Witness Name: Dr Peter Bramley
Statement No.: WITN6664001
Exhibits: WITN6664002-006
Dated: 3rd February 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PETER BRAMLEY

I provide this statement in response to the request under Rule 9 of the Inquiry Rules 2006 dated 16 August 2021.

I, Peter Bramley, will say as follows: -

Section 1: Introduction

1. Name: Dr Peter Nigel Bramley
   DOB: GRO-C 1959
   Address: GRO-C Perthshire. GRO-C
   GRO-C
   Occupation:Previously Consultant in General Medicine, Gastroenterology and Hepatology, Forth Valley Health Board 1995 till 2017.
   Honorary Senior Lecturer in Medicine, University of Glasgow 1997 to 2017.
   Currently Strategic and Clinical Lead for the Forth Valley Sexual Health and Blood Bourne Virus Managed Care Network, 2009 onwards

   Qualifications:-
   B.Sc (Hons) 1St Class Physiology Leeds 1981
   M.B.Ch.B Leeds 1984

M.R.C.P. (UK) 1987
F.R.C.P. (Edin) 1998

Previous Employment History:
1984-1985 - House Officer for Professorial Surgical and Medical Units, Leeds General Infirmary.
1985-1987 - SHO/Registrar Rotation Medicine. St James's University Hospital, Leeds.
1987-1989 - Gastroenterology Registrar, Professorial Medical Unit, St James's University Hospital, Leeds.
1989-1992 – Hepatology Registrar in Regional Liver Transplant Unit, St James's University Hospital, Leeds.
1992-1995 - Senior Registrar General Medicine and Gastroenterology, Aberdeen Royal Infirmary, Grampian Health Board
1995-2017 - Consultant General Physician, Gastroenterologist and Hepatologist, Stirling Royal Infirmary and Forth Valley Royal Hospital.

Relevant Clinical Interests:
Involved in Multicentre Trials of Interferon therapy for Hepatitis B and C from 1989 in Leeds. Developed Interferon treatment protocols for Hepatitis C in Aberdeen from 1992.
Led the Development of the Forth Valley Hepatitis and Hepatology Service from 1996
Co-Chair of the SIGN guideline 92 (published 2006) and SIGN guideline 133 (published 2013) on the Management of Hepatitis C.
Co-Chair of the Health Improvement Scotland (HIS) - Quality Indicators for Hepatitis C (2012)

Section 2: Responses to criticism of Leila Ann Law

At paragraph 8 of witness W2181's statement, she suggests you misrepresented her husband's medical history in a letter to his GP. This letter is exhibited at WITN2181002. W2181 challenges your reference to her husband's former IV

drug use, and states that her husband "was not addicted to drugs". She also notes she is "suspicious" as to your motivations for recording this information.

2. I have reviewed the content of my letter with reference number WITN2181002. I have several points I wish to make in response to the criticism above. I have clear recollections of Mr Law and his wife, as they became regular attendees during his treatment journey to cure his hepatitis C infection.

3. My standard practice was that clinic letters were dictated onto a tape dictaphone once the patient had left the room, and my secretary transcribed it later and recorded the date typed and available to be sent out to the GP and other recipients. This makes the letter a contemporaneous record of my immediate impressions of the consultation with the patient and is also a summary of my handwritten notes I also take during the process of the 30-45 minute consultation new patients with blood borne virus infections were allocated.

4. My practice has always been in situations when dictating letters where sensitive information is being recorded or has been discussed, is to clearly state who was present during the appointment. So, if Mrs Law had been present during that meeting that would have been made clear by naming her in the first sentence, so the GP is aware of what has been discussed with whom.

5. This practice of naming all present during a consultation can be seen in a subsequent letter which had been identified within an archived digital folder of letters my secretary typed in 2002 (WITN6664002) when I met up with Mr and Mrs Law two years following his successful treatment course. The Forth Valley Hepatitis database administrator has carefully searched all other similar digital archived folders and found no other letters referring to Mr Law or his treatment.

6. In the initial clinic letter (WITN2181002) I also refer to Mr Law's previous partner and the fact she had already been tested for Hepatitis C and found to be negative. If Mrs Law had been present at the consultation I would have also commented in the clinic letter on her own hepatitis status. Our standard

practice would have been to offer her testing at the same time her husband had further blood tests performed, as we offered testing to partners and other family members when they were present. For young children we had an arrangement with the Paediatric team to obtain blood samples for Hepatitis screening. If partners were not present, I would advise the patient to bring in their partner for testing and information sharing at the next clinic visit or, if they didn't want to do that, advise them to visit their own GP for Hepatitis testing.

7. It was often the case that hepatitis patients with a new diagnosis first attended on their own without their partner, as any issues the patient may have giving or receiving sensitive personal information, or worries around the diagnosis, often had to be allayed before they seemed comfortable involving family. We then actively encouraged family to be brought along for later visits.

8. It was clear in the initial consultation that there were two possible routes of Mr Law's HCV infection, with the most likely being needle sharing on a regular basis given the recognition by the patient of HIV and hepatitis infections in his circle of drug using acquaintances from that period in his life. My own recollection was that he was very reluctant to disclose his previous history of intravenous drug misuse to his current partner as he was adamant he had very clearly moved on in his life. There was also the possibility he acquired Hepatitis C earlier from blood products following an accident in 1979. This I recorded in the letter and my usual practice would then be to obtain as much evidence as possible to build a case for this route of infection so that an application could be made to the Skipton Fund for consideration for ex-gratia payments.

9. In situations like Mr Law's, when it was obvious that he was reluctant to disclose his past drug history to his current partner, I would be careful not to discuss that likely route of transmission in follow up clinics, as we moved forward into the work up for treatment.

10. It is not helpful to go back over this issue if he is no longer placing himself at risk of further infections, and instead focus on improving his overall health, preparing the patient for future treatment.

11. Time can also be spent evidence gathering for alternative routes of transmission. This involved obtaining hospital notes from Law Hospital, and identifying any written evidence of blood products being given, together with the identification numbers for each product. This information would then be given to the Scottish National Blood Transfusion service via its director, Dr Frame, and they would carry out cross checks on any retained samples or, if that particular donor had been subsequently found to be hepatitis C positive, on future donations. I would also routinely ask the patient to ask family or friends who had visited them if they could provide a written statement that they saw a blood transfusion being given whilst in hospital.

12. Mrs Law states, in paragraph 37 of W2181, that we requested whatever evidence was available to support his case of being exposed to hepatitis C via blood products for the application to the Skipton Fund ex-gratia payment scheme for which we provided evidence following his treatment, when it became available in 2004.

13. Mrs Law calls into question my motives for recording IV drug use information. I had no reason to misrepresent this. My professional and personal integrity and honesty would be questioned and I would have been severely sanctioned if I deliberately lied about information a patient disclosed to me or made up false information. It is also essential information to have documented, and every patient attending the service is asked about all previous risks including drug misuse, as it may have a bearing on ensuring a successful treatment program with awareness of risk of relapse into drug misuse due to the rigours of treatment. In short, deliberately misrepresenting what a patient has told me is something I would simply not do.

14. At that time, I was also managing many other patients who had may have acquired hepatitis C via blood products or alternative routes, and I saw my role as an advocate for all of them to present their case for ex-gratia payments without prejudice, clearly stating the possible routes of transmission and

providing as much evidence as possible to support one route over an alternative explanation. This I did for Mr Law once the Skipton Fund became involved.

15. In the end, the Skipton Fund adjudicators make the decision on the evidence I provided. On occasion I have helped patients prepare appeals for reconsideration to the Skipton Fund panel. I have done so in cases similar to that of Mr Law, where there is more than one clear route of transmission.

At paragraph 9 of witness W2181's statement, she states that you did not provide her or her husband with much information following his hepatitis C diagnosis, and comments that she does not understand why he was not given the diagnosis sooner.

16. As indicated in response 1 above, it is clear to me that Mrs Law was not present in my first or second consultation with Mr Law, and as stated in the initial clinic letter (WITN2181002), I discussed hepatitis C with Mr Law and gave him written literature about it to take home. In the second clinic letter (WITN2181004), which followed an appointment with Mr Law on 15 January 1998 where he again attended alone, I discussed further investigations including liver biopsy. I again discussed with him the fact that he had not used any IV drugs for many years. At each subsequent clinic visit I always gave the patient time to ask questions and check their understanding, as an important role of the doctor is to empower the patient to make informed choices about their treatment. On any occasions when Mrs Law did appear with her husband in clinic, I would have spent some time explaining and checking her understanding of hepatitis C and treatment options, as well as allowing time for questions as family support is essential to help patients through treatment.

17. A specially trained Hepatitis Nurse specialist is present at every Hepatitis Clinic. The Hepatitis Nurse was available to spend more time on explanations and chatting to patient and relatives. Prior to starting on any treatment, at that time, we had a seven-page Hepatitis Clinic proforma with checklists. Its purpose was to ensure that all aspects of patient understanding and knowledge of hepatitis C and treatment to be started are complete. The proforma checklist is

completed by the hepatology nurse and myself. (An actual redacted patient pro forma from September 1999 is included as WITN6664003 as an example, together with actual treatment clinic letters sent explaining the treatment regime from that period of the Service).

18. As regards why he was not given the Hepatitis C diagnosis sooner, my first information about this patient was a letter from Dr Frame, Consultant at the Blood Transfusion Service on 17/03/1997 directly referring him to myself. The patient was first tested positive for Hepatitis C on 11/02/1997. Unfortunately, Mr Law then failed to attend the first two clinic appointments we sent him and on our third attempt on 23/10/1997 we had our first meeting. As per my initial clinic letter (WITN2181002) he was already aware of his hepatitis C diagnosis having been contacted by the Blood Transfusion Service after donating blood for the first time.

19. That test on his donation of blood in February 1997 was likely to have been the first occasion Mr Law had been tested for Hepatitis C. That is outwith my control.

20. Likewise, the 7 month delay in not being able to discuss his hepatitis C diagnosis with myself as a specialist was due to his non attendance at two previously arranged clinic appointments.

21. A copy of the initial referral letter and all subsequent letters contained in Mr Law's hospital note folder are no longer available as all written and typed hospital notes were destroyed according to the Forth Valley Health Board in 2008 in line with the national guidance on notes retention.

22. As the Forth Valley Hepatitis Clinic was set up with specific funding arrangements by the health board in 1997, in order to provide specialist assessment and treatment service for a newly emerging "difficult to treat" infection, we were asked to provide audit information on all our clinic and treatment activities, so in that era, copies of initial letters were retained for a local "hep C File" written folder, before a Scotland wide National Hepatitis C

database held electronically was developed. The information above was entered into the national database in the early 2000's by an independent Health Protection Scotland administrator from our local written data source and a printout of data held nationally on Mr Law is included (WITN6664004).

At paragraph 10 of the witness W2181's statement, she states that you refused to test her for hepatitis C "on the basis that the test was too expensive".

23. I don't believe I told Mrs Law that I would not test her based on the cost of the hepatitis test. My reasons are as follows:

24. First, I would never refuse to test any patient or relative based on cost. Cost doesn't come into the equation when trying to prevent long term harm from a treatable infection.

25. Second, we were set up as a specialist service by the health board in order to provide seamless services for those infected and affected by hepatitis C including the testing and advice to patients and families.

26. Third, in that period we were engaging with Mr Law, the cost of a Hepatitis C test was approximately £5, and we regularly tested partners and whole families in our clinic

27. Fourth, those who did not wish to be tested in the clinic, at Stirling Royal Infirmary, were directed to their own GP for testing at their convenience.

28. I surmise from Mrs Law's witness statement **W2181** paragraph 10 that it was her own preference, or Mr Law's instruction to her, to go to her own GP in order to have hepatitis testing performed. As part of my discussions with Mr Law on his initial clinic visit and subsequently, would have been to advise him that his partner is tested for Hepatitis C by ourselves at clinic or if they preferred via their own GP.

At paragraphs 15, 16 and 17, of witness W2181's statement, she compares her husband's treatment and involvement in a drug trial, to that of a "guinea pig". She notes that at the end of the trial it was concluded that her husband's treatment had involved an unnecessarily high dosage for a longer than necessary period. She describes your attitude when sharing this information as "dismissive".

29. I am obviously concerned and upset if that was the long-lasting view that Mrs Law has held over these last 22 years about what happened around Mr Law's treatment.

30. It is certainly true that at the end of 1997 when Mr Law first came along to meet me that the current treatment for Hepatitis C was 12 months of interferon monotherapy, and that as part of my discussions around possible treatments there was the prospect of a new more effective combination of interferon and ribavirin, which was currently undergoing multi- national trials.

31. During 1997-1998, all Scottish hepatitis treatment clinics were discussing setting up our own Scottish open label trial, where every patient received the same interferon / ribavirin combination so we could access the ribavirin drug before it became officially licensed in the UK and gained full approval.

32. This was because the evidence from the initial reports of the multinational trials showed a significant improvement of cure rates from 19% to 43%

33. During this time 1997-1998, because of the low cure rate with interferon used alone, only patients who needed immediate therapy with serious disease were started on interferon mono therapy, whilst we waited to see what was happening with license approvals for the addition of Ribavirin in Hepatitis C treatment.

34. In early 1999, The Scottish Health Purchasing Information Centre produced a report for all Scottish Health Boards reviewing the worldwide trial evidence and licensing applications, and recommended interferon and ribavirin combination

therapy as first line therapy for hepatitis C (WITN6664005), and on that basis the Forth Valley Health Board agreed to provide additional funding for the service to use combination therapy to treat all patients with hepatitis C.

35. My own view is that it is likely that Mrs Law remembers what would have been a lot of discussion in clinic in 1998 and early 1999 around the current stage of knowledge with the trials of ribavirin and interferon, in the run up to a decision to start treatment on her husband. This switch to using this more effective combination occurred at the same pace around Scotland and England as soon as local funding agreements were in place.

36. So, it is true that Mr Law was one of the early patients in Forth Valley to undergo fully approved treatment with combination therapy but this combination was fully licensed and had been adopted as best practice across the world earlier in the year and was not part of a trial.

37. In preparation for starting the new combination treatment Mr and Mrs Law were extensively counselled by myself and the hepatology nurses and this would have been signed off on the proforma previously mentioned (WITN6664003)

38. Mr Law was given the fully licensed and approved treatment as per the manufacturers' recommendations of 3 million I.U. interferon subcutaneously 3 times per week, and weight based ribavirin twice per day orally. The dosing regime was checked and signed off by our specialist Hepatitis Pharmacist to allow it to be prescribed.

39. The only time this dose regime was modified is when certain blood values are reached, such as the haemoglobin value dropping to below 10 then the ribavirin dose is reduced by half until the haemoglobin climbs back into the normal range then the dose is modified upwards again. That often takes 2-3 weeks.

40. If the White Cell Count drops then the interferon dose is reduced for a spell which is often 2-3 weeks and is then increased again. This monitoring continues throughout the duration of the treatment. Likewise, if significant side

effects occur, doses can be temporarily reduced till the side effects settle. The aim being to try and ensure the best possible cure rate by keeping as close to the manufacturers' recommended dose for as long as possible.

41. Because of the extensive and frequent monitoring of blood tests and assessments of patients' wellbeing we performed during the treatment process, it may seem to patients to resemble a trial rather than standard NHS therapy, but that is simply reflective of how difficult and important it was to treat hepatitis patients safely with these drugs.

42. In relation to Mrs Law's statement that her husband was excessively treated in dose and duration, I can only comment by saying that this was not a trial. We were following Scotland wide agreed recommendations and manufacturers' drug licence agreements. As time went on, over the next few years, more data became available from further multi-centre trials, and new types of interferon preparation and genotype testing became available. It became possible to select patients who needed longer or shorter courses but at the time that Mr Law was treated he was given the standard dose and duration most likely to give him a cure. Which it did.

43. When I read the clinic letter WITN6664002 from 2002 referring to when I met up with Mr and Mrs Law two years after the treatment had finished, it gives no indication that there were significant issues with Mr Law's general health or any concerns they had regarding his treatment or recovery. It does comment on his black moods being more frequent, and the offer of longer term follow-up was made but was not taken up, with the 24/07/2002 being the last time he was seen at clinic.

44. It was at the end of 2001 that pegulated interferon Alpha -1b and ribavirin received US and UK licences and was starting to be used routinely within Scottish treatment centres. This regime needed once per week, long acting Peg interferon injections and for some patients a lower dose of ribavirin. I accept it was possible that Mrs Law misinterpreted my general discussion at

that clinic or previous clinics following the end of the treatment, on what the future for treatment would look like for hepatitis patients, but Peg interferon had just as significant side-effects if not more than standard interferon, but needing fewer injections and duration for certain groups of hepatitis C patients.

45. For completeness, I might add that in all my discussions with Mr and Mrs Law I certainly did not at any time intend to be dismissive in anything I said to them.

At paragraph 39 of witness W2181's statement, she states her belief that her husband's involvement in the drug trial and the prolonged period of high dosage he received were direct contributors to his death.

46. I have partially addressed this issue under response 4 above. Mr Law received the recommended dose and duration throughout his standard licensed treatment, and any dose reduction which was required for side-effects or for haematological changes in his haemoglobin or white cell counts would have been carefully monitored and the dose adjusted up or down accordingly.

47. The hepatology team and I were very saddened to hear of Mr Law's death from a heart attack 5 years after finishing the successful course of hepatitis treatment. We all had fond memories of Shug (the name he became known to us by) and Mrs Law's spell with us, and they would both brighten up the clinic with their presence.

48. I am not aware of any evidence that would link heart disease with the drugs used for treating hepatitis C, but I am aware of strong evidence, which the national database in Scotland has provided and was published in 2015 in Hepatology Journal (WITN6664006), that undergoing successful treatment for hepatitis C with interferon and ribavirin, when examined across the whole treated Hep C population, in the longer term significantly reduces the risk of dying from cardiovascular disease, the mechanism of this is not clear. However, I appreciate that will be no consolation or comfort to those who have lost family to fatal heart disease with or without hepatitis C.

Section 3: Other Issues

49. I have nothing further to add.

Statement of Truth

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

Signed GRO-C

Dated 3rd February 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
	Letter dated 24th July 2002	WITN6664002
	Patient pro forma from September 1999	WITN6664003
	National Database information	WITN6664004
	Letter dated 16th March 1999	WITN6664005
	Hepatology Journal 2015	WITN6664006