Witness Name: Richard Lee
Statement No.: WITN4408001
Exhibits: WITN4408002 - 006
Dated: 2 July 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF RICHARD LEE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 12 May 2020.

I, Richard Lee, will say as follows: -

Section 1: Introduction

1. My name is Richard Lee and my date of birth is GRO-C 1950. My address is GRO-C GRO-C. I have the following professional qualifications: BSc; MB,BS; FRCP; FRCPath.

2. After training and qualification in 1974 at King's College Hospital Medical School, London, and further experience in hospitals in and around London, I was appointed Consultant Haematologist at the Royal Devon & Exeter Hospital in 1985. In addition to my role as a general haematologist with clinical, laboratory, administrative and teaching responsibilities, I was Director of the Exeter Haemophilia Centre between 1985 and 2010. During this time, I represented the local centre within the national organisation, UK Haemophilia Centre Directors Organisation (UKHCDO). I retired fully from clinical practice in 2010. I am currently a Trustee of a leukaemia charity based in Exeter.

Section 2: Responses to criticism of W2510

3. I, Richard Lee, make the following statement after reviewing the medical records provided to me by the Royal Devon & Exeter Hospital by encrypted email. I believe these are the same records that have been disclosed to the witness.

4. In the 1980s, non-A non-B hepatitis (NANBH) was a known risk of blood transfusions. As the disease often remained silent for many years, haemophilia patients were routinely monitored by regular checks of liver function. Careful surveillance for blood-borne infections such as HBV, NANBH and later HIV was already in place when I took over the patients from my predecessor, Dr John Edgcumbe, on his retirement in 1985. The first time I met these patients I made a point of explaining the purpose of these tests. I do not recall any patient who was not aware of these blood-borne infections. Naturally they were concerned because of their exposure to multiple blood transfusions and because there was no treatment at the time. Extensive media coverage of contaminated blood incidents added to their worries but also prompted questions in the clinic. There was no requirement for formal written consent before testing as far as I remember and I appreciate that by today's standards that may be considered inadequate.

5. Mr Miller's liver function was first noted to be abnormal in 1987. Subsequent enquiries through UKHCDO revealed he had received treatment with commercial factor IX concentrate from US donors in 1985 and 1986 in Leeds so it was not possible to conclude that NHS factor IX (which he had hitherto received exclusively) was the source of infection.

6. I have no specific recollection of the individual consultations referred to and my records did not routinely include every detail of advice. However, it was my normal practice to be open with patients, giving them as much information as they wanted about tests and diagnoses. Sometimes there was much to discuss, at other times less so if there was no new information, but there was never any attempt to restrict the flow. On the contrary, I encouraged my patients to raise questions of concern to them or to ask for clarification of any advice they may have received from me or from other sources such as the Haemophilia Society which provided valuable support for many. Thus I feel there were ample opportunities for advice to be sought and given, not only during routine consultations but also in intervening periods, particularly as haemophilia patients had open access to the department at all times.

7. In Mr Miller's case, at our first meeting on 2 April 1985 (Exhibit WITN4408002), I gave him a Haemophilia Society leaflet and encouraged him to join. In my experience, and that of other clinicians, the ability of patients to retain or recall details of what were discussed varied considerably. I promoted membership of the Haemophilia Society as a way of providing an alternative source of regular information on matters of concern to haemophilia patients and also support on many levels. I recall many articles in their newsletters highlighting hepatitis and HIV issues as well as advice on insurance and social services.

8. At our next meeting on 16 December 1985 (Exhibit WITN4408003), I recorded he had become a member of the Haemophilia Society and was fully conversant with the AIDS issue, had been counselled and was not worried. It was my routine at the time to re-discuss issues of risk and to provide an opportunity for dialogue. It was not limited to HIV although it was the main concern for many; hepatitis, routes of transmission, inhibitor development were also discussed as far as patients wanted. As evidence, I refer you to my letter dated 6 August 1986 (Exhibit WITN4408004) recommending immunization against HBV. The notes I made that day were meant to serve as a reminder to myself that he was well informed, or so I thought.

9. In 1988 when the diagnosis of NANBH was made, relatively little was known about the disease and there was no treatment available. It was the norm then to adopt a watch and wait approach and, although I cannot be certain, I thought I had made that clear to him.

10. Even when the hepatitis C virus (HCV) was identified in 1989 and although a reliable test for detecting HCV became available in 1992 our understanding of HCV was still very limited. It was known that most patients with transfusion-related HCV remained asymptomatic for many years. Progression to liver fibrosis, cirrhosis and hepatocellular carcinoma (HCC) was known to occur in a minority of patients but the rate of progression was highly variable and influenced by many factors including alcohol consumption, HIV or HBV coinfection and other comorbid conditions. In general, it was estimated that the time interval from infection to cirrhosis and HCC was in the region of 10 – 20 years, often longer. The impact of HCV on normal intimate relations was not considered a major issue. Most experts believed the risk of sexual transmission was low in normal heterosexual relationships. Nevertheless, as my discussions often included comparisons with HIV and HBV, which some patients also suffered from, I would have mentioned that additional security could be provided by practising safer

sex using condoms. Not sharing toothbrushes and razor blades would also have been advised in relation to questions about transmission. At a consultation on 6 November 1990 (Exhibit WITN4408005), I recorded that I informed him his test for HCV antibody was positive but as the test could not indicate whether the virus was still active, transmission via the sexual route was still potentially possible. There were no treatments available until 1994 when Interferon-alpha was approved for treatment of HCV in the UK.

11. Regarding the letter dated 6th July 1992 (previously exhibited as WITN2510003 by Mr Miller), the reasons for referring Mr Miller to Professor Bloom were as stated in the letter. It was generally accepted at the time that treatment for HCV would be more successful if undertaken in the early stages of the disease. In 1992, when clinical trials of interferon were beginning, I assessed that given his young age, relative fitness and lack of clinical evidence of advanced disease, he could be a suitable candidate for such treatment. At least he should be offered the opportunity. Although I have no detailed recollection of that consultation, given the time available in a follow-up clinic, I probably limited my discussion to the risks and benefits of early treatment, a broad overview of the proposed trial and the reasons why this could not be provided in Exeter at the time. Should he decide to pursue the matter there would be time set aside later for more detailed discussions.

12. The lack of funding referred to in my letter related not only to the cost of the drug but to the array of additional tests and specialist staff needed to run a clinical trial. Ideally a hepatologist and associated specialist nurses and counsellors in liver diseases would be supervising the treatment and monitoring for side effects and complications. These services did not exist in Exeter at the time. Additional funding would be needed to put these in place and I realised it would not be feasible within a reasonable timescale. Furthermore, the practical challenges of monitoring the patient from a distance seemed insurmountable. On the other hand, there was a possibility he could access the treatment through a larger centre that might already have the appropriate facilities. As he lived in Wales, it seemed sensible to approach Prof. Bloom who was in charge of the Regional Haemophilia Centre in Cardiff, where more likely the facilities we lacked would be available. It would be for Prof. Bloom to decide if he could provide treatment under the clinical trial. If so, there would be strict conditions attached including the provision of counselling as part of the consent procedure. He would have been given written information covering all aspects of the trial including the chances of success or failure and the side effects of the drug. Presumably Mr Miller received the necessary

information before proceeding to treatment in 1993. When Prof. Bloom acknowledged receipt of the referral (Exhibit WITN4408006), he commented that he too was having great trouble in obtaining funding for the drug.

13. I am sorry that Mr Miller's recollection of that consultation is at variance to that documented in the letter and I have no explanation for this. I regret also that despite my best efforts to secure early treatment for him, and to provide timely information and support while he was under my care, his needs were not fully met. For these shortcomings I offer my sincere apologies.

Statement of Truth

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

Signed GRO-C

Dated 2/7/20

Table of exhibits:

Date	Notes/ Description	Exhibit number
02/04/1985	Notes of first consultation	WITN4408002
16/12/1985	Notes of consultation	WITN4408003
06/08/1986	Letter	WITN4408004
06/11/1990	Notes of consultation	WITN4408005
10/07/1992	Letter	WITN4408006