Witness Name: Dr Norman Gourlay
Statement No.: WITN5259001
Dated: February 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR NORMAN GOURLAY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 14 December 2020.

I, Dr Norman Gourlay, will say as follows: -

Section 1: Introduction

Please set out your name, address, date of birth and any relevant professional qualifications relevant to your work at the Skipton Fund (SF).

1) My full name is Dr Norman James Gourlay and I reside at an address known to the Inquiry. My date of birth is GRO-C 1956.

2) My qualifications are as follows:

MBChB	1979	Glasgow University
MRCGP	1983	Royal College of General Practitioners
Dip RS (dist)	1990	Cambridge University
MA (dist)	1994	Swansea University (Philosophy of Health Care)
MTh	1999	Glasgow University (Concept of Personhood)
D Med Eth	2012	Keele University (Distributive Justice in respect to HIV patients)

Please describe your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.

3) In summary my employment history began in 1979 when I entered my training to be a General Practitioner. I then became a Principal in General Practice in 1983 until 2003. Since then and to date I have worked as a Portfolio Medico-Legal General Practitioner.

4) In rather more detail:

1974 – 1979	Medical Student, Glasgow University
Aug 1979 - Jan 1980	Medical JHO Heathfield Hospital, Prestwick
Feb 1980 - July 1980	Surgical JHO RAI, Paisley
Aug 1980 - Jan 1981	Orthopaedic SHO & Casualty Officer, Ayr County Hospital
Feb 1981 - July 1981	Obstetric SHO Irvine Central Hospital
	Aug 1981- Jan 1982 Medical Registrar, Ballochmyle Hospital (Rheumatology)
Feb 1982 - July 1982	Medical Registrar, Irvine Central Hospital (Respiratory and ID)
Aug 1982 - July 1983	GP Registrar, Frew Terrace Practice, Irvine.
	Police Surgeon, Irvine.
	Medical Practitioner, Irvine Central Hospital (ID)
Aug 1983 - July 1986	GP Principal, Three Man Practice, Exeter.
Aug 1986 - July 1990	GP Principal, Lusaka, Zambia. (800 known HIV cases on list)
	Mission Hospital HIV Liaison Officer
Aug 1990 - Nov 1990	GP Locum West of Scotland (Glasgow)
Dec 1990 - Sept. 2003	Single-handed General Practitioner Muasdale, Argyll.
	Medical Officer, Campbeltown Hospital.

	Medical Officer, Ronachan House, Substance Abuse Centre. Medical Member, Tribunal Service. GP Trainer. Basics General Practitioner. General Practice Research Practitioner.
Sept 2003 - June 2011 (Oxford)	Portfolio Medico-legal General Practitioner Regular Sessions as GP Locum. Oxford Regular Sessions in Out of Hours Service, Oxford OOH Registrar Supervisor Personal Injury Claim Report Writer (2006-2011) GP Negligence Report Writer (from 2007) Medical Member, Tribunal Service Medical Appraiser, Tribunal Service (2006-11) GP Oxford Appraiser. (2005-2011) GP QOF Assessor (2009-11) National Advisor to St John Ambulance (2004-5) Member FTP GMC (from 2006) Member Skipton Fund Appeals Panel (from 2009)
July 2011- Oct 2011 (Kinghorn)	Portfolio Medico-legal General Practitioner
Nov 2011 onwards (Arrochar)	Portfolio Medico-legal General Practitioner Regular Sessions GP Locum, OOH GP, and OOH GP Supervisor until 2015 (I still have a Licence to Practice and remain on a GP Performers List) Occasional Sports Event Medical Officer GP Expert Witness (ongoing) Medical Member, Tribunal Service (Ongoing) Scottish GP Appraiser (2013/14) Chair, MPTS FTP Panels (2011-2015) Member Skipton Fund Appeals Panel (Closed 2017)

	Member EIBSS (Ongoing)
	Member NI Infected Blood Appeals Panel (from 2018)

Committee Posts

1980-1982 Junior	Member of the West of Scotland BMA Hospital Staff Committee
1988-1990	Chair of Zambian Christian Medical Fellowship
1995-2003	Member of the Argyll and Clyde Trainers Group
1996-1999	Member of West of Scotland Research Ethics Committee
1996-2002	Member of the West of Scotland Practice Research Group
2004-2005	Member of the Voluntary Aid Societies Medical Committee
2015-2019	Member of the Scottish Legal Aid Quality Assurance Committee
2019	Member of the Ministries Council of the Church of Scotland
2018-2020	Member of the Loch Long Jetty Association (Scot. Charity)
2020	Member of the EIBSS Joint Review Group

5) In summary from the perspective of the Skipton Fund Appeals Panel, I had my general medical training in the period 1974-1983 and have been an independent General Practitioner since 1983. I thus have personal experience in working in both Primary and Secondary care settings in the period prior to 1991. As a General Practitioner I have had some greater experience of blood borne viruses and drug abuse than many of my colleagues. I have had considerable experience of commenting upon other General Practitioners' records as an Appraiser and through negligence work. I have had an academic interest in Bioethics and have very considerable experience of working with lawyers in different jurisdictions.

Please set out the positions you have held at the SF, including any committees, working parties or groups relevant to the Inquiry's Terms of Reference, and describe how you came to be appointed to those positions.

6) The only position which I have held in regard to the Skipton Fund was as the GP member of the Skipton Fund Appeals Panel from 2009 until its closure in 2017.

Please specify how much time you spent each month on SF work.

7) I was contracted to work 4-8 days per year and on average, including reading time, this would reflect the minimum and maximum time that I spent working for the Appeals Panel per year.

Please set out the basis upon which you were engaged by the SF (ie as an employee or a consultant).

8) I was engaged on a self-employed contractor status.

Please describe your role and responsibilities in the above position(s) with the SF.

9) I was engaged to adjudicate in conjunction with the rest of the Appeals Panels in regard to appeals raised by appellants who disputed the decisions made by the Skipton Fund Assessors in regard to their individual cases.

Did you attend Board Meetings at the SF? If so, how frequently did you attend and for what purpose?

10) No.

Did you attend any regular meetings with the SF? If so, what was their purpose and how frequently did they take place? Were minutes kept of these meetings?

11) No, I did not attend any meetings with the Skipton Fund other than Appeals Panel meetings.

What induction, training and information did you receive from the SF as to its functions, aims and objectives? What did you understand the aims and objectives of the SF to be? What principles or philosophy underpinned its establishment and working?

12) I received literature from the Skipton Fund in regard to the nature of their work and the basis of the decision making in regard to applications. I joined the Appeals Panel after it had been functioning for three years and thus there was a considerable amount of informal training arising during the Panel hearings themselves.

13) I understood that the Skipton Fund had been set up by the Government as a semi-independent body to fairly administer the ex gratia payments which the Government had agreed to in regard to persons infected with Hepatitis C from blood products and tissues administered to them by the NHS prior to 1991.

14) I understood that the overriding objective of the Skipton Fund was to administer these ex gratia payments fairly. This meant both that payment should not be made to those who did not qualify and at the same time effort should be made to facilitate the receipt of appropriate payments by those who did qualify.

Please set out your membership, past or present, of any other committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

15) None.

Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided.

16) I have never provided evidence in any form to other inquiries, investigations or litigations in relation to the viruses mentioned or blood or blood products.

Section 2: The Appeals Panel

Please describe how you became appointed as a medical panel member (General Practitioner) of the Appeals Panel. In particular:

a. ***How did you learn about the position?***
b. ***Please describe the appointment process.***

17) As far as I recall, I saw the position advertised in the general section of the British Medical Journal medical vacancy section. It may well have been advertised in other ways in addition. My recollection is that some information was made available to the candidates about the position prior to the interview process and we were required to make written application citing referees. A number of General Practitioners were interviewed by an Interview Panel in London for this position. The Legal Chair of the Appeals Panel sat on the interview Panel with two others. I do not now recall the positions held by the other interviewers, but they themselves did not sit on the Appeals Panel.

18) The application process was a competitive process which as far as I am aware was conducted according to the tenets of both the Code of Practice for Scientific Advisory Committees and the Code of Practice issued by the

Commissioner for Public Appointments. It was overseen by the NHS Appointments Commission. I note that my initial formal appointment letter dated 2 October 2009 was signed by the Chair of the Appointments Commission.

19) After my initial appointment the appointment was reviewed in conjunction with Appraisal Reports from the Panel Chair and subsequently renewed in 2012 and then again in 2016.

Who else sat on the Appeals Panel with you during your tenure?

20) In the period 2009 - 2013:

Professor Mark Mildred - Legal Chair
Professor David Mutimer - Hepatologist;
Dr Patricia Hewitt (Ainley) - Haematologist
Ms Annie Hitchman - Lay

21) In the Period 2013 - 2016:

Professor Mark Mildred - Legal Chair
Professor Peter Mills - Hepatologist
Dr Patricia Hewitt (Ainley) - Haematologist
Ms Annie Hitchman - Lay

22) In the period 2016 - 2017:

Professor Mark Mildred - Legal Chair
Professor Peter Mills - Hepatologist
Dr Patricia Hewitt (Ainley) - Haematologist

How many people sat on each Appeal? The Inquiry understands it to be the Chair, a medical member and a lay member. Is that correct?

23) The routine procedure was that the entire Panel sat on each Appeal. For the bulk of the period of the Skipton Fund Appeals Panel that meant a Panel of five, a Legal Chair, three medical members and a lay member.

Were you as General Practitioner required to sit on every appeal?

24) Yes.

Was there a legal member of the Panel? If so, who was this and what was their role?

25) Yes. Professor Mark Mildred. His role was to organise and chair the meetings. This involved leading the discussion and facilitating the decision-making process. In addition to making space for the various members of the Panel to contribute from their own expertise Professor Mildred had the task of giving his own particular expertise, that is, legal guidance to the proceedings. Professor Mildred had the primary role of crafting the determination letter after each Panel meeting, although at times he was aided in this process by further contributions from the other Panellists in particular over the phrasing of any technical medical issue. Decision making, while led by Professor Mildred, was generally one of a consensus agreement within the Panel following a full discussion with Professor Mildred being tasked to consider the legal robustness of the reasons given for the determinations. It was routinely the case that the panel would decide that there was the potential for further useful information to be received to aid the decision making process and the case would be adjourned to the next date when an attempt to get more information was made. Professor Mildred, as Chair, would be responsible for drafting the explanation as to why we were unable to make a decision in such cases.

26) Whilst I have little recollection of this, it is likely that Professor Mildred was also involved in liaising more closely with the administrative staff of the Skipton Fund than the rest of the panel. He was certainly involved in recruitment.

The Inquiry also understands that the Appeals Panel included the Chair, a Hepatologist, and a Haematologist [SKIP0000030_105, page 9 and 10]. Did each of these panel members participate in every appeal?

27) Yes, as did the Lay Member when in post.

Did the Appeals panel have a legal member, or any legal advice available to it? If so, please give details.

28) Yes, Professor Mark Mildred, as detailed in paragraph 25 above.

Did you as a medical member (General Practitioner) of the Appeals Panel have a hand in recruiting the other members of the panel? If so, how did you go about this? If not, who recruited them?

29) I personally did not have any formal role in the appointment process, which I believe was advertised and interviewed for in a competitive fashion akin to that which I have detailed in my paragraph 17 above.

Did the SF provide administrative support to the Appeals Panel in terms of the provision of documents, and the listing of appeals? If not, who did?

30) Yes.

How frequently did the Appeals Panel meet to conduct appeals?

31) Approximately three times a year. The frequency of the Appeals Panel meeting reflected the number of cases which were to be heard and in

general terms the number of cases diminished over the years and as a result the gap between meetings somewhat lengthened.

Where did the Appeals panel meet?

32) The general pattern was that one meeting per year was held physically face to face and the remaining meetings were conference telephone hearings. The venues for the face to face meetings were usually hired rooms in London in academic institutions.

Section 3: Procedural Issues: The Appeals Panel

Were there any guidance/criteria/policies in place for the determination of appeals under the scheme which set out the powers of the Appeals Panel and how they should be exercised? You may find [SKIP0000030_023] of assistance. If so:

33) Yes there were guidances/criteria/policies in place explaining the remit and the terms of the Skipton Fund, the Application Process, and the remit of the Appeals Panel.

34) As far as I know most of these were published on the web and certainly the Skipton Fund administrator would have routinely made these available to Appellants.

Were they publicly available? If so, where?

35) Yes, for a considerable amount of general advice, both by post from the Skipton Fund and on the internet.

How frequently, if at all, were they updated? Please describe the process.

36) This would be best addressed by administrators at the Skipton Fund.

37) I am aware in general terms that the arrangements put in place by the DofH evolved over time as a result of discussions between campaigners and the DofH. In general terms the DofH would inform the Skipton Fund of any changes and they would in turn inform the Appeals Panel. As part of this process the literature of the Skipton Fund would have been updated. In general the expectation was that the Skipton Fund was designed to be a facilitating organisation.

What guidance was provided to those seeking to appeal against a decision made by the SF in relation to:

a. The procedural requirements of an appeal?
b. How the appeals were processed by the Appeals Panel?
c. Any additional evidence the appellant could provide to assist their appeal?

38) This would best be addressed by the Administrators of the Skipton Fund. I know that letters were sent from the Skipton Fund to Appellants detailing the procedure and the type of material that the Appeals Panel would find helpful in adjudicating the appeals.

Were there any time limits on appeals, or fees payable by those bringing an appeal against an SF decision?

39) There were no time limits on appeals.

40) As far as I am aware there were no fees intrinsic to the Appeals process.

41) There were also no limits imposed on raising further appeals against the appeal decision, although Appellants were generally encouraged not to make a further appeal if they did not submit any further evidence or any material new argument.

42) Appellants had the right to seek Judicial Review of our decisions, if they believed that they had a legal case so to do. I would assume that this would have involved fees.

43) Some applicants sought legal and other representations in order to better organise their appeal, and this may have involved them in expense.

44) I believe that the Skipton Fund gave some small financial assistance to Appellants to obtain necessary medical evidence such as notes – but this would need to be confirmed by the administrators.

Please confirm if the appeals process was to hear appeals:

a. **By applicants who did not meet the eligibility criteria for a stage 1 payment, or**
b. **By beneficiaries against decisions that they did not meet the criteria for a stage payment, or**
c. **Both?**

45) Both.

What was the question the Appeals Panel had to determine on an appeal against a determination that the person did not meet the eligibility criteria for stage 1? You may wish to refer to SKIP0000030_105 and SKIP0000033_058.

46) The fundamental question was whether the Appellant met the criteria on the balance of probabilities to achieve an ex gratia payment. As noted at paragraph 37 the criteria evolved over time. Essentially a qualifying person on the balance of probabilities became infected by hepatitis C virus as a result of being treated with NHS blood, blood products or tissue before September 1991, or was secondarily infected by a qualifying person through being in a specified relationship with that person and through receiving the virus through designated means. For the criteria to be met the infection had to become a chronic infection of hepatitis C.

What was the standard and burden of proof on an appeal against a decision that an applicant did not meet the criteria for a stage one payment? Please explain what was meant in the SF application form by the phrase 'most probably' regarding the standard of proof required.

47) The burden of proof fell on the Appellant to demonstrate that they met the criteria.

48) The standard of proof was the civil standard of more likely than not or on the balance of probabilities.

What was the question the Appeals Panel had to determine on an appeal against a determination that an applicant did not meet the eligibility criteria for stage 2? You may wish to refer to [SKIP0000030_105].

49) The fundamental question was whether the Appellant met the criteria on the balance of probabilities to achieve an ex gratia payment for stage 2. The criteria evolved over time but essentially payment was made to those who had on the balance of probabilities received specified significant secondary complications of being infected with hepatitis C such as cirrhosis of the liver, primary liver cancer and B-cell non-Hodgkins lymphoma. Those who received stage 2 awards had first to meet the criteria for a Stage 1 award.

What was the standard and burden of proof on an appeal against a decision that an applicant did not meet the criteria for a stage two payment?

50) The burden of proof fell on the Appellant to demonstrate that they met the criteria.

51) The standard of proof was the civil standard of more likely than not or on the balance of probabilities.

Please describe your role in the appeals process.

52) My role was to contribute from my professional experience and make professional judgements regarding the merit of the Appellants cases in regard to the published criteria of the Skipton Fund and with the rest of the panel make a determination in regard to outcome. We each brought different perspectives to the discussion, my perspective being that of a General Practitioner who had practised in the time in question. The primary element of my role was to advise on the meaning of General Practice notes which were submitted and to advise regarding the likelihood that more information would or would not be available within Primary Care records. As a panel we would discuss the case in full, each contributing to elements as appropriate to our background and knowledge.

Please describe how an appeal was conducted. In particular:

a. **Were papers provided to the panel in advance?**
b. **Was anyone from the SF there to present the SF's case in the appeal? If so, who was this?**
c. **How long did it take on average to consider each appeal?**
d. **Were the panel able to call for further evidence, or make their own investigations?**

53) In general terms the bundle submitted by the Appellant for the Appeal was given to the Panel around two weeks before the Panel Meeting in question. The appellant had been advised by the Skipton Fund, and sometimes by independent advisors, as to what would be useful to present to the Panel. The bundles submitted were usually in the order of around 100 pages but they could vary widely between around 20 – 500 pages, dependent upon the amount of medical notes the Appellant believed would be helpful to the case that they were making. It was customary for Skipton Fund to accept and

forward to the panel any additional evidence which an Appellant wished to submit up until around 24 hours before the Panel met. On occasions if an Appellant believed that they had substantial evidence which would be helpful and which they had not got in time then they decided to defer their hearing until the next Panel Meeting.

54) It was customary that the medical members each made brief notes of the cases to be discussed to highlight in particular their understanding of the medical issues involved and these notes were circulated to the Panel as a whole. These initial informal notes were indicative primarily of the clinical issues involved and were not determinative of the eventual judgment of the Panel.

55) During the Panel Meeting, the discussions were led by the Legal Chair who was always careful to ensure that everyone's views were heard on each case and who allowed any with particular experience of any specific aspect of each case to fully explain their understanding of the issues to the Panel. The aim was to reach a consensus that everyone could support although in theory a case could potentially have been decided by a majority vote.

56) Essentially the discussions of the Panel were held *in camera.* There was no-one present from either the Appellant or representing anyone else such as the Department of Health or the Skipton Fund. For the majority of cases we were aware of the decision that had been taken by the Skipton Fund in regard to the binary question of award or reject, and we were aware of the broad reason for their decisions, but not aware of the specific details of the considerations by the Skipton Fund Assessors.

57) Our understanding was that we were acting completely independently of the Skipton Fund, or indeed of the Department of Health in regard to the judgments that we made, while we were bound by the same rules and reasoning processes as were open to the assessors for the Skipton Fund.

58) The time taken on each case varied considerably in respect to the complexities of the points involved. Some decisions were very finely balanced, others were more obvious given clear merits or demerits of the case in respect of the regulations which we were applying. In the case of Appellants making further applications to the Appeals Panel the emphasis would have been placed upon any new evidence which was being adduced, nonetheless there would remain opportunity to reconsider the original decision if we believed this was merited. As a guide I would suggest that between 10 and 40 minutes would have been devoted to each case in the Panel hearing itself. There was however no hard rule regarding how long we were prepared to spend on each case. What was determinative of the time spent was upon the overarching need to reach a reasoned consensus. In this regard it should be recalled that not every case was brought to a final conclusion at each Panel Meeting. If consensus could not be readily achieved it was more likely in such a case that further evidence would have been requested and the decision deferred until the next meeting.

59) The Panel routinely made their own investigations, particularly regarding clinical matters, through generic literature searches. Occasionally the Panel would write to a Clinician whose views had been submitted to the Panel to ask for further information from that Clinician as to the basis of the view that they had submitted. Most commonly, for the sake of transparency, the Panel would request further information directly from the appellant and would give an indication of the type of further evidence which would be helpful for the panel to see. This was often indeed the type of information which had already been suggested to the Appellant by the Skipton Fund, but we found that making more specific request sometimes allowed the Appellant to furnish information which was both to their benefit and generally in the interests of Justice.

Why were appellants not able to attend to make representations in person (please refer to the Appeals Panel Terms of Reference within document [SKIP0000030_105], page 8])? In the letters of rejection written to appellants Mark Mildred, on behalf of the Appeals Panel, would typically state that the

panel had no power to hold hearings – what was the source of this restriction on the appeal panel's powers?

60) Appellants were not allowed to appear in person because this was a rule established as part of the original processes of the Appeals Panel. The Appeals Panel operated within a defined constituted structure. I would assume that this was agreed between the DofH and the Skipton Fund from the outset.

Was any action taken by the SF in so far as you are aware, to review the eligibility criteria for SF payments, in light of the decisions made by the Appeals Panel?

61) I do not know. As we were working entirely within the eligibility criteria it does not seem logical to suggest that our decisions would have changed the eligibility criteria. The eligibility criteria did change, but that was as a result of decisions by the Department of Health. Various pressure groups would have been liaising with the Department of Health and one factor in these discussions would have been likely to have been the decisions being made by the Appeals Panel. The Appeals Panel was not a pressure group and had no remit to engage with the Department of Health over their regulations.

In an email dated 20 May 2011, from Nick Fish to Mark Mildred, it states 'As expected, there has been an increase in appeals, already up to 6 new ones' - [SKIP0000001_006] page 7. Please explain why there was an expectation of an increase in the number of appeals against SF decisions in 2011?

62) There were two types of issues which changed our expectation regarding appeals:

- A change in the criteria, widening the scope of the payment categories, and thus bringing in a new cohort of people, who may have been excluded previously.

- Increased publicity for the Fund, such as TV coverage, a new Inquiry, or an advertising campaign from the DofH.

63) I do not know what specifically caused Mr Fish to comment on an expected increase in appeals in this instance.

Was there a procedure in place to consider appeals made on an urgent basis? If so, what was that procedure?

64) This would best be answered by the administrators of the Skipton Fund. In general terms the answer would be no – as the Panels tended to meet once a sufficient number of cases had built up for a session. If however, there was no pressure of cases then at times the Panel would meet to consider a smaller number of cases than usual, in order to not unreasonably extend the gap between meetings. I do not recall us ever meeting to discuss a single 'urgent case'.

What practical support or assistance was available to applicants to help them in making appeal applications? Did many applicants take advantage of this assistance?

65) This would best be answered by administrators of the Skipton Fund. My impression from reading letters between the Skipton Fund and Applicants, which were within the Appeals bundle, was that they were helpful to the applicants in giving general advice and support through the Appeals process. Many Applicants additionally sought advice and help from outside sources including interest groups, legal firms and their MPs.

Section 4: The Skipton Fund Appeals Panel substantive decision making stage one

In an appeal refused on 3 October 2013 Mark Mildred, on behalf of the Appeals Panel, expressed the view that it would be extremely unlikely that in 1950 blood would be infected with HCV [SKIP0000068_007] pages 2-3. Did you share this view? Please explain what your view was based upon, including any relevant literature. Do you remain of this view?

66) As a preface to answering this question I would thank the Inquiry for providing the example of the case documentation *[SKIP0000068_007].* My answer will however be of a generic nature without wishing in any way to revisit the specific decision made in the case in question. Given that for data protection reasons I no longer am in possession of any documents relating to my views on the case, or the *in camera* discussions surrounding the case, and given that the decision reached would have been a Panel rather than an individual decision, it would be inappropriate for me to seek to go behind or explain the specific decision made.

67) In respect of the general question being asked I did and do share the view that in 1950 it was extremely unlikely that any one unit of blood would be infected with hepatitis C.

68) In further explanation – it was statistically unlikely that any particular unit of blood would be infected with hepatitis C at any stage. The question here however would presumably be whether it was even more unlikely that a unit of blood would be so infected in 1950, as compared for instance to 1970 or 1980? In other words was it likely that hepatitis C infected blood would more commonly be available for transfusion in the later period than in 1950?

69) As a General Practitioner I would defer to the opinion of the Haematologist and the Hepatologist on the Appeals Panel in regard to a definitive assessment of these questions and in particular in regard to the academic basis of their positions.

70) As a guide to the Inquiry, of my own more informal understanding of the situation, I would make the following points:-

- There can be no definitive statement of the incidence on hepatitis C in 1950s blood as the tests were not available and the blood will not have been stored for this purpose.

- Genetic studies suggest that hepatitis C had evolved over thousands of years and therefore it is likely that there would have been hepatitis C in the community in 1950.

- There are modelling techniques which can be utilised to estimate the prevalence of hepatitis C in different societies which tend to suggest an upsurge in cases in the period 1960-1980.

- It is generally accepted that in middle and higher income countries the increase of hepatitis C infection was as a result of drug abuse and transfusions, whereas in lower income countries there was a greater occasion of iatrogenic infection caused by poor sterilisation techniques of needles and instruments involved in health care. Again it is generally accepted that transfusion became more commonplace in the United Kingdom after the Second World War and IV drug abuse became much more commonplace in the 1960s. It would therefore be reasonable to consider it likely that the numbers of persons infected with hepatitis C in 1970 would be greater than the number of people infected in 1950 and by inference the number of blood donors who were infected would be greater and the chance of catching an infection of hepatitis C from a blood transfusion would be greater.

In an appeal refused on 3 November 2009 [SKIP0000048_382] Mark Mildred, on behalf of the Appeals Panel, expressed the view that it took 35 years for HCV to progress to cirrhosis and therefore considered it unlikely that the appellant's liver cancer arose from an infection he alleged had taken place in 1990. The Inquiry has received a report from a panel of experts [EXPG0000001] who have advised the Inquiry about the rates of progression to cirrhosis for those with HCV. In particular the Inquiry has been advised that:

a. **Estimates of the rate of progression from infection to cirrhosis vary widely, but have been estimated at 1-2%/year, with approximately 20-30% with cirrhosis after 20 years (but estimates range from 2-40% in different studies) and 40% at 30 years (page 28).**
b. **A range of factors have been associated with more rapid progression of liver disease, including greater liver inflammation, older age, high alcohol intake, co-infections (particularly HDV and HIV), diabetes and obesity (page 27 – 28).**

Please explain:

(i) What if any steps the Appeals Panel took to investigate what factors may have been in play for each appellant (such as in the case of [SKIP0000048_382]) which may explain a faster rate of progression of the HCV? In particular the Inquiry notes that in that case there was evidence that the appellant had a history of excessive alcohol use. Was this taken into account by the Appeals Panel (see page 38)?
(ii) What material you based your view on about the rates of progression of HCV set out in the refusal letter on 3 November 2009 upon, and whether this remains your view?
(iii)What weight, if any, you gave to the medical opinion on the cause of the HCV infection expressed by the clinician filling in the form for the application to the SF. (For example in [SKIP0000048_382] the consultant in Gastroenterology, Dr Carty, had concluded that a blood transfusion administered in 1990 could have been responsible for the appellant's liver disease (p. 52)).

71) As a preface to answering this question I would thank the Inquiry for providing the example of the Stage One case documentation *[SKIP0000048_382]).* My answer will however be of a generic nature without wishing in any way to revisit the specific decision made in the case in question for the reasons outlined in 35 above.

72) The Appeals Panel has always been aware that cirrhosis can be caused by a number of conditions irrespective of hepatitis C and additionally that hepatitis C as a co-factor with these other conditions can lead to earlier onset of cirrhosis in some individuals. Similarly the Appeals Panel has always been aware that the rate of development to cirrhosis, if this happens at all in any one case, will vary considerably between one individual and another. For the majority of individuals who develop cirrhosis this happens after a number of decades have passed, and while it may be reasonably argued that for some individuals this will happen quicker, it is still true to say that the likelihood of anyone developing cirrhosis in a short period of time is low, and thus if cirrhosis is present and is thought to be due to hepatitis C, then the probability is that the hepatitis C infection has been present for some decades.

73) It is generally accepted that while hepatitis C induced liver cancer can arise in the absence of cirrhosis, it much more commonly arises in conjunction with or as a consequence of having cirrhosis. Thus purely in terms of probability it is reasonable to surmise that the occurrence of a liver cancer associated with hepatitis C is statistically most likely to arise after the onset of cirrhosis and thus after the period of time which one would anticipate that it would take to develop cirrhosis.

74) An assessment of the connection between hepatitis C and cirrhosis in the context of the Skipton Fund Appeal Panel was generally conducted in the context of a Stage Two rather than a Stage One application. If the onset of the cirrhosis was thought to be surprisingly close to the time that had been accepted for the initial infection to have arisen (in the Stage One decision) then the Panel would be alive to the thought that hepatitis C may have been a material contributing factor to the rapid onset of the cirrhosis as a co-factor. The Panel would in this context take account of any other factors which had been presented to it such as the presence of excessive alcohol intake or HIV infection.

75) It should be noted that to award a Stage Two payment in respect to cirrhosis the Panel would need to be convinced on the balance of probabilities that the hepatitis C infection was a material factor in regard to the onset of the cirrhosis, whether as the sole factor or as a co-factor. It was not sufficient that the Appellant had hepatitis C and had cirrhosis, there would need to be a connection between the two facts. In general terms the Panel did accept that if a person had cirrhosis and had hepatitis C then the Stage Two payment should be awarded. The logic however would be that if a person had cirrhosis already through for instance excessive alcohol intake and then subsequently developed hepatitis C through a transfusion that the hepatitis C did not cause the cirrhosis.

76) It would remain my view that the average time from hepatitis C infection to cirrhosis and subsequent liver cancer was somewhere in the region of 35 years. I note that this is in line with the position held by the Panel of Experts commissioned by the Inquiry. In such matters in practical terms I would have deferred to the Hepatologist on the Skipton Fund Appeal Panel.

77) As part of the Appeals Panel I would always consider carefully the opinion presented by the Clinician who signed the application form for each Appellant. Considerable weight would be given to their opinion, although there were factors which routinely would adjust the weight which might be in play in each situation. Such factors include-

- How long had the Clinician been involved in the care of the Appellant.
- Whether the Clinician had any personal knowledge of the information which was being conveyed from previous history taking or older notes.
- Whether the Clinician was simply conveying what had been told to them by the Appellant.
- The expertise of the Clinician in regard to the matters which were being conveyed. In this context was the Clinician a Hepatologist, a Gastroenterologist, a Haematologist, a General Practitioner or a Nurse.
- Whether the Clinician was expressing a logically consistent argument.

- Whether the Clinician was using terms such as 'possibly', 'probably' or 'certainly'.
- Whether the Clinician was acting as an advocate for the Appellant.
- Whether the Clinician was expressing positions which were clinically accurate.

In an appeal refused on 15 August 2012 the panel concluded that an episode of jaundice was not caused by the alleged treatment with blood products as the gap between the two was too long (7 months) [SKIP0000027_006]. The panel considered the letter from Dr Murphy who asserted that there are longer incubation periods described in the literature than 26 weeks, but rejected his view on the basis that the average interval between infection and jaundice was 8 – 12 weeks. In circumstances where there was no other identified cause for the HCV and jaundice event, what weight did the panel give to the opinion of Mr Murphy that the appellant's disease progression could be atypical?

78) Again, I would thank the Inquiry for providing the example of the Stage One case documentation *[SKIP0000027_006].* My answer will however be of a generic nature without wishing in any way to revisit the specific decision made in the case in question for the reasons outlined in 35 above.

79) It is reasonable to state that on many occasions it remained possible that a particular event gave rise to hepatitis C, or that a particular condition required a transfusion, even if they were not likely to do so. The remit of the Panel was to make decisions on the balance of probability. Therefore the fact that something was possible in any one instance, but after considering all the sources of evidence was not believed to be statistically likely, was insufficient to pass the Civil Standard test, irrespective of who might advocate that it should.

80) It is noteworthy that it was not part of the Appeals Panel's process to identify the likely actual cause of the hepatitis C, other than through blood products, simply to examine whether there was evidence that it was probably caused through NHS blood products prior to September 1991. On occasion the patient may have been unknowingly infected with hepatitis C through means other than a blood transfusion.

Missing or incomplete medical records

What approach did the Appeals Panel take to the assessment of whether an appellant could prove on the balance of probabilities, that they had been infected with HCV by blood/blood products, where the relevant part of the appellant's medical records were missing or had been destroyed? In particular:

a. **What standard of proof was applied?**
b. **What weight was given by the panel to other evidence submitted by the appellant that he/she had had treatment with blood/blood products (for example a clear account of having received a transfusion either from the appellant or from friends, families, or clinicians?**

81) The standard of proof throughout was always the Civil Standard of more likely than not.

82) Clearly if medical records were available which showed that a transfusion or other blood products had been given then this established the situation. The vast majority of these cases would have received an award without recourse to the Appeals Panel. The Appeals Panel generally read cases where such medical records were not available, including where the Appellant had mistaken a notation of being cross-matched for potential blood transfusion as being proof of transfusion having taken place.

83) For many years the Skipton Fund Appeals Panel changed the decision in favour of the Appellant in around 50% of cases. For the vast majority of these cases there was no clear evidence within the medical notes of the reception of blood products, otherwise they would not have come to the Panel for decision. This demonstrates that considerable weight was given to other matters in addition to the clearly stated medical recording of receiving blood products.

84) Such matters included:-

- Testimony of the Appellant to the event in question.
- Testimony of Witnesses to the event in question.
- The nature of the event in question.
- Arguments raised on behalf of the Appellant by Clinicians.
- Arguments raised on behalf of the Appellant by Advocates.
- The nature of the medical notes which were supplied in regard to their incompleteness, their brevity, any correlating factors.

What approach did the panel take to appeals in which the appellant had medical records for the relevant period, but they did not record the treatment that was said to have caused the infection. In particular:

a. Did the panel consider that treatment with blood or blood products were inevitably recorded in medical notes, or did they consider that there may have been cases (particularly many years ago), when this may not have occurred? An example of the material available to the Appeal Panel on this issue can be found in the letter written in the case of [SKIP0000048_382] at pages 13-14.

85) As a preface to answering this question I would again thank the Inquiry for providing the example of the Stage One case documentation *[SKIP0000048_382]).* My answer will however be of a generic nature without wishing in any way to revisit the specific decision made in the case in question for the reasons outlined in 35 above.

86) The Panel would not have considered that blood and blood products were inevitably included in every form of medical record. They would however anticipate that blood products would be appropriately recorded in medical notes in most instance, where this was required, such as in a drug kardex, an anaesthetic record, an IV infusion record or a comprehensive inpatient medical note. In other words where it is commonplace to record blood products one would expect them to be recorded. Nonetheless even in these situations someone may well have forgotten to complete the record properly.

b. Did the panel consider that treatment with blood or blood products were inevitably recorded in discharge summaries/medical summaries, or did they consider that there may have been cases (particularly many years ago), when this may not have occurred? An example of the material available to the Appeal Panel on this issue can be found in [SKIP0000047_003] page 3, in which Mr Fish acknowledged that blood transfusion records were often kept separately from other medical notes.

87) The Appeals Panel did not consider that treatment with blood or blood products were inevitably recorded in discharge summaries/medical summaries. They would be commonly mentioned, but not inevitably so. The corollary to that would be that it would be very rare to read that a blood transfusion was <u>not</u> required on such a summary. At times phrases were used which might suggest that there were no major complications including transfusion, such as 'the patient made an uneventful recovery'.

c. Did the panel always take at face value an assertion by an NHS body that the records being provided were 'complete' notes, (see [SKIP0000041_003] as an example)?

88) It would have been unusual for the Panel to read from any NHS body the assertion that the records provided were complete. In such a circumstance we would have accepted that this was the opinion of the NHS body in question, but not necessarily true, because for most NHS bodies it would be

difficult for them to be sure that no more notes were available from another source.

89) In practical terms what would be apparent would be on perusing the medical notes supplied whether each aspect of the medical note that we would expect to be present was presented. In such a situation the Panel would be likely to assume that the notes were essentially complete.

How could the panel weigh the appellant's evidence that (s)he received treatment by blood or blood products against the lack of a record of the treatment in the medical records, in circumstances where the panel did not hear oral evidence or representations from the appellant?

90) The Panel would do so, as in any paper hearing, through reading the papers submitted by the Appellant. If the Panel thought that the Appellant could enlarge usefully upon the information supplied they were encouraged to do so for the next scheduled hearing. Whether this lack of oral evidence being heard was prejudicial to the Appellant was not within the gift of the Panel.

How did the panel weigh on the one hand (i) the appellant's evidence that (s)he received treatment by blood or blood products and (ii) the opinion of the clinician filling out the application form who had examined and treated the appellant or an assisting expert, as to the causation of the HCV infection, against the panel's view on the likelihood of blood or blood products having been provided to the appellant given the nature of the appellant's condition and treatment. For an example of an appeal in which this issue arose you may find [SKIP0000027_006] of assistance.

91) In every case the Panel considered the evidence fully and balanced the various strands of the evidence according to the cogency of the argument and the likelihood of the event. The Panel paid particular attention to the testimony of the Appellant in all cases. It was commonplace in some

situations to find that the description of the clinical circumstance might make a transfusion seem unlikely, but not impossible. In such a circumstance if the Appellant gave clear evidence of remembering that in their particular case blood products were utilised then this would sway the Panel into agreeing with the Appellant even where statistically a transfusion was less likely and there was no medical note available. The Panel similarly weighed carefully the evidence given by any supporting Clinician, although it was often the case that such evidence was simply a matter of saying that 'the patient told me that' and was not necessarily an independent source of information.

How much weight did the panel give to evidence that there was no other potential mode of infection of HCV other than treatment by blood or blood products?

92) The Panel would bear this in mind, but in the absence of the reasonable probability of blood products being utilised, it would be difficult to give this particularly heavy weight as an argument. In many cases it would be difficult for any one person to be certain how, or when, they became infected with hepatitis C.

The Inquiry has noted that there a number of appeals that were refused on the basis that the panel had concluded that it was unlikely blood or blood products would have been given for the procedure/injuries held responsible by the appellant for his/her infection with HCV (see for example [SKIP0000028_006]). As to this:

a. Did members of the panel give their expert views on these matters?

93) Intrinsically the Panel was an expert Panel which was constituted and appointed to make judgements on these clinical and legal matters. The Panel had broad experience of working in both Secondary and Primary Care in the period from the 1970s onwards. It is clear that no Panel could be constituted to contain a specific expert with experience of every branch of

medicine and surgery over every period in time which was being covered by the Panel's decisions.

b. Were there occasions when further expert opinion was sought?

94) Yes, there were rare occasions when other expert opinion was sought in regards to specific practice at the time. Much more commonly there were many instances when the medical members would carry out literature searches in respect to procedures prior to meeting together as a Panel to discuss the matters. However for most instances of procedures or processes such a search was not required and the matter would fall within the understanding of the medical members present.

c. What if any account was taken of changing medical practice and the more liberal use of blood and blood products decades ago than is considered good practice now?

95) This was very well recognised by the Panel.

Anti-D Immunoglobulin

Appellants who alleged their HCV arose from infection from anti-D immunoglobulin received rejection letters citing a literature review provided to the SF by the National Blood Service that anti-D immunoglobulin produced by Bio Products Laboratory (BPL) in England and Wales and the Scottish National Blood Transfusion Service (SNBTS) in Scotland was safe and therefore not a possible route of hepatitis C infection.

a. Were you provided with a copy of this literature review? If you have a copy of this literature review, please provide a copy of this in your response. Was it this document [SKIP0000031_071]? If so, would you accept that on the basis of this letter, infection with HCV by anti-D immunoglobulin in the UK cannot be entirely ruled out?

96) I have previously seen a copy of a literature review which is also cited by the Inquiry as *[SKIP0000031_071].* I do not know if this is the only literature review which has been done. I agree that on the basis of that review infection with anti-D immunoglobulin cannot entirely be ruled out in some exceptional clinical cases most of which were picked up in a historic look-back exercise and identified.

b. Was any attempt made to share this information with the rejected applicants?

97) I do not know and this would be best addressed by the Administrators of the Skipton Fund. The Panel's decision making would certainly have been informed by such literature reviews.

c. Was anything done to establish the source of the anti-D immunoglobulin given to applicants when deciding the outcome for these types of applications?

98) The circumstances of each case would have been considered as to whether the clinical situation was exceptional or not.

Intravenous Drug Use

What standard of proof was applied when determining if an infection was as a result of IV drug use as opposed to treatment with blood/blood products?

99) As always, the civil standard of proof, more likely than not or on the balance of probabilities.

The Inquiry understands that the SF commissioned an expert report for the Appeals Panel on the probability of being infected with HCV when using IV drugs for up to two years, from Dr Ramsey at the Health Protection Authority (see the letter of instructions of 11 October 2006 [SKIP0000031_221], and the report at [SKIP0000031_217]). Was this the only report the Appeals Panel received?

100) I do not know if this was the only report received by the Skipton Fund. As far as I can recall this is the only report which I have previously seen.

Was this report provided to appellants? From the files seen by the Inquiry, it would appear that it was not as a matter of routine (by way of example [SKIP0000018_004]). Why was this? Did you have any concerns about the fairness of relying on a report to determine an application that was not disclosed to the appellant? If so, what did you do about it?

101) This would be best addressed by the Administrators of the Skipton Fund. I do not know if this report was provided to appellants, or indeed appellant's representative bodies. The Panel consistently and routinely relied upon professional evidence from various sources in coming to its judgements. It did not occur to me that it would be helpful to the majority of Appellants or practical to share references to various professional papers in each reply. I would not have seen this as a matter of a lack of transparency and therefore I personally did not do anything about it.

How did the Appeal panel weigh the opinion expressed in this report about the risk of infection from IV drug use against the specific evidence given by each appellant as to their own drug use? By way of example:

a. **In case [SKIP0000018_004], how did the panel weigh the evidence of the appellant (supported by her parents and her clinician) that she never shared needles, as she took IV drugs for a short period of time alone, at home, using equipment from a needle exchange, against the statistical evidence in the report?**

b. In case [SKIP0000068_010] how did the Panel weigh the opinion of the appellant's specialist nurse that it was the blood transfusion rather than the IV drugs that was the cause of the infection, against the information about risk in the report?

102) As a preface to answering these questions I would again thank the Inquiry for providing the examples of the case documentation *[SKIP0000018_004] and [SKIP0000068_010].* My answer will however be of a generic nature without wishing in any way to revisit the specific decisions made in the cases in question.

103) It is noteworthy that the Report quoted emphasises the increased risk of hepatitis C transmission at the early stages of using opioid drugs and also emphasises that the risks involved, while heightened by sharing needles, were not confined to sharing needles. As a General Practitioner I had particular experience of supervising a drug rehabilitation centre in the period 1990-2003 and have an awareness of the difficulties that drug users have in general, although not necessarily as individuals, in accurately recalling the detail of all their past involvement with drugs. As in every case the Panel would have taken careful cognisance of the credibility of the evidence being put before it as well as the statistical risks of hepatitis C, as far as they could be ascertained.

Section 5: Relationship with Government

Did the Department of Health (or any other Government department) have any influence or play any part in how the Appeals Panel operated or the decisions it took? If so, please give details.

104) No, not in any direct way with the decision making process. The DofH set the parameters under which we were making our decisions.

Did you, or others on the appeal panel, raise any concerns and issues with the Department of Health about the SF Appeals Panel, or the SF criteria for eligibility? If so, please explain what concerns and issues were raised. What was the response of the Department of Health to those matters being raised?

105) I did not. I do not know if any issues were raised by the Chairman or others.

Section 6: Complaints

Was there a complaints process for the SF? If so how did it operate?

106) I do not know for certain. This would best be addressed by the administrators of the Skipton Fund. In respect to the Appeals Panel there was a right to seek Judicial Review.

What information was provided to appellants about the complaints procedure?

107) I do not know. See paragraph 106 above.

How common was it for the Skipton Fund Appeals Panel to receive complaints? How many complaints were you aware of being made?

108) As far as I know we did not receive complaints. We did however receive further applications from Appellants who were unhappy about our decisions.

Did potential beneficiaries or beneficiaries articulate concerns about the SF and/or the Appeals Panel to you? If so, what was the nature of their concerns and how frequently were these issues raised with you? Were you able to bring

them to the attention of the senior management? If so, what was the response? If not, why not?

109) The only concerns that I was aware of were in the form of further applications from Appellants who were concerned that the decision had not gone in their favour. Some of these concerns would have been in relation to the fairness of our decision making, others would have been in regard to the fairness of the parameters of the scheme. We had no role in defining the parameters of the scheme. In regard to unhappiness about our decisions we would always look again at the decision that we had made and we were particularly assisted in this regard if the Appellant gave further information or otherwise explained why they believed our decision was wrong.

Section 7: Other

Do you consider that the SF and the appeals panel was well run? Do you consider that it achieved its aims and objectives?

110) In my experience, apart from occasional administrative hiccups with the provision of papers both the Skipton Fund and the appeals panel appeared well run.

Were there difficulties or shortcomings in the way in which the SF operated or in its dealings with beneficiaries and applicants for assistance?

111) This should perhaps best be addressed to the Skipton Fund rather than to a member of the Appeals Panel who was not intrinsically involved with the running of the Skipton Fund. From the point of view of the Skipton Fund acting as the secretariat for the Appeals Panel they performed their duties reasonably.

Please provide any other information you may have that is relevant to our Terms of Reference.

112) I have nothing to add to the answers I have provided.

Statement of Truth

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

Signed _____ GRO-C

Dated _____23rd February 2021_____