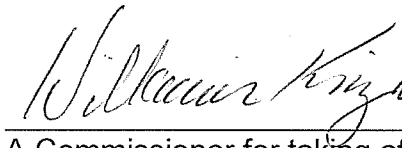
"Une personne atteinte ou ayant été atteinte de thalassémie majeure n'est pas visée par le présent sous paragraphe a);"

4. Par l'ajout d'un paragraphe 4.10 :

"Les personnes directement infectées atteintes de thalassémie majeure ont le droit de présenter les preuves requises à des fins d'indemnisation et de recevoir les indemnités prévues par le Régime à l'intention des hémophiles infectés par le VHC, mutatis mutandis, comme si elles étaient des hémophiles directement infectés, et elles sont réputées être, pour les fins de la Convention et du Régime à l'intention des hémophiles infectés par le VHC, des hémophiles directement infectés, sous réserve que la condition figurant au paragraphe 4.01(5) du Régime à l'intention des hémophiles infectés par le VHC ne s'applique pas, et leur conjoint et leurs enfants qui sont des personnes indirectement infectées au sens du régime à l'intention des transfusés ainsi que les membres de la famille ont également le droit de présenter les preuves requises à des fins d'indemnisation et de recevoir les indemnités prévues par le Régime à l'intention des hémophiles infectés par le VHC, sous réserve que la condition figurant au paragraphe 4.01(5) du Régime à l'intention des hémophiles infectés par le VHC ne s'applique pas."

qp/s/qlmlt

This is Exhibit "B" referred to in the
affidavit of Asvini Krishnamoorthy
sworn before me at Toronto, Ontario
this 29th day of January, 2016



A Commissioner for taking affidavits
within the Province of Ontario

#1638
23

Court file # 98-CV-141369

SUPERIOR COURT OF JUSTICE

BETWEEN:

DIANNA LOUISE PARSONS, MICHAEL HERBERT CRUICKSHANKS, DAVID TULL, MARTIN HENRY GRIFFEN, ANNA KARDISH, ELSIE KOTYK, Executrix of the Estate of Harry Kotyk, deceased and ELSIE KOTYK, personally

Plaintiffs

and

THE CANADIAN RED CROSS SOCIETY, HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO and THE ATTORNEY GENERAL OF CANADA

Defendants

Proceeding under the *Class Proceedings Act, 1992*

Court File No. 98-CV-146405

BETWEEN:

JAMES KREPPNER, BARRY ISAAC, NORMAN LANDRY, as Executor of the Estate of the late SERGE LANDRY, PETER FELSING, DONALD MILLIGAN, ALLAN GRUHLKE, JIM LOVE and PAULINE FOURNIER as Executrix of the Estate of the late PIERRE FOURNIER

Plaintiffs

and

THE CANADIAN RED CROSS SOCIETY, THE ATTORNEY GENERAL OF CANADA and HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO

Defendants

Proceeding under the *Class Proceedings Act, 1992*

PLAINTIFFS' FACTUM IN ACTION 98-CV-141369 FOR AUGUST 18, 1999 MOTION

GIGNAC, SUTTS
Barristers and Solicitors
600 Westcourt Place
251 Goyeau Street
Windsor ON N9A 6V4

HARVEY T. STROSBERG, Q.C.
(519) 258-9333 (telephone)
(519) 258-9527 (fax)

Solicitors for the plaintiffs
in action # 98-CV-141369

TABLE OF CONTENTS

FACTUM

DEFINED TERMS AND ACRONYMS

1. This factum contains the following defined terms and acronyms:

(a) **Agreement** means the 1986-1990 Hepatitis C Settlement Agreement between the Parties made as of June 15, 1999, and tendered to the court on an earlier attendance on June 15, 1999.

(b) **anti-HBc test** means a blood test which detects the antibodies to the Hepatitis B core antigen associated with the viral inner core which reflects active viral replication in the blood.

(c) **Approval Date** means the date when the last judgment or order of the Courts approving the Agreement becomes final, provided there are no material differences in said judgments or orders.

(d) **Canada** means The Attorney General of Canada.

(e) **CRCS** means The Canadian Red Cross Society.

(f) **Class Actions** means collectively the Transfused Class Actions and the Hemophiliac Class Actions.

(g) **Class Action Counsel** means the counsel for the representative plaintiff(s) in each of the respective Class Actions.

(h) **Class Members** means collectively the Transfused Class Members and the Hemophiliac Class Members, and **Family Class Members** means collectively the Transfused Family Class Members and the Hemophiliac Family Class Members.

(i) **Class Period** means the period from January 1, 1986 to July 1, 1990, inclusive.

(j) **Court** means any one of the Superior Court of Justice for Ontario, the Supreme Court of British Columbia and the Superior Court of Quebec, and **Courts** means collectively the Superior Court of Justice for Ontario, the Supreme Court of British Columbia and the Superior Court of Quebec.

(k) **Federal Government** means the Government of Canada.

(l) **FPT Governments** means collectively the Federal Government and the Government of each Province and Territory in Canada.

(m) **Funding Agreement** means the Funding Agreement between the Parties made as of June 15, 1999, and tendered to the court on an earlier attendance on June 15, 1999.

(n) **HBV** means Hepatitis B virus isolated in the late 1960s or 1970.

(o) **HCV** means the Hepatitis C virus isolated in late 1988 or 1989.

(p) **Hemophiliac** means a person who has or had a congenital clotting factor defect or deficiency including a defect or deficiency in Factors V, VII, VIII, IX, XI, XII, XIII or von Willebrand factors.

(q) **Hemophiliac HCV Plan** means the plan which is Schedule B to the Agreement.

(r) **Hemophiliac Class Actions** means collectively the Ontario Hemophiliac Class Action, the **British Columbia Hemophiliac Class Action** which means *Mitchell et al.* v. *Canada et al.*, Action no. A981187 (Vancouver) and the **Quebec Hemophiliac Class Action** which means *Page et al.* v. *Canada et al*, Action no. 500-06-000068-987 (Montreal).

(s) **Hemophiliac Class Members** means collectively the Ontario Hemophiliac Class Members, the Class certified in the British Columbia Hemophiliac Class Action and the Class certified in the Quebec Hemophiliac Class Action, and **Hemophiliac Family Class Members** means collectively the Ontario Hemophiliac Family Class Members, the Family Class certified in the British Columbia Hemophiliac Class Action and the Family Class certified in the Quebec Hemophiliac Class Action.

(t) **NANBHV** means the non-A, non-B hepatitis virus first described in about 1974, a high percentage of which is now known to have been caused by HCV.

(u) **Ontario Class Actions** means collectively the Ontario Transfused Class Action and the Ontario Hemophiliac Class Actions.

(v) **Ontario Class Members** means collectively the Ontario Transfused Class Members and the Ontario Hemophiliac Class Members, and **Ontario Family Class Members** means collectively the Ontario Transfused Family Class Members and the Ontario Hemophiliac Family Class Members.

(w) **Ontario Hemophiliac Class Action** means *Kreppner et al.* v. *Canada et al.*, Action no. 98-CV-146405 (Toronto).

(x) **Ontario Hemophiliac Class Members** and **Ontario Hemophiliac Family Class Members** have the meanings set out in paragraphs 4 and 6 respectively, of the May 11, 1999 order of Mr. Justice Winkler in the Ontario Hemophiliac Class Action.

(y) **Ontario Transfused Class Action** means *Parsons et al.* v. *Canada et al.*, Action no. 98-CV-141369 (Toronto).

(z) **Ontario Transfused Class Members** and **Ontario Transfused Family Class Members** have the meanings set out in paragraphs 4 and 5 respectively, of the May 11, 1999 order of Mr. Justice Winkler in the Ontario Transfused Class Action.

(aa) **Other Courts** means collectively the Supreme Court of British Columbia and the Superior Court of Quebec.

(bb) **Party** means any one of the representative plaintiffs in the Class Actions or of the FPT Governments, and **Parties** means collectively the representative plaintiffs in the Class Actions and the FPT Governments.

(cc) **PT Governments** means collectively the Government of each Province and Territory in Canada.

(dd) **Plan** means either the Hemophiliac HCV Plan or the Transfused HCV Plan, and **Plans** means collectively the Hemophiliac HCV Plan and the Transfused HCV Plan.

(ee) **Program** means the program devolved from the Federal/Provincial/ Territorial Assistance Program for HIV Secondarily-Infected Persons announced by the FPT Governments on December 15, 1998.

(ff) **Releasees** has the meaning set out in Section 1.01 of the Agreement.

(gg) **Spouse** has the meaning set out in Section 1.01 of either Plan.

(hh) **Transfused Class Actions** means collectively the Ontario Transfused Class Action, the **British Columbia Transfused Class Action** which means *Endean et al.* v. *Canada et al.*, Action no. C965349 (Vancouver) and the **Quebec Transfused Class Action** which means *Honhon et al.* v. *Canada et al.*, Action no. 500-06-000016-960 (Montreal).

(ii) **Transfused Class Members** means collectively the Ontario Transfused Class Members, the Class certified in the British Columbia Transfused Class Action and the Class certified in the Quebec Transfused Class Action, and **Transfused Family Class Members** means collectively the Ontario

Transfused Family Class Members, the Family Class certified in the British Columbia Transfused Class Action and the Family Class certified in the Quebec Transfused Class Action.

(jj) **Transfused HCV Plan** means the plan which is Schedule A to the Agreement.

(kk) **Trust** means the trust to be created pursuant to the Funding Agreement.

(ll) **Trust Agreement** means the trust agreement which the court will be asked to order.

(mm) **Trust Fund** means the trust fund to be established pursuant to the Funding Agreement.

INTRODUCTION

2. The Ontario Class Actions claim damages on behalf of the following: persons who contracted HCV by means of a blood transfusion in Canada received during the Class Period; hemophiliacs who received or took blood or blood products in Canada during the Class Period and who are or were infected with HCV; Spouses or children secondarily-infected by such persons; and family members.

Affidavit of R. Douglas Elliott ("Elliott affidavit"), motion record, vol. 2, tab 3, p. 219, para. 4

3. The Ontario Class Actions assert tortious conduct by the CRCS, Federal Government and Ontario, whose operation and oversight of the blood system during the relevant period is alleged to have failed to prevent the infection of the Ontario Class Members.

Elliott affidavit, motion record, vol. 2, tab 3, p. 219, para. 4

4. The FPT Governments and the representative plaintiffs in the Transfused Class Actions and the Hemophiliac Class Actions agreed to settle and entered into the Agreement, subject to the approval, without any material differences, of this court, the Supreme Court of British Columbia and the Superior Court of Quebec.

Elliott affidavit, motion record, vol. 2, tab 3, p. 219, para. 5

5. The Cabinet and Treasury Board of each of the FPT Governments have approved the Agreement.

Elliott affidavit, motion record, vol. 2, tab 3, p. 220, para. 6

6. The Agreement provides that the FPT Governments will pay or have promised to pay approximately $1,207,000,000, inclusive of interest as at September 30, 1999, to the Class Members and Family Class Members in the Class Actions and to a small group of spouses and children secondarily-infected with HIV by their Spouse or parent who was primarily-infected with HIV by the Canadian blood supply. The settlement provision allowing for the income earned by the trust fund to accumulate tax-free adds another $357,000,000 in value to the settlement.

Elliott affidavit, motion record, vol. 2, tab 3, p. 220, para. 8
Eckler Report, motion record, vol. 3, tab 5, p. 564

7. According to the actuarial calculations, the amount in issue in the Ontario Transfused Class Action is $635,500,000.

Eckler Report, exhibit 4 on cross-examination of Levi and Segal

8. The settlement amount of approximately $1,207,000,000 is the largest settlement in a personal injury action in Canadian history.

Elliott affidavit, motion record, vol. 2, tab 3, p. 220, para. 9

THE NATURE OF THIS MOTION

9. By this motion, the representative plaintiffs seek the court's approval to settle the Ontario Class Actions on the terms set out in the Agreement and seeks ancillary orders to begin implementing the settlement. However, the settlement will only be effective if it is also approved by the British Columbia and Quebec courts.

10. The Agreement departs from the common law requirement of a single, once-and-for-all lump sum assessment and instead establishes a system of periodic payments to Class Members and Family Class Members depending on the evolving severity of their medical condition and their needs. In this regard, the words of Dickson J. are apposite:

> *The subject of damages for personal injury is an area of the law which cries out for legislative reform. The expenditure of time and money in the determination of fault and damage is prodigal. The disparity resulting from lack of provision for victims who cannot establish fault must be disturbing. When it is determined that compensation is to be made, it is highly irrational to be tied to a lump sum system and a once-and-for-all award.*
>
> *The lump sum award presents problems of great importance. It is subject to inflation, it is subject to fluctuation on investment, income from it is subject to tax. After judgment new needs of the plaintiff arise and present needs are extinguished; yet, our law of damages knows nothing of periodic payment. The difficulties are greatest where there is a continuing need for intensive and expensive care and long-term loss of earning capacity. It should be possible to devise some system whereby payments would be subject to periodic review and variation in the light of the continuing needs of the injured person and the cost of meeting those needs.*
>
> ***Andrews v. Grand & Toy Alberta Ltd.* [1978] 2 S.C.R. 229 at p. 236**

11. It is submitted that what is fair, reasonable and in the best interests of the Class Members and the Family Class Members should be measured against what is hypothetically achievable in the context of a court's assessment of damages, discounted by the probability of exculpation of Ontario and the Federal Government at the trial of the common issues.

12. Tort law does not provide for recovery of every loss. Fairness does not connote perfect compensation. Reasonableness allows for a range of possible resolutions. The best interests of Class Members must be weighed against the risks and costs of litigation and the result which may be achieved if the common issues were litigated on the merits.

> ***Dabbs* v. *Sun Life Assurance Company of Canada*** **(1999), 40 O.R. (3d) 429 at p. 440 (Gen. Div.)**

13. Some criticism has been directed at the Agreement because the FPT Governments have not arranged for CMHC to offer mortgage insurance to Class Members, or because income tax deductions similar to disability deductions were not offered or because other income tax amendments were not implemented. This type of criticism, however, presupposes a political solution satisfactory to Class Members and others infected with HCV. A political solution is beyond the purview of the court's jurisdiction. The proposed settlement cannot and should not be measured against a "political wish list."

14. Significantly, this settlement gives each Class Member the right to opt out of the settlement and pursue individual litigation.

THESE ACTIONS HAVE BEEN CERTIFIED AS CLASS ACTIONS

15. Mr. Justice Winkler certified the Ontario Transfused Class Action by order dated June 25, 1998. Mr. Justice Winkler then amended this order by order dated May 11, 1999. The certification of the Ontario Transfused Class Action as a class proceeding has not yet been advertised.

Elliott affidavit, motion record, vol. 2, tab 3, p. 228, para. 31; exhibit C, pp. 345-362

16. Mr. Justice Winkler certified the Ontario Hemophiliac Class Action by order dated May 11, 1999. The certification of the Ontario Hemophiliac Class Action as a class proceeding has not yet been advertised.

THE CANADIAN RED CROSS SOCIETY

17. During the Class Period, the CRCS carried on a national system of blood collection in Canada.

Elliott affidavit, motion record, vol. 2, tab 3, p. 230, para. 37

18. The CRCS applied for and received protection from its creditors under the *Companies' Creditors Arrangement Act*, R.S.C. 1985, c. C-36 (the "*CCAA*") by

order of Mr. Justice Blair dated July 20, 1998, whose stay order has subsequently been extended by further orders of the court.

Elliott affidavit, motion record, vol. 2, tab 3, p. 220, para. 35

19. The CRCS has made no contribution to the settlement. This motion for judgment does not affect the CRCS.

Elliott affidavit, motion record, vol. 2, tab 3, p. 220, para. 7

HEPATITIS

20. Hepatitis is an inflammation of the liver that can be caused by various infectious agents, including infections caused by contaminated blood and blood products. The inflammation consists of certain types of cells infiltrating the tissue and producing by-products called cytokines or producing antibodies which damage liver cells and cause them to die. The death process of the cells is called necrosis.

Affidavit of Dr. Frank Anderson ("Anderson affidavit"), motion record, vol. 4, tab 6, p. 896, para. 5
Elliott affidavit, motion record, vol. 2, tab 3, p. 234, para. 51, p. 237, para. 60

HEPATITIS C VIRUS

21. HCV was first described in or about 1974, and was then referred to as NANBH. HCV was identified in late 1988 or 1989.

Anderson affidavit, motion record, vol. 4, p. 896, para. 5

22. HCV is known to possess the following characteristics:

(a) it may be transmitted through the blood supply if there is no, or no effective, donor screening;

(b) it has a 15 to 150-day incubation period;

(c) it has a long latency period during which a person infected may transmit the virus to others through blood and blood products, or sexually, or from mother to fetus; and

(d) it has no known cure.

Elliott affidavit, motion record, vol. 2, tab 3, p. 237, para. 61

SURROGATE TESTING FOR HCV

23. An indicator of liver inflammation is the elevation in the blood of certain enzymes which are released from inflamed cells. One such enzyme is alanine transaminase (ALT). The presence of ALT is not specific for HCV but indicates liver inflammation from any cause. The ALT level found in serum can therefore be used as a marker of liver dysfunction. Thus, ALT testing is a surrogate test for HCV.

Anderson affidavit, motion record, vol. 4, tab 6, p. 897, para. 5

24. During the Class Period, the surrogate tests capable of being used to identify blood donors suspected of being infected with HCV included the following:

(a) a test to measure ALT in a donor's blood because, as explained, an increased level of ALT is indicative of liver inflammation possibly caused by the hepatitis virus; and

(b) an anti-HBc test which detects exposure to HBV and is relevant to the detection of HCV because of the assumption that a person exposed to HBV is more likely than normal to have been exposed to HCV, since both viruses are blood-borne and since the populations with higher rates of seroprevalence were believed to be similar.

Elliott affidavit, motion record, vol. 2, tab 3, p. 238, para. 63

25. The surrogate tests for ALT and anti-HBc identify different subsets of blood donors.

Elliott affidavit, motion record, vol. 2, tab 3, p. 238, para. 64

26. By about August 1, 1986, all or virtually all volunteer blood banks in the United States screened blood donors by using surrogate tests to identify persons with ALT and anti-HBc in their blood.

Elliott affidavit, motion record, vol. 2, tab 3, p. 242, para. 78

THE PROBABILITY OF SUCCESS AT TRIAL

27. In the plaintiffs' theory, the defendants ought to have caused the surrogate tests for ALT and anti-HBc to have been used in the Canadian blood system throughout the Class Period. But the surrogate tests were not used during the Class Period. It was only on or about June 30, 1990 that all blood centres in Canada tested potential blood donors for HCV.

Elliott affidavit, motion record, vol. 2, tab 3, p. 247, para. 95

28. Had surrogate testing been implemented in Canada in the Class Period, the incidence of post-transfusion hepatitis would have been reduced by as much as 75% and the incidence of post-transfusion HCV would have been reduced by as much as 85%.

Elliott affidavit, motion record, vol. 2, tab 3, p. 248, para. 96

THE LIABILITY OF THE CRCS

29. In the plaintiffs' theory, the CRCS owed a duty of care to the Ontario Class Members. The standard of conduct expected was that of the U.S. voluntary blood bankers who in the Class Period had implemented surrogate testing. The failure to implement surrogate testing constituted negligence.

Elliott affidavit, motion record, vol. 2, tab 3, p. 257, para. 128

30. On balance, plaintiffs' counsel believe that the probability of success against the CRCS is very high because the decision-makers within the CRCS were well-informed yet failed to properly inform the Canadian Blood Committee ("CBC") about the situation in the United States, electing instead to await a better test so as to reduce the waste of blood which was in short supply in some locations. Still the CRCS has insufficient assets to pay all the damages which may be assessed against it and it is involved in a *CCAA* proceeding.

Elliott affidavit, motion record, vol. 2, tab 3, p. 265, para. 155

THE LIABILITY OF ONTARIO AND THE FEDERAL GOVERNMENT

31. The FPT Governments established the CBC as an unincorporated association in 1981 and each of them appointed a representative to it.

Elliott affidavit, motion record, vol. 2, tab 3, p. 258, para. 130

32. The CBC had the following mandate:

(a) to serve as the funnel through which the PT Governments funded Canada's blood program;

(b) to ensure that standards for blood, blood products and blood substitutes were developed and that such standards were met;

(c) to supervise and direct the blood program in accordance with policies developed by the FPT Governments; and

(d) to oversee the cost and funding of the blood program in Canada and approved the programs and budgets of the CRCS.

Elliott affidavit, motion record, vol. 2, tab 3, p. 258, para. 131

33. The CRCS had to account in some fashion to the CBC. The CBC had oversight powers and could have directed the CRCS if it had chosen to do so.

Elliott affidavit, motion record, vol. 2, tab 3, p. 259, para. 134

34. In framing the Class Action, the representative plaintiffs claim damages against Ontario and the Federal Government on the following grounds:

(a) the CRCS was their agent;

(b) they are vicariously liable for the acts and omissions of the CRCS; and

(c) they were independently negligent.

Elliott affidavit, motion record, vol. 2, tab 3, p. 257, para. 129

35. Because the CRCS operated and acted independently from the FPT governments, plaintiffs' counsel believe that a court will probably conclude that the CRCS was not the agent of Ontario and the Federal Government and that, therefore, Ontario and the Federal Government are not vicariously liable for the CRCS' acts and omissions.

Elliott affidavit, motion record, vol. 2, tab 3, p. 258, para. 133, 134, 135
***Lewis* v. *British Columbia*, [1997] 3 S.C.R. 1145**

36. In respect of liability, the best argument against Ontario and the Federal Governments is one framed in negligence. A court will probably conclude that Ontario and the Federal Government owed Class Members, who were potential users of the blood system, a duty of care. Under our Constitution, health is a shared responsibility. The CBC's duty was "*[t]o direct the Canadian blood system in accordance with the principles established by the Minister of Health for the therapeutic use of human blood, blood products or their substitutes.*" The PT Governments funded the system and controlled it through the CBC. The Federal Government had regulatory authority, and exercised it partially.

Elliott affidavit, motion record, vol. 2, tab 3, p. 261, para. 141

37. What is the standard of conduct expected in these circumstances? The FPT governments would argue that there was a *bona fide* dispute as to the benefits of surrogate testing and that other countries, France and the United Kingdom, for example,

did not implement surrogate testing in the Class Period. They would also argue that the decision not to implement surrogate testing in the Class Period was a matter of policy.

Elliott affidavit, motion record, vol. 2, tab 3, p. 261, para. 142

38. During the trial of the common issues, the court would decide whether the decision not to implement surrogate testing was a policy or an operational decision.

Elliott affidavit, motion record, vol. 2, tab 3, p. 262, para. 143
***Just* v. *British Columbia*, [1989] 2 S.C.R. 1228**

39. In 1986, the CRCS estimated that the cost of implementing surrogate testing would be $8,971,000 in the first year. If the costs of recruiting, collecting and processing the additional donors required to offset the lost cost of the blood caused by the surrogate testing were also taken into account, the cost estimate would rise to $19,941,000.

Elliott affidavit, motion record, vol. 2, tab 3, exhibit D, p. 365

40. In July, 1989, the CRCS estimated the cost of surrogate testing to be $10,390,800.

Elliott affidavit, motion record, vol. 2, tab 3, exhibit E, p. 368

41. The failure to closely supervise and regulate the CRCS, with its expertise in blood, can arguably be characterized as a policy decision, given the paucity of Government resources and the need to deploy those resources to regulate other aspects of the health care system.

Elliott affidavit, motion record, vol. 2, tab 3, p. 263, para. 147

42. Documents of the Bureau of Biologics ("BoB") suggest that one of the reasons that the BoB rejected the CRCS request to be more heavily regulated was that the BoB was already over-extended, and that the procurement of additional resources in the political climate of the day would have been difficult.

Elliott affidavit, motion record, vol. 2, tab 3, p. 263, para. 149

43. The CBC was comprised of deputy ministers, assistant deputy ministers, and directors. It was charged with budgetary control and most of the appointees had financial administration backgrounds. This fact alone points to a "policy" function. Moreover, the written mandate of the CBC contains references to "policy," "budget," "resources" and "costs." However, references in this written mandate to "setting standards" and "to direct the Canadian Blood system" suggest an operational function.

Elliott affidavit, motion record, vol. 2, tab 3, p. 263, para. 150

44. The use of surrogate tests involves the balancing of social, political and economic factors, all of which are the hallmarks of a policy decision as demonstrated by the following:

(a) the CBC specifically considered cost when making its decision suggesting a policy cost/benefit analysis;

(b) the surrogate tests were not specific and sensitive and there would have been a significant amount of good blood discarded, thus reducing the availability of blood needed for surgery and increasing the costs to the health care system as a result of increased recruitment costs for blood donors;

(c) a positive ALT test would require that the donor be notified, but what physicians were to tell the donor was uncertain because the meaning of a positive ALT test was unclear at the time; and

(d) medical opinion was far from unanimous in favouring the use of surrogate testing; its use varied widely throughout the world and even from region to region in the United States.

Elliott affidavit, motion record, vol. 2, tab 3, p. 264, para. 151

45. Whether a particular factual matrix is either policy or operational is often difficult to decide. The observation is made in Klar, *Tort Law*, (2d) at p. 237 that "close examination of [the cases] reveals the difficulty and unpredictability inherent in the policy/operational dichotomy." In the opinion of plaintiffs' counsel, the probability of success against the Federal Government and Ontario is no more than 65%.

Elliott affidavit, motion record, vol. 2, tab 3, p. 264, para. 156

46. This factum will first provide an overview of the settlement, then an analysis of the settlement explaining why the representative plaintiffs in the Ontario Transfused Class Action and Class Action Counsel believe the settlement is fair, reasonable and in the best interests of the Class Members and the Family Class Members.

OVERVIEW OF THE SETTLEMENT

THE SETTLEMENT TERMS

47. The Agreement and the Funding Agreement executed by the Parties comprise the proposed settlement. This section of the factum is intended to provide only

a précis of the settlement; it does not repeat word-for-word the provisions in the documents or the detailed definitions therein.

48. The Agreement creates the following two Plans:

(a) the Transfused HCV Plan to compensate persons who are or were infected with HCV through a blood transfusion received in Canada in the Class Period, their secondarily-infected Spouses and children and their other family members; and

(b) the Hemophiliac HCV Plan to compensate hemophiliacs who received or took blood or blood products in Canada in the Class Period and who are or were infected with HCV, their secondarily-infected Spouses and children and their family members.

49. To fund the Agreement, the FPT Governments promised to pay the settlement amount of $1,118,000,000 plus interest accruing from April 1, 1998 totalling approximately $1,207,000,000 as at September 30, 1999.

50. The Funding Agreement contemplates the creation of a Trust funded on the following basis:

(a) a payment by the Federal Government to the Trust Fund, on the date when the last judgment or order approving the settlement of the Class Actions becomes final, of 8/11ths of the settlement amount, being the

sum of approximately $877,818,181, subject to adjustments plus interest accruing after September 30, 1999 to the date of payment; and

(b) a promise by each PT Government to pay a portion of its share of the 3/11ths of the unpaid balance of the settlement amount as may be requested from time to time until the outstanding unpaid balance of the settlement amount together with interest accruing has been paid in full.

51. The FPT Governments have agreed that no income taxes will be payable on the income earned by the Trust, thereby adding, in effect, a present value of about $357,000,000 to the settlement amount.

Eckler Report, motion record, vol. 3, tab 5, p. 564

52. The Agreement provides that the following will be paid from the Trust Fund:

(a) persons who qualify in accordance with the provisions of the Transfused HCV Plan;

(b) persons who qualify in accordance with the provisions of the Hemophiliac HCV Plan;

(c) Spouses and children secondarily-infected with HIV to a maximum of 240 who qualify pursuant to the Program established by the FPT Governments (which is not subject to Court approval);

(d) final judgments or Court approved settlements payable by any FPT Government to a Class Member or Family Class Member who opts out of one of the Class Actions or is not bound by the provisions of the

Agreement or a person who claims over or brings a third-party claim in respect of the Class Member's receiving or taking of blood or blood products in Canada in the Class Period and his or her infection with HCV, plus one-third of Court-approved defence costs;

(e) subject to the Courts' approval, the costs of administering the Plans, including the costs of the persons hereafter enumerated to be appointed to perform various functions under the Agreement;

(f) subject to the Courts' approval, the costs of administering the Program, which Program administration costs, in the aggregate, may not exceed $2,000,000; and

(g) subject to Court approval, fees, disbursements, costs, GST and other applicable taxes of Class Action Counsel.

GENERAL ADMINISTRATION

53. The Agreement provides for the appointment of individuals with particular expertise to perform specific functions under the Agreement, Funding Agreement and Plans, as follows:

(a) a professional Trustee will hold the Trust Fund, invest the monies as directed, provide funds to the Administrator and others as required, record transactions and report;

(b) a professional Administrator will administer the Plans, assist in the making of claims, receive and evaluate claims, requisition, receive and

forward to claimants payments out of the Trust Fund, record transactions and report;

(c) the Joint Committee of plaintiffs' Class Action Counsel will generally oversee administration of the Agreement, Funding Agreement and Plans, retain actuaries to assess the financial sufficiency of the Trust Fund, receive advice from the Investment Advisors and apply to the Courts as required;

(d) Fund Counsel will defend and advance the interests of the Trust and the decisions of the Administrators in the appeal process and apply to the Courts as required;

(e) Auditors will audit the accounts of the Administrator and Trustee and report; and

(f) Investment Advisors will develop an investment strategy for the Trust Fund in accordance with the investment guidelines approved by the Courts.

THE COURTS WILL ENSURE THAT THE TRUST FUNDWILL BE ALLOCATED FAIRLY

54. To ensure the fair allocation of the Trust Fund, the following safeguards and limitations have been built into the Plans:

(a) the actuarial soundness of the Plans will be monitored by the Court and will be reviewed automatically every three years. In addition, a review can be triggered at any time, by the Court, the Joint Committee or Class Action Counsel;

(b) the Administrator will hold back or limit a part of some of the compensation payments under the Plans as hereafter detailed until the Courts are satisfied that the Trust Fund can meet its obligations. At that point, the monies initially held back or the amount to which the person would have been entitled but for the limit imposed (the "holdbacks") plus interest at the prime rate will be released to the claimants; and

(c) the Courts will retain the power to adjust the Plans to ensure that each Class Member and each Family Class Member receives a fair share of the Trust Fund within the parameters of the Plans.

THE PLANS

QUALIFICATION FOR PAYMENT UNDER THE PLANS

55. The Plans recognize the difficulty of satisfying the burden of proof of causation.

56. Under the Transfused HCV Plan, a person claiming to be a primarily-infected person must:

(a) establish that he or she was transfused with blood in Canada during the Class Period and is HCV positive; and

(b) swear that he or she never used non-prescription, intravenous drugs and that, to the best of his or her knowledge, was not infected with HCV before the Class Period began.

57. Once the evidentiary burden particularized in the preceding paragraph is satisfied, the Administrator can request a consent to a traceback procedure to prove that the person claiming was not infected with HCV by a blood transfusion in Canada during the Class Period.

58. Under the Hemophiliac HCV Plan, a person claiming to be a primarily-infected hemophiliac must:

(a) establish that he or she is a hemophiliac who received or took blood or blood products in Canada during the Class Period and is HCV positive; and

(b) swear that he or she never used non-prescription, intravenous drugs.

59. The Spouse, Child, Grandchild, Parent, Grandparent or Sibling (all as defined in the Plans) of a deceased HCV infected person, who had qualified under a Plan before his or her death or is qualified by his or her representative following his or her death, will be entitled to compensation in accordance with the provisions of the Plans upon delivery of satisfactory proof of their relationship to the deceased.

60. The family members enumerated in the preceding paragraph as well as the former Spouse of a deceased HCV infected person who qualify as outlined therein, to whom the HCV infected person was providing support or was under a legal obligation to provide support on the date of his or her death (the "approved dependants") will be entitled to compensation in accordance with the provisions of the Plans.

TIME LIMITS

61. Except as expressly provided in the following two paragraphs, no one may make a first claim under the Plans after June 30, 2010 unless:

(a) the claim is made within one year of the claimant reaching his or her age of majority; or

(b) the claim is made within three years of the claimant first learning of his or her infection with HCV and the Court grants leave to apply for compensation.

62. A secondarily-infected Spouse must claim within the following time limits:

(a) three years of the date of first claim of his or her primarily-infected Spouse or the date his or her Spouse opts out;

(b) in accordance with the provisions set out in paragraph 63 where the primarily-infected person is deceased; or

(c) in accordance with the provisions set out in paragraph 61 where the primarily-infected person has not made a claim.

63. Death-related claims must be brought under the Plans within the following time limits:

(a) the representative of the estate of a deceased HCV infected person must apply within the later of two years from the Approval Date or three years from the date of death of the Class Member; and

(b) each dependant and family member of a deceased HCV infected person must apply within the later of two years from the Approval Date or from the date of death of the Class Member or within one year of the claimant reaching his or her age of majority.

COMPENSATION WHERE THE HCV INFECTED PERSON IS ALIVE

64. The medical conditions of persons who qualify as HCV infected persons are, of course, far from uniform. Some are now free of the disease, others are more grievously ill. Compensation levels are generally intended to reflect the severity of the medical conditions. However, all Class Members who qualify as HCV infected persons, however, are entitled to a fixed payment as compensation for pain and suffering and loss of amenities of life based upon the stage of his or her medical condition at the time of qualification under the Plan and to additional compensation subsequently if and when his or her medical condition deteriorates to a medical condition described at a higher compensation level. This compensation could be a single payment of $10,000, for a person who has cleared the disease, or it could be one or more payments totaling $225,000 for a person who has decompensation of the liver or a similar medical condition.

65. If Class Members undergo compensable HCV drug therapy such as interferon or ribavirin alone or in combination, they will be entitled to a payment of $1,000 for each month of completed therapy. In this event, compensation could amount to as much as an additional $24,000 but, on average, is more likely to be about $9,000. But the Plan does not impose a limit on the amount to be paid to a person for compensable HCV drug therapy.

66. Class Members whose medical condition deteriorates and whose conditions are described at compensation level 3 (subject to the election and the disability threshold described below), or a higher compensation level (4 or above) and whose HCV caused loss of income or inability to perform his or her household duties will be entitled to compensation for loss of income or loss of services in the home.

67. Class Members whose medical conditions deteriorate even further and whose conditions are as described at compensation level 6 will be entitled to costs of care, such as home nursing services.

68. The Class Member is also entitled to reimbursement for all uninsured generally accepted treatment costs, medication costs and out-of-pocket expenses such as travel, hotels or meals attributable to his or her infection with HCV.

69. The chart annexed as Appendix A to this factum describes the medical conditions caused by HCV that trigger the various compensation levels and sets out the entitlements generally available at each level.

70. Reference was earlier made to holdbacks. One of these holdbacks is applied at compensation payment level 2. A claimant who is entitled to $20,000 compensation payment at level 2 will initially be paid $15,000 while $5,000 will be held back in the Trust Fund. If satisfied that there is sufficient money in the Trust Fund, the Courts may then declare that the holdback is removed in accordance with Section 10.01(1)(i) of the Agreement and Section 7.03 of the Plans. Claimants with monies held back will then receive the holdback amount with interest at the prime rate from the date they first became entitled to the payment at level 2.

71. Notwithstanding any of the provisions of the Hemophiliac HCV Plan, a primarily-infected hemophiliac who is also infected with HIV may elect to be paid $50,000 in full satisfaction of all of his or her claims and those of his or her family members and dependants.

72. Persons infected with HCV and secondarily-infected with HIV who qualify under a Plan (or, where the person is deceased, the estate and his or her approved family members and dependants) may not receive compensation under the Plan until entitlement exceeds the $240,000 entitlement under the Program after which they will be entitled to receive any compensation payable under the Plan in excess of $240,000.

CALCULATION OF LOSS OF INCOME OR LOSS OF SERVICES IN THE HOME

73. Under the Plans, generally, only those Class Members who have bridging fibrosis or a more serious condition (level 4 or higher) are entitled to claim their loss of income or their loss of services in the home. Persons who have developed pre-bridging fibrosis or who have been advised to undergo HCV drug therapy may elect to waive the $30,000 fixed compensation payment at level 3 and claim their loss of income or their loss of services in the home if they are regularly unable to work at the substantial duties of their usual employment or the substantial household duties they would normally provide such that they work no more than 20% of their usual work week or perform no more than 20% of the household services they normally provide.

74. Payment of loss of income is made on a net basis after deductions for income tax that would have been payable on earned income and after deduction of all collateral benefits received by the Class Member. Loss of income payments cease upon a Class Member reaching age 65. A claim for the loss of services in the home may be made for the lifetime of the Class Member.

75. Initially, the holdbacks or limits imposed on a Class Member who makes a claim for loss of income under either Plan are as follows:

(a) where pre-claim earned income exceeds $75,000, it is deemed to be the cap or the starting point from which income loss is calculated; and

(b) only 70% of the annual loss of net income is paid.

76. If the Courts perform a sufficiency review of the Trust Fund and vary or remove the holdbacks or limits on payments in accordance with the provisions of the Agreement and Plans, claimants will receive the holdback, or such portion as the Courts direct, with interest from the time their wage loss was calculated with the limit imposed.

77. Examples of the loss of income calculation under Section 4.02 of the Plans are found at *Appendix B*. The example at each income level is calculated showing the effect on income loss for a person who is 100% disabled and a person who is 50% disabled. Each example also shows the initial limit of payment to 70% of the calculated loss of income. The highest income level example shows the effect of capping the earned income at $75,000 on the calculation of income loss.

78. If a HCV infected person who normally performed household services in his or her home reaches the compensation level 4 or higher or reaches the medical condition and meets the disability threshold at compensation level 3 and makes the election, and is not receiving loss of income payments, he or she is entitled to receive compensation for loss of services in the home at the rate of $12 per hour to a maximum of 20 hours per week if his or her infection with HCV causes an inability to perform those services.

THE COMPENSATION PAYABLE UNDER THE PLANS WHERE THE HCV INFECTED PERSON DIED BEFORE JANUARY 1, 1999

79. If a Class Member who died before January 1, 1999, would have qualified as a HCV infected person but for the death, and if his or her death was caused by HCV, compensation will be paid on the following terms:

(a) the estate will be entitled to receive reimbursement for uninsured funeral expenses to a maximum of $5,000 and a fixed payment of $50,000, while approved family members will be entitled to compensation for loss of the deceased's guidance, care and companionship on the scale set out in the chart at paragraph 82 below and approved dependants may be entitled to compensation for their loss of support from the deceased or for the loss of the deceased's services in the home ("Option 1"); or

(b) at the joint election of the estate and the approved family members and dependants of the deceased, the estate will be entitled to reimbursement for uninsured funeral expenses to a maximum of $5,000, and the estate and the approved family members and dependants will be jointly entitled to compensation of $120,000 in full settlement of all of their claims ("Option 2").

80. Under the Hemophiliac HCV Plan, an alternate election is available to the estate, family members and dependants of a deceased primarily-infected hemophiliac who was also infected with HIV which is to be paid $72,000 in full satisfaction of their claims.

THE COMPENSATION PAYABLE UNDER THE PLANS WHERE THE HCV INFECTED PERSON DIES ON OR AFTER JANUARY 1, 1999

81. If a Class Member who dies on or after January 1, 1999, had qualified or would have qualified as a HCV infected person but for the death, the estate is entitled to all compensation he or she could have claimed at the disease-based compensation levels up to the time of death which had not already paid to the Class Member (see the chart at Appendix A). Additionally, if the death of the HCV infected person on or after January 1, 1999 was caused by HCV, the estate will be entitled to receive reimbursement for uninsured funeral expenses up to a maximum of $5,000, approved family members of the deceased will be entitled to compensation for loss of guidance, care and companionship of the deceased on the scale set out in the chart at paragraph 82 below and approved dependants of the deceased may be entitled to compensation for their loss of support from the deceased or for loss of the deceased's services in the home.

THE COMPENSATION PAYABLE TO FAMILY MEMBERS FOR LOSS OF GUIDANCE, CARE AND COMPANIONSHIP

82. Each approved family member of a qualified HCV infected person whose death was caused by HCV is entitled to be paid the amount set out below for loss of the deceased's guidance, care and companionship:

Familial Relationship to Deceased	Compensation Payable
Spouse	$25,000
Child under the age of 21 years at the time of death of family member	$15,000
Child 21 years of age or older at the time of death of family member	$5,000
Parent or Sibling	$5,000
Grandparent or Grandchild	$500

CALCULATION OF DEPENDANTS' LOSS OF SUPPORT OR LOSS OF SERVICES IN THE HOME

83. Under the Plans when a deceased HCV infected person's death is caused by HCV, the approved dependants may be entitled to claim for loss of support until such time as the deceased would have reached age 65 but for his death.

84. Payments for loss of support are made on a net basis after deduction of 30% for the personal living expenses of the deceased and after deduction of any pension benefits from CPP received by the dependants.

85. The same or similar holdbacks or limits will initially be imposed on the claim by dependants for loss of support under the Plans as are imposed on a loss of income claim. The $75,000 cap on pre-claim gross income will be applied in the calculation of support and only 70% of the annual loss of support will be paid. If the Courts determine that the Trust Fund is sufficient and vary or remove the holdbacks or limits, the dependants will receive the holdbacks, or the portion the Courts direct, with interest from the time when loss of support was calculated subject to the limit.

86. Failing agreement among the approved dependants on the allocation of loss of support between them, the Administrator will allocate loss of support based on the extent of support received by each of the dependants prior to the death of the HCV infected person.

87. Examples of loss of support calculations under Section 6.01 of the Plans are found at Appendix C. The example at each income level is calculated showing the effect on loss of support of whether the dependants receive a CPP retirement pension in respect of the deceased or not. Each example also shows the 30% deduction for the personal living expenses of the deceased and the imposition of the holdback of 30% on the loss of support calculation. The highest income level example shows the effect of initially capping the earned income, which is the basis for the calculation of loss of support, at $75,000.

88. If a loss of support claim is not payable in respect of the death of a HCV infected person whose death was caused by his or her infection with HCV, but the approved dependants resided with that person at the time of the death, then these dependants are entitled to be compensated for the loss of any services that the HCV infected person provided in the home at the rate of $12 per hour to a maximum of 20 hours per week.

COMPENSATION SUMMARY FOR DEATH CLAIMS

89. Apart from the alternate election under the Hemophiliac HCV Plan outlined in paragraph 80 above, the chart below summarizes the compensation that may be payable under the Plans to the estate, the approved family members and approved dependants of a person who would have qualified as a HCV infected person but for his or her death if the death was caused by his or her infection with HCV. One exception is set out in the footnote to the chart.

Compensation Payable if HCV caused the HCV Infected Person's Death	HCV infected person died before January 1, 1999		HCV infected person dies on or after January 1, 1999
	Option 1 or Option 2		
Up to $5,000 for uninsured funeral expenses is payable to the estate.	yes	yes	yes
Compensation of $50,000 may be payable to the estate.	yes	no	no
Compensation of $120,000 may be payable jointly to the estate, qualified family members and qualified dependants.	no	yes	no
Compensation may be payable to each qualified family member (see chart above) for loss of guidance, care and companionship of the deceased.	yes	no	yes
Compensation may be payable for the qualified dependants' loss of support from the deceased or loss of deceased's services in the home.	yes	no	yes
All Compensation the deceased was or would have been entitled to which had not been paid, up to the date of death, is payable to the estate.	no	no	yes*

* The HCV infected person's death does not have to have been caused by his or her infection with HCV for this compensation to be payable.

ADDITIONAL PROVISIONS CONCERNING COMPENSATION AVAILABLE UNDER THE AGREEMENT AND/OR THE PLANS

90. The Agreement and/or the Plans further provide, generally, that:

(a) all compensation payments to claimants who live in Canada will be tax free;

(b) compensation payments will be indexed annually to protect against inflation;

(c) compensation payments other than payments for loss of income will not affect social benefits currently being received by claimants;

(d) life insurance payments received by or on behalf of claimants will not be taken into account for any purposes whatsoever under the Plans; and

(e) no subrogation payments will be paid directly or indirectly.

CLAIMS APPEAL PROCESS

91. Claimants will have the right to appeal the Administrator's decision concerning their claims to either a Court-appointed Arbitrator or a Referee, as they elect. The Arbitrator's decision will be final and binding. The Referee's decision, however, may be appealed to the Court if the amount in dispute exceeds $10,000. The chart annexed as Appendix D outlines the appeal process.

RELEASES AND RELATED MATTERS

92. Each Class Member who does not opt out and each Family Member who does not opt out or is not deemed to opt out will be deemed to have released and discharged the Releasees from any and all actions whatsoever of every nature or kind

which he or she ever had, now has or may hereafter have in any way relating to or arising from:

(a) in the case of the Ontario Transfused Class Member, his or her infection with HCV through a blood transfusion received in Canada in the period January 1, 1986 to July 1, 1990;

(b) in the case of the Ontario Hemophiliac Class Member infected with HCV, his or her receipt or taking of blood products in Canada in the period January 1, 1986 to July 1, 1990;

(c) in the case of a secondarily-infected Spouse or child, his or her infection with HCV by his or her Souse or parent; or

(d) in the case the claims of other family members and/or dependants, the infection with HCV of their family member by one of the foregoing means.

93. Each Class Member who does not opt out and each Family Member who does not opt out or is not deemed to opt out must before receiving any payments under a Plan deliver a release substantially in the form attached as an appendix to the Plan and consent to a dismissal of any action or other proceeding in any way relating to the infection of a primarily-infected person with HCV during the Class Period including the infection of a secondarily-infected person commenced against any Releasee.

THE ONTARIO CLASS ACTIONS INCLUDE NON-RESIDENTS

94. The Ontario Class Actions include all Class Members and Family Class Members in Ontario and elsewhere other than those included in the Quebec and British Columbia Class Actions. The Ontario court has jurisdiction to make this order.

Carom v. *Bre-X Minerals Ltd.* (1999), 43 O.R. (3d) 441 (Gen. Div.)

THE SETTLEMENT IS FAIR AND REASONABLE AND IN THE BEST INTERESTS OF THE CLASS MEMBERS

95. For all the reasons set out below, the representative plaintiffs in the Ontario Transfused Class Action and plaintiffs' Counsel Group believe that this settlement is fair and reasonable and in the best interests of the Class Members and the Family Class Members.

THE PLANS ARE ADEQUATELY FUNDED

96. To assess whether or not the Plans are adequately funded, an important question has to be addressed: How many persons were infected with HCV by blood transfusions in Canada in the Class Period? Class Action Counsel and the FPT Governments sought to provide the answer by commissioning a study from the Canadian Association of the Study of the Liver Working Group on Hepatitis C Prognosis ("CASL Report"). Dr. Murray Krahn chaired the study group and Dr. Heathcote, Dr. Scully, Dr. Seaff and Dr. Wong were members of the working group. The group "was asked to

construct a natural history model of HCV. The intent ... was to generate a model that would be used ... as a guide to disbursing funds" to Class Members. Reports were also obtained from Dr. Remis. All these physicians have generated the best possible evidence of the number of persons infected with HCV by transfusions during the Class Period and this evidence is before the Court.

CASL Report, motion record, vol. 3, tab 5, p. 663

97. Actuaries Jack Levi and Murray Segal of Eckler Partners Ltd. ("Eckler") were also retained to provide further assistance to the Courts. They and other actuaries at Eckler spent well over 700 hours consulting on aspects of the settlement terms and preparing the actuarial report which begins at motion record volume 3, page 510, a report based, in large measure, on the CASL Report and statistics generated by that working group.

Transcript of cross-examination of Levi and Segal, pp. 119-121

98. When analyzing and estimating the amount of Trust Fund assets and the amount of Trust Fund liabilities, the actuaries assumed the largest number of transfused persons and hemophiliacs and a 100% take-up rate. Based on these assumptions, the actuaries have concluded that:

(a) before payment of holdbacks, the Trust Fund would have a surplus of $34,173,000; and that

(b) after payment of holdbacks of $92,706,000, the Trust Fund would have a $53,300,000 deficit.

99. Class Action Counsel designed the Plans intending that the estimated amount of Trust Fund liabilities would exceed Trust Fund assets assuming a 100% takeup rate, because counsel believe that the takeup rate would not be 100%. To design the Plans otherwise would be to pay less to Class Members and Family Class Members.

Transcript of cross-examination of Levi and Segal, pp. 60-61

THE NUMBER OF CLASS MEMBERS

100. The number of hemophiliac Class Members is approximately 1,628. For the most part, the hemophiliacs infected with HCV have been identified.

Dr. Walker, motion record, vol. 5, tab 13, p. 1250, para. 21

101. The number of persons infected with HCV by a transfusion of blood in the Class Period is termed the "transfused cohort size." The evidence of transfused cohort size depends upon the initial modeling done by Dr. Remis and the CASL study.

102. Dr. Remis estimated that, excluding hemophiliacs, 15,707 persons were infected with HCV by transfusions in the Class Period. But, because of deaths not caused by HCV, CASL reduced the projected transfused cohort size to about 8,104 as at January 1, 1999. CASL's statistics were relied upon by Eckler to project 76 HCV-related deaths prior to January 1, 1999. Thus, according to CASL, as explained by Eckler, the transfused cohort size is 8,180 (8104 + 76). Levi and Segal considered that

assumptions in the CASL Report about mortality were reasonable because of the age of the population.

CASL Report, motion record, vol. 3, tab 5, p. 696
Eckler Report, motion record, vol. 3, tab 5, pp. 517-518
Transcript of cross-examination of Levi and Segal, pp. 46-50

103. As stated above, Dr. Remis estimated that 15,707 persons were infected with HCV by transfusions in the Class Period. But in comparison to the CASL Report, Dr. Remis projected more deaths not attributable to HCV in the period before January 1, 1999. Dr. Remis projected the number of survivors in mid-1998 to be 6,600. If his calculation is adjusted for deaths from mid-1998 to January 1, 1999, Dr. Remis' estimate of the transfused cohort size is 6,459 as of January 1, 1999.

Remis Report, motion record, vol. 3, tab 5, p. 657
Eckler Report, motion record, vol. 3, tab 5, p. 557
Transcript of cross-examination of Levi and Segal, p. 50

104. The Eckler Report calculated Trust Fund liabilities using the highest number of Class Members and therefore generated the most conservative estimate. Had the Remis model been used, Eckler estimated that the Trust Fund liabilities would have been $130,000,000 less.

105. In other words, if Eckler had employed Remis' estimates Eckler would have concluded, assuming a 100% take-up rate, that:

(a) before payment of holdbacks, the Trust Fund would have a surplus of $164,173,000; and that

(b) after payment of holdbacks of $92,706,000, the Trust Fund would have a $76,700,000 surplus.

Eckler Report, motion record, vol. 3, tab 5, p. 562

IF THE TAKEUP RATE IS 94% OR LESS, THERE WILL BE A SURPLUS IN THE TRUST FUND

106. Eckler estimated that as of September 30, 1999 the Trust Fund assets and Trust Fund liabilities would be as follows:

Trust Fund assets	1,207,385,000
Trust Fund liabilities: before payment of holdbacks	1,173,212,000
Surplus: before payment of holdbacks	34,173,000
Holdbacks	92,706,000
Deficit assuming 100% takeup	53,300,000

Eckler Report, motion record, vol. 3, tab 5, pp. 551-552

107. Again, Eckler's calculations of Trust Fund liabilities and holdbacks assume that every Class Members will claim under the Plans.

108. But if only 6% of the Class Members do not claim, the Trust Fund liabilities will be reduced by $54,000,000 because, according to Eckler, Trust Fund liabilities are reduced by $10,800,000 for each 100 persons who do not claim. The arithmetic underlying this calculation is as follows:

500 class members ÷ 8180 class members = 6%

500 class members x $10,800,000/100 class members = $54,000,000

Eckler Report, motion record, vol. 3, tab 5, p. 554

109. In *Telectronics*, the name of every class member implanted with a medical device was known, a circumstance equivalent or at least analogous to knowing the identities of all the Class Members infected with HCV. Yet, in *Telectronics* only 72% of the 1,101 Class Members took up the offer of compensation.

Woltz affidavit, motion record, vol. 2, tab 4, p. 394, para. 14

110. The Final Report of the Blood Recipient Notification Project for Hepatitis C for British Columbia discloses that letters were delivered to 51,623 persons urging them to be tested for HCV. But only 38,989 (75.5%) came forward and were tested.

Report, motion record, vol. 3, tab 5, p. 777

111. It is submitted that the takeup statistic for the 1,101 individuals who made up the cohort in *Telectronics* is salient and predictive. In *Telectronics*, each member of the cohort was individually identified. A notice program and a telephone program were implemented. Despite all this, and despite the fact that most of the 1,101 individuals were notified about the class action and the settlement, only 72% of those implanted with a lead claimed under the settlement.

112. If Eckler's estimate of Trust Fund liabilities is reduced by 28%, based upon a takeup rate of 72%, the Trust Fund will have a surplus of $295,924,000, calculated as follows:

Trust Fund assets	1,207,385,000
Trust Fund liabilities (before holdbacks) is $1,173,212,000 reduced to 72%	844,712,640
Surplus before holdbacks	362,672,360
Holdbacks of 92,706,000 reduced to 72%	66,748,320
Surplus assuming 72% takeup	295,924,040

113. Actuarial evidence as applied to an individual plaintiff has been recognized as a useful tool and the best available means but, nonetheless, "illusionary." Yet, actuarial evidence "in terms of group experience" as prepared by Eckler for use in this motion is powerfully persuasive evidence.

Andrews v. *Grand & Toy Alberta Ltd., supra*, at p. 236

114. The court should conclude, therefore, that the takeup rate in the Class Actions will not exceed 94%; that Eckler's estimates of Trust Fund liabilities should be reduced; and that the Plans are adequately funded.

115. Some complain that the Class Members should not bear the risk of fund insufficiency. But this criticism ignores the reality that the defendants would not settle the Class Actions on the basis of liability for an unlimited amount. The defendants will only pay an unlimited amount if the representative plaintiffs are successful at the trial of the common issues. Even then, the defendants' liability for an unlimited amount would then arise within the context of a once-and-for-all, one-time only assessment of damages for each Class Member. Alternatively, if the defendants must guarantee the sufficiency of the Trust Fund they would then certainly insist on reducing payments.

THERE ARE RISKS ASSOCIATED WITH A TRIAL

116. As previously stated, success against Ontario and the Federal Government is by no means guaranteed. Counsel estimate that the probability of success on the common issues is about 65%. It is submitted that a substantial discount is warranted because of the 35% risk that the Federal Government and Ontario will mount a successful defence and that no money will be available after the trial of the common issues.

Elliott affidavit, motion record, vol. 2, tab 3, p. 52, para. 156

ALL PT GOVERNMENTS CANNOT BE SUED IN ONTARIO

117. There are serious procedural difficulties associated with suing, in Ontario, the PT Governments other than Ontario. As only the Federal government and Ontario are defendants, there is a risk that the Court will make a finding of several liability which would result in less than 100% recovery even if liability is established against Ontario and the Federal government. This is exacerbated by the fact that the CRCS is in CCAA.

Elliott affidavit, motion record, vol. 2, tab 3, p.267, para. 162

SETTLEMENT NOW ELIMINATES FURTHER DELAY

118. The cause of action for each Class Member arose at least nine years ago. If there is no settlement, a further delay of approximately five years will be inevitable.

In the interim, many Class Members will die and over time proof of damages and causation will only become more difficult. It is submitted that the certainty of a settlement now rather than protracted litigation is in the best interests of the Class Members and the Family Class Members.

Elliott affidavit, motion record, vol. 2, tab 3, p. 268, para. 166, 167

SETTLEMENT DOES NOT GIVE EFFECT TO AVAILABLE DEFENCES

119. The settlement does not give any effect to the possible defence of contributory negligence. Because consumption of alcoholic beverages, for example, exacerbates HCV, this defence would undoubtedly be pleaded and established against some Class Members who would then be found contributorily negligent because they had consumed alcoholic beverages with knowledge of their infection.

Elliott affidavit, motion record, vol. 2, tab 3, p. 270, para. 173

120. The settlement also gives no effect to a limitation period defence, an issue which would otherwise be problematic for some Class Members. About 42 Class Members died two years or more before this action commenced and their actions are statute-barred. The defendants will also plead that the limitation period of six (6) years runs from the date of infection. This defence must be taken seriously. All these issues are ignored under the settlement.

Eckler's Report, exhibit 4, on cross-examination of Levi and Segal, p.3
***Trustee Act*, R.S.O. 1990, c. T. 23, s. 38**
***Family Law Act*, R.S.O. 1990, c. F. 3, s. 61(4)**

THE AWARDS FOR NON-PECUNIARY GENERAL DAMAGES APPROXIMATE, IF NOT EXCEED, AMOUNTS WHICH WOULD BE AWARDED AT AN ASSESSMENT

121. The maximum award for non-pecuniary general damages as at January 1, 1999 is $260,500.

Eckler's Report, exhibit 4, on cross-examination of Levi and Segal, p.3

122. Under the Plan, the maximum award for non-pecuniary general damages will range from $225,000 to $249,000, or more, depending upon the number of compensable HCV drug therapy treatments, such as interferon/ribavirin treatments, a Class Member has undergone.

123. It is submitted that the amount paid for non-pecuniary general damages at each level under the Plans approximates, even exceeds, the amount that would be assessed at a trial.

124. Some criticize the Plan on the basis that the damages paid to persons at level 1 and level 2 are insufficient to compensate those suffering from fatigue. According to the uncontradicted evidence of Dr. Anderson:

(a) fatigue is the most common, the most subjective and the most difficult symptom to assess;

(b) many persons infected with HCV through a transfusion had a serious illness that necessitated the transfusion, and it is difficult to determine

whether symptoms of fatigue are attributable to the underlying illness or the infection with HCV; and

(c) the most common opinion is that the incidence of severe fatigue in the population of persons infected with HCV is approximately 10%, while 5% to 10% of the general population also suffer from severe fatigue.

Anderson affidavit, motion record, vol. 4, tab 6, pp. 911-2

125. The inevitable result of the settlement process was that some compromises had to be made. If separate compensation was to be payable for fatigue, administrative costs would have been increased because, given the subjective nature of the complaint and the issue of causation, an assessment by reference would have been required for each claim. More importantly, if separate compensation was awarded for fatigue, the fixed amount payable at higher compensation levels for more serious medical conditions would necessarily have been adjusted downward. Bearing in mind these factors as well as Dr. Anderson's observation that the incidence of fatigue in the general population approximates the incidence of fatigue in the population of persons infected with HCV, bearing in mind, too, that the settlement reflects a compromise, no separate compensable category for fatigue is provided within it.

THE CLASS MEMBERS' DAMAGES WILL BE ASSESSED INDIVIDUALLY AND ONLY ONCE IF THERE IS A TRIAL

126. If this action proceeded to trial and if the representative plaintiffs were successful at the trial of the common issues, the damages of each Class Member would

then be quantified and fixed forever during a once-and-for-all lump sum assessment. Each assessment, of course, would take into consideration the various risks associated with the medical modeling underlying the Plans and reflected in the Eckler actuarial report, but the variations would be exacerbated because the actuarial and medical evidence would necessarily be applied to the individual Class Member.

***Andrews* v. *Grand & Toy Alberta Ltd., supra,* at p. 236**

127. But a special benefit of the Plans is that a Class Member may reapply, time and again, for additional compensation if and when his or her condition attributable to HCV worsens. This essential feature of the Plans, their flexibility, effectively eliminates the undesirable but inevitable prospect that at trial the once-and-for-all lump sum assessment will either over-compensate or under-compensate because it is based on only those probabilities disclosed by the evidence at the trial. By contrast, the Plans allow for periodic reassessment, a substantial benefit to all Class Members, but especially so for minors who, on a statistical basis, are more likely at this time to be in the early stages of the disease. This settlement model embodies and reflects the following dictum of Dickson, J. in *Andrews*:

> *It should be possible to devise [a] system whereby payments would be subject to periodic review and variation in the light of the continuing needs of the injured person and the costs of meeting those needs."*
>
> ***Andrews* v. *Grand & Toy Alberta Ltd., supra,* at p. 236**
> **Waddams, The Law of Damages, Looseleaf edition, pp. 3-1-10**

LOSS OF INCOME

128. In a traditional assessment and calculation of damages in a personal injury action in Canada, income tax that would have been payable by the plaintiff on future earnings is not to be deducted. By contrast, in the United Kingdom and Australia, for example, income tax is deducted in assessments of damages. The argument for making the deduction is that the plaintiff could not have been said to have lost more then his net after tax income.

> ***Queen in Right of Ontario* v. *Jennings*, [1966] S.C.R. 532**
> ***Cunningham* v. *Wheeler*, [1994] 1 S.C.R. 359 at p. 417-18**
> ***British Transport Commission* v. *Gourley*, [1956] A.C. 185 (H.L.)**
> ***Cullen & Trappell* (1980), 54 A.L.J.R. 295**
> **Waddams, The Law of Damages, Looseleaf edition, pp. 3-48-50**

129. Under the Plans, the starting point for the calculation of loss of income is earned gross income which is capped at $75,000. Then deductions are made for the notional income tax that would be payable, notional CPP and UIC contributions and collateral benefits actually received.

130. Loss of income is payable only if a Class Member has developed bridging fibrosis or has developed non-bridging fibrosis in the portal areas of the liver with fibrosis bands extending out from the portal area and the Class Member elects to waive the $30,000 payment at level 3. In effect, this means that some claims for loss of income relating to fatigue may not be recoverable.

131. Only 3.9% of persons employed full year, full time earn annually $75,000 per year or more. It is submitted that this cap (which may be removed if the fund is sufficient) does not have widespread effect.

Elliott affidavit, motion record, vol. 2, tab 3, p. 272, para. 180

132. As noted above, under the Plans collateral benefits are also deducted in calculating loss of income. Although the court in a damage assessment will not usually deduct collateral benefits such as long term and short term disability benefits, the insurer paying the disability benefits is subrogated to the rights of the insured. Deduction of collateral insurance benefits actually received in calculation of income loss does not affect Class Members because if a Class Member received reimbursement for loss of income without deduction for collateral benefits, he or she would hold the amount representing the collateral benefits in trust for the insurer who is subrogated to the Class Members' rights. In short, the Plan does not allow subrogation.

***Ratych* v. *Bloomer* (1990), 107 N.R. 335**
***Ledingham* v. *Ontario Hospital Services Commission* [1975], 1 S.C.R. 332**

133. Deduction of other contributions such as employment insurance benefits and CPP contributions are also made when calculating loss of income under the Plans. But these deductions are offset by the fact that there are no deductions for the costs associated with working (such as travel, parking, uniforms, work clothes or union dues) which would be made in a traditional damage assessment for loss of income.

134. The calculation of loss of income has been simplified under the Plans and the simplification process offers the following tangible benefits to the Class Member:

(a) the loss of income is assumed to continue, without interruption, until retirement. This is a substantial benefit to the Class Member because in virtually all cases the courts will reduce the calculation of future income loss to account for risk factors such as underlying health factors;

(b) the loss of income is assumed to continue until age 65. Depending upon the nature of the Class Member's employment, retirement may well occur before age 65; and

(c) the loss of income is indexed according to the Pension Index. Thus, an individual's income will always, at least, keep pace with inflation.

135. Further, a Class Member may lead evidence that his or her earned income would have increased beyond his or her three best years (4.01(2)(b)(i)). This possibility, too, allows the Class Member the opportunity to increase the amount of recoverable net income loss.

136. It is submitted that the criteria for recovery of loss of income are fair and reasonable.

CLAIM FOR COST OF REPLACEMENT SERVICES

137. A person who qualifies to claim loss of income may elect instead to receive payment to compensate for loss of services. The maximum is $12,480 per year. This payment is made for life.

THE TAX-FREE NATURE OF PAYMENTS

138. All payments from the Plans made to Class Members and Family Class Members are tax free, eliminating the need for gross-up.

MINORS

139. Objections have been made on behalf of only nine children across Canada.

140. Under the Plans, the manner of calculation of net loss of income is beneficial to minors. The net loss of income is calculated based on the assumption of full-year, full-time employment from age 18 at the Average Industrial Wage until age 65 without regard to gender. On reaching the age of 18, a minor may prove that he or she would have earned more than the Average Industrial Wage. This assumption that a minor on reaching age 18 would earn the Average Industrial Wage and work a full-year, full-time from age 18 to age 65 is especially beneficial to the minor because a court will rarely, if ever, assess damages on such favourable assumptions.

141. Because the income payable under the Plans is not taxable, CPP contributions will not be made. As a result, a minor who eventually attains age 65 will not be entitled to a CPP retirement pension. According to Mr. Segal's actuarial calculations, assuming maximum CPP contribution, the lump sum equivalent present value at age 18 of the CPP pension commencing at age 65 is valued at $17,544 for a male and at $23,181 for a female. But the present value at age 18 of the maximum contributions is about $37,448 for a male and $38,087 for a female. In other words, no loss arises as a result of the fact that no contribution was made to CPP, because the present value of the contributions exceeds the present value of the pension.

Eckler Report, exhibit 7, on cross-examination of Levi and Segal

142. If a minor attains age 18 and is attending university part-time, but otherwise would qualify for loss of income, he or she is entitled to be paid loss of income on the basis of the Average Industrial Wage. This income will permit him or her to attend university year round, at a reduced course load, so that he or she may graduate within the normal time for the discipline.

143. The costs of litigation and the time an individual trial will take are also relevant here: the costs of individual litigation are so substantial and the delay so great that few, if any, minors or their representatives would commence litigation on an individual basis.

SOCIAL BENEFITS

144. The FPT Governments have agreed that payments under the Plans (except for loss of income) will not affect eligibility for social benefit programs.

FAMILY CLASS MEMBERS

145. Family Class Members are not paid any amount under the Plans until the death of a Class Member. But for most Family Class Members the value of the claim is modest. If the death of the Class Member is caused by HCV, the Family Class Members are paid fixed amounts, based on the familial relationship. These amounts approximate the non-pecuniary general damages amount which would traditionally be assessed in Ontario but exceed what would be awarded in other provinces.

***Mason* v. *Peters* (1983), 39 O.R. (2d) 27 (C.A.)**

146. In a tort action in Ontario, family members would no doubt be entitled to assess some amount to compensate for the added burden of raising a child with HCV. But this burden will vary greatly depending upon individual circumstances and the extent of the child's symptoms during his or her minority, and it may also depend upon the underlying condition that led to the transfusion in the first instance.

DEATH CLAIMS

147. January 1, 1999 is a cutoff date in respect of death claims. If a Class Member's death on or before January 1, 1999 was caused by HCV, a claim may be made either for:

(a) $50,000 for damages plus an amount for uninsured funeral expenses to the estate, plus the family members' claims and the dependants' claims for loss of support or loss of services in the home; or

(b) a lump sum of $120,000 payable jointly to the estate, family members and dependants jointly plus an amount to the estate for uninsured funeral expenses.

148. If a HCV infected person died on or after January 1, 1999, the estate may recover all amounts the deceased would have been entitled to claim up to the time of death that had not already been paid and, if HCV caused the death, the estate would be entitled to up to $5,000 for uninsured funeral expenses and Family Class Members would be entitled to the payments provided under the Plans.

149. This action was commenced on February 10, 1998. As of that date, according to section 28 of the Act, limitation periods were suspended in favour of the Class Members and Family Class Members.

150. However, in each province a limitation period applies to death claims. In Ontario, if any person died more than two years before February 10, 1998, the claim

would be statute-barred unless an action was commenced for damages. Very few such actions were commenced. As a result, many of the estates and Family Class Members entitled to receive payments under the Plan for deaths prior to January 1, 1999 would not recover but for the settlement because their claims are statute-barred.

CAUSATION

151. Some have objected to the requirement of proving that HCV caused the Class Member's death. But proof of causation is integral to the tort system, and a person infected with HCV may or may not have died because of HCV. Under the Plans, so long as HCV "materially contributed" to the Class Member's death, his or her death was "caused" by HCV.

> ***Athey* v. *Leonati et al.* (1996), 203 N.R. 36 at pp. 43-4**
> ***Bonnington Castings, Ltd. v. Wardlaw*, [1956] 1 All E.R. 615 (H.L.) at pp. 618, 620, 622**

LACK OF INSURABILITY SHOULD ONLY BE A MARGINAL CONSIDERATION

152. Some objectors have noted that under the Plans persons infected with HCV cannot purchase life insurance. This is true, in part. To the extent that a medical examination is required as a condition precedent to the issuance of an insurance policy, persons with HCV would not qualify. But this is not always the case. For example, accident insurance is issued without the need for a medical examination.

153. According to the July 30, 1999 Eckler Report, slightly more than half of the amount of life insurance in force in Canada is under group policies, the bulk of

which is on groups of employees or members of trade unions and associations. This type of group insurance is typically issued without requiring evidence of good health and is usually convertible into individual insurance at standard rates without requiring evidence of insurability of the person upon leaving the group.

Eckler Report, exhibit S, on cross-examination of Levi and Segal

154. To the extent that a person infected with HCV is a member of a group, he or she may have life insurance available. Many Class Members also had the opportunity to buy life insurance or actually purchased life insurance before they were infected with HCV.

155. Even without HCV, some Class Members would not qualify for life insurance because their underlying medical conditions that necessitated the transfusion leading to the infection with HCV would have disqualified them.

156. The premiums that an insured pays for life insurance include the actuarial estimated value of the expected death benefits as well as a margin for commissions, other expenses of issuing and administering the coverage and the profit of the insurance company.

157. It is questionable whether a claim for loss of insurability results in a compensable loss in tort because the adverse economic impact of the possible inability to purchase life insurance is fully offset by the savings of the premiums that would have otherwise been paid for it.

Eckler Report, exhibit 6, on cross-examination of Levi and Segal
***Lang* v. *Rabel*, [1996] B.C.J. No. 1691 (B.C.S.C.); affirmed [1998] B.C.J. No. 2168 (B.C.C.A.)**

158. If there is a claim for loss of insurability, the value is nominal. On only one occasion in Canada has a court awarded damages for lack of insurability and that was for the plaintiff's inability to secure a disability policy. The amount of damages awarded was $5,000.

***Nicolls* v. *B.C. Cancer Agency*, [1999] B.C.J. No. 1475 (B.C.S.C.)**

JUDGMENT SOUGHT

159. The representative plaintiffs seek a declaration that the Agreement and Plans are fair, reasonable and in the best interests of the Class Members and the Family Class Members and other ancillary orders in accordance with the draft judgment which has been circulated to all counsel and which will be produced to the court.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

August 9, 1999

Harvey T. Strosberg Law Ms

HARVEY T. STROSBERG, Q.C.
Counsel for the plaintiffs

HEATHER RUMBLE PETERSON.
Counsel for the plaintiffs

PATRICIA A. SPEIGHT
Counsel for the plaintiffs

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APPENDIX A

PROPOSED DISEASE-BASED COMPENSATION SCHEDULE FOR HCV-INFECTED CLASS MEMBERS

Level	MEDICAL CONDITIONS CAUSED BY HCV	COMPENSATION: Maximum Cumulative Fixed Payments as Compensation for Damages	Fixed Payments as Compensation for Damages	Loss of Income or Compensation for Loss of Services in the Home (choice one or the other)	Additional Payment if you take HCV Drug Therapy	Reimbursement for Uninsured Treatment and Medication Costs	Reimbursement for Out-of-Pocket Expenses	Reimbursement for Care Costs
6	You are considered a Level 6 claimant if: 1. you receive a liver transplant; or 2. you develop: a) decompensation of the liver; b) hepatocellular cancer; c) B-cell lymphoma; d) symptomatic mixed cryoglobulinemia; e) glomerulonephritis requiring dialysis; or f) renal failure.	$225,000*	You will receive $100,000	Yes	$1,000 per month of completed therapy	Yes	Yes	up to $50,000 per year
5	You are considered a Level 5 claimant if you develop: a) cirrhosis (i.e. fibrous bands in the liver extending or bridging from portal area to portal area with the development of nodules and regeneration); b) unresponsive porphyria cutanea tarda which is causing significant disfigurement and disability; c) unresponsive thrombocytopenia (low platelets) which is associated with purpura or other spontaneous bleeding, or which results in excessive bleeding following trauma or a platelet count below 30 X 10^9; or d) glomerulonephritis not requiring dialysis.	$125,000*	You will receive $85,000	Yes	$1,000 per month of completed therapy	Yes	Yes	No
4	You are considered a Level 4 claimant if: you develop bridging fibrosis (i.e. fibrous tissue in the portal areas of the liver with fibrous bands bridging to other portal areas or to central veins but without nodular formation or nodular regeneration).	$60,000*	There is no further fixed payment paid at this level	Yes	$1,000 per month of completed therapy	Yes	Yes	No
3	You are considered a Level 3 claimant if: a) you develop non-bridging fibrosis (i.e. fibrous tissue in the portal areas of the liver with fibrous bands extending out from the portal area but without any bridging to other portal tracts or to central veins); or b) you receive compensable HCV Drug Therapy (i.e. interferon or ribavirin); or c) you have had or meet a protocol for compensable HCV Drug Therapy even though you have not taken the therapy.	If you elect OPTION 1 $60,000	OPTION 2 If you waive the $30,000 payment, you may claim loss of income or compensation for loss of services in the home OPTION 1 You receive $30,000	Yes No	$1,000 per month of completed therapy	Yes	Yes	No
2	You are considered a Level 2 claimant if: a) you test positive on a polymerase chain reaction (PCR) test demonstrating that HCV is present in your blood.	$30,000	You will receive $15,000 immediately plus a further $5,000 if and when the Court says that the Fund is sufficient	No	Not applicable	Yes	Yes	No
1	You are considered a Level 1 claimant if: your blood test demonstrates that the HCV antibody is present in your blood.	$10,000	You will receive $10,000	No	Not applicable	Yes	Yes	No

* assuming the $30,000 Fixed Payment was not waived at Level 3

APPENDIX B

EXAMPLES OF LOSS OF INCOME CALCULATIONS

	EXAMPLE 1		EXAMPLE 2		EXAMPLE 3		EXAMPLE 4	
	100% disability	50% disability	100% disability	50% disability	100% disability	50% disability	100% disability	50% disability
Average of 3 highest years of earned income	25,000	25,000	50,000	50,000	75,000	75,000	100,000	100,000
Application of $75,000 cap on earned income	n/a	n/a	n/a	n/a	n/a	n/a	75,000	75,000
Less ordinary deductions	5,378	5,378	14,494	14,494	25,660	25,660	25,660	25,660
Pre-disability net income	19,622	19,622	35,506	35,506	49,340	49,340	49,340	49,340
Current earned income	n/a	12,500	n/a	25,000	n/a	37,500	n/a	50,000
Proportionate reduction to current earned income ($50,000 x 75,000/$100,000)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	37,500
Less ordinary deductions	n/a	1,804	n/a	5,378	n/a	9,910	n/a	9,910
Post-disability net income	n/a	10,696	n/a	19,622	n/a	27,590	n/a	27,590
Annual loss of net income	19,622	8,926	35,506	15,884	49,340	21,750	49,340	21,750
Initial benefit or 70% of annual loss of net income	13,735	6,248	24,854	11,119	34,538	15,225	34,538	15,225

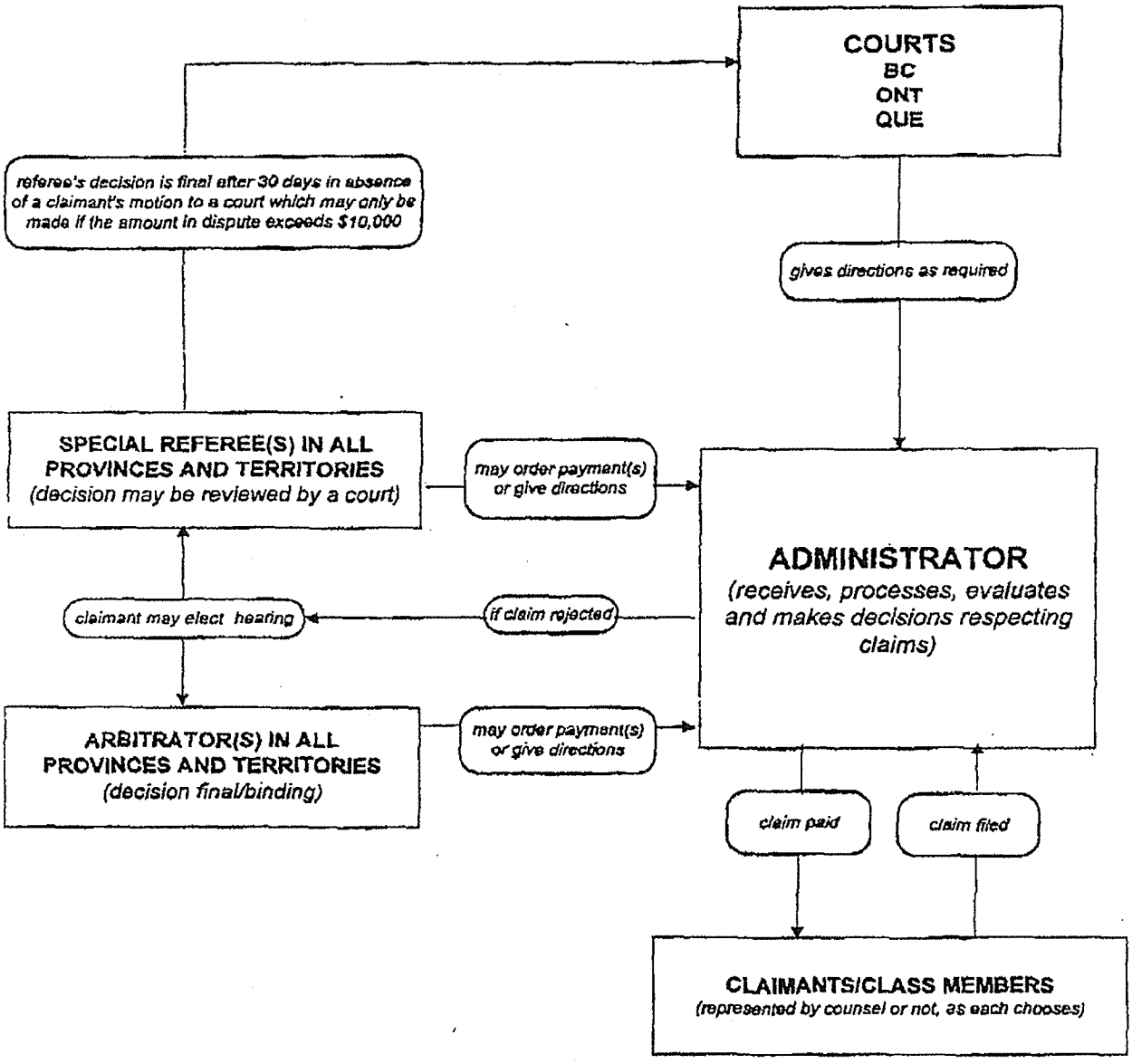
APPENDIX C

EXAMPLES OF LOSS OF SUPPORT CALCULATIONS

	EXAMPLE 1		EXAMPLE 2		EXAMPLE 3		EXAMPLE 4	
	No CPP Spousal Pension	CPP Spousal Pension	No CPP Spousal Pension	CPP Spousal Pension	No CPP Spousal Pension	CPP Spousal Pension	No CPP Spousal Pension	CPP Spousal Pension
Average of deceased's 3 highest years of earned income	25,000	25,000	50,000	50,000	75,000	75,000	100,000	100,000
Application of $75,000 cap on earned income	25,000	25,000	50,000	50,000	75,000	75,000	75,000	75,000
Less ordinary deductions	5,378	5,378	14,494	14,494	25,660	25,660	25,660	25,660
Deceased's net income	19,622	19,622	35,506	35,506	49,340	49,340	49,340	49,340
CPP Spousal Pension	n/a	3,852	n/a	4,974	n/a	4,974	n/a	4,974
Proportionate reduction to CPP Spousal Pension ($4,974 x 75,000/$100,000)	n/a	3,852	n/a	4,974	n/a	4,974	n/a	3,731
Annual loss of net income	19,622	15,770	35,506	30,532	49,340	44,366	49,340	45,609
Less 30% allowance for personal living expenses of the deceased	5,887	4,731	10,652	9,160	14,802	13,310	14,802	13,683
Annual loss of support	13,735	11,039	24,854	21,372	34,538	31,056	34,538	31,926
Initial benefit or 70% of annual loss of support	9,615	7,727	17,398	14,960	24,177	21,739	24,177	22,348

APPENDIX D

THE CLAIMS AND APPEAL PROCESS



SCHEDULE A

1. *Andrews* v. *Grand & Toy Alberta Ltd.* [1978] 2 S.C.R. 229 at p. 236

2. *Dabbs* v. *Sun Life Assurance Company of Canada* (1999), 40 O.R. (3d) 429 at p. 440 (Gen. Div.)

3. *Lewis* v. *British Columbia,* [1997] 3 S.C.R. 1145

4. *Just* v. *British Columbia,* [1989] 2 S.C.R. 1228

5. *Carom* v. *Bre-X Minerals Ltd.* (1999), 43 O.R. (3d) 441 (Gen. Div.)

6. *Trustee Act*, R.S.O. 1990, c. T. 23, s. 38

7. *Family Law Act,* R.S.O. 1990, c. F. 3, s. 61(4)

8. Waddams, The Law of Damages, Looseleaf edition, pp. 3-1-10

9. *Queen in Right of Ontario* v. *Jennings,* [1966] S.C.R. 532

10. *Cunningham* v. *Wheeler,* [1994] 1 S.C.R. 359 at p. 417-18

11. *British Transport Commission* v. *Gourley,* [1956] A.C. 185 (H.L.)

12. *Cullen & Trappell* (1980), 54 A.L.J.R. 295

13. Waddams, The Law of Damages, Looseleaf edition, pp. 3-48, 50

14. *Ratych* v. *Bloomer* (1990), 107 N.R. 335

15. *Ledingham* v. *Ontario Hospital Services Commission* [1975], 1 S.C.R. 332

16. *Mason* v. *Peters* (1983), 39 O.R. (2d) 27 (C.A.)

17. *Athey* v. *Leonati et al.* (1996), 203 N.R. 36 at pp. 43-4

18. *Bonnington Castings, Ltd.* v. *Wardlaw*, [1956] 1 All E.R. 615 (H.L.) at pp. 618, 620, 622

19. *Lang* v. *Rabel,* [1996] B.C.J. No. 1691 (B.C.S.C.); affirmed [1998] B.C.J. No. 2168 (B.C.C.A.)

20. *Nicolls* v. *B.C. Cancer Agency,* [1999] B.C.J. No. 1475 (B.C.S.C.)

DIANNE LOUISE PARSONS et al.
JAMES KREPPNER et al.
Plaintiffs

THE CANADIAN RED CROSS SOCIETY
et al.
Defendants

Court File No. 98-CV-141369
Court File No. 98-CV-146405

SUPERIOR COURT OF JUSTICE

PROCEEDINGS COMMENCED AT TORONTO

PLAINTIFFS' FACTUM IN ACTION 98-CV-141369 FOR AUGUST 18, 1999 MOTION

GIGNAC, SUTTS
Barristers and Solicitors
600 Westcourt Place
251 Goyeau Street
Windsor, Ontario
N9A 6V4

HARVEY T. STROSBERG, Q.C.
Tel: (519) 258-9333
Fax: (519) 258-9527

FILE: 44-900-000
REF: HTS/ba

This is Exhibit "C" referred to in the
affidavit of Asvini Krishnamoorthy
sworn before me at Toronto, Ontario
this 29th day of January, 2016

William Knight

A Commissioner for taking affidavits
within the Province of Ontario

274
25'429

Court file # 98-CV-141369

SUPERIOR COURT OF JUSTICE

B E T W E E N:

DIANNA LOUISE PARSONS, MICHAEL HERBERT CRUICKSHANKS,
DAVID TULL, MARTIN HENRY GRIFFEN, ANNA KARDISH,
ELSIE KOTYK, Executrix of the Estate of Harry Kotyk, deceased
and ELSIE KOTYK, personally

Plaintiffs

and

THE CANADIAN RED CROSS SOCIETY,
HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO
and THE ATTORNEY GENERAL OF CANADA

Defendants

Proceeding under the *Class Proceedings Act, 1992*

Court File No. 98-CV-146405

SUPERIOR COURT OF JUSTICE

B E T W E E N:

JAMES KREPPNER, BARRY ISAAC, NORMAN LANDRY, as Executor
of the Estate of the late SERGE LANDRY,
PETER FELSING, DONALD MILLIGAN,
ALLAN GRUHLKE, JIM LOVE and PAULINE FOURNIER
as Executrix of the Estate of the late PIERRE FOURNIER

Plaintiffs

and

THE CANADIAN RED CROSS SOCIETY,
THE ATTORNEY GENERAL OF CANADA and
HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO

Defendants

Proceeding under the *Class Proceedings Act, 1992*

FACTUM FILED ON BEHALF OF THE REPRESENTATIVE PLAINTIFFS IN THE HEMOPHILIAC CLASS ACTION (FOR AUG. 18, 1999 MOTION)

PART I - FACTS

1. This factum is filed on behalf of James Kreppner and Barry Isaac, Representative Plaintiffs in action number 98-CV-146405, in support of the approval of a Settlement Agreement (the "Settlement" or the "Agreement") and certain ancillary relief requested in a Notice of Motion dated July 10, 1999.

THE CLASS

2. Class Members are persons who have a congenital blood clotting defect or deficiency and who received or took blood or blood products between 1986 and 1990 and are or were infected with the Hepatitis C Virus ("HCV"). Class Members also include certain family members and individuals secondarily infected by Hemophiliac Class Members.

Certification Order of Mr. Justice Winkler, dated May 11, 1999.

THE NATURE OF HEMOPHILIA

3. Hemophilia is a genetic, life-long bleeding disorder. Human blood contains clotting proteins that assist in solidifying blood clots to stop bleeding. A person with hemophilia lacks one of the proteins necessary to clot blood. When one of these proteins is absent, defective or diminished in quantity, clotting does not occur or it occurs more slowly than normal.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 10 and 11.

4. The three most common clotting factor defects or deficiencies are Hemophilia A (defect or deficiency in factor VIII protein), Hemophilia B (defect or deficiency in factor IX proteins) and von Willebrands (defect or deficiency in von Willebrand clotting factor). There are other coagulation diseases which, although less common than Hemophilia A, Hemophilia B or von Willebrands disease, are the result of a deficiency or defect in clotting factor proteins.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 12 to 15.

5. While the term may be medically inaccurate, for ease of description, "Hemophiliac" will be used to describe all persons with a defect or deficiency in any clotting factor protein and will not necessarily be confined to those with Hemophilia A or Hemophilia B.

6. Hemophiliacs are often classified into the categories of severe hemophilia, moderate hemophilia or mild hemophilia, depending on the level of clotting protein in their blood in comparison with normal levels.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 17.

7. Severe Hemophiliacs have less than one percent of the normal levels of factor VIII or factor IX in the blood. They experience haemorrhages and require treatment as frequently as several times a month. There is no obvious cause for the bleeding.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 17.

8. Moderate Hemophiliacs do not bleed as often as severe Hemophiliacs. They have one to five percent of the normal factor levels in their blood. Haemorrhages often result from minor trauma.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 17.

9. Mild Hemophiliacs have between five and thirty percent of the normal clotting proteins in their blood. They may only become aware of their bleeding disorder after surgery, tooth extraction or serious injury.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 17.

10. The most common and debilitating form of bleeding experienced by Hemophiliacs is internal bleeding into joints and muscles. Internal bleeding into organs, particularly the brain, is considered most dangerous.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 20.

TREATMENT OF HEMOPHILIA

11. Persons with bleeding disorders require treatment with the missing clotting factor from an outside source. Treatment of hemophilia requires the infusion or transfusion of blood or blood products in an attempt to provide the body with enough clotting factor proteins to stop a bleed as soon as possible.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 20.

12. Historically, the only replacement therapy for the treatment of hemophilia involved the transfusion of whole blood.

Commission of Inquiry on the Blood System in Canada, Final Report, 1997, vol. 1, p. 165.

13. Significant developments in the treatment of hemophilia began in the 1950s, when transfusions with whole blood were replaced by infusions of plasma, the liquid part of blood that contains the clotting factors. Fresh frozen plasma is derived from donations of whole blood. The plasma is frozen soon after the blood is donated in order to preserve factor activity. The plasma is thawed before being infused by Hemophiliacs.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 22.

Commission of Inquiry on the Blood System in Canada, Final Report, 1997, vol. 1, p. 165.

14. In the 1960s, cryoprecipitate became the standard treatment for most Hemophiliacs affected by a factor VIII deficiency. Cryoprecipitate is derived from fresh frozen plasma and is rich in factor VIII.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 23.

Commission of Inquiry on the Blood System in Canada, Final Report, 1997, vol. 1, p. 165.

15. Freeze dried concentrates ("factor concentrates") became available in Canada in the late 1960s. The new risk that came with the use of factor concentrates was a result of the method of their manufacture. The factor concentrates were manufactured by pooling fresh frozen plasma from thousands of donors and extracting the clotting factor proteins. Any single unit of plasma could contain bacteria or viruses and, depending upon the micro-organism, could contaminate the entire pool and hence the final concentrate.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 24.

Commission of Inquiry on the Blood System in Canada, Final Report, 1997, vol. 1, p. 167.

16. Commencing in July 1985, all factor concentrates used in Canada were manufactured using a heat treating method intended to kill the human immunodeficiency virus ("HIV") that causes AIDS. Prior to July 1985, over eighty percent of all severe Hemophiliacs were infected with HIV.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 25.

17. As of July 1988, factor concentrates distributed in Canada were manufactured using a wet-heat treated or vapour-heat treated process intended to kill HIV and HCV.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 26.

18. In 1993, a Factor VIII preparation made by recombinant DNA technology became available in Canada and a recombinant Factor IX preparation became available in 1998. These recombinant factors are reported not to carry any risk of viral infection.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 27.

THE FAILURE OF THE CRCS AND FPT GOVERNMENTS

19. The Canadian Red Cross Society ("CRCS") and the Federal, Provincial and Territorial governments ("FPT governments") did not conduct surrogate tests for HCV on blood collected in Canada. The CRCS and FPT governments also failed to require testing for HCV of purchased blood from the United States to be used to manufacture factor concentrates.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 28.

20. This failure to conduct surrogate testing resulted in high levels of HCV contamination in plasma pools from which factor concentrates were manufactured for infusion by Canadian Hemophiliacs.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 29.

21. In July 1985, the CRCS and FPT governments began to sell and distribute factor concentrates that had been manufactured using a dry-heat treated process. This was done at a time when it was well known in the United States that the dry-heat treated process was only partially successful in killing HCV.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 30 and 31.

22. The CRCS and FPT governments failed to expeditiously introduce or insist on the use of modern heat-treating techniques for factor concentrates. A wet-heat treated factor concentrate was not used in Canada until 1988. The wet-heat treatment was more effective in killing HCV.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 32.

23. The CRCS and the FPT not only failed to insist on the use of wet-heated factor concentrates for Canadian Hemophiliacs, but they also decided not to introduce surrogate testing. This exacerbated the risk for Hemophiliacs because large amounts of plasma from HCV infected donors were added to the plasma pools that were used to manufacture factor concentrates. The level of infection that resulted overwhelmed the viral removal capabilities of the dry-heat treatment process.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 33.

24. Even after July 1988, when the CRCS began distributing only wet-heat treated factor concentrates for infusion by Hemophiliacs, wet-heat treated concentrates continued to be produced from plasma pools which contained blood that had not been surrogate tested for HCV. As a result, an unnecessary element of risk persisted.

Affidavit of James Kreppner, motion record, vol. 5, tab 11, para. 46.

ESTIMATING THE NUMBER OF HEMOPHILIACS INFECTED WITH HCV

25. It is estimated that at approximately 1,650 Hemophiliacs have been infected with HCV.

Affidavit of Irwin Walker, motion record, vol. 5, tab 13, para. 21.

26. It is further estimated that of the 1,650 Hemophiliacs infected with HCV, approximately 640 Hemophiliacs were previously infected with HIV ("co-infected Hemophiliacs").

Affidavit of Irwin Walker, motion record, vol. 5, tab 13, para. 16.

27. Approximately 340 of the co-infected Hemophiliacs have died.

Affidavit of Irwin Walker, motion record, vol. 5, tab 13, para. 17.

28. Approximately 7 Hemophiliacs infected only with HCV have died in circumstances in which their doctors have indicated that liver failure was a contributing factor in their death.

Affidavit of Irwin Walker, motion record, vol. 5, tab 13, para. 22.

CONSEQUENCES OF HCV INFECTION

29. HCV is a virus that infects the liver and causes hepatitis. Hepatitis is inflammation of the liver which can lead to cirrhosis and sometimes liver cancer. The health risks and complications from HCV infection are set out in the Affidavit of Dr. Frank Anderson.

Affidavit of Dr. Frank Anderson, motion record, vol. 4, tab 6.

30. The nature and course of hepatitis can vary depending on the causative agent, the state of health of the infected person, and interactions of the many factors that affect the liver. Many individuals infected with HCV will suffer in varying degrees. In some cases, the immune system of the body responds, and the virus may be cleared from the body. It may not be cleared completely, however, and may remain dormant for many years. Often, in the early stages of HCV, infected persons will show no symptoms. The disease may progress slowly and infected individuals may develop chronic hepatitis, cirrhosis of the liver, or some other end-stage liver disease 10 to 20 years after infection.

Affidavit of Dr. Frank Anderson, motion record, vol. 4, tab 6, para. 15.

Commission of Inquiry on the Blood System in Canada, Final Report, 1997, vol. 1, p. 39.

31. The health risks and complications from HCV infection are further exacerbated in the case of Hemophiliacs because of their underlying clotting factor defect or deficiency and, in the case of co-infected Hemophiliacs, because of HIV infection.

NATURE OF THE HEMOPHILIACS' CLAIM AGAINST THE FPT GOVERNMENTS

32. The Hemophiliacs' claim against the FPT governments is in part based on the failure of the FPT governments to insist on the introduction of surrogate testing for HCV in a timely and expeditious manner. This part of the claim is essentially identical to the claim of the Transfused Class and is described in the Affidavit of R. Douglas Elliott.

Affidavit of R. Douglas Elliott, motion record, vol. 2, tab 3.

33. The Hemophiliacs assert additional claims based on the failure of the FPT governments to ensure the introduction of modern heat-treating techniques (wet-heat treatment) for factor concentrates. It is alleged that the FPT governments knew or ought to have know that these techniques would kill HCV.

> *Kreppner et al v. Canadian Red Cross Society et al*, Fresh Statement of Claim, filed, para. 27 to 34.

34. The Hemophiliacs' claim is complicated by a number of liability and evidentiary issues, including:

i. in the case of many Hemophiliacs, a lengthy history of use of blood and blood products before 1986;

ii. the fact that a traceback search is impossible for pooled blood products such as factor concentrates; and

iii. in the case of co-infected Hemophiliacs, the impact of their underlying HIV infection.

THE PROPOSED SETTLEMENT

35. The Settlement is premised on negotiating counsels' best attempts, within the parameters of compromise, to mimic the relief to which an individual claimant would be entitled if successful against the FPT governments at trial.

36. The Settlement also attempts to recognize the fact that some HCV infected persons may never become ill while others may become seriously ill many years from now. Only time will determine how seriously any individual will be affected.

37. The Settlement consists of a common Agreement, supported by a specific Transfused Plan and a specific Hemophilia Plan.

> *The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999*, motion record, vol. 1, tab 2.

38. The Settlement provides the following cumulative fixed payments to infected Class Members:

i. an initial payment of $10,000;

ii. a further payment of $20,000 ($5,000 to be held back) to all infected Class Members who demonstrate through PCR testing, that the HCV is actively circulating in their blood;

iii. a payment of $30,000 to all HCV infected Class Members who qualify or have received compensable HCV Drug Therapy and do not elect to claim loss of income at this level;

iv. a payment of $65,000 to all HCV infected Class Members who have developed a serious liver disease as a result of their HCV infection, such as cirrhosis of the liver; and

v. a payment of $100,000 to all HCV infected Class Members who had a liver transplant or are suffering from end-stage liver disease.

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, motion record, vol. 1, tab 2.

39. The Settlement provides that a claimant who is at level four (bridging fibrosis) or beyond, or who qualifies and has so elected at level three, may recover loss of income subject to certain holdbacks as described in the Agreement. Alternatively, claimants who are not employed outside the home may claim up to $12,400 a year to compensate for loss of services in the home.

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, motion record, vol. 1, tab 2.

40. The Settlement provides for the payment of uninsured medical services and expenses associated with seeking and obtaining medical treatment for HCV. In addition, a payment of $1,000 per month is provided as assistance for those undergoing a course of compensable HCV drug therapy with interferon (alone or in combination with other drugs).

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, motion record, vol. 1, tab 2.

41. Uninsured costs of home care up to a maximum of $50,000 per year will be provided to infected Class Members who suffer from, in effect, end-stage liver disease.

> *The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999*, motion record, vol. 1, tab 2.

42. The estates of infected Class Members who died from HCV before January 1, 1999 may elect to be compensated by a $50,000 payment to the estate and additional payments to dependants and family members, or alternatively, they may elect to receive lump sum payment of $120,000 to be made to the estate and all family members. Regardless of their election, such estates will be entitled to claim up to $5,000 for uninsured funeral expenses.

> *The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999*, motion record, vol. 1, tab 2.

43. Estates of infected Class Members who died after January 1, 1999 will be entitled to claim all amounts the Class Member would have been entitled to under the Settlement had the Class Member remained alive. If the infected Class Member died from HCV after January 1, 1999, additional compensation will be paid to dependants and family members.

> *The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999*, motion record, vol. 1, tab 2.

44. All payments to Class Members will be made on a tax-free basis.

> *The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999*, motion record, vol. 1, tab 2.

45. All payments to Class Members will be indexed so as to provide increased payments in response to inflation.

> *The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999*, motion record, vol. 1, tab 2.

46. Settlement payments (other than loss of income and loss of support) will not affect a Class Member's entitlement to social benefits paid out pursuant to the social benefits legislation scheduled in the Agreement.

> *The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999,* motion record, vol. 1, tab 2.

47. Claimants will have the right to appeal a denial of benefits to either a court-appointed arbitrator or a court-appointed referee. In some circumstances, they will have a further right of appeal to the court.

> *The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999,* motion record, vol. 1, tab 2.

BENEFITS OF SPECIAL SIGNIFICANCE TO THE HEMOPHILIA COMMUNITY

48. While the benefits provided in the Transfused Plan and in the Hemophilia Plan are similar, there are some important distinctions resulting from the unique circumstances of Hemophiliacs related to evidentiary issues, complications from co-infection with HIV and the nature of hemophilia generally.

49. The distinctions between the Transfused Plan and the Hemophilia Plan include the following:

i. Claims of Hemophiliac Class Members will not be subject to a traceback search to establish that the HCV infection was within the Class Period (or not outside of the Class Period). This reflects the history of product usage by Hemophiliacs and the fact that traceback searches on factor concentrates are virtually impossible;

ii. Hemophiliacs will not be required to undergo invasive testing (such as liver biopsies) to prove entitlement to compensation. This reflects the fact that biopsies may be medically or psychologically contra-indicated for an individual Hemophiliac. Further, invasive testing may be inefficient from a cost-benefit

analysis due to the amount of blood product that may be required for Hemophiliacs before, during and after the procedure;

iii. Estates and family members of Hemophiliacs who died prior to January 1, 1999 and who were co-infected with HIV and HCV at the time of their death may elect to receive a one-time payment of $72,000. This reflects the difficulty in proving the cause of death of someone who may have died many years earlier (in some cases, up to 12 years earlier) at a time when they were co-infected with two diseases. The difficulty is further compounded by the emerging state of medical knowledge of HIV, HCV and their complications, particularly in the late 1980s; and

iv. Co-infected Hemophiliacs may elect a one-time lump sum payment of $50,000 in lieu of all other benefits under the Hemophilia Plan. This option reflects the reality that many co-infected individuals, given the current state of their health, do not wish to become involved in a long-term program.

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, Schedule "B": Hemophiliac Plan, motion record, vol. 1, tab 2.

50. While the average recipient of a blood transfusion is a mature adult, the congential nature of hemophilia often results in infusion at a very young age. Therefore, the hemophilia community was particularly concerned about young people who were not able to enter the work force or complete their education as a result of their HCV infection. Young people whose infection with HCV has prevented them from entering the work force will be able to claim loss of income based on either the standard industrial wage or, with proof, based on an estimate of what they would have earned had their HCV infection not prevented them from entering the work force.

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, motion record, vol. 1, tab 2.

FUNDING AND SETTLEMENT ADMINISTRATION

51. It is proposed that the Settlement be administered by a professional claims administrator who will operate from a bilingual claims centre in Ottawa, providing on-going, day by day administration of the claims.

Affidavit of David L. Robins, motion record, vol. 6, tab 14.

52. Subject to the provisions of the Funding Agreement, the Settlement funds will be held by a professional Trustee who will forward funds to the administrator as required to pay the claimants.

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, motion record, vol. 1, tab 2.

53. Funds in the possession of the Trustee will be invested in accordance with Investment Guidelines to be approved by the court, as recommended by an Investment Advisor appointed by the court.

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, motion record, vol. 1, tab 2.

54. It is respectfully submitted that the best available evidence demonstrates that the Transfused Plan and Hemophiliac Plan are adequately funded to pay out all claims. The expert actuarial report of Eckler Partners Ltd. is based on conservative estimates of class size. The expert actuarial report assumes that every class member will claim under the Plans. It is submitted that a 100% take-up rate is highly unlikely. Furthermore, allowances have not been made for future advances in medical treatment to arrest and delay the development of the hepatitis disease.

Report of Eckler Partners Ltd., motion record, tab 5, p. 508.

PART II – ISSUE AND LAW

ISSUE

55. Is the Settlement fair, reasonable and in the best interests of those affected by it?

LAW

56. A settlement is not binding unless it is approved by the court. The test for court approval is that the court must be satisfied that in all the circumstances the settlement is fair, reasonable and in the best interest of the class as a whole. The burden of establishing the reasonableness of the settlement rests with the parties proposing the settlement.

> *Class Proceedings Act, 1992*, s. 29 (2).
>
> *Dabbs v. Sun Life Assurance Co. of Canada* (1998), 40 O.R. (3d) 429 at 440.

57. In *Dabbs v. Sun Life Assurance Co. of Canada*, Mr. Justice Sharpe noted:

> *"...all settlements are the product of compromise and the process of give and take [in] settlements rarely give all parties exactly what they want. Fairness is not a standard of perfection. Reasonableness allows for a range of possible resolutions. A less than perfect settlement may be in the best interests of those affected by it when compared to the alternative of the risks and costs of litigation."*
>
> *Dabbs v. Sun Life Assurance Co. of Canada* (1998), 40 O.R. (3d) 429 at 440 (Gen. Div.).

58. In *Ontario New Home Warranty Program v. Chevron Chemical Co.*, Mr. Justice Winkler stated:

> *"The exercise of settlement approval does not lead the court to a dissection of the settlement with an eye to perfection in every aspect. Rather, the settlement must fall within a zone or range of reasonableness."*
>
> *Ontario New Home Warranty Program v. Chevron Chemical Co.*, O.J. No. 2245, *unreported decision of Mr. Justice Winker*, June 17, 1999 (Gen. Div.).

59. In *Dabbs v. Sun Life Assurance Co.,* the court stated that the following factors were a useful list of criteria for assessing the reasonableness of a proposed settlement:

i. likelihood of recovery, or likelihood of success;
ii. amount and nature of discovery evidence;
iii. settlement terms and conditions;
iv. recommendation and experience of counsel;
v. future expense and likely duration of litigation;
vi. recommendation of neutral parties if any;
vii. number of objectors and nature of objections;
viii. the presence of good faith and the absence of collusion.

Dabbs v. Sun Life Assurance Co., O.J. No. 1598, *unreported decision of Mr. Justice Sharpe,* February 24, 1998 (Gen. Div.).

LIKELIHOOD OF RECOVERY AND LIKELIHOOD OF SUCCESS

60. The Affidavit of R. Douglas Elliott describes the difficulties of recovery for both Hemophiliac and Transfused Class Members in respect of the failure of the FPT governments to introduce surrogate testing for HCV.

Affidavit of R. Douglas Elliott, motion record, vol. 2, tab 3.

61. Hemophiliac Class Members face additional obstacles in proving their claims.

62. Hemophiliac Class Members have unique problems of an evidentiary nature, as described in paragraph 34 above, based on their long history of product usage and the fact that traceback searches on hemophilia blood products is virtually impossible. These factors militate against the success in litigation for Hemophiliacs.

AMOUNT AND NATURE OF DISCOVERY, EVIDENCE OR INVESTIGATION

63. While examinations for discovery have not been held in this action, it is respectfully submitted that the documentary and oral evidence disclosed at the Commission of Inquiry on the Blood System in Canada before Mr. Justice Horace Krever was far in excess of what might have been disclosed through a discovery process in these proceedings.

Commission of Inquiry on the Blood System in Canada, Final Report, 1997.

SETTLEMENT TERMS AND CONDITIONS

64. The Settlement terms and conditions are set out in the Settlement Agreement and accompanying Schedules. They are described more generally in paragraphs 35 to 50 above.

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, motion record, vol. 1, tab 2.

65. The Settlement Agreement reflects the special nature of HCV infection in that it provides for compensation on a sliding scale, depending upon the level of illness, while at the same time permitting individuals who are not ill today to return to the fund in the event of future illness.

The 1986-1990 Hepatitis C Settlement Agreement and Funding Agreement made as at June 15, 1999, motion record, vol. 1, tab 2.

RECOMMENDATION AND EXPERIENCE OF COUNSEL

66. This Settlement is recommended by senior and experienced counsel from across Canada. Many counsel involved participated in the Krever Commission of Inquiry on the Blood System in Canada and they bring to this settlement a wealth of knowledge on all issues related to the potential liabilities of the FPT governments and potential costs of pursuing this litigation to trial.

67. This case presents very complex issues of liability and damages. Counsel have assessed these problems and the probability of success on the merits. They have concluded that the settlement is well-advised and reasonable.

FUTURE EXPENSE AND LIKELY DURATION OF LITIGATION

68. Blood litigation in Canada has proven to be extremely costly and time-consuming. Cases involving individuals infected with HIV have taken in excess of ten years to litigate. Few, if any cases have reached a final resolution.

Pittman Estate v. Bain (1994), 112 D.L.R. (4th) 257 (Gen. Div.).

Walker Estate v. York Finch General Hospital (1999), 43 O.R. (3d) 461 (C.A.).

RECOMMENDATION OF NEUTRAL PARTIES

69. The Settlement has been welcomed by The Childhood Cancer Foundation - Candlelighters Canada. The organization is a national support and information network with international affiliation, dedicated to enhancing the quality of life of children and teens with cancer, their families and those who care for and about them.

70. The Settlement has also been welcomed by the Canadian Hemophilia Society and its President, Erma Chapman.

NUMBER OF OBJECTORS AND NATURE OF OBJECTIONS

71. Twenty-three objections to the Settlement were received from Hemophiliac Class Members: one from Ontario, twenty from British Columbia and two from Quebec.

PricewaterhouseCoopers L.L.P. Report, para. 8, p. 4.

72. Nineteen of the twenty objections received from British Columbia are primarily concerned with the fact that the Settlement is limited to persons infected in the Class Period. These objectors do not object to the terms of the Settlement; rather, they submit that the Settlement should be extended equally to all persons infected with HCV through the blood system.

PricewaterhouseCoopers L.L.P. Report, para. 9, p. 4.

73. Other issues raised in the objections relate to a concern that the plan does not contemplate reimbursing a participant's fixed dollar cap drug plan for drug expenses related to HCV, and that the level payments for general damages are too low.

PricewaterhouseCoopers L.L.P. Report, para. 10, p. 4.

74. It is submitted that the small number of objections is an indication of the fairness and reasonableness of the Settlement.

THE PRESENCE OF GOOD FAITH AND THE ABSENCE OF COLLUSION

75. The Settlement Agreement is the product of many months of good faith, arduous bargaining among well-experienced counsel across Canada. Counsel have explored the issues objectively, thoroughly and carefully, and have assessed the probabilities of ultimate success. Counsel for both sides agree that the Settlement is well-advised and necessary.

SUMMARY

76. Given the uncertainties of litigation described above, the complexity of the case and the concomitant risks and costs necessarily inherent in taking this litigation to completion, it is respectfully submitted that the Settlement secures an adequate advantage for class members in return for the surrender of litigation rights related to HCV infection.

PART III – NATURE OF ORDER SOUGHT

77. The representative plaintiffs seek a declaration that the Agreement and Plans are fair, reasonable and in the best interests of all Class Members. The representative plaintiffs also seek other procedural orders in accordance with the draft judgment which has been circulated to all counsel and which will be produced to the court.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

August 9, 1999

BONNIE A. TOUGH
Counsel for the Hemophiliac Representative Plaintiffs

DIANNA LOUISE PARSONS et al. and THE CANADIAN RED CROSS SOCIETY et al
-and-
JAMES KREPPNER et al. and THE CANADIAN RED CROSS SOCIETY et al

Court File No: 98-CV-141369

Court File No: 98-CV-146405

SUPERIOR COURT OF JUSTICE

Proceedings commenced at TORONTO

Proceedings under the *Class Proceedings Act, 1992*

FACTUM FOR HEMOPHILIAC CLASS ACTION

GIGNAC SUTTS
600 – 251 Goyeau Street
Windsor, ON N9A 6V4

Harvey T. Strosberg, Q.C.
Tel: (519) 258-9333
Fax: (519) 258-9527

Solicitors for the Plaintiffs in 98-CV-141369

Hodgson Tough Shields DesBrisay O'Donnell
36 Toronto Street, Suite 550
Toronto, ON M5C 2C5

Bonnie A. Tough
Tel: (416) 304-6402
Fax: (416) 304-6406

Solicitors for the Plaintiffs in 98-CV-146405

This is Exhibit "D" referred to in the
affidavit of Asvini Krishnamoorthy
sworn before me at Toronto, Ontario
this 29th day of January, 2016

William Kingus

A Commissioner for taking affidavits
within the Province of Ontario

CANADA
PROVINCE DE QUÉBEC
DISTRICT DE MONTRÉAL

NO : 500-06-000016-960

COUR SUPÉRIEURE
Recours Collectifs

DOMINIQUE HONHON

Requérante,

c.

PROCUREUR GÉNÉRAL DU CANADA

PROCUREUR GÉNÉRAL DU QUÉBEC

SOCIÉTÉ CANADIENNE DE LA CROIX-ROUGE

Intimés,

et

FONDS D'AIDE AUX RECOURS COLLECTIFS

et

LE CURATEUR PUBLIC DU QUÉBEC

Mises-en-cause

NO : 500-06-000068-987

DAVID PAGE

Requérant

c.

SOCIÉTÉ CANADIENNE DE LA CROIX-ROUGE

PROCUREUR GÉNÉRAL DU CANADA,

PROCUREUR GÉNÉRAL DU QUÉBEC,

Intimés,

et

ÉTIENNE SAUMURE

Intervenant

et

FONDS D'AIDE AUX RECOURS COLLECTIF

et

LE CURATEUR PUBLIC DU QUÉBEC

Mis-en-cause

PLAN D'ARGUMENTATION

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INTRODUCTION

I. RECOURS COLLECTIF :

Recours collectif pour l'Hépatite C – période du 1er janvier 1986 au 1er juillet 1990 inclusivement (ci-après désignée « période visée »).

A) RECOURS DES TRANSFUSÉS

1. **Le Québec :**

Le 21 juin 1996, madame Dominique Honhon a déposé une requête pour autoriser l'exercice d'un recours collectif contre le Procureur Général du Canada (ci-après désigné le « P.G.C. »), le Procureur Général du Québec (ci-après désigné le « P.G.Q. ») et la Société Canadienne de la Croix-Rouge (ci-après désignée la « S.C.C.R. »).

Le 23 février 1998, l'Honorable Juge Danielle Grenier faisait droit à la requête et autorisait l'exercice du recours.

- Requête ré-amendée pour autoriser l'exercice d'un recours collectif par madame Dominique Honhon, 20 février 1999 (ci-après désignée « Requête Honhon »).

  Onglet 1

2. **La Colombie-Britannique :**

Le 19 septembre 1996, madame Anita Endean déposait une requête pour autoriser l'exercice d'un recours collectif contre le P.G.C., le Procureur Général de la Colombie-Britannique et la S.C.C.R.

Le 22 mai 1997, l'Honorable juge K. Smith faisait droit à la requête.

- *Anita Endean* c. *CRCS, Attorney General of Canada, Her Majesty the Queen in Right of the Province of B.C.*, Vancouver, 22 mai 1997, dossier C965349.

  Onglet J-1

3. **L'Ontario :**

Le 10 février 1998, madame Louise Parsons, Michael Herbert Cruickshanks, David Tull, Martin Henry Griffen, Anna Kardish, Elsie Kotyk déposaient une requête pour autoriser l'exercice d'un recours collectif contre le P.G.C., le Procureur Général de l'Ontario (ci-après désigné le « P.G.O. ») et la S.C.C.R.

Le 25 juin 1998, l'Honorable juge Winkler faisait droit à la requête. Le 11 mai 1999, ledit jugement fut amendé faisant du groupe de l'Ontario une classe nationale englobant les autres provinces canadiennes à l'exception du Québec et de la Colombie-Britannique.

- Cahier des pièces déposé pour l'audition du 17 juin 1999.

B) RECOURS DES HÉMOPHILES

1. Le Québec :

Le 7 mai 1998, Monsieur David Page a déposé une requête pour autoriser l'exercice d'un recours collectif contre le P.G.C., le P.G.Q. et la S.C.C.R.

Le 22 avril 1999, l'Honorable juge Nicole Morneau faisait droit à la requête.

- Requête amendée pour autoriser l'exercice d'un recours collectif par monsieur David Page (ci-après désigné « Requête Page »).

  Onglet 2

2. La Colombie-Britannique :

Le 1er mai 1998, Monsieur Christopher Forrest Mitchell a déposé une requête pour autoriser l'exercice d'un recours collectif contre le P.G.C. et la S.C.C.R.

3. L'Ontario :

Le 24 avril 1998, Monsieur James Kreppner a déposé une requête pour autoriser l'exercice d'un recours collectif contre le P.G.C., le P.G.O. et la S.C.C.R.

Le 11 mai 1999, l'Honorable juge Winkler faisait droit à la requête. Le 11 mai 1999, ledit jugement a été amendé faisant du groupe de l'Ontario une classe nationale englobant les autres provinces canadiennes à l'exception du Québec et de la Colombie-Britannique.

- Cahier des pièces déposé pour l'audition du 17 juin 1999.

C) GROUPES AUTORISÉS AU QUÉBEC

1. Les Transfusés :

a) Description du groupe

Madame Dominique Honhon a été autorisée à exercer un recours collectif pour le groupe de personnes ci-après décrit :

i. des personnes ayant reçu, au Québec, une transfusion de sang, tel que ci-après défini, entre le 1er janvier 1986 et le 1er juillet 1990 inclusivement et qui sont ou ont été infectées par le virus de l'Hépatite C;

ii. d'un époux ou d'un conjoint infecté indirectement par le virus de l'Hépatite C par un époux ou un conjoint qui est une personne décrite au paragraphe (i);

iii. d'un enfant infecté indirectement par le virus de l'Hépatite C par un parent qui est une personne décrite aux paragraphes (i) et (ii); ou

iv. d'un membre de la famille d'une personne décrite aux paragraphes (i), (ii) ou (iii);

(ci-après le « Groupe-transfusés »)

le sang étant défini comme suit :

le sang total et les produits sanguins suivants : les concentrés de globules rouges, les plaquettes, le plasma (frais congelé et stocké) et les globules blancs. Le sang ne comprend pas l'albumine à 5%, l'albumine à 25%, le facteur VIII, le facteur VIII porcin, le facteur IX, le facteur VII, l'immunoglobuline anti-cytomégalovirus, l'immunoglobuline anti-hépatique B, l'immunoglobuline anti Rh, l'immunoglobuline antivaricelleuse-antizostérienne, l'immunoglobuline sérique, (FEIBA) FEVIII Inhibitor Bypassing Activity, Autoplex (complexe prothrombine), l'immunoglobuline antitétanique, l'immunoglobuline intraveineuse (IVIG) et l'antithrombine III (ATIII). »

b) Demandes au nom du Groupe-transfusés

Par son recours collectif, Madame Dominique Honhon demande une indemnisation pour les personnes qui, comme elle, ont été contaminées par le VHC suite à l'utilisation du sang ou des produits sanguins collectés, fabriqués, distribués et approuvés par les Intimés durant la période visée.

c) Faute alléguée

De façon générale, la faute reprochée aux Intimés par madame Dominique Honhon est la suivante :

> « Avoir négligé ou refusé ou omis d'implanter ou d'exiger l'implantation, dès janvier 1986, ou ultérieurement, des tests indirects aux fins de protéger les receveurs ou utilisateurs de sang et dérivés du sang et ainsi améliorer la sécurité et la qualité des réserves de sang et dérivés du sang et préserver celle-ci d'une contamination au VHC alors que l'on connaissait ou que l'on aurait dû connaître les risques élevés d'une contamination à l'HNANB par les transfusions de sang ou dérivés du sang; »

Requête Honhon, par. 116

Onglet I

d) Les questions traitées collectivement

Les questions de faits et de droit identifiées par l'Honorable juge Grenier devant être traitées collectivement sont les suivantes :

a) les Intimés avaient-ils l'obligation de prendre les moyens nécessaires à prévenir et minimiser les risques pour les receveurs de sang et dérivés du sang de contamination par le VHC;

b) les Intimés ont-ils commis une faute en négligeant, en refusant, en omettant d'implanter ou en négligeant d'exiger l'implantation des tests indirects ALT et anti-HBc ou l'un ou l'autre d'entre eux à quelque moment au cours de la période débutant le 1er janvier 1986 et se terminant le 1er juillet 1990;

c) *dans l'éventualité où la Cour concluait affirmativement aux questions A) et B) quelle aurait été la réduction de l'incidence de l'Hépatite C post-transfusionnelle du fait de l'implantation des tests de dépistage indirects ALT et anti-HBc ou l'un ou l'autre d'entre eux;*

d) *la réponse à la question C) a-t-elle une conséquence sur le fardeau de preuve des membres du groupe au stade des réclamations individuelles; dans l'affirmative laquelle?*

2. **Les Hémophiles :**

a) Description du groupe

Monsieur David Page a été autorisé à exercer un recours collectif pour le groupe de personnes ci-après décrit :

« i. des personnes atteintes de l'hémophilie qui ont reçu ou se sont administrés, au Québec, du sang ou des produits sanguins, tel que ci-après défini, entre le 1er janvier 1986 et le 1er juillet 1990 inclusivement, et qui sont ou ont été infectées par le virus de l'Hépatite C;

ii. d'un époux ou d'un conjoint infecté indirectement par le virus de l'Hépatite C par un époux ou un conjoint qui est une personne décrite au paragraphe (i);

iii. d'un enfant infecté indirectement par le virus de l'Hépatite C par un parent qui est une personne décrite aux paragraphes (i), (ii); ou

iv. d'un membre de la famille d'une personne décrite aux paragraphes (i), (ii), ou (iii);

(ci-après le « Groupe-hémophiles »)

le sang étant défini comme suit :

« le sang total et des produits sanguins, y compris les concentrés de globules rouges, les plaquettes, le plasma (frais congelé et stocké) et les globules blancs et le cryoprécipité et les produits de facteur de coagulation, notamment le facteur VII, le facteur VIII, le facteur IX, fournis directement ou indirectement par la Société canadienne de la Croix-Rouge. Le sang ne comprend pas l'albumine à 5%, l'albumine à 25%, l'immunoglobuline anti-cytomégalovirus, l'immunoglobuline anti-hépatique B, l'immunoglobuline anti Rh, l'immuno-globuline antivaricelleuse-antizostérienne, l'immunoglobuline sérique, l'immunoglobuline antitétanique, l'immunoglobuline intraveineuse (IVIG) et l'antithrombine III (ATIII). »

b) Demandes au nom du Groupe-hémophiles

Par son recours collectif, Monsieur David Page demande une indemnisation pour les personnes qui, comme lui, ont été contaminées par le VHC suite à l'utilisation du sang ou des produits sanguins collectés, fabriqués, distribués et approuvés par les Intimés durant la période visée.

c) Faute alléguée

De façon générale, les fautes reprochées aux Intimés par Monsieur David Page sont les suivantes :

1. Avoir négligé ou refusé ou omis d'implanter ou d'exiger l'implantation, dès janvier 1986, ou ultérieurement, des tests indirects aux fins de protéger les receveurs ou utilisateurs du sang et dérivés du sang et ainsi améliorer la sécurité et la qualité des réserves de sang et dérivés du sang et préserver celle-ci d'une contamination au VHC alors que l'on connaissait ou que l'on aurait dû connaître les risques élevés d'une contamination à l'HNANB par les transfusions de sang ou dérivés du sang;

2. Avoir négligé de recourir au procédé d'inactivation virale approprié pour les produits sanguins destinés aux hémophiles.

- Requête et Affidavit Page.

Onglets 2 et 20

d) Les questions traitées collectivement

Les questions de faits et de droit identifiées par l'Honorable juge Morneau devant être traitées collectivement sont les suivantes :

a) les Intimés avaient-ils l'obligation de prendre les moyens nécessaires à prévenir et minimiser les risques pour les receveurs de sang et dérivés du sang de contamination par le VHC;

b) les Intimés ont-ils commis une faute en négligeant, en refusant, en omettant d'implanter ou en négligeant d'exiger l'implantation des tests indirects ALT et anti-HBc ou l'un ou l'autre d'entre eux à quelque moment au cours de la période débutant le 1er janvier 1986 et se terminant le 1er juillet 1990;

c) dans l'éventualité où la Cour concluait affirmativement aux questions A) et B) quelle aurait été la réduction de l'incidence de l'Hépatite C post-transfusionnelle du fait de l'implantation des tests de dépistage indirects ALT et anti-HBc ou l'un ou l'autre d'entre eux;

d) la réponse à la question C) a-t-elle une conséquence sur le fardeau de preuve des membres du groupe au stade des réclamations individuelles; dans l'affirmative laquelle?

D) PROJET DE RÈGLEMENT

1. **Approbation :**

Les représentants des recours collectifs et les gouvernements fédéral, provinciaux et territoriaux (ci-après désignés « gouvernements *FPT* ») et ont conclu un projet de règlement de ces recours collectifs conditionnel à l'approbation par les tribunaux du Québec, de la Colombie-Britannique et de l'Ontario sans différence matérielle.

Ce projet de règlement a reçu l'approbation des Cabinets et Conseil du Trésor de chacun des gouvernements FPT.

Le règlement proposé prévoit que les gouvernements FPT s'engagent selon les conditions du projet de règlement, à payer une somme de UN MILLIARD DEUX CENT SEPT MILLIONS DOLLARS (1 207 000 000 $) incluant les intérêts au 30 septembre 1999, aux personnes décrites dans les recours collectifs et à un groupe beaucoup plus restreint de personnes indirectement contaminées par le VIH qui n'ont pas été indemnisées aux termes de programmes antérieurs.

- R.A.E. : Régime d'aide extraordinaire annoncé à l'égard du VIH par le gouvernement du Canada le 14 décembre 1989.
- P.P.T.A. : Programme provincial et territorial d'aide annoncé à l'égard du VIH par les gouvernements des provinces et des territoires le 15 septembre 1993.
- Rapport actuariel ECKLER, p. 43, no 10.4.

Les représentants des recours collectifs sont fiers de présenter et de recommander à la Cour l'approbation du projet de règlement pour les motifs suivants :

- le projet fournira rapidement aux victimes une indemnisation pour les dommages subis;
- le règlement proposé élimine tous les risques et aléas d'un procès;
- les indemnités sont payables en fonction de la sévérité de la maladie;
- les membres bénéficient d'une possibilité de réajustement de leur indemnité;
- les indemnités prévues sont à plusieurs égards équivalentes sinon plus généreuses que les indemnités généralement accordées par les tribunaux de droit commun;
- le projet de règlement est juste et raisonnable.

2. **Exclusion de la S.C.C.R. :**

La S.C.C.R. ne fait pas partie de ce projet de règlement s'étant placée depuis juillet 1998 sous la protection de la *Loi sur les arrangements avec les créanciers des compagnies*, S.R.C. 1985, ch. C-36 (ci-après désignée la « LACC »).

Le jugement à intervenir sur la requête en approbation du projet de règlement ne peut donc avoir aucun effet légal ou conséquence à l'égard de la S.C.C.R. en raison des ordonnances de sursis de procédures rendues à l'égard de la S.C.C.R.

- Diverses Ordonnances rendues en vertu de la LACC.

  Onglet 3

- Lettre des procureurs de la S.C.C.R.

  Onglet 4

- 16^{e} rapport en date du 22 juillet 1999 de la firme Ernst & Young, séquestre nommé par la Cour en vertu de la LACC.

  Onglet 5

3. **Curateur public :**

Le Curateur public du Québec a été récemment mis au fait du projet de règlement. Les documents de règlement lui ont été soumis pour fins de commentaires afin de s'assurer de la conformité des termes du projet de règlement avec la *Loi sur le curateur public* (L.R.Q., c. C-18). La position du Curateur public est plus amplement décrite à sa lettre du 9 août 1999. Nous avons retenu la suggestion du Curateur public quant à la conclusion à inclure au jugement.

- Lettre du Curateur public du Québec en date du 9 août 1999.

  Onglet 6

4. **Fonds d'aide aux recours collectifs :**

Le Fonds d'aide aux recours collectifs a reçu signification de la requête en approbation de la transaction et ne s'y oppose pas.

- Lettre du Fonds d'aide aux recours collectifs en date du 30 juillet 1999.

  Onglet 7

II. NATURE DE LA PROCÉDURE

A) PROCÉDURE :

Requête pour approbation d'une transaction en vertu de l'article 1025 C.p.c.

B) BUT RECHERCHÉ :

Le but recherché est de donner un effet légal au projet de règlement une fois que le Tribunal sera satisfait qu'il sert bien les intérêts des membres absents :

- *Delaunais* c. *P.G.Q. et Fonds d'Aide*, (1992) R.J.Q. 1578, pp. 1578-1580);

  Onglet J-2

- *Acef-Centre et Francine Power* c. *Bristol-Meyers Squibb Company*, C.S.M. 500-06-000004-917, 8 août 1995, Honorable juge André Denis;

  Onglet J-3

- *Dabbs* c. *SunLife Assurance Co. of Canada*, (1998), O.J., No. 1598, Ontario, Ct. Gen. Div. 96-Ct-022862, 5 février 1998;

  Onglet J-4

- *Pelletier* c. *Baxter Health Care Corp.*, J.E. 98-1200;

  Onglet J-5

- *Podmore* c. *SunLife du Canada*, C.S.M., 500-06-000015-962, 15 janvier 1998, l'Honorable juge Louis S. Tannenbaum.

  Onglet J-6

C) **AVIS AUX MEMBRES :**

Le Tribunal, en conformité avec les articles 1025 C.p.c. et 63 R.P.C.S., a ordonné la signification d'avis publics pour aviser les victimes que les requérants demandaient l'approbation de la transaction :

- jugement de l'Honorable juge Nicole Morneau en date du 17 juin 1999; (déjà au dossier);
- affidavit de Ron Etherington;

  Onglet 8

- séance d'information le 8 juillet 1999 au Groupe-transfusés à Montréal;

  Onglet 9

- envoi postal aux membres transfusés absents et figurant sur nos listes après le 8 juillet 1999;

  Onglet 10

- séance d'information le 28 mars 1999 au Groupe-hémophiles tenue à Drummondville;
- envoi postal d'une copie de l'entente et de la brochure explicative à tous les membres hémophiles inscrits, soit cent soixante-huit (168) membres.

  Onglet 11

Conformément aux avis publiés, les opposants pouvaient et ont transmis à la firme PriceWaterhouse Coopers des oppositions :

- affidavit de Pierre Seccaraccia, de la firme PriceWaterhouse Coopers;

  Onglet 12

- chaque opposant du Québec a reçu un avis de convocation pour le 1er *septembre 1999, en salle 15.03 du Palais de justice de Montréal;*

  Onglet 13

La situation en Ontario :

- lettre de Me Peterson déjà produite lors de la conférence préparatoire du 5 août 1999;

La situation en Colombie-Britannique :

- lettre de Me Sharon Matthews déjà produite lors de la conférence préparatoire du 5 août 1999.

D) **QUESTION EN LITIGE :**

La question en litige est de déterminer si le projet de règlement est juste, équitable, raisonnable et dans le meilleur intérêt des membres des deux recours collectifs.

Critères applicables :

- Aux fins de répondre à cette question, nous proposons d'appliquer les critères développés par la jurisprudence et qui sont énumérés dans le jugement *Dabbs* c. *SunLife Assurance Co. of Canada*, soit :

1) « Likeliwood of recovery, or likelihood of success;

2) Amount and nature of discovery evidence;

3) Settlement terms and conditions;

4) Recommendation and experience of counsel;

5) Future expenses and likely duration of litigation;

6) Recommendation of neutral parties if any;

7) Number of objectors and nature of objections;

8) The presence of good faith and the absence of collusion. »

Onglet J-4

Cette jurisprudence ontarienne a été reprise par l'Honorable juge J. Halperin dans l'affaire *Pelletier* c. *Baxter Health Care Corp.*, J.E. 98-1200. Avant d'analyser ces critères, un aperçu des faits pertinents aux présents recours est nécessaire.

III. L'HÉPATITE ET LE NOMBRE DE PERSONNES INFECTÉES

A) LA MALADIE :

Le Dr Bernard Willems, hépatologue, viendra décrire ce qu'est l'hépatite et, plus particulièrement l'histoire naturelle de l'Hépatite chronique C.

- Curriculum vitae du Dr. Bernard Willems et liste des publications;

  Onglet 14

- Rapport d'expert du Dr. Bernard Willems, en français.

  Onglet 15

Voir aussi:

- Requête Honhon, par. 40 à 51;

  Onglet 1

- Affidavit du Dr. Frank Anderson et pièces à son soutien;

  a) Curriculum vitae du Dr. Anderson;

  b) « Representative review articles » par le Dr. Anderson;

  c) « Hepatitis Knowledge Network Newsletter » publiée par le Dr. Anderson;

  Onglet 16

- Article : Poynard et al, « Natural History of Liver Fibrosis Progression in Patients with chronic Hepatitis C », The Lancet, 22 mars 1997, vol. 349, p. 285;

  Onglet 17

- Affidavit du Dr. Bryce Larke de la S.C.C.R. (ci-après « Affidavit Larke »), par. 5 à 9; 13 à 31; 37 à 45; 53 à 58;

  Onglet 18

- Affidavit du Dr. Irwin Walker :

  a) Curriculum vitae du Dr. Irwin Walker;

  b) « Chart setting out the incidence of factor deficiencies in individuals »;

  c) Article rédigé par le Dr. Irwin Walker intitulé « Survey of the Canadian Hemophilia Population »;

  d) Article rédigé par le Dr. Irwin Walker et al. intitulé « The Canadian Hemophilia Registry (CHR) as the Basis for a National system for Monitoring Use of Factor Concentrates », publié en 1995 »;

  e) Article rédigé par le Dr. Irwin Walker et al. intitulé « Causes of Death in Canadians with Hemophilia 1980-1995 », publié en 1998;

  Onglet 19

- Requête David Page;

  Onglet 2

- Affidavit de David Page et les pièces à son soutien.

  Onglet 20

B) <u>LE NOMBRE DE VICTIMES :</u>

1. **<u>Témoignage du Dr. Robert S. Remis</u>**

   À cet égard, nous ferons entendre le Dr. Robert S. Remis :

   - Curriculum vitae du Dr. Robert S. Remis;

     Onglet 21

   - Rapport d'expert du Dr. Robert S. Remis, 6 juillet 1999.

     Onglet 22

   - (R-8) Étude effectuée par le Dr. Robert S. Remis, MD, MPH, FRCPC, Estimation du nombre de transfusés infectés par le virus de l'Hépatite C au Canada, 1960-1985 et 1990-1992 :

     Onglet 23

- (R-6) Étude effectuée par le Dr. Robert S. Hogg, Kevin J.P. Craib, Michael O'Shaughnessy et David Pi et Martin Schecter « Through the looking glass : The Health and Socio Economic Status of Hepatitis C Positive Transfusion Recipients, 1986-1990 » :

  Onglet 24

  - Curriculum vitae de M. Robert S. Hogg

    Onglet 25

- (R-7) Étude intitulée « Estimating the Prognosis of Hepatitis C. Patients Infected by Transfusion in Canada between 1986 and 1990 », effectuée par Canadian Association for the Study of the Liver Working Group on Hepatitis C Prognosis :

  Onglet 26

  - Curriculum vitae du Dr. Murray Krahn;

  Onglet 27

  - Lettre du 10 juin 1999 du Dr. Murray Krahn.

  Onglet 28

IV. LES RECOURS :

A) LA REQUÉRANTE MADAME DOMINIQUE HONHON :

Madame Dominique Honhon est résidente de Hull et a reçu le 21 février 1989, lors d'un accouchement pratiqué au Centre Hospitalier de l'Outaouais, des transfusions de culots globulaires, un dérivé du sang, collectés, fabriqués, distribués et approuvés par les Intimés.

♦Extraits du dossier médical de Madame Honhon (R-1)

Onglet 29

Avant le 21 février 1989, elle n'avait jamais reçu de transfusion de sang ou de dérivés du sang et n'avait jamais ressenti de problème ou été suivie pour un problème de santé relié à sa fonction hépatique.

Ce n'est qu'en février 1994 qu'elle apprît que son profil sanguin présentait une anomalie suite à la communication de résultats de tests sanguins effectués à sa demande aux fins d'obtenir une augmentation de sa couverture d'assurance-vie, laquelle lui a d'ailleurs été refusée.

♦ Documents relatifs au refus de couverture (R-2)

Onglet 30

Inquiétée par ce refus et les résultats communiqués, elle requît une investigation de sa condition, laquelle confirma au printemps 1994 le bilan hépatique anormal et une sérologie de l'Hépatite C positive;

♦ Requête Honhon, par. 2 à 5

Onglet 1

- Interrogatoire de Madame Honhon, pages 34 à 46.

  Onglet 31

B) **LE REQUÉRANT, MONSIEUR DAVID PAGE :**

Monsieur David Page est atteint de l'hémophilie B sévère, résultant d'une déficience en facteur IX, une condition qui entraîne des hémorragies internes, surtout dans les articulations; la maladie a été diagnostiquée à l'âge d'un an, en 1953.

De juillet 1985 jusqu'au début des années 1990, il a reçu, comme traitement pour sa maladie, des produits sanguins faits de concentrés de facteur IX fabriqués aux États-Unis par la compagnie Cutter (aujourd'hui Bayer), obtenu à partir du plasma de donneurs canadiens collecté et distribué par la S.C.C.R.

Depuis 1979, l'année de la création du Centre pour l'hémophilie de l'est du Québec, il a subi des tests de laboratoire incluant, entre autres, des tests pour mesurer les enzymes du foie; ces tests se sont toujours avérés normaux.

En novembre 1993, suite à une visite annuelle au Centre d'hémophilie pour l'est du Québec, il a été informé par lettre que les tests confirmaient la présence des anticorps du virus de l'hépatite C. Selon son médecin, l'infection était causée par les produits sanguins qu'il avait utilisés; il n'y avait alors aucune indication en ce qui concerne la date de l'infection.

- Requête Page, par. 2.1 à 2.19

  Onglet 2

- Affidavit de David Page.

  Onglet 20

C) **L'INTERVENANT, MONSIEUR ÉTIENNE SAUMURE :**

Dans le cadre des traitements qui lui ont été administrés afin de contrôler son hémophilie, l'Intervenant a reçu de nombreuses transfusions sanguines ou dérivés du sang.

À compter de l'année 1985, l'état de santé de l'Intervenant s'est progressivement détérioré.

En 1988, admis d'urgence dans un établissement de santé, on diagnostiquait, grâce à des tests de dépistage indirect, une HNANB.

Ce résultat fut confirmé subséquemment par un diagnostic du HCV.

D) **LES INTIMÉS :**

1. **Le P.G.C. (Gouvernement du Canada) :**

   La santé est à la fois de compétence fédérale et provinciale. Le gouvernement fédéral exerce un pouvoir de réglementation sur le sang et dérivés du sang au Canada;

- Requête Honhon, par. 8 à 14;

  Onglet 1

- Requête Page, par. 3.09 à 3.11;

  Onglet 2

- Le Bureau des produits biologiques (ci-après désigné « *B.O.B.* »);

- Le Laboratoire de lutte contre la maladie (ci-après désigné « *L.L.C.M.* »);

- *Loi sur la santé nationale et Bien-être social*, L.R.C., 1985, c. N-10;

- *Loi sur les aliments et drogues*, L.R.C., 1985, c. F-27 (ci-après désignée « *L.A.D.* ») :

Le P.G.Q. (Gouvernement du Québec) :

Les provinces canadiennes exercent les compétences qui leur sont dévolues par la Constitution dont la responsabilité principale dans le domaine des soins de la santé. Les provinces jouent, dans ce contexte, un rôle dans la transmission des données sur la santé publique.

- Requête Honhon, par. 15 à 19;

  Onglet 1

- Requête Page, par. 4.1 à 4.5.

Dans le cas de l'exercice de cette compétence, le Gouvernement du Québec a adopté diverses lois, plus particulièrement :

- *Loi sur le ministère de la santé et services sociaux*, L.R.Q., c. M-19.2;

- *Loi sur la santé et les services sociaux*, L.R.Q., c. S-5;

- *Loi sur la protection de la santé publique*, L.R.Q., c. P-35.

En vertu de ces lois, le Gouvernement du Québec doit assurer la protection des utilisateurs de sang et dérivés du sang et prendre les mesures d'urgence nécessaires à cette protection lorsque la santé publique est menacée.

Le Gouvernement du Québec, par son ministère de la santé, participait de 1983 à 1991 au Comité canadien du sang (ci-après désigné « *CCS* »), lequel, bien que non régi par un texte de loi, avait pour fonction d'assurer la direction et le financement du programme de sang opéré par la S.C.C.R.

Le CCS fut en avril 1991, remplacé par l'Agence canadienne du sang (ci-après désignée « *ACS* »), qui avait pour mandat, selon sa loi constitutive :

« Diriger, coordonner et financer les divers éléments du système canadien du sang qui ont besoin d'une orientation nationale conformément aux principes établis par le Ministère de la santé pour l'utilisation du sang humain, des produits sanguins et de leurs succédanés à des fins thérapeutiques. »

reprenant dans un texte formel, le mandat jusque là confié au CCS.

3. **La S.C.C.R. :**

La S.C.C.R. détenait de facto le monopole dans le domaine de la distribution du sang et dérivés du sang au Canada. Elle se considérait d'ailleurs responsable du maintien, de la sécurité et de la sûreté du sous-système canadien des réserves de sang et dérivés du sang. L'objectif du programme des services transfusionnels de la S.C.C.R. consistait à faire en sorte que le système de santé canadien dispose d'un approvisionnement en produits de qualité, qu'il s'agisse de sang ou dérivés du sang.

- Requête Honhon, par. 20 à 24;

  Onglet 1

- Requête Page, par. 3.01 à 3.03;

  Onglet 2

- Affidavit Larke, par. 4.

  Onglet 18

Dans le cadre de la prestation de ces services, les services transfusionnels de la S.C.C.R. étaient également tenus de gérer efficacement leurs propres opérations, de veiller à ce que leurs méthodes et produits soient conformes à la réglementation et à toutes les normes de l'industrie, de planifier ses activités en vue de répondre aux autres besoins des établissements canadiens ainsi que d'appuyer la recherche dans le domaine de la médecine transfusionnelle.

- La S.C.C.R. s'est placée sous la protection de la LACC en juillet 1998;
- Les successeurs de la S.C.C.R. sont :
  - HEMA-Québec;
    - Lettre de Héma-Québec

    Onglet 32
  - Service canadien du sang (ci-après désigné « SCS »);
    - Requête en intervention dans le recours collectif de l'Ontario.

    Onglet 33

E) **AUTRES ACTEURS IMPORTANTS :**

- Dr. Roger Perrault;

- Dr. Martin G. Davey;
- Dr. Blair Wittemore;
- Dr. John Brian McScheffrey;
- Dr. Morris A. Blajchman;
- Dr. Victor Feinman;
- Requête Honhon, par. 25 à 33.

Onglet 1

V. LE SANG, DÉRIVÉS DU SANG ET LEUR TRAITEMENT :

A) GÉNÉRAL

- Procédures normalisées quant à la collecte du sang;
- Requête Honhon, par. 35;

  Onglet 1

- Procédures normalisées quant au traitement des dons de sang;
- Requête Honhon, par. 36;

  Onglet 1

- Tous les dons de sang sont soumis à deux séries de tests :

  1. la première consiste à déterminer le groupe sanguin selon les systèmes ABO et RH;
  2. la deuxième consiste à soumettre les échantillons à plusieurs tests de dépistage pour certaines maladies infectieuses. Dans les faits, durant la période pertinente, les tests suivants étaient effectués sur tous les dons de sang :

     i. syphilis;

     ii. antigènes de surface du virus de l'Hépatite B (HBsAg);

     iii. VIH.

Seules les unités dont tous les tests sont négatifs pouvaient être mis en circulation car elles n'étaient plus supposées représenter un danger pour la santé. Si l'un des tests s'avérait positif, ces donneurs ne pouvaient plus faire don de leur sang et ce renseignement était consigné dans le registre informatisé du donneur de la S.C.C.R.

- Affidavit Larke, par. 59 à 63.

  Onglet 18

B) PARTICULARITÉS QUANT AUX HÉMOPHILES

Jusqu'au début des années 1950 : transfusion de sang total.

À compter du début des années 1950 : les transfusions de sang total sont remplacées par des infusions de plasma frais congelé.

Au cours des années 1960 : le traitement standard devient le cryoprécipité, un dérivé du plasma frais congelé.

À compter de la fin des années 1960 on utilise des concentrés lyophilisés (facteurs déshydratés par congélation rapide).

À compter de juillet 1985, tous les facteurs concentrés utilisés au Canada étaient manufacturés à partir d'un procédé de traitement à la chaleur à l'état sec du sang pour éliminer le VIH.

À compter de juillet 1988, les facteurs concentrés distribués au Canada sont manufacturés en utilisant une méthode de traitement à la chaleur à l'état liquide ou à la vapeur.

À compter de 1993, on utilise une préparation du facteur VIII produite en utilisant la technologie de l'ADN recombinant qui ne comporte aucun risque d'infection virale.

À compter de 1997, il en est de même pour le facteur IX.

- Affidavit de David Page, en date du 17 août 1999.

  Onglet 20

VI. LA RESPONSABILITÉ CIVILE DES INTIMÉS :

A) HISTORIQUE

L'analyse rétrospective du contexte factuel relatif à l'introduction des tests indirects aurait constitué une part importante du procès aux fins de pouvoir répondre aux deux questions collectives identifiées par les Honorables juges Grenier et Morneau, à savoir :

> « *a) Les Intimés avaient-ils l'obligation de prendre les moyens nécessaires à prévenir et minimiser les risques pour les receveurs de sang et dérivés du sang de contamination par le VHC?*
>
> *b) Les Intimés ont-ils commis une faute en négligeant, refusant, omettant d'implanter ou négligeant l'implantation des tests indirects ALT et anti-HBc ou l'un ou l'autre d'entre eux à quelque moment au cours de la période débutant le 1er janvier 1986 et se terminant le 1or juillet 1990? »*

Aux fins de brosser ce bref aperçu historique, nous avons préparé un texte joint en Annexe. Une mise en garde s'impose cependant comme le rappelait l'Honorable juge L'Heureux-Dubé dans l'arrêt *Lapointe* c. *Hôpital Le Gardeur* (1992) 1 R.C.S., 351-352.

Onglet J-7

- Sommaire des faits relatifs à l'introduction des tests indirects de dépistage et documents pertinents;

  Cahier des faits

- Affidavit de David Page en date du 17 août 1999.

  Onglet 20

B) LA FAUTE

1. Difficultés inhérentes à l'établissement de la faute :

- Les chances d'établir une faute durant la période visée quant à l'établissement des tests indirects auraient varié sensiblement au fur et à mesure que les développements scientifiques intervenaient.

  Ainsi, au début de 1986, l'établissement d'une norme américaine quant à l'établissement des tests indirects aurait été plus difficile à démontrer qu'en 1989. Dans le même sens, l'établissement d'une norme mondiale en 1986 aurait été, à toutes fins pratiques, impossible alors qu'en 1989 et 1990, il aurait pu en être autrement.

  Les victimes contaminées à la fin de la période visée avaient donc, en quelque sorte, de meilleures chances de réussite que celles contaminées au début de 1986.

- En l'absence d'une norme, nous aurions prétendu que la prudence aurait dicté l'introduction des tests indirects ou de l'un des deux tests. Cette prudence se serait-elle imposée de la même façon durant toute la période?

- La faute aurait-elle été conjointe et solidaire entre tous les intimés? Ultimement, un tribunal aurait pu en venir à la conclusion que seul un des Intimés a commis une faute. Si cet Intimé s'était révélé être la S.C.C.R., le recouvrement de la créance des victimes aurait été illusoire.

- Le Gouvernement fédéral, par le B.O.B. et le L.L.C.M., avait-il l'obligation d'agir pour prévenir la contamination des victimes? Pouvait-il déléguer à la S.C.C.R. son pouvoir sur cette question de santé publique?

- Le Gouvernement fédéral, par le B.O.B. et le L.L.C.M., pouvait-il se réfugier derrière la L.A.D. pour prétendre ne pas avoir d'obligation légale d'agir à l'égard du sang complet et ce, avant les amendements à la Loi en 1989?

- Le Gouvernement fédéral, par le B.O.B. et le L.L.C.M., avait-il l'obligation en vertu des Chartes de porter secours à des personnes en danger au fur et à mesure qu'il prenait connaissance des données scientifiques?

- Les gouvernements auraient-ils pu invoquer l'absence de responsabilité en prétendant qu'ils ne pouvaient être tenus responsables puisque la non introduction des tests constituait une décision de nature politique et non une décision de nature opérationnelle?

- Le Gouvernement du Québec, à titre de membre du C.C.S., avait-il l'obligation d'agir pour prévenir la contamination des victimes? Le Gouvernement du Québec pouvait-il se contenter d'agir passivement et se fier à la S.C.C.R. à laquelle il avait, comme les autres provinces et le fédéral, délégué de facto un monopole et ses pouvoirs?

- Le Gouvernement du Québec avait-il l'obligation, en vertu du tissu législatif en place au Québec, de forcer l'instauration des tests de dépistage indirects?

- La S.C.C.R. constituait-elle un mandataire des gouvernements engageant leur responsabilité?

- La délégation de pouvoirs à la S.C.C.R. par les gouvernements quant à la qualité du sang, tout en maintenant un contrôle financier sur ses activités, leur permettait-elle de s'exonérer de toute responsabilité? À l'inverse, la S.C.C.R. n'était-elle pas en droit de prétendre, ne serait-ce qu'en garantie, à la seule responsabilité de l'État?

2. **Particularités pour les hémophiles :**

Les problèmes reliés à l'établissement de la faute se posent pour les hémophiles en des termes quelques peu différents, soit :

- Outre ce qui précède, l'établissement d'une norme mondiale concernant l'utilisation des tests indirects pour les dons de plasma aurait été difficile à faire puisque les États-Unis n'ont pas introduit le test anti-HBc au cours de la période 1986-1990 et n'ont introduit le test ALT qu'à compter de février 1987. Il est à noter cependant que l'Allemagne et certains centres transfusionnels européens utilisaient le test ALT pour le plasma au cours de la période visée.

- L'établissement d'une norme concernant l'utilisation du procédé d'inactivation virale à la chaleur à l'état liquide avant le mois de décembre 1987, date à partir de laquelle Santé Canada a exigé l'utilisation de ce procédé, aurait également dû être fait par le requérant David Page, ce qui n'aurait évidemment pas manqué de porter à controverse;

L'ensemble de ces questions démontre qu'il était fort difficile de prévoir avec exactitude le résultat final d'un éventuel procès sur cette seule question de la faute.

Malgré le nombre important de poursuites déposées au Canada contre les Intimés ou certains d'entre eux, peu de jugements ont été rendus et quelques exemples que nous avons démontrent l'ampleur des difficultés auxquelles se sont heurtés ces recours.

- Affidavit Larke, par. 91 à 93;

  Onglet 18

- Exhibit 63;

  Onglet 34

- *X* c. *PGQ et S.C.C.R.*, [1992] 500-06-000012-910, le 10 août 1992, juge François Bélanger;

  Onglet J-8

- *Godin* c. *PGQ et S.C.C.R.*, C.A.Q. [1993], 500-09-001564-921;

  Onglet J-9

- *Sutherland* c. *S.C.C.R.*, [1994] 17 O.R. (3d) 645;

  Onglet J-10

- *Pittman* c. *S.C.C.R.*, [1994] 112 D.L.R. (4d) 257;

  Onglet J-11

- *Walker* c. *CRCS*, [1997] 39 C.C.L.T. (2d) 1 et [1999] 43 O.R. (3d) 461, C.A.;

  Onglet J-12

- *Roberge* c. *Bolduc*, [1991] 1 R.C.S. 374;

  Onglet J-13 - NON MIS

- *Villemure* c. *Hôpital Notre-Dame*, [1973] R.C.S. 716, p. 718, [1970] C.A., 538;

  Onglet J-14

- *G.* c. *C.*, [1960] B.R. 161, p. 167;

  Onglet J-15

- *Neuzen* c. *Korn*, no 23775, 2 février 1995 et 19 octobre 1995;

  Onglet J-16

- *Anderson* c. *Chasney*, [1949] 4 D.L.R. 71 (Man. C.A.) conf. par [1950] 4 D.L.R. 223 (C.S.C.);

  Onglet J-17

- *Hollis* c *Dow Corning Corp.*, [1995] SCJ no 104, 26;

  Onglet J-18

- BAUDOUIN, J.-L., La responsabilité civile, 4e édition, Cowansville, Ed. Yvon Blais Inc. 1994, n° 143, p. 101.

  Onglet J-19

C) LIEN DE CAUSALITÉ

1. Généralités :

Cet élément essentiel de la responsabilité civile demeure souvent difficile à établir, surtout dans les dossiers de responsabilité médicale.

En l'espèce, à partir de la définition des groupes et des questions en litige, cet élément faisait partie à la fois des questions collectives et individuelles à être décidées.

Questions collectives aux termes des jugements des Honorables juges Grenier et Moreau :

> *« c) dans l'éventualité où la cour concluait affirmativement aux questions a) et b), quelle aurait été la réduction de l'incidence de l'hépatite C post-transfusionnelle du fait de l'implantation des tests de dépistage indirects ALT et anti-HBc ou l'un ou l'autre d'entre eux;*

d) la réponse à la question c) a-t-elle une conséquence sur le fardeau de preuve des membres du Groupe au stade des réclamations individuelles; dans l'affirmative laquelle? »

En réponse à ces questions, l'étude des docteurs Blajchman et Feinman a été déterminante puisqu'elle a établi que le taux de réduction des HNANB aurait été de 80% à 85 % avec l'introduction des tests indirects.

- R-36 : Étude : « Post-transfusion Hepatitis : Impact of Non-A Non-B Hepatitis Surrogate Tests », the Lancet, vol 345, 7 janvier 1995.

  Onglet 35

- Requête Honhon.

  Onglet 1

Cependant, cette étude fut l'objet de critiques et, encore là, un long débat aurait été nécessaire aux fins d'établir avec plus de précision le taux de réduction des HPT.

Peu importe l'issue de ces questions collectives, les membres auraient eu à établir individuellement le lien de causalité. Il y aurait alors lieu de tenir compte de la nature du virus et des modes de transmission :

• intravenous drug use	:	61%
• multiple sexual partners	:	22%
• unknown	:	15%
• transfusions	:	11%
• family member with Hepatitis C	:	8%
• known history of Hepatitis C	:	6%
• other risks	:	6%
• homosexual contact	:	4%
• occupational exposure to blood	:	4%
• dialysis	:	2%

- Affidavit Larke (Exhibit 9: « *Hepatitis C Risk Factor-A Community Profile, BC Health and Disease Surveillance* », Volume 4, No 11/12, November and December 1995).

  Onglet 36

Chaque membre aurait eu à établir par prépondérance de preuve qu'il a été contaminé par transfusion et non par un des autres modes de transmission ci-avant mentionnés.

Dans une deuxième étape, ayant établi par prépondérance que la cause la plus probable de la contamination était la transfusion, chaque membre aurait dû démontrer que cette transfusion a été la cause de sa contamination; donc, la mise en place d'une procédure de « traceback » pour retrouver le donneur de sang de l'unité impliquée aux fins de déterminer la séropositivité de celui-ci.

Cet exercice, facile en soi dans la mesure où l'on parle d'un seul donneur, est beaucoup plus difficile lorsque plusieurs donneurs sont impliqués.

- Affidavit Larke, par. 32 à 36.

Onglet 18

- Exhibits 21 et 22 : H. Vrielink et als., *Look-back Study of Infectivity of Anti-HCV ELISA – Positive Blood Components*, The Lancet, Volume 345, January 14, 1995; B. Willems et als., *Distribution of Genotypes in Liver Damages in HCV-RNA Positive Blood Donors and Relationship between Hepatitis C Virus (HCV) Genotypes and Sources of Infection in HCV-RNA Positive Blook Donors,*, Can J. Gastroenterol, Volume 10, Supplement A, February,1996 .

2. **Les hémophiles :**

La question de la causalité se pose en des termes quelques peu différents pour les hémophiles.

Comme on le sait, au cours de la période visée, le traitement de l'hémophilie ne se faisait pas à partir de sang total, mais plutôt par des infusions de concentrés de plasma. Le plasma est la partie liquide du sang qui contient les facteurs coagulants déficients chez les hémophiles. En tout temps pertinent au recours, les concentrés de plasma étaient faits à partir d'un pool de plasma fabriqué par des dons provenant de milliers de donneurs, desquels on avait extrait les facteurs coagulants. Au Canada, jusqu'en juillet 1988, les concentrés étaient ensuite chauffés à l'aide d'un procédé à l'état sec, pour assurer l'inactivation virale, puis placés dans des petits dispositifs transportables. À compter de juillet 1988, les facteurs concentrés distribués au Canada étaient produits en utilisant un procédé à la chaleur à l'état liquide, nouvelle technique d'inactivation beaucoup plus sécuritaire pour les hémophiles.

Le fait pour les Intimés de ne pas avoir procédé aux tests indirects a entraîné un haut niveau de contamination au VHC des pools de plasma, avec lesquels étaient manufacturés les facteurs concentrés destinés aux hémophiles canadiens. Devant un tel niveau de contamination, le procédé d'inactivation virale à la chaleur à l'état sec utilisé jusqu'en juillet 1988 était inefficace dans l'élimination du VHC présent dans les pools de plasma. Même à compter de juillet 1988, où les produits ont commencé à être traités à la chaleur à l'état liquide, le risque de contamination des hémophiles n'était pas totalement éliminé puisque les concentrés de plasma ont continué d'être fabriqués à partir de pools de plasma qui contenaient du sang qui n'avait toujours pas été soumis aux tests indirects pour le VHC.

En terme de causalité, cette réalité pose un double problème pour les hémophiles, l'un d'ordre individuel et l'autre d'ordre collectif.

Au niveau individuel, la plupart des hémophiles se traitaient à l'aide de concentrés en provenance des pools de plasma contaminés et ce, même avant la période visée. Dans ce contexte, il aurait fallu que chacun des membres individuellement puissent démontrer, par prépondérance de preuve, qu'il a effectivement été contaminé par un produit fabriqué ou distribué durant la période visée et non avant. Évidemment, compte tenu de la méthode de fabrication des pools de plasma à partir d'une multitude de dons, le « traceback », pour les hémophiles, s'avère totalement impossible.

Au niveau collectif, Monsieur David Page aurait eu à démontrer, par prépondérance de preuve, que si les Intimés avaient eu recours aux tests de dépistage au cours de la période visée, l'utilisation du nouveau procédé à la chaleur à l'état liquide, dès le 1er janvier 1986, aurait permis d'éliminer substantiellement les risques de contamination des pools de plasma distribués aux hémophiles.

- BERNARDOT, Alain, KOURI, Robert P., La responsabilité civile médicale, Sherbrooke, Les Éditions Revue de Droit, Université de Sherbrooke, 1980, p. 72;

  Onglet J-20

- *Laferrière* c. *Lawson*, [1991] 1 R.C.S. 541;

  Onglet J-21

- *Snell* c. *Farrell*, [1990] 2 R.C.S. 311;

  Onglet J-22

- BAUDOUIN, J.-L., La responsabilité civile, 4e édition, Cowansville, Ed. Yvon Blais Inc., 1994, no 466, p. 278 et no 475, p. 283.

  Onglet J-23

- *Houde* c. *Côté*, [1987] R.J.Q. 723, p. 727;

  Onglet J-24

- *Gburek* c. *Cohen*, [1988] R.J.Q. 2424, pp. 2446-2447;

  Onglet J-25

D) LES DOMMAGES

Les requêtes n'indiquaient aucun montant de dommages. Cette question est analysée dans le cadre de l'étude du projet de règlement de façon comparative avec ce qui pourrait être accordé par les tribunaux de droit commun.

- Étude comparative des dommages – tableaux 1 à 4

En l'espèce, la question des dommages aurait été purement individuelle car chaque membre aurait eu à établir le degré de sévérité de la maladie, ses dommages pécuniaires, etc.

Le règlement est par ailleurs plus avantageux qu'un jugement de droit commun où les dommages sont attribués sous la forme d'une somme forfaitaire sous réserve de l'article 1616 C.c.Q.

- *Andrews* c. *Grand & Toy Alberta Ltd.*, [1978] 2 R.C.S. pp. 229-236.

  Cahier dommages

Comme nous l'avons vu, l'Hépatite est une maladie progressive et imprévisible. Il est donc impossible d'établir avec certitude l'état de santé du patient pour une période de temps donnée. Au surplus, les connaissances scientifiques démontrent que cette progression peut s'échelonner sur une période de dix à vingt ans.

Le rajustement périodique prévu à l'entente est plus avantageux que l'article 1615 C.c.Q. qui prévoit une réévaluation dans les trois ans suivant le jugement. Cependant, pour une maladie évoluant sur une période de dix à vingt ans, ce délai de trois ans risque de ne pas changer grand chose à l'entente proposée.

- BAUDOUIN, J.-L., La Responsabilité Civile, 5e édition, p. 210, note 274.

  Onglet J-26

D'autre part, le tribunal aurait tenu compte, dans l'établissement des dommages, d'une éventuelle faute contributive d'un tiers ou de la victime elle-même. Ainsi, la consommation d'alcool aurait été, par exemple, un élément important à considérer puisqu'elle aggrave sensiblement l'évolution de la maladie.

E) LA PRESCRIPTION

Pour de nombreuses victimes dont la contamination est intervenue avant ou durant la période visée, la prescription est déjà acquise.

- Avant 1994 : articles 2260a) et 2262 C.C.B.C.
- *Loi sur l'application de la réforme du Code civil*, article 6
- Articles 2908, 2925 et 2956 C.c.Q.
- *X* c. *PGQ et S.C.C.R.*, 1992, 500-06-000012-910, le 10 août 1992, juge François Bélanger

  Onglet J-8

- *Godin* c. *PGQ et S.C.C.R., C.A.Q.*, 1993, 500-09-001564-921.

  Onglet J-9

VII. LE PROJET DE RÈGLEMENT :

A) GÉNÉRALITÉS

Il n'est pas de notre intention de reprendre ici en détail les termes et conditions du règlement sinon que de mettre en lumière les grandes lignes de celui-ci.

♦Règlement relatif à l'Hépatite C 1986-1990

Onglet 38

La philosophie ayant présidé à la négociation et à la rédaction du projet de règlement est la suivante :

- Indemnisation selon des critères objectifs;
- Réajustement périodique de l'indemnisation pour tenir compte du caractère progressif de la maladie;
- Éviter la discrimination entre les membres des groupes;
- Indemnisation similaire pour tous les Canadiens;

- Minimiser l'intervention de professionnels pour le dépôt de la demande d'indemnisation aux termes du programme;
- Préserver les droits de tous les réclamants de contester une décision de l'administrateur du programme.

B) ANALYSE DU RÉGIME À L'INTENTION DES TRANSFUSÉS :

1) Définitions : (art. 1.01)
   a) *fonds en fiducie; risque assumé par les victimes*
   b) personne directement infectée
   c) personne indirectement infectée
2) Buts et forces exécutoires (art. 2.01 et 2.02)
3) Preuve exigée aux fins d'indemnisation :
   a) réclamation par une personne directement infectée (art. 3.01)
   b) preuve supplémentaire (art. 3.03)
   c) procédure d'enquête (art. 3.04)
   d) date limite de la première réclamation (art. 3.08)
   e) lien de causalité (renversement du fardeau)
4) Indemnisation (art. 4)
   a) montants payables;
   b) étude comparative avec le droit commun
      - Tableaux 1 à 4
      - Jurisprudence en matière de dommages
5) Indemnisation en cas de décès (art. 5)
6) Indemnisation des personnes reconnues à charge et membres reconnus de la famille (art. 6)
7) Réajustement des paiements (art. 7)
8) Nature des paiements (art. 8)
9) Administration
10) Règlement des différends.

C) PARTICULARITÉS DU RÉGIME DES HÉMOPHILES :

1. Définition (art. 1.01) :

   Hémophile directement infecté.

2. Preuve exigée aux fins d'indemnisation :
   a) Réclamation d'un hémophile directement infecté (art. 3.01).

b) Procédure d'enquête :

– Aucun « Traceback »

– Aucune biopsie

3. Indemnisation (art. 4) :

Paiement forfaitaire pour les co-infectés (art. 4.08(2)).

4. Indemnisation en cas de décès (art. 5).

VIII. LES INTERVENANTS À ÊTRE NOMMÉS PAR LE TRIBUNAL AUX TERMES DE L'ARTICLE 10.01 DE LA CONVENTION DE RÈGLEMENT

Nous proposerons à la Cour de reporter à une date ultérieure la nomination des divers intervenants.

IX. RAPPORT ACTUARIEL

Nous nous proposons maintenant d'établir à la Cour que le fonds de 1,207 $ MILLIARD est suffisant aux fins d'indemniser l'ensemble des victimes membres des groupes.

Nous établirons aussi que le risque assumé par les victimes est raisonnable.

À cet égard, nous ferons entendre M. Jacob Lévy de la firme d'actuaires Eckler & Associés Ltée :

- Curriculum vitae de Monsieur Jacob Lévy et document de présentation de la firme Eckler et Associés Ltée;

  Onglet 39

- Rapport actuariel de la firme Eckler et Associés Ltée;

  Onglet 40

- Rapport intitulé « Report of the Blood Recipient Notification Projected for Hepatitis C », Rapport final, 4 mai 1998;

  Onglet 41

- Rapport de Andrew Wister, Ph.D., intitulé « Expert Report on Family Configurations for Hepatitis C Class Action Case »;

  Onglet 42

- Curriculum vitae de Monsieur Andrew Wister, Ph.D.;

  Onglet 43

- Extrait (page 20) d'un document publié par Statistiques Canada, février 1999, intitulé « Employment Earnings and Hours »;

  Onglet 44

- Extrait (page 13) de l'édition 1998 d'une publication intitulée « Canadian Life and Health Insurance Facts »;

  Onglet 45

- Extraits (pages 50-54) d'un document publié par Statistiques Canada, « General Social Survey Analysis Where Does Time Go? », août 1991, préparé par Andrew S. Harvey, Katherine Marshall et Judith A. Frederick;

  Onglet 46

- Policy Precis of the McMaster Centre for Health Economics and Policy analysis working Paper/Policy commentary Series Paper « Variation in Pharmacare Coverage Across Canada »;

  Onglet 47

- Extraits de « The *Canada Pension Plan Act* provisions pertaining to the definitions of the Consumer Price Index and the Pension Index »;

  Onglet 48

- « Treasury Board of Canada Secretariat Travel Directive »;

  Onglet 49

- Affidavit de Margaret Woltz, 12 juillet 1999 :

  Onglet 50

  a) « Certification order of Mr. Justice Brokenshire in *Nantais et al* v. *Telectronics et al*, dated August 29, 1995 »;

  b) « Order of Mr. Justice Brokenshire in *Nantais et al* v. *Telectronics et al* dated November 24, 1995 »;

  c) « Judgment of Mr. Justice Brokenshire in *Nantais et al* v. *Telectronics approving settlement* dated October 3, 1997 ».

- Copie de l'interrogatoire de Messieurs Jacob Lévy et Murray Segal en Ontario, le 4 août 1999.

  Onglet 51

X. LES OPPOSITIONS

A) LES TRANSFUSÉS :

Les oppositions seront commentées verbalement lors de l'audition.

B) LES HÉMOPHILES :

Vu le nombre plus restreint d'oppositions, des commentaires ont été intégrés dans un tableau :

- Tableau de réponse aux oppositions.

Onglet 52

XI. LES CONCLUSIONS

A) ARGUMENTATION SUR LES AVANTAGES DU RÈGLEMENT

En guise de conclusion, nous entendons reprendre les critères développés par la jurisprudence dans l'affaire *Dabbs* afin de démontrer que le projet de règlement est juste, équitable, raisonnable et dans le meilleur intérêt des membres des deux groupes et doit en conséquence être approuvé.

1. Chances de succès et chances de recouvrer la créance
2. Ampleur et *nature* de la preuve
3. Termes et conditions de l'entente
4. Recommandations et expérience des procureurs
5. Dépenses et durée d'un litige
6. Recommandations de parties neutres

   - Affidavit de Pierre Desmarais, Directeur Général, Société Canadienne de l'Hémophilie – Section Québec

     Onglet 53

7. Nombre de personnes qui s'objectent et nature des objections
8. Bonne foi et absence de collusion.

B) PROJET DE JUGEMENT

MONTRÉAL, le 20 août 1999

MARCHAND MAGNAN MELANÇON FORGET
Procureurs de Dominique Honhon

(S) PETIT BLAQUIÈRE DAGENAIS

PETIT BLAQUIÈRE DAGENAIS
Procureurs de David Page

This is Exhibit "E" referred to in the
affidavit of Asvini Krishnamoorthy
sworn before me at Toronto, Ontario
this 29th day of January, 2016

William Knights

A Commissioner for taking affidavits
within the Province of Ontario

#4548
115

No. C965349
Vancouver Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

Anita Endean, as representative plaintiff

Plaintiff

AND:

The Canadian Red Cross Society
Her Majesty the Queen in Right of the Province of British Columbia, and
The Attorney General of Canada

Defendants

AND:

Prince George Regional Hospital, Dr. William Galliford,
Dr. Robert Hart Dykes, Dr. Peter Houghton, Dr. John Doe,
Her Majesty the Queen in Right of Canada, and Her Majesty the Queen
in Right of the Province of British Columbia

Third Parties

Proceeding under the *Class Proceedings Act*, R.S.B.C. 1996, C. 50

SUBMISSIONS OF THE REPRESENTATIVE PLAINTIFF ON APPLICATION FOR APPROVAL OF THE PROPOSED SETTLEMENT

CAMP CHURCH & ASSOCIATES
4th Floor, 555 West Georgia Street
Vancouver, BC V6B 1Z5

J.J. Camp, Q.C.
Sharon D. Matthews
Tel: (604) 689-7555
Fax: (604) 689-7554

Counsel for the Plaintiff in Action No. C965349

::ODMA\GRPWISE\CC_DOM.CC_PO.SSDATA:62337.1

GRANT KOVACS NORELL
930 - 1040 West Georgia Street
Vancouver, BC V6E 4H1

Bruce Lemer
Tel: (604) 609-6699
Fax: (604) 689-6688

Co-Counsel for the Plaintiff in Action No. C965349

BLAKE CASSELS & GRAYDON
2600 - 595 Burrard Street
Box 49314
Vancouver, BC V7X 1L3

Marvin Storrow, Q.C.
David Gruber
Tel: (604) 631-3300
Fax: (604) 631-3309

Counsel for the Plaintiff in Action No. A981187

THE MINISTRY OF ATTORNEY GENERAL
LEGAL SERVICES BRANCH
1301 - 865 Hornby Street
Vancouver, BC V6Z 2H4

D. Clifton Prowse
Keith Johnston
Tel: (604) 660-3093
Fax: (604) 660-2636

Counsel for the Defendant and Third Party Her Majesty the Queen in Right of the Province of British Columbia in Action No. C965349

DEPARTMENT OF JUSTICE
900-840 Howe Street
Vancouver, BC V6Z 2S9

Ivan Whitehall, Q.C.
Catharine Moore
John R. Haig, Q.C.
Laura Wanamaker
Tel: (604) 666-2061
Fax: (604) 666-2760

Counsel for the Defendant and Third Party Attorney General of Canada/Her Majesty the Queen in Right of Canada in Action No. C965349 and the Defendant the Attorney General of Canada in Action No. A981187

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DEFINED TERMS AND ACRONYMS

Act means the *Class Proceedings Act*, RSBC 1996, c.50

anti-HBc test means a blood test which detects the antibodies to the Hepatitis B core antigen associated with the viral inner core which reflects active viral replication in the blood.

Approval Date means the date when the last judgment or order of the Courts approving the Settlement Agreement becomes final, provided there are no material differences in said judgments or orders.

BC Hemophiliac Class Action means which means *Mitchell et al.* v. *Canada et al.*, SCBC Action No. A981187 (Vancouver Registry)

BC Transfused Class Action means this class action

BC Transfused Class Members means all British Columbia residents who:

a. received Hepatitis C positive whole blood, packed red cells, platelets, plasma (both fresh frozen and banked) or white blood cells ("whole blood and blood products") during the Class Period in British Columbia (the "Transfusion") and were infected with the Hepatitis C virus as a result of the Transfusion and have tested positive for the antibody to the Hepatitis C virus;
b. have been infected with the Hepatitis C virus by a spouse or parent who was infected with the Hepatitis C virus as a result of receiving whole blood and blood products during the Class Period;
c. are the personal representatives of all residents of British Columbia who have become deceased as a result of being infected with the Hepatitis C virus as result of receiving whole blood and blood products during the Class Period; and
d. are the executors or administrators of the estates of all residents of British Columbia who have become deceased subsequent to being infected with the Hepatitis C virus as result of receiving whole blood and blood products during the Class Period.

British Columbia means Her Majesty the Queen in Right of the Province of British Columbia

Canada means The Attorney General of Canada.

CRCS means The Canadian Red Cross Society.

Class Actions means collectively the Transfused Class Actions and the Hemophiliac Class Actions.

Class Action Counsel means the counsel for the representative plaintiff(s) in each of the respective Class Actions.

Class Members means collectively the Transfused Class Members and the Hemophiliac Class Members

Class Period means the period from January 1, 1986 to July 1, 1990, inclusive.

Court means any one of the Superior Court of Justice for Ontario, the Supreme Court of British Columbia and the Superior Court of Quebec, and **Courts** means collectively the Superior Court of Justice for Ontario, the Supreme Court of British Columbia and the Superior Court of Quebec.

Federal Government means the Government of Canada.

FPT Governments means collectively the Federal Government and the Government of each Province and Territory in Canada.

Funding Agreement means the Funding Agreement between the Parties made as of June 15, 1999, and tendered to the court at an earlier attendance on June 16, 1999.

HBV means Hepatitis B virus isolated in the late 1960s or 1970.

HCC means hepatocellular cancer

HCV means the Hepatitis C virus isolated in late 1988 or 1989.

Hemophiliac means a person who has or had a congenital clotting factor defect or deficiency including a defect or deficiency in Factors V, VII, VIII, IX, XI, XII, XIII or von Willebrand factors.

Hemophiliac HCV Plan means the plan which is Schedule B to the Settlement Agreement.

Hemophiliac Class Actions means collectively the Ontario Hemophiliac Class Action, the British Columbia Hemophiliac Class Action and the Quebec Hemophiliac Class Action means.

Hemophiliac Class Members means collectively the Ontario Hemophiliac Class Members, the Class certified in the British Columbia Hemophiliac Class Action and the Class certified in the Quebec Hemophiliac Class Action

Krever Inquiry means the Commission of Inquiry on the Blood System in Canada with Mr. Justice Krever as the Commissioner

NANBHV means the non-A, non-B hepatitis virus first described in about 1974, a high percentage of which is now known to have been caused by HCV.

Ontario Hemophiliac Class Action means *Kreppner et al.* v. *Canada et al.*, Action no. 98-CV-146405 (Toronto).

Ontario Transfused Class Action means *Parsons et al.* v. *Canada et al.*, Action no. 98-CV-141369 (Toronto).

Party means any one of the representative plaintiffs in the Class Actions or of the FPT Governments, and **Parties** means collectively the representative plaintiffs in the Class Actions and the FPT Governments.

PT Governments means collectively the Government of each Province and Territory in Canada.

Plan means either the Hemophiliac HCV Plan or the Transfused HCV Plan, and **Plans** means collectively the Hemophiliac HCV Plan and the Transfused HCV Plan.

Program means the program devolved from the Federal/Provincial/ Territorial Assistance Program for HIV Secondarily-Infected Persons announced by the FPT Governments on December 15, 1998.

Quebec Hemophiliac Class Action means *Page et al.* v. *Canada et al*, Action no. 500-06-000068-987 (Montreal)

Quebec Transfused Class Action means *Honhon et al.* v. *Canada et al.*, Action no. 500-06-000016-960 (Montreal).

Releasees has the meaning set out in Section 1.01 of the Settlement Agreement.

Settlement Agreement means the 1986-1990 Hepatitis C Settlement Agreement between the Parties made as of June 15, 1999, and tendered to the court at an earlier attendance on June 16, 1999.

Spouse has the meaning set out in Section 1.01 of either Plan.

Transfused Class Actions means collectively the Ontario Transfused Class Action, the British Columbia Transfused Class Action and the Quebec Transfused Class Action

Transfused Class Members means collectively the Ontario Transfused Class Members, British Columbia Transfused Class Action Class Members and the Quebec Transfused Class Action Class Members

Transfused HCV Plan means the plan which is Schedule A to the Settlement Agreement.

Trust means the trust to be created pursuant to the Funding Agreement.

Trust Agreement means the trust agreement which the court will be asked to order.

Trust Fund means the trust fund to be established pursuant to the Funding Agreement.

INTRODUCTION

Nature of the Application

1. This is an application by the representative plaintiff for an order approving the proposed settlement of the BC Transfused Class Action on the terms set out in the Settlement Agreement and for ancillary orders to begin implementing the settlement.

2. The proposed settlement is a pan-Canadian settlement which allows persons infected with HCV through the blood supply from January 1, 1986 - July 1, 1990 to be compensated for the effects of the disease based on their individual circumstances now and in the future.

3. The terms of the Settlement Agreement provide that it will not be efficacious unless the courts in BC, Ontario and Quebec approve it, without material differences, in each of the BC Transfused Class Action, the BC Hemophiliac Class Action, the Ontario Transfused Class Action, the Ontario Hemophiliac Class Action, the Quebec Transfused Class Action and the Quebec Hemophiliac Class Action. This application is proceeding concurrently in this Court with an application in the BC Hemophiliac Class Action. Applications are proceeding at the same time in Ontario for approval of the Ontario Transfused Class Action and the Ontario Hemophiliac Class Action. Applications will be proceeding on August 23, 1999 for approval of the Quebec Transfused Class Action and the Quebec Hemophiliac Class Action.

Background of the Litigation and Settlement Negotiations

4. This action arises out of the infection of the BC Transfused Class Members or their family members with HCV through the Canadian blood supply during the Class Period. This action was brought in 1996 by Anita Endean pursuant to the *Class Proceedings Act*, R.S.B.C. 1996, c.50 (the "*Act*") (Authorities, Tab 1) for damages for personal injuries and wrongful death.

5. The defendants are the CRCS which supplied the impugned blood and blood products to the BC Transfused Class Members throughout the Class Period, and both British Columbia and Canada, which funded and regulated the CRCS blood program through the Canadian Blood Committee (the "CBC") throughout the Class Period.

6. The action against the CRCS is framed in negligence for supplying infected whole blood and blood products to the BC Transfused Class Members in breach of its duty to take all reasonable steps to ensure that the blood and blood products it supplied would not cause disease in those who received them. Particulars of the negligence include: (a) the failure, throughout the Class Period, to implement surrogate tests available to identify markers of HCV in the blood of donors so that blood infected with HCV could be rejected before being transfused; and (b) the failure to implement a test to detect the antibody to HCV (the "HCV antibody test") in a timely manner.

7. Endean alleges that British Columbia and Canada were negligent in failing to take steps to cause the CRCS to implement the surrogate tests and that the CBC and the CRCS were agents of the Canada and British Columbia and accordingly, Canada and British Columbia are vicariously liable for the acts of the CRCS and the CBC.

8. The plaintiff also pleads that British Columbia and Canada, through their agent the CBC, intentionally destroyed evidence relevant to the plaintiff's action in negligence and that the plaintiff's ability to prosecute her claim has been irreparably prejudiced by these actions ("spoliation"). The plaintiff sought general damages, economic damages and punitive damages. The Court of Appeal ruled that spoliation is not a stand alone cause of action in Canada and ordered the certification order be amended to remove the pleading. Leave to appeal this issue to the Supreme Court of Canada was granted and the matter is set to be heard on December 10, 1999.

9. This Court certified this action to proceed as a class proceeding pursuant to the *Act* on May 22, 1997. All of the defendants appealed. The CRCS abandoned its appeal on the eve of the appeal and the appeal only proceeded on the issue of spoliation.

10. On March 27, 1998, shortly before the Court of Appeal handed down its reasons on the appeal, the FPT Governments announced they were prepared to offer up to $1.1 billion to compensate all Canadians who were infected with HCV through the

blood supply during the Class Period and to compensate persons secondarily infected with HIV by persons who were infected through the blood supply.

11. Since that time, the parties have been primarily occupied with negotiating the proposed compensation. Although a date for the trial of the common issues is set to commence January 17, 2000, there have been no examinations for discovery and only a preliminary production of documents by Canada. However, in late 1997 Mr. Justice Krever issued the Report of the Krever Inquiry. This report canvasses many of the factual issues of this case.

Lemer Affidavit, Chambers Brief, vol.6, para.13, p.1588

12. The CRCS applied for and received protection from its creditors under the *Companies' Creditors Arrangement Act*, R.S.C. 1985, c. C-36 (the "*CCAA*") by order of Mr. Justice Blair dated July 20, 1998. The stay against the CRCS has been extended by further orders of the court.

Elliott affidavit, Chambers Brief, vol. 2, tab 3, p. 220, para. 35

13. On December 18, 1998 a framework agreement for compensation was reached between the representative plaintiffs in the Class Actions and the FPT Governments. By June 15, 1999, all of the parties executed the formal settlement documentation and shortly thereafter presented it to the Courts for approval.

The Role of the Court in Approving the Settlement

14. All settlements of actions certified pursuant to the *Act* must be approved the by the court: *Act,* s.35 (Authorities, Tab 1). The role of the court on this application is to consider whether the settlement is fair, reasonable and in the best interests of the B.C. Transfused Class Members as a whole or to reject it if it not does not meet that test. It is not the role of the court to rewrite the terms of the Settlement Agreement but to scrutinize the settlement carefully because it will bind a number of persons who are not before the court and the court must ensure that it will not "sell short" the potential rights of those unrepresented parties.

> *Haney Iron Works v. Manufacturers Life Insurance Co.* (1998), 169 DLR (4th) 565 (BCSC) at 572 (Authorities, Tab 12)
> *Sawatzky v. Societe Chirugicale Instrumentarium Inc.* [Q.L. 1999 BCJ No.1814] (SC) at p.5 (Authorities Tab 27)
> *Dabbs v. Sun Life Assurance Co. of Canada* [Q.L. 1998 OJ No.1598] (*"Dabbs No.1"*), (Authorities Tab 8) further reasons at (1998), 40 OR (3d) 429, at p.439-440 (*"Dabbs No.2"*) (Authorities Tab 9)
> *Harrington v. Dow Corning Corp.* [QL 1999 BCJ No.321] (SC) (Authorities Tab 13)

FACTS

The Natural History of Hepatitis C

15. This action is brought as a personal injury action arising out of the infection of Class Members and/or their family members (in the case of claims brought on behalf of deceased persons) with HCV. The proposed settlement was designed to reflect the unique features of HCV disease process, including the vast differences in symptoms and clinical conditions that persons infected with HCV experience.

16. Hepatitis means inflammation of the liver which can damage and kill liver cells. The virus causing Hepatitis C was identified in late 1989 and before that time it was known as non-A non-B hepatitis.

Anderson Affidavit, Chambers Brief, vol.4, p.896-897

17. HCV is transmitted parentally. That means that blood of a person infected with HCV must come into contact with the blood of another person for that other person to become infected with HCV. The most common means of transmission of HCV is sharing needles during intravenous drug use ("IVDU"). Prior to testing blood donations for antibodies to HCV in 1990, the second most common means of transmission of HCV was the transfusion or receipt of blood or blood products. Less common means of transmission include use of intra-nasal cocaine, body piercing, tattoos, sexual transmission and perinatal transmission (in vitro transmission from mother to child). Rare means of transmission include exposure during health care occupations and household transmission. A portion of the population which is infected with HCV does not report exposure to a known means of transmission of the virus.

Anderson Affidavit, Chambers Brief, vol.4, p.899

18. The incidence of HCV among the population of IVDU is very high. Some estimates put it at 80% or higher after 10 years of IV drug use. For this reason, if a person has participated in IVDU and has been infected with HCV, the most likely cause

of the infection is IVDU unless a causal link can be drawn to some other source of infection, such as a traceback which establishes that a donor of the blood received by the person has been infected with HCV.

Anderson Affidavit, Chambers Brief, vol.4, pp.900-901

19. Among blood recipients, a "traceback" can be used to attempt to link an infected blood donor with an infected recipient. A traceback procedure is one in which the units of blood received by a person are identified and the donor of the blood is located and tested. If the donor tests positive for the HCV antibody, the connection between the donor and the recipient is considered to be strong enough to presume that the donor's blood was the cause of the infection in the recipient.

Anderson Affidavit, Chambers Brief, vol.4, p.900

20. The rates of sexual transmission reported in the literature are very low. The ranges typically reported are a lifetime risk between 0 and 4% for all sexual partners. The rates of perinatal transmission reported in the literature are also low, ranging between 0 and 3%. These rates obviously apply only to women of childbearing years, not the whole infected population.

Anderson Affidavit, Chambers Brief, vol.4, p.901

21. Blood tests are now used to determine whether a person is or was infected with HCV. An antibody test detects the antibody to HCV in the blood of a person and

reveals whether or not the person has ever been infected with HCV. It does not disclose whether that person is currently infected with HCV or when that person became infected with HCV. A polymerase chain reaction test ("PCR" test) reveals whether detectable levels of the virus are present in the blood of a person, and as such determines whether a person is currently infected with HCV. Tissue from a liver biopsy can also be tested for and/or reveal the presence of the antibody to HCV or the virus itself.

Anderson Affidavit, Chambers Brief, vol.4, pp.902-903

22. Once infected with HCV, a person will either clear HCV after an acute stage of the illness within approximately six months of infection, or the person will develop chronic HCV infection. Acute HCV infection is extremely mild and many patients are neither sick nor aware that they have contracted hepatitis C. At present, the medical literature establishes that approximately 20-25% of all persons infected clear HCV within approximately one year of infection. Those persons will still test positive for the antibody but will not test positive on a PCR test, nor will they experience any progressive liver disease due to HCV.

Anderson Affidavit, Chambers Brief, vol.4, pp.902, 905
Dr. Brian Kneteman Vol 4 Page 717

23. Persons who do not clear the virus after the acute stage of the illness have chronic HCV. They may or may not experience progressive liver disease due to HCV,

depending on the course the HCV takes in their body and whether treatment subsequently achieves a sustained remission.

Anderson Affidavit, Chambers Brief, vol.4, p. 905

24. HCV causes inflammation and necrosis of liver cells. The level of inflammation varies among HCV patients. The various levels of inflammation are referred to as grades and the grading system is from 0 (no inflammatory cells) to 4 (inflammation throughout the whole of the liver lobule).

Anderson Affidavit, Chambers Brief, vol.4, pp.905-906

25. Inflammation and necrosis results in scarring of liver tissue (fibrosis). Fibrosis also appears in various patterns in HCV patients, and these patterns are referred to as stages, usually 1 through 4 (cirrhosis). A clear benchmark of disease progression after no fibrosis but before cirrhosis is whether the pattern of fibrosis is such that the scar tissue in one portal area of the liver extends out and joins other scar tissue in another portal area or to a central vein. This pattern is called bridging fibrosis. Fibrosis which does not have a bridging pattern is referred to as non-bridging fibrosis. Bridging fibrosis is a clear benchmark because it is readily apparent on a biopsy and because once a patient reaches bridging fibrosis, that patient is more likely to progress to cirrhosis, the most serious form of fibrosis, unless the disease progression is arrested at that point.

Anderson Affidavit, Chambers Brief, vol.4, pp.906-908

26. If a patient is cirrhotic, they are either a compensated cirrhotic (liver is able to function relatively normally), or a decompensated cirrhotic (liver function is failing). A compensated cirrhotic has generally more than one third of the liver which is still free from fibrosis. Decompensated cirrhosis occurs when approximately 2/3 of the liver or more is compromised and the liver is no longer able to perform one or more of its essential functions. It is diagnosed by the presence of one or more conditions which alone or in combination are life threatening without a liver transplant. This clinical state of affairs is also referred to as liver failure or end stage liver disease. Once in decompensation, a person will generally die within approximately 2-3 years unless he or she receives a liver transplant.

Anderson Affidavit, Chambers Brief, vol.4, pp.908-909

27. Some patients who progress to cirrhosis but not to decompensated cirrhosis may develop hepatocellular cancer ("HCC"). This is a cancerous tumour which originates in the liver. Life expectancy after this stage is approximately 1-2 years.

Anderson Affidavit, Chambers Brief, vol.4, p.909

28. Symptomatology of HCV infection can be difficult to assess because many of the symptoms are similar to common viruses and influenza types of illness. Many persons infected with HCV through a transfusion had a serious illness which necessitated

the transfusion and it can be difficult to determine whether symptoms are attributable to that underlying illness or the infection with HCV.

Anderson Affidavit, Chambers Brief, vol.4, p.911

29. The common symptoms of chronic HCV infection, prior to the disease progressing to cirrhosis or HCC, are fatigue, weight loss, upper right abdominal pain, mood disturbance, tension and anxiety. Of those symptoms, fatigue is the most common, the most subjective and the most difficult to assess. HCV patients report it as a feeling of exhaustion and lack of energy. There is controversy among medical community as to the prevalence of fatigue among persons infected with HCV. Some studies suggest severe fatigue is no more prevalent among persons infected with HCV than it is in the general population. Others suggest the contrary. The most common view is that approximately 10% of persons infected with HCV suffer from severe fatigue, while 5-10% of the general population suffers from severe fatigue. There is general consensus that persons infected with HCV who have used intravenous drugs report more fatigue and more severe fatigue than persons infected with HCV who have not used intravenous drugs. There is also general consensus that the level of fatigue experienced by an individual infected with HCV does not correlate with liver enzyme levels, or with the degree of inflammation or fibrosis on biopsy and may fluctuate from time to time.

Anderson Affidavit, Chambers Brief, vol.4, pp.911-912

30. Once a patient develops cirrhosis, additional symptoms may occur including: skin lesions, ascites (fluid in the abdomen), subacute bacterial peritonitis (abdominal infection), peripheral oedema (swelling in the legs), ecchimosis (a tendency to bruise), gynecomastia (breast enlargement in men), testicular atrophy, loss of male distribution of body hair, palmer erythema (redness of the palm), finger nail changes, portal hypertension and esophageal varices (back pressure in the veins of the liver, spleen and stomach) and splenomegaly (enlarged spleen).

Anderson Affidavit, Chambers Brief, vol.4, pp.912-913

31. At least 50% of HCV infected patients who have not progressed to decompensated cirrhosis or HCC are clinically asymptomatic. Of those who are symptomatic, a maximum of 50% are disabled from employment or work in the home. Overall then a maximum of 25% of persons who have not reached decompensated cirrhosis are disabled from work or employment in the home.

Anderson Affidavit, Chambers Brief, vol.4, pp.914, 919

32. The symptoms of decompensated cirrhosis cancer can generally be described as "liver failure" and include: portal hypertension, esophageal varices, (bleeding veins), ascites, jaundice, gastrointestinal hemorrhage, hepatic encephalopathy (built up toxins causing adverse effects in the brain), protein malnutrition, abnormal blood clotting factors

which can cause excessive bruising and bleeding, and subacute bacterial peritonitis (infected fluid in the abdomen).

Anderson Affidavit, Chambers Brief, vol.4, pp.914-916

33. For reasons which are not clear, but possibly due to the constant stimulation to the immune system caused by chronic viral infection, some patients with HCV suffer from conditions which are not as a result of liver disease but which are considered to be associated with HCV infection. They range from various forms of skin conditions to a type of lymphatic cancer, the association of which with HCV is still debated. Some of these associated conditions are medically urgent.

Anderson Affidavit, Chambers Brief, vol.4, pp.916-918

34. Almost all patients who develop HCC and decompensated cirrhosis are totally disabled from working.

Anderson Affidavit, Chambers Brief, vol.4, p.919

35. The medical tools most commonly used to assess an HCV infected person are blood tests and liver biopsies. The blood tests determine the presence of HCV, the presence of inflammation, the liver function, platelet count and rule out other liver disease. Biopsies are used to obtain a sample of liver tissue for microscopic examination and reveal

the extent and nature of inflammation and fibrosis in the liver and to rule out conditions other than HCV. Biopsy is the most accurate tool to assess the severity of the disease.

Anderson Affidavit, Chambers Brief, vol.4, pp.919-921

36. Two types of therapy using the drug interferon are presently approved for use in Canada. The first is interferon alpha monotherapy. The second is a combination of interferon alpha with ribavirin. The monotherapy has an overall sustained response rate of approximately 25% and the combination therapy has an overall sustained response rate of approximately 40%. Those who have a sustained response will not have any further progression of fibrosis and will not have inflammation or new necrosis of liver cells. They are "cured", although the fibrosis which has already occurred cannot be reversed.

Anderson Affidavit, Chambers Brief, vol.4, pp.923-924

37. The course of therapy is approximately 12 months and both types of therapy can cause significant side effects. These types of therapy are not recommended for patients who have certain complicating health conditions. Research continues to improve the treatments and the rate of sustained response to treatment.

Anderson Affidavit, Chambers Brief, vol.4, pp.925-928

38. If a patient progresses to decompensated cirrhosis, the only effective treatment is a liver transplant. This process does not cure the infection, but starts the infection again from the beginning.

Anderson Affidavit, Chambers Brief, vol.4, pp.928-929

39. There are few, if any, effective treatments for HCC.

Anderson Affidavit, Chambers Brief, vol.4, pp.929

40. There is some controversy pertaining to the treatment of children in part due to the absence of symptoms and a slower progression of disease.

Anderson Affidavit, Chambers Brief, vol.4 p.930

41. Disease modelling undertaken by the Canadian Association for the Study of the Liver "CASL") reveals the following probabilities of various medical outcomes for persons transfused who were infected with Hepatitis C as a result of a transfusion:

	YEARS POST TRANSFUSION			
PROBABILITIES OF MEDICAL OUTCOMES	**10**	**20**	**30**	**LIFETIME**
Probability of dying from all causes	46.4	61.7	76.3	100%
Probability of dying from HCV related causes	0.3	2.5	5.6	12.3%
Probability of developing HCV related cirrhosis	5.6	13.4	18.9	24%
Probability of developing HCV related decompensated cirrhosis or cancer	1	4.4	8.4	15.3%

Matthews Affidavit, Exhibits A (Eckler Report) and D (CASL Report), Chambers Brief Vol.3, pp. 571 and 697

Factual Synopsis Pertaining to Liability

42. To completely succeed at the trial of the common issues, the representative plaintiff must establish on a balance of probability that the CRCS, British Columbia and Canada ought to have implemented surrogate testing on or before January 1, 1986.

Elliott Affidavit, Chambers Brief, Vol.2, p.248, para.98

43. During the Class Period, the CRCS carried on a national system of blood collection in Canada.

Elliott affidavit, Chambers Brief, vol. 2, p. 230, para. 37

44. The CRCS' blood programme (with the exception of 20% of the donor recruitment costs) was funded entirely by the PT Governments during the Class Period through the CBC. The FPT Governments participated on the CBC. The CRCS was required to present a detailed budget each year for approval by the CBC.

Elliott Affidavit, Chambers Brief, Vol.2, p.255, para.123

45. The plaintiff alleges that during the Class Period the defendants knew or ought to have known that surrogate tests were available to assist in detecting the presence of HCV in blood donors and that the defendants failed to implement these tests. Some of the members of the American Association of Blood Banks implemented surrogate testing in early 1986 and the Association mandated its use in mid 1986. Research completed after

the Class Period showed that the implementation of the surrogate tests in Canada would have detected up to 85 percent of blood donors infected with HCV.

Elliott Affidavit, Chambers Brief, vol.2, p.237-248, para 62-96

46. During the Class Period, there was some disagreement within the scientific and blood banking communities in both North America and Eurgope regarding the validity and relevance of certain U.S. studies that supported surrogate testing as well as the appropriateness of the response of the U.S. blood banks to the issue of surrogate testing.

Elliott Affidavit, Chambers Brief, Vol.2, p.248-254, para.97-118

47. Throughout the Class Period, the CRCS was concerned that blood donations would be lost through the introduction of surrogate testing. This concern was partly related to the blood shortages which were being experienced at that time, the difficulty and expense of recruiting new donors and the cost of those units of blood that would be discarded. Finally, because Canada was not self-sufficient in plasma, discarding units would result in increased reliance on the purchase of commercial products for hemophiliacs which some believed were less safe.

Elliott Affidavit, Chambers Brief, Vol.2, pp.254, para.120

48. In the opinion of Class Counsel, the CRCS clearly did not meet the standard of U.S. voluntary blood bankers. However, other countries and blood agencies outside the U.S. chose not to implement surrogate testing in the Class Period. The CRCS will argue

that there were two respectable bodies of scientific opinion, and that the CRCS reasonably chose not to implement surrogate testing during the Class Period.

Elliott Affidavit, Chambers Brief, Vol.2, pp.256-257, para.126-128

49. It is very likely that the CRCS only has insurance to respond to Class Members' claims for the month of January, 1986. If a plan of arrangement is approved under the CCAA, the amount of funds available to satisfy all creditors, including the persons included in the Transfusion Class Actions and Hemophiliac Class Actions, is not likely to exceed $100 million. In the event that no plan of arrangement is approved, the available funds are likely to diminish because of the costs of protracted litigation. In addition to the claims of persons included in the Transfusion Class Actions and Hemophiliac Class Actions, there are also claims from trade creditors, and from a large number of persons infected with HCV and HIV who are not Class Members.

Elliott Affidavit, Chambers Brief, Vol.2, pp.229-30, para.36

50. Because the the CRCS blood programme was funded through the CBC, the PT Governments would have borne the costs of surrogate testing. The CRCS estimated in 1986 that the cost of implementing surrogate testing would be $8,971,000 in the first year. The cost rose to $19,941,000 if the cost of recruiting, collecting, processing the additional donors required to offset the loss caused by the surrogate tests was also

considered. In 1989, the CRCS provided an updated estimate to the CBC. The estimated cost of surrogate testing at that time was $10,390,800.

Elliott Affidavit, Chambers Brief, Vol.2, pp.255-6, para.124

51. The CBC was comprised of deputy ministers, assistant deputy ministers, and directors. It was charged with budgetary control and most of the appointees had financial administration backgrounds. The mandate of the CBC contains references to classical policy concerns such as "policy", "budget", "resources" and "costs". On the other hand, the preamble's statement "to direct the Canadian Blood system" suggests an operational function, as do the references to "setting standards".

Elliott Affidavit, Chambers Brief, Vol.2, p.263, para.150

52. British Columbia and Canada will argue that the CBC made a policy decision not to implement surrogate testing because of the costs estimated by the CRCS and their perception of the limited benefits to be derived from this cost expenditure.

THE LAW PERTAINING TO SETTLEMENT APPROVAL

The Legislative Framework

53. The *Act* governs this proceeding and section 35 of the *Act* stipulates that all settlements must receive approval of the Court. It reads as follows:

> 35. (1) A class proceeding may be settled, discontinued or abandoned only
>
> (a) with the approval of the court, and
>
> (b) on the terms the court considers appropriate.
>
> ...
>
> (3) A settlement under this section is not binding unless approved by the court.
>
> (4) A settlement of a class proceeding or of common issues affecting a subclass that is approved by the court binds every member of the class or subclass who has not opted out of the class proceeding, but only to the extent provided by the court.

Authorities Tab 1

54. In addition, this application is brought pursuant to section 12 of the *Act* which allows for the court to make incidental orders necessary to ensure the fair and expeditious determination. Section 12 reads as follows:

> 12. The court may at any time make any order it considers appropriate respecting the conduct of a class proceeding to ensure its fair and expeditious determination and, for that purpose, may impose on one or more the parties the terms it considers appropriate.

Authorities Tab 1

55. Finally, this application is brought pursuant to Rule 6(14) of the *Rules of Court*, which pertains to persons under a disability, and reads as follows:

> (14) Unless an enactment otherwise provides, where a claim is made by or on behalf of a person under disability, no settlement, compromise, payment or acceptance of money paid into court,

whenever entered into or made, so far as it relates to that person's claim, is binding without the approval of the court.

Authorities Tab 2

The Jurisprudence

56. The foremost question is whether the proposed settlement is fair, reasonable and in the best interests of the BC Transfused Class Members.

Haney at 572 (Authorities Tab 12)
Sawatzky at pp. 5-6 (Authorities Tab 27)
Dabbs No.1 at para. 9 (Authorities Tab 8)
Dabbs No.2 at 439-440 (Authorities Tab 9)

57. Although the court is required to scrutinize the settlement carefully on behalf of absent class members, the standard of fairness, reasonableness and the best of interests of class members is not a standard of perfection, nor is there only one "reasonable" settlement. Sharpe, J. (as he then was) put it this way in *Dabbs No. 2* at p.440 (Authorities Tab 9):

> "On the other hand, all settlements are the product of compromise and a process of give and take and settlements rarely give all parties exactly what they want. Fairness is not a standard of perfection. Reasonableness allows for a range of possible resolutions. A less than perfect settlement may be in the best interests of those affected by it when compared to the alternative of the risks and costs of litigation."

58. The court's role is also not to assess the proposed settlement from the perspective of any particular Class Member, but rather the court must concern itself with

the interests of the class as a whole. Class Members will be afforded the right to opt out, which has been held to alleviate the concerns of a particular Class Member.

Dabbs No. 1 p.3, para.11 (Authorities Tab 8)
Sawatzky at p.4 (Authorities Tab 27)

59. The following criteria have been considered in determining whether a settlement is fair, reasonable, and in the best interests of the Class Members:

(a) likelihood of recovery, or likelihood of success;

(b) amount and nature of discovery evidence;

(c) settlement terms and conditions;

(d) recommendation and experience of counsel;

(e) future expense and likely duration of litigation;

(f) recommendation of neutral parties, if any;

(g) number of objectors and nature of objections; and

(h) the presence of good faith and the absence of collusion.

Dabbs No.1 at para. 13 (Authorities Tab 8)
Haney at p.571 (Authorities Tab 12)

60. In *Dabbs No.1* at para 14 (Authorities Tab 8), Sharpe J. adopted the following quote from *Sparling v. Southam Inc.* (1988), 66 OR (2d) 225 (High Ct. Just.) at 230 (Authorities Tab 28) pertaining to the settlement of a derivative action:

> "'In approaching this matter, I believe it should be observed at the outset that the courts consistently favour the settlement of lawsuits in general. To put it another way, there is an overriding public interest in favour of settlement. This policy promotes the interests of litigants generally by saving them the expense of trials of

> disputed issues, and it reduces the strain upon an already overburdened provincial court system.
>
> In deciding whether or not to approve a proposed settlement under s.235(2) of the Act, the court must be satisfied that the proposal is fair and reasonable to all shareholders. In considering these matters, the court must recognize that settlements are by their very nature compromises, which need not and usually do not satisfy every single concern of all parties affected. Acceptable settlements may fall within a broad range of upper and lower limits.
>
> In cases such as this, it is not the court's function to substitute its judgment for that of the parties who negotiate the settlement. Nor is it the court's function to litigate the merits of the action. I would also state that it is not the function of the court to simply rubber stamp the proposal.
>
> The court must consider the nature of the claims that were advanced in the action, the nature of the defences to those claims that were advanced in the pleadings, and the benefits accruing and lost to the parties as a result of the settlement.'"

THE SETTLEMENT IS FAIR, REASONABLE AND IN THE BEST INTERESTS OF THE BC TRANSFUSED CLASS MEMBERS

The Likelihood of Recovery or Likelihood of Success

61. The Court must assess the Settlement Agreement against the likely outcome had the case gone to trial. In doing so, the approval hearing should not become a trial on the merits because one of the purposes of the settlement is to avoid such a trial. Rather the Court must be given sufficient evidence and analysis of the issues to reach "an intelligent and objective opinion of the probabilities of ultimate success should the claim be litigated".

Dabbs No.1 at p.4 (Authorities Tab 8)
Newman v. Stein 464 F.2d 689 (2nd Cir.- 1972) at p.692 (Authorities Tab 21)
Young v. Katz 447 F.2d 431 (5th Cir. - 1971) at p.433 (Authorities Tab 31)

62. To date, there have been no Canadian judgments arising out of infection with HCV from a blood transfusion or blood product. However, two judgments have been handed down arising out of HIV infection transmitted through blood transfusions. These cases centered on the allegation that the CRC failed to implement appropriate donors screening and testing procedures. The plaintiff succeeded in *Walker v. CRCS* (1997), 39 CCLT (2d) 1 (Ont.Gen. Div.) (Authorities Tab 30), appeal allowed in part (1999), 43 OR (3d) 461 (CA) (Authorities Tab 31) (leave to appeal to the Supreme Court of Canada pending). The plaintiff failed in *Pittman v. CRCS* (1994), 112 DLR (4d) 257 (Ont. Gen. Div.). These decisions provide some helpful guidance. First, the CRCS will be held to the standard adopted by equivalent organizations in the United States. Second, the CRCS will be held to a professional standard of care which will permit the CRCS to prefer one reputable body of opinion over another.

63. The case in negligence against the CRCS is strong although not without risk. However, the CRCS has filed for protection under the *CCAA* and an examination of the assets of the CRCS discloses that the CRCS would only be able to satisfy a very small percentage of any judgment obtained by the class claimants. Hence, it will be necessary for the class claimants to obtain judgment against the FPT Governments in order to make a full or substantial recovery.

64. The case against the FPT Governments is both more complex and more risky. First, the FPT Governments will allege that they have discharged their duty of care by delegating to an independent contractor, the CRCS. Whether a duty may be delegated depends upon relevant statutory provisions, the factual circumstances and policy considerations. There is authority for the proposition that a party on whom the law has imposed a statutory duty to do a positive act cannot escape liability by delegating the work to an independent contractor. There is also authority for the proposition that in some circumstances, the duty to take reasonable care may well be discharged by hiring and, if required, supervising a competent contractor to perform the particular work. In this case, the applications of these principles is complicated by the evidence that the CRCS misled the FPT Governments on the issue of surrogate testing.

Lewis v. British Columbia, [1997] 3 SCR 1145 (Authorities Tab 19)
Elliott Affidavit, Chambers Brief, vol.2, para.138, p.260-261

65. In addition, the plaintiff alleges that the CRCS was the agent of the FPT Governments who are vicariously liable for the acts of the CRCS. The evidence available to date indicates that the CBC exercised a considerable degree of financial and administrative control over the CRCS. Although the outcome is uncertain, it is the opinion of Class Counsel in British Columbia that there will be a finding that the CRCS was the agent of the FPT Governments. This opinion is not shared by Class Counsel in Ontario.

Lemer Affidavit, Chambers Brief, vol.6, para.16, pp.1589-1590
Elliott Affidavit, Chambers Brief, vol.2, para.133, p.259

66. The plaintiff also alleges that the CBC was negligent in its supervision of the CRCS. In the opinion of Class Counsel, there is a strong case that the CBC's actions were inadequate in this respect.

67. All of the foregoing will be defended by the FPT Governments on the basis that they were balancing social, political and budgetary goals and as such, these actions were policy decisions which cannot be reviewed by the court.

68. The policy-operational dichotomy is both factually and legally intensive. This area of the law has been the subject of several judicial pronouncements by the Supreme Court of Canada including *Just v. British Columbia,* [1989] 2 S.C.R. 1228) (Authorities Tab 15). On a factual basis, there is no doubt that surrogate testing would have cost many millions of dollars each year. The CRCS has estimated that the cost of surrogate testing and the cost of replacing lost blood would amount to as much as $20 million dollars per year. There was also a significant and reputable body of scientific opinion in the U.S. and in Europe that considered surrogate testing to be ineffective and that had to be weighed against the cost of undertaking it. If the FPT Governments were successful in establishing that their actions and inactions were in the nature of policy, the representative plaintiff

would have to establish that they were not bona fide in order to overcome this defense. It is the opinion of class counsel that the policy defense is formidable.

Elliott Affidavit, Chambers Brief, vol.2, para. 143-152, p.262-264

Lemer Affidavit, Chambers Brief, vol.6, para.19-20, pp.1590-1591

69. The representative plaintiff has also sought the right to seek judgment on the basis of spoliation but for the time being the law of this province is that it is not an independent tort.

70. In summary, Class Counsel are of the view that there is a strong case against the CRCS and a better than even chance of succeeding against the FPT Governments.

The Amount and Nature of the Discovery Evidence

71. As noted above, there has been little formal discovery but the proceedings before Mr. Justice Krever and the Report of the Krever Inquiry provided counsel with a substantial body of evidence and a form of discovery on the factual issues.

The Settlement Terms and Conditions

72. The goal of counsel for the representative plaintiffs was to develop a compensation scheme which provided for damages equivalent to those which would be available to the Class Members had the representative plaintiffs been successful at a trial on the common issues. In the course of the negotiations some compromises were made

but also significant gains were achieved in terms of betterment of court style damages. The following sections describe the Settlement Agreement and the Funding Agreement, discuss the compromises which were made and the betterment of court style damages which were achieved.

The Terms of the Settlement Agreement and the Funding Agreement

73. The Settlement Agreement and the Funding Agreement, executed by the Parties, comprise the proposed settlement.

74. The Settlement Agreement creates the following two Plans:

(a) the Transfused HCV Plan to compensate persons who are or were infected with HCV through a blood transfusion received in Canada during the Class Period, their secondarily-infected Spouses and children and their estates and certain family members in the event of their death; and

(b) the Hemophiliac HCV Plan to compensate Hemophiliacs who received or took blood or blood products in Canada during the Class Period and who are or were infected with HCV, their secondarily-infected Spouses and children and their family members.

75. The BC Transfused Class Members will be compensated in accordance with the HCV Transfused Plan. A summary of the benefits under the Plan are contained in the charts which are attached as Appendix "A" to these submissions.

76. Class counsel strived for a compensation package which would equate to likely damages handed down by our courts on a full liability basis. Class Counsel believe we have largely succeeded in this endeavour.

Qualification for Payment Under the Plans - Article 3

77. Under the Transfused HCV Plan, a person claiming to be a primarily-infected person must:

(a) establish that he or she was transfused with blood in Canada during the Class Period and is or was infected with the HCV virus; and

(b) swear that he or she never used non-prescription, intravenous drugs and that, to the best of his or her knowledge, was not infected with HCV before the Class Period began.

78. Once this evidentiary burden is satisfied, the Administrator can request a consent to a traceback procedure. A traceback will only disqualify a person from compensation if the traceback establishes that the person received blood before the Class

Period from a donor who tests positive for the antibody to HCV or that the donor or all of the donors of blood received during the Class Period test negative for the antibody to HCV.

79. A person who is disqualified based on the traceback procedure or has used intravenous drugs may be eligible for compensation if they can nevertheless establish on the balance of probabilities that they were infected with HCV for the first time by blood received from a transfusion during the Class Period.

80. In the case of the death of an HCV infected person, the Estate, Spouse, Child, Grandchild, Parent, Grandparent or Sibling (all as defined in the Plans) will receive compensation if the deceased HCV infected person qualified before his or her death or if the personal representative of the deceased qualifies the deceased person after his or her death.

81. No one may make a first claim under the Plans after June 30, 2010 unless:

(a) the claim is made within one year of the claimant reaching his or her age of majority; or

(b) the claim is made within three years of the claimant first learning of his or her infection with HCV and the Court grants leave to apply for compensation.

82. Death related claims are an exception to the above. They must be brought within the following time limits:

(a) the representative of the estate of a deceased HCV infected person must apply within the later of two years from the Approval Date or three years from the death; and

(b) each dependent and family member of a deceased HCV infected person must apply within the later of two years from the Approval Date or from the death or within one year of the claimant reaching his or her age of majority.

Compensation For Pain, Suffering and Loss of Amenities - Article 4.01

83. The medical conditions of persons who qualify as HCV infected persons are, as described above, far from uniform. Some are now free of the disease, others are grievously ill. Compensation levels are intended to reflect the severity of the medical conditions. All Class Members are entitled to a fixed payment as compensation for pain and suffering based upon the stage of his or her medical condition at the time of qualification under the Plan. They are also entitled to additional compensation if and when his or her medical condition deteriorates. The levels of compensation for pain suffering and loss of income are as follows:

Level	Medical Condition	Compensation
1	HCV Antibody Positive	$10,000
2	HCV PCR Positive	$20,000*
3	Non-Bridging Fibrosis or has undergone or met a protocol for compensable HCV drug therapy	$30,000 or loss of income if the Class Member waives the damages for pain and suffering
4	Bridging Fibrosis	No additional damages for pain and suffering, loss of income is triggered
5	Cirrhosis, porphyria cutanea tarda, thromobocytopenia, or glomerulonephritis	$65,000 and loss of income
6	liver transplant, decompensation of the liver, HCC, B-cell lymphoma, mixed cryoglobulinemnia, glomerulonephritis requiring kidney dialysis, or kidney failure	$100,000 and loss of income
Compensable HCV Therapy	Undergoes compensable HCV drug therapy - interferon monotherapy or combination therapy or other court approved therapy	$1,000 per month of completed treatment

* subject to an initial holdback of $5,000

84. The compensation is cumulative and any person who qualifies at any of the above levels is entitled to all of the payments at the levels prior to that level.

Loss of Income or Services in the Home - Articles 4.02 and 4.03

85. From Level 4 (bridging fibrosis) on, all Class Members who are disabled from working at employment or in the home due to their infection with HCV are entitled to receive payment for loss of income or loss of services in the home. Class Members at Level 3 (non-bridging fibrosis or compensable HCV drug therapy) have the option of either seeking loss of income payments or damages for loss of services in the home if they

forego the $30,000 payment for pain and suffering at that level, and if they are at least 80% disabled from working at their normal occupation.

86. Payment for loss of income is made on the basis of the average of the three highest years of income net of taxes and after deduction of all collateral benefits received by the Class Member. Loss of income payments cease upon a Class Member reaching age 65. Class Members who were infected as children and are not able to establish an earnings history are entitled to claim on the basis of average industrial wage. They may also prove on the balance of probabilities that their earnings would have been higher than the average industrial wage. Similarly, the average of three years of highest net income is subject to the right of the Class Member or the Administrator to prove that some other base figure should be used.

87. A claim for the loss of services in the home may be made for the lifetime of the Class Member and is compensated at $12 per hour up to a maximum of 20 hours per week.

88. Initially, the limits imposed on compensation for loss of income are as follows:

(a) where pre-claim earned income exceeds $75,000, it is deemed to be the cap or the starting point from which income loss is calculated; and

(b) 70% of the annual loss of net income is paid.

89. Appendix B to these submissions demonstrates examples of the loss of income calculation under Section 4.02 of the Plans. The examples at each income level are calculated showing the effect on income loss for a person who is 100% work impaired and a person who is 50% work impaired. Each example also shows the initial limit of payment to 70% of the calculated loss of income. The last example demonstrates the effect for the calculation of income loss of capping the earned income at $75,000.

Eckler Partners letter dated August 3, 1999, Chambers Brief, vol.7, pp.1670-1671

Costs of Care - Article 4.04

90. Class Members who reach Level 6 (liver decompensation, HCC, and other medically urgent associated conditions) will be entitled to receive compensation for costs of care recommended by a physician, such as home nursing services, up to a maximum of $50,000 per calender year.

Uninsured Treatment and Medication and Out of Pocket Expenses- Articles 4.06 and 4.07

91. The Class Members are also entitled to reimbursement for all uninsured generally accepted treatment costs, medication costs and out-of-pocket expenses such as travel, hotels or meals attributable to HCV. Costs of HCV compensable drug therapy are

covered in addition to the $1,000 per month payment for the pain and suffering sometimes associated with taking the drug therapy.

Death Before January 1, 1999 - Article 5.01

92. If a Class Member died before January 1, 1999, and would have qualified as a HCV infected person but for the death and if his or her death was caused by HCV, compensation will be paid on the following terms:

(a) the estate will be entitled to receive reimbursement for uninsured funeral expenses to a maximum of $5,000 and a fixed payment of $50,000;

(b) family members will be entitled to compensation for loss of the deceased's guidance, care and companionship;

(c) dependents may be entitled to compensation for their loss of support from the deceased or for the loss of the deceased's services in the home; or

(d) at the joint election of the estate and the family members and dependents of the deceased, the estate will be entitled to reimbursement for uninsured funeral expenses to a maximum of $5,000, and the estate and the family members and dependents will be jointly entitled to compensation of $120,000 in full settlement of all of their claims.

Death After January 1, 1999 - Article 5.02

93. If a Class Member dies on or after January 1, 1999, and qualified or would have qualified as a HCV infected person but for the death, compensation will be paid on the following terms:

(a) the estate is entitled to all compensation described in Article 4 of the Plan that the deceased could have claimed up to the time of death;

(b) the estate will be entitled to receive reimbursement for uninsured funeral expenses up to a maximum of $5,000;

(c) family members of the deceased will be entitled to compensation for loss of guidance, care and companionship of the deceased; and

(d) dependents of the deceased are entitled to compensation for their loss of support from the deceased or for loss of the deceased's services in the home.

Dependants' Loss of Support or Loss of Services in the Home - Article 6.01

94. Under the Plans when a deceased HCV infected person's death is caused by HCV, the approved dependents are entitled to claim for provable loss of support until such time as the deceased would have reached age 65 but for his death.

95. Payments for loss of support are made on a net basis after deduction of 30% for the personal living expenses of the deceased and after deduction of any pension benefits from CPP received by the dependents.

96. The same or similar holdbacks or limits will initially be imposed on the claim by dependents for loss of support under the Plans as are imposed on a loss of income claim.

97. Failing agreement amongst the approved dependents on the allocation of loss of support between them, the Administrator will allocate loss of support based on the extent of support received by each of the dependents prior to the death of the HCV infected person.

98. Examples of loss of support calculations under Section 6.01 of the Plans are found at Appendix C. The example at each income level is calculated showing the effect on loss of support of CPP retirement pensions in respect of the deceased. Each example also shows the 30% deduction for the personal living expenses of the deceased and the imposition of the 30% holdback on the loss of support calculation. Examples are also provided showing the effect of initially capping earned income at $75,000.

Eckler Partners letter dated July 30, 1999, Chambers Brief vol.7, pp.1666-1671

99. If an approved dependent resided with a deceased HCV infected person at the time of the death, then instead of loss of support, these dependents are entitled to be compensated for the loss of any services that the HCV infected person provided in the home at the rate of $12 per hour to a maximum of 20 hours per week

Loss of Guidance, Care and Companionship - Article 6.02

100. Family members of a qualified HCV infected person whose death was caused by HCV are entitled to be paid the amount set out below for loss of the deceased's guidance, care and companionship:

Familial Relationship to Deceased	**Compensation Payable**
Spouse	$25,000
Child under the age of 21 years at the time of death of family member	$15,000
Child 21 years of age or older at the time of death of family member	$5,000
Parent or Sibling	$5,000
Grandparent or Grandchild	$500

Additional Provisions Concerning Compensation

101. The Settlement Agreement and Funding Agreement further provide that:

(a) all compensation payments to claimants who live in Canada will be tax free (Funding Agreement, Article 3.02(2), HCV Tranfused Plan, Article 8.01);

(b) compensation payments will be indexed annually to offset inflation (Transfused HCV Plan, Article 7.02);

(c) compensation payments other than payments for loss of income will not affect social benefits currently being received by claimants (Transfused HCV Plan, Article 8.02);

(d) life insurance payments received by or on behalf of claimants will not be taken into account for any purposes whatsoever under the Plans (Transfused HCV Plan, Article 8.03); and

(e) no subrogation payments will be paid directly or indirectly (Transfused HCV Plan, Article 8.04).

Claims Appeal Process

102. Claimants will have the right to appeal the Administrator's decision concerning their claims to either a Court-appointed Arbitrator or a Referee, as they elect. The Arbitrator's decision will be final and binding. The Referee's decision, however, may be appealed to the Court if the amount in dispute exceeds $10,000. The chart annexed as Appendix D outlines the appeal process.

Releases and Related Matters

103. Each Class Member who does not opt out will be deemed to have released and discharged the Releasees from any and all actions whatsoever of every nature or kind

which he or she ever had, now has or may hereafter have in any way relating to or arising from:

(a) in the case of the BC Transfused Class Member, his or her infection with HCV through a blood transfusion received in Canada in the period January 1, 1986 to July 1, 1990;

(b) in the case of a secondarily-infected Spouse or child, his or her infection with HCV by his or her Souse or parent; or

(c) in the case the claims of other family members and/or dependants, the infection with HCV of their family member by one of the foregoing means.

104. Before receiving any payments under a Plan, each Class Member must deliver a release and consent to a dismissal of any action or other proceeding they may have commenced.

Opting Out

105. Each Class Member has the right opt out. Those who opt out and obtain a judgment against the FPT Governments will be paid out of the Trust Fund. One third of the defence costs pertaining to any litigation brought by persons who opt will be paid out of the Trust Fund.

Funding Agreement

106. The FPT Governments are obligated to pay the settlement amount of $1,118,000,000 plus interest accruing at Treasury Bill rates from April 1, 1998 totalling approximately $1,207,000,000 as at September 30, 1999. This is the limit of what they must pay to extinguish the claims of all members of the class actions which are the subject of the Settlement Agreement.

107. The Trust Fund is funded on the following basis:

(a) a payment of 8/11ths of the settlement amount by the Federal Government to the Trust Fund, on the date when the last judgment or order approving the settlement of the Class Actions becomes final; and

(b) monthly payments by each PT Government to make up the remaining 3/11ths. The PT Governments are obligated to pay accrued interest from April 1, 1998 at Treasury Bill rates.

108. The FPT Governments have agreed that no income taxes will be payable on the income earned by the Trust, thereby adding in effect, a present value of about $357,000,000 to the settlement amount.

Eckler Report, Chambers Brief, vol. 3, pp.562-564

109. The Funding Agreement provides that the following amounts will be paid from the Trust Fund:

(a) compensation to persons who qualify in accordance with the provisions of the Transfused HCV Plan;

(b) compensation to persons who qualify in accordance with the provisions of the Hemophiliac HCV Plan;

(c) $240,000 to each spouse and child secondarily-infected with HIV to a maximum of 240 claimants who qualify pursuant to the Program established by the FPT Governments (which is not subject to Court approval), which Program payments, in the aggregate, may not exceed $57,600,000;

(d) final judgments or Court approved settlements payable by any FPT Government to a Class Member or Family Class Member who opts out of one of the Class Actions or is not bound by the provisions of the Settlement Agreement or a person who claims over or brings a third-party claim in respect of the Class Member receiving or taking of blood or blood products in Canada in the Class Period and his or her infection with HCV, plus one-third of Court approved defence costs;

(e) subject to the Courts' approval, the costs of administering the Plans, including the costs of the persons to be appointed to perform the various functions under the Settlement Agreement;

(f) subject to the Courts' approval, the costs of administering the Program, which Program administration costs, in the aggregate, may not exceed $2,000,000; and

(g) subject to Court approval, fees, disbursements, costs, GST and other applicable taxes of Class Action Counsel.

Administration and Ongoing Supervision

110. The Settlement Agreement provides for the appointment of the individuals with particular expertise to perform specific functions under the Settlement Agreement, Funding Agreement and Plans as follows:

(a) a professional Trustee to manage the Trust, provide funds to the Administrator and others as required, record transactions and report;

(b) a professional Administrator to administer the Plans, assist in the making of claims, receive and evaluate claims, requisition, receive and forward to claimants payments out of the Trust Fund, record transactions and report and retain medical experts as necessary;

(c) the Joint Committee of plaintiffs' Class Action Counsel to generally oversee administration of the Settlement Agreement, Funding

Agreement and Plans, retain actuaries to assess the financial sufficiency of the Trust Fund, receive investment advice and apply to the Courts as required;

(d) Fund Counsel to defend and advance the interests of the Trust and the decisions of the Administrators in the appeal process and apply to the Courts as required;

(e) Auditors to audit the accounts of the Administrator and Trustee and report; and

(f) Investment Advisors to develop an investment strategy for the Trust Fund in accordance with the investment guidelines approved by the Courts.

111. The following safeguards and limitations have been built into the Plans:

(a) the Trust Fund and administration will be audited annually;

(b) the actuarial soundness of the Plans will be monitored by actuaries and by the Court and will be reviewed automatically every three years. In addition, a review can be triggered at any time, by the Court, the Joint Committee or Class Action Counsel;

(c) the Administrator will hold back or limit some of the compensation payments under the Plans until the Courts are satisfied that the Trust Fund can meet these obligations. At that point, the monies initially

held back or the amount to which the person would have been entitled but for the limit imposed (the "holdbacks") will be released to the claimants with prime rate interest;

(d) the Courts will retain the power to adjust the Plans to ensure that each Class Member and each Family Class Member receives a fair share of the Trust Fund within the parameters of the Plans; and

(e) Fund Counsel are appointed to defend the interests of the Trust Fund.

Areas of Compromise and Objections

Risk of Sufficiency of the Trust Fund

112. As noted above, the Settlement Agreement limits the obligations of the FPT Governments to pay $1,118,000,000, plus interest accruing from April 1, 1998 to satisfy the claims of all Class Members, the claims of those who would be Class Members but who have opted out, as well as the costs of administering the Plans the Trust and the costs of the Program.

113. The FPT Governments made it clear at the outset and throughout the negotiations that their offer was up to $1.1 billion. The challenge was to strive to achieve a fair settlement within this envelope. As the negotiations proceeded, and more information became available, particularly with respect to the likely size of the cohort, it became apparent that the $1.1 billion was sufficient to achieve court style damages for the

Class Members given the likely size of the cohort, but only if the Class Members were prepared to accept the risk of insufficiency. If they were not, the FPT Governments would not agree to the quantum and range of damages described above, and, in the opinion of Class Counsel, the Class Members would have left a very substantial amount of money on the settlement table. Class Counsel enhanced the settlement offer by negotiating a further $18 million in exchange for the agreement that the Class Members would assign their actions against the CRCS to the FPT Governments, by negotiating an agreement with the FPT Governments to pay interest from the date of the announcement of the proposal (approximately $80 million to date) and by negotiating tax free treatment of the investment income of the Trust Fund. To September 30, 1999, the value of the offer is approximately $1,207,000,000 not including the value of the tax free treatment of the investment income (approximately $357,000,000).

114. The best epidemiological, medical and actuarial evidence available indicates that there will be no insufficiency. The key elements to this assessment were identified, evidence was amassed, and the actuarial report of Eckler Partners was commissioned. The Eckler Report synthesizes this information and calculates that, excluding holdbacks (discussed below), the assets of the Trust Fund exceed the liabilities by approximately $34 million as at September 30, 1999.

Matthews Affidavit, Chambers Record, vol.3 Exhibit A (Eckler Report), pp.508-573

115. Eckler Partners were required to rely on a number of assumptions in making these calculations. Where there was uncertainty as to the accuracy of the information, Eckler Partners were instructed or asked to make conservative assumptions. Other assumptions where there was less uncertainty in the evidence were neutral. The major assumptions, their source and nature are as follows:

(a) **Cohort Size.** The number of Class Members who are entitled to claim is a critical component. The reports of Remis, CASL and Dr. Irwin Walker address this issue. Because many of the Class Members had serious underlying illnesses which caused their transfusions, the rate of death among this group within 10 years of infection is very high. The epidemiological evidence on this issue conflicts. Eckler Partners were instructed to use the estimate from CASL which resulted in an assumption that more infected persons are alive to claim compensation. Eckler Partners performs a sensitivity analysis on this issue which indicates that for each change in cohort size by 10%, the liabilities change by $87.8 million. This is a conservative assumption.

Matthews Affidavit, Chambers Brief, vol.3 para.5, p.486 and Exhibits A (Eckler Report) p.554 B (Remis Report), C (Remis Report) and D (CASL Report), pp.574-712 and Walker Affidavit, Chambers Record, vol.5, pp.1245-1279

(b) **Take-Up Rates.** In a similar medical device class action case pertaining to faulty pacemakers, in which all of the claimants were

known to Class Counsel and efforts were made to contact them directly about their rights to compensation, only 72% of the cohort applied for compensation. This issue is compounded in this case where the disease process, if any, can be asymptomatic and many persons do not and may never know they are infected. Despite the evidence that it is very unlikely that all eligible Class Members will come forward to claim, Eckler Partners was asked to assume a 100% take-up. Eckler Partners also performs a sensitivity analysis on this issue which shows that if the take up rate is between 70% and 80% (ie: similar to that in the pacemaker case), then the liabilities will be reduced by $176 - $263 million. This is likely to be the case. The assumption of 100% take-up is a very conservative assumption.

Matthews Affidavit, Chambers Record, vol. 3, Exhibit A (Eckler Report) pp.554-555, Exhibit C (Remis) pp.633-634 and Woltz Affidavit, Chambers Brief. vol.2, pp.390-394

(c) **Prevalent Infections.** Dr. Remis opines that some persons who were infected before the Class Period may not be screened out by the eligibility qualifications. It is very difficult to estimate what number, if any, of prevalent claims there are and how many of those claimants will attempt to claim compensation under the Plans and how effective eligibility screening will be. Eckler Partners performs a sensitivity

analysis on this issue. They were not asked to assume non-eligble claimants would participate.

Matthews Affidavit, Chambers Brief, vol.3 Exhibits A (Eckler Report) p.560 and C (Remis Report) p.634-635

(d) **Disease Modelling and Clearance Rate.** When and how many Class Members will progress to the various disease states is critical to determining the amounts and timing of compensation. CASL was commissioned to study and report on this issue. In addition, Dr. Frank Anderson, a leading Canadian gastroenterologist who has treated in excess of 1000 HCV patients provided advice throughout the negotiations. Dr. Irwin Walker also addressed this issue with respect to hemophiliacs. The clearance rate is important because it affects the numbers of persons who are chronically affected with the disease and who will receive compensation beyond Level 1. This is fairly well established in the literature and the 20% assumption on this point is slightly conservative. CASL asserts that its disease modelling likely overestimates the probabilities of disease progression and death after 25 years. Nevertheless, Eckler Partners was asked to assume these overestimations. Moreover, Eckler Partners was not asked to assume any tempering of disease progression based on improvements in treatment in the coming years, despite the record of

recent improvements and the evidence of ongoing research. These are very conservative assumptions.

Matthews Affidavit, Chambers Brief vol.3, Exhibits A (Eckler Report) pp.556, 565 D and E (CASL Reports) pp.713-717 in particular and F (Medical Literature pertaining to disease progression) pp.660-725; Anderson Affidavit, Chambers Brief, vol.4, paras. 21 and 62, pp. 905, 927-928

(e) **Disability Rates and Loss of Income Calculations.** Dr. Anderson provided estimates of the numbers of persons who would be disabled from working at the various HCV disease stages. His estimates are maximums and are higher than those found in the B.C Survey. Eckler Partners was also asked to assume average incomes which are higher than those reported in the B.C. Survey. These are conservative estimates.

Anderson Affidavit, Chambers Brief. vol.4, paras. 42-44, p.919; Matthews Affidavit, Chambers Brief vol.4, paras 9-11 and 13-14, Exhibit A (Eckler Report) and Exhibit G (B.C. Survey), pp. 487-490, 526-530 and pp.755 - 758

(f) **Loss of Services.** Income loss ceases at age 65. It was assumed that all Class Members who were claiming income loss would then go on to claim loss of services in the home. This is a very conservative assumption. To temper that assumption, and because there was no statistical information as to when loss of services claims tend to diminish, Eckler Partners was asked to assume that those claims, on

average, would cease at age 75. This is a liberal assumption. Together, these assumptions are neutral.

Matthews Affidavit, Chambers Brief vol.3, para.16 and Exhibit A (Eckler Report), p.490 and 531-532

(g) **Opt Outs.** The Settlement Agreement provides for one third of the defence costs and the judgments of persons who opt out and successfully sue the FPT Governments to be paid out of the Trust Fund. Eckler Partners was asked to assume that the costs of the judgments will be $10 million and one third of the costs of the defence will be $533,000. These are neutral assumptions.

Matthews Affidavit, Chambers Brief, vol.3., para.31, 43 and Exhibit A (Eckler Report) pp. 497, 503-504, 538-539 and 544-546

(h) **Administration Costs.** These costs are based on the proposal given the by the Administrator selected by Class Counsel, subject to court approval. These estimates are neutral.

116. The evidence is overwhelming that this Trust Fund will be more than sufficient to pay the Class Members in accordance with the Plans.

Holdbacks

117. As noted above, the negotiation strategy was to ensure that the Trust Fund was sufficient to pay the maximum amount of damages possible. One way the Plans protect against uncertainty is to defer certain payments until there is some experience with the Plans to reassess sufficiency. Class Members will be paid the deferred amounts plus interest at prime rate, if and when the Courts order that the deferred amounts can be paid out.

118. The holdbacks are as follows:

(a) $5,000 of the $20,000 Level 2 damages for pain and suffering;

(b) 30% of the net claim for loss of income or loss of support;

(c) the Class Member's damages for loss of income or loss of support over a pre-claim gross income of $75,000.

The Plans provide that the Court may order them to be removed in the above priority.

Income Loss

119. Income loss claims have been compromised in accordance with the holdbacks described above and by the deductibility of income tax and collateral benefits.

120. Income tax deductibility in personal injury awards was recently reconsidered by the Supreme Court of Canada in *Cunningham v. Wheeler*, [1994] 1 S.C.R. 359 at 416-

418 (Authorities Tab 7). Cory, J. for the majority held that income tax should not be deductible because it is a matter between the state and the litigant and is subject to amendment of the *Income Tax Act*. In this case, we have the unique situation where the state is the defendant, and the state has agreed not to claim income tax on these benefits. It is submitted that although this approach is different from the normal approach, it does not under compensate the Class Members because they can never be taxed on the amounts they receive.

121. With respect to collateral benefits, again this was an area of some compromise. *Cunningham v. Wheeler* also addresses this issue and reviews the law as laid down in *Ratych v. Bloomer*, [1990] 1 SCR 940 (Authorities Tab 25). In essence, those collateral benefits which are the subject of a right of subrogration or are in the nature of an insurance policy for which the plaintiff paid some form of consideration are not deductible. Those which have no subrogation rights or which have not been paid for by the plaintiff in any way are deductible. The Plans provide all collateral benefits except life insurance are deductible. However, no subrogated claims whatsoever are payable out of the Trust Fund. Accordingly, the compromise is limited to those collateral benefits which are not the subject of subrogation rights and which have been paid for by the Class Member. It is submitted that this was a small compromise.

122. Only 3.9% of persons employed full year, full time earn annually $75,000 per year or more. This cap, which will be removed if and when the Trust Fund is declared to be sufficient, does not have widespread affect.

Elliott Affidavit, Chambers Brief, vol. 2, p. 272, para. 180

Causation

123. Some object to the requirement of proving that HCV caused the Class Member's death. This is not an area in which the Settlement Agreement compromises the rights of the Class Members because causation is integral to the tort system. The Supreme Court of Canada has recently introduced more flexibility in causation in personal injury cases. Hence, it can now be argued that as long as HCV "materially contributed" to the Class Member's death, his or her death was "caused" by HCV, even if there were other factors involved.

Athey v. Leonati, [1996] 3 SCR 458 at pp.466-468 (Authorities Tab 5)

Loss of Insurability

124. Many persons infected with HCV, regardless of whether they have cleared the virus, will not qualify for some types of insurance if a medical examination is required. The Plans do not specifically provide compensation for loss of insurability.

125. The value of loss of insurability is nominal because the insurance benefits are offset by the savings of premiums necessary to pay for the insurance coverage. There is controversy as to the entitlement to make such a claim but this Court has awarded $5,000 - $7,500 for the loss of the ability to purchase disability insurance.

July 30, 1999 Report of Eckler Partners, Chambers Brief, vol.7, p.1665
Lang v. *Rabel* [Q.L. 1996 BCJ No.1691]; appeal dismissed [Q.L. 1998 BCJ No.2168] (Authorities Tabs 17 and 17)
Nicolls v. *B.C. Cancer Agency* [Q.L. 1999 BCJ No. 1475] (Authorities Tab 23)
Dupuis v. Daniels [Q.L. 1992 BCJ No.517] (Authorities Tab 11)

Are General Damages Sufficient? What About Fatigue?

126. Some of the objections criticize the awards for non-pecuniary damages, particularly the $10,000 Level 1 payment, on the basis that chronic fatigue is not adequately compensated. Level 1 Class Members cleared the virus in the acute stage and will have no ongoing disease process or symptoms. They should not be experiencing fatigue due to infection with HCV.

Anderson Affidavit, Chambers Brief, vol.4 para.15 and 21, pp.902 and 905

127. All persons who do not clear the virus will receive general damages ranging from $25,000 to $225,000 plus $1,000 per month for each month of completed HCV Drug Therapy. These damages are adequate if not generous at each compensation level when compared to awards made by our courts in cases of chronic illnesses.

McMillan v. Heeren [QL 1987 BCJ No. 3008] (Authorities Tab 21)
- fibrositis syndrome resulting in chronic aching and stiffness, sleep disturbance, chronic fatigue - non-pecuniary damages of $25,000

Trapasso v. Hendricks [QL 1996 BCJ No.3160] (Authorities Tab 29)
- concussion, soft tissue injuries and headaches resulting in chronic fatigue, insomnia and severe depression - non-pecuniary damages of $25,000

DiFranco v. Sung [QL 1997, BCJ No. 2904] (Authorities Tab 10)
- soft tissue injuries to head and neck causing depression, disturbed sleep chronic fatigue probably attributable to fibromyalgia - non-pecuniary damages of $35,000

Martin v. Reeve, unreported, April 2, 1990, Vancouver No. C854300 (Authorities Tab 20)
- renal failure causing the death of both kidneys and necessitating kidney transplantation - non-pecuniary damages of $70,000

Hunt v. T&N, plc, unreported, March 2, 1990, Vancouver No.C885383 (Authorities Tab 14)
- $105,000 in general damages in an asbestos personal injury case where exposure to asbestos caused mesothelioma, a terminal and painful cancer which reduced life by 16 years

Nicolls v. BC Cancer Agency (Authorities Tab 23) 1999
- medical negligence causing cervical cancer, sterilization and fatigue and radiation therapy for 2 months, $125,000 for non pecuniary damages $5,000 for loss of insurability

Chattu v. Pankratz, [QL 1991 BCJ No.481] (BCCA) (Authorities Tab 6)
- $165,000 in general damages in a case where medical negligence resulted in leg amputation, renal failure, nerve damage and reduced life expectancy

Pittman v. CRCS (1994), 112 DLR (4th) 257 (Authorities Tab 24)
- infection with HIV through the blood supply - non-pecuniary damages of $180,000

Do the Plans Adequately Compensate Minors?

128. Some indicate that the needs of children have not been addressed in these Plans because children will be infected for life and may be more vulnerable to the risk of insufficiency. The insufficiency risk has been addressed above. This Settlement serves the needs of children very well, particulary because of the ability for Class Members to come back and have damages reassessed time and time again. The medical evidence points to a slower, less insidious course of the disease in children. Based on this evidence, if a child went to court today his or her one time lump sum damages would be heavily discounted. A one-time only assessment of damages would serve children poorly because

of the spectre of insufficient compensation in the event of a worse case scenario in the future. This Settlement affords children protective insurance against such risks.

Anderson Affidavit, Chambers Brief, vol.4, para.67-68, pp.930-931

129. In addition, special provision was made for children with respect to loss of income. If they have not had a chance to establish an earnings history, they will be deemed to have lost income at least the average industrial wage. If they can prove on the balance of probabilities that they would have earned more, they will have their income loss calculated based on that higher figure, but they cannot go below average industrial wage.

Do the Plans Adequately Compensate Older Persons?

130. Some object that the compensation is inadequate for older persons because they are in greater need of funds. The compensation matrix is individually tailored to the circumstances of each Class Member, and does not discriminate against any group.

It Is Not Lump Sum Compensation And It is Not Equal to the HIV Payment

131. Some objectors have complained that the compensation should be similar to the HIV payment, which offers the same compensation to each person, regardless of their circumstances. In the case of HCV, "one size fits all" compensation would work an injustice because it would vastly over compensate some people (those who have cleared the virus and have never had any symptoms), while vastly under compensating others

(those who reach the end stages of the disease, and have significant income loss and will leave behind dependents). The Settlement Agreement has been tailored to fit this particular disease and should not be compared to the HIV package which was imposed, not negotiated, on persons with a different disease.

Compensation Is Limited to Those Transfused in the Class Period

132. Many of the BC objections appear to be part of a letter writing campaign which pertains to the FPT Governments' decision to limit compensation to the Class Members. This is not an objection which is relevant to this proceeding because the Court is only considering the interests of the Class Members, all of whom were infected during the Class Period.

Summary on Compromises - The Right to Opt Out

133. Given the liability concerns, the compromises reached were very modest in comparison to typical compromises made when settling cases every day in this Province. Moreover, should any Class Members believe they can achieve a better outcome if they were to try their individual case, they have the right to opt out and do so.

Areas of Negotiated Betterment of Court Based Damages

Ongoing Assessment of Damages

134. The Settlement Agreement departs from the common law requirement of a single, once-and-for-all lump sum assessment and instead establishes a system of periodic payments. Under this Settlement, the Class Members may reapply, time and time again, for additional compensation if and when his or her HCV condition worsens, income losses or loss of services are encountered, out-of-pocket expenses are incurred or death results from an HCV related cause. This flexibility effectively eliminates the over compensation or under compensation of lump sum awards. In so doing, the words of Dickson J. are apposite:

> The subject of damages for personal injury is an area of the law which cries out for legislative reform. The expenditure of time and money in the determination of fault and damage is prodigal. The disparity resulting from lack of provision for victims who cannot establish fault must be disturbing. When it is determined that compensation is to be made, it is highly irrational to be tied to a lump sum system and a once-and-for-all award.
>
> The lump sum award presents problems of great importance. It is subject to inflation, it is subject to fluctuation on investment, income from it is subject to tax. After judgment new needs of the plaintiff arise and present needs are extinguished; yet, our law of damages knows nothing of periodic payment. The difficulties are greatest where there is a continuing need for intensive and expensive care and long-term loss of earning capacity. It should be possible to devise some system whereby payments would be subject to periodic review and variation in the light of the continuing needs of the injured person and the cost of meeting those needs.

Andrews v. *Grand & Toy Alberta Ltd.* [1978] 2 S.C.R. 229 at p.236 (Authorities Tab 4)

135. This Settlement achieves this laudable goal in the context of a disease which cries out for such a solution. If this action proceeded to trial and if the representative plaintiffs were successful at the trial of the common issues, the damages of each Class Member would then be quantified and fixed forever on a lump sum basis. Each and every assessment, of course, would take into consideration the myriad of probabilities reflected in both the medical modelling underlying the Plans and the assumptions set forth in the Eckler Report.

Andrews v. *Grand & Toy Alberta Ltd.* (Authorities Tab 4)

136. The periodic reassessment is of substantial benefit to all Class Members but is especially beneficial to minors who, on a statistical basis, are more likely, at this time, to be in the early stages of the disease and who face the greatest risk of under compensation in the traditional court model of assessing damages..

Death Claims

137. The Settlement Agreement provides for deceaseds' estates to be paid $50,000 for all damages the deceased could have claimed if he or she died of HCV prior to January 1, 1999, or a combination payment of $120,000 for the estate claims and the claims of the dependents. If the deceased died after January 1, 1999, the deceased's estate is entitled

to all of the deceased's proveable past losses under the Plan, regardless of the cause of death.

138. These provisions constitute a significant advantage over the legislative and common law provisions in British Columbia which hold that in the event of the death of a plaintiff prior to judgment in British Columbia, the plaintiff's estate cannot maintain an action for pain and suffering, or death due to personal injury. His or her estate will be entitled to pecuniary damages incurred prior to the death only and loss of expectation of life if the death was not caused by the injuries over which the suit is brought.

Estate Administration Act, RSBC 1996, c.122 (Authorities Tab 3)
Lankenau v. Dutton (1988), 46 CCLT 256 (SC) (Authorities Tab 18)

139. The Plans provide for loss of care, guidance and companionship to more family members than does the law of British Columbia, including awards to parents, siblings, grandparents and grandchildren. One exception to this betterment is that children under age 21 are limited to $15,000 for loss of care, companionship and guidance. In British Columbia, damages up to $30,000 are customarily awarded to young children. This is a compromise which is more than offset by the enhanced general damages to the deceased parent's estate and by the enhanced damages for loss of care, guidance and companionship to the Spouse of the deceased.

Simplified and Expeditious Damages Assessment

140. Each Class Member will also benefit from a streamlined and user friendly claims process rather than a formal trial like hearing with evidentiary and other legal issues. The Administrator is charged with assisting Class Members with their claims and will have an adjunct office staffed to perform this function. This will eliminate or vastly reduce individual legal fees and disbursements compared to those which would be incurred in a damage assessment trial. Our Court encourages cost effective forms of dispute resolution of individual issues in class actions: *Romanchuk v. Sun Life Assurance Co. of Canada*, unreported, November 28, 1997, Vancouver Registry No. C964248 (S.C.) (Authorities Tab 26).

141. Class Members have the safeguard of the right of appeal to a Court appointed arbitrator or referee and a further appeal from a referee to this Court. The arbitrator, referee and this Court all have the power to award costs in appropriate cases. These provisions strike a fair balance between administrative efficiency and independent judicial review.

No Mitigation

142. Certain lifestyle choices influence the outcome of infection with HCV. Because the liver is a clearing house, ingestion of some substances, most notably alcohol, but also some over the counter medications and herbal remedies can worsen the course of

the disease. In the standard personal injury case, these issues can be used by the defendants to argue for a reduction in the plaintiff's damages. Compensation under the Plans is not subject to reduction for mitigation issues.

Income Tax

143. Income tax is not payable on any payments made to Class Members including *Family Compensation Act* damages, nor is it payable on any of the income earned by the Trust Fund. The value to the Trust Fund of not paying tax on the income earned is approximately $357,000,000.

Social Benefits

144. Payments received pursuant to the Settlement Agreement cannot be used to negatively affect the Class Member's entitlement to any social benefits, with the following exceptions:

(a) payments for income loss and loss of support can be taken account in determining a Class Member's entitled to income replacement social assistance; and

(b) if the Class Member receives social assistance for payment of drugs, his or her drug costs relating to the treatment of HCV will be paid out of the Trust Fund.

In other words, social assistance payments which do not arise out of the Class Member's infection with HCV are grandfathered, and, in particular, the payments for general damages cannot generally be taken into account in a means test for social assistance. This was an exceptionally hard issue to resolve in the negotiations as it required the FPT Governments to identify and amend a substantial body of legislation.

Limitation Periods

145. Limitation Periods are not taken into account. Although the certification of this case tolls the limitation period from September, 1996, this is a substantial benefit to those Class Members who otherwise would have been subject to a limitation defence because their cause of action had expired prior to September, 1996.

Summary on Areas of Betterment

146. The value of the ability to obtain compensation over time to Class Members infected with this slowly progressive disease cannot be overstated. This crucial feature was achieved in the context of only making minor compromises.

Recommendation and Experience of Counsel

147. All class action counsel endorse this pan-Canadian settlement and recommend it as a hard fought compromise of complex and risky litigation which is in the best interests of all Class Members. This settlement came about as a result of the collaboration of many

experienced counsel across the country. Four of the senior counsel and their qualifications are as follows:

J.J Camp, Q.C. - lead counsel in the BC Transfused Class Action; lead counsel on the pan-Canadian negotiations; senior Canadian trial and appellate counsel with significant experience in mass tort litigation; past President of the Canadian Bar Association.

Harvey T. Strosberg, Q.C. - lead counsel in the Ontario Transfused Class Action; lead counsel on the pan-Canadian negotiations; experienced Canadian counsel on class actions (*Telectronics, Bre-X*); experience in HIV litigation including appearances at the Krever Inquiry; senior Canadian trial and appellate counsel; past Treasurer of the Law Society of Upper Canada.

Pierre R. Lavigne - lead counsel in the Quebec Transfused Class Action; lead counsel on the pan-Canadian negotiations; experienced counsel in Canada in terms of Hepatitis C litigation (7 years involvement); counsel at the Krever Inquiry for persons infected with Hepatitis C.

Bonnie Tough - lead counsel in the Ontario Hemophiliac Class Action; lead counsel on the pan-Canadian negotiations; counsel to the Hemophiliac Society at the Krever Inquiry; experienced counsel in contaminated blood litigation pertaining to HIV.

These lawyers were assisted by many other senior trial and appellate counsel with experience in contaminated blood litigation and class action litigation, many of whom were involved in the Krever Inquiry and HIV litigation for many years.

148. Collectively, the greatest amount of experience in Canada on class action, mass tort litigation and contaminated blood litigation in Canada was brought to this litigation and to the negotiations of this settlement. Class Counsel have recommended that their clients accept this settlement and all representative plaintiffs have accepted this recommendation and endorse the settlement.

Endean Affidavit, Chambers Brief, vol.6, p.1592
Mitchell Affidavit, Chambers Brief, vol.6, p.1594
Kreppner Affidavit, Chambers Brief, vol.5, p.1190
Page Affidavit, Chambers Brief, vol.5, p.1235
Parsons Affidavit, Chambers Brief, vol.4, p.1047

149. In addition, the FPT Governments were represented by senior experienced counsel in the negotiations. Ivan Whitehall, Q.C., is Chief Counsel in the Department of Justice and has a vast amount of litigation experience. Clif Prowse is senior counsel in the Ministry of the Attorney General, Legal Services for the Province of British Columbia and has had experience with contaminated blood litigation on behalf of the Province of British Columbia. Messrs. Whitehall and Prowse co-chaired the negotiations on behalf of the FPT Governments. The provinces of Quebec and Ontario were also separately represented at the negotiating table by counsel experienced with contaminated blood issues.

Future Expense and Likely Duration of the Litigation

150. It is unlikely that the litigation will ever proceed against the CRCS. The trial of the common issues against British Columbia and Canada will be both long and costly and the subject of appeals, given the significance of the liability issues and the magnitude of the damage exposure. So far as Class Counsel know, this is the largest personal injury settlement ever generated in Canada. Ebbett affidavit P-2674265 Lemen - P-1591

Recommendation of Neutral Parties

151. The Public Trustee has been consulted on proposed settlement. Although that office will have some criticisms of the settlement, it is anticipated that the Public Trustee will endorse the settlement as one which overall is in the best interest of children and persons under a disability.

Number of Objections and Nature of the Objections

152. In British Columbia, a total of 36 objections were filed. Of those, 20 were based on the fact that non Class Members are not being compensated. Of the other 16, two did not raise objections to this Settlement. Accordingly, out of a cohort of approximately 1000 Class Members, 14 objected to various provisions of this Settlement on substantive grounds. The general nature of their objections have been described above and addressed.

153. Neither the nature nor the volume of objections call into question the overall fairness or reasonableness of this Settlement Agreement. In fact, it can be argued that the limited number of objections supports the overall fairness and reasonableness of the Settlement Agreement.

The Presence of Good Faith and the Absence of Collusion

154. The parties negotiated at arms length in long, hard negotiations. The Parties struggled mightily to find a workable solution to this difficult disease in order to fairly compensate the members of six class actions across Canada. All parties retained physicians and other experts to provide advice. In addition, the parties commissioned reports from independent parties, including disease modelling by the Canadian Association for the Study of the Liver, and a survey of the BC Tranfused Class Members (the BC Survey) to provide independent, neutral evidence on which the compensation could be based.

Matthews Affidavit, Chambers Brief, vol.3, Exhibits D (CASL Report) p.663 and G (BC Survey) pp.733-735

155. It took 9 months to negotiate a framework agreement and another 6 months to finalize it and receive the approval of all of the Governments of Canada. Although it is fair to say that the process took a long time, this was an extraordinarily complex set of negotiations.

CONCLUSION

156. This Settlement Agreement is an outstanding response to the unique features of HCV and compares very favourably to the type and quantum of damages each Class Member would receive if the representative plaintiff was successful at the trial of the common issues and the Class Members successfully recovered damages in their individual cases. The Settlement Agreement has been carefully designed to ensure sufficiency of the Trust Fund and to provide for a fair, inexpensive and streamlined process for applying for and receiving compensation. This Settlement Agreement is fair, reasonable and in the best interests of the Class Members and should be approved.

NATURE OF THE ORDER SOUGHT

157. The representative plaintiff seeks an order approving the Settlement Agreement and making other ancillary orders to implement the Settlement Agreement as described in the draft Order which will be circulated and provided to the Court for review.

ALL OF WHICH IS RESPECTFULLY SUBMITTED

DATED at Vancouver, British Columbia, this 15th day of August, 1999

J.J. Camp Q.C.

Sharon D. Matthews

Camp Church & Associates
Solicitors to the Representative Plaintiff

REFERENCES TO AUTHORITIES

APPENDIX A

Level	MEDICAL CONDITIONS CAUSED BY HCV	COMPENSATION TO HCV INFECTED PERSONS						
		Maximum Cumulative Fixed Payments as Compensation for Damages	Fixed Payments as Compensation for Damages	Loss of Income or Compensation for Loss of Services in the Home *(claim one or the other)*	Additional Payment if you take HCV Drug Therapy	Reimbursement for uninsured Treatment and Medication Costs	Reimbursement for Out-of-Pocket Expenses	Reimbursement for Care Costs
6	You are considered a Level 6 claimant if: 1. you receive a liver transplant; or 2. you develop: a) decompensation of the liver; b) *hepatocellular cancer;* c) B-cell lymphoma; d) symptomatic mixed cryoglobulinemia; e) glomerulonephritis requiring dialysis; or f) renal failure.	$225,000*	You will receive $100,000	Yes	$1,000 per month of completed therapy	Yes	Yes	up to $50,000 per year
5	You are considered a Level 5 claimant if you develop: a) cirrhosis (i.e. fibrous bands in the liver extending or bridging from portal area to portal area with the development of nodules and regeneration); b) unresponsive porphyria cutanea tarda which is causing significant *disfigurement and disability;* c) unresponsive thrombocytopenia (low platelets) which is associated with purpua or other spontaneous bleeding, or which results in excessive bleeding following trauma or a platelet count below 30 X 10^9; or d) glomerulonephritis not requiring dialysis.	$125,000*	You will receive $65,000	Yes	$1,000 per month of completed therapy	Yes	Yes	No
4	You are considered a Level 4 claimant if: you develop bridging fibrosis (i.e.fibrous tissue in the portal areas of the liver with fibrous bands bridging to other portal areas or to central veins but without nodular formation or nodular regeneration).	$60,000*	There is no further fixed payment paid at this level	Yes	$1,000 per month of completed therapy	Yes	Yes	No
3	You are considered a Level 3 claimant if: 1. you develop non-bridging fibrosis (i.e. fibrous tissue in the portal areas of the liver with fibrous bands extending out from the portal area but without any bridging to other portal tracts or to central veins); or 2. you receive compensable HCV Drug Therapy (i.e. interferon or ribarivin); or 3. you have met or meet a protocol for compensable HCV Drug Therapy *even though you have not taken the therapy.*	if you elect OPTION 1 $60,000	OPTION 2 If you waive the $30,000 payment, you may claim loss of income or compensation for loss of services in the home OPTION 1 You receive $30,000	Yes No	$1,000 per month of completed therapy	Yes	Yes	No
2	You are considered a Level 2 claimant if: you test positive on a polymerase chain reaction (PCR) test demonstrating that HCV is present in your blood.	$30,000	You will receive $15,000 immediately plus a further $5,000 if and when the Court says that the Fund is sufficient	No	Not applicable	Yes	Yes	No
1	You are considered a Level 1 claimant if: your blood test demonstrates that the HCV antibody is present in your blood.	$10,000	You will receive $10,000	No	Not applicable	Yes	Yes	No
	*assuming the $30,000 Fixed Payment was not waived at Level 3							

COMPENSATION TO APPROVED HCV PERSONAL REPRESENTATIVES, DEPENDANTS AND FAMILY MEMBERS				
COMPENSATION PAYABLE IF HCV CAUSED THE HCV INFECTED PERSON'S DEATH	**HCV Infected person died from HCV before January 1, 1999**		**HCV infected person dies of HCV on or after January 1, 1999**	**HCV infected person dies after January 1, 1999 and death is not caused by infected person's infection with HCV**
	Option 1 $50,000 +	**Option 2 $120,000**		
Up to $5,000 for uninsured funeral expenses is payable to the estate.	yes	yes	yes	no
Compensation of $50,000 may be payable to the estate.	yes	no	no	no
Compensation of $120,000 may be payable jointly to the estate, qualified family members and qualified dependants.	no	yes	no	no
Compensation may be payable to each qualified family member for loss of guidance, care and companionship of the deceased as follows: (a) $25,000 Spouse; (b) $15,00 for each child under the age of 21 at the date of death of the HCV infected person; (c) $5,000 for each Child over 21at the date of death of the HCV infected person (d) $5,000 for each Parent; (e) $5,000 for each Sibling; (f) $500 for each Grandparent; and (g) $500 for each Grandchild.	yes	no	yes	no
Compensation may be payable for the qualified dependants' loss of support from the deceased or loss of deceased's services in the home.	yes	no	yes	no
All Compensation the deceased was or would have been entitled to that was not paid, up to the date of death, is payable to the estate.	no	no	yes	yes

APPENDIX B

EXAMPLES OF LOSS OF INCOME CALCULATIONS

	EXAMPLE 1		EXAMPLE 2		EXAMPLE 3		EXAMPLE 4	
	100% disability	50% disability	100% disability	50% disability	100% disability	50% disability	100% disability	50% disability
Average of 3 highest years of earned income	25,000	25,000	50,000	50,000	75,000	75,000	100,000	100,000
Application of $75,000 cap on earned income	n/a	n/a	n/a	n/a	n/a	n/a	75,000	75,000
Less ordinary deductions	5,378	5,378	14,494	14,494	25,660	25,660	25,660	25,660
Pre-disability net income	19,622	19,622	35,506	35,506	49,340	49,340	49,340	49,340
Current earned income	n/a	12,500	n/a	25,000	n/a	37,500	n/a	50,000
Proportionate reduction to current earned income ($50,000 x 75,000/$100,000)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	37,500
Less ordinary deductions	n/a	1,804	n/a	5,378	n/a	9,910	n/a	9,910
Post-disability net income	n/a	10,696	n/a	19,622	n/a	27,590	n/a	27,590
Annual loss of net income	19,622	8,926	35,506	15,884	49,340	21,750	49,340	21,750
Initial benefit or 70% of annual loss of net income	13,735	6,248	24,854	11,119	34,538	15,225	34,538	15,225

APPENDIX C
EXAMPLES OF LOSS OF SUPPORT CALCULATIONS

	EXAMPLE 1		EXAMPLE 2		EXAMPLE 3		EXAMPLE 4	
	No CPP Spousal Pension	CPP Spousal Pension	No CPP Spousal Pension	CPP Spousal Pension	No CPP Spousal Pension	CPP Spousal Pension	No CPP Spousal Pension	CPP Spousal Pension
Average of deceased's 3 highest years of earned income	25,000	25,000	50,000	50,000	75,000	75,000	100,000	100,000
Application of $75,000 cap on earned income	25,000	25,000	50,000	50,000	75,000	75,000	75,000	75,000
Less ordinary deductions	5,378	5,378	14,494	14,494	25,660	25,660	25,660	25,660
Deceased's net income	19,622	19,622	35,506	35,506	49,340	49,340	49,340	49,340
CPP Spousal Pension	n/a	3,852	n/a	4,974	n/a	4,974	n/a	4,974
Proportionate reduction to CPP Spousal Pension ($4,974 x 75,000/$100,000)	n/a	3,852	n/a	4,974	n/a	4,974	n/a	3,731
Annual loss of net income	19,622	15,770	35,506	30,532	49,340	44,366	49,340	45,609
Less 30% allowance for personal living expenses of the deceased	5,887	4,731	10,652	9,160	14,802	13,310	14,802	13,683
Annual loss of support	13,735	11,039	24,854	21,372	34,538	31,056	34,538	31,926
Initial benefit or 70% of annual loss of support	9,615	7,727	17,398	14,960	24,177	21,739	24,177	22,348

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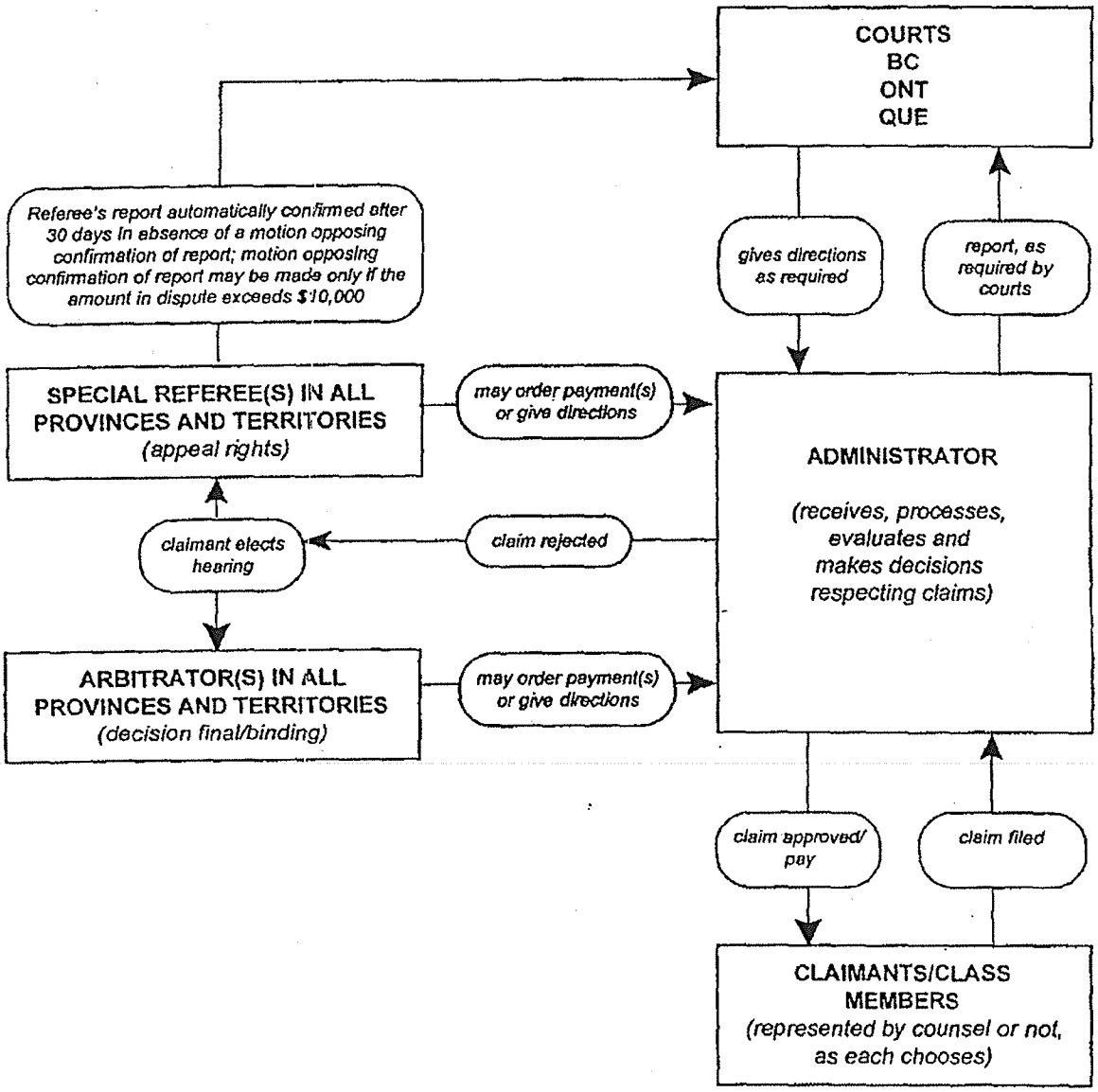
APPENDIX D
THE CLAIMS PROCESS



This is Exhibit "F" referred to in the
affidavit of Asvini Krishnamoorthy
sworn before me at Toronto, Ontario
this 29th day of January, 2016

William Knights.

A Commissioner for taking affidavits
within the Province of Ontario

Estimating the Prognosis of Hepatitis C Patients Infected by Transfusion in Canada between 1986 and 1990

Canadian Association for the Study of the Liver
Working Group on Hepatitis C Prognosis

Murray Krahn MD MSc, Department of Medicine, The Toronto Hospital and University of Toronto (Chair)

Jenny Heathcote MD, Department of Medicine, The Toronto Hospital and University of Toronto, Toronto.
Linda Scully MD, Department of Medicine, Ottawa Civic Hospital and University of Ottawa, Ottawa
Leonard Seeff MD, National Institutes of Health, Bethesda MD.
John Wong MD, New England Medical Center and Tufts University, Boston MA.

Table of Contents

1. Executive Summary

At the request of the Federal government of Canada, provincial governments, and Hepatitis C claimants, i.e. individuals infected with hepatitis C virus during the period of 1986 to 1990, an impartial group, the Canadian Association for the Study of the Liver (CASL) was asked to construct a natural history model of hepatitis C. The intent of this effort was to generate a model that would be used by all parties, as a guide to disbursing funds set aside to compensate patients infected with hepatitis C virus through blood transfusion. In November of 1998, CASL approached individuals with expertise in hepatitis C epidemiology, hepatitis C clinical care, and decision modeling to assist in the construction of a model.

The group began with a model of the natural history of hepatitis C (the Bennett/Wong model) that had already been published and was widely accepted, with the intent of updating it, addressing the concerns of stakeholders regarding the validity of the model, and adapting it to the Canadian context.

The working group evaluated and accepted the validity of the structure of the Bennett/Wong model, but subsequently simplified it. Each parameter in the model was reviewed. Key parameters were updated by systematically reviewing and synthesizing the literature. Confidence limits and/or plausible ranges were identified for key model parameters. The cumulative probability of acquiring cirrhosis, decompensated liver disease, and liver death were predicted using baseline values for each parameter. Monte Carlo simulation using plausible ranges for each variable was performed to estimate the degree of uncertainty attached to the prognostic predictions of the model.

The revised model predicted that, for the transfusion cohort as a whole, the 20 year and lifetime cumulative probability of developing liver cirrhosis was 13.4% and 24.9% respectively. Similarly, the 20 year and cumulative lifetime probability of dying of HCV-related liver disease was 2.5% and 12.3% respectively. The likelihood of developing HCV related complications was much higher in younger individuals, largely because the elderly do not live long enough to develop decompensated liver disease. The prognosis of individuals alive in 1999 is much better than that of the cohort as a whole, because competing mortality from diseases for which individuals were transfused has largely abated within 10 years of transfusion.

2. Background

In 1990 a serologic test became available to test donated blood for hepatitis C virus (HCV). Prior to this time, many individuals became infected as the result of transfusion. Between the period of 1986 and 1990, surrogate marker testing was employed in the United States, which decreased the risk of HCV infection in transfusion recipients. Surrogate marker testing was not performed in Canada during this period.

On March 27, 1998 federal, provincial, and territorial governments announced an offer of financial assistance to individuals who were infected with HCV, directly or indirectly, through the blood system between the periods of January 1, 1986 and July 1, 1990. Up to $1.1 billion was to be made available to compensate claimants, who included hemophiliacs, secondarily infected HCV claimants, those with HIV who became co-infected with HCV, secondarily infected individuals, as well as all others with HCV infection acquired through transfusion during the period in question.

In order to settle on an appropriate compensation scheme, the federal and provincial governments as well as the claimants reviewed a number of models of the natural history of hepatitis C. Because there was disagreement regarding the natural history of the disease, all parties approached the Canadian Association for the Study of the Liver, an impartial body with no stake in the outcome of compensation negotiations, to produce the best available model of the natural history of HCV, within the very short time frame that was available. In November of 1998, CASL approached individuals with expertise in hepatitis C epidemiology, hepatitis C clinical care, and decision modeling to assist in the construction of a model.

3. Methods

3.1 Choosing a Model

The group decided to review and adapt existing models of the natural history of HCV, in part because of the short time frame. We reviewed models published by Bennett and Wong et. al. [1,2], Kim et. al.[3], Shiell et. al.[4], Dusheiko et. al.[5], and Anderson et. al (unpublished). The group chose to adapt the Bennett/Wong model because it is arguably the best known and most widely accepted model of the natural history of HCV, concerns about some individual model parameters notwithstanding. In addition, we chose this model because of members of our group had direct access to and familiarity with the Bennett/Wong model.

The Bennett/Wong model is Markov state transition model[6] programmed in DecisionMaker 7.0 (Pratt Medical Group, Boston MA). In this type of model, a set of health states relevant to the research question is defined. The cohort whose prognosis is being modeled is allocated among health states at the beginning of the simulation. Time elapsed is divided into cycles, and transitions among health states are modeled with each time cycle. Time spent in each health state is recorded, so that the cumulative proportion of the original cohort that enters each health state, as well as life expectancy (and, in some circumstances, quality

adjusted life expectancy, net cost, and cost effectiveness) can be calculated.

3.2 Validating and Editing the Model Structure

Any model of the natural history of disease can be thought of as having two components: a model structure, and model parameters. "Structure" includes the health states that are represented in the model, and the allowable transitions between health states. Model parameters include the numerical values assigned to transitions between health states.

Our group evaluated both the structure and parameters of the Bennett/Wong model. Many of the parameters in the original model were changed. This is described in section 3.3 below. However, the structure of the original model was not changed substantially.

After reviewing the structure of the model, the group reached a consensus that important clinical events were accurately represented in the model. However, to ease the task of data review and synthesis, the model was slightly simplified by aggregating all forms of "decompensation". Thus, the revised model (Figure I) contains only a "decompensation" health state to replace the health states of "ascites", "refractory ascites","variceal bleeding", and "hepatic encephalopathy" that were present in the original model. In addition, the "mild chronic hepatitis" health state was changed to a "chronic HCV infection" health state to reflect the fact that the health state in the revised model includes all patients with chronic HCV infection that are not represented in the other health states. Thus, this health state includes patients without evidence of chronic hepatitis by histology, as well as patients with mild chronic hepatitis. Other health states were preserved, largely in their original form.

Several other adaptations were carried out to the Bennett/Wong model. Because our practice survey (see below) indicated that Canadian hepatologists would treat patients with mild and moderate hepatitis and cirrhosis, the revised model allows these options. Canadian hepatologists indicated that current treatment is almost exclusively combination interferon/ribavirin therapy. Thus, therapy is represented as combination treatment rather than monotherapy as depicted in the original model.

Finally, we constructed submodels that predict the prognosis of each 10 year age stratum. These submodels were aggregated in one large 90 state model to predict the prognosis of the entire transfused cohort. Simulations were performed that predicted the prognosis of each cohort of HCV-infected transfusees for the calendar years between 1986 and 1990.

3.3 Estimating Model Parameters

3.3.1 Data Sources

We used multiple data sources to supplement and revise the parameter estimates in the original Bennett/Wong model. First, we reviewed the parameter estimates used in previous natural history

models. Subsequently, we performed systematic searches of electronic databases and reviewed investigators' files to obtain relevant published studies describing the natural history of hepatitis C. We relied on a previous report commissioned by Health Canada to provide estimates of the number of individuals infected with HCV during the period of 1986 to 1990[7]. Dr. Robert Remis very kindly provided the original spreadsheets used to predict survival in this work. The Canadian Association for the Study of the Liver provided us with a report of a workshop on the natural history of hepatitis C [8]. We received data from provincial departments of health in British Columbia, Saskatchewan, Prince Edward Island, and Nova Scotia regarding the mortality experience of transfusion recipients, as well as from the B.C. Blood Recipient Notification Project[9]. We received data regarding the number of transplants performed in Canada from the Multiple Organ Retrieval Programme, and transplant data from the Toronto Hospital (personal communication, Dr. Les Lilly), as well as transplant survival data from the Canadian Organ Replacement Registry (CORR). Finally, we commissioned a survey of Canadian hepatologists to evaluate current practice patterns with respect to pharmacologic treatment of patients with HCV infection.

3.3.2 Data Synthesis

When multiple data sources were available to estimate a single model parameter, we generated evidence tables to summarize the relevant evidence. Individual panel members were assigned to review all studies within a given area. The entire panel then reviewed the aggregated data and provided a consensus judgment on which studies should be included in the data synthesis. Criteria for inclusion were a) similarity of the study group to the post transfusion cohort whose prognosis was being estimated, and b) methodologic adequacy. For example, in synthesizing studies evaluating the prognosis of hepatitis C induced cirrhosis, the panel judged that only studies that focused exclusively on hepatitis C induced cirrhosis should be included, as there is some evidence that the prognosis of patients with cirrhosis related to other etiologies may have a different prognosis. With respect to methodologic adequacy, the panel judged, for example, that prognostic studies for chronic hepatitis whose selection criteria included presentation to a tertiary care centre for treatment should be excluded, as this method of selection obviously introduces a bias toward selection of the most severely affected individuals with HCV infection.

Means, standard errors, and 95% confidence intervals were calculated for studies that met the panel's inclusion criteria. To generate a summary estimate of the mean rate, we weighted each study by it's inverse variance, using the method described in Rothman et. al.[10]. This method weights each study according to the precision of its rate estimate. Precision is related to the observed rate and number of person-years of observation, which in turn is a function of sample size and mean duration of follow-up. Alternate methods of aggregating survival data were discussed by the panel, but could not be employed because of the heterogeneity

in the way in which studies reported outcome events.

This method of data aggregation uses a "fixed-effects" model, in which variation in study results is attributed entirely to random variation, and not to systematic differences in populations or study designs[11-15]. Variation in studies, however, was substantial with respect to both of these variables. Thus, it is likely that a fair degree of heterogeneity did exist among studies, and that a "fixed-effects" model likely overestimates the precision of the mean estimate (95% confidence intervals too narrow). In addition, for some parameter estimates (eg. excess mortality in transfusion recipients), a 95% confidence interval could not be estimated directly from the data. For both of these reasons, the 95% confidence interval was not always used as the "plausible range" in Monte Carlo simulation. Mean rates were always used for our "baseline estimates", but on occasion, the panel suggested alternate (usually wider) estimates for plausible ranges in Monte Carlo simulation.

3.4 Analytic Method

As indicated above, we predicted prognosis using a Markov state-transition model. Cumulative proportions of individuals entering each health state were tabulated using the "baseline" estimates for each parameter reported in Table 1. To estimate the degree of uncertainty associated with each of these estimates, Monte Carlo simulation was performed, using the plausible range for each estimate. We assumed that the probability-density function for most probability and utility estimates followed a beta distribution[16-18], though selected parameters (e.g. transfusion-related mortality) were modeled using a normal distribution. We assumed that the "baseline" value represented the mean of this distribution, and that the plausible range represented the 95% confidence interval.

3.5 Model Parameters

3.5.1 Number, Age, and Gender of HCV Infected Individuals

Two separate groups must be borne in mind when considering both the number and age distribution of HCV infected individuals. The first group are those individuals who actually acquired hepatitis C infection at the time of transfusion. This analysis primarily considers the prognosis of the first group. The second group includes all individuals who are currently HCV positive and have had a transfusion between 1986 and 1990. This second group includes the first, as well as individuals who became infected through other means, but were nonetheless transfusion recipients. It is important to bear in mind the distinction between these groups, because it may be difficult in practice to identify only group I. Lookback programmes, such as the BC lookback, identify group II, a larger, and much younger group overall.

We used the estimates of the number and age distribution of HCV infected individuals from Remis et. al.[7]. This estimate pertains to the number of patients with chronic HCV infection who acquired infection through the blood supply (Group I). This estimate implicitly accounts for the approximately 15% of

patients who become acutely infected but do not progress to chronic infection.

The estimate of age distribution reported in Remis et. al. was derived from the demographic distribution of transfusion recipients in the study of Vamvakas et. al.[19] and adjusted after reviewing the data reported in Chiavetta et. al. (Chiavetta JA, Freedman J, Cotterchio M, HerstRJ, Tam F, Wall A. Descriptive Epidemiology of red blood cell transfusion in Central Ontario, unpublished manuscript).

It should be noted, however, that the age distribution of transfusion recipients differs quite markedly from the age distribution of transfusion recipients who on lookback are found to have chronic HCV infection (Group II). Table 3 and Figure 3 show age distributions from Remis et. al. and from the BC lookback programme. The BC data is bimodal, with twin peaks around ages 35 and 70, whereas the Remis estimate has a single peak at age 67. It is likely that some of the difference in age distribution is accounted for by the presence, in the BC cohort, of individuals whose HCV infection predated transfusion.

Because we have taken the perspective of modeling outcomes in those infected through transfusion, we have opted to use the Remis estimate. However, it should be noted that it is often difficult in practice to ascertain the method by which HCV was acquired. Thus, our predictions for the cohort of those infected through the blood supply (Group I) may require some adjustment when attempting to predict the prognosis of the entire cohort of patients who are HCV positive and have had a transfusion (Group II).

3.5.2 Excess Mortality in Transfusion Recipients (Table 4)

In order to accurately predict the prognosis of HCV infected patients, it is necessary to determine accurately how many individuals remain alive and at risk of HCV-related complications at any given time. However, predicting non-HCV related mortality is not straightforward.

Age and gender-specific mortality rates for members of the Canadian population are available from population life tables. However, numerous studies have shown that the mortality experience of transfused patients is much different from that of the general population, largely due to the illnesses for which transfusion is indicated. For example, a study of 45 Toronto area hospitals reported an in-hospital mortality rate of 13%, as compared to 2% in patients that were not transfused [20]. Studies from tertiary care centres have reported 1 year mortality rates as high as 55% [21,22].

The most reliable data are available from population-based investigations of post-transfusion mortality. In this type of study design, all transfused individuals residing within a geographically or administratively distinct region are identified and and vital status determined after a period of time has elapsed. Two such studies are available. Whyte et. al. reported a two year mortality rate of 24.9% among transfusees in New Zealand. The best extant study is the retrospective cohort study

of Vamvakas and Taswell. This study reported a 10 year mortality rate of 52% among all individuals transfused in Olmsted County Minnesota in 1981 (n=802). It established age, gender, transfusion intensity, and type of transfusion as risk factors for mortality[19]. Transfusion practice was somewhat more restrictive in Olmstead County than in Canada in the early 1980's[7]. Thus, because of a (theoretically) lower burden of co-morbidity, Canadian populations may have had more favorable mortality rates.

Canadian Data Describing Mortality in Transfusion Recipients

Limited data are available describing the experience of Canadian transfused populations. The BC lookback program evaluated the mortality experience of all individuals transfused within BC between the periods of January 1985 and June 1990. This study reported an overall mortality rate of 39.8% at 9.75 years among 106,401 individuals who received a transfusion between the years 1985 and 1990. As indicated in Remis et. al., approximately 5% of short-term deaths may not have been captured in the lookback program[7], so the actual mortality rate may be as high as 45% at 10 years.

The Department of Health in Nova Scotia has also conducted a lookback programme. Phase I of the programme, which evaluates only patients transfused at the Queen Elizabeth II Health Sciences Centre in Halifax, reported a 12 year mortality rate of 59.1% (personal communication, Diane MacDonald, Department of Health, Nova Scotia). Lookback programmes are also in place in Saskatchewan and Prince Edward Island, but these programmes were unable to provide current mortality data.

Because the British Columbia data describe the mortality experience of a large, geographically defined area, they are more likely to accurately reflect the mortality experience of the entire transfused Canadian cohort than the Nova Scotia data, which is drawn from a tertiary care referral centre. This introduces a substantial referral bias, which, as other studies have shown, can dramatically increase short term post transfusion mortality rates.

Mortality in Hepatitis C Patients

Predicting Outcomes Based on Transfusion Intensity

Patients who acquire hepatitis C infection through the blood supply may be at higher risk of death (from non-liver causes) than the cohort of all transfusion recipients. As indicated, the study of Vamvakas and Taswell clearly implicated transfusion intensity as an independent risk factor for mortality [19]. Survival at 10 years in this study was 55%, 41%, and 22%, for patients receiving <4 units, 4-10 units, and >10 units respectively. Moreover, both the BC lookback programme[9] and a study from Baltimore[23] showed that the number of units of blood received among HCV infected patients was 3-4 fold higher than non-HCV infected patients (8 and 24 units, 6 and 23 units respectively).

Remis et. al. used the intensity of blood transfusion as an

additional weight to predict survival among HCV infected patients[7]. Their predictions of non-hepatitis related survival among HCV-infected individuals (10 year survival= 44%) used the survival data of Vamvakas, adjusted downward to account for the additional mortality attributable to additional transfusion intensity in the HCV infected cohort (see Figure 1, Unit Adjusted Survival). The final survival curve used in Model 1 of the the Remis report, however, adjusted this survival curve upward somewhat to account for the better survival in the B.C. cohort relative to the Vamvakas cohort. In this model, 10 year survival for the entire transfused cohort was approximately 55%

Survival Data from Post-transfusion Studies

Post-transfusion studies which describe progression rates to cirrhosis often also report mortality rates. Because most deaths in this population are unrelated to liver disease, overall mortality rates are quite similar to non-liver death rates. Table 4 reports estimated annual non-liver mortality rates, and excess mortality rates from these studies.

Annual mortality rates were calculated under the assumption that mortality follows an exponential function (constant mortality rate) over the study interval[24,25]. Excess mortality, i.e. the annual rate of death above that expected for the general population, and attributable to excess morbidity associated with transfusion, was calculated by subtracting average age and sex-related mortality rates from life tables for the general population from the reported aggregate mortality rate. As shown in Table 4, average annual mortality rates range from 0 to 3.9% per year, and excess mortality rates ranged from 0 to 3.2% per year.

The advantage of using this data is that it is the only data we have which directly estimates mortality rates in patients with post-transfusion hepatitis (mostly HCV). However, there are limitations. Referral bias is a problem, since most studies are sited in tertiary care referral centres. Some short-term deaths may have been missed, because patients would of necessity have to live long enough to develop post-transfusion hepatitis to meet the inclusion criteria of most of these clinical studies. In addition, many of these studies examine the prognosis of subgroups that may not represent the overall post-transfusion cohort. The studies of Seeff[26] and DiBisceglie[27], for example, mainly evaluated patients receiving elective surgery, and would not accurately represent the prognosis of patients with hemophilia or HIV.

Estimating Mortality Rates for the HCV Natural History Model

Figure 2 shows a series of survival curves relevant to the transfused, HCV infected cohort. The first survival curve (Unadjusted survival) shows expected survival for a cohort of members of the general population, age and gender matched to the transfused cohort. The lowest survival curve represents the estimate by Remis et. al. for survival of the transfused cohort, adjusted for excess mortality attributable to increased

transfusion intensity in HCV infected individuals. The "excess mortality" curve shows survival of the entire cohort, under the assumption of an excess mortality rate of 1.2% per year (precision-weighted average for all post transfusion studies) for the first 10 years post transfusion. We assume that after 10 years, mortality reverts to population-mean mortality [19]. The final curve (Vamvakas adjusted) shows estimated survival for the entire transfused cohort using survival data from Vamvakas et al. Relative hazard rates (the rate ratio of annual instantaneous mortality, Vamvakas vs. life table) were computed for three age strata (<40, 40-64, 65+). A revised life table and survival function was estimated for the entire cohort using the age and gender distribution of the transfused cohort, and life table survival data, adjusted using relative survival estimates.

Which of these survival curves most accurately predicts the prognosis of the HCV infected population is uncertain. Using the BC data would assume that no excess mortality attributable to transfusion intensity. The "1.2% Excess Mortality" model reports a survival experience for HCV infected patients that is better than the BC cohort's survival for all transfusion recipients, a result which seems implausible, as the prognosis of HCV infected patients is likely worse than that of the cohort as a whole. The "Unit Adjusted" estimate by Remis et. al. is plausible, and would assign a large penalty attributable to transfusion intensity, but is unsupported by actual data from HCV infected groups.

In view of the very large degree of uncertainty represented in these widely varying estimates, our group felt that we could only say that the true estimate of excess mortality lay somewhere between the extreme values of the "1.2% Excess Mortality" model and the "Unit Adjusted" model. We chose to use the "Vamvakas" model for our baseline estimates because it lay between the extremes, and because we believed that the Vamvakas model accurately reflected the early high mortality rate associated with transfusion, and the interaction of age and transfusion-associated mortality (higher excess mortality in older age groups), neither of which are reflected in the simpler excess mortality models. To compute plausible ranges for Monte Carlo simulation, we adjusted the relative hazards for the three age cohorts to simulate the 1.2% "Excess Mortality" survival curve and the "Unit Adjusted" survival curve.

3.5.3 Chronic Hepatitis C Infection

Development of Cirrhosis

We attempted to identify all published decision models and studies using the method described in section 3.3.1 (Table 5). Published decision models report estimates of the annual rate of progression to cirrhosis which range from 1.6-5.5% per year, for cumulative 20 year rates of 19-67%.

We used the taxonomy developed by Seeff[29] to aggregate individual studies characterizing the prognosis of HCV infection. Seeff identified 4 types of study: post transfusion studies, chronic liver disease studies, retrospective analyses of historically defined transfusion associated hepatitis, and

retrospective-prospective non-A non-B and C hepatitis studies. Post transfusion studies are studies in which individuals who develop post transfusion hepatitis are prospectively followed. Chronic liver disease studies are prognostic studies that select individuals for inclusion who present for clinical care, usually at tertiary care centres. Retrospective analyses of historically defined transfusion associated hepatitis studies are case series in which an attempt is made to ascertain the time elapsed since infection by determining the date of transfusion at which time infection was presumably acquired. Retrospective-prospective studies are those in which a post-transfusion or post-infection cohort is identified retrospectively, and then prospectively followed over time.

Tables 5b-5f present the studies we identified within each category[26,27,29-48]. As indicated in section 3.3.2, we derived event rates by simply dividing the number of events (cases who progress to cirrhosis) by the number of person-years in the study, to arrive at a rate (of progression to cirrhosis) per person year. For each study type, we averaged rates by weighting the event rate by the inverse variance of the event rate. At the bottom of each table we report a mean rate and standard error for each type of study design.

Mean annual rates ranged from <0.008 for retrospective-prospective studies to 0.025 for chronic liver disease studies. Because the rate at which individuals progress to liver cirrhosis is perhaps the single most important parameter in the model, our group carefully considered how to aggregate this quite disparate data. We considered several issues. The first was surveillance bias. Because cirrhosis is a histological diagnosis, it cannot (except for decompensated cirrhosis) be established in the absence of a liver biopsy. Indications for liver biopsy, however, were rarely clearly identified, and appeared to be quite variable in all study designs, though liver enzymes were usually elevated in patients who were biopsied. Serial biopsy was uncommon, except in selected Japanese studies[34,41]. Because the primary outcome was not systematically sought, therefore, most studies probably underestimated, to some extent, the rate at which their populations developed cirrhosis. Additionally, in some retrospective studies, a significant proportion of the inception cohort is no longer available for evaluation, largely because of death. Evaluation of cirrhosis rates in survivors, therefore, may not be representative of cirrhosis rates in the entire cohort, if progression of liver disease and overall death rates are related.

The other, and perhaps more important potential bias is selection bias. In chronic liver disease studies, only patients who present for clinical care are followed. This should serve to disproportionately select those patients with more advanced disease, and therefore faster progression rates, from the entire population of HCV infected individuals. The mean rate for this type of study (Table 5c) is indeed higher than, for example, post transfusion studies or retrospective-prospective studies in which selection bias might be expected to be less of a concern.

Selection bias is also a potential problem in retrospective

analyses of historically defined transfusion associated hepatitis. Here, patients are selected by their presentation with advanced disease, usually cirrhosis. Again, this disproportionately selects patients with a poor prognosis, and inflates the mean progression rate.

Post transfusion and retrospective-prospective studies, however, may also offer a biased estimate of the prognosis of post-transfusion hepatitis. Studies by Seeff et. al. and Feinman et. al. (personal communication, Dr. V. Feinman) indicate that a significant minority of patients with "post transfusion hepatitis" already had markers of HCV infection at the time of transfusion. Two populations with different mean progression rates may therefore be present in groups identified as having "post-transfusion hepatitis".

Our group believed that chronic liver disease and retrospective analyses of historically defined transfusion associated hepatitis studies were too biased to be of value for our purposes. We therefore aggregated the post-transfusion studies and the Seeff study, their differences notwithstanding, to arrive at our overall estimate of mean progression rates for a post transfusion cohort. We considered, but ultimately excluded the Irish Women's study, because we believed that a cohort that was young and female (both characteristics which select for good prognosis[45]) was too dissimilar from our mixed gender, much older post-transfusion cohort to be included in the final pool of studies.

Our group also considered the issue of duration of disease progression. From prospective studies, it is not possible to ascertain whether patients with chronic hepatitis continue to progress after 25 years. The best data which address this question directly are case series which retrospectively determine the date of transfusion and presumptive infection.
Tong, for example, reports a mean duration to cirrhosis of 20.6 years, with a range of 10-30 years[43]. Using a similar selection method to construct his study sample, Poynard related mean fibrosis stage to time elapsed since presumptive infection[45]. He found a linear relationship between these variables, though the rates at which individuals progressed to cirrhosis varied widely, with approximately 5% of all patients being "rapid fibrosers" and approximately 5% being "slow fibrosers". Poynard estimated that 33% of patients had a median expected time to cirrhosis of less than 20 years, that 36% of patients would have an expected mean time to cirrhosis of 20-50 years, and that the remainder would never progress.

From this data, we concluded that some progression to cirrhosis probably does occur beyond 20-25 years, but that a high degree of uncertainty surrounds any such estimate. In our natural history model, we opted to set transition rates for the very long term to the same parameters used to model shorter-term outcomes (<25 years). This reflects our belief that the natural history of this disease represents an orderly progression (albeit at different rates) between mild chronic hepatitis, moderate chronic hepatitis, and cirrhosis. The effect of leaving these rates

constant is to allow transition rates to cirrhosis to increase slowly with time, for the entire cohort, as more individuals enter the "moderate chronic hepatitis state". The effect on the cumulative proportion of the original cohort experiencing cirrhosis, however, is more than offset by the high competing mortality from non-liver related diseases. As the cohort as a whole ages, baseline mortality rates rise. Because the cohort is already advanced in years (median age = 62) at time of transfusion, the proportion surviving to 20 years who remain at risk of developing cirrhosis thereafter is only 30-40% (see Figure 2). Thus, the overall proportion of the cohort that develops cirrhosis in our model after 20 years is far lower than the proportion developing cirrhosis before this time.

Our model may, however, overestimate cumulative event rates in the long term because we were not able to adjust transition rates to account for the changing population of the HCV cohort over time. As the "rapid fibrosers" develop cirrhosis and are no longer at risk, the mean progression rate in individuals who remain at risk falls. In view of the uncertainty surrounding long term estimates, and the large effect of competing mortality from non-liver causes, our group believed that this simplification introduced only a modest degree of error.

Development of Hepatocellular Carcinoma (HCC)

Most patients who develop HCC develop cirrhosis first. In contrast to chronic hepatitis B virus infection, development of HCC directly from chronic hepatitis is rare. One Japanese study reported that all 124 HCV patients in their case series of HCC had histological evidence of cirrhosis[49]. Other Japanese studies report a measurable incidence of HCC in patients whose original histological diagnosis was chronic hepatitis (Table 5g)[39,50]. Whether these patients developed cirrhosis first cannot be determined from the published reports. In European and North American series, HCC is much less common, and very infrequently mentioned in prognostic studies of HCV patients that exclude cirrhotics. Our group estimated the mean annual rate for this very uncommon event at 1/10,000 per year.

3.5.4 Cirrhosis

We selected and aggregated prognostic studies for cirrhosis using the method described above. Results are reported in Table 6.

Four recent papers provided most of the data used to estimate the prognosis of patients with hepatitis C and biopsy proven cirrhosis. Ikeda et.al.[51] was a prospective study of 795 consecutive patients with cirrhosis studied between 1974 and 1989. All the subjects were Japanese, some were infected with hepatitis B(195) some with hepatitis C (364) and some with neither hepatitis B nor C but had cirrhosis probably due to excess alcohol consumption. The major outcome of the paper was to assess the rate of development of hepatocellular carcinoma. Patients had alphafetoprotein measurement performed every two months and an ultrasound performed at least once a year. Very few

patients with viral hepatitis had been treated with Interferon or were cirrhotic at baseline, though 27.8% of the patients in this study were followed from hepatitis through to cirrhosis and beyond. The major cause of death in patients with chronic hepatitis C +/- alcohol consumption was hepatocellular carcinoma. The rates for HCC in those co-infected with HCV were: at the third year 10.4%, at the fifth year 21.5%, at the tenth year 53.2%, and the fifteenth year 75.2%! The overall survival for the whole group of patients, i.e. both hepatitis C and/or hepatitis B +/- alcohol was 98% at one year, 96% at the second year, 92.8% at the third year, 87.8% at the fourth year, 94.1% at the fifth year, 73.5% at the seventh year, 57% at the tenth year and 30.9% at 15 years. Overall there was a 50% survival at 12.3 years.

The next major paper studying the morbidity and mortality of compensated cirrhosis due to hepatitis C was published in 1997 by Fattovich et. al.[52]. This was a retrospective study of patients from around Europe, said to have cirrhosis due to hepatitis C unrelated to excess alcohol consumption. About half the patient had cirrhosis when they entered the study and half the patients had hepatitis at the start of the study but were followed through to cirrhosis and beyond. The annual mortality at the median follow-up of 5 years was only 1.9%, 30% of the mortality was not due to liver disease, 33% was due to HCC and 37% was due to liver failure. Rates for HCC were 4% at 3 years, 7% at 5 years and 14% at 10 years. The overall survival of patients who had compensated heptitis C was 96% at 3 years, 91% at 5 years and 79% at 10 years.

The third paper reviewed was published by Niederau et. al.[53]. This was a follow-up of 830 patients with chronic hepatitis C infection, 500 of whom underwent a liver biopsy. Patients were not excluded if they drank alcohol to excess but were considered to suffer from alcohol abuse if greater than 80 grams of alcohol had been consumed daily. The authors performed a multivariate regression analysis of various risk factors that affected survival. They established that inpatients with both cirrhosis and no cirrhosis the standardized mortality ratio (SMR) was markedly increased in patients who were less than 50, both if their disease had been present for less than 15 years or greater than 15 years. However in patients who had cirrhosis for <15 years but who were older than 50 the SMR was barely elevated (1.3). In those who had had the disease for more than 15 years, SMR was 3.9 In the patients who were <50 years, SMR values ranged between 22.5 and 30.6 depending on the duration of the cirrhosis. Of those 141 patients who were cirrhotic at the time of entry into the study, the 3 year survival was 96%, 5 year survival 80% and 10 year survival 77%. The mean follow-up was 50 months.

The final paper reviewed was published by L. Serfaty [54]. This paper reviewed the outcome of 103 patients diagnosed with hepatitis C positive cirrhosis, all compensated at entry to the study with no evidence of HCC, co-infection with HIV, or a history of excess alcohol consumption. 59 of these 103 patients were treated with Interferon, and patients were followed up and transplant or death rates reported. The rate of hepatocellular

carcinoma at 2 years was 3% and at 4 years was 11.5%. The rate of decompensation in those given Interferon was 3.4 % at 2 years and 11% at 4 years whereas those who did not receive treatment with Interferon had a much higher rate of decompensation, 33% at 2 years and 38% at 4 years. It must be realized that Interferon treatment was not administered on the basis of a randomized controlled trial, i.e. it is likely that those who had more serious cirrhosis were unsuitable candidates for Interferon and therefore were likely to progress more rapidly to decompensation. Decompensation was not due to the development of HCC in these patients. Similarly the overall survival in those treated with Interferon was 97% at 2 years and 95% at 4 years whereas those who did not receive Interferon, the 2 year survival was 92% and the 4 year survival is 63%. The mean duration of follow-up was 70 months.

The rate of development of HCC in the Japanese patients published by Ikeda is very much higher than that reported in patients from the Western world. This could be because the rate of HCC is higher in Japaese patients or it could be that they have had HCV infection for very much longer, eg. starting in childhoood when given injections with contaminated needles.

The rates of decompensation and development of HCC derived from a pooled analysis of these four studies (4.6% and 1.7% per year respectively) are very similar to the rates observed in previous decision analytic studies. The probability of death, given decompensated cirrhosis was, unfortunately, only available in a single study[52].

3.5.5 Decompensated Liver Disease

Death given decompensated liver disease is modelled as in the original Bennett/Wong model. However, we derived Canadian estimates for the likelihood that patients with end stage liver disease would be transplanted. Table 7a outlines the assumptions involved in these calculations. In brief, we estimated the number of patients dying of HCV-related liver disease in Canada by extrapolating from US estimates, and adjusting for the difference in HCV prevalence between countries. Note that this involves an assumption that current relative prevalence is similar to remote (30-40 years ago) relative prevalence. We then calculated the prevalence of decompensated liver disease by dividing annual deaths by the annual mortality rate. We estimated the number of transplants in Canada for HCV related decompensated liver disease from data provided by the Multiple Organ Retrieval Programme and the Toronto Hospital. We calculated an annual rate of transplant, given decompensated liver disease by dividing the annual number of HCV transplants by the number of patients with HCV-related decompensated cirrhosis. Finally, using our model, we estimated the proportion of patients with decompensated liver disease who would be excluded from transplantation by age criteria, and used this to adjust the annual rate of transplant for patients younger than age 65.

3.5.6 Transplant (Tables 7b-7c)

Three recent papers on the post transplant outcome in patients undergoing transplant for decompensated HCV without complicating HCC have been reviewed. The first paper, Gane et.al. reported the survival of 149 patients transplanted for HCV[55]. In this study 3 and 5 year reported survivals were 73% and 70%. The mean followup period was 5 years and there was no difference in survival of those transplanted for HCC from patients transplanted at the same institution for conditions other than decompensated HCV. However, the rate of development of cirrhosis in HCV positive patients was 20% in those with HCV, significantly higher than that seen in 5 years of HCV negative patients. Boker et. al. reported the prognosis of 61 patients transplanted for decompensated HCV without HCC[56]. Their 3 year survival was 67% and both the 5 year survival and the 10 year survival was 62%.

Finally, a recent paper by Charlton reported the experience of multiple North American transplant centres[57]. In 166 patients transplanted for decompensated HCV, the median followup was 5 ears; 3 and 5 year survivals were 84% and 81% respectively.

These data for patients transplanted for hepatitis C report a survival experience post transplant not dissimilar from transplant registry data from the US and Canada (United Organ Sharing System, Canadian Organ Replacement Registry) which reports survival for all transplanted patients.

3.5.7. Treatment

Proportion of Patients With Chronic HCV Infection Who Are Identified (Table 1)

In Canada, it is estimated that 0.8% of the general population are anti-HCV positive[7]. Approximately 30% of the predicted number of patients with HCV infection have been identified as having HCV infection[7]. However, this figure may not be accurate as HCV infection has not been reliably reported until the past few years.

The only published study addressing this question is from France. In 1994, a large survey of 6,283 randomly selected patients from 4 centres were tested for anti-HCV antibody and 72 were found positive. Of this group, only 17 or 24% were previously aware of their seropositivity prior to enrollment in the study [58]. However, with increased awareness of HCV both by physicians and patients since 1994, and with the recent interest in compensation, the frequency of testing for HCV has gone up dramatically, especially in blood transfusion recipients. Based on this data, our group estimated that approximately 30% of patients had been identified as being HCV positive by 1999.

Proportion Contacted in Lookback and Tested for HCV

In the near future, provinces will be implementing lookback programmes to identify individuals who are HCV positive. Perhaps the best guide to the efficacy of these programmes is the BC experience. In September 1996 the Blood Recipient Notification Project attempted to identify all individuals transfused between January 1985 and June 1990. Of those transfused, 85% were contacted and advised to be tested for HCV. 61% of those

contacted, or 52% of the overall cohort were tested. We used these figures in our model, though we recognized some potential sources of error. Not all provinces will immediately implement a programme as effective as British Columbia's. On the other hand, we recognized that a higher proportion of transfusess may come forward for testing, some spontaneously, if compensation serves as an incentive. To recognize this uncertainty, our estimate includes very wide plausible limits (overall probability of being tested for HCV, given transfusion= 0.52 +/- 0.25).

Proportion of Patients Receiving a Liver Biopsy Who Present for Care (Table 1)

Practicing hepatologists within the group estimated that between 40% and 70% of patients aged <65 presenting to a hepatologist are currently offered a biopsy. For those older than 65 years, 0-30% are offered a biopsy. At present, biopsy tends to be offered mainly to patients with elevated ALT levels without contraindications to antiviral therapy. However, the existence of a compensation programme may provide an incentive toward biopsy for patients (and to a lesser extent, to physicians interested in their welfare). Bearing these considerations in mind, our group estimated that approximately 60% of patients <65, and approximately 10% of those >65 would be biopsied.

Post-transfusion Hepatitis C Patients Treated

No Canadian data exists which describes current practice patterns with respect to antiviral therapy. Practice patterns in other countries probably cannot be generalized to Canada. We therefore constructed a questionnaire (Appendix) and sent it to 15 Canadian hepatologists. Twelve returned completed questionnaires for an overall response rate of 73%. Responses are reported in Table 8.

Nine hepatologists indicated that they only prescribe combination treatment; only three Canadian hepatologists indicated that they would currently consider any patient for monotherapy with interferon. When responses were combined, only 1% of patients are currently being treated with IFN alone, and this number is expected to fall in the future. Therefore, we opted to represent only combination therapy in our model.

Hepatologists indicated that approximately 30% of HCV patients were not candidates for therapy because of coexisting morbidity, and that 32% of patients with mild hepatitis, 45% with moderate hepatitis and 40% with compensated cirrhosis would be treated. These estimates can be compared with data supplied by the manufacturer of Ribavirin, which reports that 1800 Canadian patients had been treated on a compassionate basis within the first 10 months of 1998.

These estimates have not, for the most part, been validated with actual data describing clinical practice patterns. In addition, they may not represent practice in the distant future, as practice patterns will no doubt evolve over time. Both of these considerations suggest that a fairly large degree of uncertainty surrounds these estimates.

Treatment Efficacy (Table 1)

Our estimate of treatment effectiveness was derived from a pooled analysis of the primary data set of the only two randomized controlled trials comparing Interferon/Ribavirin therapy to placebo[59,60]. We did not pool the overall effect estimates, as both of these trials compared combination therapy to monotherapy. Rather, we pooled the sustained response estimates for the combination therapy arms of both trials.

Our group considered the issue of whether the results of these trials could be applied to the post-transfusion cohort. We were concerned in particular about the issue of genotype. Data from the RCT's suggest that sustained response rates are lower in genotype 1. No data, unfortunately, are available which characterize the distribution of genotypes in post-transfusion patients in Canada. Other data suggest that the prevalence of genotype 1 among all HCV patients is approximately 55-60% in Canada, slightly lower than the 65% prevalence observed in the combined trial groups. In the absence of more precise data, we opted to use the pooled estimate from both trials, which includes all genotypes.

4.0 Results

We applied the Remis et. al. analysis for Canadians who were transfused from 1986 through part of 1990 to 10 different age cohorts: 0-9, 10-19, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79, 80-89, and >= 90, respectively. Mortality arose from 3 etiologies: 1) as occurs in the general population (General Population in Tables 9-10); 2) as occurs in the general population and as related to the disease that necessitated the transfusion (Posttransfusion in Tables 9-10); and 3) as occurs in the general population, as related to the disease that necessitated the transfusion and as due to chronic hepatitis C (CHC) (Posttransfusion CHC in Tables 9-10). To determine the effect of potential treatment with the current standard regimen of ribavirin and interferon, we assumed that 51% of those patients alive 10 years after transfusion would be screened and assumed that 60% of patients equal to or over the age of 18 and less than the age of 65 would be biopsied (10% of all other patients would receive liver biopsy but not be treated) and a proportion of those with particular histological characteristics would receive treatment (Posttransfusion CHC and Treated in the tables below). The following tables present the primary results for the overall post transfusion cohort from the time of transfusion assuming that transfusion occurred on average in 1988.

The underlying disease which led to the transfusion carries a substantial mortality burden, nearly doubling the likelihood of dying from any cause by 10 years after the event. By 10 years after transfusion, there is little mortality related to chronic hepatitis C, but over the next 10 years (year 10 to 20), hepatitis C related mortality rises eight-fold. During the

subsequent 10 years (year 20 to 30), hepatitis C related mortality doubles. These results are consistent with hepatitis C being a relatively slowly evolving disease requiring decades for disease progression. The high likelihood of dying from the disease that necessitated the transfusion and the relatively slow progression of hepatitis C reduces the number of transfusees that may survive long enough to develop complications from the hepatitis C. Thus, the relatively older age of the Canadian transfusion cohort results in a 13.9% likelihood of developing cirrhosis after 20 years. Based on the above assumptions, 6.8% of the initial cohort would receive treatment with interferon and ribavirin (37% of treated patients-some with cirrhosis-would have a sustained viral negative response) would reduce this likelihood to 13.4% after 20 years. The effects are modest because only a small proportion of the cohort receives treatment, and the benefit of a sustained viral negative response is averaged with those who did not respond and those who were never treated.

The appendix contains the disaggregated results for each age cohort and demonstrates the effect of non-hepatitis C related mortality. Older patients are likely to die before developing complications from chronic hepatitis C whereas younger patients with a longer life expectancy have an increased risk of developing complications from hepatitis C that then shortens their life. The average life expectancy for an age and gender matched cohort from the general population would be 25.6 years and that for a posttransfusion cohort would be 20.6 years. Posttransfusion chronic hepatitis C infection reduces this life expectancy to 18.2 years and treatment of a small proportion of the cohort would increase the life expectancy to 18.3 years. Although only 13.9% of the cohort develop cirrhosis, the life expectancy in this group is substantially shortened.

The results above are predictions based from the time of transfusion, approximately in 1988. Using the same outcome results, we have adjusted the tables to reflect prognosis for those who are alive in 1999 and who have not already developed each complication. Thus, these results reflect what may happen over the next 10 to 20 years (from 1999 to 2008 and to 2018). These tables reflect the prognosis of the select population who are alive in 1999 and who have not developed the complication listed in the tables yet. These likelihoods in general appear much higher than those in the prior result tables for two reasons. First, these patients have had hepatitis C for 10 years so that many have developed some fibrosis in their liver and over the next 10 years may develop bridging fibrosis or cirrhosis. Second, although the surviving cohort is 10 years older, the likelihood of dying from all causes from 1998 to 2008 (~29%) should be lower than that predicted to occur in the cohort from 1988 to 1998 (~46%). These patients have survived the excess mortality related to the disease that led to the transfusion. We have limited this disease related mortality to a 10 year duration starting from the year the transfusion occurred, so the mortality risk over the remainder of the cohort's life is limited to that in an age and gender matched general population.

Tables 11a and b present sensitivity analyses that explore the effects of uncertainty in our prognostic model. Table 11a reports the results of our Monte Carlo simulation that simultaneously considers all sources of uncertainty in the model. The observed standard deviations (SD) are very wide, reflecting the fact that the overall uncertainty in the prognostic model is high. For example, the 20 year probability of cirrhosis (13.9%) has an associated SD of 15%. This can be interpreted as follows: there is a 68% chance that the true estimate lies within 1 SD of the baseline estimate (0-29%) and a 95% chance that the true estimate lies within 2 SD of the baseline estimate (0-44%). Much of the overall model uncertainty has to do with uncertainty in estimates of non-hepatitis C mortality. Were this parameter excluded, the overall uncertainty would be significantly smaller.

Table 11b reports results using alternate estimates for age distributions. As indicated in section 3.5.1, alternate approaches can be taken to estimating the age and gender distribution of HCV infected individuals. Our baseline estimate reports results using the Remis et. al. estimates. Table 9g shows how these results would change if the age distribution from the BC Lookback Programme were used. Using the BC estimates would increase the number of individuals expected to develop complications of infection, because this much younger cohort lives longer, and therefore has more opportunity to develop adverse HCV-related outcomes.

Our projections differ somewhat from those put forth by an earlier working group (Remis et. al.) largely because the assumptions regarding non-HCV mortality differ. To enhance the comparability of these reports, we also report in Table 12 the results generated using our model, but the assumptions of the earlier working group with respect to non-HCV mortality. As might be expected, the probability of developing complications, overall, is lower when higher mortality rates are used, as in the previous working group model.

5.0 Discussion

Our attempt to project the natural history of the 1986-1990 post transfusion HCV infected cohort has limitations. Perhaps foremost among these is our lack of understanding of the long-term prognosis of the disease. For periods beyond 25 years, projections remain particularly uncertain. The wide confidence intervals surrounding long-term projections highlight this uncertainty.

Other key limitations are lack of applicability of these projections to children and special groups. Our model does not incorporate age-specific transition probabilities. Some data suggest that age of acquisition strongly affects prognosis, with progression to cirrhosis much more likely in individuals who are older at the time of infection. In contrast, children appear to have a better prognosis, at least for the first few years after infection[61-64]. Less than 5% of the post transfusion cohort was younger than 20 years. We therefore did not adjust our prognostic model to account for age differences. The implication of this is that age-specific prognoses (Appendix Tables), particularly those of younger children who will live many years with their disease, must be interpreted with caution.

In addition, our model does not accurately reflect the prognosis of hemophiliacs or patients coinfected with HIV. In these groups, progression rates to cirrhosis and competing mortality rates differ. Cumulative death and cirrhosis rates for these subgroups, therefore, cannot be derived directly from our results.

In our forecasts, we are projecting not only disease-specific prognoses, but also Canadian practice patterns, including those pertaining to response to lookback and other notification programmes, and rates of biopsy, antiviral therapy, and transplantation. Current practice is our only guide to conjectures about the future, but this approach to prognostication is subject to significant error.

Finally, consumers of these estimates are advised to bear in mind that they represent our group's best estimates of the prognosis of individuals infected through transfusion. As discussed above, it will be difficult, if not impossible, in practice to distinguish between those who acquired HCV infection prior or subsequent to transfusion, and those whose infection was transfusion-related. Because the former group is much younger, on average, their prognosis will differ. Age at infection is associated with risk of progression, so the annual rate of development of decompensated liver disease is likely somewhat lower, overall, for this group. On the other hand, they will live longer, as they are younger at time of transfusion, and therefore will have a greater lifetime risk of developing decompensated liver disease.

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le 1- Summary Probability Table

	Age	Baseline Rate		Low	High	Source
ss Mortality, All Transfusees		Excess mort. for 10 years post trans.		0.5 x	1.50 x	see Table 4 and Figure 2
Chronic Hepatitis						
Remission		0.002		0.001	0.004	Original Model
Moderate chronic hepatitis		0.041*derived constant*				See Table 5
erate chronic hepatitis						
Cirrhosis		0.073*derived constant*				See Table 5
HCC		0.0001		0.0000	0.0020	Consensus judgment- see Table 5
osis						
Decompensation		0.046		0.038	0.054	Weighted Average, see Table 6
HCC		0.017		0.013	0.022	Weighted Average, see Table 6
mpensated Cirrhosis						
Death		0.136		0.074	0.202	Weighted Average, see Table 6
Transplant		0.033		0.017	0.049	Table 7
Death		0.860				Original Model
transplantation						
Death (first year)		0.169		0.127	0.210	Weighted Average, see Table 6
Death (after first year)		0.034		0.024	0.043	Weighted Average, see Table 6
ortion of Post-transfusion Hepatitis C Patients Identified as Hepatitis C						
Prior to 1999		0.3		0.2	0.4	LCDC, Dubois et.al.
Of remainder, contacted in lookback		0.85				BC lookback programme, Consensus judgment
Tested for HCV, given contact		0.6				Consensus judgment
Overall prob. test		0.52		0.27	0.77	Calculated
r Biopsy						
Proportion alive in 1999	<65	0.6		0.40	0.80	Consensus judgment
getting a liver biopsy	>65	0.1		0.00	0.20	Consensus judgment
Mortality, Liver Biopsy		0.0002		0.0001	0.0003	Consensus judgment
ortion of Post-transfusion Hepatitis C Patients Treated						
Prior to 1999		0		0.05	0.15	Consensus Judgment
Post 1999		as per survey (see below)				
nbination Interferon/Ribavirin						
Sustained response						pooled analysis, RCT's
mild hepatitis		0.361	0.436	0.286		
moderate hepatitis		0.432	0.488	0.376		
chronic hep c fibrosis		0.208	0.374	0.042		
ortion of Patients Eligible for Treatment						
Mild chronic hepatitis	<65	0.317		0.261	0.372	Practice Survey of Hepatologists- see Table 7
Moderate chronic hepatitis	<65	0.450		0.387	0.513	
cirrhosis	<65	0.396		0.337	0.455	
Mild chronic hepatitis	>65	0		0	0	Practice Survey, hepatologists
Moderate chronic hepatitis	>65	0		0	0	
cirrhosis	>65	0		0	0	

*obability of progression from mild to moderate chronic hepatitis, and from moderate to cirrhosis adjusted to yield an overall progression rate to cirrhosis of 1.05%/yr (0.8-1.3%/yr) at 20 years. See Table 5f.

Table 2 Summary of HCV Infections Canada, 1960-92

(adapted from Remis et. al.)

Year	Number of units admin	Per-unit HCV risk	HCV infections
1992	449,995	0.00017	75.2
1991	1,899,981	0.00017	317.7
1990b	1,424,985	0.00037	524.1
1990a	474,995	0.00185	852.1
1989	1,570,984	0.00201	3046.7
1988	1,602,984	0.00223	3425.0
1987	1,656,983	0.00246	3882.2
1986b	641,243	0.00278	1687.7
1986a	1,068,739	0.00278	2812.9
1985	1,745,182	0.00317	5191.9
1984	1,702,183	0.00356	5631.0
1983	1,576,084	0.00383	5582.8
1982	1,458,885	0.00400	5383.7
1981	1,378,686	0.00400	5087.7
1980	1,296,687	0.00400	4785.1
1979	1,268,078	0.00400	4679.6
1978	1,255,403	0.00400	4632.8
1977	1,176,288	0.00400	4340.8
1976	1,231,887	0.00400	4546.0
1975	1,218,688	0.00400	4497.3
1974	1,166,088	0.00400	4303.2
1973	1,210,088	0.00400	4465.6
1972	1,089,089	0.00420	4202.6
1971	1,002,890	0.00420	3869.9
1970	930,520	0.00420	3590.7
1969	948,690	0.00420	3660.8
1968	946,890	0.00420	3653.8
1967	897,991	0.00420	3465.2
1966	856,391	0.00420	3304.6
1965	819,392	0.00420	3161.9
1964	804,392	0.00420	3104.0
1963	765,392	0.00420	2953.5
1962	726,393	0.00420	2803.0
1961	663,193	0.00420	2559.1
1960	626,294	0.00420	2416.7

Table 3 Age and Gender Distribution

At Transfusion (Remis et. al.)

Age	Males	Females	Both
0-4	0.0089	0.0087	0.0176
5-9	0.0053	0.0054	0.0107
10-14	0.0096	0.0096	0.0192
15-19	0.0125	0.0129	0.0254
20-24	0.0163	0.0159	0.0322
25-29	0.0200	0.0202	0.0403
30-34	0.0118	0.0150	0.0268
35-39	0.0127	0.0165	0.0292
40-44	0.0159	0.0232	0.0391
45-49	0.0202	0.0279	0.0481
50-54	0.0284	0.0360	0.0644
55-59	0.0332	0.0421	0.0754
60-64	0.0394	0.0598	0.0993
65-69	0.0749	0.1011	0.1760
70-74	0.0603	0.0596	0.1199
75-79	0.0399	0.0525	0.0924
80-84	0.0283	0.0410	0.0693
85-89	0.0044	0.0035	0.0079
90+	0.0038	0.0030	0.0068
Total	0.4459	0.5541	1.0000

HCV Positive (BC Lookback Programme)

Age	Number	Proportion
5	30	0.0158
10	22	0.0116
15	22	0.0116
20	80	0.0420
25	130	0.0683
30	205	0.1077
35	245	0.1287
40	207	0.1088
45	130	0.0683
50	110	0.0578
55	115	0.0604
60	125	0.0657
65	140	0.0736
70	150	0.0788
75	120	0.0631
80	52	0.0273
85	15	0.0079
90	5	0.0026
90+	0	0.0000
	1903	1.0000

able 4, Excess Mortality in Transfusees, Derived from Post transfusion Studies

Prospective studies of transfusion-associated non-A, non-B hepatitis followed-up from onset of acute disease

author	country	selection method	outcome	serial biopsy	IFN	n	mean age	population mortality	events	survival fra of event	mean followup	person-years	aggregate mortality	excess mortality	SE	weight (1/VAR)
i Bisceglie	USA	AST	death	yes	no	39	52	0.007	9	0.769	10	378	0.024	0.017	0.007	22802
remolada	Italy	AST	death	some	no	104	53	0.008	10	0.904	6	783	0.013	0.005	0.002	162660
oretz	USA	AST	death	no	no	80	51	0.007	31	0.667	10	832	0.037	0.030	0.006	27678
lattson	Sweden	AST	death	no	no	61	41	0.002	5	0.918	13	793	0.006	0.005	0.002	173453
arrera	*Spain*	AST	death	no	no	41	58		?		8	246				
ealdi	Italy	AST	death	some	no	15	48		0	1.000	3	52				
eeff	USA	AST	death	no	no	568	49	0.011	268	0.490	18	10224	0.026	0.015	0.001	664781
												13308				1051375
								mean, excess mortality						0.0124		
								SEM						0.001		
								95% CI						0.010	0.014	

able 5
utcomes, Chronic Hepatitis

able 5a
ection Models

	Bennett	Kim	Dusheiko low	Dusheiko high	Dusheiko Shiell
ial prob. of mild chronic hepatitis	1.000	0.500	NA	NA	NA
ial prob. of moderate chronic hepatitis	0.000	0.500	NA	NA	NA
nnual probability of moderate chronic hepatitis	0.041	NA	NA	NA	NA
nnual probability of cirrhosis, given mild hepatitis	0.000	0.010	NA	NA	NA
nnual probability of cirrhosis, given moderate hepatit	0.073	0.100	NA	NA	NA
umulative probability of cirrhosis, 20 years*	0.280	0.667	0.189	0.367	0.200
verall annual probability of cirrhosis, 20 years	0.016	0.055	0.011	0.022	0.011
robability of IFN treatment	1.000	1.000	1.000	1.000	1.000

estimated by using the approximation: survival free of events=1-e^(-rt), where r= annual event rate
and t= years elapsed

able 5b
ost transfusion Studies — Prospective studies of transfusion-associated non-A, non-B hepatitis followed up from onset of acute disease

uthor	country	selection method*	outcome	serial biopsy	IFN	n	events	survival fra of event	mean followup	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
h Bisceglie	USA	AST	cirrhosis	yes	no	39	8	0.795	10	0.021	378	0.007	17900	378
Iemolada	Italy	AST	cirrhosis	some	no	104	16	0.844	8	0.021	783	0.005	37858	783
Koratz	USA		cirr or LF	no	no	80	10	0.875	10	0.012	828	0.004	58558	828
Mattson	Sweden	AST	cirrhosis	no	no	24	2	0.917	13	0.006	312	0.005	46872	312
Barrera	Spain	AST	cirrhosis*	no	no	41	5	0.878	8	0.020	246	0.009	12103	246
											2547		185092	2547
			mean rate						0.014					
			SEM						0.002					
			95% CI						0.009	0.018				

*AST=selected by elevated AST post transfusion, TC=referral to tertiary care centre

Table 5c
Chronic Liver Disease — studies of outcome of chronic hepatitis C among persons with already established chronic liver disease

Takahashi	Japan	TC	cirrhosis	some	no	100	42	0.580	11	0.038	1100	0.006	28810	1100
Roberts			cirrhosis			57	5	0.920	10	0.008	570	0.004	71250	570
Tong	USA		cirrhosis	no		131	0		4					
Vaquer	Spain	TC	cirrhosis	yes	no	27	5	0.815	4	0.044	113	0.020	2552	113
Kobayashi	Japan	TC	cirrhosis	yes	no	140	13	0.907	10	0.010	1344	0.003	138949	1344
Verbaan	Sweden	TC	cirrhosis	no	no	94	30	0.681	10	0.032	940	0.008	29453	940
Mattson	Swedan	TC	cirrhosis	yes	no	13	5	0.815	4	0.100	50	0.045	497	50
Mattson*	Sweden	TC	cirrhosis	yes	no	37	9	0.757	5	0.051	176	0.017	3432	176
Realdi	Italy	TC	cirrhosis	some	no	15	4	0.762	3	0.068	52	0.038	769	52
Yousuf	Japan	TC	cirrhosis	yes	no	111	19	0.829	5	0.034	555	0.008	16212	555
Yano	Japan	TC	cirrhosis	yes	no	70	35	0.500	9	0.057	616	0.010	10842	616
Hopf	Germany	TC	cirrhosis	most	no	86	21	0.756	8	0.031	688	0.007	22540	688
											6204		325305	6204
			mean rate						0.019					
			SEM						0.002					
			95% CI						0.016	0.023				

*contains some of the same patients as the earlier study

Table 5d

Retrospective Analysis of Historically Defined Transfusion Associated Hepatitis*

Kiyosawa			cirrhosis					0.500	21	0.033
Tong	USA	TC	cirrhosis	no	no		131	0.542	21	0.030
Gordon**	USA	TC	cirrhosis	no		0.236	627	0.475	25	0.030
Poynard	France	TC	cirrhosis	no	no		2235	0.500	30	0.023
Yano	Japan	TC	cirrhosis	no	no		155	0.703	9	0.040
			mean rate					0.025		

* approximation, as estimated mean time to cirrhosis, not median time, are reported

** from reported K-M survival curves

Table 5e

Retrospective-Prospective Studies of NANB and C Hepatitis

Irish	cirrhosis	232	0.976	17	0.001	3944	
German	cirrhosis	160					
NHLBI	cirrhosis	103	0.850	20	0.008	2060	

Table 5f

Summary- post transfusion studies + retrospective-prospective transfusion studies

author	country	selection method	outcome	serial biopsy	IFN	n	events	survival fre of event	mean followup	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
Di Bisceglie	USA	AST	cirrhosis	yes	no	39	8	0.795	10	0.021	378	0.007	17900	378
Tremolada	Italy	AST	cirrhosis	some	no	104	18	0.844	8	0.021	783	0.005	37858	783
Koretz	USA		cirr or LF	no	no	80	10	0.875	10	0.012	828	0.004	68558	828
Mattson	Sweden	AST	cirrhosis	no	no	24	2	0.917	13	0.006	312	0.005	46672	312
Barrera	Spain	AST	cirrhosis*	no	no	41	5	0.878	6	0.020	246	0.009	12103	246
NHLBI	USA	AST	cirrhosis	no	no	103	15	0.850	20	0.008	2060	0.002	253509	2060
											4607		438601	4607
			mean rate						0.0105					
			SEM						0.002					
			95% CI						0.008	0.013				

Table 5g

Hepatocellular Carcinoma

author	country	selection method	outcome	serial biopsy	IFN	n	events	survival fre of event	mean followup	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
Tsukuma	Japan		HCC		no	677	26	0.962	3	0.013	2014	0.003	156019	2014
Tradati	Italy		HCC		no	345			4					
Yousuf			HCC		no	111	16	0.856	5	0.029	555	0.007	19252	555
											2569		175271	2569
			mean rate						0.015					
			SEM						0.002					
			95% CI						0.010	0.019				

Table 6
Probability of Adverse Outcomes, Given Stable, Compensated Cirrhosis

Table 6a
Decision Models

	Bennett	Kim	Dusheiko low	Dusheiko high	Shiell
annual probability of ascites	0.025	NA	NA	NA	NA
annual probability, variceal hemorrhage	0.011	NA	NA	NA	NA
annual probability, encephalopathy	0.004	NA	NA	NA	NA
combined annual probability of decompensation	0.040	0.040	0.050	0.050	**0.019
probability of HCC	0.015	NA	NA	NA	**0.019

** estimated by using the approximation: survival free of events=1-e^(-r*t), where r= annual event rate and t= years elapsed
** Shiell et. al. estimate a cumulative probability of 20% at 20 years

Table 6b
Decompensation

author	outcome	n	events	survival fre of event	mean followup	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
Fattovich	decomp	355	65	0.817	5	0.037	1775	0.005	48471	1775
Ikeda	decomp									
Niederau	decomp	141	80	0.433	4	0.136	588	0.015	4314	588
Serfaty	decomp	103	19	0.816	3	0.055	343	0.013	6204	343
							2706		58990	2706
	mean rate					0.046				
	SEM					0.004				
	95% CI					0.038	0.054			

2706

Table 6c
Hepatocellular Carcinoma

author	outcome	n	events	survival fre of event	mean followup	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
Fattovich	HCC	384	29	0.924	5	0.015	1920	0.003	127117	1920
Ikeda	HCC	354								
Niederau	HCC	141	13	0.908	4	0.022	588	0.006	26550	588
Serfaty	HCC	103	11	0.893	3	0.032	343	0.010	10716	343
							2851		164384	2851
	mean rate					0.017				
	SEM					0.002				
	95% CI					0.013	0.022			

Table 6d
Death, Given Decompensated Cirrhosis

author	outcome	n	events	survival fre of event	mean followup	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
Fattovich	Death	65		0.500	2	0.138	128	0.033	924	128
Ikeda	Death	354								
Niederau	Death	141								
Serfaty	Death	103								
							128		924	128
	mean rate					**0.138**				
	SEM					**0.033**				
	95% CI					**0.074**	**0.202**			

Table 6e
Death, Given Compensated Cirrhosis

author	outcome	n	events	survival fre of event	mean followup	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
Fattovich	Death	384	51	0.867	5	0.027	1920	0.004	72282	1920
Ikeda	Death	354								
Niederau	Death	141	31	0.780	4	0.053	588	0.009	11134	588
Serfaty	Death	103	16	*0.845*	3	0.047	343	0.012	7367	343
							2851		90784	2851
	mean rate					**0.031**				
	SEM					**0.003**				
	95% CI					**0.025**	**0.038**			

Table 7

Outcomes Post Transplantation

Table 7a

Annual Probability of Transplant, Given Decompensated Liver Disease

Liver deaths per year, US	8300	CDC
relative population	0.10	US/CAN census data
HCV infections US	3900000	
HCV infections, Canada	240000	Remis et al
Relative prevalence, HCV infection (CAN/US)	0.60	calculated
Liver deaths per year, HCV, Canada	511	calculated
Median survival, decomp	5.00	Fattovich
Annual mortality rate	0.14	Fattovich
Annual prob death, decomp liver disease	0.13	calculated
Prevalence of decomp liver disease, HCV	3946	calculated
Proportion of transplants, HCV	0.21	Toronto Hospital data
Total transplants, Canada, per year	315	MORE
Transplants for HCV	65	calculated
Annual prob of transplant, given decomp HCV	0.0166	calculated
Proportion of transplant cohort with decomp HCV over age 65	0.5	calculated
Proportion of those >65 receiving transplant	0	assumption
Corrected annual probability of transplant, age<65	0.0331	calculated

Table 7b

Death, Given Transplant, Year 1

author	outcome	n	events	survival free of event	mean follow-up	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
All Transplants										
CORR	Death	2170		0.850	1	0.163				
UNOS	Death			0.822	1	0.198				
HCV Transplants Only										
Baker	Death	61	16	0.700	1	0.357	61	0.078	171	61
Charlton 1998 000	Death	166	18	0.890	1	0.117	166	0.026	1424	166
Gane	Death	149	31	0.790	1	0.236	149	0.040	632	149
							376		2228	376
	mean rate					0.169				
	SEM					0.021				
	95% CI					0.127	0.210			

Table 7c

Death, Given Transplant, Year 2-5

author	outcome	n	events	survival free of event	mean follow-up	annual rate	person years	SE rate	weight (1/VAR)	weighted rate
All Transplants										
CORR	Death	2170		0.918	4	0.021				
UNOS	Death			0.904	2	0.050				
HCV Transplants Only										
Baker	Death	61	2	0.700	4	0.030	244	0.011	8042	244
Charlton 1998 000	Death	166	6	0.890	4	0.039	664	0.008	16820	664
Gane	Death	149	4	0.790	4	0.030	596	0.007	19710	596
							1504		44573	1504
	mean rate					0.034				
	SEM					0.005				
	95% CI					0.024	0.043			

Table 8

Practice Survey

	Interferon and Ribavirin													Mean MEAN	Standard Deviation	Standard Error	Maximum Value	Minimum Value
1 What % not treated because of co-morbidit	25	40	50	20	40	45	20	30	20	NR		50	20	30	15	1.38	50	0
2 What %, overall, do you treat?	35	40	17.5	30	20	37.5	75	60	75	NR		20	50	38	23	2.12	75	0
3 % treated with normal ALT	0	0	0	0	5	0	0	100	40		0	0	0	12	30	2.72	100	0
4 % treated with mild hepatitis	10	40	20	NR	10	NR		75	70	80	NR	50	25	32	30	2.77	80	0
5 % treated with moderate hepatitis	40	40	40	NR	30	NR		75	100	90	NR	50	75	45	35	3.16	100	0
6 % treated, compensated cirrhosis	80	40	75	NR	10	NR		50	75	20	NR	50	75	40	32	2.95	80	0
7 % treated, decompensated cirrhosis	0	0	0	NR	2	0	0	10	0		0	0	0	1	3	0.26	10	0
8 What criteria, no IFN																		
9 Older than 65?																		
	Interferon Alone																	
1 What % not treated because of co-morbidity				60								40	15	10	23	2.05	60	15
2 What %, overall, do you treat?				10								5	0	1	5	0.45	10	0
3 % treated with normal ALT				0								10	0	1	6	0.52	10	0
4 % treated with mild hepatitis			NR									10	0	1	6	0.52	10	0
5 % treated with moderate hepatitis			NR									10	0	1	6	0.52	10	0
6 % treated, compensated cirrhosis			NR									10	0	1	6	0.52	10	0
7 % treated, decompensated cirrhosis			NR									0	0	0	0	0.00	0	0
8 What criteria, no IFN																		
9 Older than 65?																		

Values represent responses of each hepatologist.
NR= no response

Table 9. Summary Result Table for Entire Transfused Population

Probability of Dying from All Causes

Population	Years Post Transfusion		
	10	20	30
General Population	24.5%	48.9%	67.5%
Posttransfusion	46.1%	59.7%	72.4%
Posttransfusion CHC	46.4%	61.8%	76.6%
Posttransfusion CHC & Treatment*	46.4%	61.7%	76.3%

Probability of Dying from HCV Related Causes

Population	Years Post Transfusion			Life-time
	10	20	30	
Posttransfusion CHC	0.3%	2.5%	5.8%	13.0%
Posttransfusion CHC & Treatment*	0.3%	2.5%	5.6%	12.3%

Probability of Developing HCV Related Cirrhosis

Population	Years Post Transfusion			Life-time
	10	20	30	
Posttransfusion CHC	5.7%	13.9%	19.8%	26.2%
Posttransfusion CHC & Treatment*	5.6%	13.4%	18.9%	24.9%

Probability of Developing CHC Related Decompensated Cirrhosis

Population	Years Post Transfusion			Life-time
	10	20	30	
Posttransfusion CHC	0.7%	3.3%	6.4%	11.8%
Posttransfusion CHC & Treatment*	0.7%	3.2%	6.1%	11:2%

Probability of Becoming Seronegative for HCV

Population	Years Post Transfusion		
	10	20	Life-time
Posttransfusion CHC	1.2%	1.7%	2.2%
Posttransfusion CHC & Treatment*	1.2%	1.7%	2.1%

* Treatment with ribavirin/interferon for 6.8% of the initial cohort with a sustained viral negative response in 37% of those treated.

Table 10. Summary Results for Populations that are Alive in 1999

Probability of Dying from All Causes from 1999 until the Year of Follow-up

Population	Year of Follow-Up 2008	2018
Posttransfusion	25.1%	48.8%
Posttransfusion CHC	28.7%	56.2%
Posttransfusion CHC & Treatment*	28.5%	55.7%

Probability of Dying from CHC Related Causes from 1999 until the Year of Follow-up

Population	Year of Follow-Up 2008	2018	Life-time
Posttransfusion CHC	4.0%	9.8%	22.4%
Posttransfusion CHC & Treatment*	2.9%	7.3%	16.9%

Probability of Developing CHC Related Cirrhosis from 1999 until the Year of Follow-up

Population	Year of Follow-up 2008	2018	Life-time
Posttransfusion CHC	16.1%	27.5%	39.9%
Posttransfusion CHC & Treatment*	11.8%	20.2%	29.4%

Probability of Developing CHC Related Decompensated Cirrhosis from 1999 until the Year of Follow-up

Population	Year of Follow-up 2008	2018	Life-time
Posttransfusion CHC	4.8%	10.2%	19.7%
Posttransfusion CHC & Treatment*	3.5%	7.7%	14.9%

* Treatment with ribavirin/interferon for 6.8% of the initial cohort with a sustained viral negative response in 37% of those treated.

Table 11. Sensitivity Analyses.

11a. Monte Carlo Simulations

		Standard Deviation	95% Confidence Interval
20 year probability of cirrhosis (cumulative)	13.9%	15%	0-44%
lifetime probability of cirrhosis	26.2%	19%	0-64%
20 year probability of liver death	2.5%	2.8%	0-8%
lifetime probability of liver death	12.3%	7.2%	0-27%

11b. Effect of Using Age Distributions Derived from the BC Lookback Programme

	Cirrhosis at 20 years (%)		*Cirrhosis* Lifetime (%)	
	BC	Remis	BC	Remis
General population	0	0	0	0
Transfused population	0	0	0	0
CHC, biopsied and treated	15.1	13.9	32.7	26.2
CHC, no treatment	16.0	13.4	35.1	24.9

Table 12. Summary Result Table for Entire Transfused Population-Using Assumptions of Remis et. al. Regarding Transfusion-Associated Mortality

Probability of Dying from All Causes

Population	Years Post Transfusion		
	10	20	30
General Population	33.3%	58.3%	73.9%
Posttransfusion	58.0%	69.7%	78.9%
Posttransfusion CHC	58.3%	71.3%	82.1%
Posttransfusion CHC & Treatment*	58.2%	71.1%	81.8%

Probability of Dying from HCV Related Causes

Population	Years Post Transfusion			Life-time
	10	20	30	
Posttransfusion CHC	0.3%	2.0%	4.5%	9.8%
Posttransfusion CHC & Treatment*	0.3%	1.9%	4.3%	9.2%

Probability of Developing HCV Related Cirrhosis

Population	Years Post Transfusion			Life-time
	10	20	30	
Posttransfusion CHC	4.8%	11.1%	15.5%	20.3%
Posttransfusion CHC & Treatment*	4.7%	10.6%	14.7%	19.2%

Probability of Developing CHC Related Decompensated Cirrhosis

Population	Years Post Transfusion			Life-time
	10	20	30	
Posttransfusion CHC	0.6%	2.6%	5.0%	8.9%
Posttransfusion CHC & Treatment*	0.6%	2.5%	4.7%	8.4%

Probability of Becoming Seronegative for HCV

Population	Years Post Transfusion		
	10	20	Life-time
Posttransfusion CHC	1.0%	1.4%	1.8%
Posttransfusion CHC & Treatment*	3.2%	2.6%	4.0%

Figure 1. Markov Model of Natural History of HCV Infection

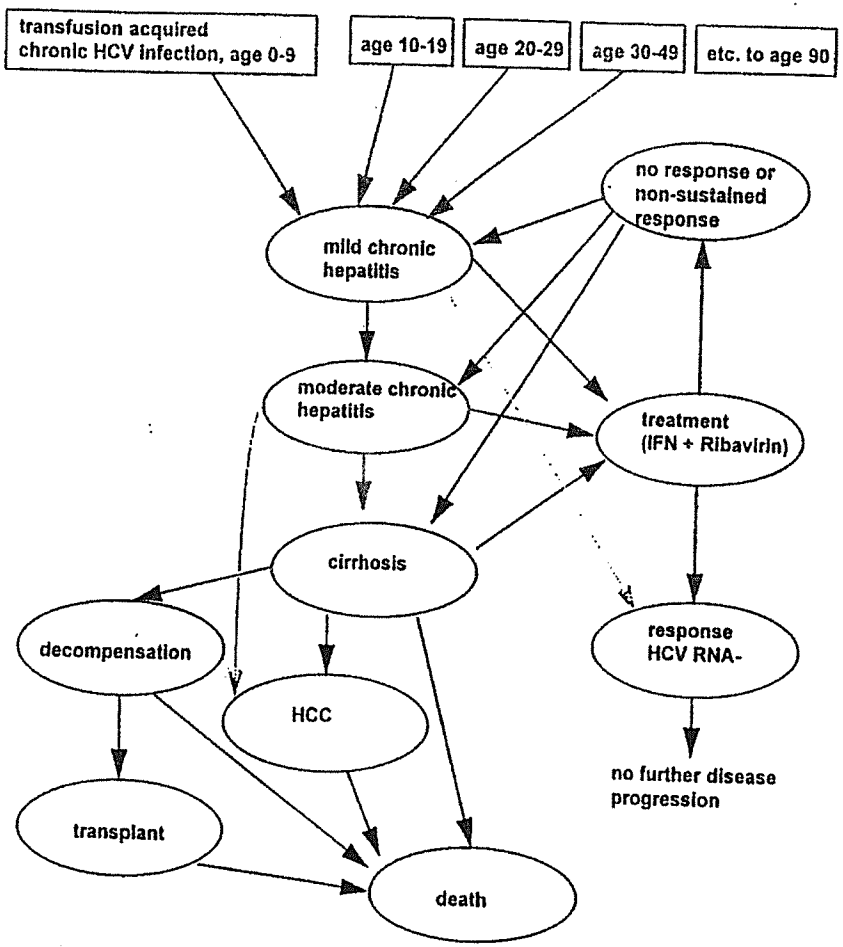
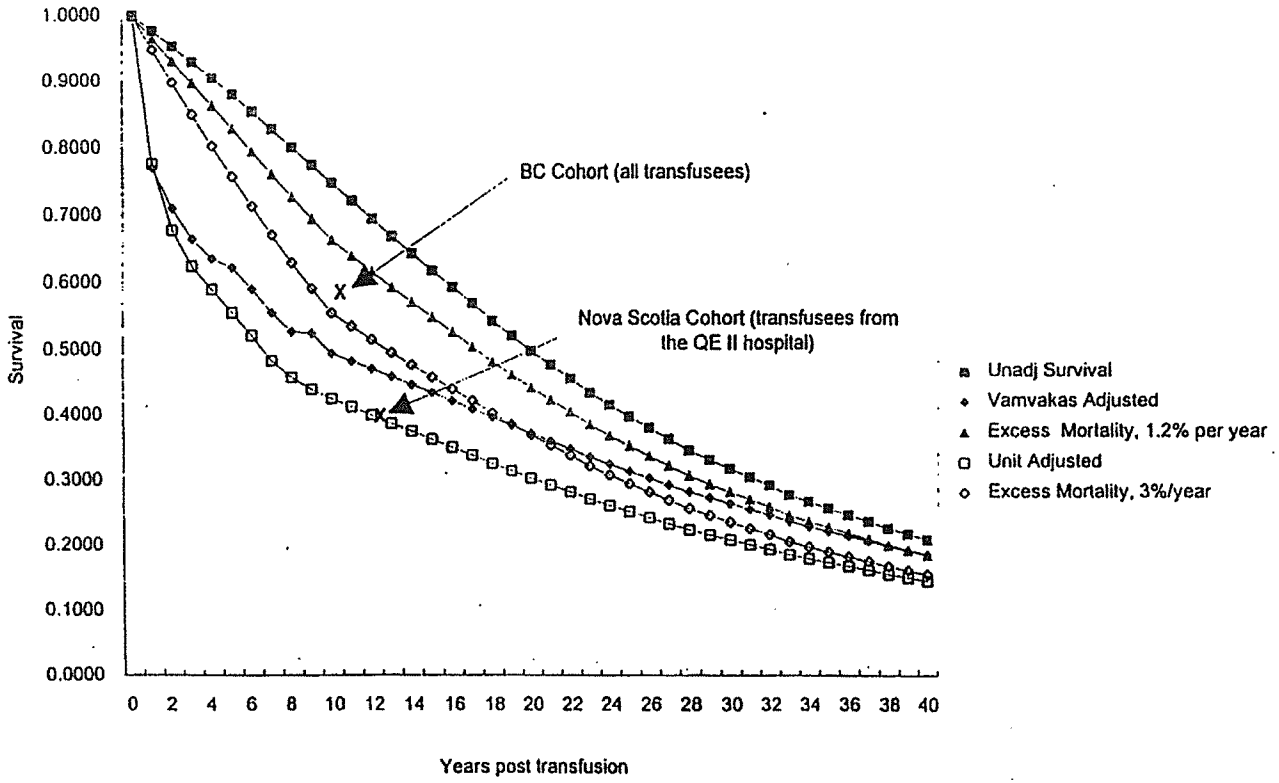
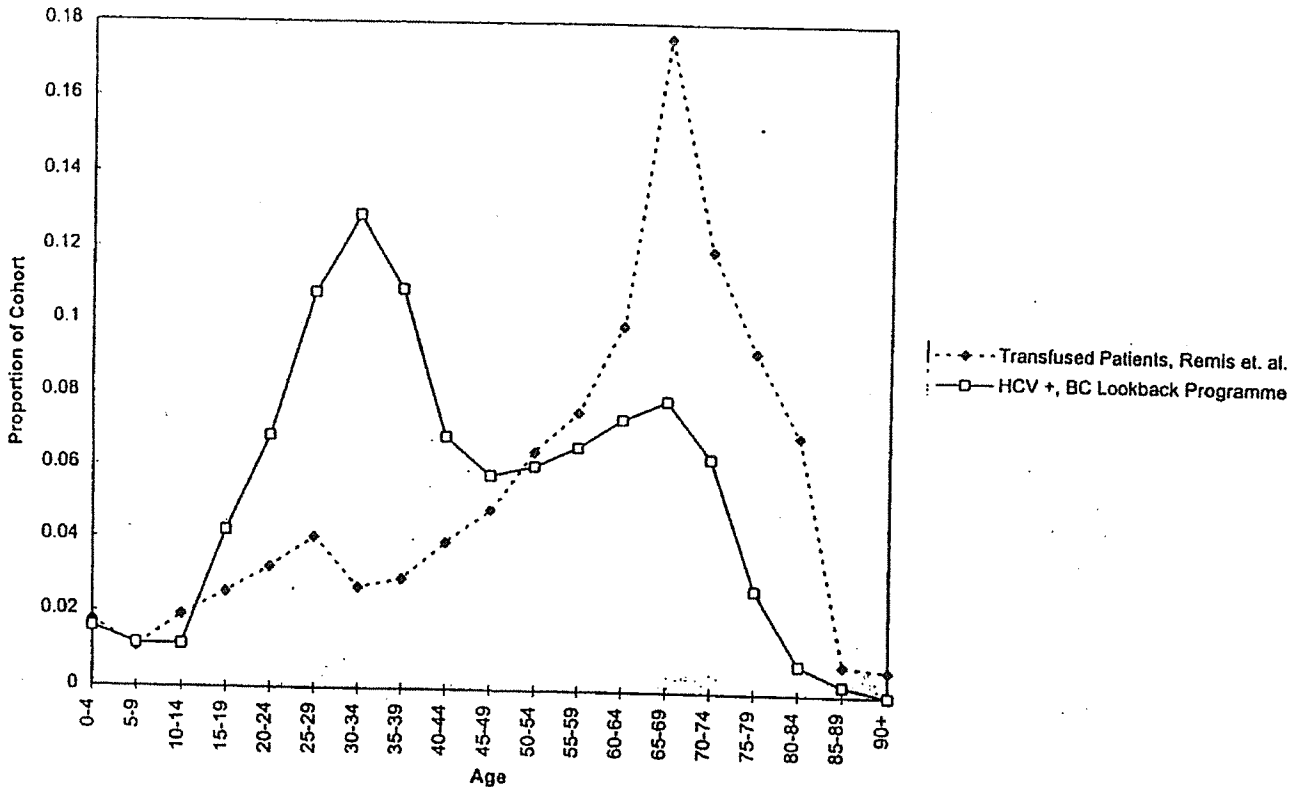


Figure 2

40 Year Survival, Chronic Hepatitis C Infection



Age Distribution, Transfused and HCV Infected Patients



APPENDIX

Appendix Table 1
Summary Results by Age Group for Transfused Population
Probability of Dying from All Causes

Age Group	Population	Years Post Transfusion 10	20	30
5	General Population	0.2%	0.9%	1.8%
	Posttransfusion	3.5%	4.2%	5.0%
	Posttransfusion CHC	3.9%	8.9%	18.6%
15	General Population	0.7%	1.6%	3.1%
	Posttransfusion	7.0%	7.8%	9.1%
	Posttransfusion CHC	7.5%	12.4%	22.2%
	Posttransfusion CHC & Treatment*	7.5%	12.2%	21.3%
25	General Population	0.9%	2.3%	5.8%
	Posttransfusion	10.7%	12.0%	15.0%
	Posttransfusion CHC	11.1%	16.3%	27.3%
	Posttransfusion CHC & Treatment*	11.1%	16.1%	26.5%
35	General Population	1.4%	4.7%	13.2%
	Posttransfusion	15.5%	18.4%	25.6%
	Posttransfusion CHC	16.0%	22.5%	36.4%
	Posttransfusion CHC & Treatment*	16.0%	22.3%	35.8%
45	General Population	3.3%	11.8%	30.3%
	Posttransfusion	16.0%	23.3%	39.4%
	Posttransfusion CHC	16.4%	27.2%	48.5%
	Posttransfusion CHC & Treatment*	16.2%	26.8%	47.7%
55	General Population	8.9%	28.3%	62.0%
	Posttransfusion	37.1%	50.5%	73.7%
	Posttransfusion CHC	37.5%	53.2%	78.0%
	Posttransfusion CHC & Treatment*	37.1%	52.7%	77.3%
65	General Population	21.0%	57.7%	92.0%
	Posttransfusion	44.7%	70.4%	94.4%
	Posttransfusion CHC	45.1%	72.2%	95.4%
75	General Population	47.5%	90.3%	99.8%
	Posttransfusion	79.6%	96.2%	99.9%
	Posttransfusion CHC	79.7%	96.5%	99.9%
85	General Population	81.2%	99.5%	100.0%
	Posttransfusion	98.7%	100.0%	100.0%
	Posttransfusion CHC	98.7%	100.0%	100.0%
95	General Population	97.5%	100.0%	100.0%
	Posttransfusion	100.0%	100.0%	100.0%
	Posttransfusion CHC	100.0%	100.0%	100.0%

* Treatment with ribavirin/interferon for 6.8% of the initial cohort with a sustained viral negative response in 37% of those treated.

Appendix Table 2.
Probability of Dying from CHC Related Causes

Age Group	Population	Years Post Transfusion 10	20	30
5	Posttransfusion CHC	0.5%	4.7%	13.7%
15	Posttransfusion CHC	0.5%	4.6%	13.2%
	Posttransfusion CHC & Treatment*	0.5%	4.4%	12.3%
25	Posttransfusion CHC	0.5%	4.4%	12.6%
	Posttransfusion CHC & Treatment*	0.5%	4.2%	11.8%
35	Posttransfusion CHC	0.5%	4.2%	11.6%
	Posttransfusion CHC & Treatment*	0.5%	4.0%	10.9%
45	Posttransfusion CHC	0.5%	4.1%	10.8%
	Posttransfusion CHC & Treatment*	0.5%	3.9%	10.2%
55	Posttransfusion CHC	0.4%	3.1%	7.0%
	Posttransfusion CHC & Treatment*	0.4%	2.9%	6.6%
65	Posttransfusion CHC	0.4%	2.5%	4.2%
75	Posttransfusion CHC	0.2%	0.8%	1.0%
85	Posttransfusion CHC	0.1%	0.1%	0.1%
95	Posttransfusion CHC	0.0%	0.0%	0.0%

* Treatment with ribavirin/interferon for 6.8% of the initial cohort with a sustained viral negative response in 37% of those treated.

Appendix Table 3. Probability of Developing HCV Related Cirrhosis

Age Group	Population	Years Post Transfusion 10	20	30
5	Posttransfusion CHC	8.2%	24.7%	41.1%
15	Posttransfusion CHC	8.0%	23.9%	39.6%
	Posttransfusion CHC & Treatment*	7.7%	22.3%	36.7%
25	Posttransfusion CHC	7.8%	23.0%	37.9%
	Posttransfusion CHC & Treatment*	7.5%	21.4%	35.1%
35	Posttransfusion CHC	7.5%	21.8%	35.3%
	Posttransfusion CHC & Treatment*	7.2%	20.3%	32.7%
45	Posttransfusion CHC	7.5%	21.5%	33.5%
	Posttransfusion CHC & Treatment*	7.3%	20.0%	31.0%
55	Posttransfusion CHC	6.2%	16.1%	22.9%
	Posttransfusion CHC & Treatment*	6.0%	15.0%	21.3%
65	Posttransfusion CHC	6.2%	13.8%	16.8%
75	Posttransfusion CHC	3.8%	5.9%	6.1%
85	Posttransfusion CHC	1.3%	1.4%	1.4%
95	Posttransfusion CHC	0.5%	0.5%	0.5%

* Treatment with ribavirin/interferon for 6.8% of the initial cohort with a sustained viral negative response in 37% of those treated.

Appendix Table 4. Probability of Developing HCV Related Decompensated Cirrhosis

Age Group	Population	Years Post Transfusion 10	20	30
5	Posttransfusion CHC	1.0%	6.2%	14.7%
15	Posttransfusion CHC	1.0%	6.0%	14.2%
	Posttransfusion CHC & Treatment*	0.9%	5.7%	13.2%
25	Posttransfusion CHC	1.0%	5.8%	13.6%
	Posttransfusion CHC & Treatment*	0.9%	5.4%	12.6%
35	Posttransfusion CHC	0.9%	5.5%	12.6%
	Posttransfusion CHC & Treatment*	0.9%	5.2%	11.7%
45	Posttransfusion CHC	0.9%	5.4%	11.7%
	Posttransfusion CHC & Treatment*	0.9%	5.0%	10.9%
55	Posttransfusion CHC	0.8%	4.0%	7.6%
	Posttransfusion CHC & Treatment*	0.7%	3.7%	7.1%
65	Posttransfusion CHC	0.8%	3.2%	4.8%
75	Posttransfusion CHC	0.5%	1.2%	1.3%
85	Posttransfusion CHC	0.1%	0.2%	0.2%
95	Posttransfusion CHC	0.0%	0.0%	0.0%

* Treatment with ribavirin/interferon for 6.8% of the initial cohort with a sustained viral negative response in 37% of those treated.

Appendix A: Treatment Questionnaire

APPROXIMATELY WHAT % OF HEPATITIS C INFECTED PATIENTS DO YOU ANTICIPATE TREATING WITH INTERFERON ALONE OR WITH INTERFERON/RIBAVIRIN COMBINATION?

		Interferon	Interferon/Rib.
1)	What % of all patients are not treatable because of co-existing conditions (eg. depression, heart disease, continuing alcohol and drug abuse)?	_____%	_____%
2)	Overall - what % of all patients with Hepatitis C do you actually treat?	_____%	_____%
3)	Patients with normal transaminases?	_____%	_____%
4)	Patients with mild hepatitis?	_____%	_____%
5)	Patients with chronic active hepatitis?	_____%	_____%
6)	Patients with well compensated cirrhosis?	_____%	_____%
7)	Patients with decompensated cirrhosis?	_____%	_____%

8) What patient criteria (laboratory or clinical) would prevent you from using Interferon?

_____

_____

_____

9) Would you treat a patient older than 65 years? Yes _____ No _____

If so, when?

_____

_____

_____

Dr. L. J. Scully Fax: (613) 761-5269

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MURRAY D KRAHN, MD, MSc, FRCPC

TORONTO GENERAL HOSPITAL
University Health Network
Division of General Internal Medicine and Clinical Epidemiology
200 Elizabeth Street, Eaton North, Ground Floor, Room 248
Toronto, Ontario, Canada M5G 2C4
Tel: 416-340-4155 Fax: 416-595-5826
e-mail: murray.krahn@utoronto.ca

June 10, 1999

This is Exhibit "E" referred to in the affidavit of Sharon Matthews made before me on July 9, 1999

A Commissioner for taking Affidavits for British Columbia

J.J. Camp
Camp Church & Associates
Barristers & Solicitors
4th Floor, Randall Building
555 West Georgia Street
Vancouver, BC V6B 1Z5

RECEIVED
JUN 16 1999

Dear Sir:

You have asked for some clarification and comment on certain aspects of our report "Estimating the Prognosis of Hepatitis C Patients Infected by Transfusion in Canada Between 1986 and 1990" (the "Report").

We were not aware that the compensation plan you have developed incorporates compensation triggers at stages of fibrosis earlier than cirrhosis and this is therefore not addressed in the Report. I have referred you and Mr. Levi to an article by Poynard et al., "Natural history of liver fibrosis progression in patients with chronic hepatitis C." Lancet 1997 March 22:349:825-832, which I have recommended Mr. Levi use to develop a model of rates of progression through fibrosis stages 1 through 4. In addition, I have provided Mr. Levi with the breakdown of

probabilities for the progression of the disease for 10 year increments between 30 years and lifetime. The provision of this information is subject to the caution which follows in this letter.

In the Report, we note that the confidence intervals pertaining to many of the probabilities developed are very wide. In lay terms, this means that we have developed estimates based on the data, these estimates must be used with a great deal of caution. The reason for these wide confidence intervals in general is that the Hepatitis C disease process has not been studied long enough to gather sufficient amounts of reliable data and as a result prognosticating the future course of the disease involves a high degree of uncertainty. In addition, the data we presently have is quite heterogeneous, particularly with respect to progression rates to cirrhosis. I hasten to add that research investigating the natural history of Hepatitis C is ongoing.

As noted in the body of the Report, there are wide differences in the results of studying the rate of fibrosis depending on the methodology of the study. Included in these differences is what I have termed in the Report as "selection bias" or "referral bias" which may paint a somewhat bleaker picture than is warranted for the 1986-1990 cohort. You will see at the bottom of page 12 of the Report the following statement: "In chronic liver disease studies, only patients who present for clinical care are followed. This should serve to disproportionately select those patients with more advanced disease, and therefore faster progression rates, from the entire population of HCV infected individuals." We limited the effect of selection bias by systematically excluding studies in which selection bias posed a major problem. However, we cannot exclude the possibility that selection bias may result in some overestimate of disease progression rates.

With respect to levels of confidence, we have more confidence in the probabilities in the report pertaining to the development of cirrhosis within 20 years of infection and the disease progress after cirrhosis. However, even the confidence interval pertaining to the 20 year probability of cirrhosis is very wide. Because the HCV disease process has only been studied for approximately 20 years, greater amounts uncertainty are introduced when we attempt to project beyond this period. At page 21 of the Report, the uncertainty is described this way, "The observed standard deviations are very wide, reflecting the fact that the overall uncertainty in the prognostic model is high." The Report also states at page 22, "Perhaps the foremost (uncertainty) is our lack of understanding of the long-term prognosis of the disease. For periods beyond 25 years, projections remain particularly uncertain. The wide confidence intervals surrounding long-term projections highlight this uncertainty."

The foremost unresolved issue pertaining to the development of cirrhosis beyond 20 years is due to the uncertainty about the progression of fibrosis. This is noted at page 13 of the Report where the following statement appears: "Our group also considered the issue of duration of disease progression. From prospective studies, it is not possible to ascertain whether patients with chronic hepatitis continue to progress after 25 years. From this data, we concluded that some progression to cirrhosis does occur beyond 20-25 years, but that a high degree of uncertainty surrounds any such estimate." We know that the disease affects those infected differently, and one of the differences is the speed at which persons develop fibrosis in the liver. Roughly speaking, we believe there are "fast fibrosers", "slow fibrosers", and "average" fibrosers. (We refer here to the overall rate of progression, and implicitly incorporate factors such as alcohol,

which are not directly related to the inherent disease process.) Within the first 20 years, most of the fast fibrosers will have already developed cirrhosis. After 20 years, the rate of development of fibrosis and ultimately cirrhosis will slow as those remaining will be mainly average and slow fibrosers. This will slow the average development time and reduce the absolute numbers who ultimately progress to cirrhosis (because of the increased likelihood of death from other causes as the infected population ages). The difficulty is that we have not yet had time to study the disease beyond 20 years so the rate of progression of the combination of average and slow fibrosers is unknown. Our group decided we could not estimate this rate, so instead of slowing the disease progression down after 20 years, we used the 20 year rate of progression to derive the 30, 40, 50, and lifetime rates. We believe this may overstate to some degree the number and proportion of individuals who will develop cirrhosis in the period beyond 20 years.

It is our opinion that a court should repose greater confidence in the estimates contained in the Report pertaining to the 20 year projection or less. I believe that further research in the next few years will improve the confidence level in these estimates.

However, it is also important to ensure that sufficient funds are set aside for later claims. We believe that the amount set aside should bear some relationship to the projections contained in our report. Although these estimates are uncertain, we strongly believe that they represent our best current estimate of what is likely to happen to this group of individuals. I understand from you that there will be a reassessment of the financial viability of the Settlement Fund in three years. I would strongly urge that funds to be set aside to support further modeling at that time when I anticipate we will be able to make prognostications with a greater degree of certainty.

Please note that the proportion of acutely infected patients who do not go on to chronic disease has been recently re-estimated by the Canadian Association for the Study of the Liver to 20-25%. We are comfortable with using these revised estimates, rather than the 15% estimate that was present in our original document.

Yours truly,

Murray Krahn MD MSc FRCPC
Chair, for the Canadian Association for the Study of the Liver Expert Committee
On Hepatitis C Modelling

This is Exhibit "G" referred to in the
affidavit of Asvini Krishnamoorthy
sworn before me at Toronto, Ontario
this 29th day of January, 2016

William Knight

A Commissioner for taking affidavits
within the Province of Ontario

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This is Exhibit "B" referred to in the affidavit of Sharon Matthews made before me on July 9, 1999

A Commissioner for taking Affidavits for British Columbia

ESTIMATING THE NUMBER OF BLOOD TRANSFUSION RECIPIENTS INFECTED BY HEPATITIS C VIRUS IN CANADA, 1960-85 AND 1990-92

Robert S. Remis MD, MPH, FRCPC
Department of Public Health Sciences, University of Toronto

in collaboration with the
Hepatitis C Working Group for Blood-borne Pathogens Division,*
Laboratory Centre for Disease Control, Health Canada

**The members of the Hepatitis C Working Group are:*

Robert Hogg, BA, MA, PhD, British Columbia Centre for Excellence in HIV/AIDS, St Paul's Hospital, Vancouver, BC;
Murray D. Krahn, MD, MHSc, FRCPC, Toronto Hospital, Toronto, Ontario;
Jutta K. Preiksaitis MD, FRCPC, Walter MacKenzie Health Sciences Centre, University of Alberta, Edmonton, Alberta;
Morris Sherman, MB, BCh, PhD, FCP(SA), FRCPC, The Toronto Hospital, Toronto, Ontario.

The following persons were observers: JoAnne Chiavetta, PhD, Canadian Red Cross Society, Toronto, Ontario; Martin Tepper MD, Shimian Zou MD and Bob Slinger MD (Field Epidemiologist), Blood-borne pathogens, Laboratory Centre for Disease Control, Health Canada, Ottawa, Ontario.

The analysis was supported by Robert W.H. Palmer, Toronto, Ontario.

June 22, 1998

EXECUTIVE SUMMARY

Under a mandate from the Blood-borne Pathogens Division, Laboratory Centre for Disease Control, we carried out a series of analyses to estimate the number of persons infected by hepatitis C virus (HCV) through blood transfusion from 1960 to 1992. Although the original request was limited to the periods 1960-85 and 1990-92, it became clear that, as a result of new insights into the per-unit risk of HCV infection and into the survival of HCV-infected transfusion recipients, it was important to reconsider the estimates carried out earlier for the period 1986-90.

We used three different models to estimate these numbers: Model 1 was a "transmission model" in which we multiplied the number of units transfused by the HCV per-unit risk to derive the number of HCV transmissions by blood, correcting for the possibility that a recipient might receive more than one infected unit. In the second stage, we estimated the survival of HCV-infected persons from the year of transfusion to mid-1998. In Model 2, we estimated the total number of HCV-infected Canadians in mid-1998 and, using the estimated proportion due to blood transfusion, we calculated the number of persons infected through transfusion. Finally, for Model 3, we derived the number of persons living in mid-1998 who had ever been transfused and, using the proportion who became infected with HCV due to blood, we calculated the number of persons infected through blood.

We were also interested to know how many Canadians were infected with HCV and had been transfused but were *not* infected through transfusion. This number could be important in the implementation of any potential compensation program. Each of the above three models was extended to obtain an estimate of the so-called "pre-existing" HCV infections.

Based on our analyses, we estimate that approximately 34,800 Canadians living as of mid-1998 were infected by HCV through blood transfusion from 1960 to 1992. The plausible limits for this estimate derived from Monte-Carlo simulation were 26,600 and 45,400. The distribution according to period of transfusion (with plausible limits) was as follows: 1960-85, 27,700 (19,800-38,200); 1986 to March 1990, 6,600 (5,200-8,100); and April 1990 to March 1992, 450 (390-520). In addition to these infections, we estimate that approximately 21,600 HCV-infected persons (plausible limits 15,700 to 28,700) were transfused but not infected through transfusion.

In all, about 3.3 million persons alive as of mid-1998 have been transfused at some time during their lifetime and about 240,000 Canadians are infected with HCV (population rate 0.8%), independent of the source of the infection. We believe that approximately 70,000 HCV-infected persons, or about 30% of all HCV-infected persons, have been diagnosed to date.

1. BACKGROUND

Before 1990, when a specific serologic test became available to test for the presence of hepatitis C virus (HCV) among blood donors, many persons receiving transfusions in Canada were infected by HCV. During the period 1986 to 1990, blood banks in the United States used surrogate testing to reduce the risk of HCV infection from units from donors more likely to be infected with HCV. In January 1998, a working group was formed to determine the number of persons infected by hepatitis C virus through transfusion during the period 1986 to 1990.

Little is known directly about the trends in post-transfusion hepatitis in Canada in the distant past. Most transfusions are administered to older patients and mortality among transfusion recipients is substantially higher than that of the general population of the same age. Nevertheless, it is also true that over half of transfusions are administered to persons less than 65 years old and that the latency for disease from blood-borne infections and, in particular, for hepatitis C may be long. Thus, there may potentially be a large number of persons infected by hepatitis C in the years before 1986 who are still alive.

An estimate of the number infected during the period 1970-85 was carried out by the Laboratory Centre for Disease Control (LCDC) in March 1998, but this work included a number of simplifying assumptions, in particular, concerning HCV prevalence among donors and survival probabilities. In May 1998, LCDC invited the members of the Working Group who prepared the estimates for the 1986-90 to review these estimates and to undertake additional analytic techniques to independently assess the earlier and later transmission of hepatitis C. It had become apparent that other techniques may be available to independently estimate the number of persons infected in this way and, thus, to "triangulate" the results of different methodologic approaches to obtain a plausible estimate. In May 1998, the Working Group was re-convened to examine transmission of hepatitis C for the period 1960-85 and July 1990 to March 1992.

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2. METHODS

2.1 Model description

Three different methods were used to estimate the number of persons infected by hepatitis C virus through transfusion in the pre-1986 period. The three methods may be briefly described as follows:

Model 1: This model may be referred to as a "transmission model". It is based on estimating that number of units of blood actually administered and multiplying by the per-unit risk of hepatitis C virus infection from donor units to obtain the number of transfusion recipients infected by HCV each year. Finally, by applying post-transfusion mortality probabilities, we calculated the number of persons surviving from the year of transfusion to mid-1998.

Model 2: This model is a prevalence, or cross-sectional, approach to estimation. We first estimated the number and prevalence of hepatitis C infections in Canada in 1998. In the second stage of analysis, the number of HCV-infected persons in Canada was multiplied by the proportion of HCV infections thought to be due to the receipt of a blood transfusion. This proportion is based on surveillance-based data and clinical series in which the risk factors of patients diagnosed with hepatitis C infection have been determined.

Model 3: This model is a cross-sectional approach somewhat similar to Model 2, except that it was carried out in the opposite direction. First, we estimated the number and proportion of persons living in 1998 who had ever been transfused. Second, we multiplied the number of transfusion recipients by the prevalence of HCV infection among transfusion recipients. The product of these two parameters provided an independent estimate of the number of persons infected with HCV through transfusion.

Besides estimating the number of persons infected by HCV through transfusion, we were also interested in evaluating the non-negligible number of persons who were transfused and HCV-infected but not infected by transfusion. The infection from another source (e.g. injection drug use) may have been before ***or*** after the transfusion but before the first HCV serologic test. This number could be important in the implementation of any program that may offer compensation to persons HCV-infected through transfusion. Methods used to estimate this number were incorporated into each of the three models.

2.2 DETERMINATION OF VALUES FOR MODEL PARAMETERS

For the three models, we used data from the published literature, unpublished manuscripts, reports and analyses as well as information from key informants to establish the most likely values for the model parameters. We also established plausible limits (to incorporate a certainty of approximately 95%) for parameters with uncertain values such that the actual value fell within this range of these limits for use in a Monte-Carlo simulation. The Monte-Carlo simulation provides an estimate of the range in model outputs taking into account the uncertainty in the model parameter values. Further details on the technique used are provided in Section 2.3 below.

2.2.1 Model 1 parameters

Model 1 was carried out by year of transfusion and incorporated age- and sex-specific parameters. The year of transfusion was grouped into the following periods: 1960 to 1985, 1985 to March 1990, and April 1990 to March 1992.

2.2.1.1 Units of blood administered 1960-92

Administrative reports for blood transfusion service activities were available for the years 1960 to 1992 from the Canadian Red Cross Society. For the years for which such data were available, namely 1970 to 1992, we summed the different components administered indicated in the administrative reports (this included whole blood, red blood cells, platelets, fresh frozen plasma, frozen plasma, stored plasma and cryoprecipitate). We considered this approach to be the most accurate measure of the number of units of fresh blood and its components actually administered. We also calculated a ratio of the number of units administered to the number of units collected, for the period for which both numbers were available. For the period 1960 to 1969, when the data on the number of units administered were not available, we used the units administered to units collected ratio for 1970 to determine the number of units administered for this period. The number of units administered by year with the ratios is indicated in Table A1.

2.2.1.2 Distribution of number of units per recipient in Canada

For several calculations within the model, it was important to have an estimate of the distribution of the number of units administered to blood transfusion recipients in Canada. For this purpose, we used the distribution developed for the study on HIV transmission by blood transfusion in Canada from 1978 to 1985 carried out by Remis and Palmer for Health Canada in 1994. Briefly, the distribution was derived from studies on each of the components including red cells, platelets and plasma, as well as from a study by Chiavetta on red cell distributions in hospitals in the Toronto region. For cryoprecipitate, key informants were used to estimate the number of persons who received cryoprecipitate and the mean number of units received in any given year. These four distributions were overlayed and weighted according to their relative importance to obtain a final, overall distribution. The distribution by units is shown in Table A2.

2.2.1.3 Age distribution of transfusion recipients

It is clear that the distribution of units administered according to the age of the recipient is an important determinant of the final result, since mortality is intimately linked to the sex and, in particular, the age of the transfusion recipient. Limited data are available on the age distribution of persons receiving blood in Canada in recent years. Therefore, for this purpose, we began with the distribution of blood as reported by Vamvakas and Taswell (*1*) to establish a starting point to determine the most likely distribution. The distribution was then adjusted to fit the data from the study by Chiavetta on red blood cell administration in 45 hospitals in the Toronto region in the late 1980's (*2*). These distributions differed somewhat, especially for younger recipients. Since each of these studies may not be representative of the situation for Canada as a whole over the study period, we used a final distribution which was intermediate between the two studies.

Finally, to validate the distribution by age, we compared the age of transfusion generated by our model to the results of the age of transfusion age distribution observed by the British Columbia Provincial Notification Program (*3*). In carrying out this comparison, we took into account the fact that most HCV infections among young adults 20 to 39 years of age were acquired by routes other than blood transfusion.

The distribution according to age and sex is shown in Table A3 and illustrated in Figure 1. Note that the median age at transfusion was approximately 64 years for men and 63 for women. This is in agreement with data from other studies on the median age at transfusion.

2.2.1.4 Per-unit risk of HCV infection, 1960-1992

The other important component of the model, namely the per-unit risk of HCV infection, is not precisely known during the period of the analysis. In fact, no studies of post-transfusion hepatitis (PTH) were carried out in Canada until the 1980's. During the course of the study, however, we were able to obtain data from six studies, five of which were from Canada, which examined HCV transmission by transfusion from 1983 through 1990 (*4-12*), helping us to derive a reasonable estimate of HCV prevalence among donors and, therefore, the per-unit risk for recipients. The prospective studies in which recipients infected by HCV before the transfusion could be eliminated from the analyses were given more weight than data from the observational, lookback studies.

For the purposes of this analysis, we used the observed HCV prevalence in the spring of 1990 when HCV screening of blood units began in Canada. It allowed us to assess the per-unit HCV risk for 1990 using observed data. Since the initial screening was carried out with the first generation EIA test (EIA1), we calculated the "true" HCV prevalence by dividing by the sensitivity. One must also take into account the observation that not all donors with anti-HCV antibody (for the most part, presumed infected) result in HCV transmission to the recipient. A number of studies have addressed this question (*13-16*); many of the issues are complex. We carefully reviewed several studies which examined PTH among blood transfusions, and re-

analysed them using the following assumptions: (1) all HCV transmissions would be identified among those with PTH; and (2) the second-generation EIA test has essentially 100% sensitivity. Based on this analysis, we concluded that EIA1 sensitivity was 80% and overall infectivity 92%. Thus, the proportion of ***infectious units*** that would be detected by EIA1 is 87%. This value corresponded closely to the observations of both Aach (*13*) and the Gonzales (*15*). Based on these parameters, the per-unit infectious HCV risk in Canada just before HCV testing began would be 0.185% (0.161%/0.87).

A number of studies carried out in 1980's were examined to attempt to estimate the per-unit risk of HCV infection associated with blood transfusion in earlier years. A summary of the studies used to estimate the per-unit infectivity from HCV derived by the authors or by our own calculation is shown in Table A4.

A prospective study by Feinman and colleagues in Toronto carried out in 1983 to 1985 (*4*) observed a rate of PTH of 9.2%. Later, stored specimens from this study were examined for EIA1 (*5*) and subsequently by EIA2 (*6*) for HCV antibody. A per-patient risk of HCV of 3.1% was observed (18 of 576). It is not clear from either of the two latter reports whether the repeat reactive EIA results were confirmed by immunoblot. We were also unable to determine precisely the mean number of units administered per patient due to inconsistencies in the data as presented. However, the authors present data on administrations in the Discussion that seemed plausible, which yielded an estimate of mean the number of units per patient received of 4.26, with a resulting per-unit risk of 0.73%.

A study carried out by Preiksaitis in blood transfusion recipients in Edmonton in 1983 to 1985 (*9*) calculated a per-unit HCV risk of 0.17%. Finally, a study carried out in Vancouver, British Columbia at the BC Women's and Children's Hospital (*10*) provided data that allowed us to estimate the per-unit HCV risk; this was 0.60%. The results of fitting a curve using the formula $1-[(1-p)^n]$ (where p is the risk per-unit and n is the number of units) suggested that there was minimal pre-existing HCV infection in this population (about 63% of patients were under 20 and 77% under 30 years of age). We plotted the estimates from different centres, adjusting for the relative prevalence of HCV when HCV screening began in 1990 (see Table A5). HCV prevalence decreased by a factor of about 2.5 fold from 1984 to 1990 for British Columbia and Edmonton. Before 1983, it appears that HCV prevalence was stable; this appeared to be the case as in the United States, based on several studies in that country summarized recently by Tobler and Busch (*17*). We assumed, based on the prevalence of HBsAg among persons at high risk for HCV and HBV, that the implementation of HBsAg testing in 1973 reduced the HCV prevalence by 5%.

We compared the U.S. experience with hepatitis C virus with that in Canada. All indications, including a population-based study from NHANES in the U.S. (*18*) and a population-based estimate in Quebec by Joly and colleagues (*19*) appeared to indicate that population prevalence, donor HCV prevalence and the incidence of HCV-PTH are each approximately double in the U.S. compared to Canada. Our estimate of a per-unit HCV risk of 0.40% for Canada in 1982 and a per-transfusion episode risk of 2 to 3% is consistent with this observation. The estimate for 1984 appears to be from 0.3% to 0.5%; it is difficult, given the lack of studies from other centres

in Canada and the limited study years, to be more precise than this. The uncertainty in the HCV per-unit risk is incorporated in the Monte-Carlo simulations (see below).

We derived an estimate for the national per-unit risk for the median year when the study was carried out by weighting the per-unit risk observed in the study using the relative prevalence of HCV among blood donors donating in 1990. Table A5 shows the summary results of this exercise and Figure 2 depicts this in graphic form. The final per-unit risk of HCV for the entire study period, i.e. from 1960 to 1992, used in Model 1 is shown in Table A6.

2.2.1.5 Correction for multiple exposures to HCV-infected units

When prevalence is low, the number of persons infected by any blood-borne pathogen can be derived simply by multiplying the number of units administered times the risk per unit due to that pathogen. However, when prevalence is more than negligible, this simple relationship no longer holds, since in such a case more than one infected unit may be transfused into any given recipient. The correct formula for calculating this risk is $1-[(1-p)^n]$ (where p is the risk per-unit and n is the number of units). To correct for this potential source of error, we adjusted the final number of persons infected by HCV according to the prevalence for each of the years in the final spreadsheet model. The correction was minimal for the per-unit HCV risk since 1990 where the correction factor was less than 1.0%. However, for the per-unit risk of 0.40% before 1983, the correction factor was about 8%. The correction factor used at each level of per-unit HCV risk is shown in Column 5 of Table A6.

2.2.1.6 Survival of transfusion recipients

The mortality among transfusion recipients in Canada is not well characterized. No prospective studies in this group have been carried out which ensure active follow-up to determine vital status for an extended period of time following transfusion. It is clear that patients who are transfused have markedly reduced survival, related mostly of course to the medical or surgical condition for which the transfusion was required. For a minority of patients (e.g. obstetrical cases, some trauma patients), life expectancy may return to virtually normal after the acute period of care (and transfusion), but for most patients survival remains compromised for a long and probably indefinite period following transfusion. The study by Chiavetta in 45 acute-care hospitals in the Toronto region observed an in-hospital (immediate) mortality of transfusion recipients of 13%, compared to 2% for patients admitted to the same hospitals who were not transfused (*2*). This is obviously much greater than for an age-matched cohort during the same, relatively brief period.

Only one population-based cohort study has been carried out to date, in Olmstead County, Minnesota, USA (*20,21*), in which 802 patients transfused in 1981 were followed for a period of 10 years. This study observed a crude 10-year survival of 48%, compared to the survival of an age-matched population of about 70%. Survival was a function of age at transfusion, gender and number of units received. In a program to notify transfusion recipients in British Columbia to

encourage HCV testing, approximately 60% of recipients identified were alive at about 9.5 years. This translates into a 10-year survival of about 58%. According to the principal investigator (*22*), approximately 5% of transfusion recipients overall who died in hospital or otherwise soon after transfusion were excluded. Thus, the corrected survival at 10 years among those transfused in B.C. from 1985-90 is probably about 55%.

There is reason to believe that mortality among residents of Olmstead County may be somewhat greater than that among Canadian transfusion recipients. According to information provided by Dr. Vamvakas (*23*), one of the two authors of the study, the transfusion service at one of the major hospitals providing care in Olmstead County adopted a conservative transfusion policy such that transfusion was reserved for patients for whom the need was life-saving and beyond doubt. Preliminary comparative calculations of transfusion intensity revealed that the transfusion rates (patients transfused/population) in 1981 using Canadian Red Cross administrative data were in fact about 10% lower in Olmstead County than in Canada as a whole. Thus, transfusion patients included in the Minnesota study may have been, on the whole, more severely ill than patients in Canada and therefore their survival would be less favourable. Thus, a 10-year survival of transfusion recipients in Canada of 55% is very plausible. This was used for the base-case analysis in Model 1.

In addition to the above considerations, any estimation of the mortality experience of transfusion recipients must take into consideration the distribution of number of units received by the recipients. Because the occurrence of an HCV infection is a probabilistic event, it follows that the distribution of number of units among those who are HCV-infected will be different from that among all transfusion recipients. HCV-infected recipients will have received a substantially higher mean and median number of units.

We carried out preliminary calculations using the distribution of number of units administered in Canada in 1985 from a study of HIV transmission by blood transfusion carried out by Remis and Palmer in 1994 for Health Canada (*24*). The number of units varied from 1 to 500 plus. For all transfusion recipients, the mean was 5.8 units per patient and the median, 3 units. We applied the formula $1-[(1-p)^n]$ using a risk per unit (p) of 0.40% to examine the distribution of number of units received by HCV-infected recipients. As expected, the distribution was very different, with HCV-infected recipients having received a mean of 37 and a median of 8 units. Though only about 2% of recipients were infected, HCV-infected recipients received almost 14% of all units administered. This phenomenon is dependent on the distribution of units to recipients and on the risk per unit. In the study of Donahue in Baltimore in 1985-86 (*12*), uninfected recipients received 8.3 units whereas HCV-infected recipients received 24.0 units (the degree of "shift" is probably underestimated since only persons surviving the first month or two following transfusion are included in such an analysis and those having received more units were more likely to have died [see below]). A similar observation was made in the B.C. hospital lookback study (*3*), with means of 6.1 and 22.7 units among all recipients and HCV-infected recipients, respectively.

The above observation is of critical importance because the mortality experience of transfusion recipients is strongly correlated with the number of units administered, with those receiving more

units having poorer survival. Thus, mortality among HCV-infected transfusion patients will be substantially higher than transfusion recipients as a whole; this is independent of HCV-status of these recipients (i.e. it is a statistical phenomenon). In the prospective study of survival by Vamvakas (*20*), only 22% of recipients receiving more than 10 units survived to 10 years compared to about 40% of those receiving 4-10 units study and 55% of those receiving less than 4 units. This is not surprising since patients who are more severely ill tend to receive more units (e.g. patients with disseminated intravascular coagulation, serious trauma with uncontrollable bleeding, etc.). Therefore, to properly apply the appropriate survival curves, in the final analysis, we weighted the survival curves using the data of Vamvakas and colleagues according to the aggregated sub-groups stratified by number of units received.

Survival has improved over the duration of the study, with mortality being lower especially for persons 60 years of age and older. Therefore, the lifetable for the years 1960-65 was used for the survival function after 10 years for the years 1960-77 and 1991 lifetable for the years 1978-92.

A summary of 40-year survival according to the different functions described in this section is shown in Figure 3. The curve indicated as "Model 1" was that applied to transfusion recipients as a whole. The survival function used in Model 1 to estimate the number of surviving HCV-infected transfusion recipients is the curve with the steepest mortality, indicated as "unit-adjusted".

2.2.2 MODEL 2 PARAMETERS

2.2.2.1 HCV prevalence in Canada, 1998

For the purposes of Model 2, it was important to have as precise an estimate as possible of HCV prevalence in the general population. To do this, we used two independent methods: we used the results of the number of seroepidemiologic studies in selected populations taking into account the strength and direction of biases in the population samples as well as the region in which the study was carried out (*25-32*). Secondly, HCV prevalence in the United States (based on actual measurement in a population-based sample) was prorated based on the relative prevalence of HCV in blood donors and also taking into account the number and prevalence of hepatitis C virus in injection drug users.

The only data available on HCV prevalence derived from a large, population-based sample were from a study by Joly and colleagues in Quebec in 1990-92; the study investigators kindly provided us with data from this study (*19*). This study measured HCV prevalence among 10,000 patients attending day surgery in 19 sentinel hospitals throughout the province of Quebec from November 1990 to October 1992 (*33*). We obtained custom outputs of this study which allowed us to standardize the final results for sex, age group, region of residence and HIV-positivity. Overall, we obtained a standardized HCV prevalence of about 0.64%. In discussions with Dr. Alary, one of the principal investigators in this study, and in the light of other considerations, we believe that this is likely a modest underestimate of the true population prevalence since injection drug users, comprising by far the largest single group affected by HCV (with HCV prevalence of

40-80%), both with respect to prevalence within the group and the proportion of total HCV infections, would be less likely to attend day surgery, tending rather to use emergency rooms for their medical services. On the other hand, transfusion recipients would likely be over-represented in this sample. This latter population would have an HCV prevalence of about two to three times that of the general population.

The Alary study also provided important indicators concerning the variation in HCV prevalence by age and sex and region of residence. More specifically, HCV prevalence appears to peak among persons 20 to 49 years of age, is about 1.5-2.0 times more prevalent in men than in women and is 2 to 3 times more prevalent in Montreal than outside this major urban centre. These observations are similar to those in several studies in the United States including the NHANES (*18*) study and a study of blood donors by Murphy (*34*).

A summary of the results of studies measuring HCV prevalence in selected populations in Canada is shown in Table A7. Based on these studies, we estimate that the overall prevalence of HCV infection in Canada is about 0.8%.

We developed a model for HCV prevalence by province in Canada, using HCV prevalence among donors when screening began, the population-based estimates from Quebec and data from other studies of special populations. The results of this analysis shown in Table A8. This type of analysis also allowed us to calculate the total number of HCV infections for each province and the proportion of all infections comprised in each province. According to these calculations, Ontario accounts for 44% of all Canadian HCV infections, British Columbia for 22%, Quebec for 15% and Alberta, 11%. The other six provinces, namely Manitoba, Saskatchewan and the Atlantic provinces and the territories together account for only about 8% of HCV infections in Canada. The age and sex specific HCV prevalences, derived from the assumption noted above, were used to develop the first part of Model 2, namely the prevalence of HCV by age group and sex. The population estimates for 1996 were obtained from Statistics Canada.

Data were available from Ontario (*35*) and from six provinces and both territories in with hepatitis C was reportable since 1994 or earlier (*36*). Correcting for the provinces for which hepatitis C is not yet reported, it appears that approximately 70,000 HCV infections have been diagnosed in Canada to 1997.

2.2.2.2 Proportion of HCV infections due to transfusion

Limited data are available on the proportion of HCV infections caused by transfusion or in which transfusion was named as a possible source (*35,37,38*). Custom outputs from the 8-city sentinel study on reported HCV cases carried out by LCDC in 1993-95 (*38*) and expert opinion within the working group allowed us to develop working estimates of the proportion of HCV infections by age and sex that were likely due to transfusion. Custom outputs were also available the surveillance program of the Ontario Ministry of Health and from a study of blood donors. The studies and databases examined are summarized in Table A9.

All data examined contained important biases that were difficult to characterize or quantify. Some analyses contained both prevalent and incident cases (with the proportion of each not known) and since, the incidence of HCV infection due to transfusion changed dramatically from 1983 to 1992, these data are difficult to interpret. Nevertheless, based on careful review of these studies, the available data is consistent with an estimate of 15% of ***prevalent*** HCV infections being due to transfusion, with a plausible range of 10 to 20%.

2.2.3 MODEL 3

2.2.3.1 Number of transfusion recipients in Canada

There is limited data available on the proportion of the Canadian population that has been transfused; therefore, we also used indirect methods allowed us to obtain plausible estimates of this number. According to a study of U.S. blood donors in the U.S. by Murphy (*34*), 6.0% of donors have been transfused. However, this is likely to be an underestimate since blood donors are generally under 65 and many of the transfusion recipients are 65 or older. Also, blood donors tend to be in better health than the population as a whole since blood transfusion recipients would be more likely to have contra-indications for donating blood. A survey in Alberta on a population sample of 1,200 adults found a lifetime history of receipt of blood or blood products of 22%. This appears to be higher than is likely in our opinion perhaps in part because of the form of the question ("Have you ever received blood or blood products?") which may have led to some misunderstanding.

A study from the Canadian Health Monitor (*39*) on the proportion of Canadians transfused between 1978 and 1985 provided for estimates in the range of 5% to 7%. The question asked in this survey was "Have you been transfused from 1978 to 1985". A similar study carried out in Quebec in the context of the *Operation Transfusion* program in 1993 (*40*) found a substantially lower number when the same question was asked: only 3% of adults asked reported a history of transfusion during the same 1978 to 1985 period.

We also used an independent method to estimate the number of persons receiving transfusions as an extension of the calculations for Model 1. We used the number of units administered in Canada from 1960 to 1992 and adjusted for the number of recipients using a mean number of units received between 6 and 7 units and subjected the recipients to a survival curve derived from our final model for survival. This survival was somewhat better than that observed by Vamvakas and only slightly lower than the British Columbia hospital-based HCV notification program; thus, we used a ten-year survival of 55%. According to this approach, from 2.3 to 2.7 million Canadians living in 1998 were transfused between 1960 and 1992, for a rate of about 7% to 9%.

Chiavetta carried out a survey on 6,000 blood donors to the Canadian Red Cross (*41*). Overall, 9.7% of donors reported ever having been transfused; this was similar for men and women.

The National Health Study (*42*), which surveyed 26,000 Canadian adults in 1996, included the following question: Between 1978 and 1985, did you receive a blood transfusion?" The results

were standardized for persons 18 years and older in Canada. Overall, 3.8% of women and 2.9% of men responded affirmatively, for a weighted estimate of 3.4% or 752,000 persons in Canada. In Model 1, we estimated that 33% of persons transfused from 1960 to 1992 were transfused from 1978 to 1985. Based on this, an estimated 2.28 million adults were transfused from 1960 to 1992. This figure does not include persons under 18 years of age; however, based on the data from Vamvakas (*1*), from Chiavetta (*2*) and from our own analysis, children represent about 4% of transfusion recipients. In addition, a substantial proportion of transfusion recipients do not realize they have been transfused (perhaps as many as 30% according to one HCV hospital-based HCV lookback program carried out in Hamilton in 1995 [*43*]), so the 2.28 million is probably an underestimate.

In summary, we feel that the limited data available and our own calculations in Model 1 support the belief that about 11% of Canadians have ever received a transfusion, with a plausible range of about 9% to 13%. This translates into an absolute number of 3.0 million persons, with a plausible range of 2.6 million to 3.8 million persons.

2.2.3.2 HCV prevalence among blood transfusion recipients

It is clear from the literature and the experience of the members of the Working Group that a not insignificant proportion of persons transfused are already infected before a transfusion. There is some data from a number of studies which provide an indication of the importance of this phenomenon. A reasonable estimate for this number would be about 1.0 to 1.2% based on data from Alberta (*44*). However, some of these pre-existing infections would be due to previous transfusion episodes, either during the same hospitalization or more importantly in earlier hospitalizations or medical treatments. For the sake of our study, we estimated it at approximately two-thirds of these infections would be due to sources other than blood transfusion. This allowed us, in Model 3, to calculate the number of infected transfusion recipients and apportion them according to whether or not the transfusion was the source of the infection.

2.3 DETERMINING PLAUSIBLE RANGES FOR POINT ESTIMATES OF MODEL OUTPUTS

For all three models, there was uncertainty about the actual values for many of the parameters. However, the degree of imprecision varied across the model parameters. Some were known with relative certainty (e.g. the number of units of blood components administered) and others were derived though indirect methods sometimes involving speculative assumptions.

Therefore, to better reflect the uncertainties involved and to provide plausible limits around our point estimates, we subjected all three models to Monte-Carlo simulation. This involves assigning a frequency distribution for each model parameter which is not precisely known and carrying out a large number of iterative calculations of model outputs using values of the model parameters sampled according to their frequency distribution. For this purpose, we used commercial software (Crystal Ball, Version 4.0, Decisioneering, Inc, Aurora, Colorado, USA) and performed 10,000 iterations for each output.

The values for the plausible range for each parameter were based on a review of all data taking into account its precision, the laboratory and sampling methods used and the representativeness of the population studies. A summary of the point estimates and plausible range used for all model parameters is shown in A10.

3. RESULTS

3.1 MODEL 1 OUTPUTS

The summary results of Model 1 are shown in Table 1. A total of 122,500 persons were infected with HCV through transfusion in Canada from 1960 to 1992: 920 persons were infected in 1990 to 1992, 15,700 from 1986 to 1990 and 105,900 from 1960 to 1985. The total number of HCV-infected recipients alive as of mid-1998 was 34,800 of whom 450 were infected in 1990-92, 6,600 in 1986-90 and 27,700 in 1960-85. Mortality in this population was substantial since less than 30% of HCV-infected transfusion recipients (34,800 of 122,500) are alive as of mid-1998. The numbers of infections in each of the three periods is shown in the lower right-hand corner of Table 1 in Column 6. The proportion of persons infected according to the period of infection is shown at the bottom of Column 7: 1.3% of HCV-infected persons living as of mid-1998 were infected in 1990 to 1992, approximately 19% for the period 1986 to 1990 and 80% for those infected in 1960 to 1985. The distribution of HCV-infected and surviving recipients is presented in Figure 5.

Table 2 shows the calculation of the most likely number of recipients who received blood and in the right columns of the table, those surviving to 1998 (using the overall survival probabilities for all transfusion recipients as indicated in Section 2.2.1.6 above). Using the range of 6 to 7 units, a plausible range for the mean number of units received, we observed that approximately 2.3 to 2.7 million Canadians living as of mid-1998 were transfused at some time in their life.

Figure 4 shows the distribution by age and sex of HCV-infected transfusion recipients as of mid-1998. Compared to the distributions of transfusion recipients, the age is shifted to the right and, due to their lower mortality, HCV-infected women predominate even more than for recipients as a whole.

Table A11 shows, as an example, the worksheet for 1984 from which the data were incorporated into the final summary sheet shown in Table 1. As seen in Table A11, the analysis was carried out by five-year age strata for males and females separately. The same per-unit risk of HCV as indicated on the bottom of the table was used for all age strata as was the correction factor for multiple exposures. The respective proportions surviving to mid-1998 are shown in Column 6 to obtain the final number of HCV-infected persons surviving to mid-1998 (Column 7) and then summed for both men and women across all ages. The final adjustment for unit-specific survival, as discussed in Section 2.2.1.6 above, is indicated at the bottom.

Column 6 of Table 2 indicates the number of HCV-infections among transfused persons who were ***not*** infected by transfusion by year of transfusion. In all, based on the analysis in Model 1, we estimate that 21,600 persons were in this category.

3.2 MODEL 2 RESULTS

As noted above, Model 2 attempts to estimate the number of persons infected by HCV through blood by first estimating the number of HCV infections and then the proportions of HCV-infected persons who were infected through blood transfusion. The output is shown in Table 3.

Overall, we estimate that approximately 0.8% of Canadians are infected with HCV, for a total 240,000 persons. Of these, 155,000 are male and 85,000 female. The highest rates, and the greatest proportion of those infected, are in the age group 20 to 39: 144,000 or 60% of all infected persons were in this age category.

Overall, we estimate from this model that 36,000 persons were infected by HCV through blood transfusion. This includes persons infected before 1960 and since 1992. Neither of these are likely to be very important because of the low incidence of HCV transmission by blood since 1992 and the low proportion of persons surviving who were infected before 1960.

From the outputs from Model 2, an estimated 204,000 people were infected through other sources. Based on a lifetime transfusion rate of 12%, approximately 24,000 persons would be infected by HCV and transfused but not infected by transfusion.

3.3 MODEL 3 RESULTS

The results of the estimation based on Model 3 are shown in Table 4. From this calculation, we observe that approximately 3.0 million persons in Canada have received a transfusion in Canada. This is slightly higher than the 2.3 to 2.7 million estimated from Model 1, but within the same order of magnitude. Based on estimate of an HCV prevalence of 2.0% among transfusion recipients alive as of mid-1998, 64,400 transfusion recipients are infected with HCV.

Based on the (imprecise) assumption that 70% were infected from transfusion and 30% from other causes, 45,000 recipients were infected through transfusion and 19,300 from other causes.

3.4 SUMMARY OF FINDINGS

A summary of the three model outputs including the plausible range generated by the Monte-Carlo simulation is shown in Table 6. The outputs for Model 1 by year of transfusion are presented in Table 7.

4. DISCUSSION

A modelling exercise involving three different approaches to estimate the number of persons infected by HCV through blood transfusion in Canada yielded an overall estimate of 34,800 persons, of whom 27,700 were infected from 1960 to 1985, 6,600 from 1986 to March 1990 and about 450 from April 1990 to March 1992. In addition to these persons infected by transfusion, an additional approximately 22,200 persons were HCV-infected and transfused but not infected through transfusion.

We believe that Model 1 provides the most plausible estimates of the extent of HCV transmission by blood in Canada, both because of the simplicity of the theoretical model used and the relative precision of the parameter values available. With the data available to the Working Group at present, Models 2 and 3 could not provide a truly independent estimate since, for each of these models, one of the two principal parameters was not known and could not be estimated with precision. Nevertheless, both Models 2 and 3 added useful information about the distribution of blood transfusion and about the epidemiology of HCV in Canada. They also lent some credence to the results of Model 1 since the values for the parameters which generate comparable results were plausible.

There are a number of important limits to our study. For many of the parameters used in our models, data for Canada for the period of study were not available. Therefore, indirect methods had to be used to derive these parameters based on expert opinion, studies from other places at other times and on general principles. To deal with the uncertainty around each of the parameters, we used Monte-Carlo simulation to obtain a range of plausible estimates around the point estimates presented in our study.

We carried out our analysis of HCV transmission and survival of HCV-infected recipients from 1960 to 1992. The estimated number of persons infected in 1960 and surviving to 1998 was not negligible (about 340 persons). Applying a back-projection to estimate cases for the period 1950 to 1959 would add approximately 2,000 additional HCV-infected persons surviving to 1998.

In addition to the uncertainty around several of the parameters used in the model, we were obliged by the limited data available as well as limited time allotted to this study to make a number of assumptions. For the purposes of Model 1, we assumed that the number of units received did not vary by age or sex. This assumption is supported by the study of Chiavetta (*2*) which showed approximately equal mean number of units for each of the age strata presented, at least for red blood cells in the Toronto region in the late 1980's. We also assumed that the distribution of units received according to age and sex and also the overall proportions for each number of each of the levels of transfusion intensity were stable over time. This is clearly not the case since transfusion practice changed substantially during the period 1960 to 1992. In particular, new indications were developed that inclusion the administration of blood components and component therapy essentially replaced whole blood administrations in the 1980's, resulting in a much more efficient use of blood. In addition, following the recognition of the HIV problem, physicians became more conservative about the use of blood. In the 1980's

and early 1990's, there was also a decrease in blood donor availability and therefore a decrease in overall collections. This latter phenomenon was particularly important in the early 1990's but, given the relatively small number of transmissions during this period, this probably affected the study results only minimally.

In our study, we did not take into account any increased mortality that may be due to liver disease from HCV among infected transfusion recipients. Although the transfusion-related survival functions and the mortality tables do take this into account, the former includes follow-up only to 10 years before such mortality would be expected, and the latter includes only a small proportion of HCV-infected persons. The effect of this mortality would not necessarily be negligible. In the United States, an estimated 8,000 to 10,000 persons are thought to die each year from the complications of hepatitis C infection (*45*). Extrapolating this figure to Canada would give 500 to 600 hepatitis C-related deaths a year; 15% or 75 to 90 would be among persons infected through transfusion. Assuming minimal mortality in the first 20 years, such deaths would begin in 1980 for a total of approximately 1,350 to 1,650 cumulative deaths to 1998. This would result in an overall 5% lower number of surviving HCV-infected transfusion recipients. All of the HCV-related excess deaths would occur among persons transfused before 1980. The decrease in the number of surviving recipients due to HCV-related deaths is approximately the same as the number of surviving transfusion recipients infected in the 1950s not accounted for in our analysis.

In our study, we estimated that about 6,600 persons were infected by transfusions received from January 1986 and April 1990. This is substantially less than the approximately 12,400 incident infections estimated surviving to mid 1997 for the same period by the LCDC HCV Working Group convened in January 1998 (of which all of the current Working Group were members). There are several possible reasons for this difference. First, we projected the survivors to mid-1998, one year later than the earlier study. This, however, would result in only about 400 deaths during the additional year. We used additional data not available to the first Working Group to assess the per-unit HCV risk, resulting in a lower estimate, approximately 75% of the previous analysis. Finally and most importantly, we used a mortality function which took into account the latest results from the BC Notification Program and the results from the Olmstead County study and also were adjusted for the greater mortality associated with the substantially higher mean number of units received by HCV-infected persons compared to all recipients. The means were 37 versus 5.8 units per patient, respectively. Mortality is significantly greater for persons receiving a greater number of units. Thus, we used a 10-year survival of about 43% compared to about 68% survival used by the January Working Group.

It will be interesting to obtain and evaluate data on persons coming forward for HCV testing in the next few years. This will help validate the modelled estimates presented in this report. However, such observational data will have to be interpreted with caution. A lookback program may be carried through a public information campaign or through an archival search and active follow-up of transfused patients. The latter will be severely limited by the availability of hospital records for the distant past and the difficulty of locating recipients, given the long time lapse. Not all transfused patients will undergo HCV testing; based on the experience from the BC Program (*3*) and the Hamilton hospital-based program (*43*), about 70% might be expected to do

so. However, this proportion might not be a reliable indication of what might happen. If there were a pecuniary incentive, the proportion may be greater but, on the other hand, for periods in the more remote past, hospital records may be poorer and the knowledge or recollection of having been transfused less reliable. Finally, there may be a significant number of HCV-infected transfusion recipients for whom the assessment of transfusion as the source of the infection may be difficult.

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TABLES

Table 1 Summary of HCV infections and number of surviving HCV-infected recipients Canada, 1960-92

1	2	3	4	5	6	7
Year	Number of units admin	Per-unit HCV risk	HCV infections	Proportion surviving to 1998	Number surviving to 1998	Cumulative number surviving to 1998
1992	449,995	0.00017	75.2	0.543	40.9	40.9
1991	1,899,981	0.00017	317.7	0.502	159.4	200.3
1990b	1,424,985	0.00037	524.1	0.479	251.2	451.4
1990a	474,995	0.00185	852.1	0.457	389.8	389.8
1989	1,570,984	0.00201	3046.7	0.439	1338.6	1,728.5
1988	1,602,984	0.00223	3425.0	0.425	1455.6	3,184.1
1987	1,656,983	0.00246	3882.2	0.412	1600.9	4,785.0
1986b	641,243	0.00278	1687.7	0.400	674.6	5,459.6
1986a	1,068,739	0.00278	2812.9	0.400	1124.4	6,584.0
1985	1,745,182	0.00317	5191.9	0.387	2009.1	2,009.1
1984	1,702,183	0.00356	5631.0	0.375	2109.0	4,118.0
1983	1,576,084	0.00383	5582.8	0.362	2022.1	6,140.1
1982	1,458,885	0.00400	5383.7	0.350	1884.2	8,024.3
1981	1,378,686	0.00400	5087.7	0.338	1719.5	9,743.8
1980	1,296,687	0.00400	4785.1	0.325	1556.1	11,299.9
1979	1,268,078	0.00400	4679.6	0.314	1469.0	12,768.9
1978	1,255,403	0.00400	4632.8	0.303	1402.9	14,171.8
1977	1,176,288	0.00400	4340.8	0.292	1267.3	15,439.1
1976	1,231,887	0.00400	4546.0	0.281	1279.0	16,718.0
1975	1,218,688	0.00400	4497.3	0.250	1125.2	17,843.2
1974	1,166,088	0.00400	4303.2	0.241	1038.0	18,881.2
1973	1,210,088	0.00400	4465.6	0.232	1037.1	19,918.3
1972	1,089,089	0.00420	4202.6	0.223	938.2	20,856.5
1971	1,002,890	0.00420	3869.9	0.214	829.2	21,685.7
1970	930,520	0.00420	3590.7	0.207	742.0	22,427.7
1969	948,690	0.00420	3660.8	0.199	728.6	23,156.4
1968	946,890	0.00420	3653.8	0.191	699.5	23,855.9
1967	897,991	0.00420	3465.2	0.184	637.0	24,492.8
1966	856,391	0.00420	3304.6	0.176	582.3	25,075.2
1965	819,392	0.00420	3161.9	0.170	538.7	25,613.9
1964	804,392	0.00420	3104.0	0.164	510.4	26,124.2
1963	765,392	0.00420	2953.5	0.158	468.1	26,592.3
1962	726,393	0.00420	2803.0	0.153	427.5	27,019.8
1961	663,193	0.00420	2559.1	0.147	375.1	27,395.0
1960	626,294	0.00420	2416.7	0.142	342.5	27,737.5
						Proportion
1990-92	3,774,961		917		451	0.013
1986-90	7,015,928		15,707		6,584	0.189
1960-85	28,761,743		105,873		27,737	0.798
1960-92	39,552,632		122,497		34,773	1.000

Table 2 Number of persons infected and surviving to mid-1998 assuming the mean number of units received (and number of "pre-existing" HCV infections from a source other than transfusion)

1	2	3	4	5	6
Number of people transfused assuming a mean number of units received of:		Proportion recipients surviving to 1998	Number of recipients surviving to 1998, assuming a mean number of units received of:		Number of recipients surviving with pre-existing HCV infection from other sources (assuming a mean of 6 units)
6	7		6	7	
74,999.2	64,285.1	0.662	49,648.4	42,555.7	399.2
316,663.4	271,425.8	0.635	201,083.7	172,357.4	1616.7
237,497.6	203,569.3	0.611	145,176.9	124,439.1	1167.2
79,165.9	67,856.4	0.584	46,196.9	39,597.3	371.4
261,830.7	224,426.3	0.565	148,248.8	127,070.4	1191.9
257,163.9	228,997.7	0.550	146,916.7	125,928.6	1181.2
276,163.8	236,711.9	0.534	147,347.8	126,298.1	1184.7
106,873.9	91,606.2	0.517	55,274.2	47,377.9	444.4
178,123.2	152,677.9	0.517	92,123.7	78,963.2	740.7
290,853.7	249,311.7	0.501	145,632.1	124,827.6	1170.9
283,697.1	243,168.9	0.485	137,476.9	117,837.3	1105.3
262,680.6	225,154.8	0.469	123,100.4	105,514.6	989.7
243,147.5	208,412.2	0.453	110,108.2	94,378.4	885.3
229,761.0	196,955.1	0.437	100,478.3	86,125.1	807.9
216,114.5	185,241.0	0.421	90,934.9	77,944.2	731.1
211,346.3	181,154.0	0.406	85,840.6	73,577.7	690.2
209,233.9	179,343.3	0.392	81,978.7	70,268.3	659.1
196,048.0	168,041.1	0.378	74,056.9	63,477.3	595.4
205,314.6	175,983.9	0.364	74,738.6	64,061.7	600.9
203,114.6	174,098.2	0.324	65,754.1	56,360.7	528.7
194,348.0	166,584.0	0.312	60,657.2	51,991.9	487.7
201,681.3	172,869.7	0.300	60,601.8	51,944.4	487.2
181,514.6	155,584.1	0.289	52,432.4	44,942.0	421.6
167,148.3	143,270.0	0.277	46,339.7	39,719.7	372.6
155,086.7	132,931.5	0.267	41,467.1	35,543.2	333.4
158,115.0	135,527.2	0.258	40,720.4	34,903.2	327.4
157,815.1	135,270.0	0.248	39,089.6	33,505.4	314.3
149,665.1	128,284.4	0.238	35,597.7	30,512.3	286.2
142,731.9	122,341.6	0.228	32,543.6	27,894.5	261.7
136,565.3	117,055.9	0.220	30,104.5	25,803.8	242.0
134,065.3	114,913.1	0.213	28,521.9	24,447.4	229.3
127,565.4	109,341.7	0.205	26,157.7	22,420.9	210.3
121,065.4	103,770.4	0.197	23,893.4	20,480.1	192.1
110,532.2	94,741.9	0.190	20,964.2	17,969.3	168.6
104,382.3	89,470.5	0.183	19,141.5	16,407.0	153.9
		1990-92	395,911	339,352	3,183
		1986-90	636,108	545,236	5,114
		1960-85	1,648,334	1,412,858	13,253
		1960-92	2,680,354	2,297,446	21,550

Table 4 Model 3 output: Number of transfusion-associated HCV infections, by sex and age group
Derived from proportion HCV-infected among persons ever transfused
Canada, January 1998

		1	2	3	4	5	6	7	8	9
		Population (000s)	Proportion ever transfused (%)	Persons ever transfused (number)	Proportion HCV infected	Proportion HCV+ recip infected by transfusion	Proportion HCV+ recip infected by other sources	Transfusion associated HCV infections (number)	Other HCV infections (number)	Total HCV infections (number)
Males	0-5	1212	0.5	6060	0.002					
	6-14	1857	1.0	18570	0.010					
	15-19	1026	1.5	15390	0.015					
	20-39	4833	6.0	289980	0.020					
	40-64	4373	18.0	787140	0.022					
	65+	1544	24.0	370560	0.027					
	Total	14845	10.0	1487700	0.023	0.7	0.3	23485	10065	33550
Females	0-5	1152	0.5	5760	0.001					
	6-14	1775	1.5	26625	0.002					
	15-19	977	2.0	19540	0.010					
	20-39	4725	8.0	378000	0.012					
	40-64	4392	20.0	878400	0.017					
	65+	2096	24.0	503520	0.022					
	Total	15119	12.0	1811845	0.017	0.7	0.3	21560	9240	30801
Both sexes	0-5	2364	0.5	11820	0.000					
	6-14	3632	2.0	45195	0.000					
	15-19	2003	1.7	34930	0.000					
	20-39	9558	7.0	667980	0.000					
	40-64	8765	19.0	1665540	0.000					
	65+	3642	24.0	874080	0.000					
	Total	29964	11.0	3299545	0.020	0.7	0.3	45046	19305	64351

Proportion transfused (%) 11
Proportion HCV infected (%) 2
Proportion HCV+ from transfusion 0.7

606

Table 4 Model 3 output: Number of transfusion-associated HCV infections, by sex and age group
Derived from proportion HCV-infected among persons ever transfused
Canada, January 1998

		1	2	3	4	5	6	7	8	9
		Population (000s)	Proportion ever transfused (%)	Persons ever transfused (number)	Proportion HCV infected	Proportion HCV+ recip infected by transfusion	Proportion HCV+ recip infected by other sources	Transfusion associated HCV infections (number)	Other HCV infections (number)	Total HCV infections (number)
Males	0-5	1212	0.5	6060	0.002					
	6-14	1857	1.0	18570	0.010					
	15-19	1026	1.5	15390	0.015					
	20-39	4833	6.0	289980	0.020					
	40-64	4373	18.0	787140	0.022					
	65+	1544	24.0	370560	0.027					
	Total	14845	10.0	1487700	0.023	0.7	0.3	23485	10065	33550
Females	0-5	1152	0.5	5760	0.001					
	6-14	1775	1.5	26625	0.002					
	15-19	977	2.0	19540	0.010					
	20-39	4725	8.0	378000	0.012					
	40-64	4392	20.0	878400	0.017					
	65+	2098	24.0	503520	0.022					
	Total	15119	12.0	1811845	0.017	0.7	0.3	21560	9240	30801
Both sexes	0-5	2364	0.5	11820	0.000					
	6-14	3632	2.0	45195	0.000					
	15-19	2003	1.7	34930	0.000					
	20-39	9558	7.0	667980	0.000					
	40-64	8765	19.0	1665540	0.000					
	65+	3642	24.0	874080	0.000					
	Total	29964	11.0	3299545	0.020	0.7	0.3	45046	19305	64351

Proportion transfused (%)	11
Proportion HCV infected (%)	2
Proportion HCV+ from transfusion	0.7

Table 5 **Modelled transfusion-associated HCV infections and other HCV-infected persons transfused by province, Canada, 1998**

Province	*1* *Population (000s)*	*2* *Number transfusion associated CV infectio number*	*3* *Prevalence ransfusion associated CV infectio 1000 pop'n*	*4* *Proportion of TA-HCV infections Canada (%)*	*5* *Number other HCV-infected persons transfused*
British Columbia	3860	7656	1.98	22.0	4752
Alberta	2790	3705	1.33	10.7	2300
Saskatchewan	1020	634	0.62	1.8	394
Manitoba	1140	902	0.79	2.6	560
Ontario	11250	15365	1.37	44.2	9537
Quebec	7390	5290	0.72	15.2	3284
New Brunswick	760	415	0.55	1.2	258
Nova Scotia	940	699	0.74	2.0	434
Prince Edward Island	140	50	0.36	0.1	31
Newfoundland	570	67	0.12	0.2	42
Canada	29860	34784	1.16	100.0	21590

Note: These estimates are subject to uncertainty; they are based on the assumption including that both transfusion-associated HCV infection and other HCV-infected persons who were transfused vary accross across provinces as does the relative HCV prevalence among blood donors in Canada in 1990

Number of TAHCV	34800
Other HCV transfused	21600

Table 6 **Summary of point estimates and plausible limits of HCV-infected transfusion recipients obtained from Models 1, 2 and 3 (rounded)**
Persons surviving as of mid-1998
Canada

	Transfusion-associated infections		*Other HCV-infected recipients*	
	Point estimate	*Plausible limits*	*Point estimate*	*Plausible limits*
Model 1	34,800	26,600 - 45,400	21,600	15,700 - 28,700
Model 2	36,000	25,300 - 49,600	24,400	19,000 - 31,000
Model 3	45,000	29,000 - 67,700	19,300	3,400 - 34,600

Table 7 **Summary of point estimates and plausible limits of HCV-infected transfusion recipients obtained from Model 1 (rounded)**
By period of transfusion
Persons surviving as of mid-1998, Canada

	Transfusion-associated infections		*Other HCV-infected recipients*	
	Point estimate	*Plausible limits*	*Point estimate*	*Plausible limits*
1960-85	27,700	19,800 - 38,200	13,300	9,700 - 17,600
1986-90	6,600	5,200 - 8,100	5,100	3,700 - 6,800
1990-92	450	390 - 520	3,200	2,300 - 4,200
Total	34,800	26,600 - 45,400	21,600	15,700 - 28,700

FIGURES

FIGURE 1

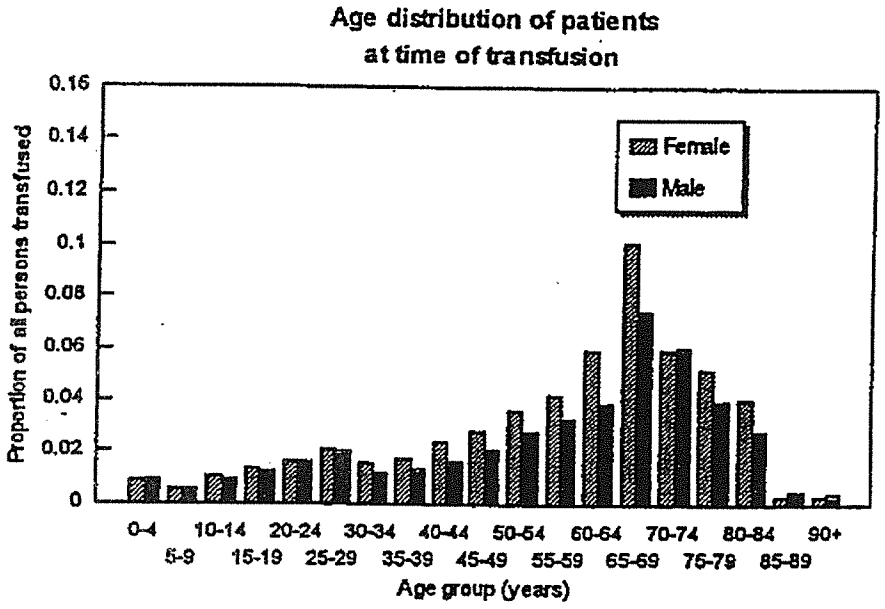

Age distribution of patients
at time of transfusion
Proportion of all persons transfused
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
Female
Male
0-4
5-9
10-14
15-19
20-24
25-29
30-34
35-39
40-44
45-49
50-54
55-59
60-64
65-69
70-74
75-79
80-84
85-89
90+
Age group (years)

FIGURE 2

Estimation of per-unit risk of HCV infection through transfusion Canada, 1980-90

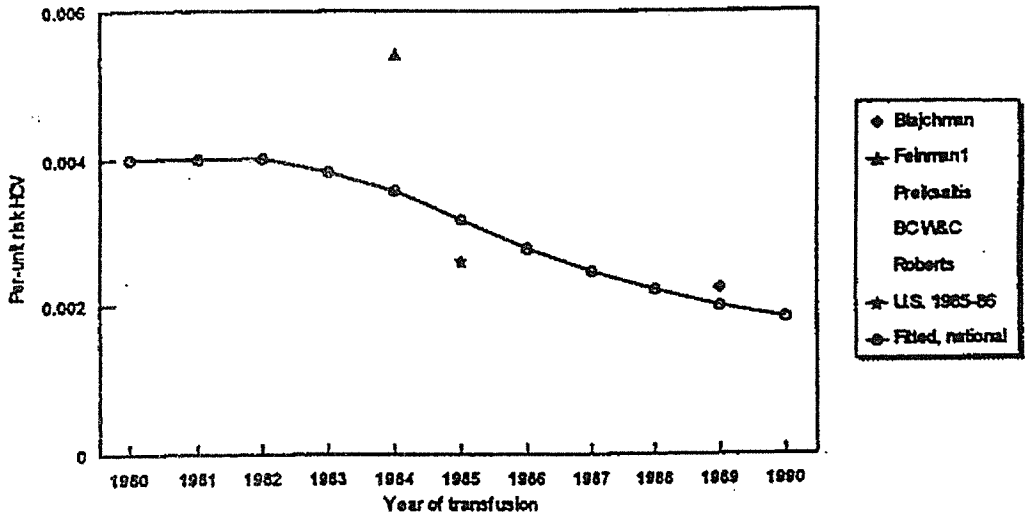


Figure 3

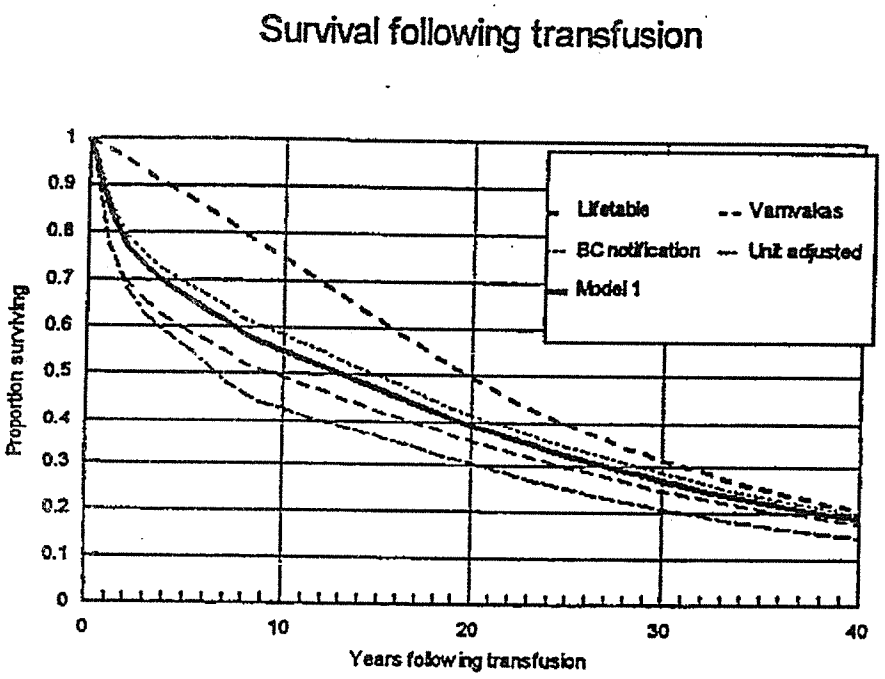

Survival following transfusion
Proportion surviving
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
10
20
30
40
Years following transfusion
Lifetable
Vamvakas
BC notification
Unit adjusted
Model 1

FIGURE 4

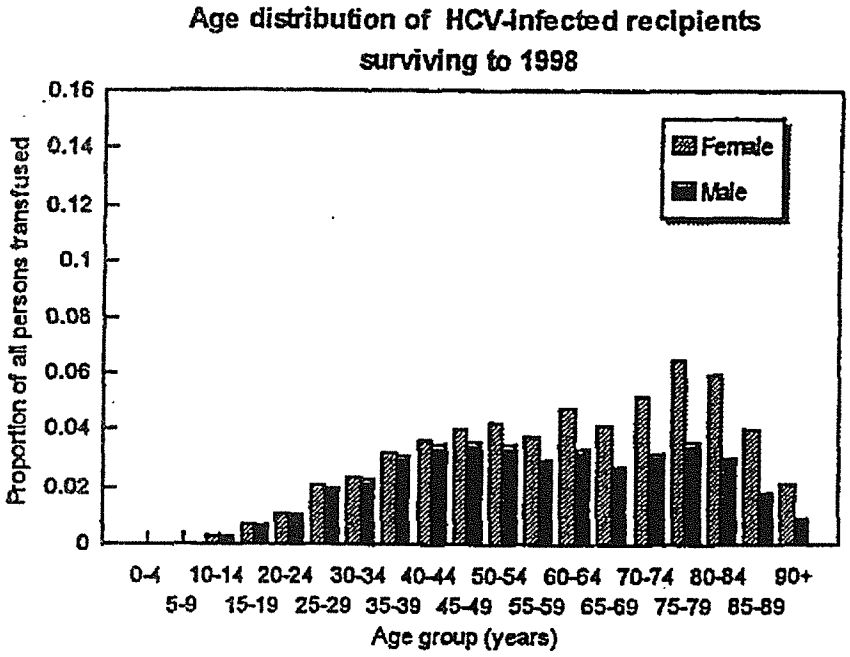
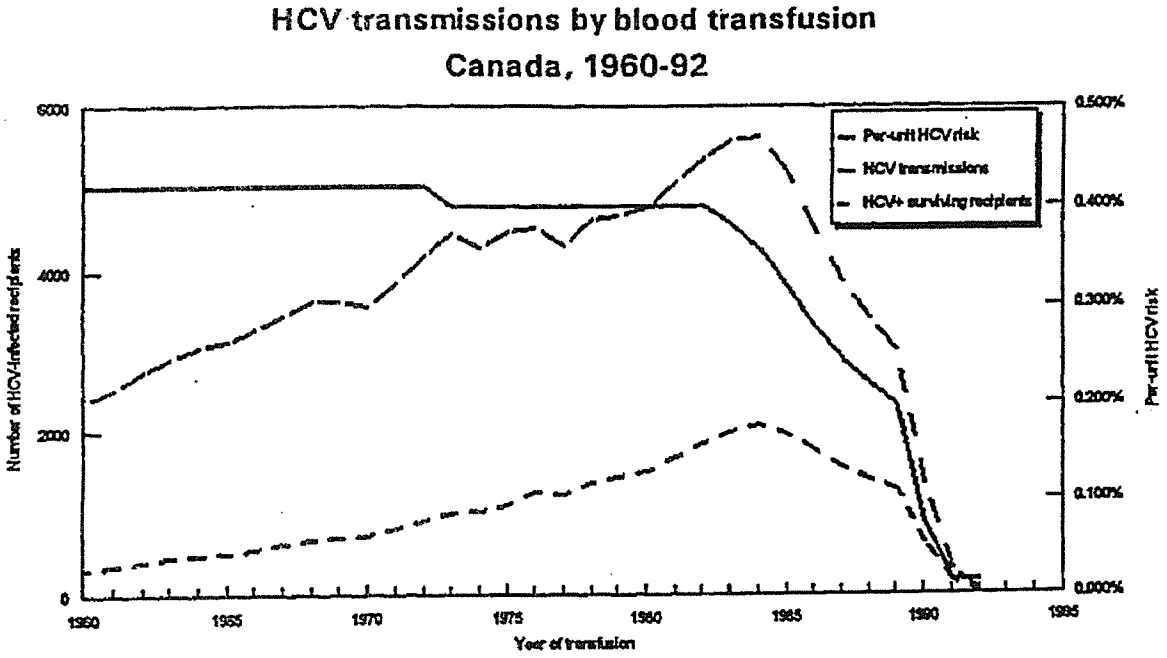

Age distribution of HCV-infected recipients surviving to 1998
Proportion of all persons transfused
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
Female
Male
0-4
5-9
10-14
15-19
20-24
25-29
30-34
35-39
40-44
45-49
50-54
55-59
60-64
65-69
70-74
75-79
80-84
85-89
90+
Age group (years)

FIGURE 5


HCV transmissions by blood transfusion
Canada, 1960-92
Per-unit HCV risk
HCV transmissions
HCV+ surviving recipients
Number of HCV-infected recipients
Per-unit HCV risk
Year of transfusion
0
2000
4000
6000
0.000%
0.100%
0.200%
0.300%
0.400%
0.500%
1960
1965
1970
1975
1980
1985
1990
1995

APPENDICES

Table A1 Units of blood and its components collected and administered Canada, 1960 to 1990

Year	Units collected	Units administered	Ratio	Partial years		Units collected	Units administered
				1992		1,218,000	*1,800,000*
1992a	304,500	450,000	1.48		0.25	304,500	450,000
1991	1,283,000	*1,900,000*	1.48				
1990b	939,000	1,425,000	1.52		0.75	939,000	1,425,000
				1990		1,252,000	*1,900,000*
1990a	313,000	475,000	1.52		0.25	313,000	475,000
1989	1,013,000	1,571,000	1.55				
1988	1,034,000	1,603,000	1.55				
1987	1,070,000	1,657,000	1.55				
1986b	689,375	1,068,750	1.55		0.625	689,375	1,068,750
				1986		1,103,000	1,710,000
1986a	413,625	641,250	1.55		0.375	413,625	641,250
1985	1,124,000	1,745,200	1.55				
1984	1,117,700	1,702,200	1.52				
1983	1,063,600	1,576,100	1.48				
1982	1,129,200	1,458,900	1.29				
1981	1,107,300	1,378,700	1.25				
1980	1,066,300	1,296,700	1.22				
1979	1,040,800	1,268,091	1.22				
1978	1,019,000	1,255,416	1.23				
1977	1,005,400	1,176,300	1.17				
1976	1,022,700	1,231,900	1.20				
1975	1,044,400	1,218,700	1.17				
1974	1,000,900	1,166,100	1.17				
1973	974,000	1,210,100	1.24				
1972	936,000	1,089,100	1.16				
1971	936,100	1,002,900	1.07				
1970	953,100	930,530	0.98				
1969	971700	948,700					
1968	969,900	946,900					
1967	919,800	898,000					
1966	877,200	856,400					
1965	839300	819,400					
1964	823,900	804,400					
1963	783,950	765,400					
1962	744,000	726,400					
1961	679,300	663,200					
1960	641,500	626,300					

Notes:
1. Number of units collected for 1963 was interpolated from 1962 and 1964
2. Number of units administered for 1960-69 based on ratio in 1970

Table A2 **Modelled distribution of number of units administered to transfusion recipients, Canada, 1985**

Number of units	*Patients*	*Total units administered*	*Proportion of patients*	*Cumulative proportion of patients*
1	21940	21940	0.083	0.083
2	83463	166926	0.314	0.397
3	38488	115464	0.145	0.541
4	34351	137404	0.129	0.671
5	21166	105830	0.080	0.750
6	15427	92562	0.058	0.808
7	8892	62244	0.033	0.842
8	7420	59360	0.028	0.870
9	5472	49248	0.021	0.890
10	4618	46180	0.017	0.908
11	3683	40513	0.014	0.921
12	2936	35232	0.011	0.933
13	2536	32968	0.010	0.942
14	2162	30268	0.008	0.950
15	1815	27225	0.007	0.957
16	1415	22640	0.005	0.962
17	1068	18156	0.004	0.966
18	801	14418	0.003	0.969
19	587	11153	0.002	0.972
22	2349	51678	0.009	0.980
27	1495	40365	0.006	0.986
38	1948	74024	0.007	0.993
65	908	59020	0.003	0.997
200	507	101400	0.002	0.999
300	267	80100	0.001	1.000
550	80	44000	0.000	1.000
Total	265794	1540318		
Mean units / patient		5.80		

Source: Remis RS, Palmer RWH. The epidemiology of transfusion-associated HIV infection in Canada, 1978-85

Table A3 Distribution of sex and age of transfusion recipients Canada, 1960-92

		Proportion of recipients			Proportion of recipients
Males	0-4	0.0089	Females	0-4	0.0087
	5-9	0.0053		5-9	0.0054
	10-14	0.0096		10-14	0.0096
	15-19	0.0125		15-19	0.0129
	20-24	0.0163		20-24	0.0159
	25-29	0.0200		25-29	0.0202
	30-34	0.0118		30-34	0.0150
	35-39	0.0127		35-39	0.0165
	40-44	0.0159		40-44	0.0232
	45-49	0.0202		45-49	0.0279
	50-54	0.0284		50-54	0.0360
	55-59	0.0332		55-59	0.0421
	60-64	0.0394		60-64	0.0598
	65-69	0.0749		65-69	0.1011
	70-74	0.0603		70-74	0.0596
	75-79	0.0399		75-79	0.0525
	80-84	0.0283		80-84	0.0410
	85-89	0.0044		85-89	0.0035
	90+	0.0038		90-94	0.0030
	Total	0.4459		Total	0.5541

		Proportion of recipients
Both sexes	0-4	0.0176
	5-9	0.0107
	10-14	0.0192
	15-19	0.0254
	20-24	0.0322
	25-29	0.0403
	30-34	0.0268
	35-39	0.0292
	40-44	0.0391
	45-49	0.0481
	50-54	0.0644
	55-59	0.0754
	60-64	0.0993
	65-69	0.1760
	70-74	0.1199
	75-79	0.0924
	80-84	0.0693
	85-89	0.0079
	90+	0.0068

TABLE A4 SUMMARY OF ESTIMATES OF POST-TRANSFUSION HEPATITIS DUE TO HCV AND PER-UNIT HCV RISK, CANADA AND USA, 1983-90

Ref	Author	Location	Period	N	n	HCV PTH	Units/ patient	Per unit HCV risk	95%CL
4, 6	Feinman	Toronto	83/12-85/10	576	18	0.031	4.26	0.0073	0.0043 - 0.0114
9	Preiksaitis	Edmonton	83/10-85/05	279	5	0.018	10.9	0.0017	0.0005-0.0039
10	Mathias	BC	82/??-85/??	1118	45	0.040	6.4	0.0061	0.0045-0.0081
7	Blajchman	To/Ha/Wp	88/??-90/04	397	5	0.0126	4.76	0.0026	0.0008-0.0060
11	Roberts	Toronto	85/12-90/05	4500?	64	0.014	?	0.0025?	
12	Donahue	Baltimore	85/??-86/??	488	19	0.039	8.91	0.0052	0.0032-0.0080

ble A5 Risk per unit of HCV PTH, Canada 1980-90

	Blajchman (multicentre study)			Feinman	Preiksaitis	Forbes	Roberts	Donahue	*Fitted curve*
	Toronto	*Hamilton*	*Winnipeg*	*Toronto*	*Edmonton*	*BC*	*Toronto*	*U.S.*	*Canada*
entre weig	1.35	1.2	0.4	1.35	0.8	1.8	1.35	2	
oportion	0.5	0.35	0.15	1	1	1	1	1	
eight	1.16			1.35	0.8	1.8	1.35	2	1
bserved	**0.0026**			**0.0073**	**0.0017**	**0.0060**	**0.004**	**0.0052**	
980									0.00400
981									0.00400
982									0.00400
983									0.00383
984				0.0054	0.0021	0.0033			0.00356
985								0.0026	0.00317
986									0.00278
987									0.00246
988							0.0030		0.00223
989	0.0023								0.00201
990									0.00185

Table A6 Per unit risk of HCV infection from blood Canada, 1960-92

Year	Measured HCV prevalence	True HCV prevalence	Per-unit HCV risk	Correction factor for multiple exposures
1992	0.00073	0.00091	0.000168	0.996
1991	0.00073	0.00091	0.000168	0.996
1990	0.00161	0.00201	0.000370	0.993
1990	0.00161	0.00201	0.00185	0.969
1989	0.00175	0.00219	0.00201	0.964
1988	0.00194	0.00243	0.00223	0.958
1987	0.00214	0.00268	0.00246	0.952
1986	0.00242	0.00303	0.00278	0.946
1986	0.00242	0.00303	0.00278	0.946
1985	0.00276	0.00345	0.00317	0.937
1984	0.00310	0.00387	0.00356	0.929
1983	0.00333	0.00416	0.00383	0.925
1982	0.00348	0.00435	0.00400	0.922
1981	0.00348	0.00435	0.00400	0.922
1980	0.00348	0.00435	0.00400	0.922
1979	0.00348	0.00435	0.00400	0.922
1978	0.00348	0.00435	0.00400	0.922
1977	0.00348	0.00435	0.00400	0.922
1976	0.00348	0.00435	0.00400	0.922
1975	0.00348	0.00435	0.00400	0.922
1974	0.00348	0.00435	0.00400	0.922
1973	0.00348	0.00435	0.00400	0.922
1972	0.00365	0.00456	0.00420	0.919
1971	0.00365	0.00456	0.00420	0.919
1970	0.00365	0.00456	0.00420	0.919
1969	0.00365	0.00456	0.00420	0.919
1968	0.00365	0.00456	0.00420	0.919
1967	0.00365	0.00456	0.00420	0.919
1966	0.00365	0.00456	0.00420	0.919
1965	0.00365	0.00456	0.00420	0.919
1964	0.00365	0.00456	0.00420	0.919
1963	0.00365	0.00456	0.00420	0.919
1962	0.00365	0.00456	0.00420	0.919
1961	0.00365	0.00456	0.00420	0.919
1960	0.00365	0.00456	0.00420	0.919

Note: HCV prevalence for period blood HCV screened, infectious prevalence was calculated as prevalence of undetected HCV (i.e. [measured HCV/sensitivity]-[measured HCV])

Sensitivity 0.8

Table A7 **Parameter values: Prevalence of hepatitis C infection in selected populations**

Reference	*Population*	*Type of study*	*Year(s)*	*N*	*Result*	*Comments*
Romanowski	STD clinic patients	Seroepid	1994-95	3765 2903	4.4% 2.0%	Men (approx) Women (approx)
Chaudhary	"Normal individuals"	Lab-based	?	256	2.0%	95% CL: 0.64%-4.5%
Roberts	Transfusion recipients, HSC	Lookback	1986-90	4496	1.4%	"Minimum estimate"
Armstrong	Cornea donors Ontario	Screening	1993-95	3228	1.0%	Mean age 75 years old
Joly	Sentinel hospitals Quebec	Anonymous	1990-92	4445 5631	0.89% 0.46%	Males Females
Johnson	EEG patients Scarborough	Outbreak investigation	1996	6000	1.3% 0.85%	Males Females
Pi	Pregnant women, BC	Prenatal sera	1994	15,000	0.9%	95% CL: 0.76%-1.1%
Louie	Teaching hospital Toronto	Anonymous	1990	1306	0.5%	EIA1 confirmed
CRCS	Volunteer blood donors	Transfusion	1990	10^6	0.124%	National prevalence

Table A8 **Modelled HCV infections (all sources), number and prevalence by province and sex, Canada, 1998**

Province	Population (000s)	HCV infections, number	HCV prevalence (%)	Proportion total HCV infections (%)	HCV prevalence (%) Males	HCV prevalence (%) Females
British Columbia	3860	52546	1.36	22.0	1.75	0.97
Alberta	2790	25380	0.91	10.6	1.17	0.65
Saskatchewan	1020	4343	0.43	1.8	0.55	0.30
Manitoba	1140	6178	0.54	2.6	0.70	0.39
Ontario	11250	105242	0.94	44.2	1.20	0.67
Quebec	7390	36235	0.49	15.2	0.63	0.35
New Brunswick	760	2844	0.37	1.2	0.48	0.27
Nova Scotia	940	4791	0.51	2.0	0.66	0.36
Prince Edward Island	140	343	0.25	0.1	0.32	0.18
Newfoundland	570	460	0.08	0.2	0.10	0.06
Canada	29860	238362	0.80	100	0.96	0.53

Note: These estimates must be considered somewhat speculative; they are based on several assumptions including that the relative HCV prevalence in blood donors in 1990 reflect the relatrive HCV prevalence in the population as a whole, and that the male:female HCV prevalence ratio is constant across all provinces

Table A9 **Parameter values: Proportion of hepatitis C infections with transfusion history**

Author	*Population*	*Type of study*	*Year(s)*	*Value*	*Comments*	
Stratton	PEI	Reported cases	1990-1995		39%	Blood/blood products
					46%	IDU
				6%	Both of above	
Darling	Victoria, BC	General	1996		12%	Received blood/blood products
				62%	IDU	
RDIS	Ontario	Reported cases	1997		7.0%	Blood recipients
			1996		7.8%	"
			1995		6.3%	"
			1994		6.7%	"
			1993		9.9%	"
			1992		9.8%	"
			1991		16%	"
			1990		20%	"
LCDC	8 health units BC/AL/SK/MN ON/PQ/PEI	Reported cases	1993-1995		30%	Blood transfusion ever (216/718)
					69%	IDU (494/715)
Delage	Quebec?	Blood donors	?	22%	Blood transfusion	
				45%	IDU	
Scully	Ottawa	Clinical series	?	33%	Blood transfusion (21/63)	
				43%	IDU (27/63)	

Table A10 Point estimates and plausible range for model parameters

			Point estimate	Lower limit	Upper limit
Model 1:	Per-unit HCV risk (%)	1990	0.143	0.129	0.159
		1989	0.166	0.149	0.184
		1988	0.195	0.156	0.244
		1987	0.225	0.180	0.281
		1986	0.260	0.208	0.325
		1985	0.310	0.217	0.443
		1984	0.356	0.249	0.509
		1983	0.383	0.268	0.547
		1982	0.400	0.280	0.571
	Survival following transfusion		0.425	0.383	0.472
Model 2:	HCV prevalence (%)		0.80	0.68	0.94
	Proportion HCV+ from transfusion		0.15	0.11	0.21
	Proportion other HCV+, transfused		0.12	0.096	0.15
Model 3:	Proportion persons transfused		0.11	0.094	0.129
	HCV prevalence among transfused		0.02	0.015	0.027
	Proportion due to transfusion		0.70	0.56	0.88

Table A11 Worksheet to calculate number of HCV-infected recipients surviving to mid-1998

	1	2	3	4	5	6	7
Gender	Age group (1994)	Population	Proportion of units admin	Number of units admin	HCV infections	Proportion surviving to 1998	Number surviving to 1998
Males	0-4	1005.9	0.0089	15,166	54.0	0.936	50.5
	5-9	1031.3	0.0053	9,100	32.4	0.931	30.2
	10-14	1031.9	0.0096	16,304	58.0	0.927	53.8
	15-19	1026.3	0.0125	21,233	75.6	0.923	69.8
	20-24	1033.5	0.0163	27,678	98.5	0.923	90.9
	25-29	1121.5	0.0200	34,124	121.5	0.920	111.7
	30-34	1334	0.0118	20,055	71.4	0.914	65.3
	35-39	1343.9	0.0127	21,598	76.9	0.902	69.3
	40-44	1191.8	0.0159	27,074	96.4	0.658	63.4
	45-49	1084.6	0.0202	34,433	122.6	0.629	77.1
	50-54	838.2	0.0284	48,315	172.0	0.584	100.5
	55-59	661.9	0.0332	56,592	201.4	0.522	105.0
	60-64	596.2	0.0394	67,105	238.8	0.436	104.0
	65-69	536.2	0.0749	127,499	453.8	0.276	125.0
	70-74	432.8	0.0603	102,713	365.6	0.175	63.8
	75-79	289.2	0.0399	67,887	241.6	0.088	21.4
	80-84	174.9	0.0283	48,147	171.4	0.037	6.3
	85-89	78.3	0.0044	7,543	26.8	0.000	0.0
	90+	32.5	0.0038	6,420	22.8	0.000	0.0
	Total	14845.1	0.4459	758,985	2,701	0.447	1,208
Female	0-4	955	0.0087	14,803	52.7	0.947	49.9
	5-9	984.5	0.0054	9,159	32.6	0.946	30.9
	10-14	987.7	0.0096	16,424	58.5	0.945	55.3
	15-19	976.5	0.0129	22,019	78.4	0.944	74.0
	20-24	1002.9	0.0159	27,063	96.3	0.943	90.8
	25-29	1102.1	0.0202	34,431	122.6	0.940	115.2
	30-34	1297.2	0.0150	25,568	91.0	0.936	85.2
	35-39	1322.5	0.0165	28,161	100.2	0.927	93.0
	40-44	1195.7	0.0232	39,519	140.7	0.696	97.9
	45-49	1074.7	0.0279	47,423	168.8	0.679	114.7
	50-54	834	0.0360	61,339	218.3	0.655	143.0
	55-59	670.7	0.0421	71,719	255.3	0.617	157.6
	60-64	616.9	0.0598	101,867	362.6	0.561	203.3
	65-69	593.1	0.1011	172,125	612.6	0.392	240.3
	70-74	547.1	0.0596	101,429	361.0	0.291	105.0
	75-79	415.1	0.0525	89,385	318.1	0.170	54.1
	80-84	292.7	0.0410	69,733	248.2	0.072	17.8
	85-89	162.3	0.0035	5,959	21.2	0.000	0.0
	90-94	88	0.0030	5,071	18.1	0.000	0.0
	Total	15118.7	0.5541	943,197	3,357	0.515	1,728
Both sexes	0-4	1960.9	0.0176	29,969	106.7	0.942	100.4
	5-9	2015.8	0.0107	18,259	65.0	0.939	61.0
	10-14	2019.6	0.0192	32,728	116.5	0.936	109.0
	15-19	2002.8	0.0254	43,252	153.9	0.934	143.8
	20-24	2036.4	0.0322	54,742	194.8	0.933	181.7
	25-29	2223.6	0.0403	68,556	244.0	0.930	227.0
	30-34	2631.2	0.0268	45,624	162.4	0.926	150.4
	35-39	2666.4	0.0292	49,759	177.1	0.916	162.3
	40-44	2387.5	0.0391	66,593	237.0	0.680	161.2
	45-49	2159.5	0.0481	81,856	291.3	0.658	191.8
	50-54	1672.2	0.0644	109,654	390.3	0.624	243.5
	55-59	1332.6	0.0754	128,310	456.7	0.575	262.7
	60-64	1213.1	0.0993	168,971	601.4	0.511	307.3
	65-69	1129.3	0.1760	299,624	1066.4	0.343	365.3
	70-74	979.9	0.1199	204,142	726.6	0.232	168.8
	75-79	704.3	0.0924	157,272	559.8	0.135	75.4
	80-84	467.6	0.0693	117,879	419.6	0.058	24.1
	85-89	240.6	0.0079	13,502	48.1	0.000	0.0
	90+	120.5	0.0068	11,491	40.9	0.000	0.0
	Total	29963.8	1.0000	1,702,183	6058.5	0.485	2935.9
	Corrected for double inf. & unit-specific survival				5631.0	0.375	2109.0
	Number of units administered			1,702,200			
	HCV prevalence			0.003559			
	Correction factor			0.929444			
	Unit-specific survival adjustment			0.772868	14	14	