Witness Name: Dr Philip Minor
Statement No.: WITN3784001
Exhibits: None
Dated:

INFECTED BLOOD INQUIRY

WITNESS STATEMENT OF DR PHILIP MINOR

I, Dr Philip David Minor, of GRO-C Hertfordshire GRO-C will state as follows: -

Section 1: Introduction

1. I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 12 November 2019.

2. My date of birth is GRO-C 1947.

3. I have a BA from Oxford in Biochemistry (1970) and a PhD from University College London (1973). I am a laboratory scientist not a clinician.

4. I joined the Division of Virology of the National Institute for Biological Standards and Control ("NIBSC") in 1979. I became Head of the Division in 1985 and I retired in 2017.

5. The Division is concerned with all virological issues related to biological medicinal products including the quality of viral vaccines and the possible viral contamination of medicines such as blood and blood products. It is involved in testing products for viral contamination and helping in the assessment and control of tests, for example by providing reference materials.

6. I was a member of the EU Biotechnology Working Party from 1985 and the WHO Expert Committee on Biological Standardisation from 1987.

7. I was involved in the Committee on the Safety of Medicine and its subcommittees on Biological Medicines and Bovine Spongieform Encephalopathy.

8. The Joint Policy Advisory Committee (JPAC) was a group set up between NIBSC and the UK Blood Transfusion Service to improve the quality of the UK blood supply. I was not a member of JPAC but I was a member of two of its scientific advisory committees, one on the care and selection of donors and the other on transfusion transmitted infections.

Section 2: Response to criticisms in statement of witness W1369

9. I have been asked to comment on paragraphs 48 to 51 of the statement of Andrew Michael March to the Infected Blood Inquiry dated 29 August 2019. I also comment on paragraphs 52 and 53 for completeness. All references in this witness statement to paragraph numbers are references to paragraph numbers in Mr March's witness statement.

10. In respect of paragraph 48, I confirm that on 19 September 2006, I attended a meeting of America's Food and Drug Administration's TSE Advisory Committee to discuss the testing of blood for variant CJD (also described as vCJD). TSE stands for Transmissible Spongiform Encephalopathies. vCJD is one of a number of human and animal diseases that are covered by the description TSE.

11. My attendance at the meeting was in my capacity as a senior member of the National Institute for Biological Standards Control (NIBSC).

12. In respect to paragraphs 49 and 50, I confirm that the words attributed to me in the transcript were indeed my words.

13. I am very sorry for the distress that my remarks at the meeting in 2006 have clearly caused Mr March. However, due I accept to my own ambiguous phrasing, it seems that my words have been interpreted by Mr March in ways I did not intend (and I am sure my immediate audience in the meeting of the Advisory Committee did not understand them in that way).

14. The discussion at the meeting centred on how any test for vCJD would need to be shown to work by means of an evaluation. There were at the time in 2006 a number of prototype tests for vCJD. Unfortunately, none of these evaluations were ultimately satisfactory.

15. Any evaluation would involve the use of appropriate human samples. All human samples used in evaluations of these tests in which NIBSC were involved had ethical approval and informed consent for storage and use for this purpose. None of the samples used were, in fact, from haemophiliacs.

16. The main role of the group at NIBSC was to act as a gate-keeper controlling access to the human samples from patients with overt clinical vCJD. As these samples were rare it was important they were only used when and where appropriate.

17. Samples from patients with clinically overt vCJD are rare because of the mercifully relatively small number of cases. NIBSC received funding from the Department of Health to oversee access to the available samples to make sure they were used in assessing tests that might work. An algorithm was developed involving assessments of sensitivity on dilutions of infected tissues and tests of specificity using samples where infection was unlikely. The process and the progress of test assessment was agreed and overseen by a committee of experts in human and animal spongieform encephalopathies including vCJD. Patient groups were represented. The committee met on a regular basis. The aim was to develop a wide expert consensus on the tests to be given access to samples, the nature of the samples, the consent issues and the processes required for the release of materials.

18. Detailed information is available on the website. https://nibsc.org/science_and_research/virology/cjd_resource_centre.aspx.

19. In respect of paragraph 49, I was addressing the Advisory Committee on the need for human samples to develop testing for vCJD. My point was the extreme difficulty in getting such samples. When I said that there were "*no* human samples" available, this was an exaggeration. There were some but they were very rare as explained above.

20. When I said *"The best way of doing this* [i.e. obtaining human samples] *clearly would be to take a human, expose them to variant CJD and then follow what happens to them."*, I was not, of course, advocating actually doing this! The idea of deliberately

exposing someone to vCJD is utterly appalling (as well as a very grave criminal offence). I was making the point that hypothetically exposing someone to vCJD would be ideal scientifically but this did not mean I was suggesting it be done deliberately.

21. With vCJD someone can be exposed but not infected. Also it is possible to be infected and for it be a number of years before the infection becomes clinically overt. Comparing samples from before infection with those at various times after infection would be scientifically ideal to establish the stage in the incubation period when and if a test could detect that a person was infected.

22. In respect of paragraph 50, when I said that "we" have some samples from haemophiliacs, I meant by "we", the scientific community. NIBSC, where I was employed, had no such samples. I refer in this statement to samples at the Royal Free Hospital in London but I believe that other haemophilia centres may also have kept samples.

23. In paragraph 50, I am recorded as having said that there was a study done at the Royal Free Hospital. This is misleading. I am aware that there were samples taken from haemophiliacs over the period late 1970s to the late 1990s but it was not the case that these samples were used in any study that I am aware of relating to vCJD.

24. In respect of paragraph 51, I can assure Mr March that his blood was not sent by NIBSC to anyone for vCJD analysis. I am able to give this assurance because I can confirm that no haemophiliac's blood was sent by NIBSC to anyone for this purpose.

25. The position in relation to consent differs between taking a sample of blood and using that sample for a test. I cannot comment in relation to consent for taking samples.

26. I can confirm that no test in respect of vCJD or otherwise should be carried out using blood without obtaining proper informed consent and to the best of my knowledge no such tests were carried out on any samples without such consent. The need for informed consent for the use of samples was very clear to all involved at the time – that is in 2006.

Section 3: Other Issues

27. There are no other issues I would like to comment on.

Statement of Truth

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

Signed GRO-C

Dated 4th December 2019

Full name: Dr Philip David Minor