Witness Name: Dr Samuel Machin
Statement No.: WITN3090001
Exhibits: NIL
Dated: 8th May 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR SAMUEL MACHIN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 April 2019.

I, Professor Samuel J. Machin, will say as follows: -

Section 1: Introduction

1. My name is Professor Samuel J. Machin and I am 70 years of age having been born GRO-C 1949. My address is known to the Inquiry. My professional qualifications include M.B. Ch.B.(Sheffield 1971) FRCP, FRC Path.

2. The positions I have held professionally include:
   - House Officer – Sheffield 1971-1972.
   - SHO in Pathology – Manchester Royal Infirmary, August 1972-July 1973.
   - Assistant Lecturer then Lecturer, Dept. of Haematology, The Middlesex Hospital Medical School. August 1973-1979
   - Research Fellow, Dept. of Vascular Studies and Thrombosis, Leuven University, Belgium 1979 –October 1980
   - Senior Lecturer, Haematology Middlesex Hospital Medical School (Honorary Consultant) October 1980-1990. During this time period the Medical School combined with University College London (UCL) and the hospital with UCH to become UCLH (University College London Hospitals), to which I was an honorary NHS consultant.
   - 1991 Professor of Haematology UCL until 2013
   - February 2013 retired from all clinical NHS duties at UCLH.

- 2014 onwards Emeritus Professor of Haematology UCL (no clinical duties).

3. My main role as Professor of Haematology was as the lead for the NHS Haematology and Transfusion Laboratory Services and senior clinician for Haemostasis, Thrombosis and Platelet Disorders. My main areas of expertise were in the Anti-Phospholipid Syndrome and Acute Thrombotic Thrombocytopenia. During the mid to late 1980's the few regular patients with Haemophilia A and B were gradually transferred to local large comprehensive care facilities in the London area.

4. In the early 1980's Prof J.W. Stewart (now deceased) was the clinical head and overall responsible for all haemophiliac patients. Prof J.W. Stewart was the Director of Haemophilia Services until his retirement in 1984-5. In the 1980's I attended the annual general meetings of the UKHCDO (United Kingdom Haemophilia Centre Doctors Organisation) when possible mainly for educational purposes.

5. I was actively involved in the British Soc. of Haematology (BSH) and the Haemostasis/Thrombosis section of the British Committee for Standards in Haematology and was actively involved for many years in evidence-based Guideline development. In 2004-2005 I was President of the BSH for 2 years.

Section 2: Response to criticism of Shelagh O'Shea

6. My specific comments on the written statement of Ms Sheila O'Shea are as follows. Her son Luke was born on GRO-C 1981 and his Middlesex Hospital number 93028560. I was able on 3rd May 2019 to access from the present Trust, all his old Middlesex Hospital and UCLH notes. I can provide contact details for the staff involved in locating the records if required. Therefore the statements in this report are based from these notes and my recollection and knowledge of usual practice at the time Luke was being seen.

7. Firstly, I unfortunately do not recollect or remember any specific meetings or consultations I may have had with Ms O'Shea or her son Luke O'Shea-Phillips. I do remember the name O'Shea-Phillips, probably as it was relatively unusual at that time being a double-barrelled surname.

8. To give context to this matter, in 1984/85 haemophilia patients, after a first exposure to conventional F.VIII concentrates had a very high incidence of NANBH (non A, non

B hepatitis). There were no reliable lab tests for NANBH at that time. To try to eliminate such possible contamination, F.VIII concentrates were sterilised by several methods, usually involving some form of heating. It was understood then becoming accepted that evidence of product safety could only be prospectively evaluated by following first exposure patients, so called virgin haemophiliacs who have not been exposed to any forms of blood or blood products previously.

9. The hepatitis C virus was not fully characterised until 1989 and a reliable FDA approved diagnostic laboratory test did not become available worldwide until September 1991.

10. From 1984 Luke would have been routinely tested for his F.VIII level, absence of any inhibitor and for presence of HIV and hepatitis B infection. The 3 later were all clear/negative.

11. There was a study being organised by Dr. P. Kernoff, lead haemophilia consultant at the Royal Free Hospital (now deceased) to assess the incidence of acute post infusion NANBH and other viral transmissions in a commercial F.VIII concentrate from Alpha Therapeutic UK Ltd. It was to this study Luke was recruited. This would have been discussed with his mother, although I acknowledge that standards of consent in the 1980's was quite different to what it is now. The nature of the study and the reasons for wishing to use the concentrate would have been explained to his parents and consent to follow-up obtained. The main focus of this study was to establish if the use of this particular heat treated F.VIII reduced the incidence of NANBH, which the study conformed it did (see. British Journal of Haematology, 1987, 67, 207-211 entitled "Reduced risk of non-A, non-B hepatitis after a first exposure to 'wet heated' factor VIII concentrate.")

12. The study involved ideally fortnightly follow-up samples for routine liver function tests, blood count and virology. It may prove impossible to adhere to this regime, however if the sampling frequency was considered sufficient to allow meaningful analysis, this would be allowed for the study analysis purposes.

13. Here are my specific response to specific paragraphs in Ms O'Shea's statement:

a) Paragraph 2:2. After his mouth bleed in May 1985 Luke was first treated with infusions of a licensed chemical DDAVP. He did not respond to this therapy and

therefore standard care at that time involved progression to providing a F.VIII concentrate to control his bleeding.

b) Paragraph 2:3. It would be normal practice for all such patients in 1984-5 to have discussions about the dangers of infections, particularly HIV, hepatitis B and other forms of hepatitis from any blood products provided. I would expect for this to have occurred with Ms O'Shea, although not necessarily directly with me. It is unfortunate that she has no recollection of this occurring and Luke's records fail to ascertain if any documented discussions took place.

c) Paragraph 2:4. Luke O'Shea-Phillips was formally diagnosed with Hepatitis C in May 1993, this is reported on a Virology report from the Trusts Laboratories. I do not recall that result. Dr Laffan took over his care in 1993.

d) Paragraph 2:7. In the early 1990's the diagnostic test would potentially report a series of false positive and false negative results, which always needed to be confirmed.

e) Paragraph 2:9. I am unable to comment upon what his hospital admission notes of November 1993 said, as I have not had access to them. I do not believe this was at UCLH. My last correspondence concerning Luke was in June 1993 to a Dr Biet at Ealing Health Authority and to a Mr Herman May 1993 a local director of Education. These letters followed discussion with his mother, probably by phone or letter, about his schooling and emergency haemophilia treatment that would have been much nearer at the Hammersmith Hospital.

f) Paragraph 2:11. I am unable to comment on how Luke's infection was specifically communicated to Luke and his mother. However I am sorry that Luke's mother's perception of how she was advised of Luke's infection is that it was patronising and condescending as I appreciate the distress this may have caused.

14. In relation to consent, all Luke's blood tests from 1984 onwards would have been obtained with parental approval. However I recognise that the standard level of consent process in the 1980s may not have involved specifically discussing the precise laboratory tests to be conducted on the blood sample obtained. It was routine practice at the Middlesex Hospital to label all blood test tubes and laboratory request forms from all haemophiliacs as (danger of infection) on yellow stick on forms.

15. Having carefully read Ms O'Shea's statement of 31.10.18 I have several specific factual comments concerning the clinical events which followed. Generally in 1984/5 all haemophilia patients, after a first exposure to conventional F.VIII concentrates had a very high incidence of NANBH with a transitory rise in some liver function tests, particularly the enzyme ALT. To eliminate such possible contamination concentrates were being sterilised by several novel methods, usually involving some form of heating. It was then becoming accepted that evidence of product safety could only be reliably prospectively evaluated by using such first exposure virgin patients. From 1984 all patients would have been routinely tested for their F.VIII level, absence of any inhibitor and for markers of HIV and Hepatitis B infection. The 3 latter tests were all clear and negative in Luke. Consent for such tests would have been obtained from his parents before testing.

16. The results of the study Luke was recruited into were subsequently published in the British Journal of Haematology, 1987, 67, 207-211 entitled "Reduced risk of non-A, non-B hepatitis after a first exposure to 'wet heated' factor VIII concentrate." and the lead author was P.B.A. Kernoff (now deceased). The results of this paper led to the widespread use of this concentrate in the UK between 1987-1990 to reduce significantly the incidence of NANBH. It is unfortunate that Luke contracted Hepatitis C despite receiving a heat treated F.VIII product that was proven by this study to give a lower risk of hepatitis C than the standard F.VIII provided at that time.

17. I am pleased to hear after a diagnosis of hepatitis C was made in 1993 Luke subsequently responded well to appropriate anti-viral therapy and he is now free of hepatitis C, with normal liver function tests and living a normal life. However I am sorry to read of the difficult period of adjustment following his initial diagnosis.

18. In relation to information shared with Luke's GP, it would have been usual practice to ensure the GP was informed regarding any haemophilia treatment received and the result of monitoring blood tests.

19. I apologise for being unable to attend the inquiry in person due to ill health but I hope that this statement is helpful to you.

Section 3: Other Issues

20. There are no other issues which I wish to raise.

Statement of Truth

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

Signed GRO-C

Dated 8th May 2019.