Witness Name: Dr Brendan Healy
Statement No.: WITN4533001
Exhibits: None
Dated: 28 July 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR BRENDAN JAMES HEALY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 26 May 2020.

I, Dr Brendan James Healy, will say as follows: -

Section 1: Introduction

1. I am a Consultant in Microbiology and Infectious Diseases employed by Public Health Wales Microbiology Cardiff and Swansea, University Hospital of Wales, Heath Park Cardiff CF14 4XW. My date of birth is GRO-C 1972.

2. I gained my primary medical qualification MB ChB from the University of Liverpool in 1998.

3. I have been looking after patients with hepatitis C since August 2002 when starting training as a Microbiology / Infectious Disease Registrar. I achieved

my Certificate of Completion of Training (CCT) in Microbiology and Infectious diseases and became a Consultant in August 2007.

4. I was appointed as a Substantive Consultant to Public Health Wales with an Honorary Contract with Cardiff and Vale University Health Board in January 2008.

5. I have looked after patients with hepatitis C as a Consultant since August 2007. I was given responsibility for overall management of hepatitis C for Cardiff and Vale in 2011 when I was appointed as the Blood Borne Virus Lead for Cardiff and Vale Health Board.

6. Subsequently in 2014 I became the National All Wales Clinical Lead for Hepatitis C including representative for the All Wales hepatitis C roll out programme and Chair of the National Liver Delivery Plan Hepatitis subgroup.

Section 2: Responses to criticism of W2375 and W2376

7. I am familiar with the concerns raised by W2375 and W2376 and I was alerted to them at the time that they were initially raised and met with the patient and her husband to explain the treatment that had been provided and to try and address their concerns.

8. I looked after W2375's wife from the point of view of her hepatitis C from 3 May 2012 to 31 October 2013. She had a history of previous treatment with pegylated interferon and ribavirin with a good response and clearance of the virus on therapy but unfortunately followed by relapse once the treatment was stopped. In early 2012, the patient was identified as somebody who was potentially eligible for treatment with the new protease inhibitor therapies (telaprevir or boceprevir).

9. The patient had very advanced liver disease (Child-Pugh B) as a consequence of long standing infection with hepatitis C. Individuals with

advanced disease are the hardest to treat and the treatments available at that time carried a significant risk of precipitating hepatic decompensation (liver failure). However, without treatment, the risk of decompensation was also high due to progressive liver damage from ongoing hepatitis C infection. There was therefore a high risk of harm whether treatment was given or withheld. Treatment was not undertaken lightly and was only started after extensive discussion and review with the patient and with other experts in hepatitis C and liver disease both locally and further afield, including with Dr Holt in Birmingham.

10. The patient was referred to Dr Holt for assessment in Birmingham and was seen by him in August 2012. Dr Holt recommended treatment with telaprevir using a lead in period with pegylated interferon and ribavirin (duration of lead in not specified). The recommendation of a lead in period was a minor deviation from the standard protocol.

11. The risks and benefits of treatment were explained to the patient prior to initiation of any therapy, both by me and by Dr Holt. She was started on treatment in December 2012 with triple therapy of telaprevir, pegylated interferon and ribavirin.

12. As indicated above, Dr Holt had recommended a lead in with pegylated interferon and ribavirin but this part of the recommendation was overlooked and not carried out. Lead in therapy with pegylated interferon and ribavirin is not standard for use of telaprevir, does not form part of the licensed indication for telaprevir and is not recommended by NICE, the Welsh or UK consensus guidelines. The guidelines and license all recommend initiation of triple therapy with telaprevir, pegylated interferon and ribavirin from the outset of treatment. Cardiff and Vale Heath Board guidelines at that time (which were followed) recommended use of triple therapy from the outset with telaprevir in previously treated patients. Although a lead in was recommended, there are potential risks with this as it extends treatment and thereby increases the duration of exposure to interferon and ribavirin. Unfortunately no option was safe for this patient as the risk of decompensation was present if we didn't

treat and if we did treat and the risk was present whether we treated with all three drugs in one go, as per the licensed indication, or with a lead in of two drugs followed by introduction of the third some weeks later. Furthermore, it is extremely unlikely that the lead in would have prevented the decompensation event particularly given that the likely causes are recognised side effects of interferon.

13. The patient had a very good virological response to treatment. Her hepatitis C viral load was undetectable within two weeks. Unfortunately, the patient suffered from significant side effects requiring admission to hospital and stopping of her medication. Her initial admission was thought to be caused by ischaemic colitis (a recognised side effect of interferon). Ischaemic colitis is a difficult diagnosis to make and there is some uncertainty whether that initial admission was related to ischaemic colitis or severe constipation with overflow diarrhoea. The diagnosis of ischaemic colitis was not supported by the histopathology results and latterly her symptoms were attributed to severe constipation with overflow diarrhoea.

14. Unfortunately following this the patient also developed liver decompensation. Following that episode her care was predominantly provided by one of my consultant colleagues.

15. I accept that having asked Birmingham for their opinion it would have been sensible to follow their recommendation. Although it is unfortunate that this recommendation was not followed, we undertook an extensive review at the time which included a discussion with Dr Holt. The review concluded that this did not contribute to the patient's subsequent death from end stage liver disease in 2014, thirteen months later. This resulted from progressive cirrhosis secondary to longstanding hepatitis C. I do however fully appreciate the concerns of W2375 and W2376 and would be very willing to discuss this further with them. I am also very sorry that, despite our best efforts, we were

unable to prevent the death of their loved one.

Statement of Truth

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

Signed GRO-C

Dated 28/7/2020