Witness Name: GRO-B

Statement No: WITN5697001

Exhibits: WITN5697002 – WITN5697013

Dated: 26 July 2021

INFECTED BLOOD INQUIRY

STATEMENT OF GRO-B

I, GRO-B GRO-B will say as follows:

Section 1: Introduction

1. I am a 58 year old Type 1 diabetic who has been co-infected with Hepatitis C (genotype 1b) as a result of my husband receiving contaminated Factor VIII.

2. My husband was diagnosed from a very early age with a severe form of Haemophilia A with a blood clotting factor VIII of less than 1%. His younger brother had the same diagnosis and sadly died of HIV and HCV in 1995 aged 38. My husband and the wife of my brother-in-law have both provided separate statements.

3. My husband read articles in the library at university about HIV and blood products coming from American sources, which made him very anxious about taking his Factor VIII treatment. He therefore only took his treatment if he was in very severe pain. His brother took treatment as recommended, and as mentioned sadly contracted HIV as well as HCV. While we remain very relieved and grateful that my husband is still with us, he has developed very severe disabilities as a result of taking less Factor VIII than he should have taken, following his fear of also becoming infected, coupled with his lack of trust of

advice given by the medical profession. My husband and I married in GRO-B and I recall around that time, a batch of commercial factor being recalled due to being categorised as unsafe. This exacerbated his already existing reluctance to taking Factor VIII.

4. We do not know the date that my husband was infected with Hepatitis C but we now know, having recently seen his medical records while producing his Inquiry Statement (GRO-B) that, without his prior knowledge, an HCV test that was carried out in October 1989, which returned positive. Our recollection is that my husband did not discover he had been infected by HCV until around 1993 which was a very memorable and upsetting time, given that our first child arrived in GRO-B 1993. Following this I was tested for HCV in 1994. A tremendous amount of soul-searching then went on as we wanted another child, as we were worrying about the risk of transmission either to me or our unborn child. Nevertheless, as we had been advised that sexual transmission was rare, see attached **WITN5697002**, we decided to try for a second child, and our daughter was born in GRO-B 1996. I was extremely relieved to discover when I was tested again in 1998 that I remained clear of the HCV virus. Very sadly my husband's haemophiliac brother died as a result of HIV and HVC co-contamination in GRO-B 1995, aged just 38, and so never met our daughter.

5. My husband underwent his first treatment for his HVC (Interferon and Ribavirin) in January 2003, and a second course (Pegylated Interferon, Ribavirin and Telaprevir) in 2013, both of which were unsuccessful. The side effects of both treatments affected him badly (see Impact Statement GRO-B). We believe that it is most likely that I became co-infected as a result of skin lesions, he developed, which frequently bled following the psoriasis he developed during his first course of treatment (see How Infected). This being due to me having open finger prick wounds on my fingers from regularly pricking my fingers to measure my blood sugar.

6. I was diagnosed with acute hepatitis C in December 2005, then discharged in March 2006 having been told I had "sero converted" the virus.

7. Towards the end of 2013, while listening to a virologist on BBC Radio 4, I heard the virologist state that viruses are clever, and can hide in organs, then re-emerge sometime later. This got me thinking and troubled me sufficiently to see my GP. I had to persuade him to agree to another HCV blood test, and on 5 January 2014 I received a call from my GP to say the result showed I was positive for HCV.

8. During a hepatology specialist nurse clinic in December 2014, my husband and I were informed that due to more advanced testing that it remains probable that I had continued to have been infected since being first confirmed positive in 2005 (further details in below 2. How infected). It was however possible, that I had also become infected again by my husband.

9. In 2015 my husband received Harvoni treatment, and we were extremely relieved to learn that it had been successful. At the same time, we remained very worried to know how cirrhotic his liver was after so many years of HCV infection, including an elevated risk of liver cancer going forwards.

10. I received Harvoni treatment in 2016, after our daughter wrote a letter to the hepatology department to make a case for me to receive treatment, which I have also been told was successful.

Section 2: How infected

11. I have Type 1 diabetes, which is well controlled with Insulin and frequent blood sugar tests, involving me pricking my fingers to squeeze blood onto a test strip.

12. My husband commenced a combination treatment of Interferon and Ribavirin in 2003, which had serious side effects. At that time, I would prick my fingers many times a day in order to test and monitor my blood sugar levels.

13. As a side effect to the Interferon and Ribavirin treatment, in addition to extreme fatigue and flu like symptoms, my husband developed psoriasis and as a haemophiliac, the sores created by that condition would bleed a lot, including on to clothing and the bed linen. As a direct consequence of this, coupled with the

wounds left after my blood testing finger pricks, I believe that this is the most likely cause of my co-infection with Hepatitis C, having previously been tested and shown to be clear in 1994 and 1998 (see attached **WITN5697002 and WITN5697006).**

14. Given the level of precautions we put in place; including barrier techniques between my husband and I, and additional cleanliness/hygiene measures; keeping myself and the children away from all blood stains and avoiding sharing saliva (e.g., not sharing drinks and keeping tooth brushes separate), my wounds from regular diabetic finger-pricking seems to be the most plausible explanation for my co-infection.

15. I was diagnosed with acute hepatitis C in December 2005. This was very stressful, because I was experiencing symptoms of acute hepatitis, including a swollen abdomen, difficulty eating (which was very challenging as an insulin-dependent diabetic), dark coloured urine and light-coloured stools plus a jaundiced appearance. The yellow tone of my skin and eyes made my condition very obvious, which made attending work in a very visible role as a senior manager very stressful, both when becoming ill and also when starting to recover, but still showing these visible signs.

16. In March 2006 (after just 3 months) I was discharged after being told that I had "sero converted" the virus. Having now received and examined my medical notes in producing this Statement, I can see that there is no evidence of the two *negative* HCV blood test results referenced in correspondence, only the positive test results. We have asked the NHS Trust concerned to re-check their records numerous times, as well as checking the records at my GP surgery and while both have the letter referencing me sero-converting, neither have a copy of negative (no viral load detected) blood test reports. This raises a question about whether the nurse specialist might have viewed another patient's records in error, while writing the letter to discharge me?

17. In late 2013, while listening to a virologist on Radio 4, I heard the virologist state that viruses are clever, and can hide in organs, then re-emerge sometime later.

This got me thinking about the HCV virus and troubled me enough to arrange to see my GP. I had to persuade him to agree to another HCV blood test, and on 5 November 2014 I received a call from my GP to say the result showed I was *positive* for HCV having previously been informed that I was negative in 2006. Mixed emotions resulted; I felt devastated to discover I was still infected but at the same time relieved I knew, so that I could hopefully be treated and not risk infecting others. I have attached a copy of these positive HCV test records and my handwritten notes from the call I received from my GP at **WITN5697003**.

18. As my husband was Genotype 1B (which was common for Haemophiliacs exposed to infected Factor VIII), it was explained to us that this had a poor response to treatment and therefore was the toughest kind to clear. Due to my exposure to HCV from my husband, I had the same genotype when I became infected. This is also detailed in my pathology report in exhibit above.

19. Following my second HCV diagnosis in November 2014, I attended an appointment with Alex File (Hepatology Clinical Nurse Specialist) in Brighton on 5 December 2014 to discuss my diagnosis and potential treatment options, I inquired whether my discharge in March 2006 could have been a mistake (following what I had heard the virologist on Radio 4 state). Alex explained that since my original testing in late 2005 and early 2006, viral testing had become more accurate, due to new machines. She informed me that previously a viral load result below 30 was considered undetectable, whereas now (i.e. in December 2014) a result below 12 is considered undetectable, so it was possible that I had been discharged when today I may not have been if virus had still been detected at that lower level, see attached records at **WITN5697004.**

20. It goes without saying that my husband and I were very anxious and concerned at this turn of events and were desperate to find the right options with regards to treatment to clear the virus as soon as possible.

21. After a year had passed, our daughter wrote a very heart-felt letter to my Hepatology Clinical Nurse Specialist in December 2015, see attached records

at **WITN5697005.** In an attempt to make a case for me also receiving Harvoni treatment, following the success of her father's treatment. This was because I had mentioned to her that I had been told that there was an internal committee of senior medical specialists coming up where decisions would be made on prioritisation for who would receive Harvoni treatment next. This letter very clearly illustrates the trauma also being experienced by our daughter in relation both her mother's and her father's infection with HCV, and the loss of her Uncle, who sadly she had never met. I will cover this further under the heading "Impact". We were then relieved to learn that I was going to be offered Harvoni treatment, which started in March 2016. While I was told this treatment had cleared the HCV virus, given my medical history, and having read articles indicating a very small risk of viral rebound after treatment, this still remains a persistent worry that I have.

22. Having now seen the correspondence relating to this decision in my medical notes, I can see that I was approved for treatment given my exceptional circumstances in view of the risk of reinfecting my husband from my blood test finger-pricking (a case my daughter had put forward, based upon also being a waste of NHS resources, were this to happen!). This letter noted that I had "potentially been infected twice", but also indicating that there was also acceptance of the possibility that I may also have remained infected throughout. It also noted that I remained at increased risk of blood exposure myself, secondary to my regular finger pick tests. I was referred to Brighton and Sussex University Hospital in April 2016 where I attended a nurse led hepatitis clinic and was treated with Harvoni for 8 weeks. Upon presentation my viral load was 56126 with bilirubin of 23, APL 62, ALT 50, AST 39 and GGT 12. I have attached a copy of these records at **WITN5697006.**

23. I completed my Harvoni treatment in June 2016. It is noted that my HCV RNA was completely undetectable by week 4 and my liver function tests were normal, there were no significant symptoms following treatment and I recovered well. See attached records at **WITN5697007.**

24. A fibroscan carried out prior to treatment was recorded as 2.9kPa, which increased to 5.4kPa in 2017 (a year post treatment). I have attached a copy of these records at **WITN5697008.** I was relieved to know that despite this less good fibroscan result, my blood test showed HCV was undetectable. Due to the fibroscan result I was asked to return in 6 months for a review. Many follow up appointments ensued and I was finally discharged from the nurse led hepatology clinic in January 2019 after further fibroscan and blood test results had been reviewed, at which time my result was 3.6kPa, see attached records at **WITN5697009.**

Section 3: Other Infections

25. In September 2017 (one and a half years post the commencement of my Harvoni treatment) I was diagnosed with breast cancer. The tumour was an aggressive grade 3 invasive duct HER 2 Positive carcinoma. I completed a course of chemotherapy, radiotherapy, and a year of Herceptin infusions (a targeted HER2 therapy) and had to take 6 months off work. As I had no family history of breast cancer, ate very healthily, regularly exercised and had a perfect weight and BMI, I started to investigate if there might have been a cause and came across reports in America linking increases in aggressive liver cancer post Harvoni treatment. I then researched if breast cancer was also being cited and found a site seeking people to come forward who might have been affected.

26. I found an article by Stefano Brillanti, Professor of Medicine (Gastroenterology) - Hepatologist based in Italy, suggesting that immune surveillance may be reduced after Harvoni anti-viral treatment started, due to a very sudden drop in HCV viral load, leaving the body not fully equipped to fight the development of cancer. I felt that this effect could apply to many types of cancer, not just liver cancer, in which case my breast cancer may have resulted from this effect.

27. On 29th November 2017 I corresponded with a lady who had written on the site, having been treated for a rare and aggressive breast cancer, post Harvoni Treatment, in which I shared a link to the article I had found by Stefano Brillanti as well as what I was being told at hepatology clinic appointments, see

WITN5697010. This included a hepatology clinic appointment in October 2017, when the hepatology nurse specialist mentioned that the consultant had commented recently that there has been "a noticeable increase in the appearance of aggressive cancers post Harvoni treatment-too much to be a coincidence". She said that having noticed this increase they had raised this with NHS England and received a response to say this had been noticed and was already being investigated.

28. As the Hepatology department would be concentrating on what is happening with liver disease (so commenting on liver cancer only), I asked them to raise the question about whether there might also be a link to breast cancer (aggressive types) being triggered. The Hepatology Nurse Specialist said she was attending a meeting covering the liver cancers being seen post Harvoni treatment and would mention my question about breast cancer linkage. I was assured that my husband was being monitored so that they can detect any liver carcinomas matters more quickly, as per the HCC guidelines.

29. The clinic also met with a medical director and pharmacologist from Gilead (Harvoni manufacturer), who reported that there was no evidence to suggest that breast cancer was linked with Harvoni treatment. This did however lead to my case being reported as an adverse reaction to Harvoni via the Adverse Safety Register at the Food and Drug Safety Agency (FDSA) in America. **WITN5697011**. It was explained during a clinic meeting that it can take many years for cases to be reported, and for action to be taken (drugs taken off the shelf due to safety concerns). In America the adverse safety cases needed to reach 0.5%. Breast cancer cases linked to Harvoni was presently 0.03%.

30. However, further to a telephone conversation I had with the Hepatology Nurse Specialist, a suggestion still hung in the balance that it was theoretically possible that a two-week window could exist when immunity is disrupted by the fast-dropping viral load that results from Harvoni treatment. The letter and my handwritten notes in **WITN5697012** summarises the outcome of my inquiries and this telephone conversation I received about the letter.

31. With hindsight, I can see that my reaction to this new diagnosis of breast cancer demonstrates my heightened anxiety and in-built lack of trust that, both my husband and I have, towards medical advice given, and new medication prescribed, based upon our experience of having both become infected with HCV via his prescribed Factor VIII medication. This fear heightened by my husband having suffered ongoing ill health arising from his previous failed HCV treatments.

Section 4: Consent

32. In terms of co-infection or the full consequences of what my husband's diagnosis were, were not explained at any time to us and it only became fully apparent many years later.

Section 5: Impact

33. When I met my husband, he was the life and soul of a party, always making people laugh, and very adventurous, including touring holidays abroad. After he started receiving his first course of HVC treatment (Interferon/Ribavirin), in addition to the psoriasis he developed, I also noticed his personality had changed. We were aware that a side effect could be depression. Since then, I have noticed that he can became more easily irritable and anxious. He is also risk-averse sometimes, including being less happy socialising, especially if this involves meeting people he doesn't already know. Clearly having discovered that I had also become infected did not help my husband psychologically.

34. My husband was very badly affected by the death of his brother; his haemophilia soulmate. I remember to this day the phone call he received from his brother shortly before he died, and the devastating impact it had, not only on my husband, but also his wife and mother. His wife received very little support and has provided her own statement to the Inquiry.

35. My husband had never been a cuddly Dad with the children, partly due to his fear of having HCV and passing it on, and partly because of the difficulty he had

lifting the children or physically playing games with them, due to his arthritic and deformed elbows and knees, and weak wrists, resulting from his Haemophilia. This level of disability I now realise was much worse than it ordinarily would have been, due to his previous decision not to treat himself as much as he should have, due to the HIV risk. Once HCV infection had been confirmed, and then on top of this we were warned of a possible CJD risk due to my husband's Factor VIII treatment, this changed both of our behaviour, especially towards the children. I felt extremely anxious and conflicted over my husband's strong belief that our children should not be told about his HCV infection. He felt they could struggle to handle it and would become distanced from him, or treat him differently, potentially also acting strangely towards him in front of other people and "give the game away", given the huge stigma associated with HIV and HCV. As their mother however, I felt a very strong maternal instinct to protect them and wanted them both to know about the ways in which they needed to be careful to avoid inadvertent infection. I therefore reluctantly agreed to not tell them, but struggled even more, and more debates were had between us as our children became teenagers.

36. Maintaining silence about HCV infection from the children then also continued when I contracted HCV towards the end of 2005, after having been suddenly taken ill with symptoms of acute hepatitis. I had been so paranoid about the children not getting the virus (trying to stop them sharing a water bottles in the car with their father, being nowhere near him if ever he was bleeding e.g., having cut himself shaving or when taking Factor treatment), I simply couldn't understand how this had happened. I felt completely numb and extremely shocked, not to mention extremely ill. All we could conclude was that, being a Type 1 diabetic, I pricked my fingers for blood sugar tests many times during each day, so it was feasible that I had inadvertently touched some of my husband's blood e.g. on bedlinen while I was asleep. Unfortunately, having developed psoriasis following Interferon/ribavirin, combined with his haemophilia his skin sores, especially on his head regularly bled.

37. While in the acute phase I was jaundiced, so it was very apparent to people e.g., work colleagues, that I was ill. Our daughter has since referenced great worry

when I attended gymnastics competition, she was competing in aged 9, with my "yellow appearance", although at the time the children had appeared to have accepted the explanation that I was a little unwell with a virus.

38. Our daughter developed anxiety, which included great difficulty getting to sleep. In 2009, at age 13, I arranged for her to see a hypnotist specialising in childhood anxiety, who among other things, taught her the "blow away" technique to try to help her. With the benefit of hindsight, assisted by our daughter having studied Psychology at university, we have all come to realise that the Obsessive, Compulsive Disorder (OCD) she developed at age 14, which focused on excessive levels of hygiene to "avoid her coming into contact with bodily fluids" was very likely to have been caused by the anxiety we were feeling and the extra cleanliness rules I had put in place in her early childhood in an attempt to protect her and her brother from HCV infection. Our daughter would only drink out of disposable cups, or failing that, cups and glasses were to be personal to her and hand-washed by her before use. She also excessively washed her hair to avoid sweat or grease in her hair. Our daughter had also developed motor tics which had become particularly troubling when she was referred to a psychiatrist to seek treatment for both issues in 2010 when she was aged 14 **WITN5697013**. The Cognitive Behavioural Therapy (CBT) she received was helpful, but despite this, her adverse reaction to drinking out of anything that another person has drunk out of and also kissing remains an on-going phobia for our daughter, now she is an adult. Further therapy to help her with these remaining phobias is being considered. She believes that this amounts to "trans-generational trauma" created by the impact of HCV infection in the family.

39. In the summer of 2011, when our daughter was aged 14, I entered the bathroom to find, to my absolute horror, our daughter shaving her legs with her father's razor. The trauma I felt at that moment was immense. Our daughter remembers me crying and being quite hysterical, then explaining why. I felt anger and huge regret about my husband's insistence that we should not tell or warn the children, and that despite best efforts in stressing that they should not share things, they had been put at risk – the very thing I had always feared when agreeing to keep his diagnosis confidential. This led to both children (aged 14

and 17) being tested for HCV, as our daughter mentioned that she believed her brother had also borrowed his father's razor. To our great relief, both results returned negative. Understandably however, both children were concerned about having been kept in the dark, and felt let down by having been put at risk. I feared how this would play out, and whether they would feel they could trust us as their parents going forwards. Our daughter has since acknowledged that she probably would have acted differently towards her father, had she known. All of this family trauma being directly caused by my husband having received infected blood!

40. Being infected whilst enduring the considerable uncertainty about how the infection was passed to me and how it could be passed on to others, increased my stress levels greatly. I became increasingly concerned about exposing people around me to Hepatitis C. Whilst I was working full time it was the norm to "hot desk", where we would share desks and therefore keyboards, screens etc. I was always diligent but the fear of exposing colleagues to the potential risks following frequent pricking of my fingers to do blood tests, was never far from my mind, especially on hot days when bleeding sometimes continued after I had thought it had stopped. I told the first aiders to ensure they would know to wear gloves if ever I needed treatment, which was a hard thing to have to divulge.

41. Notwithstanding the fear of posing a risk to other people around me, there was the dreadful worry that I could potentially reinfect my husband who had successfully completed his Harvoni treatment and having spent previous years undergoing unsuccessful and harmful HCV treatment. I also experienced great stress, worrying about whether, during the 9 years when I had believed I was clear, I could have spread traces of infected blood around to those around me from pricking my fingers, including our children.

42. In 2013 when my husband was undergoing his second course of treatment (Pegylated Interferon, Ribavirin and Telapevir), we were warned about being vigilant for a red skin rash and advised that if it covered more than a percentage of my husband's body (from memory more than 50%, but it may have been a

higher percentage), it would be potentially life threatening and he would need urgent medical attention. I remember one day trying to work out what percentage of his body the rash covered, by adding together different percentages from his torso, legs, arms etc, which was not easy but also highly stressful as I understood how serious it would be if I got it wrong. I took photographs to help the assessment, and we decided that it perhaps was not quite at the stated percentage, albeit close. When we shared the photos at the next appointment they asked for copies and my husband's permission to be shared within the medical profession because it was such a good example of such a severe rash!

43. Over the years since I have known him, my husband has developed severe physical disability due to limiting and minimising his use of Factor VIII, having lost trust in the medical profession and fearing what else could go wrong from treatment he was being recommended to take. He would not for example, agree to take the medication prophylactically, which was against the advice of his Haemophilia Centre. This has severely limited the quality of his life as well as the life we have been able to lead as a family. He is often unable to sit in public places, such as in theatres, or travel on public transport, due to his knees no longer bending, his legs sticking out in front of him, and great difficulty in being able to sit down and stand up again. If he had not limited his treatment, in the way he did (especially following the death of his brother), we are certain that his physical disability would not have been nearly as bad is it is now. When meeting other haemophiliacs of a similar age at meetings leading up to and during the current Inquiry, there is a marked difference between the level of disability my husband endures, compared to other haemophiliacs. Again, all of this directly due to the impact of having received infected blood products.

44. Due to psychological stress and trauma caused to myself, my husband and our children, I wish my identity to remain confidential and I would like to fully exercise my right to anonymity.

Section 6: Treatment/Care/Support

45. My husband and I have been told that there is a discretionary fund available via the England Infected Blood Support Scheme (EIBSS) for us to organise counselling. To date we have not taken this up because it has been hard enough re-visiting all of these traumatic experiences over so many years while preparing for this Inquiry, that our preference at this time is to avoid delving even more on this via counselling. We are considering seeking some therapy (as opposed to counselling) for our daughter, to assist her with the phobias and anxiety that her experiences as a child that our HCV infections have left her with.

Section 7: Financial Assistance

46. As my husband has explained in his Statement, he left a very well-paid job in a director position, with a final salary pension, to set up his own company so that he could work from home due to the tiredness and other adverse effects he was suffering from his HCV infection. We have both had unrecoverable costs and time in attending various HCV appointments over the years and my husband still attends regular monitoring appointments involving scans and blood tests. We also paid towards the cost of the treatment our daughter received from a psychiatrist in 2005 (private medical cover from my employment paid the majority). Due to my employment terms, which included paid sick leave, I did not suffer any financial loss from any unpaid leave arising from my co-infection.

Section 8: Other Issues

47. I am wondering why patients who had previously been recorded in medical records as having sero-converted their HCV infection, were never followed up by the NHS to check they were still negative after more accurate testing equipment had been introduced? How many more people are there like me, who thought their immunity had removed the infection and are not aware that they may still be infected? I was fortunate to have heard a programme on BBC Radio 4!

48. Is there any risk of a link between Harvoni treatment and the subsequent development of aggressive forms of cancer, including breast cancer? I

understand that there is not currently felt to be a link. Only time will tell if a sufficient number of cases emerge. Indeed, even if they do, these cases may not be reported to the FDSA because those affected may not realise there could be a link with Harvoni, and that in these circumstances they should report their diagnosis to the Adverse Safety Register at the FDSA in America.

Statement of Truth:

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

Dated the 26th day of July 2021

Signed: GRO-B

GRO-B