Witness Name: James Digings
Statement No: WITN0659001
Exhibits: WITN0659002
Dated: 25 October 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF JAMES PHILIP FRANCIS DIGINGS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 13 December 2019.

I, James Philip Francis Digings, will say as follows: -

Section 1. Introduction

1. My name is James Philip Francis Digings and my date of birth is GRO-C GRO-C 1957. My address is GRO-C GRO-C. I am semi-retired and live with my 92-year-old mother. I do some freelance writing and sub editing online and I play the drums in a band.

2. I graduated from the London University with a degree in Classics in 1984 and as a graduate I drifted into the Civil Service as an Executive Officer (EO) in the Lord Chancellors Department. After a year in this position, I moved to the Committee for the Safety of Medicines (CSM) at Market

Towers, Vauxhall. My responsibility was to take minutes for the CSM and for its sub-committee on Biological Products.

3. I did also take minutes for smaller meetings and for admin professionals.

4. I later became the PA to the Head of the Department, which involved finding material to answer questions that arose. I remember having to read through Hansard daily to see if anything relevant was discussed in parliament. The Head of the Department at the time was Norman Hale. He would be privy to the matters discussed in the CSM and sub committee meetings but would not usually be present.

5. I did not take up any promotion to pursue a career path in the Civil Service and remained an Executive Officer for 10 years at the CSM, before accepting a job offer to become a bookshop manager.

6. In September 2018 I heard something on Radio 4 about the Infected Blood Inquiry and it occurred to me that I took the minutes for meetings where the licensing of blood products was discussed. I decided to email the Inquiry so I could contribute any information known from the meetings.

7. I confirm that I have chosen not to be legally represented and that I am happy for the Inquiry team to assist me with my statement.

Section 2. Committee for the Safety of Medicines

8. The Sub Committee on Biological Products was one of the three sub committees of the Committee for the Safety of Medicines (CSM). It would meet every two months and its purpose was to make recommendations on biological products for the CSM to consider at its next meeting. The CSM would meet monthly.

9. The chairman of the sub committee on Biological Products at the time was Dr John Hargreaves. He was also a member of the CSM, so would present the recommendations made by the sub committee.

10. Both the CSM and the sub committee on Biological Products met at Market Towers, Vauxhall. Approximately 40 people would attend the CSM meetings and around 15 people would attend the meetings of the sub committee.

11. Twenty individuals would attend the meetings of the CSM permanently and around 8 individuals for the meetings of the sub committee on Biological Products.

12. Sir John Badenoch is a name that comes to mind as being one of the prominent members of the sub-committee, but I am sure I would recognise other individuals listed in the minutes. I do not recall his capacity, but he was an expert in the medical field.

13. GPs were not present at the CSM or sub-committee meetings.

14. The sub committee on Biological Products would meet for around 2-3 hours, but the CSM would meet for the whole day as they had a lot more to consider.

15. Usually an hour would be spent discussing a particular topic.

16. Our office consisted of 2 Executive Officers and 2 Administrative Officers and our responsibility was to put the agenda and minutes together for the meetings of the CSM and its Sub Committee on Biological Products. We had a good team but it was very busy.

17. The Higher Executive Officer was Keith Fowler and his principle was Geoff Grimshaw, who was the secretary to the CSM. David Haggar was a senior civil servant and the head of the department was Mr Hale.

18. Nearly every medical or scientific official in the department would have belonged to one of the sub-committees.

19. An agenda was always sent out prior to every meeting and it was the responsibility of the Administrative Officer (AO) to distribute the agenda to attendees.

20. Recommendations of the sub committee were made on recommendation sheets, which would be copied onto the CSM agenda for discussion. The CSM would decide whether to grant a licence for the drug product. If rejected, the company could make a written representation or attend a hearing.

21. Hearings would involve the drug company visiting one of the CSM's meetings to make a presentation on their product and answer any further questions. A decision would be made by the CSM afterwards and sent on to the drug company.

22. If any clarifications were required, the CSM would have corresponded by letter and memo, but I was not involved in such correspondence.

23. If the CSM agreed to the recommendations made by the sub committee on Biological Products, they would be sent straight to the pharmaceutical company to implement.

24. The CSM was very keen for pharmaceutical companies to monitor the drugs produced.

25. Experts in particular areas would often be called in to the sub committee meetings to provide advice on the drug products.

26. I do not recall any major disagreements during the meetings of the sub committee and it was always a pretty informal discussion.

27. The minutes were always commercial in confidence as the material was confidential and could not be disclosed outside of the meetings. I presume the minutes would have been distributed to only those present at the meeting.

28. The drug companies would not have been told of matters reported in the minutes, as the CSM communicated only formally with them.

29. Many of the attendees to the CSM and sub committee meetings also worked for drug companies. I recall a discussion over whether people should declare their interests. Just before I left a disclosure of interest policy was implemented, requiring attendees to declare if they were involved with any drug product. From what I remember, if they had a direct interest with a drug product they would have to leave the meeting, but if they merely worked for the same company without a direct interest to the product, they could still sit in on the meeting.

30. The attendees were top experts in the pharmaceutical field, so even if they were also working for the drug company being discussed, they would still have relevant information to contribute.

31. I do not recall the sub committee on Biological Products directly considering issues which are relevant to the matters under investigation by the Inquiry. The committee existed just to license products, so was involved at the preliminary stage of drug supply.

32. I definitely remember vCJD being discussed in the meetings, but more in relation to human growth hormone than factor products for haemophiliacs. From what I can recall, the discussions on vCJD were very pragmatic and scientific.

33. There was a lot of discussion around scrapie and whether prions (disfigured molecules) could be transferred from sheep to humans

through the food chain. Senior individuals from the Ministry of Agriculture, Fisheries and Food (MAFF) provided input to the debate.

34. I had the impression that the CSM was rightly cautious to ensure everything was safe for use. The CSM, at least at my time, seemed to err on the side of caution, perhaps to avoid any repetition of the 'Opren' case, where the drug gave arthritis relief to many, but unfortunately also caused a few deaths. I tended to think (with no medical expertise of course) that allowing a drug with clear warnings of possible adverse reactions might be the best course to follow. In so much as a lot of drugs might provide great benefit to many people but also cause adverse reactions in a few. My view is that the CSM were rightly cautious of claims by drug companies, and generally requested additional information for license applications, to ensure all necessary assurances were provided.

35. I do not remember the sub-committee ever considering issues relating to the treatment for any individuals who contracted infection through blood or blood product.

36. I do recall hepatitis and heat treatment being discussed by the sub-committee on Biological Products however, I do not recall the specifics of the discussions.

37. I do have a few of my own personal copies of minutes but I do not have them to hand today. I can try and find the copies of minutes I have which are stored elsewhere. Online I have found a copy of the minutes of a Sub-Committee on Biological products meeting held on 7 March 1984, which I exhibit as **WITN0659002**. During this meeting the sub-committee were unable to recommend the grant of a product licence for Hyate: C (Porcine Factor VIII: G) from Speywood Laboratories Ltd on the grounds of safety and quality. The sub-committee did however recommend a grant of a product licence for Factor VIII H.S from Hoechet UK Ltd on a series of conditions, including providing further information on the heat treatment process.

38. I do not remember anything being discussed in relation to HIV/AIDS.

39. The office next door to ours dealt with adverse reactions from drug products. They had a separate sub-committee and its chairman would also be present at the CSM meetings. I did not take the minutes for this sub-committee.

40. Adverse reactions were a very important issue for the CSM to consider and they were recorded on 'yellow cards', usually submitted by GPs. The CSM had the authority to withdraw a drug product from use because of adverse reactions, as was the case with Opren – a drug used to treat arthritis.

41. I do not recall any adverse reactions from blood products being considered, but there may be discussions recorded in the meeting minutes. Unfortunately, it is too long ago for me to recall specifics of such discussions, but the minutes of these meetings would of course be helpful.

42. A large room of the office at Market Towers was used to store the minutes of meetings. The building closed down after I left the Civil Service and I am not sure where the CSM moved to. I think the medicines division merged with the medicines commission and changed its name.

43. The minutes were badly stored. When I had to search for minutes on Opren I found that a lot were misfiled or missing.

Section 3. Other Issues

44. I do not remember any involvement of the CSM or its sub-committees in any litigation concerning the use of infected blood products. Litigation was never discussed in any of the meetings at which I was present and I presume it would have been dealt with by the administration department.

45. I was surprised to find some of the sub committee minutes online although names have been redacted, but I do have some of my own copies in London which I will try to find and give to the Inquiry.

Statement of Truth

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

Signed _J P Digings_ GRO-C

Dated 25 October 2020