lan McPhail DOB: 1.11.58

Glasgow Western Infirmary/Gartnavel General Hospital Number: 50618440E

Professor Peter R. Mills MD, FRCP I was a Consultant Hepatologist at the Western Infirmary and Gartnavel General Hospital in Glasgow in 2005 and ran the Virus Hepatitis Treatment program. I retired as a Consultant employed by the Greater Glasgow and Clyde Health Board in 2016.

I have been asked to respond to the following two criticisms made by Mr McPhail to the Infected Blood Inquiry on 5.11.18.

3. Criticism by witness W2214

The criticism has been made by a witness with Inquiry reference number W2214 in relation to his treatment at the Gartnavel Hospital between 2006 and 2007.

3.1. At paragraph 5 of witness W2214's statement, the witness explains that he was informed of his HCV diagnosis in 2005. At paragraph 10 he states that due to the number of previous tests he had which showed "deranged LFT results" which were in his medical records, he should have been told sooner than 2005 that he had HCV.

3.2. At paragraph 22 of witness W2214's statement and as evidenced by exhibit WITN2214009, the witness states that he was forced to wait a significant amount of time for HCV treatment and he should have received it sooner. Witness W2214 states that he was told the treatment was expensive and was then put through a series of tests. He further states that this was the hospital "spinning out" the start of his treatment to another year due to funding.

Response to criticism 3.1

Mr McPhail was seen by myself at the Liver Clinic first on 18.5.05. He had been referred by his GP, Dr Kearney, with a history that his liver function tests had been abnormal for 18 months.

The patient has a history of bout alcohol dependence going back to his late teens and had been attending the Alcohol and Drug Dependency Clinic since 2003. He was thought by his GP to possibly have alcoholic cirrhosis and his efforts were concentrated on reducing the patient's alcohol intake. This had been successful but it was puzzling that the liver tests remained abnormal. Mr McPhail was overweight (BMI 29.5) and suffered a myocardial infarction in 2003. He was started on statins which often are associated with abnormal liver tests. Switching to two different statin drugs also failed to resolve the abnormal liver tests. Dr Kearney had therefore been working hard to understand the problem and on failing to succeed referred the patient to the Liver Clinic.

When I saw Mr McPhail on 18.5.05 I did not immediately have an explanation for the abnormal liver tests. Possibilities included alcohol-related liver damage, a fatty liver related to obesity, or some other cause for liver damage. I advised that he remain abstinent from alcohol and worked at getting his weight down. I undertook blood tests for a full liver screen of other conditions and found that he had chronic hepatitis C infection. This was unexpected and only on further questioning was a history of blood transfusion of 2 units following a haematemesis at the age of 17 years picked up as a likely source for this infection. I wrote to his GP with full results of the blood tests on 28.6.05 (WITN2214004) and asked him to discuss the diagnosis with the patient. This was still the era of paper hospital records. The patient had a large file which was being regularly moved around the hospital at this time. Results of these full blood tests took several weeks to be reported and then required the notes and all the test results to be presented to the consultant to allow a report to be dictated. It then took several days for the letter to be typed, proof read, signed and mailed to the GP. This is the reason that it took until June to write to the patient's GP. It would be standard practice for a consultant to write to the GP to ask them to inform a patient of their infection. It is best done face to face by somebody who knows the patient. The next available outpatient clinic appointment at my own clinic may have been some six months away.

Mr McPhail had several health problems and has attended 6 different specialty clinics (liver, lipid, cardiology, alcohol and drug dependency, psychiatry and a nurse-led treatment clinic) over the period 2005-2009.

Mr McPhail was experiencing increasing angina in May 2005 and attended for coronary angiography on 6.6.05. This showed left coronary artery narrowing and he was scheduled for dilatation and stenting. He attended for a cardiology pre-assessment clinic with Dr Stephen Robb, Consultant Cardiologist and perhaps a nurse Rachel Blanck on 7.7.05. The team recognised that he had chronic hepatitis C and on discussion agreed to inform the patient of this on 7.7.05. At this time, it would appear that the GP had not had an opportunity to inform the patient of his infection following upon my letter of 28.06.2005. This was done very thoroughly and documented in excellent detail (WITN7116017). The coronary stenting went ahead, with the team taking appropriate precautions, on 11.7.05. This treatment proved effective and his cholesterol therapy further modified.

Mr McPhail therefore had several possible causes for chronic liver disease which his GP had thoroughly explored. On failing to find an explanation the GP referred him for specialist liver assessment and chronic hepatitis C was immediately discovered, although this came as a surprise. In 2003 to 2005 it would not have been routine for a GP to screen patients for hepatitis C virus infection. At this time, there was very commonly a delay in making the

diagnosis of chronic hepatitis C infection and this patient was about average for time. However, he had three other problems which distracted from considering hepatitis C initially and his only risk factor was not declared. Therefore, I do not accept his criticism that there was an undue delay in making the diagnosis of chronic hepatitis C. Many people in the community still carry hepatitis C infection for years without knowing that they are infected.

Response to criticism 3.2

During the period 2005-2008 there were significant changes to the treatment regimens for chronic hepatitis C. The Virus Hepatitis Group at Gartnavel General Hospital were at the forefront of clinical trials and management protocols for the management of hepatitis C and had the largest population of patients to treat in Scotland. I led the treatment section of the Scottish Intercollegiate Guidelines Network guideline on the management of hepatitis C which was published in 2006. The Greater Glasgow Health Board (GGHB) were proactive in making treatment available to patients in Glasgow, long before other health boards in the UK. Treatment protocols at the time were demanding for patients and driven by factors such as virus genotype, IL28B genotype, severity of liver fibrosis, body weight, alcohol intake, mental health, drug interactions and other health conditions. Preparation for this arduous treatment required assessment of all these issues.

Pegylated Interferon alpha 2a injections weekly and Ribavirin tablets twice daily became the standard of therapy at the time. The GGHB did its own cost-effectiveness studies and concluded that while this therapy was expensive it saved lives and was fully justified as an expense. New budgets were established to cover the cost of treatment including regular viral PCR tests and laboratory costs, pharmacy issues, drug costs, liver biopsy assessments, psychiatric support, dietitian support and a team of trained nurses appointed to supervise the therapy. Additional consultants were also appointed. All of these were being put in place at this time. A waiting list for patients thought suitable for therapy was established and pursued actively.

Mr McPhail was found to have genotype 1a hepatitis C which required 48 weeks of therapy. This is the most demanding of treatments with multiple side-effects. The success of therapy was about 40% at the time and required everything to be optimal to succeed. There was concern that Mr McPhail might have cirrhosis which at the time might require even longer therapy so liver biopsy was undertaken. The Hospital Anxiety and Depression Scale Score (HAD) showed abnormal scores for both so psychiatric advice was undertaken prior to and throughout treatment. He also required dietitian support during therapy.

Mr McPhail was first put on the waiting list for therapy on 19.9.06 and listed to commence therapy on 3.4.07. However, further assessment was then required and he finally was thought

to be ready to start therapy on 4.2.08. A range of assessments and support are required before commencing this difficult to tolerate therapy. This was a time of rapidly changing criteria for commencing therapy which brought about a slight delay to allow completion of the new assessments required. While this was over two years since the diagnosis was first made the hepatitis C infection progresses very slowly and he had only mild inflammation on liver biopsy some 30 years after being infected by blood transfusion. The key to successful therapy is proper preparation and support which is what this patient achieved. He found therapy very difficult but with the excellent support he received he was able to complete the 48 weeks of treatment with reduced doses of the drugs. He had an early and sustained viral response with clearance of and cure from his hepatitis C virus infection.

He was managed by a large team of health care workers under my regular guidance. His condition during therapy was discussed weekly by the whole team. He may not have been aware of all the activity taking place on his behalf.

I therefore do not agree with his criticism that treatment was delayed or held back by funding issues. He was very fortunate to have been attending a unit in Glasgow where he was properly prepared for treatment and supported to enable a good outcome. His treatment was fast tracked by the GGHB who deserve great credit for their early recognition of the benefits to patient care and the establishing of a budget for this new development.

Professor Peter R Mills Retired Consultant Physician and Hepatologist

Statement of Truth

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

Signed

Dated <u>17 February 2022</u>