Witness Name: Dr Elizabeth Mayne

Statement No. WITN0736006

Exhibits: N/A

Dated: 21 February 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ELIZABETH MAYNE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 3 December 2019.

I, Dr Elizabeth Mayne will say as follows: -

1. In order to further elucidate my speculation, I will provide the Inquiry with conclusions gleamed from considering the infectivity and clinical manifestation of three viruses:-

    a) The Human Immune Deficiency Virus (HIV)
    b) The Herpes Simplex Virus (The cold sore virus)
    c) The Hepatitis C Virus (now HCV, previously known as non A and non B Hepatitis)

    Where and if appropriate I will reference documents, already encoded for witness W1372 and available to the Inquiry.

    HIV

2. Statistics: It is not difficult to recall the data for the overall U.K. percentage of treated Haemophilia patients who became infected with HIV. I believe it to be 44.5%. Some regions in England and Wales attained figures greater than 70%. The comparable figure for Northern Ireland (N.I) was 14.5%, clearly anomalous. I well recall presenting the NI data to a meeting of the United Kingdom Haemophilia Director's Organisation (UKHCDO) in Autumn 1985. Some colleagues, not unsurprisingly were politely sceptical about the veracity of the results. Further testing was carried out by all centres. In NI I organised for all samples to be tested in

duplicate and simultaneously in the Belfast Virology Laboratory and in the Middlesex Hospital (London). *The NI results were unchanged.*

3. An examination of the figures pertaining to Scotland helps provide a clue as to the discrepant results. The late Doctor Howard Davies, the Senior Scottish Haemophilia Centre Director maintained that all patients in Scotland should be treated with locally derived product manufactured by the Scottish National Blood Transfusion Service (SNBTS). His successors maintained his policy. Initially the figures for HIV infection ran parallel to the NI figures. The situation changed when unwittingly a volunteer gave a blood donation in the "window" of viral infection; namely, after becoming infected and before the screening test became positive. I do not remember the number of patients who became HIV positive as a result of this tragedy. The group became known as the Edinburgh cohort. Its existence raised the Scottish figures to more than those in Northern Ireland, and yet still significantly less than in England and Wales.

4. All statistical details were lodged within the UKHCDO secretariat, which until my retirement in 1999 was located in the Churchill Hospital Oxford. I believe it may have been re-located.

5. The NI Figures and how they were achieved provided yet further pointers regarding the infectivity of HIV. The Northern Ireland Blood Transfusion Service (NIBTS) did not have the capability to manufacture concentrate. It provided local volunteer derived, single donation cryoprecipitate. Therefore, in the mid 1970's when I initiated a Home Treatment Programme (HT) for severely affected patients commercial Factor Concentrate had to be used. The following policy for the NI Haemophilia Centre was drawn up by myself and is as follows:

    i) All HT patients would be treated with only one product: KRYOBULIN Immuno Ltd Vienna

    ii) All non HT patients would be treated with HEMOFIL Travenol Laboratories USA.

    iii) All children would continue to be treated with cryoprecipitate. There were 2 exceptions; namely 2 severely affected children who were entered into the HT group.

    No child became HIV positive in Northern Ireland.

6. At the time there was little scientific basis for the preceding policy, merely my innate apprehension about injecting material repeatedly, and at frequent intervals by the intra venous route, into young patients.

7. At the time, I used what I considered to be the best and safest product for those patients who logically would need/use the most Factor, namely the HT group. I selected KRYOBULIN because I found the Company business-like, straightforward

and their packaging was ideal. Incidentally, the source of their donors was within Europe. The second product for the non HT patients was Hemofil, with which I had been familiar for several years, from 1971.

In summary the products used within the Centre was as follows:

a. HT Group KRYOBULIN Immuno
b. Non HT Group – Haemophil Travenol Ltd USA
c. Children Cryoprecipitate (NIBTS)

However, demand exceeded supply within the HT group. The patients found that using the prophylaxis resulted in a normal lifestyle. UK wide knowledge of good results in NI, plus increased demands, resulted in Immuno being unable to fulfil NI orders. Therefore, a further supply of Factor VIII was obtained from Armour Pharmaceutical Ltd USA.
In later years when heat treated product became available supplies were received from SNBTS and Elstree. No supplies were received from the Republic of Ireland.

8. Results:- Of the 110 annually treated patients, 43 were on Home Treatment (HT). Of this group 15 became HIV positive. The patients had received comparable amounts of Factor Concentrate to those in the rest of the UK. The 16th positive HIV patient was a spouse within the HT group. *There were no positive patients in the non-HT group and no children sero converted.*
The number 16 is accurate however, the final number included in the HT group may be 43 or 47, my memory eludes me.

9. A conjectural conclusion may be appropriate; I speculate that repeated injections of treatment regardless of plasma source may induce a degree of immune tolerance, perhaps mediated through alteration within the Complement system? It does not seem to matter whether the treatment is Cryoprecipitate, or Concentrate sourced in Scotland, Europe or the USA.

Figures from Scotland and NI would indicate the Cryoprecipitate may well have been the safest product available at that time. However, it was cumbersome to use, accurate dosage was impossible and HT impracticable. The advent of Factor VIII Concentrate in small vials and with accurate dosage revolutionised life for the Haemophilic patient.

Furthermore, an alternative explanation might have a straightforward numerical basis. Each company utilised approximately 25,000 donors. If, due to large patient numbers, financial constraints or problems relating to product availability any one patient could be treated with 2, 4 or even up to 6 different products, thus their exposure could be increased even to 125,000 donors, leading to the possibility of increased viral conversion.

Regardless of underlying reason, there seems to be a definite pointer to the fact that patients do better on one product.

10. In further support of this, one severely affected patient was treated with a batch of a new concentrate which was contaminated by HIV. The Company, Armour Pharmaceutical Ltd USA informed me after it had been used. The patient was in the HT group and thankfully did not sero-convert. He was witness GRO-A

11. Herpes Simplex Virus

The Inquiry may be perplexed by reference being made to this virus. It was prompted by the sight of the painful eruptions of the virus infection in several non-haemophilia patients. They reminded me of the complex behaviour of the Hepatitis C virus. Both exhibit dormancy. In Herpes simplex infected individuals, the presence of the virus is non apparent, until its activity is triggered by the co-existence of another virus, e.g. the common cold or influenza, further it can be stimulated into activity by prolonged exposure to sunlight. Other viruses such as varicella (chicken pox) behave in a similar fashion.

This dormancy and triggering mechanisms are common to both infections.

Hepatitis C (HCV)

12. This seems to be the most complex virus and most insidious in its behaviour. It may lie dormant for years. The witness W1372 was asymptomatic for almost 30 years, but once the devastating clinical fatigue developed - the patient's life became unbearable.

13. Prior to 1991 HCV was termed non-A non-B Hepatitis. After that year tests for HCV antibody were developed. Rapidly followed by tests for the presence of viral and RNA and viral sub-types. Eventually anti-viral treatment was monitored by viral load testing from a single blood sample.

In summary the virus:-

- may or may not cause clinical jaundice
- may or may not cause initial abnormal liver function tests
- may or may not lie dormant for up to 30 years.

14. The witness W1372 did have clinical jaundice with abnormal liver function tests in 1976. He had no further clinical symptoms for 30 years.

15. In 1995 his HCV test demonstrated the presence of HCV *antibody*. The interpretation of this result indicated that he had encountered the HCV virus previously but did not

have current clinical infection. Thereafter, in 1996 his test result indicated the presence of viral RNA.

16. If the analogy with Herpes Simplex is valid, it would be reasonable to suggest that witness W1372 had been infected by an episode of triggering viral infection. He was commenced on appropriate therapy for HCV but continued to have serious clinical symptoms of viral infection and side effects of treatment.

17. Analysis of his treatment data showed that he received Factor IX in Feb of 1992 (BioTransfusion Ltd, UK) it is possible that this treatment introduced a different sub-type of Hepatitis C. There is no proof.

18. The witnesses record of Factor IX treatment indicated that in total he received products from five different sources. He was treated with Oxford Factor IX on the majority of occasions. However, on isolated occasions, he received concentrate Prothrombplex, on another occasion Replinine, also one treatment with Alpha IX, and finally from BPL (Elstree) (see exhibit WITN13720002). It is not possible to pinpoint any particular product as the cause of his original HCV infection or speculated re-infections.

19. However utilising hindsight, it would seem reasonable that the policy of using one product for one patient, to me, might have been beneficial for all patients.

20. **Conclusion:** To speculate is defined as to form a theory or conjecture without any firm evidence (definition from the OED, 2004 Edition). I have gleaned that repeated intravenous injection of concentrate regardless of plasma source appears to reduce the incidence of HIV infectivity. It is not possible to make a similar statement for the infectivity profile for HCV infection.

Other Information

21. In addition, I would like to offer further comments having read the transcript of the deposition of the witnesses Trevor and Louise Marsden as presented to the Inquiry on 8 October 2019. I would like to draw attention to two inaccuracies at the commencement of the transcript and to comment on a further observation of one of the witnesses. (W1371).

22. There was no Doctor Jones in the Royal Belfast Hospital for Sick Children. Trevor would have been under the care of Professor (then Dr) John Bridges. In addition, the transfer age to adult care in The Royal Victoria Hospital was 13 years of age, not 18.

23. I suspect Trevor may have become confused by the name. Doctor Frank Jones acted as locum Consultant to the Adult Haemophilia Centre during the Interim between the tenure of Dr Julia Anderson and the arrival of Dr Gary Benson, both of whom were appointed as full time 'haemophilia' medical consultants, unlike myself who was appointed in 1972 as a full time clinical haematologist with an interest in bleeding and clotting disorders.

24. Later within the deposition of Louise Marsden she referred to the 1985 HIV meeting as bizarre. She was completely correct in her description. I agree. The explanation is as follows. I had been up all the previous night dealing with the unclottable blood of a patient in the Intensive Care Unit. The hospital was full to capacity. Therefore, the normal venue for the meeting was unavailable. It had been commandeered for emergency bed space. I think the full capacity was related to an increased incidence of influenza and pneumonia. However, the only available space for the meeting was the historic Old Surgical Extern Theatre. It was unsuitable in every respect. The space was confined; the seating was unsuitable for disabled patients and the general impression inhibitory. It was not possible to cancel the meeting as transport had been arranged for the disabled patients and others were coming from far afield e.g. Londonderry, Strabane and Enniskillen. Professor John Bridges attended as support. He was concerned that I might pass out from fatigue. I have not discussed this aspect of the meeting previously as it seemed irrelevant. However, in view of Louise Marsden's apposite description I thought I should enlarge on the detail to the Inquiry.

Statement of Truth

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

Signed GRO-C

Dated 21-2-2020