Witness Name: Professor Geoffrey Dusheiko Statement No.: WITN3754104 Exhibits: none Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR GEOFFREY DUSHEIKO

I provide this statement on behalf of the Royal Free London NHS Foundation Trust in response to the request under Rule 9 of the Inquiry Rules 2006 dated 9 September 2021.

I, Professor Geoffrey Dusheiko, MB, BCh, FRCP FCP(SA) will say as follows: -

Section 1: Introduction

- 1. I am Emeritus Professor of Medicine at the Royal Free Hospital and University College London School of Medicine and Consultant Hepatologist at Kings College Hospital London.
- I was previously employed by the Royal Free London NHS Foundation Trust ("the Trust") as, successively, Senior Lecturer, Reader in Medicine, Professor of Medicine and Honorary Consultant from 1988 to 2015. Within this role, my responsibilities included inpatient and out-patient care of patients with chronic viral hepatitis.
- 3. I have been asked to write this witness statement on behalf of the Trust to respond to certain criticisms raised in the witness statement of Ms Ingrid Western (witness W2062), dated 14 August 2019. I have been unable to review the records held by the Trust in relation to Ms Western, to assist me in preparing this witness statement, as the patient has refused access to her medical records. This limits the extent to which either I or the Trust can respond to the points in Ms Western's statement, but I set out my responses below based on my recollections of Ms Western and of the general position and practice within the Royal Free at the relevant times.

Section 2: Response to Criticism by witness W2062

- 4. The Inquiry has requested that the Trust respond to the following comments made by Ms Western.
- 5. At paragraphs 26 and 27 of her statement, Ms Western advises that
 - 5.1. "On three separate occasions I had interferon treatment in an effort to clear the virus. On the first two attempts (interferon only at the Royal Free Hospital in 1995, and combination interferon and ribavirin in 1997) the treatment was stopped after three months as my white blood cell count was low and no substantial improvement was seen. WITN2062011.

Later in November 2010, under the care of Kings College Hospital, after my second liver transplant, I had a third treatment of pegylated interferon and ribavirin. I seemed to respond better on this 3rd attempt and a few weeks into the treatment the virus was undetectable so I continued the treatment, with an aim of continuing treatment for 52 weeks. Unfortunately I had a viral breakthrough at week 48 so that attempt was in vain and stopped. WITN2062012".

- 5.2. As noted, we have been unable to review Ms Western's medical records to respond to this criticism. Several clinical letters have been provided:
- 5.3. [WITN2062010] a clinical letter dated 8 October 1999 indicates that Ms Western had chronic hepatitis C, thrombocytopaenia and splenomegaly suggestive of portal hypertension. (Her platelet count was 56) Her previous stage 4b Hodgkins disease was in remission, following bone marrow transplantation. She had not previously responded to a three-month course of interferon and ribavirin. The letter indicated that liver transplantation would be a consideration and indeed she was referred to the Transplant unit.
- 5.4. Unfortunately, dose limiting toxicities were observed during her treatment with alpha interferon. [WITN2062011], a clinical letter dated 30 December 1999, indicated that in 1995 a liver biopsy showed developing cirrhosis with hepatic iron overload. Ms Western was treated with interferon alpha 4.5 units three times weekly in June 1995, but the interferon was stopped when her platelet and white cell counts fell to unacceptable levels. She received a combination of interferon alpha and ribavirin

which commenced in February 1997 but was stopped in May 1997. Unfortunately, interferon has a deleterious effect on white cell counts and platelets as detailed in the attached manuscript: Interferon alpha has myelosuppressive effects and red blood cells, white cells and platelets are commonly diminished during treatment. As Ms Western had pre-existing leucopaenia and thrombocytopaenia, a dose limiting effect on white cell counts and platelets precluded prolonged use of interferon alpha, particularly in a patient with a fragile bone marrow lineage following her previous high dose chemotherapy and autologous bone marrow transplant. Hepatitis C has also been associated with thrombocytopaenia. (See exhibit [WITN3754019] which was provided to the Inquiry as an exhibit to my previous statement [WITN3754005])

- 6. At paragraph 28 of her witness statement, Ms Western explains her understanding that
 - 6.1. "...ribavirin treatment may have been available as early as 1992. There is a letter from my consultant at the Royal Free Hospital to the Royal Marsden in 1992 noting: 'It may be possible to treat her with ribavirin as this is a nucleoside analogue which has been known to suppress hepatitis C in a proportion of patients. We have obtained reasonable results in patients treated in a pilot study, and have now embarked on a placebo controlled study. It is difficult to obtain ribavirin through the NHS at the moment from this hospital, but I could make enquiries. Alternatively, Miss Western could be, if she agrees, entered into our trial of ribavirin shortly." WITN2062013. However I was not offered ribavirin treatment until 1997".
 - 6.2. Whilst I have not had the opportunity to review Ms Western's own medical records in this respect, I am able to confirm that ribavirin monotherapy was being investigated in two placebo-controlled trials in 1992. Both these trials showed that ribavirin monotherapy could improve serum aminotransferases, but the drug was not a potent direct inhibitor of hepatitis C virus. Subsequently ribavirin was only used in combination with interferon or other antiviral agents.
- 7. At paragraph 35 of her statement, Ms Western alleges that in 1995 she waited over five months for a liver biopsy, which was required before starting her first course of interferon treatment. She also refers to exhibit WITN2062020 which is a letter from Ms Western to me dated 10 April 1995 in which states:

7.1. 'I am writing to you as I am concerned that I have not yet been in for my liver biopsy. It has now been approximately 5 months (since last December) from my last visit to Dr Wonke to remove the iron from my liver and I have still not been in for the biopsy prior to my alpha interferon treatment. I was originally booked into Hassall ward for 8th February but the ward was closed for sometime due to a virus. I was then rescheduled to come in on Monday 3rd April, but no beds were available nor have been available since that time.

When I last had a liver biopsy, some 2 years ago, I was not required to stay in overnight and I wonder if it might not be possible for this to be done again in the same way to avoid the problem of a bed not being available....

I do appreciate that there is probably a "back-log" of admissions to Hassall ward due to it being closed for a few weeks but I am very keen to proceed with things as soon as possible.'

- 7.2. It is difficult to respond to Ms Western's criticism without access to her medical records. However, I would note that a delay of this length for an elective liver biopsy would be unusual. Ms Western has, however, referenced a critical period when bed shortages on the liver ward were limited by an outbreak of infection. However, day-case biopsies became the norm and alleviated delays.
- 8. At paragraph 55 of her witness statement, Ms Western advises that her body had rejected her first transplant in December 2006. She alleges that she was told by the team at the Royal Free Hospital that she would be re-transplanted but that she became very ill whilst waiting for the second transplant and that, in September 2007, the team advised that they had changed their mind and would not be providing a second transplant. Ms Western alleges that the team stated that "*it would be a 'waste' of an organ as it would just get infected again by HCV although that was always the case if someone had HCV. Then one day they simply told me to go find a hospice (to die in)*".
 - 8.1. Again, it is not possible to comment further without access to Ms Western's medical records, but it is my opinion that it is unlikely and improbable that the transplant team would have couched a difficult conversation in these terms.

- 9. Following on from the above paragraph 55, at paragraph 56 of her statement, Ms Western states that:
 - 9.1. "Fortunately I happened to have a friend who is an oncologist and he said that what they had done was not right and I should try to get in to see the team at Kings College Hospital – which I believe has the best liver unit in the country. I was seen by Dr Agrawal in hepatology, and he was very shocked at what the Royal Free had done to me and after assessing me, he agreed to take me on and to re-transplant the rejected organ. This was towards the end of 2007 and I was again, very ill at the time".
 - 9.2. Again, it is difficult to respond to Ms Western's criticism without access to her medical records. The multidisciplinary transplant meeting minutes would be required, and the Liver Transplant Unit at the Royal Free would need to respond. However, it is correct that opinions and the options offered can vary between transplant units. As mentioned above, it is my recollection that a second opinion was sought for Ms Western from Kings College Hospital. The opportunity to obtain a second opinion is a mechanism designed to safeguard patients and to act in their interests.
 - 9.3. Thus, whilst I am unable to confirm this without review of her medical records, it is my recollection that a second opinion was sought for Ms Western from Kings College Hospital. [WITN2062012], a clinical letter from Kings College Hospital (clinic date 2 December 2011) sets out the chronology of events and a problem list. According to this letter a liver transplant was performed at the Royal Free Hospital in December 2006 for hepatocellular carcinoma and hepatitis C cirrhosis. A second transplant for multifactorial graft failure in the first graft was performed at Kings College Hospital in September 2008. Ms Western developed recurrent hepatitis C in the second graft (2010) and a liver biopsy showed F4 fibrosis (and F5 fibrosis in August 2012, WITN2062016). She commenced treatment with a low ascending dose of interferon on 12 November 2010. Although her HCV RNA was undetectable after 16 weeks, she unfortunately relapsed, after a dose reduction, at week 52. She had required erythropoietin and granulocyte colony stimulating factor to support her bone marrow and blood counts.
 - 9.4. I cannot access her notes at Kings College Hospital without her permission. I understand she received sofosbuvir, ledipasvir and ribavirin when these became

available. She attained a sustained virological response, thankfully, and not before time. [WITN2062016] and [WITN2062017]

- 10. At paragraphs 60 and 61 of her witness statement, Ms Western states that she was under the care of the Royal Free Hospital when she received her first Skipton Fund payment in January 2006. She advises that she was under the care of Dr Patch of the transplant team and that he completed the necessary form to be provided to receive payment. However, Ms Western states that she does "not recall any particular medical professional at the Royal Free, or otherwise, informing me about any financial assistance. As I remember, it was something I found out by myself by reading as much as possible about HCV and particularly about people who had received contaminated blood…".
- 10.1. I am unable to review Ms Western's medical records for any discussions that may have taken place. I do recollect however that the Trust Liver Unit and hepatitis team routinely informed patients regarding ex gratia funding from the Skipton Fund and the applications of many patients from the Royal Free Hospital who applied to the Skipton Fund were supported.

Section 3: Other Issues

11. I would just highlight that exhibit WITN2062011 is incorrect. Page 1 of exhibit WITN2062011 is from a letter from Dr Patch setting out the findings from his clinic on 23 December 1999, whereas page 2 is a letter from me setting out my findings from a separate clinic in April 1992; the full letter relating to that clinic in April 1992 is at exhibit WITN2062013.

Statement of Truth

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

Signed _	GRO-C
	GDusheiko 2022.03.31 09:42:17 +01'

Dated 31 March 2022_____