Witness Name: Professor David Mutimer
Statement No.: WITN3989001
Exhibits: None
Dated: 10/02/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR DAVID MUTIMER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 17 December 2020.

I, Professor David Mutimer, will say as follows: -

Section 1: Introduction

1. My name is David John Mutimer. I live in GRO-C Birmingham. My birth date is GRO-C 1958. My professional qualifications are MBBS (Monash University, Melbourne, 1980), MD (Monash University, Melbourne 1998), and I am a Fellow of the Royal College of Physicians (London).

2. Graduated MBBS 1980.
   Postgraduate training in Melbourne teaching hospitals 1981-86.
   Research Fellow, Freeman Hospital, Newcastle upon Tyne, 1986-89.
   Registrar, then Honorary Consultant Hepatologist Queen Elizabeth Hospital, Birmingham 1989-present date. Clinical Service Lead 2000-2010.
   Senior Lecturer, then Reader, then Professor of Clinical Hepatology University of Birmingham, 1996-present date.

3. I was a member of the Skipton Fund Appeals Panel from 2006 until 2012. I don't remember the circumstances of my appointment to the panel. The panel included a Liver Specialist, with a subspecialist interest in blood borne viruses, so I was suitably qualified.

4. This varied significantly from month to month. I recall that there was quite a bit of work to be done at the time that the Panel was initially assembled, so workload would have been greatest in the earlier years of my appointment. I have not kept any records of my time as a member of the Panel, but I think that we met, either face to face or virtually approximately every 3 months. We discussed a number of appeals at each meeting. The appeals were circulated to panel members in advance of each meeting so that each member could express an independent view of each case. These views were assembled before the meeting, then discussed by the Panel. After discussing specific cases, the Panel also discussed generic issues, particularly issues that might have consistently arisen in discussion of the Appeals. I recall that the preparation for each meeting may have taken a few hours and the meeting itself about the same again.

5. I was appointed as a Panel Member, perhaps as a consultant.

6. Patients who were refused Skipton Fund payment could request that their case would be reviewed by the Appeals Panel. My role was to contribute my skills and knowledge of hepatitis C infection to the Panel discussions about these cases. For Skipton Fund part 1 payment, the collective responsibility of the panel was to decide in each case whether hepatitis C infection was **more likely than not** to be a consequence of transfusion with hepatitis C contaminated blood or blood products. Part 2 Skipton Fund payment was made to patients who had suffered more severe consequences of hepatitis C infection. In cases where the Skipton Fund had decided that patients had not demonstrated that they had suffered these severe consequences, then the patient could ask the Appeals Panel to examine the case and to decide whether it was **more likely than not** that severe consequences had been suffered.

7. No, I don't recall ever attending a Board meeting at SF.

8. No, I only met with the Appeals Panel.

9. I don't recall receiving any specific induction or training for the work that I performed for the Appeals Panel. I understood that the Skipton Fund was established to provide financial compensation to patients who were infected with hepatitis C in the UK as a consequence of receiving contaminated blood or blood products. I believe that the

payments were made for compassionate reasons and were not an admission of fault on the part of the NHS.

10. None relevant.

11. I was a witness for The Penrose Enquiry into hepatitis C virus contamination of blood products in Scotland (2010/11). I recall that I was specifically asked to give expert opinion about a number of cases. I don't have any records or copies of any statements that I prepared for that work (though it is a public record).

Section 2: The Appeals Panel

12. I don't remember the details surrounding my appointment to the Appeals Panel. I believe that the panel was designed to include a lawyer (QC level perhaps), a General Practitioner, a Haematologist, a Hepatologist and a Lay Person. I don't know who established this criterion.

13. The membership is as stated above.

14. All members of the Panel sat on every appeal. My opinion was required for every appeal. The Chairman of the Panel was a legal person. Professor Mark Mildred performed this role during the time that I was a member of the Panel.

15. No, I played no role in recruiting or appointing the other members of the Panel. Though, on my retirement from the Panel, I think that I made a specific recommendation to the Chairman about a Hepatologist who might follow me. I don't remember the process for appointment of Appeals Panel members. I think that only one was replaced during my years on the Panel. That was the GP, and I don't know who or how the replacement was appointed.

16. Yes, there was administrative support.

17. I think that there was no fixed interval between meetings and that the frequency was highest initially to deal with a number of appeals. My recollection is that we may have met up to 4 times per year, sometimes less frequently.

18. We usually met in London, at suitable meeting rooms. Occasionally, Panel members would dial in for the meeting.

Section 3: Procedural issues: The Appeals Panel

19. Yes, I think that the process had been established before the Panel was set up. I did not design the process.

20. I think that the document SKIP0000030_023 was in the public domain on the Skipton Fund website. We applied the guidance described in that document. I don't recall that the principles and guidance were changed during the years that I sat on the Panel.

21. I think that SF applicants were advised that they could appeal against a negative decision made by the SF. The SF was in existence before the need for an Appeals Panel was realised so before the Appeals Panel was established. I can't remember what advice had been given to SF refusals before the existence of the Appeals Panel. The procedure was simple. The original SF application and the letter from the SF to the applicant that explained the justification for refusal were both provided to the Appeals Panel. Based on the Panel Members' views, a consensus or majority view was reached about the application. There were 3 basic outcomes, including appeal upheld, appeal declined, and further evidence needed from the applicant (to be discussed at next meeting). Most often, the Appeals Panel were asking for additional evidence about the injury or surgery that may have required blood products.

22. I'm not aware that there were time limits applied.

23. Yes, we heard appeals from applicants who did not meet eligibility for either stage 1 or stage 2 SF payments. Also, usually for stage 2 payments, we dealt with appeals that were made by beneficiaries.

24. The Appeals Panel was asked to determine the probability that an applicant was infected by blood or blood products, given in the UK, that may have been contaminated with hepatitis C. So, there were 2 possible issues to address in each case. Was it likely (greater than 50% probability) that the applicant received blood products? Was it likely, again greater than 50% probability, that a transfusion was the source of hepatitis C?

25. The standard that we applied was greater or less than 50% probability. We asked the applicants to provide as much written evidence as possible concerning the circumstances of their contact with blood products. In the majority of cases, the original application had been declined by the SF because documentary evidence of transfusion was lacking. However, this was frequently a consequence of NHS or local policies to destroy old medical records. So, the Appeals Panel sought a more complete description from the applicant (or witnesses) of the injury/surgery and its management. The Panel carefully considered these statements to determine the credibility and probability that the injury/surgery would have required treatment with blood products. "Most probably" refers to greater than 50% likelihood.

26. Stage 2 applicants had already been awarded stage 1 payment, so it had been decided by SF (possibly after appeal) that the applicant had probably been infected by hepatitis C as a consequence of receiving contaminated blood products in the UK. Eligibility for stage 2 required that the applicant had developed specific complications of that infection, most often progression to cirrhosis of the liver. So, if rejected by SF, the Appeals Panel would examine the evidence and sometimes ask for specific additional evidence that the applicant had developed those specific complications. The most frequent question was "is there a greater than 50% likelihood that the applicant has cirrhosis (or one of the other specific complication of hepatitis C)?"

27. The standard was greater or less than 50% likelihood. The applicant was asked to provide as much evidence as possible to support the claim. Sometimes it was likely that the applicant's own specialist might be able to provide additional information, so we might suggest to the applicant that they should seek that information.

28. As the Hepatologist on the Appeals Panel, I had the most knowledge and experience in the assessment of liver disease severity. So, my role in determining eligibility for part 2 payment was crucial. However, in all cases of stage 1 and 2 appeals, all Panel members made a contribution to the discussion and decisions that were taken by the Panel.

29. Papers were circulated in advance of the meeting. No, SF was not represented at our meetings. From memory, I think that the initial examination of the applicant's refused application would take about 15 minutes. Frequently, there was a consensus of views about individual applications, so decisions at Panel could be taken quite quickly. That reflected the good preparation that members undertook prior to Panel. A minority of

cases took a majority of time. Some cases, and the science and issues surrounding our discussions, would have taken up to 30 minutes to discuss at Panel. We were able to ask the applicant to provide further evidence if we felt that the evidence would inform our decision. On a few occasions, the Panel agreed to get some additional medical or surgical advice. Because of the breadth of clinical experience on the Panel, we would usually know someone who might provide some helpful generic advice. For instance, an applicant may have had a history of specialist ENT surgery, with a procedure that the panel was unfamiliar with. In that case, I might offer to speak with a colleague to get simple generic guidance. For example, I might ask a colleague if the procedure described is major or minor surgery, and whether it is the type of procedure that never, sometimes or always requires blood transfusion. This view would be fed back to the Panel at the next meeting. Also, occasional generic issues might require a literature review. For instance, one was the probability that a deceased patient with both HIV and hepatitis C infection would have had cirrhosis at the time of death. I undertook a literature review and concluded that the majority (more than 50%) would have had cirrhosis at time of death, even if the cirrhosis was not apparent. Based on this evidence, the Panel were able to deal with stage 2 applications from the beneficiaries of HIV/HCV coinfected patients. In the absence of any evidence that the patient did not have cirrhosis, the Panel concluded that cirrhosis was probably present. Hence, stage 2 payment could be made.

30. Appellants often attached letters of explanation containing information that was sometimes helpful to the Panel. Also, appellants frequently responded in letter to questions and requests made by the panel. But, appellants were not seen in person. Overall, I don't believe that personal representation would have contributed to the rigor or fairness of the process. I'm not sure if that possibility had been considered when the terms and processes of the panel were designed.

31. I think that the SF applied a higher burden of proof. In general, that meant that many claims were scuppered by the routine destruction of old medical records. This was clearly not the fault of the appellant or the SF. However, the Appeals Panel was able to explore the details of the injury/surgery that may have required exposure to blood products, and then apply a rule of probability, instead of documented certainty, about the likelihood of receipt of contaminated blood products.

32. I think that we were concerned that some appellants were refused and may have not appealed to the Appeals Panel despite having a good case to do so. Some of those

may have made successful application to the Appeals Panel, but they may have been dissuaded by their own inability to find documentary evidence of transfusion. I don't remember if the SF changed its own criteria or thresholds in response to the practices of the Appeals Panel.

33. I can't readily explain this comment by Nick Fish.

34. No, I don't recall any process to consider triage of applications according to urgency.

35. I think that the document SKIP0000030_125 includes additional information that will have been useful in helping refused applicants to decide whether to apply to the Appeals Panel and also has guidance on what type of documentation may be helpful to the Appeals Panel. I can't recall if this information was posted on the SF website or whether it simply accompanied the letter of a negative decision taken by the SF.
Apart from information on the SF website, I'm not aware of any additional support or assistance being made available to applicants. As far as possible, where the likelihood of a successful appeal was significant, the Appeals Panel gave additional instructions or advice.

36. I see that this particular audit was undertaken by Dr John Dracass who was the GP member of the Appeals Panel at the time. I think that this audit was shared with and discussed by all members of the Appeals Panel. I don't remember if further audits like this one were undertaken. They would have been minuted and documented if they were undertaken. I think that the Appeals Panel acted within a fairly narrow remit, and it was clear after a bedding in period that limited types of appeals were being submitted and that a limited number of themes were appearing. That audit was done at a relatively early time-point in the life of the Appeals Panel, and I don't believe that there were any changes to the practices or policies of the panel after that early period. That was an appropriate time to undertake the audit, but I would be surprised if any of us saw the need for later audits. The membership of the panel was really quite stable and the consensus attitude to appeals was established and maintained without difficulty.

Section 4: The Skipton Fund Appeals Panel Substantive decision-making

37. Yes, I remain of that view. It is based on my understanding and knowledge of the epidemiology of hepatitis C in the UK. The founders of hepatitis C infection in the UK

were from 2 groups. One group includes the injecting drug users, many of whom began this practice abroad, but later returned to the UK. This was probably not observed in the 50's but became more common in the 60's and later. The other founding group includes migrants from countries that had endemic hepatitis C. Migration at that time was not from countries with high prevalence. The majority of migration-associated hepatitis C in the UK is historically from the Indian subcontinent, most of which came after the 50's. Perhaps the best evidence of absence of hepatitis C from the UK in the 50's comes from looking at the incidence of hepatitis C associated liver failure and liver cancer. Before the 1980's, HCV-associated liver failure and liver cancer were extremely rare. Thus, the probability of being exposed to HCV by blood transfusion in this country in the 50's was very unlikely, perhaps not at all.

38. Yes, I referred to this above. I undertook a literature review on behalf of the Panel. I concluded, and presented my findings to the Panel, that people dying with HIV/HCV coinfection had a high (more than 50%) probability of having cirrhosis by the time of death. In many cases, of course, death was due to complications of the HIV. However, the literature review found evidence that liver disease and progression to cirrhosis accelerates as HIV progresses. Also, post-mortem studies found a high likelihood of cirrhosis in this group. I think that my review will have been minuted by Professor Mildred at one of the Appeals Panel meetings. Also, I think that my review directly affected the policy of the SF as indicated by the minutes of the Board of Directors of the SF (SKIP0000030_085). Unfortunately, I can't find a copy of the review with references.

39. I think that case SKIP0000048_382 may have been more complicated than Professor Mildred's letter suggests. On reviewing that document in its entirety, I see that possible exposure was in 1990 and by 2006 the patient had cirrhosis and by 2008 had liver cancer. Cirrhosis within 16 years of infection is not common, and there is typically an additional decade between development of cirrhosis and the subsequent development of liver cancer. This is a very rapid progression if the infection date was 1990, though it is feasible. In this case, the country of birth was Italy and the HCV genotype was the type commonly seen in Italy. However, it may have been acquired in the UK. Also, the nature of the injury was not one that would have typically required transfusion. Overall, most likely exposure was to hepatitis C in Italy as a younger man, and transfusion was probably not required for the injury sustained in 1990. So, I maintain my view that the probability is that the injury

sustained in Poole did not lead to hepatitis C infection with the subsequent rapid development of cirrhosis and liver cancer. Though it is possible, the Panel is asked to deal with probabilities. I would draw your attention to the SF application as completed by Dr Carty. In my view, Dr Carty presents the case fairly, noting that the patient thinks (Dr Carty underlines this) he was transfused. Dr Carty does not state that it was probable that infection arose in Poole in 1990. Dr Carty acknowledges the possibility, but also mentions that the patient was born in Italy and that infection could have occurred before 1990. So, the opinion of the clinician has not been ignored, but was indeed insightful in my view.

40. I think that the Skipton Fund had to decide what fibroscan value to use to diagnose cirrhosis. That was not the domain of the Appeals Panel. However, it was an emerging technique in 2008 and published data were not plentiful. The fibroscan value could not be used in isolation to diagnose or exclude cirrhosis. Other laboratory and imaging techniques were also needed. My email to Nick Fish was a good summary of the issue at that time.

41. I reviewed this file. It appears that the injury was sustained early August and jaundice developed in April, so the proposed incubation period was at least 8 months (>32 weeks). An incubation period of that duration is possible, but most unusual. So we agreed that it would need to be atypical. As Dr Murphy suggests in his letter, we did not feel that the evidence was sufficiently compelling to substantiate the claim.

42. The panel did its best to establish, either with hospital documents or witness statements, that the injury/surgery required the administration of blood products. Sometimes it was obviously an injury requiring transfusion, sometimes the injury was so minor that the need for transfusion was not credible. For cases in between, we carefully considered whatever evidence and statements could be put forward by the applicant. On a few occasions, if the nature of the surgical procedure was obscure, we would speak with an allied professional to get some guidance of the magnitude of the surgery and haemorrhagic risks associated with the specific procedure.

43. In this case, we had to consider the likelihood of transfusion according to the elements of the patient record which were available. Indirect evidence, for example the results of blood tests that may have been included in the file, was also considered. The absence of documented transfusion did not directly lead to refusal of a claim. On the contrary, evidence of transfusion was sometimes found by members

of the panel when others before us had failed to do so. The members of the Panel were fully aware that medical documentation was and is frequently inadequate, and the members examined the evidence with this in mind.

44. In cases where evidence of transfusion was lacking, the Appeals Panel had to examine the available evidence and decide, on balance of probabilities, whether the event likely required transfusion and whether that transfusion was associated with risk of hepatitis C contamination. Written evidence was sufficient in this respect.

45. With respect, I think that this issue has been discussed in previous sections.

46. The panel had to consider the possibility of other sources of infection. In this respect, identification of an alternative and likely source of infection (eg injecting drug use) made it less likely that blood transfusion was the source of HCV infection. So, absence of an alternative source of infection was an important consideration. One particularly difficult type of patient was the patient with a long history of chronic problems requiring repeated admissions to hospital and repeated hospital procedures. In the absence of an alternative source of infection, I think that this type of patient probably got infected by nosocomial spread of the virus. Thus, in my opinion, the NHS treatment was the likely source of infection. However, the SF makes payment only when the infection is transfusion-associated, so this type of patient does not benefit from the SF.

47. The Panel Members gave their views on many occasions. The panel was constructed to include medical practitioners with appropriate knowledge and skills, including Patricia Hewitt, an expert in transfusion medicine over a long period of time. Perhaps on 2 or 3 occasions we sought advice from hospital colleagues and fed this back to the Appeals Panel. We recognise that transfusion practices have changed over time and that blood transfusion was used more frequently in olden days.

48. I don't remember the literature review in question and I certainly don't have a copy of it. I don't know the answer to these questions. Anti-D contamination is typically associated with recognisable and large outbreaks of HCV infection. I understand that this has not been observed in recipients of anti-D in the UK.

49. This problem arose on a number of occasions. The majority of transfusion recipients claimed exposure to a limited number of products during a short period, and this

could be the source of HCV infection. In general, however, the vast majority of transfusion recipients in the UK did not acquire HCV. In contrast, the majority of injecting drug users do get exposed to HCV, and drug use is clearly the main source of HCV in the UK. For a patient who was transfused and who had a history of drug use, the overwhelming probability is that the injecting drug use was the source of the HCV. It is possible that the transfusion was responsible, but the panel decided on probabilities.

50. Yes, the letter indicates that the Panel wishes to obtain Dr Ramsay's expert opinion on this matter. The information directly informs the issue of competing causes of HCV infection ie transfusion-associated vs injecting drug use in the same person. I don't remember if we asked for similar reports to inform other dilemmas.

51. I don't think that the report was provided directly to appellants, though Professor Mildred's letters to the appellants would have included the relevant conclusion that the risk associated with injecting drug use is exponentially greater than the risk of single unit transfusion in the UK prior to the introduction of HCV screening. I don't think that we considered whether or not to provide the entire report to unsuccessful appellants. I certainly had no concerns about relying on this report to adjudicate those cases where transfusion and injecting drug use were competing causes of infection.

52. These cases are more difficult. I have seen a very large number of patients who are convinced that their injecting drug use was a sterile procedure without risk of acquisition of blood borne virus infection. However, someone somewhere showed them how to do it, and needle exchange provides sterile needles and syringes but not the additional paraphernalia that are involved in injecting drug use. The practice of the injecting drug user almost inevitably exposes them to HCV infection, and this needs to be compared with the risk of HCV-associated blood transfusion in the UK pre HCV screening (ie less than 1:1,000 for a single unit exposure).

53. Yes, possibly I anticipated the conclusion of the Appeals Panel in this case. It's not clear to me why I was approached in this case. I was best equipped to answer his query. Certainly, I would never have made a unilateral decision to refuse SF payment. The event probably was a breach of best practice. I don't remember this case, so I certainly can't remember any other cases where this approach was offered or given. I don't recall being concerned by the performance of the SF. The fact that

we could reverse their decisions reflected the way that the SF panel versus the Appeals Panel were established. I never felt that the independence of the Appeals Panel was threatened. This event may have been more likely to occur because Nick Fish provided the secretariat for both the SF panel and the Appeals Panel.

Section 5: Relationship with Government

54. No, to the best of my knowledge there was never any direct influence of Government on our practice.

55. No, I don't think that we had cause to raise concerns about the SF or the Appeals Panel. Certainly, the Appeals Panel proved essential. It would have been unfair if patients had been refused payment when the balance of probability was that they were deserving it.

Section 6: Complaints

56. I don't think so.

57. I don't know. I think that the letters from Professor Mildred marked the end of the process, so far as the Appeals Panel was concerned.

58. I was not aware of any complaints about the performance or conclusions of the Appeals Panel.

59. No, I was never approached by beneficiaries or potential beneficiaries with concerns about the SP or the Appeals Panel.

Section 7: Other

60. Yes, I believe that they were well run. The SF definitely needed the Appeals Panel to make sure that justice was delivered in many cases. The requirement of the SF to have documentation when most of the relevant medical records had been destroyed was unfortunate and upset a number of patients. The remit of the Appeals Panel corrected for this.

Statement of Truth

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

GRO-C

Signed ___David Mutimer_____

Dated ____10/2/2021_____