Witness Name: Dr Elizabeth Mayne
Statement No.: WITN0736005
Exhibits: None
Dated:

INFECTED BLOOD INQUIRY

THIRD WRITTEN STATEMENT OF DR ELIZABETH MAYNE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 4 September 2019.

I, Dr Elizabeth Mayne, will say as follows: -

Section 1: Introduction

1.1 I would refer to paragraphs 1 to 3 of my written statement dated 20th May 2019.

1.2 This statement is based on my octogenarian memory as consultation with the patient's notes would be too onerous a task for my failing eyesight.

1.3 Prior to addressing specific criticisms it is pertinent to point out that Mr. William Trevor Marsden does not suffer from *severe* Haemophilia B. Definitions are provided below. They depend on the percentage levels of Factor IX in the patient's circulating blood. The severity of patient's condition and his Factor IX level are shown on each patient's Haemophilia card. Patients are advised to keep it with them at all times or otherwise wear a suitably engraved Medic - Alert bracelet. The latter became more popular as all too often the card went into the washing machine!

1.4 Definitions:-

(i) 0-2%: SEVERE

It is characterised by inexplicable and spontaneous bleeding into joints, muscles and occasionally into soft tissues, plus abnormal and prolonged bleeding following trauma or surgical intervention.

(ii) 2.5 - 5%: MODERATE

In this category it is usual for a degree of accidental or surgical trauma to occur before there is abnormal and prolonged bleeding. The diagnosis often may be made following the patient's first dental extraction. Inexplicable joint bleeding is not usually associated with moderate cases.

(iii) 5-25%: MILD

It is usually asymptomatic until adult life, and associated with severe trauma or surgical intervention. In such cases, if there is no family history of excessive bleeding and the diagnosis can be a shock.

1.5 Mr. William Trevor Marsden, or Trevor, as he was known to me, has moderate Haemophilia B (also known as Christmas Disease, after the first sufferer Robert Christmas, whom I was privileged to meet).

1.6 Trevor has never suffered from spontaneous joint or muscle bleeds. It is possible that both husband and wife thought that he did have the severe condition. Possibly neither truly understands the terminology, as Trevor's wife was clearly upset and surprised when she saw patients with the severely affected condition and its characteristic joint deformities who were present at the "HIV" meeting in 1985.

1.7 The patient was termed as suffering from moderate Haemophilia B in the discharge summary of the 1970s when he had a trauma induced ankle bleed which was treated with U.K. Factor IX Concentrate from Oxford. It was followed by the development of clinical jaundice and, as were the rules in these days, he was transferred to the N.I. Fever Hospital at Purdysburn.

Section 2: Responses to criticism of witness W1371

2.1 ***"In paragraph 11 of witness W1371's first statement, she recalls you stating that the date of witness W1372's infection with Hepatitis C ("HCV") was discovered through retrospective testing of witness W1372's blood samples, all of which had been kept and stored. Please comment on this."***

2.1.1 The patient developed clinical jaundice in the 1970s. It developed while he was in the Royal Victoria Hospital being treated for a traumatic bleed into his left ankle. In keeping with rules and regulations he was transferred to the Northern Ireland Fever Hospital. There, his blood was tested for all known causes of jaundice. The results were negative. Therefore, the Virology laboratory, as was their practice, kept an aliquot of the patient's serum to be retested in the future when other infections might be discovered or might evolve. I am also aware that the failure to retain an aliquot of patients' serum has, on occasion, caused criticism as the clinician in question was unable to determine the precise time of seroconversion to a viral illness.

2.1.2 The Hepatitis C Virus became isolated in 1991. Tests became available to detect HCV antibody around that time but tests for active HCV infection were not available until 1993. As far as I can

recall, I believe that the original 1976 sample was re-tested in 1991. In 1991 a further sample was taken and tested and a further sample was taken and tested in 1993, making three tests in all. The customary length of time elapsed between testing and results becoming available. Patients were seen as soon as possible after their results were received for consultation and discussion.

2.1.3 Present day practice would require oral or written permission to carry out viral blood tests. At the time in question, locally, nationally and internationally, expediency seemed paramount and specific consent was often not obtained. Quite unlike the situation relating to HIV testing, when no test was ever carried out without consent of the patient. Refusal to have any test was acceptable at all times.

2.2 ***"In paragraph 15 of witness W1371's first statement, she states that you should not have informed witness W1372 about his infection with HCV during a review appointment at which he had no support or family presence. In paragraph 21, witness W1371 further claims the manner in which witness W1372 was told about the infection was "criminal", and displayed a "complete lack of empathy" on your part. Please comment on this."***

2.2.1 At the time in question the witness presented himself as a mature adult and a married man. Although he was not seen frequently by himself I was well aware of his anxiety about his episode of jaundice in the 1970s almost thirty years previously.

2.2.2 Dr Orla McNulty (the only full-time medical member of the Haemophilia Centre staff) and a member of the nursing staff, either Sister Farell or Nurse Collete McAfee, and myself met with the patient. We sat together and chatted for almost an hour about the jaundice. It was pointed out to the witness that he had survived for 30 years feeling fairly well and that his liver function tests were good. We were unable to predict his future which may have been the aspect of the meeting which, en route home, may have caused the patient great anxiety. He may have forgotten but it was suggested at the time if he had any further questions or worries he could contact the Centre and make a further appointment. He also could make contact with the Centre's Social Worker.

2.3 ***"In paragraph 19 of witness W1371's first statement, she claims that witness W1372 should have been told about his HCV infection earlier. The witness further claims that witness W1372's medical records show that tests conducted in 1991 confirmed his HCV diagnosis, but that this wasn't communicated to him at the time. Please comment on this."***

2.3.1 The test in 1991 demonstrated that the witness had "met" the Hepatitis C Virus at some time. It showed that he had antibody but not active infection at the time of testing. He was clinically well.

Therefore he was not informed about this particular result. It was thought it might cause undue anxiety and worry. At that time, it was unclear what the future would hold for someone with such a result. By 1993, a test became available which could detect active Hepatitis C infection. It took time before the test came into routine use. The witness' definitive result of active infection was obtained in March 1996 and confirmed in August 1996. It was now felt important that he should know the findings hence the invitation to come and meet with the staff.

2.3.2 Some months later a specific Liver Clinic was set up for patients with Hepatitis C infection under the aegis of a Consultant Hepatologist. It had early teething problems but was firmly established by 1997.

2.4 ***"In paragraph 20 of witness W1371's first statement, she states that you were patronising during a consultation she attended with witness W1372. The witness claims she asked you several questions to which you did not provide answers and that you said that the witness was asking for more information than was necessary to know. Please comment on this."***

2.4.1 There was a considerable degree of confusion at this time caused by lack of precise knowledge as to how HCV would ultimately affect patients. I was fully aware of the situation, as I travelled on a monthly basis to meetings in Scotland and also to other meetings in the UK and Europe. Specifically, I tried to bring back knowledge to Northern Ireland and relay it to the patients. It was not always easy to answer the patients' questions. It was felt better not to speculate about what might or might not happen in the future. It is regrettable that the witness found the presentation of the paucity of information patronising.

2.5 ***"In paragraph 20 of witness W1371's first statement, she claims you offered to test her for HCV but at the same time told her that she did not have the virus. Please comment on this."***

2.5.1 I am confused about the contents of this paragraph. I think I was implying that it was very unlikely that the test should turn out to be positive but I was extremely willing to carry it out.

2.6 ***"In paragraph 22 of witness W1371's first statement, she claims that you said there was no risk of HCV transmission during unprotected sexual intercourse. Please comment on this."***

2.6.1 I do not recall this part of our conversation but the witness is probably correct that at that time I did not feel it was likely that HCV would be transmitted through unprotected intercourse.

2.7 ***"In paragraph 23 of witness W1371's first statement, she claims that you did not fully inform her of the implications of HCV***

infection, nor the risk of transmission, until 2006. More generally, she claims there was no openness or transparency in giving information about HCV to infected people and their families. Please comment on this."

2.7.1 This paragraph underlines the need for the witness and her husband to have discussed these matters with experts. During the early 1990s, concerns regarding the implications of having HCV infection grew by leaps and bounds. Clinical symptoms were developing and the most common complaint was of extreme lethargy, therefore, in 1995 a residential weekend for all patients and Centre staff was arranged. It was to take place in the Killyhevlin Hotel in Enniskillen. It was fully sponsored by 9 international pharmaceutical companies. A number of experts, both Virologists and Haemophilia Doctors came from England and Scotland to address the conference. In addition, they made themselves available to individuals. I have referred to the residential weekend at paragraph 6.2 of my first written statement of 20th May 2019.

2.7.2 I do not remember the witnesses being present at the residential weekend, at least I do not remember seeing or speaking with them on that occasion. If they were not present it is sad as they might have received much help and advice.

2.8 ***"In paragraph 25 of witness W1371's first statement, she claims that once she was informed of the risks associated with witness W1372's HCV infection, you implied that the smallest amount of blood or bodily fluids could transmit the infection to others, which she found shocking. Please comment on this."***

2.8.1 It is possible that the witness has confused some comments made by me when I tried to explain the difference between the two viruses. HIV was an easy virus to destroy once it came outside of the body. If blood was spilt the virus could easily be eliminated by using a warm cloth or some bleach to wipe it away. The HCV virus was more complex. It could exist within the human body for maybe 25-30 years without making its presence felt. It was unclear whether if blood was spilt containing active HCV, it could be as easily removed as HIV.

2.9 ***"In witness W1371's second statement, she describes a meeting she attended with W1372 which you held to inform patients about HIV and AIDS. In paragraph 8 of her statement, she claims that you stated all the haemophiliacs in the room would be tested for HIV because you were "erring on the side of caution". In paragraph 9, she claims that the patients were only given the option to choose whether or not they wanted to know the results of their testing, not to consent to the testing itself. Please comment on this."***

2.9.1 HIV testing was offered to all those who had been in receipt of blood factor concentrates. The witness is correct, because in carrying out such a

widespread testing it probably was "erring on the side of caution." However at the time of actually testing, the patient was invited to give consent and if they had any difficulty in doing it the test was easily postponed until a future date or not carried out at all in accordance with the patient's wishes. Several patients postponed testing but none refused. It seemed only right and proper that they should be given the opportunity to know or not know the results. One of the secretaries took a note of the names of patients who did not wish to know the result. The witness' husband decided that he did not want to be tested at the time and he did not wish to know the result. This was noted. Then the witness herself requested to be given the result. Her husband looked surprised and I think possibly I raised my eyebrows.

2.10 ***"At paragraph 11 of witness W1371's second statement, she claims that the thing the attendants of the meeting wanted most was to know more about HIV and how at risk they were. However, witness W1371 claims that no one was provided with information about, nor counselling for, HIV. Please comment on this."***

2.10.1 In response to this paragraph each patient when tested received the maximum amount of knowledge available and was offered appointments at any time to discuss important issues relating to HIV.

2.11 ***"At paragraph 14 of witness W1371's second statement, she claims nobody was prepared to speak up against you. Please comment on this."***

2.11.1The content of this paragraph is extraordinary. Patients always had free access to staff members to discuss whatever matters they felt were important. Frequently many patients availed themselves of the facility. I could not possibly enumerate the number of hours I spent counselling patients on a one to one basis.

2.12 ***"At paragraphs 15 and 26 of witness W1371's second statement, she claims that you were patronising and belittling to her when she asked to know the results of witness W1372's testing. Please comment on this."***

2.12.1 To the best of my knowledge I have never stooped to patronise anyone. I have too much respect for the needs of all patients at all times.

2.13 "***At paragraph 23 of witness W1371's second statement, she claims the period of time in which she and witness W1372 had to wait for the result of the HIV testing was highly stressful. She states that there was no advice about what to do in the interim. Please comment on this."***

2.13.1 The carrying out of HIV testing was complex and time-consuming quite contrary to the present day when results utilising DNA technology may be available on the day of sampling. In the 1980s it was customary to

confirm the original result by a second testing before telling the patient. In such a vital testing one had to ensure that no mistakes took place in sampling or labelling. All patients had to wait a similar length of time for the results. It would have been invidious to offer advice or speculate on results during the interval between testing and results.

2.14 ***"At paragraph 25 of witness W1371's second statement, she claims that the haemophiliacs who attended the meeting should have been cautioned that there were likely to be financial implications for them if they tested positive for HIV. Please comment on this."***

2.14.1 The witness is making comments about the situation as it was in 1985. No one was then aware of the implications of a positive diagnosis. The layman's response from then on at times was bizarre. Medical colleagues did not wish to sit beside me at meal times! One could not see the extraordinary implications of the tragic HIV situation and certainly there were other priorities to deal with clinically other than being concerned about financial implications of the diagnosis.

2.14.2 Much later following a vigorous campaign involving myself and many others in the U.K. we achieved a lump sum payment to be made to affected individuals. I was involved with the Macfarlane Trust to provide help for those who were affected over and above the original lump sum payment. The Eileen Trust was also set up in parallel to aid those infected through receiving blood transfusions in the U.K.

Section 3: Responses to criticism of witness W1372

3.1. ***"At paragraph 14 of witness W1372's first statement, he claims that he was not informed prior to his diagnosis with HCV that he had even been tested for it. He further claims that he was not informed he had been tested for Hepatitis A and B or HIV. Please comment on this."***

3.1.1 It is apparent that the witness genuinely believes the content of this paragraph. However, he was tested for Hepatitis A, and Hepatitis B in the 1970s and then many years later for HIV with his express permission for the latter.

3.2 ***"At paragraph 16 of witness W1372's first statement, he claims he was not told about his HCV infection for five years. He further claims he would not be surprised if the infection had been identified years before he was told, as his blood samples were regularly taken from him in visits to the hospital. Please comment on this."***

3.2.1 Regular blood samples were taken from patients at all visits to the Centre. This was to ensure that they had not developed an inhibitor to their own specific clotting factor as this would alter their future management to a significant degree. As previously stated in earlier

responses, samples from the 1970s were retained as was customary in the protocols of the Northern Ireland Virus Laboratory. The patient's final diagnosis of active HCV was not made until after the 1993 test was in routine use, i.e. in 1996. Prior to that time he was designated as having Non A, Non B Hepatitis.

3.3 ***"In paragraph 17 of witness W1372's first statement, he states that you did not tell him anything about HCV besides the fact that he was infected with it. In paragraph 20, he states he was only given information about HCV when he was called back to discuss Interferon treatment. It was in this consultation that you told him he may have been infected by blood products administered for a sprained ankle in 1976. Please comment on this."***

3.3.1 Opportunities were provided for the witness to obtain information on HCV infection but he is quite correct that he was infected at the time of his sprained ankle in 1976, when he was treated with Oxford Factor IX.

3.3.2 During the early 1970s there was no concentrate or product available designed specifically to treat patients with Haemophilia B. In order to ameliorate this situation I contrived to produce locally a product to correct the Factor IX deficiency. I took my research to Dr Ethel Bidwell in Oxford. She was head of Blood Transfusion and the Plasma Fractionation Unit. I told her of my research orally at the end of a U.K. Haemophilia Directors meeting. She was unimpressed. I left the details with her and returned to Belfast with "a flea in my ear". I went to work late the next morning to be greeted by the departmental staff who told me that someone from Oxford had been on the phone three times and would I please return the call immediately.

3.3.3 The call came from Dr. Bidwell who commented on my research and said that it was amazing. She further informed me that Lille and the C.N.T.S in France had just perfected a similar process. Their product would be released in about 6 weeks' time. It was being called PPSB. She was disappointed on my behalf that my research was too late for implementation. A vigorous discussion took place about the manner in which discoveries are made i.e. in different parts of the world, similar ideas are engendered simultaneously. At the conclusion of our phone call, she suggested that Oxford would send us in Northern Ireland some of their own Factor IX concentrate. At the time it was not freely available and Northern Ireland was fortunate to receive such material manufactured from volunteer plasma in England.

3.3.4 The Oxford Factor IX was coded 9D. This was given to the witness in 1976. Commercial products were not introduced until the mid-1980s when U.K. supplies were unable to cope with demand.

Material was imported from Europe or the U.S A. It occurs to me that the witness might have been re-infected or developed a second infection with a different Hepatitis C subtype. It could have occurred following receipt of imported commercial Factor IX in 1983. I would refer to the blood bank notes exhibited to Mr. Marsden's statement.

3.3.5 The 1976 episode of jaundice affecting the witness was documented and referred to The Hepatitis Working Party of the UKHCDO.

3.4 ***"In paragraph 22 of witness W1372's first statement, he states it would have been helpful if he was provided information about his HCV infection sooner. He claims this information would have helped him act quicker and be more careful with his health. Please comment on this."***

3.5 ***"In paragraph 23 of witness W1372's first statement, he claims you informed him of his infection in a cold manner, showing no compassion or empathy. He states he was "left to deal with a virus which [he]thought they could do nothing about." Please comment on this."***

3.5.1 In response to both 3.4 and 3.5, the witness would have benefitted if he had been able to attend the Enniskillen residential weekend as referred to at paragraph 2.7.1 above.

3.6 ***"In paragraph 26 of witness W1372's first statement, he claims that when W1371 asked you if she was at risk of being infected through intercourse, you told that she would be "absolutely fine". He claims the risk of transmission to W1372 was in fact very high, and it was a miracle his son was born without HCV. He states he was never given any advice regarding the risk of transmitting HCV, and this was something he only discovered years later through articles and the media. Please comment on this."***

3.6.1 I do not recall this conversation with the witness. I have no further comments to make about the contents of this paragraph.

3.7 ***"In witness W1372's second statement, he describes the meeting he attended with witness W1371 described above in paragraph 2.9 onwards. In paragraph 5 of his statement, he claims he was not asked if he wished to be tested, and was not given any information about HIV. Please comment on this."***

3.7.1 Sadly the contents of this paragraph are inaccurate.

3.8 ***"In paragraph 13 of witness W1372's second statement, he claims the issue of HIV testing of haemophiliacs should not have been***

discussed in an open forum, but should instead have been done on an individual private basis. Please comment on this."

3.8.1 Three open meetings were held regarding the problems of HIV infections. Two were held within the confines of Ward 37, RVH. In addition to patients attending the meetings, RVH members of the porting, catering and cleaning staff were all invited to attend and express their worries and queries about HIV infection. The staff expressed much gratitude at having all their problems aired and clarified. Unfortunately, the meeting to which the witness and his wife attended had *per force*, to be held in an alternative venue. This was because a terrorist episode had necessitated the occupation of all bed space in the hospital.

3.8.2 The alternative venue was unsuitable for severely affected patients as the seating was not appropriate for patients with severe joint disabilities. Therefore, proceedings were foreshortened and perhaps not as much information as previously was presented. I seem to recall that on this occasion Professor John Bridges, Head of Academic Haematology and Consultant Clinical Haematolgist attended as a support for myself as I had been up all the previous night on emergency hospital business. It was neither practical nor possible to carry out long consultations on an individual basis, but the situation was addressed as far as possible when the person was having the test carried out.

3.9 ***"In paragraph 6 and 7 of witness W1372's second statement, he states that you made a "big thing" out of the fact that he didn't want to know the results of his HIV test but witness W1371 did. Please comment on this."***

3.9.1 I do not recognise the witnesses' comments in this paragraph.

3.10 ***"At paragraph 11 of witness W1372's second statement, he claims it was not appropriate to inform witness W1371 of his test results via letter. Please comment on this."***

3.10.1 There was no intention to relay this information but the secretarial staff had a difficult job to complete and they would have assumed despite the clipboard entry that you would be pleased to know the negativity of the result. It was the policy of the Centre not to send positive information via a letter either patients were told when they came to the Department or else I myself visited them to discuss the positive results.

3.11 ***"At paragraph 12 of witness W1372's second statement, he claims that he should have been tested for HIV earlier than he was. Please comment on this."***

3.11.1 HIV testing was carried out at the earliest opportunity.

Section 4: Other Issues

4.1 I would refer to section 3 of my statement of 20th May 2019.

Statement of Truth

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

Signed GRO-C

Dated 30th September 2019.