Witness Name: Samantha Silver
Statement No.: WITN3422001
Exhibits: None
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THE INFECTED BLOOD INQUIRY

WITNESS STATEMENT OF SAMANTHA SILVER

I, Samantha Silver, a Partner of Kennedys Law LLP, 25 Fenchurch Avenue, London EC3M 5AD, will say as follows:

WHO IS MAKING THE STATEMENT AND IN WHAT CAPACITY

1. I am instructed by Armour Pharmaceutical Company ("Armour") to assist this Inquiry. As explained in the Corporate Structure section below, Armour prepared factor concentrate in the US and distributed it in the UK via its UK company, Armour Pharmaceutical Company Limited ("APCL").

2. Armour is providing instructions to assist the Inquiry further to its Rule 9 Requests because at the time relevant to the matters within the Inquiry's Terms of Reference, the company distributing factor concentrate in the UK was an Armour affiliate.

3. Before I address those requests, on behalf of APCL I would like to express our condolences to those who have lost loved ones and those who continue to suffer the impact of HIV and hepatitis.

CORPORATE STRUCTURE

4. Armour is an American pharmaceutical company that was founded in Kankakee, Illinois in 1951.

5. Over the years, Armour has had several different parent companies. It was purchased by Greyhound in 1970. Greyhound then sold Armour to Revlon, Inc. ("Revlon") in 1977.

6. In 1986, the William H. Rorer Group purchased Armour from Revlon. Armour's parent company changed again in 1990 when Rhône-Poulenc acquired and merged with Rorer, changing Rorer's name to Rhône-Poulenc Rorer.

7. In the UK, APCL was incorporated in 1959. In 1982, after the Revlon acquisition, the company changed its name to Revlon Healthcare Limited. Similarly, with the acquisition by William H. Rorer, the company's name changed to Rorer Healthcare Holdings in 1986. The company was dissolved in 2010.

8. At the same time that APCL changed its name to Revlon Healthcare Limited, a new company was formed, also called APCL, which underwent several different name changes over the years as parent companies changed.

9. In 1995, Armour and the German company Behringwerke AG entered into a joint venture called Centeon LLC ("Centeon"). Armour continued to exist, but Centeon began making factor concentrate, and Centeon took over supplying factor concentrate to the UK. At the same time, Centeon UK Limited was created.

10. In 1999, the parent companies of Armour and Behringwerke (Rhône-Poulenc Rorer and Hoechst), merged and formed Aventis. At that time, the Centeon entities became Aventis Behring entities.

11. In 2004, Aventis completed the divestment of the Aventis Behring entities to CSL Limited. Aventis Behring thereafter adopted the ZLB Behring name, which was later changed to CSL Behring.

12. Thus, the company that was once Centeon UK Limited is currently called CSL Behring Holdings Limited. CSL Behring Holdings Limited is the parent company of CSL Behring UK Limited.

13. For the avoidance of doubt, since 2004, the ultimate parent company of what is now CSL Behring has been CSL Limited. Armour is not now and never has been a subsidiary of CSL Limited. Armour and CSL Behring are therefore not part of the same group of companies and there is no corporate relationship between them.

14. After the divestment, Armour remained a subsidiary of Aventis.

15. In relation to the UK companies, I have seen and reviewed relevant documents including filed accounts from Companies House to confirm the corporate structure. In relation to the US companies, I have seen relevant information and documentation from Armour, and relevant information in the public domain, to confirm the corporate structure.

BLOOD DERIVATIVES SUPPLIED BY ARMOUR

16. Armour began making factor VIII concentrate in 1974.

17. Armour's factor concentrates were made in Kankakee, Illinois, and sold in the United States and other countries around the world.

18. Armour's factor concentrates were never made in the UK. They were sold in the UK by APCL.

19. Armour's first antihemophilic factor concentrate was Factorate Generation I, which was used for the treatment of haemophilia A. It was licensed in the United States in 1974 and in the United Kingdom in 1976. Improvements in factor concentrate processing led to the development of Factorate Generation II, which incorporated advanced purification. Generation II Factorate was also referred to as High Potency Factorate or Factorate HP. It was licensed in the United Kingdom in June 1979. Further improvements led to the development of Factorate HT, a factor VIII concentrate (which also came in Generation I and Generation II) that was heat-treated, and was licensed in the UK in February 1985.

20. Some patients in the UK would have received some Factorate products before the applicable license date on a named-patient basis.

21. After notification by a UK physician of two cases of HIV antibody sero-conversion associated with the use of Factorate, and consultation with the Department of Health and Social Security, on 7 October 1986 Armour withdrew Factorate from the UK market.

22. The next Armour factor concentrate supplied to the NHS was Monoclate P, which was licensed on December 13, 1989. Monoclate P is a monoclonally processed and pasteurized factor VIII concentrate and remains on the market today.

23. From the time that they came on the market, Armour's factor concentrates warned of the risk of hepatitis transmission. In the 1970s and 1980s, there were two known forms of hepatitis – hepatitis A and hepatitis B. Hepatitis B was known to be potentially transmitted by blood and blood derivatives like factor concentrates. At that time, it was also known that blood and blood derivatives transmitted other as yet unidentified, forms of hepatitis. Hepatitis that was not identified as hepatitis A or hepatitis B was referred to as non-A non-B (or NANB) hepatitis. The hepatitis C virus was identified in 1989, and a test was licensed in 1990. Hepatitis C screening was introduced in the UK in 1991. It was subsequently learned that the vast majority of NANB hepatitis cases were in fact hepatitis C.

24. As requested by the Inquiry, we have provided a list of all batch numbers for Factorate distributed in the UK from 1980, a schedule of which has previously been provided to the Inquiry.

DOCUMENTS RELATING TO UK LITIGATION

25. APCL and Armour faced litigation in the late 1980s and early 1990s from HIV-infected haemophiliacs from the UK. At the time, APCL searched for relevant documents, which were provided to counsel. Counsel retained those

documents and have reviewed them to identify documents responsive to the Inquiry's requests.

26. Although litigation in the UK was short-lived, litigation against Armour in the US continued for several years. Most cases involved haemophiliacs and their representatives from the US. In 2003, however, several UK plaintiffs brought suit against Armour in the US federal court. In connection with that litigation, counsel for Armour searched for documents related to the shipment of Factorate to the UK. Extensive searches were conducted of Armour documents held in locations in Illinois, Pennsylvania and New Jersey to respond to requests served by the UK haemophiliacs in the US litigation.

27. In 2006, litigation of the claims of the UK haemophiliacs and their representatives was concluded in the US court and commenced in the UK. Counsel have reviewed the collected documents from the US proceedings to identify any relevant APCL documents. Such documents were included in the schedules provided to the Inquiry. The claims brought in the UK were concluded without the need for any documents to be collected or produced.

28. A search has also been undertaken of hard copy files collected from Reed Smith. In 2007, Reed Smith merged with Richards Butler, a former UK law firm which acted for Armour and APCL in UK litigation in the late 1980s and early 1990s. A schedule of responsive documents was provided to the Inquiry.

ARCHIVING SYSTEM

29. During the entire period that Factorate was sold, all records were kept in hard copy form. We are not aware of how APCL archived documents, other than as discussed in this statement and further to collections for the purposes of US and UK litigation.

DOCUMENT REPOSITORIES

30. I am informed that during the period that Factorate was sold in the UK, Armour documents were archived in locations in Illinois and Pennsylvania. From the late 1990s, documents were also stored in New Jersey.

DOCUMENT RETENTION AND DESTRUCTION POLICIES

31. We are not aware of APCL's retention and destruction policies and processes, insofar as they are relevant to the Inquiry's Terms of Reference and have not found any information relevant to this within the documents reviewed.

32. We are aware that Armour shipping records predating 1980 have been destroyed. These were destroyed in the normal course of business before the litigation discussed above and therefore before the collections for the purposes of litigation were carried out. Once US litigation commenced, Armour retained all shipping records. At the time, U.S. regulations required retention of shipping records for one year after the batch's expiration date. *See* 21 C.F.R. § 211.180. We do not know whether APCL sales documents predating 1980 were also destroyed but it is possible. The schedules of responsive documents provided to the Inquiry list documents dating back to 1975. We have been able to access documents dating back this far because once litigation involving HIV transmission commenced, Armour and APCL retained relevant documents.

Statement of Truth

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

Signed GRO-C

SAMANTHA SILVER

Dated 19 December 2019