Witness Name: Dr Brian Colvin
Statement No.: WITN3343001
Exhibits: WITN3343002-3
Dated: 11 June 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR BRIAN COLVIN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 31 May 2019.

I, Brian Colvin, will say as follows:

Section 1: Introduction

1. Name: Dr Brian Colvin
   Address: GRO-C Kent GRO-C
   Date of Birth: GRO-C 1946
   Qualifications: MA MB BChir FRCP FRCPath

2. Positions held: Senior Lecturer The London Hospital Medical College – later Barts and The London Queen Mary's School of Medicine and Dentistry (Honorary Consultant Haematologist The Royal London Hospital Haemophilia Centre Director) 1977-2007

3. Member United Kingdom Haemophilia Centre Doctors (formerly Directors) Organisation (UKHCDO) 1975 (approximately) - present
   Chairman UKHCDO 1993-1996
   Honorary Membership UKHCDO awarded 2009
   Member Haemophilia Society 1970s - Present

Section 2: Response to Criticism of Courtenay Hildyard

4. I have read Mr Hildyard's statement, in which he describes a medical report which I wrote concerning his contraction of Hepatitis C (HCV). The report itself and a date have not been provided for me, nor have the medical notes on which my report would have been based, but I estimate that the report must have been written in 1995, nearly 25 years ago. I have no written or personal record of the case or the circumstances that led to my report being written, nor any way of knowing whether a full set of medical notes was provided for me. A definitive response is therefore not possible.

5. Mr Hildyard states that, in my report, I acknowledge that cryoprecipitate was the cause of his HCV infection and this view is supported by the letter to him sent by Deas Mallen Souter, Solicitors. Their letter, which is incomplete in your correspondence to me, states that my report "has set out exactly what treatment you received and, where possible, the circumstances".

6. The diagnosis of haemophilia A in Mr Hildyard's case has now been challenged but I believe that my report would have been written on the assumption that the diagnosis was correct. There is also some reference in the papers you have sent me to a possible platelet disorder.

7. I can confirm that the prescription of cryoprecipitate for a person with mild haemophilia A in 1983 was appropriate for the management of significant trauma.

8. I note from the documents that I was unable to find any evidence of negligence in this case.

9. Mr Hildyard states that I "cite that, given Mr Hildyard's alcohol consumption, he would have succumbed to liver disease in any case". No reference to this is made in the solicitor's letter included with the documents and without sight of the complete letter, the medical notes and my full report I can make no comment on this aspect of the case.

10. Mr Hildyard appears to claim in paragraph 7 of Other Issues that he was treated with a large pool factor concentrate in1981. For this view he relies on the Nursing Record

of 27.10.81, which states "Factor 8 given at 09.00 hours" (WTN 02344002). It is entirely possible, or even probable, that a member of the nursing staff would not distinguish between cryoprecipitate and a large pool factor VIII concentrate when writing a note.

11. It is important to appreciate that cryoprecipitate is itself a concentrate of factor VIII and the Nursing Record submitted to me does not, in my opinion, prove that any particular concentrate, whether cryoprecipitate or a large pool concentrate, was administered on that date. There is no indication of the origin of the blood product.

12. Mr Hildyard states that "it would appear that I was treated with Factor VIII on two occasions in 1981 and 1983 not Cryoprecipitate as previously believed". He also states "The transfusion from 1983 is missing from the National Record". It should be noted that Mr Hildyard describes an attack of jaundice which appears to have occurred in 1983 following blood product administration. If this is the case then, on the balance of probabilities, it is unlikely that he received a large pool concentrate in 1981since, had he been so treated, he would certainly have been infected with HCV on that day, (unless infection had occurred from any prior transfusion of blood products). [Earlier infection would have made it less likely that he would develop an acute attack of jaundice following blood product treatment in 1983.] The attack of jaundice in 1983 could have arisen from treatment with either cryoprecipitate or a large pool concentrate, Cryoprecipitate was thought to be safer, but could transmit hepatitis and neither product could be virally screened or inactivated at that time.[1,2] In summary I have not seen clear evidence in the papers submitted to me by the Inquiry that a large pool concentrate has been administered to Mr Hildyard.

13. The letter from Messrs Deas, Mallen Souter is clear, in that the solicitor explained to Mr Hildyard that there was no breach of duty identified by me in my report and concluded that there was no realistic prospect of successfully bringing a medical negligence action in his case. If a Breach of Duty of Care could be established, only then could the issue of Causation be relevant. Any comment on alcohol consumption could only have been relevant in the context of Causation (including prognosis).
I am not able to understand the suggestion that I influenced eligibility for Legal Aid. My role as an expert witness was only to give a view on legal liability.

Section 3: Other Issues

14. In 1983 the prevalence of non A-non B hepatitis (which later became known to be HCV infection) in the United Kingdom (UK) blood donor community was approximately 0.3%[1] and the number of donor units of cryoprecipitate administered to Mr Hildyard would be needed to calculate the statistical risk of infection in his case. The use of cryoprecipitate at that time carried the same risk of hepatitis as a normal blood transfusion of the same number of units transfused. If a donor contributing blood to a dose of cryoprecipitate was infected with HCV then it is likely that acute hepatitis, possibly with jaundice, would follow[1].

15. All cryoprecipitate used in the UK in this period was of British donor origin and none was sourced from the United States of America (USA).

16. We now know that the incidence of non A-non B hepatitis infection in people with haemophilia treated for the first time with large pool concentrates sourced either from the UK or the USA in the early 1980s was very high.[2] In his paper, published in 1985, Dr Kernoff wrote "Since clotting factor concentrates are usually prepared from pools of at least 1,500 donor plasmas, it is not surprising that the overall attack rate following a first exposure to these products should approach 100%, whether they are of volunteer or commercial origin". (see 2.8 above).

17. I retired from the NHS in 2009 after 40 years' service. From 2008 - 2015 I acted as a consultant to Pfizer Haemophilia, mainly in Europe, with the title "Medical Director Haemophilia", but I have never been an employee of any USA based pharmaceutical company. My consultancy had a particular emphasis on supporting the use of pathogen safe recombinant products in haemophilia care and promoting health care for people with haemophilia in Europe and beyond and I still occasionally chair meetings for Pfizer.

18. In 2018 I received a Recognition Award from the European Association for Haemophilia and Allied Disorders (EAHAD) for my "outstanding contribution to the global haemophilia community".

References

1. Lee, C.A et al. (1985) Acute fulminant non-A, non-B hepatitis leading to chronic active hepatitis after treatment with cryoprecipitate, Gut, 26, 639-641.

2. Kernoff P.B.A (1985) High risk of non-A non-B hepatitis after a first exposure to volunteer or commercial clotting factor concentrates: effects of prophylactic immune serum globulin British Journal of Haematology, 60, 469-479.

Statement of Truth

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

Signed GRO-C

Dated 11/6/19