

## **INFECTED BLOOD INQUIRY**

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### **WRITTEN STATEMENT OF DAVID GAO**

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**I, David Gao, will say as follows:**

1. I am the Chief Executive Officer of Bio Products Laboratory Holdings Limited ('BPLH'). My employment with BPLH, as part of the executive team, commenced on 3 December 2018. Prior to joining BPLH as CEO, I served as CEO and Executive Chairman of China Biologics from May 2012 to June 2018. My prior experience in executive and senior positions was with BMP Sunstone Corporation and Motorola Inc, dating back to 1989. I am a US citizen and have experience in many global markets, including US, China and Europe.
2. BPLH is a privately owned company registered in the UK and Bio Products Laboratory (BPL Ltd) is its wholly owned subsidiary.
3. As I have been an employee of BPLH for less than a year, almost all of the questions that the Inquiry have asked are not within my own knowledge or memory. I have therefore made this statement with the assistance of available documents and from information provided by a small number of current BPL Ltd staff who were employed by a BPL Ltd predecessor entity in junior roles in the past and who remain employed by BPL Ltd today. Dates that I have provided

in this statement are based on the best possible, but limited, information that is available to me. However, the Inquiry should verify dates with the public sector Core Participants to the Inquiry who had closer involvement with the issues that BPL Ltd have been asked to address or confirm dates by other means in order to ensure accuracy.

4. By way of initial background, BPL Ltd is now a privately-owned company; BPL Ltd's predecessor entities had a history of NHS public-sector ownership. In approximately 2011, Bio Products Laboratory ('BPL') was transferred out of NHS Blood and Transplant to the new legal entity called Bio Products Laboratory Limited, which was a wholly owned subsidiary of Plasma Resources UK Limited that, in turn, was 100% owned and managed within the NHS by the Department of Health ('DH'). Two years later, in 2013, BPL Ltd was partly privatised by DH who sold a significant majority stake to Bain Capital, a private investment firm. Full privatisation was achieved when our current owners, a group controlled by Creat Group Corporation ('Creat'), acquired BPLH from Bain and DH in 2016.
5. I will provide further details of this below but want to set out at the start that, as explained above, the existing corporate entity of BPL Ltd was not in existence during the relevant time period of the Inquiry's request for information between 1970 and 1995. I fully acknowledge that the request is not limited to this time period, but my view is that this is an important distinction to make at the start of this statement to avoid any confusion concerning identity.
6. To emphasise this point this statement refers to BPL Ltd's predecessor entities as 'BPL (NHS)' as a reference to different forms of NHS ownership and management in the past as outlined in paragraphs 15-23 below. I refer to "BPL Ltd" when referring to the current company (from the point of privatisation in 2013). BPL (NHS) should also be taken to refer to Blood Products Laboratory and Bio Products Laboratory.
7. I would be grateful if the Inquiry, and Core Participants of the Inquiry, would also use these specific descriptions and nomenclature to ensure that the

necessary distinction between the BPL Ltd of today and the BPL (NHS) of the past is made throughout the Inquiry's investigations and evidence gathering and within the Inquiry's final report.

8. Any documents relevant to the Inquiry's Terms of Reference that BPL Ltd now holds are documents created or acquired by predecessor entities (which I outline below).

## **Background**

9. I thought it may assist the Inquiry to set out some initial current information about BPL Ltd before responding to the specific questions asked by the Inquiry team.
10. The aim of BPL Ltd is to provide safe and effective medicines to patients who need them. We invest in the latest research, technology and manufacturing methods, and continuously adapt to ensure that we continue to serve all our stakeholders effectively.
11. The present holding company BPLH consists of two operating divisions - BPL Plasma, Inc. and BPL Ltd. BPL Plasma, Inc. (BPL Plasma) was created for the purposes of the 2013 privatisation and is headquartered in Austin, Texas and operates in the USA. It was formerly known as DCI Biologicals. It collects plasma from donors in about 50 centres across the US. Plasma collection is regulated by both US Food and Drug Administration ('FDA') and UK Medicines and Healthcare products Regulatory Agency ('MHRA'), and BPL Plasma adhere strictly to industry standards. BPL Plasma facilities provide a collection environment to secure clinical safety and hygiene of both donors and plasma. It is staffed with trained personnel, dedicated to supporting donors through the process that leads to the donation of plasma.
12. Plasma collected by BPL Plasma in the US is shipped to the headquarters of the UK-based BPL Ltd in Elstree, United Kingdom. The plasma is fractionated at a site with about 1000 employees involved in operations, R&D, quality,

medical, regulatory affairs, commercial and other functions. Fractionation is the process which separates plasma into component proteins, which are then purified into therapeutic products that are used to treat patients. Fractionation allows multiple protein products to be extracted from each plasma pool, effectively providing treatment for patients with different clinical needs. Ultimately, the final products are commercially available in the UK, USA and many other countries around the world.

13. I address the previous organisations that evolved into today's UK-based BPL Ltd below. As a public-sector entity the previous organisation BPL (NHS) adapted over many years, as a result of technological, commercial and environmental changes, such as the emergence of variant Creutzfeld Jakob Disease ('vCJD') in the UK. This development meant that non-UK plasma became preferred for use in manufacturing. As far as BPL Ltd is aware in approximately 2002 the DH acquired Life Resources Inc which primarily traded as DCI Biologicals (a company collecting plasma in the US) to serve as BPL (NHS)'s primary source of plasma. BPL Ltd are not aware of the relationship and structure of these companies but plasma from DCI Biologicals was provided to BPL (NHS) on a routine basis from May 2004. Integration of the plasma supply from DCI Biologicals, now named BPL Plasma, was part of the privatisation process.
14. The following paragraphs deal with the specific questions that the Inquiry team have asked BPL Ltd.

#### **BPL's corporate ownership, organisation and structure from 1948 to date**

15. A structure chart of our understanding of the history of the predecessor, publicly owned organisation of BPL (NHS), including privatisation to BPL Ltd, is at **[WITN2954002]**. This is from the best available information that remains within the private company. We believe the dates to be accurate, but due to the limited information we have, they may not be completely accurate.

16. The structure chart shows that during the time that BPL (NHS) was in existence, its control and operations had been transferred between a number of public authorities. These include the Medical Research Council, North West Thames Regional Health Authority, the Central Blood Laboratories Authority, the National Blood Authority and NHS Blood and Transplant. The specific dates of transfer between these organisations will be recorded in Statutory Instruments.
17. The structure chart shows that the original organisation was established at some point in the 1950s when the Medical Research Council ('MRC') established Blood Products Laboratory as part of the Lister Institute in Elstree, Hertfordshire. This was with the agreement of and funding from the Ministry of Health.
18. Our understanding is that BPL (NHS) then became part of the North West Thames Health Authority in approximately October 1978.
19. The control of BPL (NHS) then changed to the Central Blood Laboratory Authority ('CBLA') on 1 December 1982 (Statutory Instrument 1982 No. 1515). CBLA took over responsibility for BPL (NHS), the Plasma Fractionation Laboratory ('PFL') and the International Blood Group Reference Laboratory ('IBGRL').
20. CBLA's control of BPL (NHS) continued until 1 April 1993, after which time CBLA was superseded by the National Blood Authority ('NBA') under Establishment and Constitution Order 1993 (Statutory Instrument 1993 No. 585). This period also marked the NBA's first attempt to bring together all the regional transfusion centres. Before this there were multiple regional blood transfusion centres which were controlled and administered by Regional Health Authorities. NBA was responsible to the Department of Health.
21. In 2005, NHS Blood and Transplant ('NHSBT') was established as a special health authority and BPL (NHS) became an operating division of NHSBT. The NBA was abolished on the 1 October 2005.

22. The operations of BPL (NHS) were then vested in a corporate entity, Plasma Resources UK Ltd and ownership of this entity was transferred from NHSBT to the Department of Health in approximately 2011. Plasma Resources UK Ltd was renamed Bio Products Laboratory Holdings Limited in November 2013.
23. In 2013, HM Government sold an 80% stake in Plasma Resources UK Ltd to Bain Capital. Bain Capital and HM Government subsequently sold their respective stakes in Bio Products Laboratory Holdings Ltd (previously called Plasma Resources UK Ltd) to Creat in 2016. Since that time BPL Ltd has been a privately-owned subsidiary company and its headquarters remain in Elstree in Hertfordshire, UK.

### **The relationship over time between BPL and other organisations**

#### *The Lister Institute (involvement with BPL (NHS) approximately 1954-1978)*

24. BPL (NHS) was part of the Lister Institute in the 1950s. The Lister Institute was originally established in 1891 as The British Institute of Preventive Medicine. The Lister Institute had a blood products laboratory as part of its facilities based on the Elstree site. My understanding is that financial pressures led the Institute to close the Chelsea laboratories in 1975 and the Elstree laboratory in 1978.

#### *The Department of Health and Social Services (as it was then known) (involvement with BPL (NHS) throughout the period until privatisation in 2016).*

25. I understand that BPL (NHS)'s development activities were predominantly promoted and funded by the Department of Health and Social Services in the past. The many different organisations that were responsible for BPL (NHS) during the time that the Inquiry is considering were ultimately responsible to the Department of Health in its different forms during this period.

#### *The Plasma Fractionation Laboratory, Oxford (approximately 1967-1992)*

26. I understand that the Oxford Laboratory, PFL, was a subsidiary of BPL (NHS)'s Elstree site and opened in 1967. PFL opened in Oxford at the Churchill Hospital Headington. The site was closed in 1992 and operations and staff were transferred to BPL (NHS).

*The International Blood Group Reference Laboratory (IBGRL) (dates of involvement with BPL (NHS) are not known)*

27. As stated above, CBLA took over responsibility for IBGRL in 1982; NBA became responsible for IBGRL starting 1 April 1993.

*The Central Blood Laboratory Authority (approximately December 1982-April 1993)*

28. I understand that at the time BPL (NHS) was part of CBLA, BPL/PFL was the only laboratory in England working on purification for plasma for therapeutic use. There was also a Scottish National Blood Transfusion Service facility in Scotland which was the Protein Fractionation Centre that did similar work to BPL (NHS) at this time.

29. My understanding is that at this time BPL (NHS) had several divisions: it produced diagnostic reagents at IBGRL located on the Radcliffe Infirmary site in Oxford and latterly on the Elstree site; fractionation of coagulation proteins took place at PFL, located on the Churchill Hospital site in Oxford; and the Elstree site was dedicated to production of albumin, coagulation factor and immunoglobulin blood products.

*The National Blood Authority (approximately April 1993-2005)*

30. BPL (NHS) was part of NBA during this period. As stated above, NBA attempted to bring together all the regional transfusion centres during this time. NBA was responsible to the Department of Health.

**A list of all persons past and present who held senior, decision-making positions within BPL, including but not limited to the roles of Director of BPL, Chief Executive Officer, Production Director, Technical Director, Head of Laboratories, and Head of Research and Development. Please provide a description of their roles and the dates of their involvement with BPL.**

31. Attached to this statement at **[WITN2954003]** is a current BPL Ltd management chart.
32. BPL Ltd's Human Resources Department ('HR') has confirmed that they do not normally hold any records relating to members of staff who have left BPL Ltd or BPL (NHS) more than seven years ago.
33. HR are able to confirm that BPL Ltd do presently employ a number of staff who were employed by BPL (NHS). These members of staff have current functional responsibilities within BPL Ltd and several have senior scientific roles. These individuals were not, and are not, part of the executive team or board of either of BPL or BPL Ltd, and were junior members of BPL (NHS) during the time period that the Inquiry is focusing upon.
34. In the absence of HR records, BPL Ltd has drafted a list of previous BPL (NHS) employees using available information, including memory of staff, in order to assist with the Inquiry's request; this list is found at **[WITN2954004]**. Unfortunately, as a result of a lack of records prior to 2012 BPL Ltd is unable to provide more than indicative dates of these individuals' involvement with BPL (NHS). Equally, no organisational or decision-making structures from BPL (NHS) are held by HR. As a result, any recollections by current BPL Ltd staff relating to past BPL (NHS) members of staff and their level of seniority (or their decision-making authority) or dates of involvement may be incomplete or mistaken. The list found at **[WITN2954004]** is provided to the Inquiry without confirmation of accuracy.

**A list of all committees and/or sub-committees and/or working groups within BPL over time, insofar as they relate to matters relevant to the Inquiry's terms of reference.**

35. The distinction between the present BPL Ltd and the previous BPL (NHS) is repeated here (see paragraph 6 above). BPL Ltd does not have a formal, comprehensive document or register which sets out the list of committees and/or sub-committees and/or working groups within BPL (NHS) over time that can be provided to the Inquiry. The following information is provided based on the best information currently available.
36. I am aware from colleagues that from the mid-1980s, BPL (NHS) established a Factor VIII Process Efficiency Working Party and a Factor IX Process Efficiency Working Party. These were internal cross-department groups which consolidated and actioned work on process efficiency, process performance, product compliance, and process and product improvements. This information comes from staff members' knowledge, and BPL Ltd staff expect that group minutes should be available within BPL (NHS) documents contained within the BPL Ltd archives that have been made available to the Inquiry.
37. Between 1993 and 1995 I understand that BPL (NHS) convened a Product Review Committee of senior staff within BPL which also included a number of external stakeholders. This information comes from staff members' knowledge, and BPL Ltd staff expect that committee minutes should be available within the BPL (NHS) documents contained within the BPL Ltd archives or in documents already disclosed to the Inquiry.
38. I understand that there was also a Research & Development (R&D) committee comprised of senior BPL (NHS) staff. This information comes from staff members' knowledge, and BPL Ltd staff expect that committee minutes should be available within BPL (NHS) documents contained within BPL Ltd archives or in documents already disclosed to the Inquiry.

39. I also understand that there were various other groups and committees which bridged the interface between BPL (NHS), its immediate umbrella authority, government departments and other bodies with an interest (e.g. transfusion service, haemophilia centre directors). From a brief review of documents disclosed to the Inquiry, BPL Ltd is aware that some minutes of these groups and the meeting papers are included within them.
40. I am also aware that there are witness statements available from previous Inquiries that may assist in helping the Inquiry understand the committees and/or sub-committees and working groups within this period that are also contained within the archived material being disclosed.

**An account of the BPL archiving system, including the means by which documents and information are indexed and can be searched to determine relevance.**

41. The distinction between the present BPL Ltd and the previous BPL (NHS) is repeated here (see paragraph 6 above). BPL Ltd archiving system is used primarily to secure the retention of documents which relate to the quality of medicinal products, which is mandatory within the pharmaceutical industry. The archiving of these documents is managed by standard operating procedure ('SOP'), and the information about each archived document box is recorded using an industry-standard, validated database called Trackwise. The Trackwise system is also used by BPL Ltd for other aspects of Quality Management. Access to Trackwise is restricted and password-protected. Actions relating to archived materials and the associated electronic record on Trackwise are limited to a few nominated archivists. The archive materials themselves are stored in areas with controlled, restricted access. BPL Ltd has used the Trackwise database to identify the archived documents currently being disclosed to the Inquiry.
42. BPL Ltd is unable to identify any policy from BPL (NHS) which relates to the archiving, retention period or destruction of electronic media which may have existed during the period of interest to the Inquiry.

43. Trackwise records can be searched using multiple search terms which include but are not limited to document type, key words, date/date range and reference numbers. The options to search predefined terms is also very large. However, given the size of the Trackwise database, unless additional and specific search criteria are included, a large amount of information that may not be relevant to the Inquiry's investigation may be retrieved. The system is also critically dependent on the accuracy and scope of the archive information entered at the record creation date.
44. Trackwise was adopted by BPL (NHS) in 2003 but archiving on this system was only implemented in 2011. I understand that archived documents which pre-date Trackwise were migrated manually. The description of archived documents was subject to the knowledge and guidance of the data-entry clerk at the time which could affect the ability to search now.
45. Current BPL Ltd staff have confirmed that before BPL (NHS) adopted Trackwise for archive records a Lotus Notes database was used. BPL Ltd staff have checked and are able to confirm that the archive document details from Lotus Notes were reliably migrated to Trackwise. At the time of migration from Lotus Notes to Trackwise the Lotus Notes content was downloaded to a .csv file which is still in existence in an unformatted and formatted form. However, the Trackwise entries would have been dependent on the indexing, storage location and destruction information previously recorded on the Lotus Notes system. This means that the file contents of archive boxes migrated to Trackwise from the Lotus Notes system could now be difficult to identify, and the fate of archive boxes which may have been destroyed before migration to Trackwise cannot be established in all cases.
46. The Inquiry should also be aware that during a significant proportion of the period covered by the Inquiry, documents of relevance would have been retained by the stakeholders at the time (this would include MRC, CBLA, NBA, NHSBT and DH). Documents could also have been submitted to the BPL (NHS) archive (please see paragraph 48), but this may not always have been the case

and BPL Ltd is unable to accurately establish this now due to the passage of time and use of different systems.

47. Given that inquiries and litigation cases have been carried out in the past, which also related to the Inquiry's current Terms of Reference, BPL Ltd have carried out an initial archive search using Trackwise based on those records previously identified as "Litigation". Relevant documents had already been collated for that purpose by individuals working for BPL (NHS) at the time who were closer to the decision-making events than current BPL Ltd staff. These documents which have been stored in hard copy archive (see paragraph 48) with BPL Ltd and have been disclosed to the Inquiry.

**An account and list of all of repositories holding materials created by BPL over the course of its history**

48. The distinction between the present BPL Ltd and the previous BPL (NHS) is repeated here (see paragraph 6 above). Archived hard copy documents and CDs/tapes are currently stored on site at Elstree or off-site using a contractor, Iron Mountain. The Iron Mountain storage facilities used by BPL Ltd are Bevedere, Hemel Hempstead, Poplar, Hoddesdon and Cowley. Batch records are kept on site at Elstree. A number of medical boxes containing information relating to clinical trials are also stored with a company called 'Restore'. Not all the documents stored at Restore are within the control of BPL Ltd and consent for disclosure may need to be obtained by a third party NHS Trust.

**NOT RELEVANT**

**NOT RELEVANT**

49. BPL Ltd does have custody and control over all documents archived by BPL (NHS), although copies may also be with predecessor organisations. These may include third-party correspondence, notes or minutes. BPL Ltd are unable to confirm if all documents held by BPL (NHS) were transferred into the custody

and control of BPL Ltd following full privatisation in 2016. However, any box archived within the Trackwise system would remain traceable even if the archive box had been transferred from BPL (NHS) to another organisation's archive facility. So, if an archived box logged in Trackwise had been transferred to third party ownership after the migration date of 2011 then Trackwise would record that the box had been permanently unarchived. Trackwise may not record the destination but the archive cannot be deleted from the system. However, if an archive box had been transferred to a third party before migration to Trackwise, this may not have been recorded on the Lotus Notes system with the same level of detail or permanence. BPL Ltd staff are aware that there is historical content relating to patient information which would be considered confidential and the Inquiry may wish to consider redaction.

50. The current BPL Ltd staff spoken to are not aware of any other historical off-site storage locations which pre-date storage provision by Iron Mountain and Restore outlined at paragraph 48. However, it remains a possibility that other storage providers and locations were used in the past by BPL (NHS).
51. Current BPL Ltd staff are also aware that before 1992, Plasma Fractionation Laboratory documents could be stored at the PFL facility on the Churchill Hospital site in Oxford. However, on closure of PFL in 1992, all documents were transferred for archiving at the BPL Elstree site. Trackwise would be able to identify archive boxes that came from PFL. Before 1992, most documents were paper as electronic storage was not readily available.

**From 1948 to date, together with an account of any material known to have been destroyed with potential relevance to the Inquiry's terms of reference. Please provide copies of any BPL retention and destruction policies as exhibits to the written statement.**

52. The distinction between the present BPL Ltd and the previous BPL (NHS) is repeated here (see paragraph 6 above). I understand that the earliest documented BPL (NHS) procedure for archiving which BPL Ltd has identified dates from 2005. Retention and destruction may have been proceduralised

before that date, but BPL Ltd does not have this knowledge. If the indexing was insufficient, it may not now be possible to find a given document, file or box of relevance.

53. BPL Ltd is aware that there are archive boxes with contents which pre-date 2004 when the retention and destruction policy was adopted. There have been physical checks of the BPL (NHS) archive in recent years to see if they contain boxes which are not listed on Trackwise. Where such boxes have been found (and there have not been many, relative to the whole archive), the contents have been reviewed and a decision made whether they needed to be retained, in which case they were logged into Trackwise for future control, or they were removed from the archive.
54. BPL Ltd is aware from searching Trackwise that one archive box within the 'Litigation' search term was reported to have been destroyed in 2008. BPL Ltd staff have identified that Trackwise records the contents of this archive box as "HIV litigation 1985-1990; HIV 86-93". Initially, BPL Ltd had been unable to assist the Inquiry with further information relating to the destruction of this box, as it pre-dated the migration of data from the previous Lotus Notes system onto the Trackwise system. However, subsequent physical searches confirmed that this archive box still existed and it has since been provided to the Inquiry.
55. BPL Ltd are aware that 262 boxes of archived BPL (NHS) material were destroyed in a fire at Iron Mountain in July 2006. BPL Ltd are unaware of the cause of the fire but are aware that the Police and the Fire Brigade were involved at the time and that there was an investigation. The boxes destroyed contained a mix of medical, GMP and laboratory archive boxes but BPL Ltd are unable to confirm if any of the content would have been relevant to the Inquiry's Terms of Reference. Identification of the archive box contents destroyed in the 2006 fire is limited by the original description entered on the Lotus Notes database which subsequently migrated to Trackwise in 2011. A list of destroyed files has been provided to the Inquiry

## **BPL Ltd involvement with the Inquiry**

56. BPL Ltd fully supports the goals and objectives of the Inquiry and understands the enormous impact that the consequences of the issues that face the Inquiry have had on individuals and their families. BPL Ltd will do its utmost possible to assist the Inquiry, recognising of course certain limitations of our ability to do this for the reasons set out in this statement.

## **Statement of Truth**

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

Signed

GRO-C

Dated

May 8th, 2019