5th March 2019

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Witness Name: Andrew James Bragg
Statement No.: WITN0195001
Exhibits: WITN0195002-006
Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF ANDREW JAMES BRAGG

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 29 October 2018.

I, ANDREW JAMES BRAGG, will say as follows: -

Section 1. Introduction

1. My name is ANDREW JAMES BRAGG. My date of birth is GRO-C 1956 and my address is known to the Inquiry. I am a Chartered Chemical Engineer and have worked in the chemical industry since leaving school. I intend to speak about the impact of contracting Hepatitis C (HCV) and subsequent treatment on my health, personal life and career.

Section 2. How Infected

2. In 1986 I graduated from Newcastle University and prior to starting work went for a long holiday in Norway. On August 18th while in Norway I had a road traffic accident resulting in multiple leg fractures and other injuries. I was treated in Haukeland Sykehus in Bergen and returned to the UK early in September. Subsequently I was then treated in Broadgreen Hospital Liverpool and Blackburn Royal Infirmary which included operations where metal implants were removed.

3. Prior to my road traffic accident in 1986 I had not experienced any prior hospital treatment and was an active blood donor.

4. In 1999 I was diagnosed with HCV by my employer after falling ill while working in India. While looking to identify the nature of the infection I had contracted in India, our Occupational Health team eventually identified I had problems with my liver which then lead to the HCV diagnosis. This was subsequently confirmed by the Regional Liver Unit at Freemans Hospital Newcastle. At this point I was then told that no treatment for HCV was available.

5. During treatment at Haukeland Sykehus I had two operations. The first addressed fractures of the tibia and a tibial nail was inserted. The second addressed fractures to my foot and ankle when wires were used to stabilise these factures.

6. After my return to the UK I was unable to work for some time and so lived with my parents in Liverpool. Immediately after I arrived in Liverpool from Norway my local GP arranged for me to be admitted for assessment at Broadgreen Hospital. I then attended the fracture clinic and also received some physiotherapy. In November 1986 they decided to remove the wires in my foot and ankle. Following on from this in December 1986 they decided to remove the screws securing the tibial nail. As a consequence of this

second procedure the tibial fractures opened up again and I was once again non- weight bearing.

7. In February 1987 I hobbled back to work and into a new appointment with ICI in Darwen, Lancashire. At this point I transferred to the out- patient care of Blackburn Royal Infirmary. I was admitted for surgery to remove the tibial nail from my right leg on 12th October 1987 and had the operation the following day. This operation did involve blood transfusion. I was discharged after one week. Due to complications with my knee I was readmitted two weeks later.

8. Over this period of treatment for my injuries I was aware that I had blood transfusions in Bergen and Blackburn but I am not personally aware if this was the case in Liverpool. In subsequent communications with Bergen they are certain they are not the source of infection because they have followed up with all four of the blood donors. I refer to a letter dated 26 April 2018 in this respect and exhibit it to my statement as **WITN0195002**.

9. A Subject Access Request (SAR) to Broadgreen Hospital was inconclusive because the records released were incomplete and not well arranged. A SAR to East Lancashire Hospitals Trust revealed that my medical records at Blackburn Royal Infirmary have been destroyed in line with hospital policy. **WITN0195003** is the letter I received from East Lancashire Hospitals Trust confirming this.

10. In 1995 I moved to a new role in ICI and was now based at GRO-C in the North East. This role supported our international operations and projects. In December 1998 I was attending a project meeting India when I fell ill. Once I had recovered sufficiently to travel I returned to the UK. The ICI Occupational Health team were concerned because I was very slow in recovering my health and they wanted to determine what the cause of the illness was. Over time they widened their investigation and eventually found I had high liver function responses. This then lead to tests for a number of

possibilities including HCV. After a positive HCV test I was referred to my GP, who in turn then referred me to the Regional Liver Unit at the Freemans Hospital in Newcastle.

11. I saw Professor Bassendine at the Freemans and had further tests including a liver biopsy. HCV infection was confirmed. Upon inquiring as to what treatment I would receive I was informed that there would be no treatment due to NHS policy which determined that treatment was too expensive.

12. I was not impressed with this response. This was particularly the case after they estimated that from the biopsy results that my liver would last between five and seven years. I took the matter to William Hague, who was then my MP. He asked for a response from the NHS. Their reply was that they did not need to treat me because I had company private medical insurance. In fact my company policy excluded out treatment generally and HCV was not included at all within the policy scope. While the NHS response was inadequate my MP chose not to take the matter any further.

Section 3. Other Infections

13. So far as I am aware, I have not contracted any other notifiable virus other than HCV.

Section 4. Consent

14. Following diagnosis at Freemans I was told that some blood samples being taken were for use with an external company funded research program. I gave consent to this.

15. When I was finally treated for HCV, this was as a part of a clinical trial using Pegylated Interferon and Ribavirin. I consented to be a participant in this trial.

Section 5. Impact

16. In late 2000 I was asked if I was prepared to participate in a clinical trial of HCV using Pegylated Interferon and Ribavirin. I agreed to this as I was aware that this was the current standard treatment for HCV in other countries. I started 48 weeks of treatment in February 2001. At the end of the trial in 2002 tests showed there was no trace of HCV. After three consecutive negative tests I was discharged from Freemans the same year. There have been no subsequent planned follow up assessments to track progress or issues post treatment.

17. Immediately after completing treatment my GP identified that my blood pressure and rest heart rate were significantly elevated. I was placed on medication to reduce my blood pressure and heart rate. This has continued to date. No investigation into the reasons for this change in my heart and vascular system function has been undertaken.

18. After HCV treatment my immune system has been much less effective I have been susceptible to both viral and bacterial infections. As a result I am frequently in poor health as I cope with successive infections. More seriously, I have had Biliary Sepsis three times (2013 twice and once in 2016) as well as Pneumonia (2016). These infections have significantly impacted on my health and ability to work. I have had four life threatening infections and it is always a concern that the next one may not be survivable.

19. During the 1990's I found that my energy levels were reducing and I frequently felt fatigued. This had an impact on career opportunities. After treatment for HCV the impact has been even more severe. The fatigue experienced is worse which is very draining and has an impact on my availability to work.

Before treatment

20. Before diagnosis with HCV I was gradually aware that over time I was not functioning in work at my previous levels. I was getting tired and fatigued more easily but put this down to a demanding job and getting older.

21. I work for a global chemical company and my roles have meant frequent travel. After diagnosis there has been a very conscious balance to be made between delivering my responsibilities and managing health risks. On occasions this has been a concern to both myself and my employer.

During treatment

22. The 48 weeks of treatment was very challenging and took a huge physical and mental toll on me. After a while I understood why there had been so many questions about my mental state before being approved for inclusion in the trial.

23. During the trial I would self-inject the PEG interferon on a Thursday evening. I chose this time so that the majority of the consequential sickness and incapacity which followed would occur over the weekend so I would have a chance of attending work the following week. I was very aware that while I needed to clear the virus I also needed to stay employed.

24. Within two hours of the injection I would be incapacitated and would be unable to leave my bed for three and sometimes four days. The Interferon reaction is like the worst dose of influenza you can imagine happening every week for a year.

25. My weight dropped rapidly and I became very anaemic. At one point the dosage of ribavirin had to be reduced because my haemoglobin levels were too low. This was a stressful period because I was aware that reducing the ribavirin dosage may compromise the chances of clearing the virus.

26. During treatment I seemed to have little resistance to bacterial infections of which I had a number. The worst was impetigo in my face, which was very

distressing. This required support from a consultant dermatologist to resolve.

27. I had a major bleed when a blood vessel in my anus burst and I was rushed to hospital. On admittance my blood pressure was 50/30 and I thought I was finished. I had a haemorrhoidectomy but this then had to be repeated as the first operation had not resolved the problem. It was a very painful experience.

Post treatment

28. There have been a number of changes of significant consequence to my health since having treatment for HCV.

Heart and vascular system

29. In the period immediately after I had completed the treatment my GP noted that my blood pressure was now significantly elevated and my rest heart rate very fast. For some reason these vital signs were not checked at all during the regular reviews at the Freemans during the trial. I was placed on medication to control blood pressure and lower my heart rate which has continued to this day. On my next visit to Freemans I asked if this was as a side effect of treatment. I was told that this was not a recognised side effect.

30. Recently I have been having problems with both control of heart rate and blood pressure which have still not been resolved.

31. As an observation at no point since 2002 has there been any attempt to determine why my blood pressure and heart rate were affected by treatment. I do not know what are the root causes, or causes for this change which I find concerning and unsatisfactory.

Immune system

32. Since treatment my immune system has been much less effective than it had been. I pick up infections, both viral and bacterial, very easily and they

persist. This can be very debilitating because there are times when I feel unwell for long periods. This can be difficult in my work and my employer has also found this a challenge because this lead to frequent periods of absence and periods where my ability to function at normal levels was significantly impaired.

33. These infections have on occasion been serious. In 2013 I had biliary sepsis twice. On the first occasion in June I was admitted to Chesterfield Royal Infirmary and then at the end of August I was admitted to James Cook Hospital in Middlesbrough. In March 2016 I was diagnosed with pneumonia and treated at the Friarage Hospital in Northallerton. In September of the same year I was back in the Friarage with biliary sepsis for a third time.

34. While I was being admitted to the Friarage in September 2016, the doctor told me that I needed to be aware that my C Reactive Protein levels were not elevated, even during dangerously high levels of infection. This comment was not followed up in any way.

35. I was advised by the hospital not to let bacterial infections progress so far in future after my third experience with sepsis. This can be a problem because I have generally had multiple GP appointments who have not recognised the potential issue before eventually getting to the point where I have to go to the hospital.

36. The GP response is typically;
    1. Wait it will improve, your symptoms are not too severe;
    2. Take a blood sample with the result the my results are in the normal range;
    3. You may have some form of infection try these pills.

37. What then happens is that on some occasions after a few weeks of lower level infection it either suddenly becomes more serious and I am either off to A&E or my body finally gets on top of the infection and it eventually slowly improves.

38. In 2018 I had two periods where infections were bordering on meeting sepsis criteria but eventually sorted themselves out. I decided that I needed to find out more about why my immune system is less effective. I contacted the regional immunology clinic and gave them a brief on my medical experience. The response was that they would see me if I had a GP referral, which I subsequently obtained.

39. I have now seen the consultant at Newcastle RVI twice and have a better understanding of the situation. One factor is that I have very low CRP levels so even a significant increase over normal would fail to exceed the threshold generally used by doctors to indicate an infection. A second factor is that my mannan binding lectin levels are significantly reduced. Both of these proteins form part of the immune system reaction process to infections.

40. This is a good example of how on occasion you need to take matters into your own hands because the system does not seem to be good at responding to patients with a medical history such as myself.

41. I have on more than one occasion been told by doctors that I should just be grateful that I am no longer HCV positive. Indeed I am, but the legacy of the treatment I received is with me every day.

Fatigue

42. This is a difficult subject. When fatigue strikes it not only affects your energy levels but also your clarity of thought. However, there are no external markers and you do not appear unwell. You know that functioning is a struggle but to others around that is not apparent.

43. For whatever reason, fatigue has been worse after treatment than before. This has added to the challenge of trying to manage a professional career and has been a limitation to career progression. I have not been able to take on professional roles I was capable of handling because I knew that I could

not consistently sustain the level of attention and performance required because of fatigue.

Diabetes

44. In 2017 I was diagnosed as being Type 2 diabetic. I suspect that this is as a consequence of either the damage to my liver from the HCV infection or the subsequent treatment.

45. Post treatment my liver function results were still consistently at three to four times above what is regarded as a normal range. This was an indication that there was on-going inflammation within my liver. In addition I had a fatty liver even though I have always followed a healthy diet and exercised as much as I could.

46. After diagnosis with diabetes I was prescribed Metformin which acts on the liver. My HbA1c levels immediately fell to the lower end of the normal range and liver function tests also fell to close to the normal maximum. This response has been sustained.

47. I am of the opinion that had Metformin be available for treatment for post HCV treatment patients with NAFLD and had doctors been aware of the potential benefits for such patients so that I had been prescribed this much earlier, that I would not have developed Type 2 diabetes.

Effect on my family

48. Diagnosis with HCV was a very stressful event. The future became very uncertain and being potentially infectious also stresses relationships. The on-going poor health also places a strain. My wife has often referred to me as 'Mr never well'.

49. As an only child I was aware that my mother would not react well to such news and so have kept this knowledge away from her. This is a hard thing to have to do.

50. I have been fortunate that my employer was very supportive, particularly during the year of treatment when I could only work part time. More recently my frequent infections have placed a stress in work. After my absence due to hospital admission with my third case of sepsis my employer actively examined if I was fit for work. The outcome of that medical assessment was that the 2010 Disability Act would apply to me. While this gives me some form of protection, the threat of disciplinary action means I still attend work on too many occasions when I am far from well. This is stressful because I feel obliged to work when far from well and this possibly results in recovery ultimately taking longer that it need to.

Section 6. Treatment/Care/Support

Prior to treatment

51. After being diagnosed with HCV I was told that treatment would not be available by the NHS. This remained the case for the following two years. At one point during that period a doctor at Freemans told me that I would have been better off having HIV because at least I would have received treatment for that infection. While the comment was clearly an honest opinion, I am very annoyed that such discrimination existed for what were both serious notifiable diseases.

Follow up after HCV treatment

52. After treatment and confirmation that I was now HCV negative I was discharged from the Regional Liver Unit. There has been no formalised follow up, review or examination since then.

53. I did manage to get myself referred back to the Regional Liver Unit in 2016 after my third case of biliary sepsis. The consultant at the Friarage had told me during treatment there that I had cirrhosis. I knew that on diagnosis in 1999 that I had fibrosis but if this had subsequently progressed then this was a concern. I contacted the Professor at the Regional Liver Unit and asked if it would be possible to see him. This was subsequently arranged by my GP. The outcome from that review was that I did not have cirrhosis.

54. There has been no attempt by my GP practice, James Cook hospital or Friarage hospital to arrange any follow up or review with an appropriate consultant despite my previous medical history and three biliary infections leading to sepsis.

Liver function tests

55. While there was no regular routine liver function tests carried out on occasion, I did ask for these on occasion. If I saw my lead GP he was sympathetic to these requests because he had been responsible for my initial referral to the Regional Liver Unit. Other GP's were of course less aware of my medical history so requesting tests could be more difficult. Since treatment my liver functions tests were consistently around three times that given as the maximum value of the normal range (ALT>40). This would imply that there was still on-going inflammation. These test results have never triggered any response to investigate further.

56. As an observation, since being diagnosed as diabetic and starting taking metformin my ALT has consistently dropped from circa 130 to circa 70. My HbA1c results have been at the low end of the normal range since starting with metformin. Metformin acts on the liver so this suggests that my liver inflammation was playing a part in developing diabetes.

Infections and immune system

57. With a history of infections since treatment it has proved very difficult to get any advice on why this has happened or if any treatment is available. There does not appear to be any interest in investigating what the long term consequences of HCV treatment is on the individual. There is a short term goal of virus elimination but there are medical consequences in achieving that aim.

Counselling

58. This has never been discussed or offered.

Section 7. Financial Assistance

59. I have not received any financial assistance in any form.

60. I only became aware of the Skipton Fund when reading an article about the establishment of the Infected Blood Inquiry. As a result I suspect that there is no routine referral of infected individuals to this support mechanism.

61. Once aware of the Skipton Fund I made an application to what by then had become EIBSS but was rejected. I gave notice that I would appeal and made SARs to Liverpool Broadgreen and East Lancashire Hospitals Trusts to obtain more supporting evidence. I had assumed in my original application that the EIBSS would already have access to my medical records. I would have thought that on application one role of the assessment team would be to gather supporting information. I think this was a reasonable assumption to have made.

62. From Liverpool I obtained fragmentary records concerning treatment between September 1986 and February 1987.

63. East Lancashire Hospitals Trust responded saying they had no records of my treatment as these had been destroyed in line with hospital policy **(WITN0195003).**

64. There was therefore no way I could then gather a detailed description of my treatment when under the care of these institutions to support my application from the information provided.

65. I also wrote again to Haukeland Sykehus in Bergen Norway. A copy of this letter is attached as **WITN0195004** and is dated 20 March 2018. As previously mentioned, they responded by saying that all four blood donors had been repeatedly tested and were all HCV negative (**WITN0195002**). They had also written to me earlier in 2001 to explain they had examined

their donor files. This letter I exhibit as **WITN0195005**. The response from Bergen has been exemplary, as was my treatment there in 1986. I do not believe that there is any credible case to assume that I contracted HCV in Bergen.

66. My appeal to EIBSS was rejected on the grounds that I cannot prove that the infection was as the result of NHS actions. I exhibit this rejection letter, dated 31 July 2018, as **WITN0195006**.

67. Any chance I may have had of proving this causal link has been compromised by the retention of only a limited amount of personal data by one hospital and the destruction of all of my files by another. As a result of the actions of these NHS organisations and given the terms of reference of the EBISS assessment panel then I have no ability to prove my case.

Section 8. Other Issues

68. In light of the difficulties explained in Section 7 above, I would ask that the Inquiry considers the following;

a. Should it be the responsibility of an individual to prove that HCV was acquired as a result action by the NHS when supporting information is of poor quality or has been destroyed? Perhaps a fairer method would be for the NHS to prove that it was not responsible for causing the infection.
b. Why are elements of the NHS able to destroy patient records without the consent of the patient? Such information may be of value or use in the treatment of long term conditions or for epidemiology studies.
c. A related but wider consideration is concerning patient records not being centralised but widely dispersed and held only at the point of treatment. As an example, since 1986 I have been registered at four general practitioners and had treatment at five different hospitals. This does not support good medical decisions or for instances such as those this Inquiry is considering.

69. Further, as a professional chemical engineer I have had the opportunity to compare and contrast the practices I have seen in practice within the NHS over this matter with those of the industry in which I am employed. I would like to make the following observations to the inquiry;

External regulatory oversight

a. In the industry in which I work we operate in the full knowledge that should there be a major incident, fatality or significant injury then we will be subject to external investigation by regulatory agencies. We will be held corporately responsible but also individuals may be held to be personally responsible. This responsibility sharpens the awareness and interest in the prevention of failures both systemically and individually.

b. As an external example it is now thirty years since the Piper Alpha disaster. The Cullen report resulted in significant changes to the regulatory framework and to the external verification of practices within the chemical and offshore processing industries. The changes proposed by Cullen are still being robustly managed and constantly subject to review, audit and improvement.

c. For the NHS, such external oversight is largely absent and it could be argued that the organisational response has been poor in this case because neither the organisation nor individuals seemed likely to be held to account. External experience would suggest this is unwise. I would therefore suggest that the Inquiry looks at if there may be a role for external regulatory review of the NHS in the event of significant failings.

Use of risk assessment and actions identified

d. Robust risk assessment mechanisms are used by most organisations to identify and respond to issues which may materially affect either the organisation or those it may have an impact on. It is clear that concerns about potential infectious agents in blood and blood products were in the

public domain long before the NHS took effective action. It is therefore important to understand what processes were in place to collect information and assess these risks.

- What were the mechanisms and systems in place to assess and act on potential risks identified with blood products and their use within the NHS?
- How were risks quantified and potential consequences and recommendations communicated?
- How were risks identified acted on?
- What were the organisation systems and roles charged with acting on such information?
- What were the individual responsibilities of those controlling these actions?

Corporate Social and Ethical Responsibility within the NHS

e. Having become aware of the scope and potential consequences for individuals of infected blood, the NHS then failed to react in a way that can be considered as being either responsible or ethical.

f. The failure to proactively seek out infected individuals and then bring the highest standards of treatment and support is truly scandalous. Yet seemingly no one in either the NHS or government felt able to stand up and challenge the approaches taken.

g. It would appear from the policies adopted that the principles of ethics and values which are integral to the medical profession do not seem to have been reflected in the wider management of this particular issue by either the health service or by government.

h. Considering the actions which were taken then, a conclusion may be that the moral compass of these organisations has not been functioning in

this case in the way one would expect. There is a wider question concerning if this is also case in other aspects of these organisations.

i. I would therefore request that the Inquiry considers to what degree medical ethics have been or should have been applied across the NHS and by government in the response to these blood infections.

HCV as a notifiable disease

j. After I was diagnosed with HCV I assumed that Freemans Hospital would inform other NHS facilities and Bergen of my infection as it was a notifiable disease. I later became aware that there had been no contact with Haukeland Sykehus so I then wrote to inform them. I do not believe that the NHS also made any attempt to contact the hospitals in Liverpool or Blackburn. The NHS should have had a duty of care to communicate a notifiable infection and to trace to source of this. So far as I am aware no attempt was ever made in my case.

Exhibited documents

WITN0195002: Haukeland Sykehus letter, 26 April 2018

WITN0195003: East Lancashire Hospitals Trust letter, 27 March 2018

WITN0195004: Haukeland Sykehus letter, 20 March 2018

WITN0195005: Haukeland Sykehus letter, 26 April 2001

WITN0195006: EIBSS Appeal panel decision, 31 July 2018

Statement of Truth

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

Signed GRO-C

Dated 5th March 2019