Witness Name: Professor Martin Wiselka

Statement No.: WITN3294001

Exhibits: WITN3294002; WITN3294003; WITN3294004; WITN3294005

Dated: 6 June 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR MARTIN WISELKA

I am providing this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 17 May 2019.

I, Professor Martin Wiselka, will say as follows: -

Section 1: Introduction

1 My name is Professor Martin Wiselka. My date of birth is GRO-C 1958. My professional address is Department of Infection & Tropical Medicine, Leicester Royal Infirmary, Infirmary Square, Leicester LE1 5WW.

2 I qualified in Medicine from the University of Oxford in 1982. My professional qualifications are: BM BCh, MA, MD, PhD, FRCP (Bachelor of Medicine and Bachelor of Surgery, Master of Arts, Doctor of Medicine, Doctor of Philosophy, Fellow of the Royal College of Physicians of London).

3 I am currently employed as a Consultant in Infectious Diseases and General Medicine at the University Hospitals of Leicester NHS Trust ("the Trust") and I have held this position since October 1992. In addition, I am an Honorary Professor of Infectious Diseases at the University of Leicester and I have held this position since December 2015.

4 My role and responsibility in these positions include being clinical lead for the Leicester Hepatitis C Operational Delivery Network and clinical lead for Hepatitis Services for Leicestershire, Rutland and Northamptonshire.

5 I confirm that I have not been a member past or present of any committees or groups relevant to the inquiry's terms of reference.

Section 2: Responses to criticism

6 I have read the statement given by Mrs Fletcher to the Inquiry and set out below my response to the criticisms she has made about me.

Background

7 I first saw Mrs Fletcher on 3 June 2015, after she had been referred by Dr Claire Chapman, Consultant Haematologist (see the letters enclosed as Exhibits [**WITN3294002**], [**WITN3294003**] and [**WITN3294004**]. I noted that she had previously received treatment for Hepatitis C with Interferon alone, Pegylated Interferon plus Ribavirin x 2 courses, and Pegylated Interferon with Ribavirin and Telaprevir in 2012, from which she relapsed following the end of treatment. I understood that her previous care had been under the Royal Free Hospital London. She had a history of thallasaemia major and previously had significant problems with iron overload affecting the liver and heart. A previous liver biopsy had shown evidence of cirrhosis, although a fibroscan performed in the hepatitis clinic showed no significant fibrosis, the improvement probably being due to iron chelation therapy. (A fibroscan measures the degree of fibrosis (scarring) in the liver and produces a score. The lower the score, the less the degree of scarring. There are 5 levels of severity of scarring, from 0 (completely normal) to 4 (cirrhosis)).

8 When I saw Mrs Fletcher in June 2015 I sent further blood tests. Mrs Fletcher unfortunately failed to attend for a follow-up appointment on 26 August 2015 and a further follow-up appointment on 11 November 2015 (see, for example, the letter enclosed as Exhibit [**WITN3294005**]).

9 She did attend on 23 December 2015, when she informed me that she was undergoing IVF arranged by Kings College Hospital London and a clinic in Spain. At the time I explained that we could offer her hepatitis C treatment with an anti-viral drug called Harvoni, but she told me that her main priority was to become pregnant, if possible, and she wanted the hepatitis C treatment to be delayed until the outcome of her fertility treatment was known. As her fibroscan result was satisfactory we agreed to see her in 6 months.

10 Mrs Fletcher attended an appointment on 27 May 2016 and we once again discussed treatment for her Hepatitis C GRO-C GRO-C She agreed to consider treatment for Hepatitis C. She was therefore discussed at our multi-disciplinary team ("MDT") meeting on 26 July 2016 and was approved for treatment with Harvoni for 12 weeks. The MDT discussion was an essential step as NHS England requires that all cases of hepatitis C requiring treatment are discussed and agreed at an MDT. Access to the relevant drugs is only possible once the treatment has been MDT approved.

11 Following MDT approval, Mrs Fletcher subsequently started a 12 week treatment with Harvoni (1 tablet once daily) on 5 September 2016, supervised by our clinical nurse specialist. I am delighted to say that she completed her course of treatment and her subsequent virus levels were all negative, including a 12 week post-treatment viral load sent on 14 March 2017. This indicated that she had made a sustained viral response (SVR) to treatment and was therefore cured of her Hepatitis C. In accordance with Department of Health guidance and protocols she had further reviews at 6 and 12 months post-treatment when her virus levels were also negative; however, in view of her previous cirrhosis she continues to be seen in the Hepatitis clinic on a 6 monthly basis with surveillance ultrasound scans to check for signs of early liver cancer.

In response to the issues raised by Mrs Fletcher:

12 Mrs Fletcher was first seen in the Hepatitis clinic following referral by the haematologists on 3 June 2015. She would have been considered for oral

treatment with Harvoni or similar agents following that visit. However, as set out above, treatment was delayed because:

- She failed to attend for two scheduled follow-up appointments (on 26.8.2015 and 11.11.2015); and
- When she was seen on 23 December 2015 she declined treatment as she was having IVF and did not want to start any drugs at that time.

13 Once she agreed to start treatment on 27 May 2016, she was promptly discussed at the MDT meeting on 26 July 2016 and started treatment on 5 September 2016.

14 Therefore, any delay in starting treatment was not as a result of the Hepatitis C service or funding, but was due to Mrs Fletcher having IVF treatment prior to 2016.

15 There was no policy of withholding treatment at the time and treatment for Hepatitis C had been actively encouraged by the Department of Health with our Operational Delivery Network having to achieve a monthly "run rate" with CQUIN funding following achievement of the required numbers of patients receiving treatment and follow up. CQUIN is the abbreviation for Commissioning for Quality and Innovation and it is a system of payments to providers like the Trust that is conditional on demonstrating improvements in quality and innovation in specified areas of care.

16 In addition, the oral drugs for hepatitis C are centrally funded via NHS England and there was no question of treatment being withheld because of any local funding issues.

17 The specific drug in question, Harvoni, was approved by NICE for hepatitis C treatment (genotypes 1 and 4) in November 2015 and was readily available after that date (NICE technology appraisal guidance TA363 published 25/11/2015).

18 Mrs Fletcher believes that she would have been treated earlier in London rather than Leicester. However, I do not believe that this is the case as the

Operational Delivery Networks operate throughout England and operate to the same national protocols and standards. Access to treatment is therefore equitable throughout the country.

19 It is correct that the haematology consultant, Dr Chapman, referred Ms Fletcher to the Hepatitis clinic where she was seen in June 2015. However, the medical notes do not support Mrs Fletcher's claim that "*she was eventually given the treatment upon her haematologist's consultant writing to you insisting she was given treatment*" and nor do I have any recollection of receiving such correspondence or any conversation of this nature.

20 As stated above, the delay in treatment until September 2016 was due to Mrs Fletcher's personal circumstances and not due to any significant delay in the service provided or funding issues.

21 Whilst I sympathise greatly with Mrs Fletcher's medical condition and problems after acquiring Hepatitis C, I consider that her allegations regarding her treatment with Harvoni are unfounded and she received an excellent standard of care, which fortunately allowed her to finally overcome her virus infection. However, she does continue to be followed-up and there is a slightly increased risk that she may develop hepatocellular carcinoma (liver cancer) in the future.

Section 3: Other Issues

22 I note that Mrs Fletcher has queried why her blood samples may still be labelled as high-risk, notwithstanding the fact that she has been cured of hepatitis C. I have read Mr Furlong's response to this in his witness statement and I have nothing further to add on this point.

Statement of Truth

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

Signed GRO-C

Dated 7th June 2019