Witness Name: Norman Fowler

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Exhibits: None

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INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF NORMAN FOWLER

Contents

I, **PETER NORMAN FOWLER**, will say as follows: -

0.1. I was Secretary of State for Health and Social Security from 14 September 1981 until 13 June 1987. I remain a member of the House of Lords. On relinquishing the post of Lord Speaker, I became an ambassador for UNAIDS. Having submitted my first witness statement to the Inquiry dated 17 July 2021 [**WITN0771001**], I gave oral evidence to the Inquiry on Tuesday 21 and Wednesday 22 September 2021.

0.2. During the course of my oral evidence, following an intervention from the Chairman, I undertook further to review my exchange of correspondence in 1985 with the Welsh Secretary, Nicholas Edwards, about the screening test for HIV in blood donations, and offer any further clarification or observations in writing. This supplementary statement addresses that issue, two other matters which I agreed to check, and makes one further observation.

1. Clarification and further observations regarding Nicholas Edwards' correspondence on HIV screening of blood donations

1.1. To re-cap on the evidence I have already given, and to provide the relevant context to Nick Edwards' correspondence, I would re-iterate that:

(1) The introduction of the screening test for HIV in blood donations was principally handled at DHSS Ministerial level by Ken Clarke and later John Patten.

(2) On 20 February 1985, Ken Clarke announced the Government's intention to introduce HIV screening of blood donations as soon as possible, and that the evaluation work for such testing was being co-ordinated. At paragraph 6.86 of my first statement [**WITN0771001**] I addressed the chronology of events at Ministerial level that led to this announcement.

(3) The introduction of HIV screening came into effect on 14 October 1985: see the announcement by Barney Hayhoe (who had succeeded Ken Clarke as Minister of State) on the day [**WITN0771089**].

(4) The events at Ministerial level between 20 February (the decision in principle) and 14 October 1985 (testing becoming effective on the ground) were summarised in paragraph 6.105 of my first statement [**WITN0771001**].

(5) Of particular note, within this period:

a. On 7 June 1995, Mr Harris put a submission to John Patten [**DHSC0002311_019**]. The essence of the choice presented to Mr Patten was between selecting an available test on the then current knowledge as soon as possible; selecting a test after evaluation by the Public Health Laboratory Service; or selecting a test after evaluation by the PHLS *and* field trials by the Blood Transfusion Service (BTS). The latter option was that recommended by officials.

b. On 10 June 1995 the CMO, Sir Donald Acheson, advised that this was a finely balanced decision, but he was in favour of the 'evaluation and field trials' approach suggested by officials [**WITN0771101**] and this was the approach that was adopted. In giving his advice, the CMO had emphasised the desirability of having tests that could be produced reliably on a large scale and would continue to be reliable on the shelf. He considered that it would be worse to be in the position of having to withdraw a test once introduced, than to be in the (then) present position of carefully evaluating the tests. But he advised that support for a different view would likely appear in the medical press.

1.2. *After* the BTS had introduced HIV screening, Nick Edwards' letter to me of 18 October 1985 [**DHSC0002311_083**] raised concern about the reliability of the tests that had been introduced by the BTS, stating:

> *"Since I wrote to you on 8 October on this subject, I have been given a detailed presentation by my officials. In the course of it, I was given the results of the evaluation by the National Blood Transfusion Service*

of the Wellcome and Organon test kits which have been recommended for use in the BTS. As the table I attach shows, 1 in 5 of "strong positive" test material was missed by the Wellcome kit, and about half of the "weak positive" material was missed by the Organon kit. I understand that the manufacturers have given assurances about future quality control but I cannot help wondering how realistic their promises are: I would have expected that firms producing kits for evaluation in the knowledge that a very lucrative contract lay in the offing would have done their utmost to ensure the highest possible degree of quality control in the material supplied.

Be that as it may, I accept that even unreliable testing is better than no testing at all. But clearly we must take every step to ensure that we get the system as foolproof as it can be. I am therefore surprised to learn that no further evaluation is planned of the other test kits which are available on the market. I believe this is because there were considerable doubts about the suitability of the other kits, such as Abbott. However, the 4 October edition of the Journal of the American Medical Association (JAMA) reports (copy attached) that 5 months of experience with other kits in the American Blood Transfusion Services have shown a very high standard of performance. Whatever doubts we might have about their claims, it does seem to me that we would be in an indefensible position if, in a few months time, the earlier doubts about the systems we are using were not allayed and we had no alternative available which the BTS could immediately turn to. In short, I consider it essential that all kits should be put into an evaluation programme. A public comparison between the report of the BTS on our present kits with the JAMA report would make life very difficult for us all!"

1.3. Following this letter, on 31 October 1985, Mr Harris put a submission to the CMO and to my Private Office with a robust draft response to Mr Edwards [**WITN0771090**]. Mr Harris' submission stated:

"I attach a draft reply to the Welsh Secretary's letter of 18 October. It also disposes of a related point raised in paragraph 4 of his letter of 8 October.

2. The reaction of Mr Edwards is understandable. He has been shown the draft report of the evaluation in the BTS of two screening tests. The purpose of the evaluation was to look hard for problems. As expected it found some. The report is a highly technical document needing expert interpretation. A group of experts examined the findings. The Welsh Office were represented on this group. The group were able to put the problems found in their proper context. They had no hesitation in recommending the general use of these tests. The performance of the tests since introduction has been monitored. Experience to date suggests they are satisfactory.

3. A fairly robust response is proposed. The introduction of a screening test, after a rigorous two stage evaluation, is one of the Government's most notable achievements in response to the challenge of AIDS. It is highly undesirable that another member of the Government should have such a negative perception of this achievement. Private attitudes can easily become reflected in the tone, if not the content, of public statements and correspondence. Damning the test by faint praise could lead to the very failure in public confidence which Mr Edwards wishes to avoid".

1.4. Based on the draft prepared by Mr Harris, I replied to Mr Edwards on 15 November 1985 [**DHSC0002482_126**],

"I am concerned that you have obtained from your officials such a negative impression of the Government's achievements in this area. This is the more surprising since your officials have participated fully in the forums which gave us the medical and scientific advice on which our policy has been based.

Perhaps the most worrying misconception is the statement "unreliable testing is better than no testing at all". This is the complete opposite of our thinking. We have based policy on the firm conviction that unreliable testing would be disastrous and would engender a false sense of security. This was the reason why we delayed the introduction of screening until we were satisfied that the tests to be used were sufficiently reliable. To achieve this objective the tests now in use have been subjected to a rigorous two stage evaluation, which to our knowledge surpasses what has been done elsewhere. The first step of the evaluation, which was carried out on a limited number of sera, identified two diagnostic kits particularly suitable for use in the BTS. The trials of these two kits carried out in the BTS was on a much larger scale and gave us a very clear indication of how the tests would perform in the field.

This first draft of the report of this evaluation did of course identify problems. This was the whole point of the exercise. The reasons for the apparent failures to which you draw attention were by no means clear cut and more work is being done to pinpoint the cause. The evaluation results were considered in detail by an "ad hoc panel" of leading experts (on which Welsh Office were represented). They had no hesitation in agreeing that routine testing of all blood donations should start, using these two test kits".

1.5. Having reviewed this exchange of correspondence further, I would clarify as follows.

1.6. **Firstly**, I do not accept that it is a sufficient summary of Mr Harris' submission of 31 October 1985 to suggest[1] that Mr Harris was saying that there should not be public criticism or concerns expressed by other Ministers. Nick Edwards had raised a point *internally* within Government. Mr Harris' concern was that if Mr

[1] c.f. the question from Counsel to the Inquiry, Transcript for 22 September 2021, page 73 line 16 *ff [INQY1000145]*

Edwards maintained his apparent negative view of the reliability of the BTS tests, the tone if not content of Welsh Office statements and correspondence ('damning the test by faint praise') could lead to the very failure of public confidence which Nick Edwards wanted to avoid. What appears to have surprised DHSS officials was that Mr Edwards' concerns were based on his officials briefing him on the *draft* report of the evaluation of the BTS screening tests, whereas the Welsh Office had been represented on a group that gave subsequent consideration to the draft report. That group had had no hesitation in recommending the general use of the tests. So it was somewhat incongruous to see concerns being raised on the basis of a draft report when the evaluation process had moved on.

1.7. **Second**, to clarify the point raised by the Chairman [INQY1000145] (Transcript for 22 September 2021, page 76, line 17 *ff*) I would say as follows:

(1) By his letter of 18 October 1985, Nick Edwards was *not* advocating for the introduction of potentially less reliable testing kits that were already on the market instead of awaiting the full evaluation of testing kits by the PHLS. In this regard, the Chairman was right to point out the PHLS-evaluated kits had already been introduced by this time.

(2) Rather, Nick Edwards' concern was about the reliability of the BTS testing kits that had already been introduced. It was in that context that Nick Edwards made the observation that, "… even unreliable testing is better than no testing at all". Nick Edwards went on to raise the question whether other tests that were already on the market (such as the Abbott test) might in fact be more reliable than the Wellcome and Organon kits that had now been introduced by the BTS.

(3) In response to this, Mr Harris' submission of 31 October 1985 and my reply to Nick Edwards of 15 November 1985 were making two key points:
    a. The expert advice had moved on since the concerns raised in the draft report on the reliability of the BTS tests. It was therefore surprising to see Nick Edwards raising concerns based on that

draft report, especially because the Welsh Office had been represented on the group that had given the tests further consideration and had been satisfied about their reliability. Moreover, experience of the tests since their introduction suggested that they were satisfactory.

b. Nick Edwards' observation that "even unreliable testing is better than no testing at all" was at odds with how DHSS had approached the whole introduction of HIV screening of blood donations. As I said in my letter of 15 November 1985, the DHSS thinking had been that unreliable testing would be disastrous and would engender a false sense of security. That was the reason why the Department had – at the earlier stage – delayed the introduction of screening until it was satisfied that the tests to be used were sufficiently reliable.

1.8. **Third**, as I sought to convey in my first statement and in my oral evidence, Nick Edwards could be quite outspoken in his views, and it is significant that he distinctly backed down on this issue. Nick Edwards' eventual response of 11 December 1985 [**DHSC0004360_061**] was carefully nuanced. But it can be fairly summarised as an acknowledgement by Nick Edwards that the subsequent work on the reliability of the BTS tests was re-assuring so that his concerns had been alleviated, while he defended having raised the concerns in the first place, and his motivation for so doing.

2. Hepatitis C as a consideration in the assessment of relative risks in 1983

2.1. By reference to evidence that had been given by Lord Glenarthur, Counsel to the Inquiry asked me whether I could assist in understanding why non-A non-B hepatitis was not part of the explicit decision-making process in 1983 when the risks of withdrawing imported Factor VIII concentrates was being considered against the risks of infection with AIDS by the use of those products (22 September 2021, page 138, line 22 *ff*) [INQY1000145]. I answered to the effect that I could not assist on this more than Lord Glenarthur had done. I noted that

the issue had not come to me at the time in any event but that I could make enquiries and see if there was anything that I could add.

2.2. On reflection on this issue, I do not think that there is anything meaningful that I can add. The decision not to withdraw the licences for imported Factor VIII concentrates (taken by the Committee on the Safety of Medicines, following the meeting of its Biologicals sub-committee) was not the subject of a submission to ministers. The extent to which Hepatitis C risks were (or were not) or should have been, included in the assessment of the balance of risk would depend, amongst other things, on the state of expert knowledge at that time of the seriousness of the HCV risk and the relative risk of HCV from imported and domestic Factor VIII concentrates. Since those issues were not raised with me at the time, I do not feel best placed to offer further comment on this topic.

3. Appointment process for the Chief Medical Officer

3.1. I indicated in my oral evidence that my belief was that the Chief Medical Officer was appointed as a Civil Service appointment in the way a Permanent Secretary would be appointed, but I offered to check this (22 September 2021, page 143, line 12 *ff*) [INQY1000145].

3.2. I note that Sir Donald Acheson mentioned in his autobiography that his position was confirmed by the Cabinet Secretary Sir Robert Armstrong[2]. That is consistent with the post being filled in the same way as other Permanent Secretary level appointments within the Civil Service.

3.3. I am informed that the BSE Inquiry published the information provided to shortlisted candidates to succeed Sir Donald Acheson which may be of some background interest on this topic[3].

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[2] Sir Donald Acheson, One Doctor's Odyssey, The Social Lesion at pg. 164 [WITN0771088]

[3] https://webarchive.nationalarchives.gov.uk/ukgwa/20080103051959/http://www.bseinquiry.gov.uk/evidence/mbundles/mbund5.htm

3.4. I have not been able to find a definitive answer to the precise process by which the CMO was appointed in my time as Secretary of State. I do not recall having any significant role in the selection or appointment of Sir Donald Acheson. Ken Stowe may well have been involved at some stage in the process as Permanent Secretary. I expect that there would have been a senior appointments panel of some kind that would have assessed high level applicants and come up with a shortlist and probably a preferred / recommended candidate. I expect (but cannot be sure) that I may have been given the opportunity to object to the preferred candidate put forward if I had good grounds to do so, and I expect (but similarly cannot be sure) that the Prime Minister would have had a right of veto over the recommended candidate. I think it likely that this was ultimately handled - or at least cleared by - No. 10. That is supported by: (i) the fact that Sir Robert Armstrong communicated the appointment to Sir Donald; (ii) the Prime Minister was Minister for the Civil Service and involved in the very top Civil Service appointments; and (iii) the Chief Medical Officer was the principal adviser on medical and public health matters, not only to Ministers in DHSS but to the Ministers in other government departments and to the Government as a whole. I think I would have remembered if I had been more significantly involved in selecting Sir Donald; I would in any event have been extremely cautious about interfering with the recommendation of a senior appointments panel where what was involved was the appointment of the Government's senior medical professional.

4. The timing of the setting up of the Expert Advisory Group on AIDS (EAGA)

4.1. Having reviewed the transcript of my evidence[4] and the questioning on the EAGA, I would like to re-emphasise the following. While it stands to reason that the EAGA was an improvement (being a bespoke committee focussed specifically on AIDS) even before the EAGA was formed, the CMO would have had access to expert advice on AIDS from his existing advisers and committees (see paragraph 6.88 of my first statement at [WITN0771001]).

[4] 22 September 2021, page 51 line 6 *ff* [INQY1000145]

Statement of Truth

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

Signed..... GRO-C

Dated..... January 26 2023