Witness Name: Patricia Hewitt

Statement No.: WITN3101004

Exhibits: WITN3101005

Dated: 14 March 2021

INFECTED BLOOD INQUIRY

FOURTH WRITTEN STATEMENT OF DR PATRICIA HEWITT

I, Dr Patricia Hewitt, will say as follows: -

1. My full name is Dr Patricia Elizabeth Hewitt. I provide this statement in response to a request made to the National Health Service Business Services Authority ("NHSBSA") under Rule 9 of the Inquiry Rules dated 9 February 2021 and in my capacity as a member of the Appeal Panel of the England Infected Blood Support Scheme ("EIBSS") that is administered by NHSBSA. NHSBSA is based at Stella House, Goldcrest Way, Newburn Riverside, Newcastle Upon Tyne NE15 8NY.

Section 1: Introduction

2. My date of birth is GRO-C 1951. My professional qualifications are MB ChB (Leeds), FRCP, FRCPath. I trained in medicine at Leeds University. I qualified in 1975.

3. I have set out below an overview of my employment history:

a. I was appointed to a Consultant Haematologist post at the (then) North London Blood Transfusion Centre in 1984. I occupied a post in donor health and blood collection. Over the following years, I increasingly specialised in clinical transfusion microbiology, which involved responsibility for the management of blood donors with positive test results for blood-borne viruses and bacteria and investigation of reports of possible transfusion-transmitted infection in patients who had received transfusions of blood and/or blood components.

b. Between 1995 and 2000, I was Lead Consultant for Transfusion Microbiology for the London and South East Zone of the National Blood Service ("NBS").

c. From 2000 to 2005, I was National Lead Consultant for the NBS. After formation of the National Blood Authority ("NBA") and then the current organisation NHS Blood and Transplant ("NHSBT"), I retained the national clinical lead role for Transfusion Microbiology until my retirement from full time employment in June 2018.

4. Prior to my employment with NHSBT and its predecessor organisations, I was employed as a Lecturer in Haematology (Honorary Senior Registrar) at Middlesex Hospital Medical School.

5. I am now retained by NHSBT to provide occasional assistance and advice as and when required.

6. I was appointed to the Skipton Fund Appeal Panel when the Panel was first set up, through a public appointment process. I continued to serve on the Appeal Panel until the Skipton Fund closed and EIBSS was established in November 2017. I was then invited to continue as a member of the EIBSS Appeals Panel, and I continue in this function today.

7. I am/was a member of the following past and present committees/groups which are relevant to the Inquiry's Terms of Reference:

a. Joint UK Blood Transfusion and Tissue Transplantation Services ("JPAC") Specialist Advisory Committee on Care and Selection of Donors;

b. JPAC Specialist Advisory Committee on Transfusion Transmitted Infection;

c. UK Blood Services Prion Assay Working Group;

d. Serious Hazards of Transfusion ("SHOT") Steering Group;

e. CJD Clinical Incidents Panel;

f. Advisory Committee on Dangerous Pathogens ("ACDP") Transmissible Spongiform Encephalopathy ("TSE") Risk Assessment Working Group

g. ACDP TSE Risk Management Working Group;

h. ACDP TSE Sub Group;

i. Council of Europe Committee of Experts on Blood Transfusion and Immunohaematology; and

j. EIBSS Appeal Panel.

Section 2: Anti-D Immunoglobulin

8. I have been asked by the NHSBSA to review the following documents:

a. a letter between the Skipton Fund and myself dated 24 February 2005 (SKIP0000031_071);

b. appeal notes for the Skipton Fund (NHBT0090738); and

c. Redacted copy of the application of beneficiary 5282 to the Skipton Fund (SKIP0000018_008).

9. In light of those documents, the NHSBSA has asked me if my opinion remains the same today as I expressed in my letter dated 24 February 2005.

10. I confirm that my view does remain the same as expressed in that letter. There is still a lack of any evidence that intramuscular anti-D immunoglobulin products have transmitted hepatitis C infection.

11. In the years following my letter of February 2005, I became increasingly concerned at the number of appeals submitted to the Skipton Fund from women who believed that they had become infected with hepatitis C through the administration of anti-Rh(D) immunoglobulin. Many of these women had been advised by their clinicians that the immunoglobulin was the likely source of their infection and some clinicians wrote letters of support that demonstrated that they did not have the full information about intramuscular immunoglobulins provided by the NHS and their acknowledged safety. In 2010, I received a letter forwarded from Nicholas Fish, who had replaced Keith Foster as administrator of the Skipton Fund. This letter was from Professor Graham Foster, a Professor of Hepatology. I do not have a copy of his letter although I attach my reply dated 15 July 2010 at **Exhibit PH1 (WITN3101005).** As can be seen from my reply, I felt that this enquiry should be used as an opportunity to prepare a document that could be provided by the Skipton Fund to clinicians who supported the view that intramuscular immunoglobulin had contributed to hepatitis C infection, so that they might be aware of all the evidence. I recruited the help of Dr Clive Dash, then Medical Director of Bio Products Laboratory ("BPL") which produced the intramuscular immunoglobulins provided to the NHS in England and Wales. Dr Dash had long experience in intramuscular and intravenous immunoglobulin production, and was able to provide the key references and publications to support the safety of intramuscular immunoglobulins.

12. As will be seen from the joint letter that Dr Dash and I produced in 2010, there is no evidence that intramuscular immunoglobulins produced by the Cohn fractionation method, as used at BPL, have ever transmitted virus infections. This fact is acknowledged by the World Health Organisation and the US Centers for Disease Control and Prevention. I therefore have no reason to change the opinion expressed in my 2005 letter.

13. When providing the above opinion to NHSBSA in February 2021, I was also shown the EIBSS exclusion criteria that applied to hepatitis C at that time. The

criteria confirmed, amongst other matters, that EIBSS would look at all available evidence regarding the risks associated with certain types of blood products at the time an applicant received the treatment, including intravenous immunoglobulin but specifically excluding intravenous anti-D immunoglobulin.

14. I had no part in the production of the EIBSS criteria and I have never been asked for my opinion on the statements contained therein before.

15. Upon reviewing the criteria I explained to the NHSBSA that it is true, as set out in my letter of 2010, that early versions of intravenous immunoglobulins could have represented a risk of hepatitis C transmission and that intravenous anti-D produced in some jurisdictions, for example by the Irish Blood Transfusion Board and others, had transmitted hepatitis C. It follows that the reference to excluding intravenous anti-D immunoglobulin as a source of hepatitis C transmission is not accurate.

16. I have been subsequently informed that, since they received my opinion, the NHSBSA plans to amend the EIBSS exclusion criteria listed on its website to make clear that only intramuscular anti-D immunoglobulin is excluded from consideration by EIBSS.

17. I stress that it is very unlikely that any new claimant would have received NHS treatment with intravenous anti-D immunoglobulin of the products which are known to have transmitted hepatitis C, for the reasons given in my letter of 2010. However, it is a remote possibility that such a woman has remained untraced, and the website must reflect that unlikely possibility.

Statement of Truth

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

Signed: GRO-C

Dated: 14th March 2021

Table of exhibits:

Exhibit number	Date	Notes/Description
Exhibit PH1 WITN3101005	15 July 2010	Letter to Nick Fish, Scheme Administrator, Skipton Fund from Dr Patricia Hewitt NHSBT and Dr Clive Dash Bio Products Laboratory