

Witness Name: Colin McKay

Statement No.: WITN7699004

Exhibits: WITN7699005-019

Dated: 28th November 2023

## **INFECTED BLOOD INQUIRY**

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### **WRITTEN STATEMENT OF COLIN MCKAY**

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I provide this statement on behalf of NHS Greater Glasgow and Clyde in response to the request under Rule 9 of the Inquiry Rules 2006 dated 20 February 2023.

I, Colin McKay, will say as follows: -

#### **Section 1: Introduction**

**Introductory paragraph to include your date of birth, address, occupation and employment history.**

1. Name: Colin McKay

Date of birth: GRO-C 1964

Address: Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G120XH

Qualifications:

- MB.ChB.: University of Glasgow, 1987
- FRCS (Glasg) :.1991
- M.D. : University of Glasgow, 1996
- FRCS (gen-surg) : 1998

Employment:

- Deputy Medical Director: Corporate, NHS Greater Glasgow and Clyde: April 2023 to present
- Chief of Medicine, North Sector, NHS Greater Glasgow and Clyde: May 2019 to April 2023
- Deputy Chief of Medicine, North Sector, NHS Greater Glasgow and Clyde: May 2018 to May 2019
- Clinical Director, Surgical Services North Sector NHS greater Glasgow and Clyde: May 2017 to May 2019
- Honorary Professor, School of Cancer Sciences, University of Glasgow: August 2017 to present
- Consultant Pancreatic Surgeon, GRO-B December 1998 to Present

## **Section 2: Response to Criticisms by W5398**

2. The criticisms I have been asked to address are:

### **Paragraph 13**

I was mainly dealt with out with the Haemophilia Centre for the hepatitis C, so I had no relationship with them. There was no requirement for me to attend the centre because I was a carrier. I don't believe that my lack of attendance at the centre is the reason for me not being diagnosed until 1995, because my other family members attended the centre. I am quite angry about the Centre as they knew who had received the affected products and never told them which of course left open the chance that the infection could have been passed onto others unknowingly.

### **Paragraph 15**

I didn't want my son GRO- to receive treatment because of the risks, I didn't want to take him to GRO-B at all. I was put under quite a lot of pressure about this and told that the treatment was safe as it was heat treated. I had to sign all sorts of disclaimers declaring that if he had a bleed the hospital would not be liable etc. Thank God I refused, because then of course it turned

out it wasn't safe as it came out about the risks of vCJD. What makes me so angry about this is that there were clearly no lessons learned for this to have then occurred again. [GRO-B] has never had anything but recombinant, so I am not even sure why he even received that letter. It's a horrible letter to receive and it made me realise how much they couldn't be trusted.

#### Paragraph 18

I fell out with [GRO-B] in a big way because of this, and I refused to take [GRO-B] at all, and I certainly wouldn't take gone myself for anything. I can't remember the details now, but I do recall being challenged on this and basically told that I was following the doctors' orders for my daughter (in relation to her [GRO-B]) but not for my son.

#### Paragraph 19

My fears about the kind of treatment my son [GRO-B] might receive were compounded when it was recommended he have his tonsils and adenoids removed in surgery at [GRO-B] Hospital in 1997. [GRO-B] had had recurrent ear and throat infections since he was a baby, and this eventually led to the procedure to remove his tonsils and adenoids being suggested by the ENT surgeon he regularly saw at Ayr Hospital. I did not want [GRO-B] to receive factor concentrate during the procedure because of the infection risk it posed. I pleaded with [GRO-B] to treat him with recombinant for the surgery instead, but they repeatedly refused. Whilst I was fighting for [GRO-B] to receive recombinant, his ear and throat infections eventually led to him giving my daughter [GRO-B] a chest infection which required treatment with IV antibiotics. This led to me writing to the company who manufactured recombinant explaining the situation and asking if they would supply it on a named patient basis on compassionate grounds for [GRO-B]'s procedure. Both our haematologist from Ayr Hospital and [GRO-B]'s Consultant wrote letters of support to the manufacturer for our request. The company granted our request and [GRO-B]'s procedure went ahead at the [GRO-B] [GRO-B]. I refused to allow the operation to be done at [GRO-B] because of their attitude. They were very unhappy that the recombinant was

**supplied in this way and made their feelings known. I had to fight to protect my son and it made me feel like nothing had been learned with the risk those treatments posed.**

3. In my role as UK IBI lead for the Board I received the aforementioned Rule 9 Request of 20<sup>th</sup> February 2023. I identified Professor [GRO-D] and Dr Elizabeth Chalmers as the most appropriate people to consider and respond to the criticisms made. They have now done so and their responses are set out below, in their own words.
4. In relation to Professor [GRO-D]'s comment at paragraph 7 below I can advise that at the time of witness W5398's treatment, NHSGGC was operating in terms of the Scottish Health Memorandum 60 of 1958 (SHM 58/60) and its accompanying schedule, followed by The Scottish Office Guidance For The Retention And Destruction of Health Records (NHS MEL(1993) 152). These successive schedules set a minimum retention period for medical records of 6 years after the conclusion of a patient's treatment in hospital, meaning that potentially relevant information to support a more detailed response may have been destroyed from the early 1990s onwards. This will unfortunately limit the response that can be provided.

**Response of Professor [GRO-D]**

5. I have been asked by the Central Legal Office to provide a response to witness W5398's statement, on behalf of NHS Greater Glasgow and Clyde. I provide this response on behalf of [GRO-D], where I worked. I understand that a second response on behalf of [GRO-B] Hospital is being provided by Dr Elizabeth Chalmers.
6. I note in witness W5398's statement, page 2, paragraphs 3-8, that she is a carrier of haemophilia B, that she received fresh frozen plasma or Factor concentrate in [GRO-B] when she gave birth to her daughter; then in the 1980s when she had wisdom teeth removed; then when she had a miscarriage requiring a D and C (dilatation and curettage). She was subsequently found to be a carrier of hepatitis C.

7. As noted in my substantive statement to the Inquiry (WITN3496013), from 1978 to 1984, I was a lecturer and honorary senior registrar, training in **GRO-D** **GRO-D** in general medicine, including occasional work at the Haemophilia Centre under consultant physicians Drs Colin Prentice and Charles Forbes. From 1985 I was senior lecturer and honorary consultant physician, assisting Dr Forbes, who was Haemophilia Centre Co-Director with consultant haematologist Dr George MacDonald. From 1988 I succeeded Dr Forbes as Centre Co-Director with Dr MacDonald, then from 1990 with consultant haematologist Dr Isobel Walker.
8. I have read copied case records from **GRO-D**, and Ayr and Crosshouse Hospitals (both under the auspices of NHS Ayrshire and Arran), to establish which blood products were given to witness W5398 for treatment of her low factor IX level, and also the management of her hepatitis. However, I am not confident that I have access to copies of the full sets of records I requested. I also requested, but have not received, copied case records from **GRO-D** **GRO-D**), or from **GRO-D** **GRO-D** and the adjacent **GRO-B**, where she also received blood products. I have also requested a copy of the National Haemophilia Register on blood products received by witness W5398, but I have not received this. I have received a copy of the **GRO-D**'s record of her blood product treatments (**WITN7699005**).

GRI Haemophilia Centre policy for management of carriers of haemophilia B.

9. As noted in my substantive statement to the Inquiry (WITN3496013), Dr Isobel Walker was appointed Consultant Haematologist with an interest in perinatal haematology in 1978 at **GRO-D** and the adjacent **GRO-D**. She developed an interest in the bleeding and thrombotic complications of women, including pregnancy complications in haemophilia carriers (8.4.13.1). In 1990 she became Co-Director of the Haemophilia Centre with myself. With Dr Ian Greer, Professor of Obstetrics and Gynaecology, she developed a combined clinic for management of gynaecological issues and pregnancy in haemophilia carriers; and they became national and international authorities on this topic (reference 26 in my substantive statement). Their evidence-based guidance (reference 26) noted:

“female carriers of haemophilia B may have levels of FIX inadequate for haemostasis even at term. It is therefore essential to check FIX levels in late pregnancy. Carriers of haemophilia B more frequently require blood product therapy to prevent or treat excessive bleeding. Levels should be raised to 40 iu/dl for vaginal delivery and to 50 iu/dl for Caesarean section. Levels should be maintained at about 40 iu/dl for at least 4-5 days.”

10. Blood product treatment was also required for carriers of haemophilia B to prevent or treat excessive bleeding after surgery (including dental), after trauma, or spontaneous bleeding (including uterine); if these were not controlled by the synthetic fibrinolytic inhibitor, tranexamic acid.
11. As I noted in my substantive statement to the Inquiry (WITN3496013), the Centre’s policy for prevention or treatment of bleeding in mild haemophilia B patients or carriers in the 1970s and 1980s was to generally prefer fresh frozen plasma to factor IX concentrates (the latter exposed patients to a larger number of blood donors and hence a higher risk of viral hepatitis) (26.1.1.2). In 1988 and 1990, UKHCDO guidance was that virally inactivated factor IX concentrates were recommended (SNBTS DEFIX in Scotland), and approved by Dr MacDonald, Dr Walker and myself as Haemophilia Centre Co-Directors.

#### Review of case records

12. **GRO-B** As a lecturer and senior registrar, I reviewed witness W5398 with Dr Charles Forbes at his Haemophilia Centre clinic on 23 November **GRO-B** when she was about 3 months pregnant. I recall that Dr Forbes, who had worked at the Centre since the 1960s and knew her family, reviewed with witness W5398 that her low factor IX level should be monitored; and informed her that if it was lower than required she would require treatment at the time of delivery with fresh frozen plasma (or factor IX concentrate if plasma was not effective) to prevent or treat excessive bleeding. Monitoring of her factor IX level showed it remained low in January **GRO-** Although she was booked for delivery at Irvine Central Hospital, Dr Forbes recommended that she be delivered at the **GRO-D** **GRO-D**, adjacent to **GRO-D**, where monitoring of factor levels

and appropriate haemostatic treatment was available. Accordingly, Dr Helen McEwan, consultant obstetrician at [GRO-D] was asked if she could arrange this (WITN7699006 – my letter of 19 January [GRO-] to Dr McEwan and general practitioner (GP)).

13. My subsequent letter to Dr McEwan and witness W5398's GP records that when W5398 was admitted for delivery of her daughter in June her factor IX level was only slightly below the lower limit of normal and therefore she was not given any fresh frozen plasma (WITN7699007 – my letter of 31 August [GRO-B] to GP and Dr McEwan). The Haemophilia Centre record does not include any blood product treatments at this time (WITN7699005).

14. 1982. Dr Lawson's letter to witness W5398's general practitioner records that she was admitted to [GRO-D] for extraction of wisdom teeth on 30 May. Her Factor IX level was 34-40 iu/dl. She was treated routinely with tranexamic acid and an antibiotic according to the Centre's protocol. After extraction on 31 May there was no excessive bleeding (WITN7699008 – Dr Lawson's letter of 1 June 1982 to GP). The Haemophilia Centre treatment record does not include any blood product treatment at this time (WITN7699005)

15. 1984. Dr Greer, who was haemophilia registrar 1983-1985 (training in haemophilia, thrombosis and general medicine before returning to obstetrics and gynaecology) wrote a letter to witness W5398's general practitioner on 13 April 1984. He noted that witness W5398 was recently admitted to the [GRO-D] [GRO-D] with a blighted ovum, which was evacuated under Factor IX cover. As I noted above, I have not received copied case records from [GRO-D]. However, the [GRO-D] treatment record includes that in March 1984, for a blighted ovum, factor IX concentrate (SNBTS DEFIX) was given in [GRO-D] (WITN7699005). Dr Greer noted that she was trying again for a family, and recommended she be booked for delivery again as she would require monitoring of FIX levels and possibly blood products. He performed liver function tests which were normal; FIX level was 40 iu/dl and there was no FIX inhibitor (WITN7699009 – Dr Greer's letter of 13 April 1984 to GP).

16. The Haemophilia Centre treatment record includes a treatment with fresh frozen plasma on 1 May 1984 for menstrual bleeding (**WITN7699005**).
17. 1985. Dr Greer reviewed witness W5398 in January 1985. He noted that she was pregnant in 1984 and had screening to determine whether or not her fetus was affected by **GRO-B**. A genetic analysis revealed that it was affected, and she opted for termination; which he noted was carried out uneventfully under fresh frozen plasma cover at the **GRO-D** at the end of 1984. As I noted above, I have not received copied case records from the **GRO-D** **GRO-D**. Witness W5398 then had further bleeding, and a scan at **GRO-D** showed no evidence of retained products of contraception. She was treated with ergometrine, antibiotics and fresh frozen plasma (**WITN7699010** – Dr Greer’s letter of 8 January 1985 to GP). The Haemophilia Centre treatment record includes a treatment with fresh frozen plasma on 7 January 1985 for post termination bleeding (**WITN7699005**).
18. I reviewed witness W5398 in July 1985. She had menorrhagia which had been treated with tranexamic acid, and Dr McEwan planned a dilatation and curettage (D and C) for 1 August. Her factor IX level was under 40 iu/dl and we arranged fresh frozen plasma treatment, with more to cover this procedure, which was performed on 1 August (**WITN76990011** – my letter of 24 July 1985 to Dr McEwan and GP). The Haemophilia Centre treatment record includes a treatment with fresh frozen plasma on 12 July 1985 for menorrhagia, and another treatment with fresh frozen plasma on 1 August 1985 for cover of D and C (**WITN7699005**).
19. On 21 October 1985 witness W5398 was seen at the Centre by Dr Spowart, Senior House Officer (training in haemophilia, thrombosis and general medicine before returning to obstetrics and gynaecology). She was 7 weeks pregnant and had fresh bleeding with abdominal pain. She received fresh frozen plasma and was advised to take bed rest at home, and was referred to Dr McEwan for an ultrasound scan (**WITN7699012** – Dr Spowart’s letter of 11 November 1985 to Dr McEwan). The Haemophilia Centre treatment record includes a treatment with fresh frozen plasma on 21 October for threatened abortion (**WITN7699005**).



20. 1986. Witness W5398 had a PG termination of pregnancy on 11 January 1986, followed by persistent bleeding, for which she received fresh frozen plasma and tranexamic acid on 16 and 17 February at [GRO-D] (WITN7699013 – case record notes of 16-17 February 1986 by Drs Bowman and Spowart). The Haemophilia Centre treatment record includes treatment with fresh frozen plasma on 6 January 1986 for amniocentesis and PG termination; and on 16 February and 17 February for post-PG termination bleeding (WITN7699005).

21. [GRO-B] Witness W5398 was safely delivered of a healthy son at the [GRO-D] [GRO-D] Factor IX level was 40 iu/dl and liver function tests were normal. There were no bleeding problems and no blood product was required (WITN7699014 – Dr McEwan's letter of 25 April 1990 to GP). The Haemophilia Centre treatment record shows that no blood product was given at that time (WITN7699005). As I noted above, I have not received copied case records from the Royal Maternity Hospital.

22. In summary, witness W5398 required treatment with blood products between 1984 and 1986 for her low Factor IX level, to treat or prevent bleeding of gynaecological or obstetric origin. On 8 occasions, this was with fresh frozen plasma, to minimise risk of hepatitis. There was close liaison between the Haemophilia Centre and consultant gynaecologist and obstetrician Dr McEwan; facilitated by the Registrar and Senior House Officer in Haemophilia during this period, Drs Greer and Spowart, who had trained in gynaecology and obstetrics. In March 1984 treatment of a blighted ovum was given with factor IX concentrate treatment at the [GRO-D] [GRO-D]

23. As noted by witness W5398 in her statement, from 1990 she elected to have her son's, and her own, haemophilia B managed by Dr McLure (consultant paediatrician) and by local haematologists in Ayr Hospital, in preference to [GRO-B] [GRO-B] and [GRO-D]

24. I reviewed witness W5398 at the [GRO-D] Haemophilia Centre on 23 February 1995. She told me that Dr McLure had recently checked hepatitis C antibody in both her son and herself and that she had a positive antibody test and normal liver function tests. Dr McLure subsequently received a report from Regional Virus Laboratory,

Ruchill, which reported that her hepatitis C antigen (PCR test) was negative in two specimens, indicating that she was not a carrier of hepatitis C. I checked these results, and that her liver function tests were normal. We had an extensive discussion on the future possibility of chronic liver disease, including that liver tests should be monitored by Dr McLure and if they became abnormal, or showed that she was a carrier of the virus by the PCR test, she should be referred for consideration of possible interferon therapy. (**WITN7699015** – my letter of 28 February 1995 to GP and Dr McLure).

25. I note from witness W5398's statement that she was referred for hepatitis monitoring to the Infectious Diseases Unit at Crosshouse Hospital, where in 1998 she was found to be hepatitis C antigen positive (**WITN7699016** – Dr Williams's letter of 2 June 1998 to Dr Eynaud, consultant haematologist, Crosshouse Hospital and GP).

26. The [GRO-D] Haemophilia Centre continued to send witness W5398 appointments for review. Dr [GRO-D] Co-Director, wrote to her on 18 December 2000 offering a review appointment, which she declined because she attended Dr Eynaud, consultant haematologist, and Dr Williams, consultant in infectious diseases, at Crosshouse Hospital (**WITN7699017** – witness W5398's letter of 5 January 2001 to Dr [GRO-D]).

27. Witness W5398 was reviewed by Dr A Alvi, Associate Specialist at the [GRO-D] Haemophilia Centre, on 22 February 2006 for review and assessment prior to her imminent surgery for newly diagnosed breast carcinoma. She was given a dose of recombinant factor IX concentrate to assess her response. Witness W5398 also consented to genetic testing for the causative mutation in her family (**WITN7699018** – Dr Alvi's letter of 9 April 2006 to Dr Eynaud).

28. The [GRO-D] Haemophilia Centre organised recombinant factor IX treatment when witness W5398 received surgery at Canniesburn Plastic Surgery Unit in [GRO-B] in 2007 (**WITN7699019** – Dr [GRO-D] letter of 20 November 2007 to Mrs Weiler-Mithoff, consultant plastic surgeon).

29. I note from witness W5398's statement that her hepatitis C was eradicated in 2018 at the Infectious Diseases Department, Crosshouse Hospital, Kilmarnock (**WITN5398003**).

#### Response to criticisms

#### Paragraph 13

30. When testing for hepatitis C became available in the 1990s, all patients who had received any blood products were advised to be tested, either by the Haemophilia Centre, or by their local doctors. The **GRO-D** case records note that on 6 April 1994 Staff Nurse Little at the Centre discussed with the patient by telephone that hepatitis testing and vaccination could be performed by her general practitioner. I note that witness W5398 was tested for hepatitis C by Dr McLure in 1994 (**WITN7699015**). Following the birth of her son in 1990, witness W5398 opted to have her haemophilia care, and that of her son, in Ayrshire Hospitals (Ayr and Crosshouse) rather than in **GRO-D**. This was provided by Dr McClure, consultant paediatrician and by consultant haematologist Dr Eynaud. Because the **GRO-D** Centres (**GRO-** and **GRO-B**) covered the large area of the West of Scotland, many patients in the region who lived far from the Centres elected to attend their local hospitals, haematologists and physicians for their haemophilia care, to avoid travel to **GRO-D** (see my Substantive Statement, page 19, Section 8.5.2.1). This was entirely reasonable, and I note that witness W5398's decision was in part due to **GRO-B** not being able to offer recombinant factor IX concentrate to her son instead of human donor concentrate (Paragraph 19).

31. When witness W5398 was discovered to have a positive hepatitis C antibody test, she attended the **GRO-D**, where she and I had an extensive discussion on the need for monitoring of her liver function tests and hepatitis antigen; and the future possibility of chronic liver disease in hepatitis antigen carriers and its management (see **WITN7699014** and paragraph above). Her choice of management of her hepatitis C by specialists in her local hospitals was entirely reasonable, and again this choice was also taken by other patients registered at the **GRO-D** Haemophilia Centre. However, the **GRO-D** Centre was always available to review at its clinics, and

to give advice and treatment to, its registered patients and their local doctors (Exhibits **WITN7699017-019**).

Paragraph 15 and Paragraph 18

32. I am sorry to hear about witness W5398's criticisms of the **GRO-B** centre about the management of her son, but I think that they should be addressed by Dr Chalmers, as they do not involve the **GRO-D** Centre.

**Response of Dr Elizabeth Chalmers**

33. The main criticism of witness W5398 regarding her son is around availability of recombinant FIX to cover tonsillectomy surgery in 1997/98. Witness W5398 makes additional comments regarding signing of "disclaimers" in connection with earlier treatment and with regard to receipt of vCJD correspondence.

**Comments:**

34. Witness W5398's son is a mild haemophiliac born in **GRO-B** and first seen at **GRO-B** **GRO-B** in 1993 (when he was **GRO-B** of age) for diagnosis and registration.

35. Following this there appears to have been little contact with the haemophilia unit at **GRO-B** either for treatment or regular clinic review. There are letters from Brenda Gibson to paediatric consultants in Ayrshire emphasising the importance of routine review at a haemophilia centre and requesting vaccinations. It is perhaps unfortunate that regular review did not take place following diagnosis as it meant that there was no relationship established with the team at **GRO-B** which may have influenced later interactions.

36. Comments made by witness W5398 regarding the signing of "disclaimers" around her son's treatment:

37. This is not a term I recognise as being part of our procedures, although I suppose it could be intended to refer to aspects of a consenting process. The episode in question I think must relate to discussions around management of dental work

carried out at GRO-B in August 1996, as this is the only significant treatment episode undertaken at GRO-B prior to the discussions about surgery in 1997.

38. Entries in the GRO-B case notes in August 1996 record that “Mum does not wish FIX to be administered preoperatively but will accept post operatively if bleeding”. Depending on the nature of the dental procedure our practice would often have been to administer a dose of FIX prophylactically pre-operatively with tranexamic acid for a few days post-procedure. In witness W5398 son’s case, taking into account Mum’s concerns about the use of plasma derived products (presumably based on her own experience having contracted HCV through exposure to non-viricidally treated products) it appears to have been agreed that prophylactic pre-op FIX would be omitted and the procedure covered with tranexamic acid alone but with the proviso that if there was excess bleeding FIX would be required as bleeding could pose a clinical risk for her son. It was well documented in other areas of the notes that “Mum does not want blood products unless absolutely necessary”. Hepatitis B vaccination was also commenced as this had not been undertaken previously. In the event there was no excess bleeding and FIX was not required. The only documented signed consent was for the dental procedure itself. At this time it was not routine practice to take written consent for blood products but it is apparent from the notes that the use of FIX concentrate would have been discussed verbally.

39. In the management of this episode we had to balance the safe management of witness W5398’s son and the wishes of witness W5398 with regard to FIX exposure. In working with families who have had prior experience of viral transmissions it was important to be sensitive to these issues when discussing treatment options. In my opinion this episode was planned and managed appropriately taking into account witness W5398’s wishes to avoid blood products if possible, while ensuring the safe management of her son.

40. Comments regarding the availability of recombinant FIX to manage witness W5398’s son’s planned tonsillectomy: The proposed tonsillectomy had been referred to in a number of clinic letters dating back to 1993 but it was only in 1997 that a decision was made to proceed. As before witness W5398’s son was not attending the Haemophilia Centre at GRO-B for regular review (despite regular

invitations to do so) but was being seen locally in Ayrshire by a consultant haematologist Dr Paul Eynaud and it was Dr Eynaud who wrote to us in July 1997 with regard to the planned tonsillectomy which was initially planned to take place locally in Ayrshire.

41. It is evident from subsequent correspondence that there was a difference of opinion with regard to the surgery being carried out locally which we did not consider to be in keeping with UKCHDO recommendations for the safe management of surgery in patients with bleeding disorders. Guidance from UKHCDO states that surgical procedures should be carried out at a haemophilia centre. This is in order that there is supervision by a consultant with experience in haemophilia management and also that there is appropriate haemophilia nursing and laboratory support. This would be particularly important for a tonsillectomy, which is a procedure associated with a not insignificant bleeding risk, even in children without an underlying bleeding disorder.

42. Although there were tensions between GRO-B and Ayrshire with regard to the venue of the planned surgery I do not believe there was disagreement with regard to the planned haemostatic cover. In a letter of 25<sup>th</sup> August 1997 back to Dr Eynaud I state the following:

43. "As DM has not required FIX concentrate to date it would be important to try to cover the procedure with recombinant Factor IX. Recombinant FIX is due to be licensed next month and although we do not expect it to be available, or indeed funded until early next year we should be able to arrange a "named patient" supply for DM."

44. Although I am unable to re-call the details of subsequent events it would appear that our ability to obtain recombinant FIX for witness W5398's son at this time was unsuccessful. There is no documentation as to the exact reasons for this at the time but it may simply have reflected the reality that we did not have access to recombinant FIX at this stage for any of the haemophilia B children under our care, other than those who were eligible for the ongoing clinical trial which we had ethical approval for. Unfortunately witness W5398's son was not eligible for this trial as it was only open to children with more severe haemophilia B. The difficulty in

obtaining recombinant FIX at the time is supported by comments in a letter from Dr Eynaud to Dr McClure dated 5<sup>th</sup> February 1998 where Dr Eynaud reports comments from Dr Henry Watson in Aberdeen who stated that “he quite frankly was quite pessimistic about being able to obtain any recombinant FIX”. The letter also stated that “he quoted an incident where he tried to obtain FIX for a baby with Christmas disease and could not obtain it locally and had to enter the baby into the recombinant FIX trial in **GRO-B**”

45. In the absence of a readily available supply of recombinant FIX the options would have been to delay the surgery until the product was available or to use high purity plasma derived FIX. Given that witness W5398's son had not previously been exposed to plasma products and that this was elective surgery I think our policy would likely have been to suggest that the surgery was delayed.

46. This would clearly have been a disappointment to the family and it would appear that subsequently either witness W5398 or Dr Eynaud (or perhaps both) wrote to the recombinant FIX manufacturer (Genetics Institute in Paris) directly to implore them to provide product on a compassionate basis and were, perhaps surprisingly, successful in obtaining a supply to cover the son's surgery. I think this would have been quite unusual at this stage. The son's surgery was subsequently undertaken in July 1998 at the Haemophilia Centre in **GRO-B** using the product obtained on compassionate basis.

47. In the light of my 25<sup>th</sup> August 1997 correspondence to Dr Eynaud, I would dispute witness W5398's criticism that **GRO-B** “repeatedly refused” to obtain recombinant FIX. As a previously untreated patient we clearly felt that it would be in his best interests to receive a recombinant product and had indicated that we would aim to obtain a supply. In the event it would appear that we were unable to obtain the product in a suitable timescale for his surgery but I think this is likely to have reflected the availability of the product in Scotland at this particular time rather than an unwillingness to facilitate its use and would have been the same for any other haemophilia B child requiring treatment at this time. I think that the term “repeatedly refused” implies a lack of co-operation and resistance to acquiring the product which I don't believe was the case.

48. Comments regarding vCJD correspondence from around 2004: Assuming, as appears to be the case, that witness W5398's son had not received plasma derived products prior to 2001 he should not have been part of the 2004 vCJD notification process. Having reviewed both his GGC and AAHB case notes I can find no evidence of vCJD correspondence which would normally have been filed in the case notes. I note however that in 2004 witness W5398's son was actually registered at [GRO-B] who would therefore have been responsible for dealing with this correspondence (although I would still have expected copies to be in his AAHB notes).

### **Section 3: Other Issues**

**If you hold evidence you consider may be relevant to the Inquiry's investigation of the matters set out in its Terms of Reference, please insert here.**

49. None.

### **Statement of Truth**

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

Signed

[GRO-C]

Dated

28/11/2023

### **Table of exhibits:**

Date	Notes/ Description	Exhibit number
	Treatment Sheet	WITN7699005
19 January 1979	Letter from Dr [GRO-D] to Dr McEwan	WITN7699006
31 August 1979	Letter from Dr [GRO-D] to Dr Groves	WITN7699007
1 June 1982	Letter from Dr Lawson to GP	WITN7699008



13 April 1984	Letter from Dr Greer to Dr Fallows	WITN7699009
8 January 1985	Letter from Dr Greer to Dr Fallows	WITN7699010
24 July 1985	Letter from Dr <b>GRO-D</b> to Dr McEwan	WITN7699011
11 November 1985	Letter from K Spowart to Dr McEwan	WITN7699012
16-17 February 1986	Case record notes of 16-17 February 1986 by Drs Bowman and Spowart	WITN7699013
25 April 1990	Letter from Dr McEwan to Dr Cattanach	WITN7699014
28 February 1995	Letter from Prof <b>GRO-D</b> to Dr Cattanach	WITN7699015
2 June 1998	Letter from Dr Williams to Dr Eynaud	WITN7699016
5 January 2001	Letter from <b>GRO-B</b> to Dr <b>GRO-D</b>	WITN7699017
9 April 2006	Letter from Dr Alvi to Dr Eynaud	WITN7699018
20 November 2007	Letter from Dr <b>GRO-D</b> to Mrs Weilor-Mithoff	WITN7699019