



## **Chronological Presentation on the Domestic Supply of Blood Products in England and Wales**

### **Appendix 1**

#### **Factor VIII Demand Estimates**

##### **Introduction**

1. This Appendix provides additional detail of the various estimates and targets that were made about the likely requirements for Factor VIII concentrates during the 1970s and 1980s. It is intended to accompany the main chronological presentation and Appendix 2: BPL/PFL Capacity, Production and Plasma Supply. Together, these documents explore the different estimates that were made at different stages, why they were made, and how they related to the policy initiatives that emerged to increase plasma supply and the production of blood products.
2. To facilitate analysis this appendix is divided into three key periods:
  - i. The first push for self-sufficiency (1973 to mid-1977)
  - ii. Beyond 1977: Stop Gap and MARP01 (mid 1977 to 1983)
  - iii. BPL redevelopment (1983 to 1990).

##### **Data issues**

3. From the data identified, it is evident that differing metrics were adopted to calculate demand for Factor VIII. From 1973 to 1975 the number of blood

donations was the predominant measure. From 1976, we begin to see the adoption of international units to calculate demand. As noted by Dr Owen in 1975, it would be challenging to translate blood donations to international units with accuracy due to the significantly varied yield of Factor VIII from blood donations.<sup>1</sup> Dr Richard Lane (Director, BPL) also highlighted that yield changed over time.<sup>2</sup> In general, no attempt has been made by the Inquiry legal team to convert blood donations into international units, though evidence is cited where others have done so.

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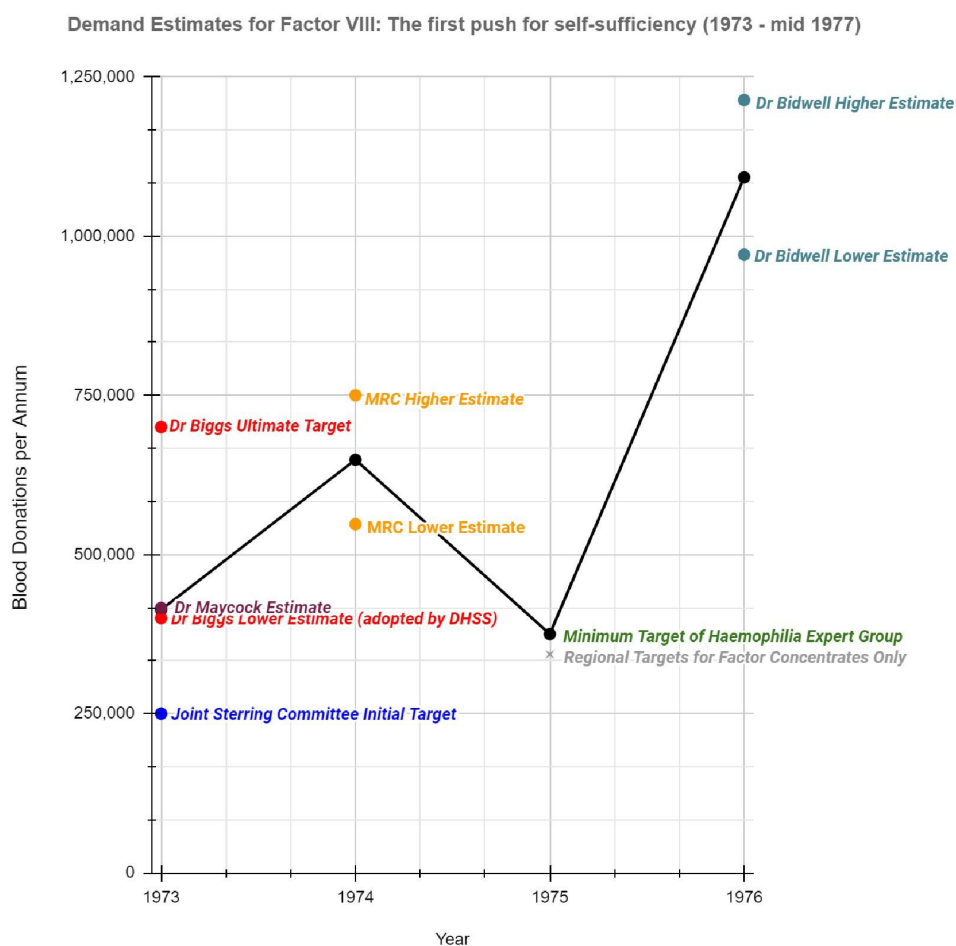
<sup>1</sup> Parliamentary Question and Written Answer, re: Dr Owen noting the challenges in converting donations to units, 6 March 1975, **DHSC0042461\_039**.

<sup>2</sup> Draft Proof of Evidence of Richard Spencer Lane for HIV Haemophilia Litigation, 10 December 1990, **CBLA0000005\_002**, pg.41, para 106. References to page numbers in this document are to the internal page numbers (not the electronic page numbers), unless otherwise stated.

## The first push for self-sufficiency (1973 - mid 1977)

### Overview of the Demand Estimates for Factor VIII (1973 to 1976)

4. The graph below outlines estimates made between 1973 and 1976 in terms of the total blood donations required per annum to achieve self-sufficiency in Factor VIII. It does not incorporate estimates prepared in 1977 (see the section below for this data) as the majority of estimates made from 1977 onward adopted the metric of international units. The graph shows an average estimate of demand across the period, represented by the black data line. Each individual estimate, represented by a data point, has been titled for ease of reference.



## **An analysis of estimates of demand during the first push for self-sufficiency (1973 - mid 1977)**

5. As is discussed in the main presentation, the first commercial licences for blood products were issued in 1973. In this context, Sir George Godber (Chief Medical Officer, DHSS) wrote to Senior Administrative Medical Officers and noted that *'the production of the human concentrate [AHG] in the UK is at present insufficient to meet the stated needs of clinicians'* and *'considerably more of this preparation would be used if it were available'*. The DHSS therefore assembled expert groups to advise on the likely trends in both the methods of treatment and future requirements for therapeutic agents including AHG. Any conclusions reached by the expert groups would form the basis for *'realistic planning for the future'*.<sup>3</sup> The DHSS also agreed that *'the UK should, as far as possible, be independent of imported concentrate'*.<sup>4</sup>
6. In addition, Haemophilia Centres were asked to complete questionnaires<sup>5</sup> to inform estimates of the total number of patients treated for haemophilia and the amounts of treatment that might be required *'if supplies were unlimited'*. The responses indicated that 2,600 patients attended a Haemophilia Centre for treatment in the UK.<sup>6</sup> Based on data for the UK as a whole, Dr William Maycock (Director, BPL) calculated that **416,000 donations** would be required to satisfy the needs for Factor VIII.<sup>7</sup> In a further paper, Dr Maycock considered that *'about four-fifths of the total number of donations will be needed in the form of concentrate'* and one-fifth would be required for

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<sup>3</sup> Letter from the Chief Medical Officer of the DHSS to all Senior Administrative Medical Officers, 6 March 1973, **DHSC0100005\_033**.

<sup>4</sup> Minutes of 147th Regional Transfusion Directors Meeting, 13 June 1973, **DHSC0105498\_005**, pg.10.

<sup>5</sup> Overall findings appear to be recorded on a Table, **CBLA0005252**. For an example questionnaire, see: Letter from CRM Prentice (University of Glasgow) to Dr MacDonald (SHHD) re Questionnaire on future requirements of Factor VIII, 13 April 1973, **CBLA0000148**.

<sup>6</sup> Letter from Dr Mary Collins to D. J. Withers (Department of Health (Australia), re: Figures of haemophilia treatment in the UK, 1978, **DHSC0002187\_074**.

<sup>7</sup> Report of 'Materials for the Treatment of Haemophilia and Christmas Disease' by W. d'A Maycock, March 1973, **DHSC0100005\_128**.

cryoprecipitate, based on Haemophilia Centre preferences at that time. This equated to **333,000 donations** (or 66,600 litres of plasma per annum) for Factor VIII concentrates.<sup>8</sup>

7. During 1973, Dr Rosemary Biggs (Director of Oxford Haemophilia Centre and Chairman of Medical Research Council (MRC) Working Party) postulated that **300,000 to 700,000 donations** (or 30m iu to 50m iu) would be required to meet the demands for Factor VIII.<sup>9</sup> Dr Biggs later revised her estimates and submitted that **400,000 to 700,000** per year would be required to '*provide optimum treatment for all haemophilic patients in Great Britain*'.<sup>10</sup>
8. The Expert Group on the Treatment of Haemophilia in March 1973 deemed that **400,000 donations** (equating to 32m iu of Factor VIII<sup>11</sup>) would be required to treat haemophiliacs of all degrees of severity, informed by an estimate of **3,000 individuals** with haemophilia.<sup>12</sup> The Joint Steering Committee on Blood Products Production agreed that Dr Biggs' lower estimate should be adopted with 700,000 donations set as an '*ultimate target*'.<sup>13</sup> In order to work toward this estimate of demand, it was decided that an initial aim for AHG should be **250,000 donations to be achieved by 1975** (this was later revised by Dr Maycock to **275,000 donations** to reflect a yield of 180-190ml of plasma from each donation).<sup>14</sup> Both the Expert Group on the

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<sup>8</sup> Report of 'Present Sources of Materials for Treatment of Haemophilia and Potential Future Sources', by W. d'A Maycock, March 1973, **DHSC0100005\_132**.

<sup>9</sup> Letter from Rosemary Biggs (Oxford Haemophilia Centre) to Dr W d'A Maycock, re: Availability of High Potency Human Factor VIII Concentrate, 5 June 1973, **DHSC0100005\_037**.

<sup>10</sup> Report of 'Factor VIII concentrates and the treatment of haemophilia' by Rosemary Biggs, undated, **PRSE0002553**.

<sup>11</sup> Penrose Inquiry Report on the SNBTS 'Self-Sufficiency and the Supply of Blood Products in Scotland' by P R Foster, January 2011, revised February 2011, **PRSE0001083**, pg.23.

<sup>12</sup> Meeting of the Expert Group on the Treatment of Haemophilia Minutes, 20 March 1973, **PRSE0004706**.

<sup>13</sup> Minutes from the first Joint Steering Committee on Blood Products Production Meeting, 20 June 1973, **PRSE0004359**.

<sup>14</sup> 2nd special RTDs meeting, 27 September 1973, **CBLA0000160**; at this meeting Paper RTD(73)24 - 'Plasma needed for the preparation of anti haemophilic concentrate' was tabled, **CBLA0000154**. The revised figure of 275,000 donations was based on BPL's fractionation capacity at the time of 1000L per week, ie about 5,500 donations per week from which between 180 and 190ml of plasma are removed, x50 weeks.

Treatment of Haemophilia and the Joint Steering Committee on Blood Products Production advocated for the UK to achieve self-sufficiency.

9. It is important to note that in a paper titled RTD(73)20, it was confirmed that Scotland was already devoting 50,000 donations annually to haemophiliacs and was therefore proportionally *'meeting the recommendations by the Expert Committee'*. The focus was therefore on increasing donations and production of AHG in England and Wales,<sup>15</sup> and the 275,000 donation target related to England and Wales only.<sup>16</sup>
10. The difference between the target for Factor VIII production of 275,000 donations and Dr Biggs' estimate of requirements was discussed by Dr Lane in his 5th draft proof of evidence prepared in relation to the HIV Litigation. He noted that *'the mismatch between the 'target' of production Factor VIII from 275,000 donations and what was actually required'* was, in his belief, due to Dr Maycock and the DHSS *'concentrating on what was believed to be the appropriate level of production to treat patients when a bleed occurred. Use of Factor VIII for home prophylaxis (which was to become the norm) was a significant factor which may in part explain some of the discrepancies between what BPL actually resolved to produce (and could reconcile with their capacity) and what others estimated was actually needed'*.<sup>17</sup> Dr Lane also referred to an internal DHSS minute sent to Dr Owen's private office in 1975 in support of this position:

'Much effort will be required of the Regional Transfusion Directors, some of whom may not see eye to eye with their clinical colleagues treating haemophiliacs. For example, some Haemophilia Centre Directors envisage home prophylaxis, whereas the present proposals are based upon home treatment of a bleed when it occurs. Other

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<sup>15</sup> Paper RTD(73)20 on the 'Provision of Plasma for AHG Concentrate', 1973, **CBLA0000155**.

<sup>16</sup> Parliamentary Questions from Lewis Carter-Jones regarding Factor VIII, includes a written answer from Dr David Owen. 6 March 1975, **DHSC0041379\_037**.

<sup>17</sup> Draft Proof of Evidence of Richard Spencer Lane for HIV Haemophilia Litigation, 10 December 1990, **CBLA0000005\_002**, pg.39-40.

Haemophilia Centre Directors, apparently, are not fully persuaded of the practicability and value of home treatment.<sup>18</sup>

11. Dr Biggs' estimates of demand prepared in 1973 were not without criticism. In December 1973, Dr Chris Bowley (Regional Transfusion Director, Sheffield) wrote that *'the calculations take on a certain air of fantasy' and 'many widely differing figures are quoted for the incidence of haemophilia in various populations but unfortunately Dr Biggs is unable to give a convincing figure of the incidence in this country'*. Dr Bowley concluded that *'only when the size of the problem is known can a realistic policy be decided'*. It is important to note here that Dr Bowley was of the opinion that an alternative arrangement should be introduced at this stage instead of increasing AHG production, including promoting haemophiliacs to live *'a full and satisfying life within the limits of their disability, rather than obeying the exhortation of the Haemophilia Society to live normally'*.<sup>19</sup> Dr Biggs defended her calculations, noting that *'my statistics were based on painful analysis of returns from 33-36 Haemophilia Centres' and that 'in all Centres the trend is upwards as more material becomes available'*.<sup>20</sup> The question of whether people with haemophilia could and should expect to lead anything more than sedentary lives was to recur in later debates about plasma and production targets.

12. In January 1974, Professor Eddie Blackburn (Consultant Haematologist at the Department of Haematology, the Royal Infirmary in Sheffield) chaired a meeting between the Directors of Haemophilia Centres and Blood Transfusion Directors. During the course of the meeting, Dr Biggs tabled an MRC Working Party Report<sup>21</sup> which concluded:

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<sup>18</sup> Memorandum from L H Brandes to Mr Alexander et al. re Dr Owen's Minute, 17 March 1975, **CBLA0000260**.

<sup>19</sup> Letter from Dr Bowley to Regional Transfusion Centres, re. Treatment of Haemophilia and Dr Biggs Estimate of demand, 17 December 1973, **CBLA0000171**.

<sup>20</sup> Letter from Dr Biggs to Dr Bowley, re. Dr Bowley's critique of Factor VIII and treatment of Haemophiliacs report, 9 October 1973, **DHSC0100005\_053**.

<sup>21</sup> Report of 'Factor VIII concentrates Made in the UK and the Treatment of Haemophilia Based on Studies made during 1969 to 1972, by Dr Rosemary Biggs et al, undated, **PRSE0002350**.

'Calculations suggest that the amount of material required for optimum treatment for all the haemophilic patients in Great Britain would be derived from **547,540 to 750,000** blood donations a year [this equated to approximately 38,327,800 and 53m iu of Factor VIII according to Dr Biggs subjective calculations<sup>22</sup>] - this would include both 'on demand' treatment and 'home treatment' of 1,000 patients who might benefit from it... clearly a 20 fold increase in fractionation cannot be achieved overnight but it is to be hoped that a very substantial increase may occur without too much delay.'

13. Professor Blackburn stated that *'with one exception [presumably Dr Bowley], the Meeting supported and wholeheartedly endorsed'* the MRC Working Party report recommendation. Professor Blackburn therefore agreed to contact the DHSS to suggest that the MRC report form the basis of future planning in the UK for the production of Factor VIII.<sup>23</sup> Professor Blackburn notified the DHSS forthwith<sup>24</sup> and this was acknowledged on 22 February 1974.<sup>25</sup>

14. The response of the DHSS to the recommendations of the meeting is discussed in detail in the main presentation, and that evidence is not repeated here. In short, £500,000 of special financing was allocated primarily to increase plasma supply, with a smaller sum going to BPL to upgrade equipment. The target for this programme was, initially, to increase blood donations dedicated to fractionation to 275,000. This was almost half the number of donations recommended by the MRC when comparing against the lower estimate of 547,540 donations. It was, though, intended as an interim target and a way of kick-starting efforts by Regional Transfusion Centres and Regional Health Authorities to increase plasma supply.

15. Dr Jack Darnborough (Director, Cambridge RTC) was concerned that this last point had not been sufficiently stressed to regional directors. He wrote to Dr

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<sup>22</sup> Letter from Dr Biggs to Prof. Blackburn, re: Estimates of demand, 28 October 1976, **OXUH0003759\_004**.

<sup>23</sup> Minutes of Haemophilia Centre Directors and Blood Transfusion Directors Joint Meeting, 31 January 1974, **CBLA0000187**.

<sup>24</sup> Letter from E K Blackburn (Sheffield Royal Infirmary) to Dr S L Waiter (DHSS), February 1974, **OXUH0003603\_004**.

<sup>25</sup> Letter from Dr S L Waiter (DHSS) to Professor E K Blackburn (Sheffield Royal Infirmary), 22 February 1974, **OXUH0003604\_003**.



Maycock in April 1975 suggesting that communications should note that the 275,000 donation target for AHG (plus 100,000 for cryoprecipitate) *'are minimum targets... 375,000 is only the initial target and that the Expert Committee suggested this should rise to 700,000'*.<sup>26</sup> Meanwhile, RTCs expressed concern that increasing donations to the initial target would be *'a tremendous strain on Transfusion Centres'*.<sup>27</sup>

16. By July 1975, the DHSS had fixed on a point in **1977** as the date by which the initial targets should be achieved. It shared regional targets with Regions based on **337,000 donations** which was noted as *'20% more than the total of 275,000 recommended by the Expert Group on Haemophilia but that figure must be regarded as the minimum'*.<sup>28</sup> This target was later increased to **347,000 donations**,<sup>29</sup> before being revised to **343,100** (accounting for a miscalculation of RTC donations).<sup>30</sup>

17. Again, as is discussed in the main presentation, there was a lack of agreement on what constituted self-sufficiency. As Mr Jackson wrote in his minute to Dr Owen's private office in July 1975, *'some Haemophilia Centre Directors envisage prophylactic treatment whereas the Department's programme is based upon home treatment of those patients for whom treatment at home can be recommended'*.<sup>31</sup>

18. The tension between the various targets set, and the principles underlying them, is reflected in discussions and correspondence in late 1975 and early 1976. In December 1975, Dr Waiter reviewed a draft article that had been

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<sup>26</sup> Letter from J. Darnborough to Dr. W. d'A. Maycock re: Draft Letter to RHAs on AHG targets, 10 March 1975, **DHSC0002359\_043**.

<sup>27</sup> Letters from Dr L. A. Derrick Tovey and G. O. Walters to Dr W. d'A. Maycock re: Draft Letter to RHAs on AHG targets, 11 March 1975, **DHSC0002359\_046**.

<sup>28</sup> Note from D.U. Jackson (DHSS) to Mr Lillywhite, re: 'Factor VIII: AHG Concentrate', 11 July 1975, **DHSC0001774**.

<sup>29</sup> Minutes of the Regional Transfusion Directors' 158th meeting, 8 October 1975, **DHSC0105496\_024**.

<sup>30</sup> Minute from Mr Jackson to Dr Maycock, 14 November 1975, **DHSC0002179\_045**; Minutes of the Regional Transfusion Directors' 159th meeting, 21 January 1976, **NHBT0016480**.

<sup>31</sup> Note from D.U. Jackson (DHSS) to Mr Lillywhite, re: 'Factor VIII: AHG Concentrate', 11 July 1975, **DHSC0001774**.

sent to her by Dr Henry Bunje of the MRC.<sup>32</sup> The correspondence and surrounding documents in the file suggest that the article was written by Dr Biggs and was intended for the MRC's annual report to be published later in 1976.<sup>33</sup> In a letter dated 11 December 1975, Dr Waiter raised strong reservations about the article:

'I have discussed with interested colleagues the sections you point out as having some implication for this Department and the consensus view is that if the article is published as it stands it could be embarrassing. For some time there has been a good deal of activity in this field particularly aimed at increasing UK production of Factor VIII Concentrate and we have based our distribution of specially allocated funds on figures which are at variance with those you quote but which we are assured by experts in the field are sound figures e.g.

1. Cost of commercial preparations...  
MRC - £5 million p.a.  
DHSS on advice - £2 million p.a.
2. ...Estimated Minimum Need  
MRC - 500,000 donations  
DHSS - 375,000 donations

There are other statements which we would like to see amended but I am really wondering whether you would consider postponing the publication of an article on haemophilia which if published at this time by the MRC would lead to more discussion [and] probably controversy about the way in which the NHS is endeavouring to become independent of commercial firms for the supply of Factor VIII concentrate. If you agree not to publish the article this year then we do not need to go further in suggesting amendments however if you feel strongly that the article should be published then I must come back to you and raise several points at a later date.

I hope you find that you can agree to my suggestion. Quite considerable interest has been generated in the Department concerning the supply of Factor VIII within the NHS and events should move quite quickly during the next 12 months. If you feel it would be helpful please telephone me and discuss this further.'

19. Mr Dutton and Mr Draper of the DHSS met with Dr Bunje and Dr Dickens of the MRC on 15 January 1976. Dr Biggs was also present. The note of the

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<sup>32</sup> "The Treatment of Haemophilia: Objectives and Limits", **DHSC0100006\_096**.

<sup>33</sup> Covering note from Dr Henry Bunje, 31 December 1975, **DHSC0100006\_095**; Note on Dr Rosemary's Biggs' article Treatment of Haemophilia: Objectives and Limits", **DHSC0100006\_098**.

meeting indicated that the article would still be published, although with certain amendments and additions, including in respect of the cost of commercial concentrates. Dr Biggs was recorded as saying that her estimate of 500,000 plus donations referred to preparations from cryoprecipitate and concentrate collectively across the UK. She *'agreed to work into the article a reference to increasing supplies of NHS freeze dried concentrate becoming available and the need, when counselling haemophiliacs, to encourage them to be reasonably circumspect in the activities they undertook.'*<sup>34</sup>

20. The Haemophilia Society also expressed concern at this time about the different targets in circulation. The minutes of a meeting held between representatives of the Society and Dr Owen in December 1975 record the former as being *'anxious that the volume target set by the Department for self-sufficiency might not be sufficient in practice - the MRC study had said a figure of 500,000 rather than 340,000 was necessary'*. In response, Dr Owen is noted to have stated that *'there were genuine professional differences on the target to be achieved but that the production capacity being established was flexible within certain limits'*.<sup>35</sup> He undertook to look at the MRC study and to write to the Society.

21. Following the meeting, Mr Draper of the DHSS prepared a submission that was sent to Dr Owen's Private Secretary, Mr Grimstone. This attached a copy of the MRC report and a draft letter to the Haemophilia Society. Mr Draper explained that the draft letter did not go into much detail on the differences between the MRC and DHSS figures for target donations, other than to note that the former was a UK-wide figure and the latter one for England and Wales. He wrote that the main factor leading to higher estimates was the view taken of the growth of home and prophylactic treatment: *'There is little that can usefully be said on these points.'* Mr Draper also commented that Dr

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<sup>34</sup> Minute from Mr Dutton to Mr Draper, January 1976, **DHSC0100006\_103**.

<sup>35</sup> Meeting Note from GE Grimstone re Deputation from the Haemophilia Society, 11 December 1975, **DHSC0100006\_093**.

Biggs' figures had varied from time to time, and that while in the report she had considered 500,000 donations were needed for concentrate alone, she had '*recently used the same figures, orally, for AHG [concentrate] and cryoprecipitate combined*'. This appears to be a reference to the meeting on 15 January 1976. He advised that the letter be left in general terms, and that these matters were '*in any case old ground, and the Society and their professional advisers are no doubt well aware of the situation.*'<sup>36</sup>

22. In the draft letter, which was attached to the submission, it was stated that '*the difference between this figure [of 340,000] and the rather higher ones suggested in the MRC report is to a large extent accounted for by genuine professional differences as to the amounts of Factor VIII required in order to achieve optimum treatment for each haemophilia patient, and also what 'optimum' treatment implies, for different individuals*'. The DHSS assured the Haemophilia Society that the Government was committed to achieving self-sufficiency in NHS production of Factor VIII and would amend the target figure if it was deemed necessary.<sup>37</sup>

23. The reassessment by Dr Ethel Bidwell (Head of PFL) In January 1976 illustrated the growing variance between evolving estimated requirements and figures used to inform the ongoing DHSS programme.<sup>38</sup> Dr Bidwell re-estimated demand for Factor VIII and concluded that the total requirement in the UK was between **36m iu** and **45m iu**. This equated to **970,920 donations** to **1,213,650 donations** according to Dr Bidwell's subjective conversion of blood donations to international units and was based on:

- A total of 3,000 patients
- An average of 12,000 - 15,000 iu per patient, per annum

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<sup>36</sup> Memorandum from M W Draper to Mr Grimstone et al. re Meeting with Haemophilia Society, 28 January 1976, **DHSC0100006\_104**.

<sup>37</sup> Draft Letter from HS2B, Department of Health and Social Security to the Reverend A Tanner, re: MRC recommendations, 28 January 1976, **DHSC0100006\_105**.

<sup>38</sup> Paper by Dr Bidwell, 'Production of Factor VIII Concentrate', 27 January 1976, **CBLA0000336**.

- A yield of 200 iu per kg of plasma (for large scale production) to 240 iu (for small scale production at PFL).

24. In her paper it was noted that in accordance with DHSS targets, BPL was to receive plasma from **343,100 donations** by June 1977, equating to approximately **12.35m iu**. It was not clear, however, according to Dr Bidwell, how the deficit identified between the DHSS target (of 341,000 donations) and the calculated demand for Factor VIII as of 1976 (of 970,920 to 1,213,650 donations) would be resolved. Moreover, capacity at BPL, PFL and PFC was estimated at around 110,000kg, equivalent to 593,340 donations, which was '*about 50 per cent of the capacity envisaged*' to achieve the upper estimate of demand of 1,213,650 donations. In turn, UK wide capacity was considered '*greatly in excess of the 343,100 donations planned for*'.<sup>39</sup>

25. On 4 May 1976, the Expert Group on the Treatment of Haemophilia met to advise the DHSS on the trends in home treatment and the resulting effect on production targets.<sup>40</sup> The Expert Group concluded that '*it must now be accepted that the old target was now quite irrelevant to the widely recognised treatment needs of haemophiliacs; it had been rendered out of date largely by the advances of home therapy*'.<sup>41</sup> The target of **343,100** donations (443,100 including cryoprecipitate) for Factor VIII represented just one third to one half of the amount of Factor VIII that would be required in the next five years.<sup>42</sup> The full requirement for Factor VIII was estimated as **35m iu** per annum.<sup>43</sup> It was however decided that a new target of production and supply would not be set until after the original 1977 target had been achieved.<sup>44</sup>

<sup>39</sup> Paper by Dr Bidwell, 'Production of Factor VIII Concentrate', 27 January 1976, **CBLA0000336**.

<sup>40</sup> Note from T.E. Dutton and Dr Sheila L. Waiter (Joint Secretaries) requesting advice from the Expert Group on the Treatment of Haemophilia, 31 March 1976, **DHSC0100007\_008**.

<sup>41</sup> Minutes of the Expert Group on the Treatment of Haemophilia and Allied Conditions meeting, 4 May 1976, **CBLA0007964**, pg.3.

<sup>42</sup> Memorandum from Mr Dutton to Mr Draper et al, re: A Co-ordinated Blood Production and Utilisation Programme, 15 June 1976, **DHSC0002181\_015**.

<sup>43</sup> Letter from T. E. Dutton to R. N. Roberts re: 35 Million iu of Factor VIII required in the next five years, 16 July 1976, **DHSC0103209\_028**.

<sup>44</sup> Note regarding AHG production, undated - likely 1976, **DHSC0100006\_144**.

26. On 12 May 1976, members of an NBTS Facilities and Production meeting also agreed that demand was rising and that a 'doubling' in current NHS efforts over the next few years would be required to expand NBTS collections and production toward self-sufficiency. It was considered desirable to increase blood collection and NHS production, compared with other tabled options such as paid donor panels, but the following difficulties were recognised:

i. The limited availability of money would necessitate arguing the case for NBTS expansion against the claims of other service development...

ii. It would be difficult to justify the size of the NBTS effort merely to cater for the needs of one particular group of patients...

iii. Apart from the pressure from and on behalf of Haemophilia patients, there was no discernible pressure on either the Department or Ministers which suggested that there were widespread shortages of blood or blood products'.<sup>45</sup>

27. In light of the above, in June 1976, Mr Dutton (DHSS) wrote to Mr Draper et al. and invited views on a comprehensive policy on the optimum utilisation of blood and its components. He stated that if the Expert Group were accurate in their reassessment, 50% to 60% of all blood collected annually in the UK would need to be used for Factor VIII.<sup>46</sup>

28. A note regarding the updated views of the Expert Group was provided to Dr Owen on 18 June 1976<sup>47</sup> who responded on 21 June 1976: '*This was inevitable and comes as no surprise at all. This only demonstrates once again why we must reform the National Blood Transfusion Service*'.<sup>48</sup>

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<sup>45</sup> Minutes of an NBTS Facilities and Production Meeting, 12 May 1976, **DHSC0002325\_008**.

<sup>46</sup> Memorandum from Mr Dutton to Mr Draper et al, re: A Co-ordinated Blood Production and Utilisation Programme, 15 June 1976, **DHSC0002181\_015**.

<sup>47</sup> Letter from TE Dutton to Mr Draper and Mr Lillywhite, re: Expert Group on the Treatment of Haemophilia Update for Minister of State, 18 June 1976, **DHSC0100006\_143**.

<sup>48</sup> Letter from G.E. Grimstone to Mr Dutton, re: Lord Owen comments on Update from the Expert Group on the Treatment of Haemophilia, 21 June 1976, **DHSC0100006\_145**.

29. With the '*daunting*' task of increasing production of Factor VIII by three times more than the DHSS programme (from around **12.35m iu in 1977**<sup>49</sup> to **35m iu within five years**<sup>50</sup>), Mr Dutton determined that the issue of yield of factor per volume of blood or plasma became especially important.<sup>51</sup> In May 1975, Mr Dutton calculated that yield from 275,000 donations would likely equate to 11,458,330 iu of Factor VIII concentrate according to his subjective calculations and therefore this level of donations '*are likely to yield far fewer international units of Factor VIII actively than will be needed if the forecasts of the experts are to be met for NHS produced material*'.<sup>52</sup> A further note prepared by Mr Dutton at the end of June 1976 provides some insight into the challenges in increasing blood collection for Factor VIII production to levels now forecasted by the Expert Group on the Treatment of Haemophilia. Mr Dutton described the Factor VIII production programme as '*a balanced programme for blood utilisation and some of the balances are very delicate*'. This included the assumption that clinicians could be persuaded to use concentrated red cells to release increased amounts of plasma for Factor VIII. He considered that significant increases in blood collection or more plasmapheresis would be required to achieve revised requirements.<sup>53</sup>

30. In July 1976, the distinction between DHSS targets and revised demand estimates by the Expert Group was explored once again. At a meeting discussed in the main presentation, Dr Maycock stated that he was working toward a target of 15m iu to be achieved by 1977, whereas Dr Rizza said that he understood the target to have been 34m to 40m iu. Dr J Stewart (a Regional Scientific Officer) commented that this resulted in '*a **shortfall of 20 million units per annum since the needs of patients had been estimated at 35***

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<sup>49</sup> Paper by Dr Bidwell, 'Production of Factor VIII Concentrate', 27 January 1976, **CBLA0000336**.

<sup>50</sup> Letter from T. E. Dutton to R. N. Roberts re: 35 Million iu of Factor VIII required in the next five years, 16 July 1976, **DHSC0103209\_028**.

<sup>51</sup> Letter from T. E. Dutton to R. N. Roberts re: 35 Million iu of Factor VIII required in the next five years, 16 July 1976, **DHSC0103209\_028**.

<sup>52</sup> Memorandum from Mr Dutton to Dr Waiter, re: AHG Factor VIII Demand Calculations, 26 May 1976, **DHSC0100006\_140**.

<sup>53</sup> Note from TE Dutton to Mr Draper et al. re: Factor VIII and Other Blood Components, 28 June 1976, **DHSC0100006\_146**.

*million units of Factor VIII*'. In response to this discussion, Dr Biggs stated that Haemophilia Centre Directors had '*never supported a target of 15 million units of Factor VIII*'.<sup>54</sup> As per the discussion above and in the main presentation, those directors endorsed the higher estimates of demand recommended by the MRC which equated to 38,327,800 and 53m iu of Factor VIII.

31. On 28 October 1976 and in response to remarks made by Dr Maycock that '*there was some surprise at the tripling of the estimate which occurred between 1973 to 1976*'<sup>55</sup>, Dr Biggs stated that she had been '*pretty consistent*' in her demands since 1973. Dr Biggs referred to both the estimate of the Expert Group (400,000 donations - 32m iu) and the MRC (547,540 donations - 38,327,800 iu) to support this statement. She considered that the target figure of 15m iu only appeared in 1976.<sup>56</sup>

32. Later in October 1976 during an exploratory meeting between Blood Transfusion Directors and Haemophilia Reference Centre Directors, members put forward a number of estimates of UK demand, with all parties estimating a figure reflecting a considerable increase in demand<sup>57</sup>:

- **40,223,807 iu** - Dr Biggs and Professor Blackburn suggested that there was need for at least this amount based on 11,058 units on average per patient per annum, and an incidence of 6.5 per 100,000.
- **42.4m iu** - Dr Peter Jones (Director, Newcastle Haemophilia Centre). It was estimated that half of this total would be required for home treatment.<sup>58</sup>

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<sup>54</sup> Minutes of HCD's, RTD's and Regional Scientific Advisors from the Supra Regional Territory Meeting, 26th July 1976, **CBLA0000391**.

<sup>55</sup> Letter from Dr Maycock to Prof. Eddie K. Blackburn, re: Escalating UK estimates of demand for Factor VIII, 25 October 1976, **OXUH0003759\_003**.

<sup>56</sup> Letter from Rosemary Biggs to Prof. Eddie K. Blackburn, 28 October 1976, **OXUH0003759\_004**.

<sup>57</sup> Exploratory meeting of Blood Transfusion Directors and Haemophilia Reference Centre Directors, 22 October 1976, **CBLA0000473**.

<sup>58</sup> Paper on 'Home Therapy in the UK' by Dr Peter Jones, February 1976, **DHSC0100007\_044**.



- **50m iu** - Professor Cash suggested that there was need for this amount as an absolute basic figure, likely informed by his study with Mary Spencely discussed below.
- **40m iu rising to 50m iu by 1979** - Dr Prentice.

33. The same meeting considered the proportion of Factor VIII that should be provided by concentrate when compared to cryoprecipitate. Dr Bloom was recorded as saying, “100% freeze dried” (i.e. concentrate). Dr Jenkins spoke of phasing out cryoprecipitate over three years.

34. On 9 November 1976, Mr John G. Watt (SNBTS) contacted Dr Biggs and referred to the above estimates as a '*series of guesses*'. Mr Watt stated that he was disappointed that the members of the meeting '*failed to underwrite the statement that adequate treatment for a haemophiliac was that which would support a normal sedentary lifestyle*'. He asserted that the failure to underwrite this qualification, or an alternative definition for adequate treatment, was '*the main problem in the supply of Factor VIII concentrate*'.<sup>59</sup> It is apparent that this lack of agreed definition on what constituted 'adequate treatment' was a variable that resulted in a wide range of estimated requirements throughout this period.

35. Mr Watt confirmed that his preference was for the SNBTS to pursue a target of 55m iu of AHG per annum for the UK as it would likely result in the production levels required to satisfy demand.<sup>60</sup> As will be explored in more detail in the presentations for Scotland and Northern Ireland, key individuals in Scotland prepared a number of national estimates and these were often higher than estimates made in England. In 1976, Professor Cash and Mary Spencely (Lecturer, UDCM Edinburgh) published a study<sup>61</sup> and estimated that

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<sup>59</sup> Letter from John G. Watt to Dr Rosemary Biggs, re: Comments on October 1976 Meeting and estimates of UK demand for Factor VIII, 9 November 1976, **OXUH0003612\_001**.

<sup>60</sup> Letter from John G. Watt to Dr Rosemary Biggs, re: Comments on October 1976 Meeting and estimates of UK demand for Factor VIII, 9 November 1976, **OXUH0003612\_001**.

<sup>61</sup> Paper by John Cash and Mary Spencely 'Haemophilia A and the Blood Transfusion Service: A Scottish Study', 18 September 1976, **PRSE0003425**.

in the region of **50m iu** of Factor VIII would be required in the UK to meet growing demand. This was significantly higher than the lower estimate of Dr Biggs of **32m iu** and Dr Bidwell's estimate of **36m iu** to **45m iu**.<sup>62</sup>

36. On 15 November 1976, Dr Biggs wrote to Professor Blackburn that she considered that a target of 40m iu of Factor VIII would be sufficient to meet demand but was *'not publicising this thought'*. This was based on the fact that the 40m iu figure had assumed that each patient would be treated every year, but this was not in fact the case with some mildly affected patients not requiring treatment annually.<sup>63</sup> Dr Biggs communicated the 40m iu estimate in response to Dr Watt's letter (referred to above) and noted that *'there must be a limit to the use of Factor VIII and that this limit envisages 'a reasonable sedentary life'. I believe that the estimate of 40,000,000 units would provide this level of treatment'*. Furthermore, Dr Biggs stated *'It might certainly be safe to aim for 55,000,000 but I am not sure that this level is essential'* and that the total Factor VIII used at that time may be *'much more than necessary'* due to the unlimited supply of commercial material.<sup>64</sup>

37. In a similar vein, further evidence from Dr Biggs illustrates a view that Factor VIII supply should not be unlimited: *'Our estimates have been bare minimum amounts of Factor VIII 'needed' to prevent crippling and to cover surgical operations. If Physicians experience a number of years with an apparently unlimited supply there is no telling how much Factor VIII will be used'*.<sup>65</sup> This view was also agreed by members of the Central Committee for the NBTS in November 1976: *'members generally considered it essential to encourage the economical use of blood and blood components, since it seems clear that the NBTS would be unable to meet an unrestricted demand by clinicians for these*

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<sup>62</sup> Paper by Dr Bidwell, 'Production of Factor VIII Concentrate', 27 January 1976, **CBLA0000336**.

<sup>63</sup> Letter from Dr Rosemary Biggs to Professor E.K.Blackburn, re: Demand estimates and sufficiency of 40m iu target, 15 November 1976, **OXUH0000684**.

<sup>64</sup> Letter from Dr Rosemary Biggs to Dr John G. Watt, **OXUH0003612\_002**.

<sup>65</sup> Letter from Rosemary Biggs to Prof. Eddie K. Blackburn, re: UK estimates of demand between 1973 and 1976 and Dr Maycock's surprise at escalation in estimates, 28 October 1976, **OXUH0003759\_004**, pg.2.

*items in the foreseeable future... In practice, it seemed necessary to make users aware of the supply limitations and to foster demand levels which took account of them.*<sup>66</sup>

38. As is set out in the main presentation and Appendix 2, by mid-1977 plasma supply had increased to the targets envisaged in the programme that accompanied the announcement of the £500,000 special financing. However, according to a letter sent to Dr Owen by the then Secretary of State, John Moore in January 1988:

'the £500,000 helped the output increase from 3.2 million units to 12.8 million units between 1975 to 1977. However the total demand for Factor VIII increased from 8.2 to 27.4 million units in the same period so that the proportion of commercial product needed remained roughly the same'.<sup>67</sup>

39. The figure of 8.2m iu was in fact an error and related to consumption of Factor VIII in the UK in 1970. Demand for all concentrates in 1974 was in the region of 20.5m iu.<sup>68</sup> In either event, the increased production of Factor VIII as a result of DHSS investment was insufficient to keep up with demand, equating to less than half of total requirements.

40. **To conclude this period (1973 to 1977)**, the programme to promote self-sufficiency in NHS Factor VIII concentrates by 1977 was informed by the lower estimate of demand prepared by Dr Biggs in 1973 of 400,000 blood donations (equating to 32m iu) and excluded prophylaxis.<sup>69</sup> Despite Blood Transfusion and Haemophilia Centre Director endorsement of higher estimates of demand prepared by the MRC in 1974<sup>70</sup>, the DHSS pressed ahead with its programme with an initial target of production based on 275,000 donations. By 1976, the Expert Group on the Treatment of

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<sup>66</sup> Minutes of the Central Committee for the NBTS Meeting, 2 November 1976, **DHSC0002181\_054**.

<sup>67</sup> Letter from John Moore to David Owen, 21 January 1988, **LDOW0000052**.

<sup>68</sup> Letter from G. L. Ross to David Owen MP, 11 April 1988, **LDOW0000057**.

<sup>69</sup> Minutes of 147th Regional Transfusion Directors Meeting, 13 June 1973, **DHSC0105498\_005**, pg.9.

<sup>70</sup> Report of 'Factor VIII concentrates Made in the UK and the Treatment of Haemophilia Based on Studies made during 1969 to 1972, by Dr Rosemary Biggs et al, undated, **PRSE0002350**.

Haemophilia concluded that advances in home therapy had rendered the DHSS targets '*out of date*'.<sup>71</sup> Varied estimates of demand were subsequently put forward in late 1976 in the region of 40m iu to 50m iu.<sup>72</sup> A view was also expressed from both Dr Biggs and the Central Committee for the NBTS that Factor VIII supply should not be unlimited. Dr Biggs noted that her estimates provided for only the '*bare minimum*' to '*prevent crippling and to cover surgical operations*'.<sup>73</sup> The NBTS stated '*In practice, it seemed necessary to make users aware of the supply limitations and to foster demand levels which took account of them*'.<sup>74</sup> From late 1976 to mid-1977, demand estimates were in the region of 50m iu, considerably above production output of **12.35m iu** of NHS Factor VIII concentrates provided for by Dr Owen's programme.<sup>75</sup> However, neither the Expert Group nor the DHSS had fixed a new target, preferring to wait until the outcomes from the £500,000 investment were achieved.<sup>76</sup>

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<sup>71</sup> Minutes of the Expert Group on the Treatment of Haemophilia and Allied Conditions meeting, 4 May 1976, **CBLA0007964**, pg.3.

<sup>72</sup> Exploratory meeting of Blood Transfusion Directors and Haemophilia Reference Centre Directors, 22 October 1976, **CBLA0000473**.

<sup>73</sup> Letter from Rosemary Biggs to Prof. Eddie K. Blackburn, re: UK estimates of demand between 1973 and 1976 and Dr Maycock's surprise at escalation in estimates, 28 October 1976, **OXUH0003759\_004**, pg.2.

<sup>74</sup> Minutes of the Central Committee for the NBTS Meeting, 2 November 1976, **DHSC0002181\_054**.

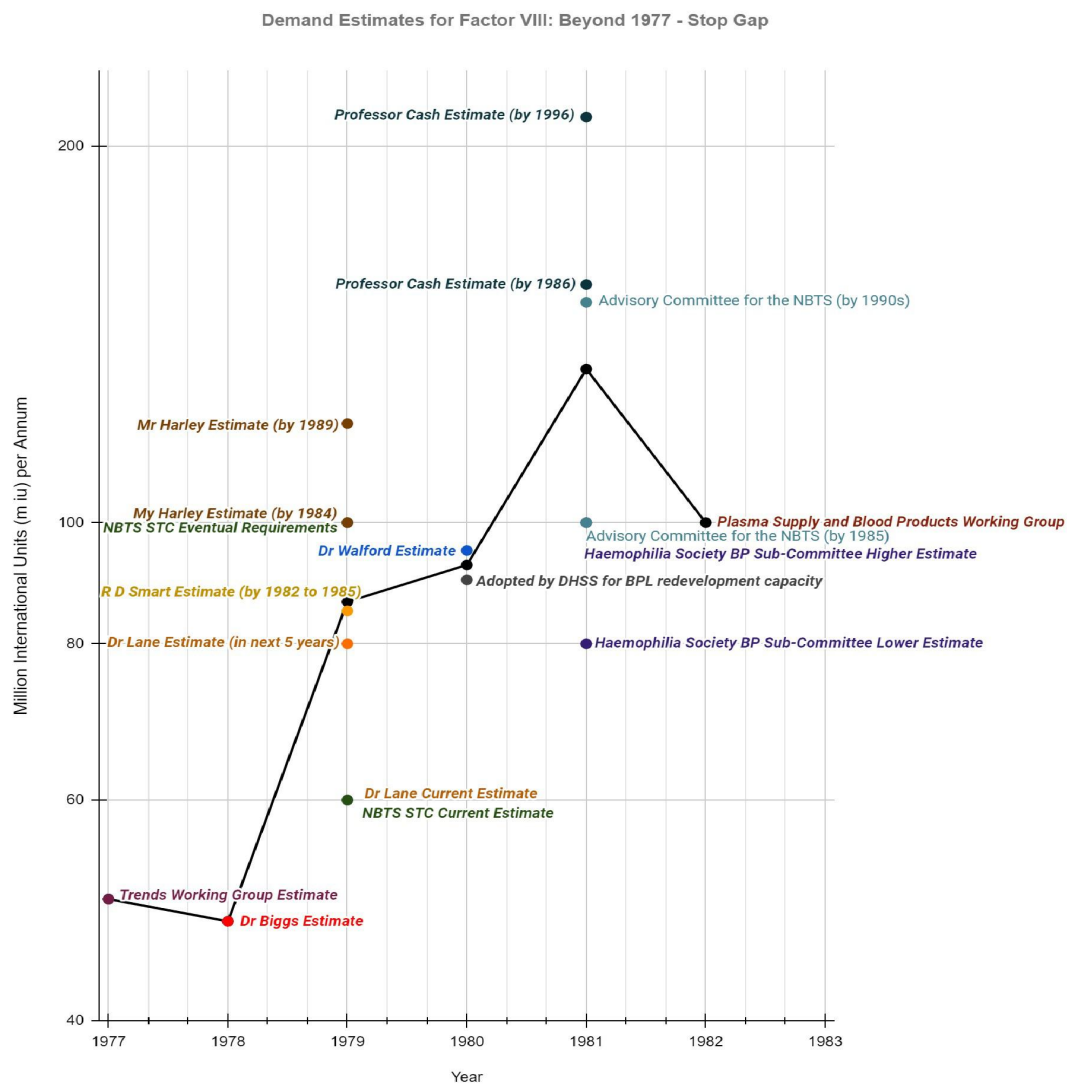
<sup>75</sup> Paper by Dr Bidwell, 'Production of Factor VIII Concentrate', 27 January 1976, **CBLA0000336**.

<sup>76</sup> Note regarding AHG production, undated - likely 1976, **DHSC0100006\_144**.

## Beyond 1977 - Stop Gap

### Overview of the Demand Estimates for Factor VIII (mid 1977 to 1983)

41. The graph below outlines estimates made between 1977 and 1983 in terms of the total international units of Factor VIII required per annum to achieve self-sufficiency. As per section I, the graph shows an average estimate of demand across the period represented by the black data line. Each individual estimate, represented by a data point, has been titled for ease of reference.



## An analysis of estimates of demand beyond 1977: Stop Gap (mid 1977 - 1983)

42. In January 1977, the DHSS (in consultation with SHHD and Welsh Office) appointed the Working Group on Trends in the Demand for Blood Products 'to consider the likely trends in the demand for blood products over the next 5 to 10 years, taking into account the practicalities of supply'.<sup>77</sup> Following an initial discussion on 3 February 1977<sup>78</sup>, the Trends Working Group met on a second occasion on 13 July 1977<sup>79</sup> and concluded:

- Based on the Council of Europe working papers, It was considered that a production target of 200gm/1000 population annually for albumin provided a reasonable margin for unforeseen circumstances;
- A commonly accepted figure for Factor VIII of **1000 iu per annum per 1000** population was likely a minimum requirement and would need to be **increased by 25%** (a level which would be satisfied by the albumin programme noted in bullet point one); and
- '*For the longer term prospect... there existed predictions that the haemophilic population could increase significantly since effective treatment had become available. It was agreed that this was a factor to be watched but not one which suggested that blood products production should be based on the demand for Factor VIII rather than on that for albumin*'.

43. In October 1977, the DHSS and Welsh Office convened to discuss the organisational changes that might be required to meet the level of demand advocated for by the Trends Working Group. It was noted that the likely recommendations would include the need to increase blood collected from 35 donations to 50 donations per 1000 population, in order to increase

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<sup>77</sup> Report of the Working Group on Trends in the Demand for Blood Products, December 1977, **DHSC0001318**.

<sup>78</sup> Minutes of the 1st Working Group on Trends in the Demand for Blood Products Meeting, 3 February 1977, **DHSC0003616\_109**.

<sup>79</sup> Minutes of the 2nd Working Group on Trends in the Demand for Blood Products Meeting, 13 July 1977, **DHSC0003616\_124**.

production of albumin from 50gm to 200gm per 1000 population. Members of the meeting agreed that Regions should be encouraged to consider the implications of the recommendations within the existing framework.<sup>80</sup> Wider considerations were also taken in respect of utilising capacity at PFC, an issue which is explored in more detail in the presentations on Scotland and Northern Ireland.

44. In December 1977, the Trends Working Group reported on its recommendations in accordance with the broad aim of the DHSS to conform to WHO resolutions and achieve NHS self-sufficiency in therapeutic blood products. A statement on page two of the report noted that the DHSS policy considered that '*demand for blood products does not necessarily reflect the need for them*'. Dr Lane later reflected on this statement and stated that the estimates that followed for self-sufficiency were targeted '*at need rather than demand*', with an assumption that current demand was equivalent to need plus wastage.<sup>81</sup> This approach is similar to the position expressed by Dr Biggs that Factor VIII supply should not be unlimited.

45. The Trends Working Group assumed that '*a blood transfusion service which collected enough blood to provide for its needs of albumin and Factor VIII could also produce enough of the other major components to meet future needs*'. Consistent with the position outlined in the second meeting, but provided in more detail, the Trends Working Group accepted the broad conclusions of the Council of Europe Study Group and estimated that 200gm per 1000 population would be required for albumin in the next 5 to 10 years. To achieve this target, it was suggested that blood collection should increase to 50 donations per 1000 population, rising to 60 donations per 1000 population in the next 10 years. In addition, a substantial increase in the clinical use of red cell concentrates was required. With regard to Factor VIII, it

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<sup>80</sup> Minutes of the organisation of the National Blood Transfusion Service Meeting, 13 October 1977, **CBLA0000043\_013**.

<sup>81</sup> Draft Proof of Evidence of Richard Spencer Lane for HIV Haemophilia Litigation, 10 December 1990, **CBLA0000005\_002**, pg.63.

was accepted that **1000 iu per annum per 1000 population** was required. The albumin programme is relevant as it was deemed sufficient to also satisfy requirements for Factor VIII in the next five to 10 years, providing 1300 iu of Factor VIII per 1000 population (based on an annual plasma yield of 8 litres per 1000 population with 4 litres per 1000 population of plasma processed for Factor VIII).<sup>82</sup> This equated to an estimated level of need of approximately **50m iu** for Factor VIII<sup>83</sup>, with approximately 74m iu provided for by the albumin programme.<sup>84</sup>

46. The Trends Working Group also noted a number of practicalities in achieving the increased requirements:

- With adequate publicity, it was not expected that any difficulty would be encountered in recruiting additional donors;
- RTCs would require '*considerable investment*' to achieve targets, including in blood-collecting resources, accommodation and equipment;
- Additional fractionation capacity was required, with the present UK capacity deemed '*less than half that we regard as essential*'; and
- Close attention was required to the future organisation of the Transfusion Services in relation to national coordination, forecasting and planning.<sup>85</sup>

47. The report was reviewed by the Standing Medical Advisory Committee who broadly endorsed the Trends Working Group recommendations but noted that '*the estimated requirements of Factor VIII might prove to be on the low side*'.<sup>86</sup> In April 1978, the Standing Medical Advisory Committee confirmed that the

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<sup>82</sup> Report of the Working Group on Trends in the Demand for Blood Products, December 1977, **DHSC0001318**.

<sup>83</sup> Note on demand and supply of Albumin & Factor VIII, August 1977, **DHSC0103249\_096**.

<sup>84</sup> Written statement of Dr Diana Walford, 5 July 2021, **WITN4461001**, pg.41.

<sup>85</sup> Report of the Working Group on Trends in the Demand for Blood Products, December 1977, **DHSC0001318**.

<sup>86</sup> Letter from A.L. Parrot to All Regional Administrators, 17 August 1978, **DHSC0002189\_013**.



estimates prepared by the Trends Working Group were likely '*reliable estimates of future need*' and supported planning for a programme to increase plasma supply accordingly.<sup>87</sup>

48. In response to the recommendations, Mr Dutton noted '*the question of the acceptance or otherwise of the Report hardly arises since essentially it says no more about Factor VIII requirements than some experts have been saying for years and which has now come to be generally accepted*'.<sup>88</sup> Mr Dutton also called for the establishment of a strong executive Committee to set out and achieve fulfilment of a 10 year Blood Components Production Programme.<sup>89</sup>

49. A period of review subsequently ensued, with the DHSS and others attempting to consider how blood product production could be scaled up to the rate deemed necessary by the Trends Working Party. The Secretary of State for Social Services, Mr Roland Moyle, told Parliament that '*the extension of clinical requirements... means that self-sufficiency has not yet been achieved, and my Department is therefore reviewing production in relation to present demands and resources*'.<sup>90</sup> The review included an assessment of different options such as handing the whole fractionation process to the commercial industry or increasing the capacity at UK laboratories. The latter was deemed more viable.<sup>91</sup>

50. On 15 December 1978, Dr Waiter expressed concern regarding the ongoing ambiguity as to what figures should be adopted: '*one real problem is to know*

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<sup>87</sup> Minutes of the Standing Medical Advisory Committee Meeting, 11 April 1978, **DHSC0103130**, pg. 4.

<sup>88</sup> Draft report from T. E. Dutton, to Parrott et al. re The development of the NBTS and the Trends report, 3 February 1978, **DHSC0002183\_009**. The document is dated as 3 February 1977 but as the Trends Working Group report was not officially published until December 1977, this appears to be a typo.

<sup>89</sup> Draft report from T. E. Dutton, to Parrott et al. re The development of the NBTS and the Trends report, 3 February 1978, **DHSC0002183\_009**. The document is dated as 3 February 1977 but as the Trends Working Group report was not officially published until December 1977, this appears to be a typo.

<sup>90</sup> Parliamentary Answer by Mr Roland Moyle to Mr Lewis Carter-Jones, 15 December 1978, **DHSC0002191\_017**.

<sup>91</sup> Memorandum from Mr Dutton to Mr D R Harris et al., 26 April 1978, **DHSC0002325\_013**.

*the real target for the self-sufficiency the NHS is striving for. Our 'working target' is 50 million iu of Factor VIII per annum for England and Wales but for example Dr Lane, director of BPL, Elstree claims this will be much higher within a few years'.<sup>92</sup> In 1978, Dr Biggs had considered approximately 48m iu was required for Haemophilia patients in the UK based on consumption figures from 1975.<sup>93</sup> Dr Lane however had stated that Factor VIII demand in 1979 was 60m iu and would likely increase to 80m iu within the next five years.<sup>94</sup> It appears that the figure of 60m iu was initially referred to as early as March 1977.<sup>95</sup>*

51. On 26 March 1979, a discussion on future demand took place at the Scientific and Technical Committee for the Central Laboratories. The Committee agreed that current demand for Factor VIII was likely in the region of 60m iu but that *'if clinicians were to retain freedom to treat their patients in the way that was considered most suitable, it was possible that the eventual requirements might well approach the 100 million iu per annum mark'.<sup>96</sup> Subsequent to the meeting, R. D. Smart prepared a paper in May 1979 in which he estimated that Factor VIII demand would likely increase to 85m iu by 1982 and remain steady at this figure until at least 1985.<sup>97</sup>*

52. In July 1979, Dr Lane produced a discussion paper for an ad hoc group of Regional Transfusion Directors that met on 25 July<sup>98</sup>. Dr Lane, Dr Waiter and Mr Dutton also attended<sup>99</sup>. Dr Tovey was in the chair, and it appears that he

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<sup>92</sup> Letter from Dr Sheila L. Waiter to Professor Ingram, 15 December 1978, **DHSC0002191\_016**.

<sup>93</sup> Chapter 4 'The Amount of Blood Required Annually to Make Concentrates to Treat Patients with Haemophilia A and B', by Dr Rosemary Biggs, 1978, **BPLL0002571\_015**, pg.9.

<sup>94</sup> Letter Dr Lane to Mr Bayliss, 9 March 1979, **CBLA0000923**.

<sup>95</sup> Minutes of a joint DHSS/SHHD Mutual problems relating to blood products Meeting, 11 March 1977, **SCGV0000001\_172**.

<sup>96</sup> Minutes of the NBTS Scientific and Technical Committee for the Central Laboratories Meeting, 26 March 1979, **BPLL0008430\_001**.

<sup>97</sup> Paper on 'Blood Products Laboratory: Redevelopment' by R.D Smart, May 1979, **CBLA0001004\_004**, pg. 2.

<sup>98</sup> Dr Lanes' discussion paper, 'Implementation of the Working Party Report on Trends in the Demand for Blood Products', 17 July 1979, **CBLA0000957**.

<sup>99</sup> Discussion paper from the Select Committee on Blood Transfusions, 'Implementation of the Working Party Report on Trends in the Demand for Blood Products', 17 July 1979, **CBLA0000957**.

had requested that Dr Lane produce the paper<sup>100</sup>. It is not clear to the Inquiry's legal team what, if any, wider disclosure the paper received.

53. Dr Lane wrote that the Trends document was valuable in assessing the needs of the NBTS in order to achieve self-sufficiency, but provided a critique of certain aspects of the document. Among the shortcomings he identified was the use of the Council of Europe document to establish albumin demand *'where parallels in Europe and UK may not exist'*. He also criticised assumptions on the percentage of whole blood collections that would be provided for fractionation, the absence of provision for ongoing cryoprecipitate production, and the estimates of plasma volume per donation. Dr Lane argued that any programme to increase NHS production of Factor VIII should instead take into account NBTS practice and facilities, and include the implementation of *'feasible modifications to NBTS practice which should enable plasma collection to be simplified'*. He also emphasised the importance of integrating the role of regional services and the central fractionation laboratories in a *"scheduled combined programme with agreed targets and dates, established financial policy and support, accountability and executive management."*<sup>101</sup>

54. Dr Lane went on to discuss BPL's Stop-Gap programme, which would increase plasma supply for Factor VIII from 62,500 to 124,800 litres per annum by 1981 and increase capacity at BPL and PFL to **30m iu per annum**<sup>102</sup> **(28.75m i.u. for BPL)**.<sup>103</sup> The capacity provided by the Stop-Gap interim programme was considerably below estimates of demand prepared since 1977 including the Trends Working Group (50m iu), Dr Lane himself (60m iu to 80m iu) and the NBTS Scientific and Technical Committee for the Central Laboratories (60m iu to 100m iu). This capacity was also below all demand

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<sup>100</sup> Compliments slip from Dr Lane, 19 July 1979, **DHSC0002490\_038**

<sup>101</sup> Dr Lanes' discussion paper, 'Implementation of the Working Party Report on Trends in the Demand for Blood Products', 17 July 1979, **CBLA0000957**.

<sup>102</sup> Dr Tovey, Paper AC(80)3 'Supply of Plasma to the BPL', November 1980, **CBLA0001209**.

<sup>103</sup> Letter from Dr Maycock to Mr Parrott, DHSS, with his Paper 'Stop Gap requirements for Factor VIII Production 1978 to 1982', 20 December 1977, **CBLA0000701**.

estimates prepared since 1973, with the exception of Dr Biggs' initial lower estimate of 30m iu in 1973.<sup>104</sup>

55. Dr Lane acknowledged that the Stop-Gap interim programme would be insufficient to achieve self-sufficiency and this would only be achieved following the completion of a redeveloped BPL. He considered that a redeveloped BPL could be commissioned at the completion of the 'Stop-Gap' programme, increasing production capacity to **90m iu** as an intermediate target for 1985-1990, and then to **120m iu**.<sup>105</sup> It is noteworthy that at this time, Mr Dutton commented in an internal DHSS document that even at that capacity BPL would be unlikely to retain any idle capacity as, once the redeveloped BPL was operational, "*demand would, on current trends, have reached that figure*".<sup>106</sup> The postulated final level of demand (120m iu) correlated with estimates prepared by Mr Harley (DHSS) who calculated 'shaky' and 'guesswork' projections of **100m iu** of Factor VIII required by 1984 and **120m iu** by 1989.<sup>107</sup>

56. In December 1979, A. E. Bell (SHHD) wrote to Dr Diana Walford (DHSS) and stated that '*we have heard informally that the Scientific Advisory Committee for the NBTS laboratories has proposed a figure of **1.8 x 10<sup>6</sup> units by 10<sup>6</sup> population per annum**, which is of course a substantial increase on the recommendation in the Trends Report*'.<sup>108</sup> The Inquiry team calculate this to be an estimate in the region of **100m iu**.<sup>109</sup> It is believed this figure relates to

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<sup>104</sup> Letter from Rosemary Biggs (Oxford Haemophilia Centre) to Dr W d'A Maycock, 5 June 1973, **DHSC0100005\_037**.

<sup>105</sup> Dr Lanes' discussion paper, 'Implementation of the Working Party Report on Trends in the Demand for Blood Products', 17 July 1979, **CBLA0000957**, pg.6.

<sup>106</sup> Memorandum from Mr Dutton to Dr Bayliss, re: The supply of blood products for the NHS and the production levels relating to Factor VIII and PPF, 11 October 1979, **DHSC0002195\_054**.

<sup>107</sup> See Appendix B of the Paper on 'The Manufacture of Blood Products for the NHS' by Mr Harley, 1979, **DHSC0103249\_033**. Tabled in a Scientific and Technical Committee for the Central Blood Laboratories, 26 September 1979, **CBLA0001005**, pg.3.

<sup>108</sup> Letter from A. E. Bell to Diana Walford, re: Future Factor VIII Concentrate Requirements and a proposal by the Scientific Advisory Committee for the NBTS, 12 December 1979, **DHSC0002195\_068**.

<sup>109</sup> Based on  $1.8 \times 100,000$  (10 to the power of 6) = 1.8m iu, multiplied by 56 (10 to the power of 6 of an approximate UK population of 56m as of 1979) = 100.8m iu.

the 'eventual requirements' of 100m iu estimated by the NBTS Scientific and Technical Committee for the Central Laboratories discussed above and would be a doubling in requirements when compared to the 50m iu forecasted by the Trends Working Group.

57. In February 1980, Mr Dutton wrote a memorandum to R. H. Evans (S. W. Thames RHA) confirming that the future requirements for Factor VIII was '*constantly being revised as new factors become apparent*' but that demand as of 1980 was likely in the region of **60m iu**, increasing to **90m iu** by the mid-1980s.<sup>110</sup> The latter figure was cited in a subsequent meeting of the Advisory Committee of the NBTS on 3 March 1980 and would inform the capacity of the redeveloped laboratory - in the region of 400 tonnes<sup>111</sup> to 410 tonnes<sup>112</sup> of plasma to meet these requirements.

58. On 18 April 1980, Dr Aronstam (Consultant Haematologist, Hampshire RHA) wrote to the British Medical Journal (BMJ) and stated that the estimate from Professor Cash and Mary Spencely of 50m iu in 1976 and Dr Biggs' estimate of 48m iu in 1978 were '*now a very serious underestimate of future requirements*'. In his opinion, this was due to:

- An '*explosive growth*' in prophylactic treatment since 1976;
- Home therapy increasing by one third in 1976;
- The '*lengthening haemophiliac life-span*' which would likely result in a doubling of the haemophilia population;
- Patients with inhibitors being treated with high doses of Factor VIII for almost all bleeds.

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<sup>110</sup> Letter from T E Dutton to R H Evans, re: Future requirements of NHS Factor VIII, February 1980, **DHSC0002331\_050**.

<sup>111</sup> Minutes of DHSS Meeting, 3 March 1980, **DHSC0002313\_030**, pg.1. See papers circulated to meeting members: Memorandum from Diana Walford to Mr Harley et al. re Blood Products Manufacture Participation by Industry Technical and Policy Brief for Supply Division, February 1980, **CBLA0001074**, in particular pg. 17.

<sup>112</sup> Chairman's Briefing Note for the meeting of the Advisory Committee on the NBTS Meeting, 1 December 1980, **DHSC0002201\_056**, pg.2.

59. With demand increasing, Dr Aronstam advocated that *'it is essential that we recognise and attempt to avert this approaching crisis'*.<sup>113</sup>

60. On 15 May 1980, Dr Diana Walford asserted that the DHSS had adopted an estimated figure of 1,700 iu per 100 population as a rough guide of projected usage of Factor VIII over the next 10 years (by 1990).<sup>114</sup> The Inquiry's legal team calculate this to equate to approximately **95m iu**.<sup>115</sup> This was considerably higher than the 50m iu recommended by the Trends Working Group and was likely informed by growing estimates prepared by NBTS Scientific and Technical Committee for the Central Laboratories and Mr Harley. As outlined by Dr Aronstam, factors such as the growth in prophylactic treatment had resulted in a surge in demand rendering many of the early 1970 estimates as insufficient for long term requirements for Factor VIII.

61. Later, in December 1980, the Parliamentary Under-Secretary of State for Health, Sir George Young, told Parliament during an Adjournment Debate that *'the demand for blood products has increased beyond what could reasonably have been predicted'*.<sup>116</sup>

62. In January 1981, Professor Cash published a paper which informed Scottish future planning. Professor Cash estimated that Factor VIII requirements would amount to 2.75 iu per million of population by 1986, increasing to 3.75 iu per million of population by 1996.<sup>117</sup> The Inquiry's legal team estimate that this

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<sup>113</sup> Letter from A. Aronstam to the British Medical Journal, re: the figures of Factor VIII supply and demand in the UK, 18 April 1980, **DHSC0002197\_084**.

<sup>114</sup> Letter from Diana Walford to Dr C. C. Connolly (SE Thames RHA), re: The Department's aim towards self-sufficiency in blood products, 15 May 1980, **DHSC0003722\_066**.

<sup>115</sup> Based on 1700 iu multiplied by 56,310 (UK population in 1980 of 56,310,000 divided by 1000 = 56,310) = 95,727,000 iu.

<sup>116</sup> Parliamentary material, re: Adjournment of debate on the Blood Transfusion Service, 15 December 1980, **NHBT0006435\_007**, pg.3.

<sup>117</sup> Paper titled 'Notes for Scottish Health Service Haemophilia Centre/Transfusion Service Directors' Meeting', January 1981, **CBLA0001252**, pg. 6; 9.

equates to approximately **155m iu**<sup>118</sup> and **211m iu**<sup>119</sup> respectively when assessed at a UK level (acknowledging that Professor Cash's primary concern was for Scotland). It is evident that both estimates were based on data from Newcastle RTC, a region with increased home treatment. Professor Cash, like Professor Aronstam, noted that factors such as rising home treatment, prophylactic therapy and improved life expectancy resulted in the '*dramatic increase*' in estimates of demand.<sup>120</sup> Again, it is notable that the estimates made in Scotland were significantly higher than figures calculated in England, an issue explored in more detail in the presentations on Scotland and Northern Ireland. Stan Godfrey of the DHSS commented on this marked increase in estimates by Professor Cash, stating that this was '*hard to square against a current use figure of 55 million international units when, as far as I am aware, there have been no cases of restrictions being placed on commercial purchases by Haemophilia Centres*'.<sup>121</sup> There was, it appears, a marked distinction in the amount of Factor VIII deemed necessary to satisfy demand between Scotland and England.

63. In 1981, the Haemophilia Society Blood Products Sub-Committee noted that the accepted estimate of demand for Factor VIII of 50m iu was '*outdated*' and that demand was expected to rise between **80m iu** to **100m iu**. Again, this increase in demand was attributed to the growth in prophylactic treatment, home therapy and increased life-span of the population of those with haemophilia.<sup>122</sup>

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<sup>118</sup> Based on 2.75 multiplied by 1,000,000 (10 to the power of 6) = 2,750,000 iu. 2,750,000 multiplied by 56.33 (UK estimated population of 56.33m divided by 10 to the power of 6) = 154,907,500 iu.

<sup>119</sup> Based on 3.75 multiplied by 1,000,000 (10 to the power of 6) = 3,750,000 iu. 3,750,000 multiplied by 56.33 (UK estimated population of 56.33m divided by 10 to the power of 6) = 211,237,500 iu.

<sup>120</sup> Report of 'A Proposal to Increase the Production of Factor VIII Concentrate in Order to Achieve Self-Sufficiency in Scotland for the Next Decade' by John D Cash, 1 February 1982, **SBTS0000613\_003**, pg.3-4.

<sup>121</sup> Letter from S. Godfrey to Dr H. H. Gunson re: Demand for Factor VIII, 10 September 1982, **DHSC0002219\_035**. Dr Godfrey appears to have calculated a figure of 132.5m iu for the UK by using a population figure of 50 million in 1982, which results in a slight underestimate.

<sup>122</sup> Report of 'The Haemophilia Society Blood Products Sub-committee', 1981, **DHSC0002213\_009**, pg.5.

64. Also in 1981, a Working Party on Plasma Supplies for the Advisory Committee of the NBTS reported that Haemophilia Centre Directors estimated that the annual requirement for Factor VIII would be **100m iu** for the UK by the mid-1980s (95m iu in concentrate, 5m iu in cryoprecipitate), and could reach **150m iu** by the 1990s.<sup>123</sup> It was noted at a meeting of the full Advisory Committee on 22 June 1981 that '*estimates more than five years ahead were highly speculative*'.<sup>124</sup>

65. During 1981 and 1982, planning commenced on the scale and needs of the redeveloped BPL (see main presentation). As is discussed above, Dr Lane had in 1979 envisaged an intermediate target for Factor VIII fractionation of **90m iu** for 1985-1990, with an ultimate target of **120m iu**. He calculated that 375,000 litres of fresh frozen plasma per annum would be required to meet the intermediate target at current yields.<sup>125</sup> In general, later documents give the proposed capacity of the plant by reference to the annual amounts of plasma to be fractionated, expressed by weight (not volume). The approval given by the Treasury in November 1982 was for a plant capable of fractionating **400,000kg** per annum, the figure that had been proposed to them by the CBLA.<sup>126</sup>

66. During this period, various other figures were suggested for the amount of plasma required to achieve self-sufficiency. In June 1981, the Preliminary Report of the Working Party on Plasma Supply had estimated that **500,000kg** would be required, based on a requirement for **100m iu** per year.<sup>127</sup> Mr Pettet of BPL identified a number of what he saw as errors in the survey that had seemingly informed the report (including confusion over measures in litres

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<sup>123</sup> Report of the 'Advisory Committee on the NBTS Working Party on Plasma Supplies' by H H Gunson, 1981. **DHSC0001132**, pg.2.

<sup>124</sup> Minutes of the 3rd Advisory Committee on the NBTS Meeting, 22 June 1981, **CBLA0001388**.

<sup>125</sup> Dr Lanes' discussion paper, 'Implementation of the Working Party Report on Trends in the Demand for Blood Products', 17 July 1979, **CBLA0000957**, pg.6.

<sup>126</sup> Letter, J.G. Colman to Mr D. Harris, 11 November 1982, **DHSC0002319\_013**. See also the main presentation.

<sup>127</sup> Preliminary Report of the Working Party to Advise on Plasma Supplies for Self-Sufficiency in Blood Products, **CBLA0001377**, pg.1. The report was presented to the Advisory Committee of the National Blood Transfusion Service at its meeting on 22 June 1982, **CBLA0001388**, §7.



and kilogrammes, and net and gross yields).<sup>128</sup> By the time of the Working Party's final report, the figure had been revised down to **435,000kg**.<sup>129</sup> In September 1981, that target was confirmed following further discussions with directors of haemophilia centres about their future needs.<sup>130</sup> On 18 December the Working Party on Plasma Supplies agreed that there was no reason to alter the estimate of 435,000 kg. It noted that demand for Factor VIII was assessed as 100m iu but that this was "*uncertain and other views contending [for] more than this have been made.*"<sup>131</sup> Notwithstanding this caveat, the 435,000kg was adopted in a letter sent to Regional Administrators the same day setting out regional plasma supply targets (intended to be achieved by 1984/1985).<sup>132</sup>

67. The Inquiry's legal team has not found any evidence that those target figures were subsequently revised, and later correspondence seems to suggest that they were not.<sup>133</sup>

68. Although the plasma supply target (435,000kg) was higher than the proposed capacity for redeveloped BPL (400,000kg), it should not be assumed that there would be an inevitable shortfall in fractionation. The plasma supply figure included an element to be used for cryoprecipitate production. As has been seen, there were also differences in the estimates made by different bodies. Further, BPL was fast-tracked as a design and build scheme and underwent redesigns over time. It is not clear how rigid the 400,000kg capacity was intended to be and by 1983 Dr Lane was referring in an internal

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<sup>128</sup> Memorandum from Mr Pettet to Dr Lane, 9 January 1981, **BPLL0008345\_001**.

<sup>129</sup> Report of the 'Advisory Committee on the NBTS Working Party on Plasma Supplies' by H H Gunson, 1981. **DHSC0001132**, pg.2.

<sup>130</sup> Minutes of the Advisory Committee of the National Blood Transfusion Service, 28 September 1981, **CBLA0001457**, §4.

<sup>131</sup> Minutes of the Working Party to Advise on Plasma Supplies for Self-sufficiency in Blood Products Meeting, 18 December 1981, **CBLA0001565x**, pg.1. Present at the meeting were Dr Gunson, Dr Robinson, Dr Walford, Dr Jim Smith (BPL) and Mr Godfrey (DHSS).

<sup>132</sup> Letter, J.F. Shaw to P. Cooke, 18 December 1981, **DHSC0001507**.

<sup>133</sup> See Mr Parker's letter to Regional Administrators date 10 August 1984 concerning plasma supply to BPL, **CBLA0001870**. This referred back to Mr Shaw's letter of 18 December 1981 as seemingly the last source of targets for plasma supply. Mr Parker's letter did not set specific figures, but instead urged RHAs to take steps to increase supply.

report to a fractionation capacity of 450,000kg per annum, something that was subsequently achieved.<sup>134</sup> It was also anticipated at this time that there may be some increases in yield in the new plant, allowing for more efficient use of plasma (although caution was expressed about how significant these would be).<sup>135</sup> In the event, the advent of heat treatment reduced yield, a matter that was not foreseen in 1981 and 1982, and which is discussed further in **Appendix 2**.

**69. To conclude this period (1977 to 1983) and the period relevant to Stop-Gap**, in 1977, the Trends Working Group agreed that **50m iu** would be required to meet future needs for Factor VIII in the UK.<sup>136</sup> This estimate was targeted at forecasting 'need', with DHSS policy considering that 'demand' did not truly reflect requirements.<sup>137</sup> The Standing Medical Advisory Committee endorsed the Trends recommendations on the caveat that 50m iu might prove an underestimate.<sup>138</sup> By 1979, a number of higher estimates exceeding that presented by the Trends Working Group had emerged, including by the NBTS Scientific and Technical Committee who estimated as much as **100m iu** would be required to satisfy eventual requirements.<sup>139</sup>

**70.** Dr Lane noted shortcomings in the Trends Working Group Report and advocated for '*feasible modifications*' that took into account NBTS practice and facilities.<sup>140</sup> It appears that the Trends recommendations were broadly adopted by the DHSS but implemented through the lens of what was 'feasible'. Such modifications were realised by the 'Stop-Gap' interim works

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<sup>134</sup> Paper by Dr Lane 'PSEC Estimates Related to BPL Manufacturing Requirements', 25 May 1983, **CBLA0001708**, pg.1

<sup>135</sup> Report of the 'Advisory Committee on the NBTS Working Party on Plasma Supplies' by H H Gunson, 1981. **DHSC0001132**, pg.22.

<sup>136</sup> Note on demand and supply of Albumin & Factor VIII, August 1977, **DHSC0103249\_096**.

<sup>137</sup> Draft Proof of Evidence of Richard Spencer Lane for HIV Haemophilia Litigation, 10 December 1990, **CBLA0000005\_002**, pg.63.

<sup>138</sup> Letter from A.L. Parrot to All Regional Administrators, re: Blood Product Consumption, 17 August 1978, **DHSC0002189\_013**.

<sup>139</sup> Minutes of the NBTS Scientific and Technical Committee for the Central Laboratories Meeting, 26 March 1979, **BPLL0008430\_001**.

<sup>140</sup> Discussion paper from the Select Committee on Blood Transfusions, 'Implementation of the Working Party Report on Trends in the Demand for Blood Products', 17 July 1979, **CBLA0000957**.

which aimed to increase production of Factor VIII to **30m iu** per annum<sup>141</sup>, considerably below all estimates prepared since 1977 (the lowest of which was 48m iu prepared by Dr Biggs in 1978<sup>142</sup>). Although Dr Lane acknowledged that those interim works would be insufficient to achieve self-sufficiency, it was clear at this stage that demand and associated estimates were accelerating beyond the capacity of BPL unless it was the subject of a full redevelopment.

71. Estimates continued to increase on an upward trajectory in 1980 and 1981, averaging 92.5m iu and 132.6m iu respectively. There was therefore a growing consensus that demand for Factor VIII would increase to (and above) the region of 100m iu, something that had been forecast in 1979 by the NBTS Scientific and Technical Committee. Many of the estimates during this period attributed the growth in prophylactic treatment and home therapy and the lengthening lifespan of people with haemophilia as key factors contributing to increased requirement forecasts.<sup>143</sup>

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<sup>141</sup> Dr Tovey, Paper AC(80)3 'Supply of Plasma to the BPL', November 1980, **CBLA0001209**.

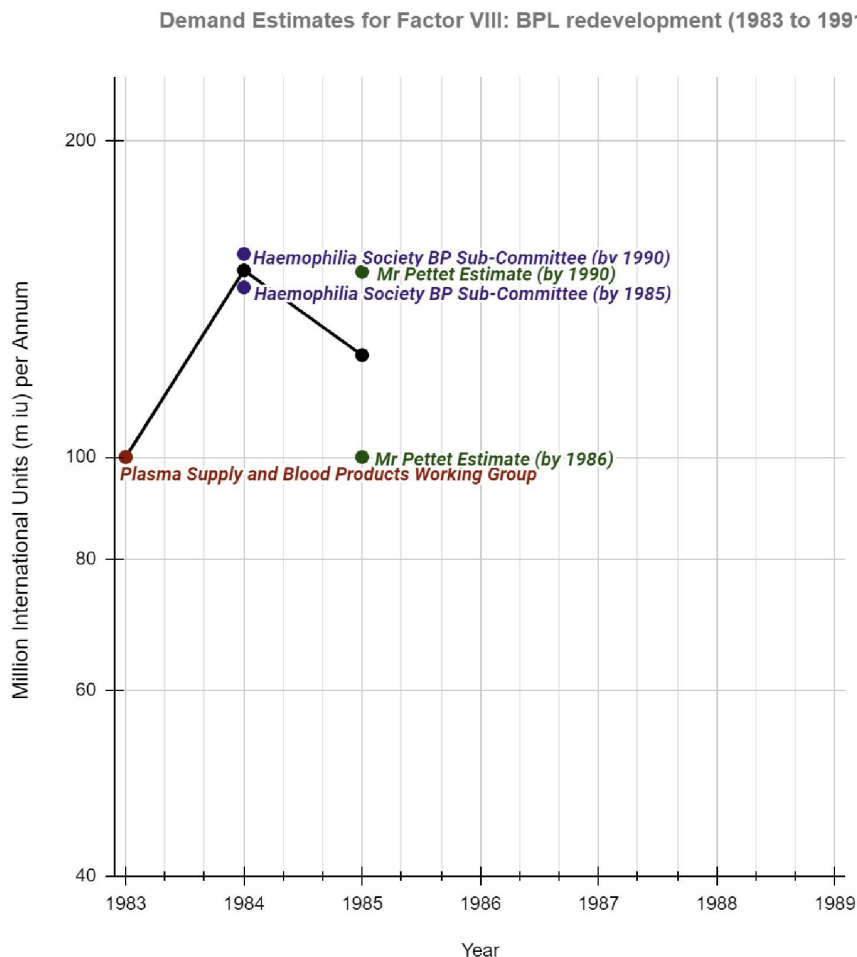
<sup>142</sup> Chapter 4 'The Amount of Blood Required Annually to Make Concentrates to Treat Patients with Haemophilia A and B', by Dr Rosemary Biggs, 1978, **BP LL0002571\_015**, pg.9.

<sup>143</sup> See for example: Report of 'A Proposal to Increase the Production of Factor VIII Concentrate in Order to Achieve Self-Sufficiency in Scotland for the Next Decade' by John D Cash, 1 February 1982, **SBTS0000613\_003**, pg.3-4.

## BPL redevelopment (1983 onward)

### Overview of the Demand Estimates for Factor VIII (1983 to 1991)

72. The graph below outlines estimates made between 1983 and 1991 in terms of the total international units of Factor VIII required per annum to achieve self-sufficiency. As per section I and II, the graph shows an average estimate of demand across the period represented by the black data line. Each individual estimate, represented by a data point, has been titled for ease of reference.



## An analysis of estimates of demand during the BPL redevelopment (1983 to 1991)

73. In January 1984, the Haemophilia Society Blood Products Sub-Committee re-estimated demand and concluded that taking into account factors that informed the 1981 estimate of 80m to 100m iu (such as increases prophylaxis, inhibitor patients, and lengthening life span), **145m iu** would be required for 1985 and **156m iu** would be required by 1990. The Sub-Committee noted that *'usage/demand for Factor VIII continues steadily to increase, with, as yet, no sign of a flattening off in demand. There certainly seems no reason to suppose that demand will level off at the arbitrary figures of 100 million units suggested by the Centre Directors or 110 million units suggested by the Council of Europe'*.<sup>144</sup> The accuracy of the Haemophilia Society's estimates was later questioned by Professor Bloom who considered that a number of invalid assumptions, such as the total number of patients that require Factor VIII treatment per year, were used to calculate demand. Professor Bloom maintained that *'I still think that the original estimates were realistic and we shall probably rise to a usage of about 100 million units by the middle of the decade [1985]'*.<sup>145</sup>

74. In January 1985, Mr N. Pettet (Product Services Manager, BPL) wrote an article for the British Blood Transfusion Society in which he stated that **100m iu** would be required in 1986 to achieve self-sufficiency and demand would increase to in the region of **150m iu** by 1990. To reach this level of demand, a programme to increase FFP supply to the redeveloped BPL toward a target of 450,000kg had been set,<sup>146</sup> and regions began to consider how to increase

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<sup>144</sup> 2nd Report of 'The Haemophilia Society Blood Products Sub-committee', 9 January 1984, **PRSE0002290**, pg.2. The reference to the 1979 Report of the Committee of Experts on Blood Transfusion and Immunohaematology on 'Preparation and use of coagulation factors VIII and IX for transfusion'.

<sup>145</sup> Letter from Prof. Bloom to David Watters, re: The Haemophilia Society Blood Products Sub-committee 1984 estimate, 29 February 1984, **BPLL0001351\_094**.

<sup>146</sup> Article on 'Self-Sufficiency in Blood Products and Plasma Supply' by N. Pettet, 5 January 1985, **NHBT0070661**.

plasma supply through plasmapheresis and SAG-M initiatives.<sup>147</sup> In a meeting with Regional Transfusion Directors on 8 October 1985, representatives of BPL estimated actual demand in 1985 for Factor VIII concentrates as being between **75 to 80m iu**.<sup>148</sup>

75. On 29 April 1987, the redeveloped BPL officially opened. In a DHSS press briefing, it was noted that the old BPL facility at that time was meeting just 30% of the demand for Factor VIII,<sup>149</sup> which was *'the same proportion (but not volume) as in 1977'*.<sup>150</sup> It was considered that the redeveloped BPL facility would eliminate the need to rely on commercial concentrates.<sup>151</sup> Secretary of State John Moore asserted in a letter to Dr Owen in January 1988 that *'it was not until we made the commitment to the new laboratory that the attainment of self-sufficiency became a realistic goal'*.<sup>152</sup>

76. In July 1988, Dr Harold Gunson, on behalf of the DHSS Plasma Supply and Blood Products Working Group, estimated that demand for Factor VIII was by that time in the region of **90m iu**. Moreover, the target set by the Plasma Supply Working Group in 1982 of **100m iu** by 1990 *'seemed to be as adequate a figure as any other'*. To achieve this level of output based on yields at that time, it was estimated that 600 tonnes of plasma would be required. In anticipation that yields would improve following BPL studies, an annual target of 550 tonnes of plasma was set to achieve self-sufficiency which would be phased up between 1988/89 to 1992.<sup>153</sup>

77. In 1989, the definition of self-sufficiency was challenged and an alternative was put forward as follows: *'It is the Government's aim to meet the demand*

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<sup>147</sup> See, for example: RHA Priority Report, 1985, **NHBT0103417**, pg.2.

<sup>148</sup> Note of Regional Transfusion Directors' Meeting at BPL, 8 October 1985, **CBLA0002263**, pg.6.

<sup>149</sup> DHSS Press Release on the Opening of the Redeveloped BPL, 28 April 1987, **DHSC0101068**.

<sup>150</sup> Report on 'AIDS, Haemophilia and Factor VIII' by Charles Medawar and Elaine Rassaby, March 1988, **SHTM0002615**, pg.19.

<sup>151</sup> DHSS Press Release on the Opening of the Redeveloped BPL, 28 April 1987, **DHSC0101068**.

<sup>152</sup> Letter from John Moore to Lord David Owen, 21 January 1988, **LDOW0000052**.

<sup>153</sup> Report on 'DHSS Plasma Supply and Blood Products Working Group - Report from the Medical Sub-Committee' by HH Gunson, July 1988, **DHSC0002019**.

*for home produced Factor VIII for the haemophiliacs in England and Wales'.<sup>154</sup>*

Dr Lane in his proof of evidence in relation to the HIV Litigation commented on the lack of agreement on the definition of self-sufficiency which resulted in an array of estimates prepared throughout the relevant period:

'The underlying problem (in retrospect) is that those involved were sometimes thinking of different things when considering self-sufficiency. For Dr Maycock and some of those in the DOH, self-sufficiency was considered to mean the amount of plasma and concentrate produced from it which was needed to treat haemophiliacs in the way they were treated using cryoprecipitate. For others (particularly some clinicians) it was the amount wanted by their patients to lead as near normal a life as possible'.<sup>155</sup>

78. **To conclude this period (1983 to 1989)**, whilst planning for the BPL redevelopment was underway, estimates of demand continued to increase. In 1984, the Haemophilia Society Blood Products Sub-Committee determined that as much as **145m iu** of Factor VIII would be required by 1985 and **156m iu** by 1990.<sup>156</sup> In 1985, BPL proceeded on an assumption that **100m iu** would be required by 1986 to achieve self-sufficiency, rising to **150m iu** by 1990. A programme to increase plasma supply to the redeveloped BPL was implemented with a target of 450,000kg set to satisfy requirements.<sup>157</sup> In 1987, the redeveloped BPL opened, although it would take some years for the factory to reach full operating capacity.<sup>158</sup> Production of NHS Factor VIII remained well below domestic demand.

79. Following the investment of £500,000 in 1974/1975, the targets set for increased plasma supply were met, but did not result in self-sufficiency being attained. By the mid-1980s, the impediment to self-sufficiency was not a lack

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<sup>154</sup> CBLA 1990 Accountability Review Submission, July 1990, **NHBT0000063\_073**, pg.18.

<sup>155</sup> Draft Proof of Evidence of Richard Spencer Lane for HIV Haemophilia Litigation, 10 December 1990, **CBLA0000005\_002**, pg.30.

<sup>156</sup> 2nd Report of 'The Haemophilia Society Blood Products Sub-committee', 9 January 1984, **PRSE0002290**, pg.2.

<sup>157</sup> Article on 'Self-Sufficiency in Blood Products and Plasma Supply' by N. Pettet, 5 January 1985, **NHBT0070661**.

<sup>158</sup> DHSS Press Release on the Opening of the Redeveloped BPL, 28 April 1987, **DHSC0101068**.

of ambition or accuracy in the targets, but an inability to attain those targets with the infrastructure that was either in place or in development.

80. Annex A will provide an overview of consumption and production to explore briefly the issue of scaling up production in accordance with demand estimates.

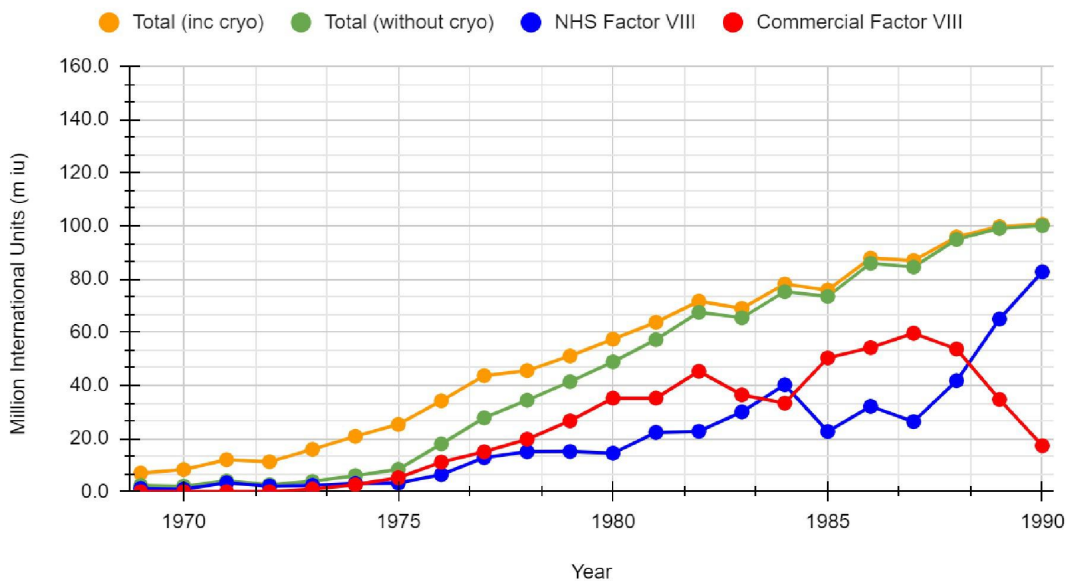


## ANNEX A

### Consumption and Production of factor concentrates in the UK

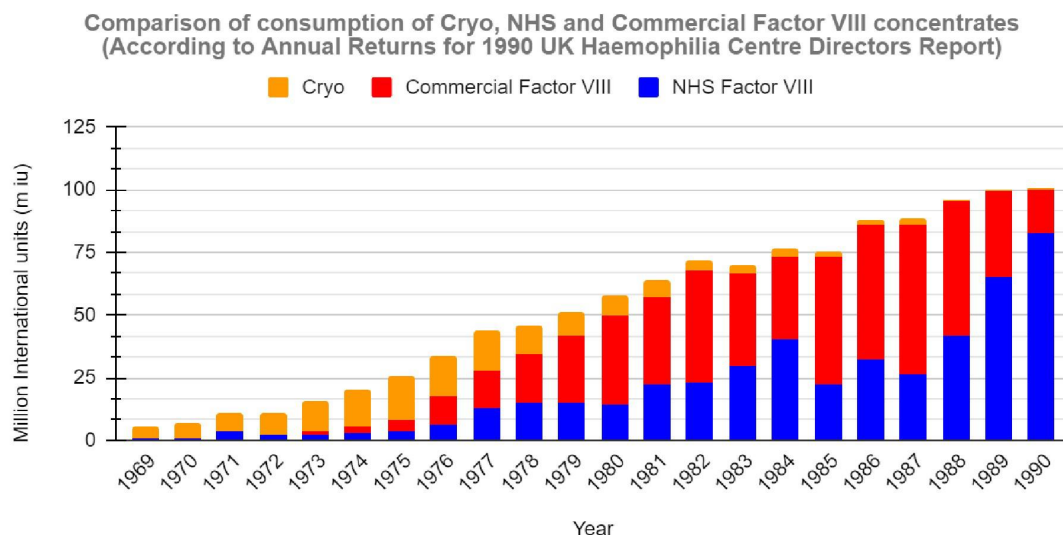
81. In order to assess the accuracy of any estimates prepared during the relevant period, it is necessary to establish the actual demand for Factor VIII concentrates. The Inquiry legal team has therefore prepared the following graph to illustrate consumption data between 1969 and 1990. This graph was presented as figure 1 in the Annual Returns for 1990 UK Haemophilia Centre Directors Report and provides a helpful overview to inform findings<sup>159</sup>:

Consumption of NHS Factor VIII and Commercial Concentrates (According to Annual Returns for 1990 UK Haemophilia Centre Directors Report)



82. A further graph in bar chart format has been prepared to assist with year on year comparisons of consumption of cryoprecipitate, NHS and commercial Factor VIII concentrates.

<sup>159</sup> Report of 'Annual Returns from the UK Haemophilia Centre Directors, 1990' by Dr C. R. Rizza, 11 December 1991, **HSOC0000596**.



83. The total consumption of Factor VIII (comprising both commercial and NHS factor concentrates) increased significantly, from in the region of 20m iu in 1976 to over 100m iu by 1989. Within this overall trajectory, particular points of interest relevant to demand estimates include:

- Between 1974 and 1988, with the exception of 1984, more commercial concentrate was used each year than NHS factor concentrate. Initiatives by the DHSS to achieve self-sufficiency during this period were therefore unable to flatten the consumption of commercial products. Significant reductions in the use of commercial products were not evident until 1988 to 1990.
- In 1976, total consumption of Factor VIII surpassed Dr Biggs' lower estimate of demand prepared in 1973 (equating to approximately 32m iu).
- Prior to 1979, the highest estimate of demand prepared between 1973 to 1978 was 50m iu (for example the estimate by Professor Cash in 1976 and the Trends Working Group in 1977). This level of demand was met, if not surpassed, from 1979. Estimates prepared in the mid to late 1970s were therefore unable to forecast accurately long term demand for Factor VIII.

- From 1979 however, and in particular in 1980 and 1981, eventual requirements were forecasted in the region of 100m iu (for example the estimate by NBTS Scientific and Technical Committee and Mr Harley in 1979). Those estimates proved to be robust when judged against the actual usage of blood products in the 1980s.

84. From the information above it appears that earlier estimates prepared during the first push to self-sufficiency (1973 to mid-1977) were more successful in estimating demand in the short to mid-term than they were in the long term. This appears to be as a result of earlier estimates not accounting for the level of growth in home treatment, prophylactic therapy and improved life expectancy of haemophiliacs. Informed by Dr Biggs' lower estimate of demand, Dr Owen's programme between 1975 to 1977 achieved output in the region of **12.35m iu** of NHS Factor VIII concentrates<sup>160</sup>, by which time consumption of Factor VIII products was in excess of 40m iu, of which 30m iu were concentrates. The estimate prepared by the Trends Working Group in 1977 of **50m iu** for Factor VIII<sup>161</sup> would have satisfied demand at that time but was surpassed in approximately 1980.

85. From 1979, factors increasing demand (prophylactic treatment, increased life expectancy, increased usage on initial home treatment) appear to have informed more accurate forecasts of longer term demand. Although the consumption graph illustrates that demand grew substantially over the relevant period (quintupling between the region of 20m iu in 1974 to the region of 100m iu by 1988), the level of demand for Factor VIII by 1988 was anticipated as early as 1979. The average estimate of demand from those identified in this research in 1980 was 92.5m iu which was sufficient to satisfy actual consumption of Factor VIII until 1987. The average estimate of demand for 1981 was 132.6m iu which was sufficient to satisfy actual consumption of

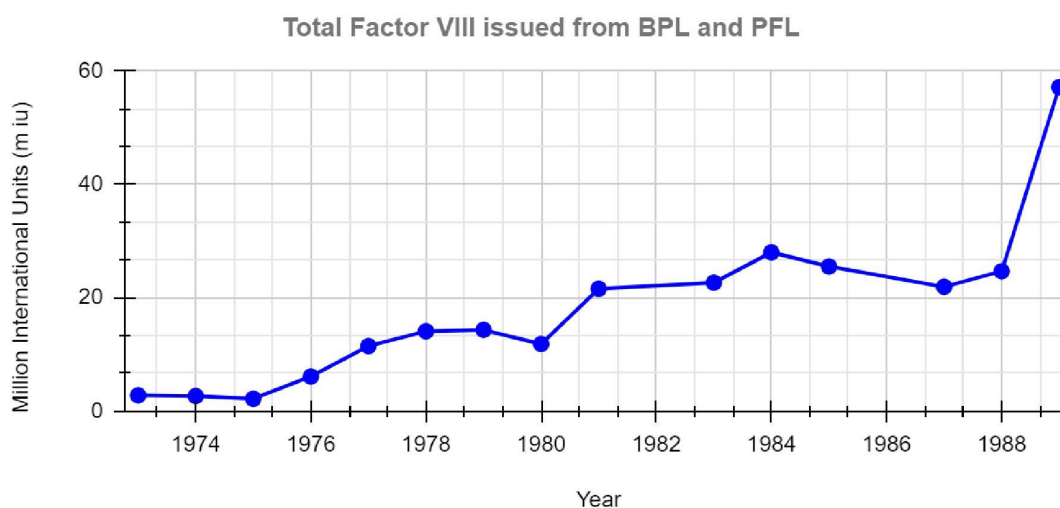
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<sup>160</sup> Paper by Dr Bidwell, 'Production of Factor VIII Concentrate', 27 January 1976, **CBLA0000336**.

<sup>161</sup> Note on demand and supply of Albumin & Factor VIII, August 1977, **DHSC0103249\_096**.

Factor VIII until at least 1990. In this period at least, demand did not accelerate ahead of the estimates.

86. The graph below provides some insight into the production of NHS Factor VIII concentrates between 1973 to 1989, illustrating the total quantity of product (in iu) issued from BPL and PFL. The data used to inform the following graph is derived from Appendix 4 to Dr Lane's Proof of Evidence<sup>162</sup>:



The data behind this graph and the wider issue of production is explored in more detail in **Appendix 1**, but as shown in the graph above, production of NHS Factor VIII concentrates increased between 1973 and 1989 but not to sufficient levels to satisfy demand. The rate of NHS production by 1989 for example (in the region of 60m iu) would have only satisfied total consumption of Factor VIII concentrates until 1980. As of 1983, the UK was importing as much as 40m iu commercial concentrate annually to fulfil demand, according to a contemporary letter written by Dr Walford.<sup>163</sup>

87. It must be borne in mind that the increase in estimates of demand in the late 1970s was a sharp one. To meet that level of supply BPL had to be

<sup>162</sup> Appendix 4 to proof of evidence of Dr R Lane Factor VIII re: Capacity, Production and Demand, **CBLA0000004\_010**.

<sup>163</sup> Letter from Diana Walford to Professor A. Hassig (Swiss Red Cross Blood Transfusion Service), re: Request for plasma free from risk of AIDS, 7 October 1983, **DHSC0002235\_093**.

fundamentally redeveloped. Such a project would inevitably take time, even were decisions to have been taken promptly and implemented effectively. Demand estimates can be increased rapidly; production capacity cannot.<sup>164 165</sup>

88. In 1982, in a BPL report for the CBLA, it was reported that *'because earlier planning and investment in BPL had seriously underestimated demand, output of key products was far below requirement, so that significant levels of costly imported products were needed by the NHS'*.<sup>166</sup> The BPL report in 1982 quoted remarks made by Dr Maycock in the 1978 report:

'It takes at least 4 to 5 years to plan and build accommodation for a plasma fractionation or any other large laboratory. It is thus impossible for a fractionation laboratory to respond quickly to a new demand unless it has unused space at its command and unless it has been designed in a manner and used techniques which allow flexibility in its accommodation in the adjustment of production methods.... The redeveloped BPL should have capacity greater than that needed to provide for the latest estimates for plasma fractions available... secondly DHSS should take a longer term view and consider a new BPL as a valuable investment which will save the Department much money'.<sup>167</sup>

89. In December 1988, the DHSS released a press release noting that 65m iu of Factor VIII were expected to be produced for the year 1989/90 equating to 70% of total requirements. The DHSS stated: *'We will, contrary to earlier expectations, still need to import Factor VIII for the time being. We are disappointed that our previous hopes for self-sufficiency will not be realised. The new BPL represents a massive exercise in scaling up from production in the old plant. Yields at this stage are lower than those previously achieved,*

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<sup>164</sup> British Medical Journal Article 'Freeze-dried Factor VIII concentrates and the NHS', 25 November 1978, **SBTS0000305\_169**.

<sup>165</sup> Letter Dr Lane to Mr Bayliss, re: funding of BPL and the production of and costs of BPL plasma products, 9 March 1979, **CBLA0000923**.

<sup>166</sup> BPL Report 'Background and Current Information for Members of the CBLA', December 1982, revised June 1985, **CBLA0002201**, pg.9.

<sup>167</sup> BPL Report 'Background and Current Information for Members of the CBLA', December 1982, revised June 1985, **CBLA0002201**, pg.9.

*and on which earlier forecasts of production were based. Because yields are lower we need to process more plasma to achieve the same level of output".*<sup>168</sup>

90. As of 1990, BPL was meeting 75% of the total requirement for Factor VIII which was in the region of 110m iu per annum. The Government's position as of October 1990 was that *'absolute self-sufficiency is likely to be unattainable given the clinician's freedom to prescribe. The policy now is one of meeting the clinical demand for home produced Factor VIII'*. It was stated that at this time, BPL was able to meet this level of demand.<sup>169</sup>

**Joshua Terry, Inquiry Legal Team**  
**Matthew Hill, Counsel to the Inquiry**  
**March 2022**

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<sup>168</sup> Press release from Department of Health re: Production at blood products Laboratory reaching record levels, 2 December 1988, **NHBT0103463\_009**.

<sup>169</sup> Guidance, re: Secretary of State Line to Take on Factor VIII Self-Sufficiency, 25 October 1990, **DHSC0046936\_009**.