Witness Name: Stephen Jenkins
Statement No.: WITN0627001
Exhibits: **Nil**
Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF Stephen Jenkins

Introduction

1. My full name is Stephen John Jenkins, Bsc, PhD, MRSB. My date of birth is GRO-C 1954. My address is known to the Inquiry

2. I am a retired scientist, I am currently single, living with my daughter.

Professional Background

3. **1972-1975** University Wales, University College Cardiff, Microbiology, BSc 2.I Hons

4. **1975-1978** University of Liverpool together with May and Baker, Dagenham. PhD, (awarded 1980), Title of thesis "Effects of Growth Promoting Agents on the Chicken"

5. **1978-1982** Bush Boake Allen, Walthamstow. Involved in the manufacture of flavours, fragrances and colours. Research Microbiologist, production of secondary metabolites in fungi

6. **1982-1994** Smith & Nephew Pharmaceuticals Ltd. Involved in the manufacture of ophthalmics, sterile burns cream, and contact lens solutions, plus other non-sterile oral and topicals.

7. In these roles above - I have worked as a Microbiologist, Microbiology Manager and Deputy Quality Assurance (QA) Manager.

8. Also as the 'Qualified Person' on Manufacturer's licence 1988.
The Qualified Persons are licensed to release medicinal products from the manufacturer to the marketplace.
As defined in directive 2001/83/ec of the European Parliament and of the Council of 6

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November 2001 on the community code relating to medicinal products for human use.

Working at BPL

9. **1994 -2005** Bio Products Laboratory as the QA Manager & Qualified Person, reporting to the Technical Director, Dr Terry Snape.

10. This role involved managing the departments responsible for quality assurance in manufacturing and testing laboratories. Included responsibility for archive of QA issued documents and QA assessed production records.

11. The quality assurance department at that time only had responsibility and authority within the quality, production and engineering departments. Medical, R&D, HR and Executive departments were not in the scope of a formal quality assurance system.

12. **2005 – 2013** Bio Products Laboratory as the Technical Director, reporting directly to the CEO.

13. I had responsibility for Quality Assurance, Quality Control Laboratories, Regulatory Affairs department and production validation department.

14. Whilst in this role I took responsibility for the archive of all technical department records, and production records.

15. I retired from work in 2013.

Records

16. Whilst I worked at the BPL, records which I believe were related to the haemophilia litigation were kept in a store room next to my office for ready access, in case of inquiries being made from DoH, National Blood Authority or Parliamentary questions.

17. The material was contained in blue 'Clifford Chance' folders. I believe there was also some material that was stored off site at the 'Iron Mountain' company, which I think Dr Snape and I retrieved on one occasion. I do not recall whether this was related to the HIV litigation.

Retention Policy of Bio Products Laboratory

18. In 1994 each department was responsible for its own record storage. Records were kept in several stores on site, none were really suitable for long term storage.

19. Production and Quality records were brought together in my time and moved to a purpose built facility under control shared with the Medical Department.

20. Whilst I was the Quality Assurance Manager I wrote a policy for the retention of batch manufacturing records and Quality Control (QC) records. I believe I did include retention of other types of records in the policy, for instance complaint records and adverse event records.

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21. At that time the only requirement for pharmaceutical production testing and distribution records was for the shelf life of the product plus one year.

22. However in the knowledge that there had been the HIV and HCV tragedies, taking into account BPL expert advice and other available guidelines I based the policy primarily on the published recommendations of the Royal College of Pathologists.

23. In due course the European requirement for retention of batch and traceability records became at least 30 years. (*Directive 2005/61/EC*).

24. Over time the archives became too full to store everything on site, so there was a contract in place to use Iron Mountain for some storage.

25. At one point there was a fire at the London Iron Mountain facility where some of the BPL records were destroyed. The Medicines & Healthcare products Regulatory Agency was informed of the destruction. The records concerned were not deemed to be so important as to require recall of the related products.

26. I believe the records post-dated anything that could be relevant to this inquiry.

27. Prior to my arrival at BPL, and possibly for a short time afterwards, distribution records (hence traceability of batches) were made and held on a "dos" based database on floppy-disks.

28. After introduction of a more robust system the IT department was asked to ensure that the old records were always recoverable, however, from my memory, I believe it was not possible to recover or preserve that information.

29. On my departure I emphasised to my successor (Mr David Wilson) the importance of retaining any records relating to the HIV/HCV events or litigation and records relating to the BSE/vCJD issue.

Currently

30. I hold no documentary evidence of the retention policy. The Quality Assurance department should be able to produce copies of all versions of the archive policy with their implementation dates.

31. I hold no BPL research documents. I hold a few of my personal training records.

32. I hold no BPL original documents nor copies of records of events prior to my employment at BPL. I do hold some copies of documents as memory aids should there be questions arising from the BSE/vCJD issue.

Working situation since leaving BPL

I have not undertaken any relevant professional work since retiring from BPL. I have done voluntary work for a couple of charities and occasionally work as a volunteer chaplain on the local canal.

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Timeline events

1989 Civil action v DoH (Are these the Clifford Chance files?)

1991 Crown Immunity ended - MHRA have power to take action against BPL

1992 Annex 14 of the Good Manufacturing Practice "Manufacture of Products derived from Human Blood or Human Plasma"

1994 SJJ Appointed QA Manager BPL. Current Technical Director was Terry Snape

1998 Annex 14 revision drafted with 30 year retention requirement

2000's Archer report refers to missing records

2004# Terry Snape left, replaced with Nick Hill

2005 Nick Hill left

2005 SJJ Appointed Technical Director, David Wilson appointed as QA manager#

2013 SJJ Left, replaced with David Wilson,

(#dates not certain)

GRO-C .....

Stephen Jenkins

27/1/22

Date