Witness Name: Dr Samuel Machin
Statement No.: WITN3090002
Exhibits: NIL
Dated: 29th 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 24 May 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 Luke O'Shea Phillips

6. My specific comments on the written statement of Luke O'Shea Phillips are as follows. Luke was born on GRO-C 1981 and his Middlesex Hospital number was 93028560. I was able on 3rd May 2019 to access from the present Trust, all his old available 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. I have already provided a witness statement on 9th May 2019 (WITN3090001) in response to a request under Rule 9 of the Inquiry Rules 2006 by Ms Shelagh O'Shea. Most of my answers are the same as those I gave to Ms O'Shea's statement. I do not recall or remember any specific discussions I may have had with Luke O'Shea Phillips, whom at this time was a young child.

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 Mr O'Shea Phillips statement:

a) Paragraph 7. His last treatment under my care at the Middlesex Hospital was on 24.12.87 for epistaxis.

b) Paragraph 8. His first treatment in May 1985 is outlined in Paragraphs 13a) and 13b) in my previous witness statement (WITN3090001).

c) Paragraph 9 and 10. It was standard for all haemophiliac patients receiving transfusion therapy to have regular tests for blood borne virus infection, such as HIV/Hep B. All patients or if children their parents were informed that routine blood tests were taken to test for specific known infections such as HIV and hepatitis B.

d) Paragraph 11. In 1985 there was widespread national and international issues for haemophiliacs receiving all forms of F.VIII concentrates, in that the risk of post-infusion NANBH in patients receiving a first exposure F.VIII concentrate approached 100%. By using a wet heated sterilised commercial concentrate, it was hoped that the incidence of NANBH would be reduced. The purpose of the study would have been explained to Luke's mother, but not specifically to a young boy.

e) Paragraph 12. Mr Ian Marshall was the trial coordinator for Alpha Therapeutics.

f) Paragraph 13. Luke had regular HIV tests or equivalent tests, which were all negative, as was standard practice with all haemophiliac patients prior to transfusions or any specific therapy.

g) Paragraph 14. The letter on 22.06.1993 was true. In fact, Luke had apparently only had 2 – 3 treatment infusions after May 1985.

h) Paragraph 15. The Hepatitis C test on 29.04.93 would seem to be the first occasion he was found to have HCV Antibody detected.

i) Paragraph 16-20. I am unable to comment on these statements as they occurred at The Hammersmith Hospital.

j) Paragraph 23. Although his treatment with a special wet heated FVIII concentrate in 1984/5 was part of a trial this became after the results were available, standard routine therapy from 1986 onwards in the UK.

k) Paragraph 24-28. The impact of hepatitis C infection is now known to be extremely variable and some patients unfortunately may develop chronic psychological issues, which may be difficult to come to terms with.

l) Paragraph 29-40. He received treatment with Interferon and Ribavirin in 2004 under the care of a specialist hepatologist. This is outside the experience of my practice but such treatment often causes considerable difficulties for the patients before it was apparently successfully concluded.

m) Paragraph 54. My intention as a treating haematologist was always to provide the most appropriate and up to date therapy to treat any acute bleeding episode with the safest therapy available at that particular time.

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 and all patients with a diagnosis of a congenital bleeding disorder as (danger of infection) on yellow stick on forms.

15. 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 (of up-to 100%) 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 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

18. 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 29th May 2019.