Witness Name: Tracey Gillies
Statement No.: WITN6932060
Exhibits: Nil
Dated: 05/07/2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF TRACEY GILLIES

I provide this statement on behalf of NHS Lothian in response to the request under Rule 9 of the Inquiry Rules 2006 dated 29 September 2022.

I, Tracey Gillies, will say as follows: -

Section 1: Introduction

Please set out your name, address, date of birth and professional qualifications

1. My name is Tracey Gillies, my date of birth is GRO-C 1966, and my professional qualifications are MBChB FRCS. My address is NHS Lothian, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG.

Please set out your current role at the Lothian Health Board and your responsibilities in that role.

2. My current role is as Executive Medical Director with consequent responsibilities and as Responsible Officer for NHS Lothian.

Please set out the position of your organisation in relation to the hospital/other institution criticised by the witnesses (for example "NHS Foundation Trust ('the Trust') operates from Hospital X and Hospital Y (formerly Hospital Z)").

3. NHS Lothian is responsible for healthcare provision for the population of the Lothian area.

Section 2: Response to Criticisms by witness W2159

The criticisms the Board has been asked to respond to are set out at paragraph 19 (page 8), paragraph 20 (page 9) and paragraph 23 (page 10) of the witness statement of witness W2159 which state:

Paragraph 19

I am asked about when I found out about my infection. On the 24th June 1993, I went for my routine six monthly check up to the Haemophilia Centre. GRO-B GRO-B I went over to get my usual touch base appointment, to tell them how I was doing, get my routine bloods done, and have the usual check of my blood levels. I went into my appointment and I was seeing Dr Rosie Dennis on this day. During that appointment she informed me that I had been infected with Hepatitis C. She seemed quite shocked that I didn't already know that I had the infection. They had tested me without my knowledge the previous year. I had gone for an appointment on the 19th June 1992, again my usual appointment. I went in, got my bloods done and everything seemed absolutely fine. They sent that blood off on the 19th June. It was reported back on the 26th June 1992 that I had Hepatitis C. I exhibit this test result as WITN2159004. I wasn't informed of this test result until the 24th June 1993. So, it was a full year later before they told me the results, GRO-B. I was a bit shocked, I was at this appointment on my own, I then had to go back to work and process these details.

Paragraph 20

Rosie at this point explained what this meant, what the plan was from there, what they had hoped to do, to get some tests done to see what my liver levels were and what kind of damage the hepatitis had done at that point. She discussed the treatment that was going to be on offer for it. She said if I needed to come back and ask any more questions, that I was to not hesitate to come back and ask. But obviously at that point I was shocked. This was bombshell news, especially as it had been a whole year and I had been back to the centre on several occasions between the 19th June 1992 and the appointment in 1993. I had been back to the centre in December 1992 for a routine

appointment. Nothing was mentioned then. I had been back in for a couple of treatments, for a couple of bleeds. Nothing was mentioned at any of these appointments. I have no idea why nothing was mentioned for that whole year. I don't know if they overlooked it, or what they did. I have no idea, there is nothing in my notes to say why it has taken them a whole year. Rosie was amazed nothing had been mentioned. There was no mention at that appointment in June 1992 to say, there's a potential that you could have been infected with Hepatitis C, we need to do a blood test to check for this and request my permission. I wasn't asked if it was ok to test for this or anything like that. They just went ahead and did it and waited for a year before telling me. I don't know if I slipped through the net, but the results are in the notes quite clearly. I exhibit a letter prepared by Rosie Denis about my consultation with her in 1993 as WITN2159005.

Paragraph 23

I think that I should have been provided with the information earlier, the year before when they tested me. To be honest they must have known at some point the potential that I may have been infected with hepatitis C. I am sure they knew there was other hepatitises out there but they just didn't have a specific name for it. They should have provided a bit more information about the risks, that this was a high risk treatment, but it was never ever mentioned. I had a lot of issues back in 1984 with abdominal pain in my sides. I also had tests and treatment for it which was an ongoing thing. I did notice that one of my blood results in my notes around this time which was in 1984 had a test result- "GT" gamma globulin test, which is an indicator of your liver function. It did say when I googled this, that it can be an indicator of hepatitis or cirrhosis. That was raised back in 1984 quite significantly and they have ringed it in my notes, but nobody mentioned there was this issue at that time. This kind of makes me think that there was obviously something going on then. In 1982 and1983 the results were normal but in 1984 it was raised and abnormal and abnormal in 1988 when tested again. Nothing was picked up on by the look of my notes. At the very minimum they should have asked me in 1992 to test me for this, after making me aware that there was this risk that I had been infected. They must have known at that time what the risk was. Certainly once they had the result they should have informed me, they should have phoned me and spoken with me or spoken to me in person. Having been in numerous times over the course of that year, nothing was mentioned until the following year which is pretty poor, I think. I work in the medical profession myself and think that this was pretty poor.

4. In my role as UK IBI lead for the Board I received the aforementioned Rule 9 Request of 29 September 2022. I identified Professor Christopher Ludlam as the most appropriate people to consider and respond to the criticisms made. He has now done so and his response is set out below, in his own words.

Response of Professor Christopher Ludlam

5. I have been supplied with a poor and apparently incomplete copy of witness W2159's medical records held by the Royal Infirmary, Edinburgh. I have not been permitted, by the witness, to view a copy of the principal medical records.

Background

6. Witness W2159 (nee GRO-B) was born on GRO-B 1970 and diagnosed by Dr Howard Davies with von Willebrand disease as a one-year-old child in November 1971 following a mouth bleed. Her father and grandfather and other relatives had previously been diagnosed with the same condition. She was issued with a haemorrhagic disease card which recorded her condition. Clinically her disorder was moderate to severe in that she was prone to joint bleeds as well as other significant and distressing bleeding including nose bleeds especially as a child.

   Under Dr Davies' care as a child her bleeds were treated with cryoprecipitate and NHS factor VIII concentrate to cover dental extractions.

   From 1980 she came under my care. She was routinely reviewed at the Haemophilia Centre and treatment was initially with cryoprecipitate (when Desmopressin was not appropriate) and later Humate-P.

Routine monitoring for potential blood transmitted infections.

7. As for all patients treated with blood products, witness W2159 from 1972 onwards was regularly monitored at routine review clinic attendances with appropriate investigations which included a full blood count, inhibitors to coagulation factors and tests for liver and renal function. Patients were also screened for infections known to be transmitted by blood products. On 6 December 1972 she was negative for hepatitis B antigen and antibody. When additional viruses were identified with the potential to be transmitted by blood products these were also included in the screening arrangements, e.g., HIV and hepatitis A virus. She was aware of the HIV situation and requested in 1989 that she should not be tested.

   During the 1970s and 1980s it was suspected that there was one or more infectious agents (or possibly other causes), for which there was no specific laboratory test, that

resulted in non-diagnostic intermittent abnormalities in liver function test results. Although initially considered not to result in a serious condition of the liver, from 1985 onwards there was increasing evidence that it had the potential, in the long term, to result in significant hepatic problems in a proportion of patients. In the absence of knowledge of its cause, or causes, it was called non-A non-B hepatitis. In 1989 a virus was identified as the probable cause of most cases and named hepatitis C virus. The initial tests for the virus were relatively unreliable but by 1991 reliable tests had been developed. As a consequence patients were subsequently routinely tested for this virus as they had been previously for other viruses, e.g., hepatitis B.

Events surrounding witness W2159 learning of the diagnosis of hepatitis C in 1993

8. Witness W2159 was regularly reviewed every six months at the Haemophilia Centre, where she also appropriately presented with bleeding and other medical episodes. At these routine visits blood would be taken for a full blood count, tests for kidney and liver function and known blood-transmitted viruses, e.g., initially hepatitis B, but subsequently HIV and hepatitis A and C. The results of these investigation would be shared with patients at a subsequent visit (or earlier if there was a clinical indication, e.g., anaemia, was identified).

9. **June 1991**. She was reviewed at a routine clinic by Dr Young (Clinical Assistant) GRO-B GRO-B. On examination her right knee was noted to 'clunk' on movement. It was noted that her anti-HBs result had become negative (it previously had been positive on 7 November 1989 as a result of previous hepatitis B vaccination). He recommended and arranged further hepatitis B vaccination.

10. **December 1991**. She was again reviewed by Dr Young and it was noted that GRO-B GRO-B two days previously and on examination she had superficial bruising on her chest. Routine bloods were taken at the clinic. Dr Young subsequently wrote to her reporting that her anti-HBs level was still negative, recommending and arranging further hepatitis B immunisation.

11. **June 1992**. She was again reviewed by Dr Young when it was noted that she had not had any recent joint bleeds but had been troubled with some GRO-B GRO-B. Her right knee was again noted to 'clonk' on examination. Routine bloods were taken including liver function tests (which were subsequently reported as normal) and for a test for antibody to hepatitis C (as this had become routine practice). As her

anti-HBs was still negative she was given a hepatitis B vaccine injection and a further one was arranged two months later.

12. **September 1992.** GRO-B and was seen by Dr Dennis (Clinical Assistant), a swab grew staph aureus and she was treated with an appropriate antibiotic.

13. **December 1992**. She was reviewed by Dr Dennis who noted that GRO-B GRO-B. Dr Dennis explained that it was then policy to review patient's hepatitis A antibody status, as there had been instances of hepatitis A transmission from clotting factor concentrates. As her anti-HA test was negative, hepatitis A vaccination was offered and she agreed to the first injection in January 1993.

14. **June 1993.** Reviewed by Dr Dennis who recorded GRO-B GRO-B. The course of hepatitis A vaccine had resulted in the development of immunity as evidenced by the appearance of anti-HA antibodies. Despite further hepatitis B vaccinations anti-HBs antibody test continued to be negative. Dr Dennis explained that her anti-hepatitis C test was positive on a blood sample taken in June 1992. As she did not know that she was being tested for hepatitis C and the test was positive she was unprepared for the result and was upset. Dr Dennis had a full conversation with her about the positive test and the possible implications. Arrangements were made for her to see Dr Peter Hayes, Consultant hepatologist.

15. **August 1993.** She was reviewed at the combined clinic at the Haemophilia Centre with Dr Hayes and myself. She was particularly concerned because her wedding was in the near future. Dr Hayes, noted the previously mild intermittently elevated liver function test results, and that on examination he could not detect any clinical evidence of chronic liver disease. He explained the hepatitis situation to her (and her fiancée who also attended) and told her of the recommended investigations which were an upper gastrointestinal endoscopy and a laparoscopy to inspect the surface of the liver. Liver biopsy was not offered (because it can be harder to maintain haemostasis in von Willebrand disease than in haemophilia A).

16. **October 1993.** She was admitted briefly to the Royal Infirmary for the gastroscopy and laparoscopy which was covered with Humate-P.

17. **November 1993.** At a combined clinic with Drs Hayes and myself the results of the investigations were explained – the laparoscopy revealed mild inflammation and gastroscopy was normal. Dr Hayes explained about interferon therapy. She indicated that she would like to think about the offer before deciding.

18. **December 1993.** When reviewed by Dr Andrews (Clinical Assistant) at the Haemophilia Centre she said that she would like to have the interferon therapy. Arrangements were made for her to start in the following month.

19. **January to July 1994**. During the course of interferon therapy she was reviewed monthly at the Haemophilia Centre.

20. **August 1994**. She was reviewed by Dr Andrews having discontinued interferon therapy a month previously. Although her hepatitis C PCR test (which measured the amount of virus in the blood) had fallen 1000 fold, the virus was still detectable in her blood. She decided that she did not wish to have further therapy because the chance of successfully eliminating the virus was low.

21. Later she underwent a further course of combined pegylated-interferon and ribavirin therapy in 2002 which resulted in a sustained virological response to hepatitis C virus. She therefore appeared to have cleared the virus; long term she continued to be anti-hepatis C PCR negative.

Events in 1984

22. In 1984 witness W2159 GRO-B This was of sufficient severity that her school attendance deteriorated. She was admitted to hospital and extensively investigated and reviewed by Dr Heading, consultant gastroenterologist. She had evidence of GRO-B

GRO-B

GRO-B

Review of Liver function tests

23. I have reviewed the available liver function test results and it is clear that she has had an occasionally raised ALT (e.g. December 1983 -46, March 1987 – 48, November 1987 – 55, June 1990 – 74, (normal range 10-40)). The gamma glutamyl transferase

(GGT) had also been intermittently raised (e.g. December 1983 – 44, November 1984 – 73, March 1987 – 58 (normal range 5-35)).

Interpretation of liver function test results

24. In witness W2159's situation there are a number of possible explanations for her raised liver function tests which were observed over many years. Clearly hepatitis viruses were a possible cause. She appears not to have contracted hepatitis B infection, nor hepatitis A. She was a candidate for non-A non-B hepatitis from blood products and this is one of the possible causes for her intermittently raised levels.

25. GRO-B and this commonly causes abnormalities of liver function tests, particularly a raised GGT.

26. GRO-B

GRO-B and the GGT was mildly elevated. This can occur with many viral infections and is a non-specific response.

Summary

27. Witness W2159 has moderate to severe von Willebrand disease and has experienced many spontaneous and post traumatic bleeds all her life. Treatment with cryoprecipitate and factor VIII concentrates has been indicated for much of her life. Her response to a test infusion of desmopressin was assessed and found to be poor indicating that this therapy was unlikely to be effective in treating or preventing bleeds. The intermittent elevations of liver function test were noted in her medical records and it is likely that these will have been mentioned to her at subsequent review clinics. It is unfortunate and regrettable that she does not recall any discussion about these. It is possible that there were not full discussions of all possible causes.

    Over a period of many years either the ALT or the GGT was only mildly raised occasionally and was often at a time when there were a number of possible causes other than viral hepatitis. It is clear that she was aware of the risk of viral infections by the repeated testing for hepatitis B infection, particularly as she had a poor response to vaccination, from being aware that HIV had been transmitted by blood products, and later from the risk of hepatitis A. It is possible that she had not been made aware, or recalls, specifically of the possibility of non-A non-B hepatitis and its diagnostic difficulty prior to 1991. It is unfortunate that following the routine introduction of hepatitis C testing in 1991, she was either not informed about this and asked for her approval, or

she does not recall it being discussed. It was an oversight that the positive HCV antibody test result was not given to her when reviewed in December that year. Her reaction to learning the information was very understandable; Dr Dennis at the clinic was very concerned and spent some time helping to discuss and explain the situation. She was reviewed and appropriately investigated by Professor Peter Hayes for hepatitis C and she was found to mild hepatitis. Although the initial treatment with interferon failed to eradicate the infection, a subsequent course of pegylated-interferon and ribavirin led to a sustained therapeutic response.

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.

28. None.

Statement of Truth

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

Signed GRO-C

Dated 05/07/2023