Anonymous

Witness Name: GRO-B
Statement No: WITN2066005
Exhibits: WITN2066006 - WITN2066013
Dated: 10th February 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF GRO-B

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

I, GRO-B will say as follows: -

Section 1. Introduction

1. My name is GRO-B My date of birth is GRO-B 1969. I reside at GRO-B GRO-B. I am a part-time office worker. I am divorced and have a GRO-B son.

2. Within my first witness statement, dated 14 August 2019 (**WITN2066001**), I discussed my late Mother GRO-B: M s possible HCV and HIV infection, how the illness affected her, the treatment received, the impact it had on her and our lives together, and her death in GRO-B 1984.

3. Also, within my first witness statement, I stated that I would be requesting access to my Mother's medical records. Thereafter, I had applied to my Mother's General Practitioner ("GP"), the hospitals, Medical Research Council, and access to medical records bureau, surrounding obtaining access to her medical records, of which, I had received limited results back.

4. However, as a result of my involvement within the Contaminated Blood Community, I identified a lady who was a mum to a young boy who had similar issues with obtaining her son's medical records. She was very assiduous in obtaining hospital files, and was able to locate a microfiche document relating to her son from Northwick Park Hospital ("Northwick Park"), Watford Road, Harrow, HA1 3UJ.

5. I asked this lady for the contact she had utilised to obtain her Son's medical records. I was directed to an individual named Mary Cahill who is the Associate Director, Digital Services at the London North West University Healthcare NHS Trust.

6. Mary with the Subject Access Team was able to facilitate the identification of my Mother's hospital records consisting of around two hundred documents on the same microfiche, for which I am very grateful. I have condensed the following documents into three folders, which I produce as exhibits (**WITN2066008 - WITN2066010),** with three additional folders of academic articles related to patients with Hypogammaglobulinaemia (now known as Primary Immune Deficiencies) and their treatment **(WITN2066011 - WITN2066013)**.

7. As you will note, the reproduction of an old microfiche film is on occasion difficult to read. I am aware, that the original microfiche is still held at London North West University Healthcare NHS Trust. I am unable to gain access to the original as it contains other patients' details.

Section 2. How Affected

8. From the research I have conducted and the documentary evidence I have obtained via my Mother's hospital records, my view is that my Mother was part of a trial in the early 1980's where an intravenous immunoglobulin product (also referred to interchangeably as "gamma globulin"), which was being made at the Blood Product Laboratory ("BPL"), was being tested.

9. As result of this trial, I believe that my Mother was infected with non-A non-B Hepatitis (now known as Hepatitis C, HCV); and from her described symptoms a possibility that she was also infected with HIV. Her symptoms included severe weight loss, chest infections, severe bronchiectasis, candida and pneumonia.

Medical Records: WITN2066008

10. This is a folder I have created, detailing letters and clinical notes regarding my Mother's treatment between 1972 and 1980. In summary, these documents detail my Mother's reaction to intramuscular immunoglobulin, such as giddiness, sickness and shivering. It is also noted that from 1973, her spleen is enlarged, and she suffered from chest infections. On some occasions, her liver could be felt below her rib cage. It is my understanding that her enlarged spleen or liver can be related to liver disease. She also suffered from pale stools and skin rashes on her legs and feet.

11. The last two documents within **WITN2066008** relate to a little further information concerning 'KVEIM' tests. Her hospital records in this file show that my Mum had a portion of a sarcoid spleen 'K32', provided by Dr Mitchell at The Brompton Hospital, inserted under the skin of her right arm on 21.2.80 to see if a reaction typical of sarcoidosis resulted. A biopsy was undertaken on 18.3.80 to examine the specimen and a Histopathology Report states 'a minor perivascular infiltrate with chronic inflammatory cells but with no evidence of sarcoid reaction.'

Medical Records: WITN2066009

12. This is a folder I have created, detailing hospital record excerpts and letters surrounding my Mother's medical treatment, dated between 1981 and 1982.

13. Contained within **WITN2066009,** is a letter, which is dated either December 1982 or 1983, from Consultant Physician, to her GP, GRO-B GRO-B. The letter states that my Mother regularly received intravenous gamma globulin therapy, but now that supplies of intravenous gamma globulin had 'run out,' she was to be given weekly intramuscular gamma globulin therapy, as well as two units of fresh frozen plasma ("FFP") every three weeks.

14. Facts in her hospital records 1981-2 mentioning treatment with certain commercial immunoglobulin products correlate with accounts of some of the trials of commercial intravenous immunoglobulin taking place in the referral centre in the early 1980's; (i) a chapter 'Intramuscular versus intravenous administration of immunoglobulin preparations' by A D B Webster and A M Lever within 'Clinical Use of Intravenous Immunoglobulins: Proceedings of a conference held at Interlaken September 15-18, 1985' ed. A Morell and U E Nydegger printed in 1986 (ISBN 0-12-523282 9) contained within a folder exhibited at **WITN2066011** details a parallel cross-over trial of ten patients with five patients being given a commercial immunoglobulin product 'propiolactone-treated IVIg' every 18 days and intramuscular therapy for alternate three month periods; which matches two cycles of a propiolactone-treated product my Mother was given between September 1981-September 1982 with intramuscular gamma globulin for three months in between, as detailed in her hospital records.

15. (ii) a British Medical Journal Publication contained within a folder exhibited at **WITN2066011.** The Publication includes an article dated 03 November 1984, by A SO, M K Brenner, I D Hill, G L Asherson, A D B Webster,

entitled 'Intravenous gamma globulin treatment in patients with hypogammaglobulinaemia.' The article discusses trials whereby an intravenous gammaglobulin treatment in patients with hypogammaglobulinemia is compared with an intramuscular preparation, or patients are given the intravenous gammaglobulin with the half-life of the IVIg and changes in serum concentrations being measured. My Mother's hospital records detail this product to be given September 1982 onwards. Her diaries show intensive blood tests for the first few weeks of treatment with the product and that the treatment ended 1 December 1982. Also, three patients within this were provided with two units of FFP every three weeks, alongside intramuscular gamma globulin therapy. This fact would otherwise correlate with my claim that my Mother was a patient in clinical trials into intravenous gamma globulin therapy.

16. In addition to the above article, contained within **WITN2066011,** is a Medical Publication within The Lancet. This refers to an article, dated 10 November 1984, by A M L Lever, D Brown, A D B Webster and H C Thomas, entitled 'Non-A, Non-B Hepatitis occurring in agammaglobulinaemic patients after intravenous immunoglobulin.' The article identifies that a trial took place whereby twenty-four patients with hypogammaglobulinemia were recruited into an open cross-over trial to evaluate the efficacy of the intravenous immunoglobulin, versus conventional intramuscular gamma globulin, in preventing infection. Twelve patients had previously been on regular weekly intramuscular gamma globulin therapy, and received two units of plasma every three weeks.

17. Alongside the fact that the pattern of my Mother's treatment is indicative of her having taken part in a trial into the efficacy of the intravenous gamma globulin, contained in **WITN2066009,** is a letter, dated 01 October 1981, from Consultant Physician. The letter states that my Mother had started on a new type of intravenous gamma globulin therapy, of which infusions were given every eighteen days. The first infusion of this therapy was given on 30 September 1981.

18. Comparatively, contained within **WITN2066011**, is an article, dated 03 November 1984, by A SO, MK Brenner, I D Hill, G L Ascherson, A D B Webster, entitled 'Intravenous gammaglobulin treatment in patients with hypogammaglobulinemia,' contained within the British Medical Journal. The article discusses a trial whereby intravenous gamma globulin treatment in patients with hypogammaglobulinemia is compared with intramuscular preparation. The article states that the patients were provided with treatment every eighteen days.

19. The facts set out within the preceding five documents, otherwise suggest that my Mother may have been a patient within the aforementioned trial.

20. Also contained in **WITN2066009,** I have made a note in handwritten form, of the blood tests my Mother received, which she noted in her diaries, from 17 September 1982 to 7 October 1982. I question the reasoning behind these tests having taken place, and what they were looking for? Given the timing just after the summer of 1982, was it for markers of an infection or the half-life of a product – or both?

Medical Records: WITN2066010

21. This is a folder I have created, detailing hospital record excerpts and letters for 1983, which describe my Mother as being very thin and emaciated. She suffered from severe bronchiectasis, candida, and pneumonia.

22. Within **WITN2066010,** there is a 'Case Summary' from a SHO for my Mother's in-patient stay at Northwick Park Hospital 23.5.1983-3.6.1983 which states that she was given intravenous immunoglobulin;

"in order that the half life of this preparation might be measured."

It also states that the Consultant Physician will be in contact to provide a supply of intravenous immunoglobulin, and she will be seen in the clinic in the near future.

23. There is also a 'History Sheet' which has an entry for 25/5 " 7.5g. Intraglobulin IV for T1/2 measurement " and a list of days for 5ml blood samples to be taken which shows ticks against days 1,2,3,4,6,9 with dates.

24. Also contained within **WITN2066010**, is a patient note, dated 25 May 1983, which contains batch numbers that my Mother received. I have replicated the note for tracing purposes, as follows:

"Dated:		***Batch:***
25/05	*Intraglobulin 7.5g 11:00 401111*	*20 dpm Increasing to 40 dpm after 10minutes 401111*
2/6	*Intraglobulin 9g 13620280*	*20 dpm – 40 dpm after 10 minutes 13600500*

Folder of Documents NANBH: WITN2066011

25. This is a folder I have created, which contains research I have obtained from the Internet and libraries related to immunoglobulins and Non-A, Non-B Hepatitis/HCV.

26. Contained within **WITN2066011**, is a Medical Publication within The Lancet. This makes reference to a letter, dated 12 February 1983, from R S Lane, L Valet, and M L Kavanagh, Blood Products Laboratory, entitled

'Human Immunoglobulin for Clinical Use.' The article states that a trial of intravenous gamma globulin prepared at BPL was due to 'begin shortly' surrounding its use in hypogammaglobulinaemia, at the Clinical Research Centre, Northwick Park Hospital. This is a clinical trial in which I believe my Mother was a patient, due to her diagnosis of hypogammaglobulinaemia, and the treatment of intravenous gamma globulin she received at Northwick Park throughout this period. Medical notes contained in **WITN2066010** demonstrate my mother received 'Intraglobulin' in 1983.

27. From documentation contained within **WITN2066011,** it is clearly evident that all people who were involved in the trial contracted Non-A Non-B Hepatitis. As I believe that my mother was one of the patients within the trial into the efficacy of intravenous gamma globulin infusions prepared by BPL, I believe that she contracted NANBH.

28. Contained within **WITN2066011**, is a Medical Publication within The Lancet. This makes reference to a letter, dated 22 October 1983, from R S Lane, Blood Products Laboratory, entitled 'Non-A, Non-B Hepatitis from Intravenous Immunoglobulin.' The article discusses a clinical trial, which took place in 1983, of an intravenous Human Normal Immunoglobulin, developed in the laboratory for the maintenance therapy of hypogammaglobulinaemia. This article states that all twelve patients developed hepatitis compatible with a Non-A, Non-B viral origin.

29. Similarly, contained within **WITN2066011,** is article within the Lancet, dated 10 November 1984, by AML Lever, D Brown, ADB Webster, HC Thomas titled 'Non-A, Non-B Hepatitis Occurring in Agammaglobulinaemic Patients After Intravenous Immunogblobulin.' This states that;

'Acute non-A, non-B hepatitis developed in twelve patients with primary hypogammaglobulinaemia during treatment with intravenous gammaglobulin prepared by Cohn fractionation of pooled plasma. The illness was clinically and histologically identical to the short-incubation

non-A, non-B, hepatitis observed in haemophiliac patients receiving factor VIII concentrates.'

30. Similarly, contained within **WITN2066012**, is a peer-reviewed medical journal named Clinical and Experimental Immunology. This contains an article, dated 1988, by G P Spickett, Margaret Millrain, Ruth Beattie, Margaret North, Jo Griffiths, S Patterson, and A D B Webster, entitled 'Role of retroviruses in acquired hypogammaglobulinaemia.' The article makes reference to an investigation over an eighteen-month period, whereby forty-two patients with Common Variable Hypogammaglobulinaemia had been attending Northwick Park Hospital, to receive intravenous gamma globulin therapy. It states that "*Three patients had contracted non-A non-B hepatitis during a trial of a new British intravenous gammaglobulin, as previously reported (Lever et al, 1984).*"

31. Contained within **WITN2066011,** is a BMJ article which includes a letter to the Editor, dated 05 June 1993, by P J Lehner, A D B Webster, Immuno Deficiency Research Group, entitled 'Hepatitis C from immunoglobulin infusions.' The letter states as follows:

"Immunoglobulin preparations in present use are treated to inactivate viruses, and screening of blood donors for hepatitis C makes the chance of infection less likely. In the early 1980s, however, several commercial immunoglobulin preparations caused outbreaks of non-A, non-B hepatitis, most of which have since been confirmed as having been hepatitis C.

In one of the best documented studies use of intravenous immunoglobulin prepared by the British Blood Products Laboratory with alcohol fractionation led to the development of non-A non-B hepatitis in 12 patients with agammaglobulinaemia. The consequences of this infection in these patients have been devastating; four of nine with common varied immunodeficiency and hepatitis C have died from liver disease; one after liver transplantation. Four of the remaining patients

with common varied immunodeficiency have died from other complications, which may have been precipitated or exacerbated by chronic hepatitis C."

32. This article highlights that of the twelve patients who contracted NANBH, four of nine with Common Varied Immunodeficiency and hepatitis C had died from liver disease, and four of the remaining patients with common varied immunodeficiency had died from other complications. As I have previously highlighted, it is my understanding that my Mother's enlarged spleen is related to liver disease. In any case, one of my mother's causes of death is Hypogammaglobulinaemia. Therefore, it could be suggested that the cause of my mother's death is attributable to either an underlying NANBH infection, or, associated complications exacerbated by chronic NANBH.

33. Also contained within **WITN2066011** is a chapter 'Intramuscular versus intravenous administration of immunoglobulin preparations' by A D B Webster and A M Lever within 'Clinical Use of Intravenous Immunoglobulins: Proceedings of a conference held at Interlaken September 15-18, 1985' ed. A Morell and U E Nydegger printed in 1986 (ISBN 0-12-523282 9) where it states;

"Table 2 shows the outcome, 2 years later, in the 12 patients who acquired nonA nonB hepatitis from British gammaglobulin. The nature of the disease is compatible with a viral aetiology – and this must be the assumption until proved otherwise. Two patients developed unusual complications which we have not seen in 15 years experience with over 200 patients with primary hypogammaglobulinaemia (i.e. spinal cord demyelination and bone marrow aplasia). Both these patients (one died within a year) had progressive liver disease; it is possible that the hepatitis virus itself or a combination of two viruses are responsible. The latter possibility is plausible since we have recent evidence of retroviral infection with "common variable" hypogammaglobulinaemia."

34. The discussion reported at the end of this Chapter has a comment by Dr ADB Webster regarding the BPL IVIg product;

> *"Some of the source material was used to make multiple batches of the new intravenous preparation. One or more of these batches transferred hepatitis."*

35. Included in **WITN2066011** is an excerpt from a peer-reviewed Medical Journal 'Vox Sanguinis' by Y Piquet, G Janvier, P Selosse, C Doutremepuich, J Jouneau, G Nicolle, D Platel, G Vezon titled 'Virus Inactivation of Fresh Frozen Plasma by a Solvent Detergent Procedure: Biological Results' dated 1992 in which it is clear that at this time (1992) Fresh Frozen Plasma was still not treated with any virus inactivation procedures.

36. Also, within **WITN2066011** is 'The Chairman's Summary' from 'Intravenous Immunoglobulins in Immunodeficiency Syndromes and Idiopathic Thrombocytopenic Purpura' from a Royal Society of Medicine International Congress and Symposium no 84, published 1985 (ISBN 0-19-922023-9) where it is stated by ADB Webster;

> *"Some of my patients have developed hepatitis after receiving plasma…..'*

37. In this folder is also an article from the peer-reviewed Quarterly Journal of Medicine, 1993; 86; 31-42 'Primary Hypogammaglobulinaemia: a survey of clinical manifestations and complications' by RA Hermaszewski and ADB Webster which reviews the records of 284 patients with immunodeficiency seen at the referral centre over the past 20 years. In this document it states that 20 patients had features consistent with NANBH (7 confirmed by molecular techniques) – of which only 11 had contracted it from the BPL trial;

"The remainder were either infected from other contaminated batches of immunoglobulin in the early 1980's, or from fresh frozen plasma infusions."

38. Another 3 patients were believed to have Hepatitis A or B, and 4 patients had hepatomegaly of unknown origin.

39. Also included in this folder is an article 'A prospective controlled crossover trial of a new heat-treated intravenous immunoglobulin' by SR Zuhrie, ADB Webster, R Davies, ACM Fay and TB Wallington, in a peer-reviewed medical journal 'Clinical and Experimental Immunology' 1995; 99: 10-15 which had been accepted for publication 14 September 1994. This states;

"Current licensed products available in the UK do not have a specific viral inactivation step in the manufacturing process, although most of these products have a good record of safety in regard to HCV transmission.'

40. The article then goes on to describe the first ever trial in the UK of a pasteurized Immunoglobulin for intravenous use. In this respect, Immunoglobulins were not treated with the same caution as other blood products. Even when it was demonstrable that patients had contracted Hepatitis C from IVIg, immunoglobulin products were not made safe through deliberate pasteurisation/virus inactivation until a *decade* after many other products which were found to transmit viruses in the early 1980's.

Folder of Documents HIV: WITN2066012

41. This folder consists of Lancet publications, relating to HTLV-III (HIV), and patients suffering with common variable hypogammaglobulinemia case reports.

42. Contained within **WITN2066012**, I have highlighted a British Medical Journal Publication, which includes an article, dated 17 August 1991, by ADB Webster, Consultant Physician, Immunodeficiency Research Group, entitled 'Intravenous immunoglobulins.' This article states *"A few patients probably acquired HIV from contaminated intravenous immunoglobulin at the beginning of the AIDS epidemic, before donors could be screened."* This would otherwise correlate with my belief previously highlighted, that my mother could have contracted HIV from contaminated intravenous immunoglobulin, or FFP which she had received as treatment.

43. Also, within the folder is an article from The Lancet dated 15 March 1986, by ADB Webster, M Malkovsky, S Patterson, M North, AG Dalgleish, R Beattie, GL Asherson, RA Weiss, titled 'Isolation of retroviruses from two patients with "Common Variable" Hypogammaglobulinaemia'. This details that 'Patient 2' who had a retrovirus isolated from his blood in August 1984 (later stated to be HIV), had already developed NANBH from the BPL Intravenous Immunoglobulin trial in August 1983, therefore having contracted both these viruses.

44. Within **WIT2066012** are articles discussing degrees of virus inactivation that may take place during 'Cold Ethanol Fractionation', and that many variables are important factors including probably both the viral load within the plasma pool and levels of relevant immunoglobulins, as well as the varying actual processes and temperature. These are included to illustrate that there were many views among professionals as to whether 'Cold Ethanol Fractionation' using various methods, would completely remove or inactivate HIV.

45. In contrast, also included is an MMWR Publication dated June 15th 1982 which details a '3--fold process' of viral inactivation that *must* take place for the Hepatitis B Virus Vaccine in the US, namely 8-M urea, pepsin at pH2 and 1:4000 formalin. Whilst at this time, other blood products were not receiving such a level of care regarding viral inactivation, either for known viruses or as yet unknown.

Folder of Documents Intraglobin: WITN2066013

46. This folder covers evidence regarding a 'propiolactone- treated IVIg' product , that I believe was being trialled on patients 1981-2 including my Mother, to verify it's effectiveness. It is my belief, that this product was believed to have some potential disadvantages relative to other intravenous immunoglobulin products in 1979, and I produce excerpts by different teams of scientists/doctors within **WIT20006013** from 'Immunoglobulins: Characteristics and Uses of Intravenous Preparations – Proceedings of a Workshop sponsored by Bureau of Biologics, FDA October 30-31 1979'. My Mother was given this beta-propiolactone treated product from September 1981 until January 1982, she then reverted back to intramuscular double doses until 12th May 1982, and she then went back on to the beta-propiolactone treated product from the 12th May 1982 to 31 August 1982. These facts surrounding my mother's treatment is confirmed in **WITN2066009** covering my Mother's treatment 1981-2.

47. **WIT2066010** includes a Case Summary from a SHO to my Mother's GP, GRO-B Essex for an in-patient stay 23.5.83 – 3.6.83. At this time my Mother was recorded as weighing just 41-42kg. The Case Summary states that she was given a dose of 'intravenous immunoglobulin in order that the plasma half-life of this preparation might be measured'. This makes me feel very upset. There are no hospital records after this Case Summary ending 3.6.83, and no record of any communication at all with her GP, or directly to my Mother, before her death in GRO-B 1984.

48. Having read all the hospital notes I feel that there are no mentions of discussions with my Mother about possible risks of products such as Fresh Frozen Plasma which I believe she received from December 1982 until her visit to the referral clinic May 1983 (from the letter previously mentioned in point [12] above). This was at a time when the risks of untreated blood products such as FFP were known by medical professionals. Also, I can

see no evidence that she was given a choice of intravenous immunoglobulins for the 1981-2 trials, when she was given one which may have had several therapeutic disadvantages. Therefore, it is hard for me to believe that she was given the opportunity to make informed decisions, and therefore give 'informed' consent.

49. If Sir Brian feels it to be appropriate, the IBI may want to seek the identity of the other patients who were given the BPL product as treatment for hypogammaglobulinaemia, who were infected with HCV or HCV and potentially HIV. Or those who received it *for other conditions* as stated in the letter from RS Lane in the Lancet 22 October 1983. In that circumstance, their relatives may want to provide statements as to what happened to their loved ones and follow the Inquiry. Otherwise, I feel that I am trying to speak up for those patients, even though I don't know who they are.

Statement of Truth

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

Signed GRO-B

Dated 10 Feb 22

Table of Exhibits:

Date	Notes/ Description	Exhibit number
21 September 2021	Letter, from Subject Access Request Centralised Team, London North West University Healthcare, Ealing Hospital.	**WITN2066006**

19 November 2021	Letter, from Paula Moreira, Assistant Operations Manager, Health Records, The Royal Free Hospital, to Ms GRO-B entitled 'Re: Access to Records ref. GRO-B	**WITN2066007**
1972 - 1980	Folder, entitled 'Patient: M Witness: GRO-B 1.2.2022. (NPH) Medical Records Excerpts.'	**WITN2066008**
1981 - 1982	Folder, entitled 'Patient: M Witness: GRO-B 1.2.2022. (NPH) Medical Records Excerpts.'	**WITN2066009**
1983	Folder, entitled 'Patient: M Witness: GRO-B 1.2.2022. (NPH) Medical Records Excerpts.'	**WITN2066010**
Undated	Folder, entitled 'Patient: M Witness: GRO-B 1.2.2022. Docs: NANBH - Related.'	**WITN2066011**
Undated	Folder, entitled 'Patient: M Witness: GRO-B 1.2.2022. Docs: HIV Related.'	**WITN2066012**
Undated	Folder, entitled 'Patient: M Witness: GRO-B 1.2.2022. Docs: Intraglobin – Related.'	**WITN2066013**