Witness Name: Geoffrey Dusheiko
Statement No.: WITN3754001
Exhibits: WITN3754002-WITN3754005
Dated: 10 October 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF GEOFFREY DUSHEIKO

I provide this interim statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 19 September 2019.

I, Geoffrey Dusheiko, will say as follows: -

Section 1: Introduction

1. My name, address, date of birth and professional qualifications are as follows:

   Geoffrey Mark Dusheiko, Liver Unit, Kings College Hospital London UK. GRO-C 1948 MB BCh (Wits) FCP(SA) FRCP FRCP (Edin)

2. The positions I have held as a doctor, the organisations in which I have held these positions and my role and responsibilities in these positions are as follows:

Intern, Medicine	Baragwanath Hospital, Johannesburg 2 January 1973 to June 1973.
Intern, Surgery	Baragwanath Hospital, Johannesburg July 1973 to December 1973
Locum Tenens position:	January 1974 to July 1974. Paediatric Ward

	Northwick Park Hospital Middlesex U.K. Dr H.B. Valman (2)
	General Practice, Johannesburg. A.E.C.I, Modderfontein
Sen. Intern Paediatrics	Johannesburg Childrens Hospital July to December, 1974.
Sen. Intern Cardiology	Johannesburg Hospital January to June, 1975.
Registrar Medicine Respiratory, Endocrine, Neurology Coronary intensive care units Haematology, General medicine,	Johannesburg Hospital July 1975 to July 1978.
Research Fellow Liver Unit	Johannesburg Hospital July 1978 to July 1979.
Visiting research associate Liver Unit (South African Medical Research Council Fellow)	Liver Diseases Section, National Institutes of Health Washington DC USA August 1979 to July 1981.
Senior Physician Hillbrow and Johannesburg Hospital (Consultant)	August 1981 to December 1983.

Unit Head Hillbrow and Johannesburg Hospital (Consultant, and Ward Head)	Jan 1984 to Dec 1987.
Guest Researcher (Vice Chancellor's Research Award)	University of Minnesota USA Sept 1986 to March 1987 Dept of Microbiology
Senior Lecturer	January 1988 Academic Dept Medicine, Royal Free Hospital School of Medicine
Reader in Medicine Medicine	Royal Free Hospital School of 1989
Professor of Medicine	Royal Free Hospital and University College School of Medicine 1996
Emeritus Professor of Medicine	University College London Medical School January 2014 Consultant Hepatologist Royal Free Hospital London 2014-2016
Consultant Hepatologist	Liver Unit Kings College Hospital London UK 2016-to date
Interim Deputy Director	Blood safety, Hepatitis HIV and STI National Infection Service Public Health England

3. I have served on NICE panels, National Institutes of Health USA hepatitis consensus panels, EASL guidelines committees, World Health Organisation advisory boards, the Skipton Fund, NHS EIBSS and have advised Thalassemia and haemophilia Societies in the past.

Section 2: Response to criticisms of Mark Ward and Richard Dudley-Smith

4. Thank you for the opportunity to respond to witness 1591. I am pleased that patients will have the opportunity to address their concerns via the infected blood inquiry. Hepatitis C infected blood products have had a profound physical, psychological and social impact on individuals. I have read Mr Ward's witness statement which describes his individual trauma and the problems he has faced. His deposition encompasses many of the trials of patients infected with hepatitis C. Nonetheless some of his allegations require addressing.

5. *At paragraph 103 of his statement, witness W1591 states he was advised by a social worker connected to the haemophilia unit at the Queen Elizabeth Hospital to stay off Interferon for as long as possible as the social worker thought witness W1591 wouldn't survive the treatment psychologically or physically. Witness W1591 states this didn't stop you trying to "push" Interferon on him. Please comment on this.*

6. I am unable to comment in detail on W1591's care in Haemophilia Unit at the Queen Elizabeth Hospital. I would, however, with respect, question the training, experience, knowledge and ability of a social worker to advise on the indications for treatment with interferon alpha. The date and chronology of the discussion that W1591 refers to is not given. Although the efficacy of interferon alpha and ribavirin is restricted, selected patients respond to treatment. The risk of hepatic fibrosis (scarring of the liver) and primary liver cancer is reduced in patients with a sustained virological response. The onus was on me to inform patients with chronic hepatitis C of the possible risk and benefits of interferon at a time when interferon was the only proven treatment for chronic hepatitis C.

7. Mr Ward refers to consultations with other physicians in the paragraph. I would be grateful if the Inquiry could forward the records of my consultations W1591 and could provide evidence for his statement that he was being coerced by me into receiving interferon treatment.

8. Interferon alpha has been previously widely used as a treatment for hepatitis C virus (HCV) infection. The goal of therapy is suppression and clearance of HCV. The accompanying

reduction in histological activity lessens the risk of cirrhosis and decreases the risk of hepatocellular carcinoma. Although successful interferon alpha treatment prolongs survival in patients with hepatitis C, the frequency of side effects has limited its effectiveness, and it has fortunately been displaced by newer, safer and more effective oral antiviral agents. Discussion regarding the rationale, indications, and potential adverse events of interferon treatment for hepatitis C was necessarily complex and detailed; I discussed the goals, response rates, on-treatment and persistent side effects of interferon treatment with all patients who were potential candidates for treatment and emphasized that patients needed to be partners to the decision to treat. Without hubris, I point out that have been a member of several national and international guideline committees and have drafted guidelines for interferon use for hepatitis C; I am fully aware of the dosage, duration, stopping and futility rules, and prospects and limitations of interferon alpha for hepatitis C, and would have discussed these with patients. I have also written editorials and guidelines directing the use of interferon-free treatments for hepatitis C and also assisted in the development of new direct acting antiviral treatments for hepatitis C (see below)[1] I have written the chapter on hepatitis C in successive chapters in a major textbook of Hepatology, charting the development of new agents. Again, without hubris, I believe that I have some knowledge of hepatitis C and its treatment. It has been a privilege to take patients with me in the clinic to attempt to cure their disease and to bear witness to the progress that has been made in treatment. W1591 is sadly one of the few exceptions in a lifetime of hepatitis and liver disease.

9. *Paragraph 105: Witness 1591 indicates that I wrote in his medical records in 2006 that he had a hypoechoic liver and he was going to speak to his partner about going on interferon. He then states that apparently, there were earlier tests showing that he had cleared the virus, however he was not told about this. Please comment on this.*

10. I would be grateful if the inquiry could furnish the relevant records. My understanding is that W1591 was noted in September 2006 to be HCV RNA-negative and had cleared hepatitis C. He was informed around this time that he no longer had detectable HCV RNA undetectable in serum. I may have commented that imaging of his liver showed a smooth contour. I can assure the inquiry that no patient with an undetectable hepatitis C RNA would have commenced interferon alpha. Any pending results to indicate the absence of

[1] Dusheiko G, Wedemeyer H. New protease inhibitors and direct-acting antivirals for hepatitis C: interferon's long goodbye. Gut. 2012 Dec;61(12):1647-52. doi: 10.1136/gutjnl-2012-302910. Epub 2012 Aug 30.

HCV viraemia would have been cross checked by myself and my team, and baseline values checked before commencing antiviral treatment.

11. *At paragraph 107 of his statement, witness W1591 states that after he raised concerns with you that hepatitis C ("HCV") might be lying dormant in his brain, you replied, "what do you want me to do, drill a hole in your head?". His partner, witness W1199, also comments on this conversation at paragraph 28 of his statement, stating that he was also present at the time and found the comment "extremely rude, unprofessional and frankly shocking". Please comment on this.*

12. I apologise if I commented in a manner that disturbed the patient. Even sentient and empathic physicians may unintentionally make a reasoned if inadvertently insensitive statement. However, the context of the lengthy consultation requires amplification. Apparently, a recorded transcript of the consultation exists (witness W1199). I would be grateful if the full record of the consultation is made available to myself and the inquiry. I recall a somewhat circular (and in the end disappointingly brittle) discussion. It took a long time to reassure the patient and his partner that W1591, fortunately, had no evidence of cirrhosis, despite what he had been told before by other clinicians, and no evidence of ongoing hepatitis C replication. (His serum albumin and aminotransferases were normal. Hepatic imaging, including an MRI scan showed that the liver had a smooth contour and no features of chronic liver disease were found. His spleen size was 9.2 cm. His fibroscan score of 4.6; he was HCV RNA negative after spontaneously clearing the virus).

13. The discussion strayed into a technical discussion of the possibility of residual defective viral hepatitis C in the liver and other potential sanctuary sites including, based on recent evidence, the brain. However, I pointed out that such evidence could only be verified by an invasive biopsy. My letter refers to a transjugular liver biopsy. A biopsy was not clinically indicated.

14. *Further in paragraph 107, witness W1591 states you told him HCV disappears all the time, contradicting information you had previously given him. Please comment on this.*

15. I would be grateful if the records could be provided. I have observed unusual and unpredictable clearance in patients with chronic hepatitis C. W1591 unexpectedly, given his immunological status, showed clear evidence that he had resolved, and had cleared hepatitis C virus. Our comprehension of the natural history of hepatitis C has evolved over time and has been continuously modified by data accrued in the years since the

identification of the virus. We have learned that hepatitis C virus may be spontaneously cleared after both acute and chronic hepatitis. The mechanisms and predictive factors that presage clearance of hepatitis C virus in chronically infected patients are poorly understood to this day. Genetic factors may influence the rate of clearance. I point out that informed physicians have a duty to enlighten and reappraise patients as new developments in medicine come to light.

16. *At paragraph 159, witness W1591 comments on you giving patients Interferon, often in large doses. Please comment on this.*

17. I am aware of the correct application and dosages of interferon alpha and have been responsible for drafting European and International guidelines.[2] Many investigators over

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[2]

J Hepatol. 2018 Aug;69(2):461-511. doi: 10.1016/j.jhep.2018.03.026. Epub 2018 Apr 9.EASL Recommendations on Treatment of Hepatitis C 2018.European Association for the Study of the Liver. Pawlotsky JM, Negro F, Aghemo A, Berenguer M, Dalgard O, Dusheiko G, Marra F, Puoti M, Wedemeyer H.

BMC Infect Dis. 2017 Nov 16;17(1):722. doi: 10.1186/s12879-017-2820-z.Effectiveness of current and future regimens for treating genotype 3 hepatitis C virus infection: a large-scale systematic review.Fathi H Clark A, Hill NR, Dusheiko G.DOI: 10.1186/s12879-017-2820-z PMCID: PMC5691805

J Hepatol. 2015 Dec;63(6):1535-6. doi: 10.1016/j.jhep.2015.09.004. Epub 2015 Sep 12.Reply to "Debilitating fatigue as a treatment indication in chronic hepatitis C".Pawlotsky JM, Aghemo A, Back D, Dusheiko G, Forns X, Puoti M, Sarrazin C; EASLRecommendations on Treatment of Hepatitis C 2015 panel.

J Hepatol. 2015 Jul;63(1):199-236. doi: 10.1016/j.jhep.2015.03.025. Epub 2015 Apr 21.EASL Recommendations on Treatment of Hepatitis C 2015.European Association for Study of Liver.Collaborators: Pawlotsky JM, Aghemo A, Back D, Dusheiko G, Forns X, Puoti M, Sarrazin C.

J Hepatol. 2014 Aug;61(2):373-95. doi: 10.1016/j.jhep.2014.05.001. Epub 2014 May 10.EASL recommendations on treatment of hepatitis C 2014.European Association for the Study of the Liver.Pawlotsky JM, Aghemo A, Dusheiko G, Forns X, Puoti M, Sarrazin C.

Liver Int. 2013 Feb;33 Suppl 1:137-50. doi: 10.1111/liv.12078.Treatment of HBeAg positive chronic hepatitis B: interferon or nucleoside analogues.Dusheiko

J Hepatol. 2012 Jul;57(1):167-85. doi: 10.1016/j.jhep.2012.02.010. Epub 2012 Mar 20. EASL clinical practice guidelines: Management of chronic hepatitis B virus infection.European Association For The Study Of The Liver.Papatheodoridis G, Buti M, Cornberg M, Janssen HL, Mutimer D, Pol S, Raimondo G, Dusheiko G, Lok A, Marcellin P.

J Hepatol. 2009 Feb;50(2):227-42. doi: 10.1016/j.jhep.2008.10.001. Epub 2008 Oct 29.EASL Clinical Practice Guidelines: management of chronic hepatitis B.European Association For The Study Of The Liver Marcellin P, Dusheiko G, Zoulim F, Esteban R, Hadziyannis S, Lampertico P, Manns M, Shouval D, Yurdaydin C.

the course of the past two decades have attempted to either reduce, abbreviate or lengthen the dose and duration of interferon treatment to improve sub-optimal responses. Emerging evidence has suggested a lower response of genotype 3 infection to 24 weeks of interferon alpha. In one case (no doubt to be presented to the inquiry) I discussed and offered a patient a longer duration of treatment for his genotype 3 infection, in the light of reports of a suboptimal response of genotype 3 to six months of interferon, to prevent relapse. A subsequent clinical trial in the UK unfortunately failed to demonstrate benefit in patients with genotype 3 and advanced fibrosis. [3]

18. **GRO-D**

19. **GRO-D**

Zoulim F, Liang TJ, Gerbes AL, Aghemo A, Deuffic-Burban S, Dusheiko G, Fried MW, Pol S, Rockstroh JK, Terrault NA, Wiktor S. Hepatitis C virus treatment in the real world: optimising treatment and access to therapies. Gut. 2015 Nov;64(11):1824-33. doi: 10.1136/gutjnl-2015-310421. Review. PubMed PMID: 26449729; PubMed Central PMCID: PMC5993679.

Webster DP, Klenerman P, Dusheiko GM. Hepatitis C. Lancet. 2015 Mar 21;385(9973):1124-35. doi: 10.1016/S0140-6736(14)62401-6. Epub 2015 Feb 14. Review. PubMed PMID: 25687730; PubMed Central PMCID: PMC4878852.

Dusheiko G. Side effects of alpha interferon in chronic hepatitis C. Hepatology. 1997 Sep;26(3 Suppl 1):112S-121S. Review. PubMed PMID: 9305675.

[3] Shoeb D et al J Hepatol. 2014 Apr;60(4):699-705. doi: 10.1016/j.jhep.2013.11.011. Epub 2013 Nov 26. Extended duration therapy with pegylated interferon and ribavirin for patients with genotype 3 hepatitis C and advanced fibrosis: final results from the STEPS trial.

GRO-D

20. GRO-D

GRO-D

GRO-D

21. *Lastly in paragraph 159, witness W1591 comments on your beliefs about financial recompense for those infected. He also raises concerns about you having been on the boards of the Skipton Fund and EIBSS, as he considers this to be a conflict of interest.*

22. *"His belief is that we should not get financial recompense for what happened as they were doing their best to help us. He even then sat on the board of the Skipton Fund and decided which of the people* GRO-D *would be able to receive financial assistance. He is also a board member of the EIBSS which made my application for SCM impossible. I consider this a clear conflict of interests"*

23. This allegation is repudiated. I was invited to serve on the Skipton Fund and subsequently the EIBSS by the board because of my expertise and experience with chronic hepatitis C and liver disease. I was vetted for conflicts of interest and similarly vetted by the EIBSS, including under company law. The Skipton Fund disbursed well over £200,000,000 to people who were infected with hepatitis C through treatment with NHS blood or blood products. A very large number of individuals who satisfied the criteria for stage one and two payments were granted ex-gratia payments during my tenure. I and my colleagues faithfully fulfilled our duty of care to the best of our ability to patients and the public. W1591 was a recipient of a stage one payment.

24 GRO-D

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed _____ GRO-C _____

Dated _10 October 2019_____

Table of exhibits:

Date	Notes/ Description	Exhibit number
2011-2018 12th and 13th editions respectively	Chapters on hepatitis C in successive editions of Sherlocks Textbook of Hepatology	1-2
2011	Citation on Textbook and HCV chapter	3