Witness Name: Dr Giangrande
Statement No.: WITN3311019
Exhibits: None
Dated: 27 March 2023

**INFECTED BLOOD INQUIRY**

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**WRITTEN STATEMENT OF DR GIANGRANDE**

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I provide this Statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 13 March 2023. I have relied solely upon the documents supplied by the Inquiry to provide this written response.

I, Dr Paul Giangrande, will say as follows: -

## Section 1: Introduction

1. Paul Leo Francis Giangrande dob: GRO-C
GRO-C, Oxfordshire GRO-C
BSc, MD, FRCP (Lond., Edin. & Ire), FRCPath, FRCPCH

**Please set out the positions you have held as a haematologist, the organisations in which you held these positions and your role and responsibilities in these positions:**

2. Consultant Haematologist at Oxford University Hospitals NHS Trust, based in the Oxford Haemophilia and Thrombosis Centre at the Churchill Hospital from April 1st 1991 until my retirement on 31st May 2015. My primary responsibility was the clinical management of both adults and children with inherited bleeding disorders.

**Please set out your membership, past or present, of any committees or groups:**

3. I was a member of the UK Haemophilia Centre Doctors' Organisation (UKHCDO) throughout my time in post in the NHS although I never held senior elected office within

that body. My primary engagement outside the hospital throughout my career was with patient organisations. I was honoured to be elected to the senior medical position within the World Federation of Hemophilia (WFH) for two consecutive terms from 2000-2008 inclusive. I was the first and only British physician to be elected to this position. I also served as Chairman of the Medical Advisory Group of the European Haemophilia Consortium (EHC) from 2013-2018 inclusive and I continue to work with this organisation but in other roles.

**Section 2: Responses to Criticisms**

4. I received copies of the Second and Third Witness Statements of WITN2151 (signed on 3 August 2021 and 23 September 2022 respectively) on 1 February 2023, together with Exhibits WITN2151003-005 inclusive and WITN2151007-020 inclusive. I was not given a copy of WITN2151's First Statement or Exhibits WITN2151022-027 inclusive. I was also not provided with copies of the relevant clinical or laboratory notes.

5. WITN2151's son was never under my care at the Oxford Haemophilia Centre: he was treated in Edinburgh. WITN2151's comments about me in her Statements refer exclusively to a medicolegal report which I prepared for her solicitor in 1999. I have specifically been asked to comment on allegations in paras. 7 and 8 of WITN2151's Second Statement and para. 6 of her Third Statement. These relate to two different topics which I address separately: treatment with factor VIII concentrate in 1983 and testing and counselling for hepatitis C (HCV).

**Treatment with factor VIII concentrate in 1983:**

6. WITN2151's son was born in GRO-B 1981. There was no prior family history of a bleeding disorder. W2151's son was treated with blood products in July 1983 for significant oral bleeding and in October 1984 for intracranial bleeding. He was subsequently infected with hepatitis C (HCV) but not HIV. At the time of his first treatment, it was not clear whether W2151's son had haemophilia A or von Willebrand disease: it was only later that he was labelled as having type 3 von Willebrand disease. I was contacted in June 1999 by a solicitor in Edinburgh (Jean Abbot of Paull & Williamsons) acting on behalf of WITN2151 who asked if I would prepare a medicolegal report. The key issue I was asked to give an opinion on was whether it had been negligent to treat the patient with factor VIII concentrate (which was given in addition to cryoprecipitate) in July 1983.

7. I agreed to prepare a report and indicated that I would do so free of charge as it was made clear to me that the family was not well off and did not have recourse to legal aid. I was provided with limited material to review: this included a written summary of the case from the solicitor as well as a statement from WITN2151. I also had a telephone conversation with the instructing solicitor on 14 July 1999. I was not provided with copies of the original clinical and laboratory records. I was also not told that Prof. Eric Preston in Sheffield had previously submitted a report on this case in 1995. This is common practice in medicolegal work as the instructing solicitor wants to be sure they receive a fresh opinion which is not influenced by other people.

8. A copy of my report dated 19 July 1999 has been provided by the Inquiry as Exhibit WITN2151005. No queries or criticisms of my report were received from either the instructing solicitor or WITN2151 after submission of my report.

9. WITN2151 says with apparent surprise in para. 7 of her Second Statement that: "Dr Giangrande openly admitted that he was an acquaintance of Dr Ludlam in this review." WITN2151 is obviously unaware that it is standard practice to declare conflicts of interest in a medicolegal report and an instructing solicitor would expect me to do so.

10. My principal conclusion was that the infusion of NHS factor VIII concentrate in July 1983 by the clinical team in Edinburgh to treat significant oral bleeding (which also required a blood transfusion) did not constitute clinical negligence. My reasoning is explained below.

11. In 1983, patients with haemophilia A were typically treated with factor VIII concentrate and most patients with von Willebrand disease were treated with cryoprecipitate. However, a minority of patients with haemophilia received cryoprecipitate and some patients with von Willebrand disease were treated with factor VIII concentrate. This is evident in the UKHCDO Annual Returns for 1983 from the Royal Free Hospital in London, which is one of the major treatment centres in this country (HCDO0000184_006 dated 21 October 2020 on Infected Blood Inquiry website). Treatment of both bleeding disorders with either product was considered acceptable at that time. With regard to concentrate, UKHCDO guidance applicable to this case was circulated to haemophilia centres in a letter dated 23 June 1983. It did not exclude the use of concentrate in young children but noted that "for treatment of children and mildly affected patients or patients unexposed to imported concentrates many directors

already reserve supplies of NHS concentrates (cryoprecipitate or freeze dried) and it would be circumspect to continue this policy" (Para. 130 on page 38 of written submission of UKHCDO to Infected Blood Inquiry [SUBS0000050] dated 22 December 2022: available on Inquiry website). The management of this case was complicated by the fact that the clinicians had to treat a significant bleeding episode without being certain whether the child had haemophilia or von Willebrand disease.

12. WITN2151 suggests that my conclusions "do not agree with those of Professor Preston" (para. 7 of Second Statement) but she also says that Prof. Preston "concluded that he was not convinced that it was medical negligence" (para. 5 of Second Statement).

13. On reading the report submitted by Prof. Eric Preston on 26 May 1995 now for the first time (Exhibit WITN2151004), I am satisfied that there was no disagreement between us on the central issue of clinical negligence. In the last paragraph of his report, Prof. Preston concluded that it was "understandable" that WITN2151's son was initially treated with factor VIII concentrate in view of the circumstances which he sets out: first clinical presentation with no previous family history; uncertainty over diagnosis (haemophilia or von Willebrand disease?); severity of bleeding judged to require immediate treatment in the middle of the night when full laboratory services were not available.

14. In para. 7 of her Second Statement, WITN2151 appears to question my opinion that "the use of DDAVP was not appropriate as it is recognised as having some toxic effects on young children." WITN2151's son was 19 months old when he presented with oral bleeding in July 1983. It remains my opinion that children with bleeding disorders under the age of two years should not be treated with DDAVP. This view is in line with current clinical practice and guidelines. Although a final diagnosis had not been established when the patient was first treated, he was subsequently diagnosed as having type 3 von Willebrand disease (Exhibit WITN2151019) and DDAVP is of no value in treating this rare subtype.

15. WITN2151 is correct in stating (para 6 of her Third Statement) that I said in my written evidence to the Inquiry that I have never used cryoprecipitate for the treatment of haemophilia in the UK (this sentence appears in answer to Question 19 in my Second Statement to the Inquiry). However, I strongly disagree with her subsequent assertions that this was something I "knew nothing about" and that I was "obviously relying on

what [I] was told by others." I started my haematology training some years after the use of concentrate superseded cryoprecipitate as regular treatment for haemophilia. In 1983, I was working in a hospital in London which was a designated haemophilia centre. I was familiar with the treatment guidelines in force at the time and it is a matter of record that I attended the UKHCDO Annual General Meeting in 1983 where the latest treatment guidelines were discussed. I have used cryoprecipitate for the treatment of bleeding disorders other than haemophilia. I have also often seen it used for the treatment of haemophilia abroad, even in recent years, through my international work with the World Federation of Haemophilia and European Haemophilia Consortium.

16. Having obtained two independent medicolegal reports from myself and Prof. Preston which both concluded that the treatment provided in Edinburgh was not negligent, WITN2151 relates in para 4 of Third Statement and Exhibit WITN2151023 that her solicitor subsequently approached three other experts in the field of haemophilia (Drs Mitchell, Winter and Hill) but no contrary opinion was ever produced.

**Testing and counselling for hepatitis C:**

17. I agree with the view expressed by Prof. Preston in his 1995 report (Exhibit WITN2151004) that it was "extremely likely" that WITN2151's son was infected with HCV through his first treatment with factor VIII concentrate in 1983. Tests for hepatitis C infection did not exist at that time: the virus was first identified in 1989.

18. W2151's son was first tested for exposure to hepatitis in 1993 (Exhibit WITN2151010). An entry in the clinical notes dated 31 May 1993 reads: "Hep C + to be discussed needs liver bloods." An entry dated 29 December 1993 makes clear that the patient was seen as an outpatient but the topic of hepatitis was not discussed. No reason was specified but it is evident that W2151's son required treatment for active oral bleeding at this unscheduled visit. I cannot read the name of the doctor who saw W2151's son that day but it was definitely not Dr Ludlam or anyone else I recall was a consultant there and so quite probably a junior doctor. An entry on 3 February 1994 documents a positive HCV PCR test result and that an appointment had been arranged in the 'liver clinic' on 1 March 1994. W2151's son, by now aged 12 years old, attended this appointment with his father (WITN2151 did not attend). Dr Ludlam saw the patient together with a liver specialist, Dr Peter Hayes, and they had a full discussion about hepatitis C and a course of interferon was initiated the following month.

19. The opinion I expressed in my 1999 report (WITN2151005) was that I believed the timeframe for testing and counselling was acceptable and in line with practice elsewhere. This remains my view. Although the family could have been told that W2151's son had been exposed to hepatitis C earlier, I believe it was reasonable to defer discussion to the appointment of 1 March 1994 which gave the family the opportunity to have a discussion with two senior consultants, with all the latest relevant information available (such as the PCR result) and without the distraction of having to also deal with another clinical problem like a bleeding episode.

20. Professor Preston documents the timeline of testing and counselling relating to hepatitis C in detail on pages 6-9 inclusive of his 1995 report (WITN2151004). However, his comments do not include any criticism of the Edinburgh team concerning the timeframe of testing or counselling.

**Conclusions:**

21. The criticisms which WITN2151 now raises for the first time about the medicolegal report which I submitted more than two decades ago in 1999 are not justified. My report generated no adverse feedback from WITN2151's legal team at the time. It is demonstrably evident that Prof. Preston and I independently came to the same conclusion about the care her son received in Edinburgh: it was not negligent. WITN2151's solicitor subsequently approached several other doctors but was unable to secure a contrasting opinion.

**Section 3: Other Issues**

None

**Statement of Truth**

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

Signed GRO-C

Dated 27 March 2023

**Table of exhibits:**

| Date | Notes/ Description | Exhibit number |
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