Witness Name: William Vineall
Statement No.: WITN4688077
Exhibits: WITN4688078
Dated: 25/05/2023

INFECTED BLOOD INQUIRY

NINTH WRITTEN STATEMENT OF WILLIAM VINEALL

I provide this statement on behalf of the Department of Health and Social Care in response to the request under Rule 9 of the Inquiry Rules 2006 dated 1 March 2023.

I, WILLIAM VINEALL, will say as follows,

Contents

Section 1: Introduction

1.1. My name is William Vineall. My professional address is 39 Victoria Street, Westminster, London SW1H 0EU and my date of birth is known to the Inquiry.

1.2. I am Director of NHS Quality, Safety and Investigations at the Department of Health and Social Care ("the Department"), and have held this role since 2016. This is my ninth statement to the Inquiry. I refer back to my previous statements for further information about my role, responsibilities and employment history. I gave oral evidence to the Inquiry on 21 May 2021.

1.3. Part of my role includes oversight of on-going inquiries or investigations pertaining to the responsibilities of the Department. I am duly authorised to make this statement on behalf of the Department.

1.4. The team in the Department that provides evidence and information to the Inquiry has sat within my directorate since late 2018. Since early 2019 the team responsible for policy and governance of the England Infected Blood Support Scheme ("EIBSS") has sat within my directorate also. I did not work in blood policy and my directorate did not encompass blood policy. Since August 2021, I have been the senior sponsor of NHS Blood and Transplant, but wider blood policy remains outside my directorate. It is important to recognise that I do not have first-hand knowledge of the evidence covered in this statement and I have largely relied on the documents available to me. The contents of this statement are true to the best of my knowledge, information and belief.

Section 2: Response to criticisms by Witness W3092

2.1. I provide this statement in response to the criticisms of the Department outlined in the written statement of a witness with the Inquiry reference number W3092, Chair of the Haemophilia Society between November 2011 and November 2015. I refer to this witness as witness W3092 throughout this statement at the request of the Inquiry.

2.2. The criticisms to which I have been referred by the Inquiry relate to a scientific and clinical review of the evidence base on hepatitis C and HIV entitled 'Reviewing the natural history of Hepatitis C infection' [**PRSE0003033, Annex 4**]. The scientific and clinical review was carried out at the Department's request by an Expert Working Group formed of members from the Advisory Group on Hepatitis ("AGH"), the Expert Advisory Group on AIDS ("EAGA"), the UK Haemophilia Centre Doctors Organisation ("UKHCDO"), the Hepatitis C Trust and the Health Protection Agency ("HPA") (the "Expert Report") [**PRSE0003033, page 9**].

2.3. The Expert Report was obtained by the Department as part of a wider internal 'Review of the support available to individuals infected with Hepatitis C and/or HIV by NHS-supplied blood transfusions or blood products and their dependants' [**PRSE0003033**]. The Review was announced on 14 October 2010 in a Written Ministerial Statement from Anne Milton MP, the then Parliamentary Under-Secretary of State (Public Health) at the Department [**PRSE0003033, Annex 1**]. The Review was conducted by the Department, *"…supported by input from relevant external experts, including the Chairs of the Macfarlane and Eileen Trusts and the Skipton Fund"* [**PRSE0003033, page 9**].

2.4. I understand that the Review was announced following, first, the Government's response to Lord Archer's inquiry report and, second, the Judgment in the March Judicial Review. The response was published on 20 May 2009 and did not adopt Lord Archer's recommendation 6(h), that there should be parity of support for those infected and affected between the UK and the Republic of Ireland [**PRSE0003033, Annex 1**]. This decision was then subject to a successful legal challenge, as explained in the Written Ministerial Statement of 14 October 2010. Ms Milton stated that: *"*[o]*n 16 April 2010 Judgement was handed down on a Judicial Review of a decision made by the previous Government not to accept a recommendation* [recommendation 6(h)] *made in the report of Lord Archer…The Judgement found against the Government, therefore I am now required to look again at this recommendation, and decide whether or not to accept it"* [**PRSE0003033, Annex 1**].

2.5. The Government confirmed in the announcement of 14 October 2010 that recommendation 6(h) would not be accepted, but the Review referred to at paragraph 2.3 above would be conducted into some aspects of Lord Archer's inquiry report's recommendations [**PRSE0003033, Annex 1**]. There is already evidence before the Inquiry on the context leading to the announcement of the Review on 14 October 2010, see for example paragraphs 4.6 to 4.17 of Anne Milton's second written statement [**WITN6437002**].

2.6. I understand that on 15 October 2010, the day following the announcement of the Review, Dr Ailsa Wight, Deputy Director of Infectious Diseases and Blood Policy at the Department, sent a letter to Professor Brian Gazzard, Chair of the EAGA [**DHSC5005275**]. The letter enclosed the Written Ministerial Statement from Anne Milton MP that announced the Review and the Review's terms of reference [**PRSE0003033, page 3 and Annex 1**].

2.7. Dr Wight explained to Professor Gazzard how the work of the Expert Working Group would operate in the context of the Review in the following terms:

> *"A key component of the review will be an assessment of the clinical evidence on the impact of living with hepatitis C infection on this group of patients who acquired the virus via transfusion or treatment with plasma-derived clotting factor. In particular, we want to understand this in comparison with the impact of living with HIV, and any specific issues for patients with underlying haemophilia. This will be used as evidence in shaping and supporting options for further support, which will be considered as part of the review."* [**DHSC5005275**]

2.8. The letter requested the assistance of the Expert Working Group and emphasised that: (i) the Department sought the Expert Report within a tight timescale and by late November 2010; (ii) the Expert Working Group was intended to be a *"…short-life working group"* that could work via correspondence with one in person meeting in London; and (iii) the Expert Working Group would *"…address a series of specific questions, and produce a short report summarising the evidence in response to those questions"* [**DHSC5005275**]. The letter indicated that Dr Wight put forward the draft questions to be considered in the Expert Report to the Chairs of each of the committees forming part of the Expert Working Group for comment.

2.9. On 26 October 2010, members of the Expert Working Group met to discuss their work on the Expert Report [**HSOC0011236**]. The minutes of the meeting noted that *"[t]he purpose of this meeting was to assess the clinical evidence on the impact of living with hepatitis C infection on patients who acquired the virus via transfusion or treatment with blood, blood products or tissues. This included comparison with the impact of living with HIV, and any specific issues for patients who were co-infected or with underlying haemophilia"* and included the questions that the Department had asked the Expert Working Group to consider at agenda item 3, which were discussed at the meeting.

2.10. The documents available to me suggest that the scope of the work that the Expert Working Group was required to undertake at the Department's request was a review of the existing clinical evidence of the impact of living with hepatitis C ("HCV") for those also experiencing HIV and/or haemophilia in answer to specific questions and to inform the Review referred to at paragraph 2.3 above. It appears to me based on the documents available that it was not an exercise in commissioning new evidence upon this subject.

2.11. On the Expert Report, paragraphs 177 to 181 of witness W3092's written statement stated:

> *"177. The Experts Report referred to in this questions [sic] was a review of published articles on general cohorts of people with Hepatitis C. It did not include the new analysis we had requested on mortality and morbidity among the specific cohort of people with haemophilia who had contracted Hepatitis C from Contaminated Blood. For example, the information we requested would have included mortality statistics for those in "Stage 1" and those in "Stage 2", with analysis to identify how long those dying in "Stage 2" had been identified as being "Stage 2". The information should have been directly accessible through analysis of Skipton Trust and NHS records.*
>
> *178. Therefore, the Experts Report did not provide evidence for the specific Contaminated Blood cohort as we had requested. From memory, the Minister had the Experts Report updated to cover articles published from about 2009 to about 2012, but these articles still looked only at the general population and therefore in no way addressed our requirement.*

179. The DoH used the Experts Report to argue that there was no evidence of the excess morbidity and mortality in the Contaminated Blood "stage 1" cohort. This was a disingenuous and unscientific use of the data, since as explained above the general populations covered in the Report and the specific Contaminated Blood cohort could be expected to have very different outcomes. The Society criticised this use of the Report and continued to demand production of the specific longitudinal analysis we had requested. (This remained prominent in the Society's Contaminated Blood Policy and in our advocacy through the APPG [All Party Parliamentary Group on Haemophilia and Contaminated Blood] *and elsewhere…)*

180. I am not a clinician, but I assume that had the DoH produced the relevant statistics we requested this would also have informed treatment. It could have been important, for example, for determining the type and frequency of tests to be done for each patient. Because this information was not available, the Contaminated Blood "Stage 1" Hepatitis C patients presumably received suboptimal treatment, possibly leading to further avoidable deaths alongside an avoidable heavier burden of illness.

181. As noted elsewhere in my answers, the analysis we requested had not been produced as at the end of my tenure in November 2015." [**WITN3092001**]

2.12. At paragraphs 172 to 176, witness W3092 explained the report the Haemophilia Society had requested and the reasons that he considered this analysis was required:

"172. The report we requested was an analysis of mortality and morbidity in the specific cohort of people with haemophilia infected by Contaminated Blood and who (a) had Hepatitis C and (b) were in "Stage 1" as determined by the DoH clinical criteria.

173. We requested this analysis primarily as an evidence base for the support needs of this population. The widespread belief among the community was that the impact of the disease on the Contaminated Blood population was very different from official statistics which reflected studies across the general population infected with Hepatitis C. This was supported by widespread anecdotal evidence and, as our Contaminated Blood Policy (Exhibit WITN3092016) stated, as agreed with the CAG [Clinical Advisory Group]*:*

"Medical evidence suggests that those individuals chronically infected with Hepatitis C, but with no visible damage to the liver, can still have chronic symptoms affecting their ability to earn a living and their need for support. The Skipton evaluation and payment regime should reflect this need"

174. There were plausible medical hypotheses that the progress of the disease would be different owing, for example, to the Contaminated Blood cohort typically being infected at an early age, with repeated re-infection, with multiple strains of the virus including genotypes which were rare in the UK but common abroad where blood products were sourced, and with a higher viral load. Also, of course, there was the unknown impact of the cohort also having haemophilia.

175. In addition, there was an underlying clinical issue that the diagnosis of "Stage 2" required identification of cirrhosis of the liver. This was not a trivial matter, as it involved a relatively inaccurate ultrasound investigation of the liver, or, for a definitive diagnosis, a liver biopsy which could be risky for people with haemophilia (and still far from 100% accurate). It is plausible that this risk made patients and clinicians delay biopsies, resulting in later diagnosis of cirrhosis among the Contaminated Blood cohort than in general cohorts of people with Hepatitis C. In any case, it is likely that at any time there were many people diagnosed as "Stage 1" who in reality were in "Stage 2".

176. In contrast, the low level of support given by the government through the Skipton fund evidenced that it saw "Stage 1" as a relatively trivial condition not creating serious needs." [**WITN3092001**]

2.13. I understand that the Review, informed by the Expert Report, resulted in Lord Lansley's announcement of new financial support measures for those infected with HCV, their dependants and bereaved spouses in January 2011. The context leading to this is explained at paragraphs 4.30 to 4.48 of Anne Milton's second written statement [**WITN6437002**].

2.14. As set out above, the issue that witness W3092 has identified in his written statement was that the Expert Report was a review of published articles on general cohorts of people with Hepatitis C. It did not include the analysis the Haemophilia Society had requested on mortality and morbidity among the specific cohort of people with haemophilia who had contracted Hepatitis C through infected blood products; it was

suggested that Hepatitis C affected haemophiliacs at Stage 1 worse than the general population for reasons that were not understood but might relate to young age of infection or repeated exposure.

2.15. I understand that this issue continued to be discussed between campaigners, the experts concerned and the Department after the Review and the announcement of the new financial support measures. On 29 November 2012, a meeting was held between Anna Soubry MP (the then Parliamentary Under-Secretary of State (Public Health)), campaigner representatives and members of the Expert Working Group that prepared the Expert Report. A note for those attending that meeting outlined the meeting's purpose:

> *"1. The purpose of the meeting is to provide an opportunity for the campaigners to put their concerns about the ill health effects of chronic hepatitis C infection to the experts, and for the experts to summarize the evidence they provided in Autumn 2010 and explain how they assess scientific evidence.*
>
> *…*
>
> *3. Any aspects of the evidence base which are identified at the meeting that are thought to merit further consideration can be put to the Advisory Group on Hepatitis for detailed consideration and advice."* [**DHSC5228647**]

2.16. A note of the meeting on 29 November 2012 prepared by a Department of Health official present recorded that one of the points campaigner representatives made about the Expert Report was that *"*[t]*he impact of hepatitis C on haemophilia had not been studied separately"* [**DHSC5055310**]. The note documented that *"*[i]*n response, members of the expert group said that their report had been an honest attempt to assess whether scientific data supported evidence of a link between various extra-hepatic conditions and hepatitis C"* and (on the subject of witness W3092's specific complaint) that *"*[s]*tudies tend to be conducted on the populations most commonly affected, but the MRC Biobank initiative plans to study 10,000 hepatitis C-infected individuals, including a specific subset of people with haemophilia."*

2.17. An email from a Department of Health official to Anna Soubry's Private Office dated 6 January 2013 attached two further notes of the meeting on 29 November 2012 made by campaigner representatives in attendance [**DHSC5166174**]. The first was prepared by two campaigner representatives from the Contaminated Blood Campaign [**DHSC5128268**]. The covering email indicates that this note of the meeting was

copied from the organisation's website by officials and sent to the Minister at the time. The Contaminated Blood Campaign representatives' note of the meeting summarised that:

> *"There was a fair amount of discussion throughout the meeting raised by TB* [Tainted Blood]*, MHG* [Manor House Group] *and HS* [Haemophilia Society]*, who made some valid points on the unique effects of HCV on haemophiliacs because of their exposure to multiple viruses and pathogens. The experts conceded that not enough research had been done in this field, but pointed out that carrying out and evaluating such research would take many years."* [**DHSC5128268**]

2.18. The covering email indicates that the second note of the meeting made by campaigner representatives was prepared by two members of Tainted Blood, published online and sent to the Minister at the time by officials [**DHSC5128269**]. The Tainted Blood note outlined *"*[c]*riticisms of the government 2010 review"* discussed at the meeting including *"*[t]*he accepted scientific limitations of describing the natural history of hepatitis C in the general population, without the added complications of haemophilia and repeated multi-pathogen exposure through contaminated blood product use, weren't reported"* and *"*[t]*he absence of a suitable epidemiological model, which would provide representative data specific to the haemophiliac/bleeding disorder population, accounting for relevant infections effects."* The note provided further details of the discussion of campaigner representatives' concern that the Expert Report had not considered those co-infected with Hepatitis C and haemophilia. At page 3 the note recorded that:

> *"<u>Unrepresentative data modelling</u>*
>
> *The limited search for evidence coupled with use of studies based on non-haemophilia populations was highlighted as failing to reflect our unique circumstances and the modified effect on disease progression by repeated infective blood product exposure.*
>
> *A strong case was made for a full epidemiological model to be established that would show how infections affect haemophiliacs and people with bleeding disorders specifically. This would uncover facts about the extent of mental impairment, fatigue, higher rates of cancer and higher mortality rates described by campaigners.*

The expert panel (Prof. Brian Gazzard) explained the challenge of identifying appropriate infection data as most studies are based on I.V. drug abusers who shared needles.

He apologised there was no patient representative but added this was very much an expert group and lay people do not understand the complexities of identifying appropriate data or issues of ascertainment (the individuals chosen to be included in a study).

He did acknowledge the lack of knowledge of multiple viral infections, the importance of identifying initial infection, length of infection and accounting for age, as progression accelerates with age.

New details of an MRC study on 10,000 people including haemophiliacs were given (Prof. Graham Foster) and the hope expressed that this would eventually provide more relevant data."

2.19. At page 4 the Tainted Blood note stated that:

"The Expert Panel expressed their disappointment that the outcome of the review had not met our needs and explained they felt they had made an honest attempt at a difficult exercise, to assess and identify data that provided evidence of HCV associated illness, and which should be taken into account by officials when they consider levels of support. They maintained they had recognised some of the associations we had put forward (mental fog, psychological changes, reduced quality of life) and had given them fair weight in the review but that other connections were less well defined." [**DHSC5128269**]

2.20. It appears from the notes of the meeting available to me that the points made in witness W3092's written statement were not ignored by the Department, but were discussed at the meeting on 29 November 2012.

2.21. The reasons why the Expert Working Group's analysis was based on the general 'cohort' of those infected with Hepatitis C were discussed at the meeting with campaigner representatives and the Department, along with the issue concerning the absence of specific analysis on those with haemophilia who had contracted Hepatitis C through infected blood products, which was acknowledged. However, it appears from the notes of the meeting above that, in the view of the experts involved in the

Expert Report, there was a dearth of medical evidence or studies on those who had co-morbidities, and specifically haemophilia and hepatitis C. The 'longitudinal analysis' requested by the Haemophilia Society did not (it appears) exist, in the view of the experts who had advised the Department. There was reference to further research work that it was hoped might assist, in the future.

2.22. The documentary evidence available to me from the notes of the meeting on 29 November 2012 referred to at paragraphs 2.16 and 2.19 above suggests that the Expert Working Group themselves had confidence in the integrity of their work on the Expert Report and did not consider that it was being used by the Department in a *"…disingenuous and unscientific"* manner, as proposed by witness W3092.

2.23. On 14 January 2013 Anna Soubry MP wrote to Professor Brian Gazzard, a member of the Expert Working Group that prepared the Expert Report that attended the meeting on 29 November 2012 and Chair of the EAGA [**WITN4688078**]. Anna Soubry thanked Professor Gazzard for attending the meeting and summarised some advice that was delivered:

> *"My understanding at the meeting was that you view a system of differential payments as reasonable, given the lack of clear evidence of a link between hepatitis C infection and various extra-hepatic conditions. For the future, we have asked the Advisory Group on Hepatitis to keep new evidence under review. Nevertheless, it was good of you to look at further scientific evidence should it be required. Please do let officials know if you become aware of new research that you think might have a bearing on the matter."*

2.24. I understand that Inquiry's Hepatitis Expert Group has considered the issue of individuals co-infected with Hepatitis C and other viruses and medical conditions, including HIV and haemophilia, at Sections 15.16 and 15.17 of the report entitled 'Expert Report to the Infected Blood Inquiry: Hepatitis' dated January 2020 [**EXPG0000001**].

2.25. In time, the issue of further support for those suffering from Hepatitis C during "stage 1" led to the introduction of the special category mechanism ("SCM"), as part of the reforms setting up EIBSS in 2017/2018. As noted at paragraph 54 of my second written statement to the Inquiry:

"The special category mechanism ("SCM") provides additional financial support for beneficiaries who suffer from hepatitis C and who are at stage 1, but whose infection, its treatment, complications or associated conditions have a long term negative impact on their ability to carry out daily activities." [**WITN4688003**]

2.26. The 'Government Response to Consultation on Special Category Mechanism and other support in England' dated October 2017 stated at paragraph 3.6 that:

"In our consultation we stated our intention to recognise the adverse impact hepatitis C infection at stage 1 (or its treatment) can have on an individual's ability to carry out routine day-to-day activities by introducing a Special Category Mechanism. This would enable stage 1 beneficiaries to apply for increased annual payments equivalent to those with HIV or stage 2 disease." [**WITN4688038**]

2.27. I refer to my second and third written statements to the Inquiry for information about the background to the development of the SCM and details on the operation of the mechanism [**WITN4688003; WITN4688055**].

Statement of Truth

I believe that the facts stated in this witness statement are true and confirm I am duly authorised to make this statement on behalf of the Department.

Signed…… **GRO-C** ……

25 May 2023

Dated……

Table of exhibits:

Date	Notes/Description	Exhibit number
14/01/2013	Letter from Anna Soubry MP to Professor Brian Gazzard	WITN4688078