SECOND WRITTEN STATEMENT OF PROFESSOR SIR KENNETH CALMAN Contents

Witness Name: Professor Sir

Kenneth Calman

Statement No.: WITN3430343

Exhibits: N/A

Dated: 18/04/2023

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF PROFESSOR SIR KENNETH CALMAN

I provide this statement in response to the request under Rule 9 of the Inquiry Rules 2006 dated 13 March 2023.

I, PROFESSOR SIR KENNETH CALMAN, will say as follows,

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Section 0: Introduction

- 0.1. My full name is Professor Sir Kenneth Charles Calman. My date of birth and home address are known to the Inquiry. A summary of my professional qualifications and employment history was provided to the Inquiry at paragraphs 1.1 to 5.6 of my first written statement dated 12 October 2022 [WITN3430001]. I refer to the request under Rule 9 of the Inquiry Rules 2006 dated 13 March 2023. The Inquiry has given me notice of criticisms contained in the written statement of a witness with the Inquiry reference number W5317 dated 12 July 2021 [WITN5317001]. I was notified of the criticisms contained within the written statement of witness W5317 by the Inquiry on 17 January 2023.
- 0.2. I provide this statement in response to the criticisms notified to me by the Inquiry outlined in paragraphs 13, 64 and 65 of the written statement of witness W5317. As the Inquiry knows from witness W5317's written statement, witness W5317's wife sadly passed away in March 1990. Witness W5317's wife was diagnosed with acute renal failure in 1974 and received many blood transfusions between 1974 and 1989 at Charing Cross Hospital, London before being diagnosed with Hepatitis C ("HCV") in 1989. I have read witness W5317's written statement and in providing this response I am very conscious of the difficult and tragic circumstances witness W5317 and his late wife experienced, linked to her medical conditions.
- 0.3. As outlined at paragraph 0.3 of my first written statement dated 12 October 2022, it is now over 20 years since I left my role as Chief Medical Officer ("CMO") for England, in the autumn of 1998, and more than 30 years since I began it [WITN3430001]. In preparing this response, I have reflected on the documents provided to me by the Inquiry and a number of additional documents that are relevant to the subject matter of the criticisms addressed to me. I must stress that what I say in this response is primarily based on the documentary

record that has been made available to me, and thoughts about it now, rather than on my direct recollection of events at the time.

Section 1: Response to criticisms by witness W5317

- 1.1. At paragraphs 12 and 13 of his written statement, witness W5317 explained the circumstances surrounding his wife's HCV diagnosis in 1989. Paragraphs 12 and 13 stated:
 - "12. In 1985, my wife was told by the renal doctors that they suspected that she had contracted Hepatitis. Three tests for Hepatitis B and one for Hepatitis A were performed, but all proved negative.
 - 13. At some point in 1989, my wife received a letter from The Senior Renal Consultant at Charing Cross Hospital saying that she had been diagnosed with Hepatitis C and requested a counselling session with us in the office. The letter was very black and white with no further information. I believe that the letter was intended to cover up criminality and possible criminal proceedings that families of those infected may bring against the NHS. I believe that this was a cover-up process and it was probably driven by the UK Chief Medical Officer." [WITN5317001]
- 1.2. As the Inquiry is aware from paragraph 2.5 of my first written statement dated 12 October 2022, I was CMO for England between 17 September 1991 and 18 September 1998 [WITN3430001]. It was the late Sir Donald Acheson who held the role of CMO for England during the time period referred to in paragraphs 12 and 13 of witness W5317's written statement. I do not now recall the details of the timing of the discovery of HCV and the beginning of diagnostic testing for this virus and I was not in post as CMO in England at the time of these developments. But as the CMO that succeeded Sir Donald and, in his absence, I will try to address the comments made by witness W5317 at this part of his written statement by referring to evidence already before the Inquiry.
- 1.3. The 'Expert Report to the Infected Blood Inquiry: Hepatitis' of January 2020 confirmed at page 4 that HCV was discovered in 1988/89 and that "...between

1973 and 1989, people presenting with an acute hepatitis illness and testing negative for hepatitis A and hepatitis B viruses", and for whom there was "...no other clinical reason for their hepatitis", were referred to as non-A, non-B hepatitis cases [EXPG0000001]. Without having seen witness W5317's wife's medical records but responding to the account in the written statement, it appears that witness W5317's wife may have been through this experience; that is, she contracted a hepatitis virus that was found not to be Hepatitis A or Hepatitis B, but it was not until 1989 that she was informed that she was suffering from HCV.

1.4. Page 17 of the 'Expert Report to the Infected Blood Inquiry: Hepatitis' explains that a diagnostic test for HCV antibody was developed shortly after the discovery of the virus, in 1989. It stated that:

"In the mid-1970s it was clear that there were cases of hepatitis occurring post-transfusion that were attributable to neither hepatitis A nor hepatitis B, resulting in the term 'non-A non-B hepatitis' (NANBH). It was known that the agent causing NANBH was transmissible from studies in primates. HCV, the responsible virus, was found using a direct molecular biological approach in 1989. This led on to the development of a diagnostic test for HCV antibody for the first time using enzyme immunoassays (EIA)" [EXPG0000001]

- 1.5. I was not, of course, the doctor responsible for testing witness W5317's wife for HCV or subsequently diagnosing her as suffering from this virus and the relevant medical records are not available to me, so I cannot comment on the exact test that was conducted or the date of that test. However, it seems from the evidence of the Inquiry's Hepatitis Expert Group that I have set out above that notification of HCV diagnosis followed on reasonably quickly from when diagnostic tests for HCV antibody first became available.
- 1.6. If this is right, then the apparently reasonably prompt performance of a diagnostic test for HCV (after the tests became available), the subsequent HCV diagnosis, notification of that diagnosis and the offer of a counselling session by the Senior Renal Consultant at Charing Cross Hospital would all be

indications of good medical practice, rather than of any attempt to cover up criminality and/or to avoid criminal proceedings that could be brought against the NHS by those infected and affected by HCV diagnoses as a result of blood transfusion. Although I was not CMO at the time of the events leading to witness W5317's wife's HCV diagnosis in 1989, I have no knowledge of any such criminality or cover up, whether driven by the late Sir Donald Acheson or otherwise.

The HCV Lookback Exercise, 1995

- 1.7. At paragraphs 64 and 65 of the written statement, witness W5317 made further allegations, including some related to the period when I held the role of CMO. Paragraphs 64 and 65 stated:
 - "64. There is no doubt in my mind that this is a criminal enterprise and so I want to see those responsible in court. First, the politicians and then the hierarchy within the NHS. If anyone commits a crime then they need to answer to it. If a doctor did something like this today, lawyers would take them to court and I believe that this should have been the case. Being brought to justice is the key for me.
 - 65. On 3rd April 1995 the UK Chief Medical Officer issued a memorandum to the medical profession asking them to identify patients who may have been infected with Hepatitis C through blood transfusions. Please see exhibit WITN5317006. The clinicians were instructed not to 'look back' if the patient was deceased. At this time, it was known that Hepatitis C could be transmitted through sexual contact, but the Chief Medical Officer was not concerned about patient partners contracting the disease to protect the NHS. I am very angered that I was never told that I was put at risk." [WITN5317001]
- 1.8. I have no knowledge to suggest that any "criminal enterprise" or cover up was perpetrated by the Department of Health in relation to the care of patients diagnosed with HCV contracted through blood transfusion during my tenure as CMO.
- Witness W5317 refers to the HCV Lookback Exercise, in April 1995. Although
 I do not now recall the specific details of this exercise, it is apparent from the

documents made available to me that individuals in the position of witness W5317 and his wife were not really the 'target' of the exercise, which was aimed at discovering those who had been infected by transfusions prior to September 1991, but whose infections had not already been identified and diagnosed. Looking at witness W5317 and his wife's experience now, it would have been hoped that, since witness W5317's wife had been diagnosed in 1989, she and witness W5317 had received appropriate counselling after that diagnosis, before her death. I am very sorry to hear witness W5317's evidence that this did not occur.

- 1.10. Turning back to the exercise in 1995: it is difficult for me to remember now the exact reasons for the advice, in my CMO letter of 3 April 1995, that not only should letters to patients who had passed away be avoided, but also for the fact that there was no further advice about the position of the sexual partners of those who had died before April 1995 [WITN5317006].
- 1.11. Looking at it now, the first part of the advice, i.e. that "...letters addressed to deceased recipients" should be avoided, would be good practice, as such letters could cause serious upset and distress. The second part of advice is more complicated.
- 1.12. I expect that the sexual partners of individuals that were identified as being at risk of having contracted HCV through blood transfusion, but had since passed away, were not included within the scope of the HCV Lookback Exercise launched in April 1995 was because, first, by the time the HCV Lookback Exercise was launched it was known that HCV was rarely sexually transmitted. I do not now recall what exactly was known at this time about the likelihood of secondary transmission of HCV to sexual partners; however, I set out some information on this issue from documents made available to me. The 'Expert Report to the Infected Blood Inquiry: Hepatitis' confirmed at page 4 that in 1992:

"[t]he UK's national infectious disease surveillance centres establish HCV antibody diagnosis reporting systems and, thereafter throughout the

decade, undertake surveys to determine the characteristics and extent of hepatitis C infection in the UK; these epidemiological initiatives demonstrate that:...(ii) the virus is rarely transmitted through sexual intercourse" [EXPG0000001]

1.13. In the context of the reasons for the decision not to introduce HCV lookback as an accompaniment to the introduction of routine screening of blood donations for HCV in September 1991, paragraph 37.5(a) of my written statement [WITN3430001] refers to a paper written by Professor Cash (National Medical & Scientific Director, SNBTS) in 1994 entitled 'Recommendations of the Standing Advisory Committee on Transfusion-Transmitted Infection [SACTTI] to the MSBT concerning the merits of adopting an HCV "look-back" policy', which provided that:

"When anti-HCV screening of blood donations was introduced in September 1991, a look-back programme was not recommended. Doubts about the long term effects of hepatitis C infection, coupled with the lack of an effective therapy for individuals so infected, appear to be the main reasons behind this recommendation. Furthermore, secondary transmission of HCV to sexual partners and offspring appears to occur rarely. This is in contrast with HIV where secondary transmission is more likely and effective counselling can reduce the likelihood of such transmission." [PRSE0001236]

1.14. The CMO's letter that I issued on 3 April 1995 when the HCV Lookback Exercise was launched included guidance on counselling and treatment options for those identified through the lookback exercise as HCV positive at Annex B [WITN5317006]. At paragraph 11 under the heading 'Epidemiology – modes of transmission' it was noted that "[s]exual transmission occurs, but the frequency is controversial – most studies indicate infection rates of less than 5% in sexual partners. However use of barrier contraception should be discussed with each couple." Paragraph 16 under the heading 'Avoiding infecting: others' added that "[a]t present there is insufficient evidence to recommend changes to current sexual practices, although regular sexual partners should be counselled and offered testing."

- 1.15. It appears therefore from the information made available to me that the science on the sexual transmission of HCV was still developing when the HCV Lookback Exercise was launched in April 1995, but that this mode of transmission was considered to be relatively rare. However, counselling on this issue was covered in the CMO letter.
- 1.16. Against that background whilst I cannot remember any discussions on this issue, it is possible that it would have been considered difficult and disproportionate to seek to trace the sexual partners of individuals who had been identified as being at risk of having contracted HCV through blood transfusion, but who had since passed away.
- 1.17. The process of the Lookback involved finding out if a patient had received a unit of infected blood (from a donor who had given blood after September 1991). That would have raised the possibility of infection, but infection would not have been confirmed without contact with the patient, counselling and testing.
- 1.18. If the patient had died, it is possible that their medical records would have confirmed that he or she had already been diagnosed as suffering from HCV: if so, it would have been expected that appropriate counselling, including on the risks of sexual transmission, would have taken place following diagnosis.
- 1.19. Considering this issue now, if the available medical records did not show that the patient had received a HCV diagnosis, and so their status was unknown, then further investigations would have involved not only identifying past partners, but making the judgement that it was appropriate to tell them that their deceased partner might have been infected with HCV (through a blood transfusion) and have transmitted it to them, and then offering testing. This is why I have said that it is possible that a tracing exercise would have been considered difficult and disproportionate.

Witness W5317's evidence

1.20. I was very glad to learn that when witness W5317 became aware of his potential exposure to HCV (which he explains was in 2009 rather than at the counselling appointment that he and his wife attended in 1989), he tested negative for HCV [WITN5317001, paragraphs 14, 20 and 53].

Statement of Truth

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

Signed	GRO-C	
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Dated	· \ ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` `	