Witness Name: Prof Christopher Ludlam
Statement No.: WITN3428024
Exhibits: None
Dated: 14 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR CHRISTOPHER LUDLAM

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 20 June 2019.

I, Professor Christopher Ludlam, will say as follows: -

Section 1: Introduction

1) My full name is Christopher A Ludlam. My date of birth is GRO-C 1946. My address is known to the Inquiry. My professional qualifications are B.Sc, M.B.,Ch.B, MRCP, MRCPath, Ph.D, FRCP, FRCPath.

2) I have set out the positions I have held as a haematologist in the curriculum vitae held by the Inquiry (WITN3428002).

3) All past and present memberships of committees and groups relevant to the Inquiry's Terms of Reference are set out in my curriculum vitae (WITN3428002).

Section 2: Responses to criticism of W2315

In paragraph 12 of Ms GRO-B first statement (WITN2315001) she describes a time when she was recommended in 1991 to have an amniocentesis and on 20th March 1991 to have an urgent caesarean section for severe pre-eclampsia. She considered that Factor FVIII therapy at that time was not safe from hepatitis C.

4) Even without having von Willebrand disease an emergency caesarean section can be immediately followed by considerable haemorrhage and the risk of this is greater having such a bleeding disorder. Bleeding is also a risk following amniocentesis. I would therefore have recommended treatment before both these procedures and discussed therapeutic options with Ms GRO-B. The treatment I would have offered would have been safe with respect to hepatitis C and HIV as the product would have been treated by an effective viricidal process. All available Factor VIII concentrates in 1991 whether treated by heat or solvent-detergent procedures were considered not to transmit HIV or HCV. As a result of our discussion she records that she decided not to have Factor VIII treatment.

5) Ms GRO-B correctly remembers that blood donations were not screened for hepatitis C until September 1991 and patients in receipt of a blood transfusion, a red cell or plasma transfusion, before this date were at risk of this viral infection.

6) Ms GRO-B gave a second statement (WITN2135002) and in paragraph 12 she gives further information in relation to the safety of Factor VIII concentrates in 1991 where she states 'As I said in my last statement, I was told by Professor Ludlam that the Factor VIII concentrate was safe at that time. I now understand that this may have been true'. She records that Scottish Factor VIII concentrate was heat-treated 'in 1987 so as to remove the infection risk from hepatitis C.' She does not remember my telling her about the viral safety procedures in the preparation of Factor VIII concentrates. I would have explained why I thought Factor VIII was safe from HCV and HIV particularly as she was concerned about safety. In this paragraph she also mentions the then unknown potential risk of vCVD which became known about in 1996.

7) The treatment I would have offered in 1991 would have been Haemate P (a heat treated factor VIII/VWF concentrate) which has a very good safety record and is made from non-UK plasma so it was likely to be a very low risk of vCJD.

Ms GRO-B's second written statement (WITN2315002)

8) In Ms GRO-B's second statement in paragraph 7 she initially refers back to paragraph 6 in her first statement in which she states 'I think my Mum was diagnosed in 1983 and I think I became aware of the diagnosis in either 1983 or 1984.' It is not clear in this paragraph what was 'diagnosed'. She was diagnosed

with von Willebrand disease a long before this time. Review of Mrs GRO-B 's Royal Infirmary clinical case notes reveal that she was diagnosed as having Von Willebrand Disease by Dr S H Davies when seen at the Blood clinic on 29th November 1959.

9) I have reviewed in detail Mrs GRO-B 's treatment prior to 1985. She first received treatment in 1960 in the year after her von Willebrand Disease was diagnosed with' Blomback AHF 1600 units'. This was the very first Factor VIII concentrate, possibly in the world, probably produced in Stockholm by the husband and wife Blomback team. It was given to cover an operation to remove an ovary which was successfully accomplished without excessive blood loss. She appears not to have received any other treatment for the following 20 years.

10) In 1981 she fell and injured her right foot and thigh – x-ray revealed a spiral fracture of her 5th metatarsal. She was treated with two infusions of cryoprecipitate and her symptoms settled.

11) In November 1982 she knocked her right thigh which swelled and was accompanied by external bruising. She was treated with cryoprecipitate daily for 3 days in hospital. Unfortunately the haematoma recurred in mid-December and she was admitted for a week during which she received further cryoprecipitate therapy which was continued as an out-patient. After settling the haematoma recurred in January 1983 and she was admitted again for 2 weeks for daily treatment. To enable her to get home she was treated with SNBTS Factor VIII concentrate (after demonstrating that it appreciatively increased the VIII ristocetin cofactor activity) on an alternate day basis for a month. This allowed to haematoma to settle and it did not recur.

12) Mrs GRO-B had therefore only received cryoprecipitate at the end of 1982 beginning of 1983 and a small amount of SNBTS Factor VIII concentrate early in 1983. She did not receive any further treatment for many years.

13) Also in paragraph 7 of Ms GRO-B 's second statement she refers back to paragraph 7 of her first statement. In the latter she remembers finding out 'about the risks' 'when we were taken into a theatre at the old Royal and vaguely told something about risks.' Again it is not clear what 'risks' she is referring to. I assume that she was referring to the December 1984 meeting of patients. This meeting was primarily about AIDS and HTLVIII. I do not recall discussion of hepatitis at this

meeting. In paragraph 7 of the second statement she states that in late 1984 'my mother was tested and found negative for that virus.' I assume this relates to her being found to be negative for anti-HTLVIII.

14) She indicates her mother 'was worried about that (anti-HTLVIII negative)' as recorded in a letter I wrote after seeing her at my clinic in February 1985. On this occasion I offered her reassurance that I thought it unlikely she was infected by HTLVIII. I will have known that she had not had any treatment after March 1983 (all of which would have been prepared in 1982 or before) and concluded that the risk of her being infected with HTLVIII to be very small. Hence my reassurance

15) Ms GRO-B 's statement continues that 'at that time she was told that the risk of sexual transmission from an infected man to an uninfected woman was thought to be less than the risk of sexual transmission in the opposite direction.' This statement appears to imply that Ms GRO-B considered that Mr GRO-B was the person potentially at risk of infection when it was Mrs GRO-B who was at risk of having the infection. It appears there may be a misunderstanding of Mr and Mrs GRO-B 's situation.

Statement of Truth

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

Signed GRO-C

Dated 14/11/20