

Wednesday, 6 October 2021

(10.00 am)

**Presentation by Counsel to The Inquiry on the
Pharmaceutical Companies (continued)**

MR HILL: Sir, we are continuing with the presentation on Alpha, Abbott, Grifols, turning to the Factor IX product, Profilnine, that was produced by Alpha and Abbott in the seventies and eighties. The Inquiry has not identified any documents to suggest that there was a product licence for this product during that time. But there is evidence that it was used in 1984 and 1985 in its heat-treated form, heated in the same way as the Factor VIII product, through the use of the heptane suspension.

In particular, the evidence suggests that that product was used by NHS clinicians because there wasn't an equivalent heat-treated NHS product at that time. The Krever Report at page 756 suggests that the heat-treated Factor IX product from Alpha was available from late October in 1984, at least in the States.

I won't go through this evidence in detail. We have already heard -- and I've given you the references to Dr Winter's evidence for this Inquiry -- which was that he was using heat-treated Factor VIII

1

yesterday, for example the donor pool sizes and the introduction of some of the testing. There are some other documents to which I would like to draw your attention in terms of plasma sources and donors.

If we could begin with an article published in 1979 but looking back at what Alpha had done in the 1970s in terms of testing, in particular for hepatitis B surface antigen.

The reference is BAYP0000021_003.

The article comes from the publication Clinical Therapeutics, volume 2, number 5, from 1979. It is written by Clyde McAuley and Kay Noel of Alpha, and it is entitled "HBsAg Testing in Commercial Plasmapheresis".

The article details the different tests introduced by Alpha during the seventies. It notes that Alpha introduced screening for all plasma donations for hepatitis B surface antigen in January 1971. David Bell in his witness statement of 2 February 2021, to which we referred yesterday, said that this was done -- sorry, I said by Alpha but of course it was by Abbott at this time -- he says that this was done by Abbott a year before it was mandated by the FDA.

The article goes on to say -- I won't bring it

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and Factor IX for his patients in 1984. A memo from 7 May 1985 from Dr Lane noted that Dr Kernoff at the Royal Free was evaluating Alpha's heat-treated Factor IX at that stage the reference is CBLA0002159. So that's May 1985.

A later letter from Alpha to Professor Bloom recorded that the Cardiff centre had received batches of heat-treated Profilnine between June and October 1985, CVHB0000002_050. And Dr Jones at the Newcastle centre stated in a document from 1990 that he had used Profilnine and Konyne in 1985 as no heat-treated NHS product was available. That's PGON0000104_001.

In May 1982, Alpha applied for a product licence for a solvent detergent-treated Factor IX product, which was known as AlphaNine at that stage. I think it had previously been preferred to as Pure Nine. (?)

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The documents suggest that the licence was granted subject to some conditions. MHRA0007156 and MHRA0007149. I don't intend to say anything more about the Factor IX products, sir.

Turning to plasma sources and plasma donors. We have covered some of this ground as we went through the licensing and the viral inactivation documents

2

up, but it's page 4 -- that in April 1973 -- it says Alpha Therapeutic Corporation but I think we should understand that to mean Abbott at the time -- replaced the initial test, which was a counterimmuno-electrophoresis test, with the first generation AusRIA-I test, so an RIA test, in April 1973.

Then a second generation test, AusRIA-II, was introduced in February 1975.

The article describes the effect that these tests had, and it does it both in prose and by reference to a figure, a graph.

I'm going to ask if we could have both of those on screen, please, Soumik. So if we could have page 5 on one side of the screen and page 6 of the article on the other side. We can see the graph there, or the figure. And on the left-hand margin, the left-hand axis, we can see it says, "Reactive Rates per 1,000 Donations", and then on the horizontal axis you have the different years starting from 1971 going up to 1979.

You can see how the years are split up according to the tests, so the first generation CEP test is the first block marked by diagonal lines. The AusRIA I first generation RIA test is marked by the

4

1 speckled dots, and the AusRIA-II test by the cross
 2 hatching.
 3 If we could return that to its pane, thank you,
 4 Soumik, I will then read through what is said in the
 5 article, and people can perhaps look at the graph and
 6 see the particular spikes that it is referring to.
 7 The second paragraph down of page 5, the authors
 8 write this and I quote:
 9 "The first period of
 10 counterimmunoelectrophoresis testing during 1971 and
 11 1972 indicated a relatively stabilised donor
 12 population. Transition from the
 13 counterimmunoelectrophoresis test to the
 14 radioimmunoassay technique, in April 1973, was marked
 15 by an enormous increase in the number of
 16 antigen-positive donations detected."
 17 I pause there, sir. That is very visible in the
 18 figure, is that spike at the point of April 1973 in
 19 the graph.
 20 "Consistent with increased sensitivity of the
 21 radioimmunoassay technique, a substantial number of
 22 donors were rejected in the ensuing five months.
 23 A subsequent slight rise in reactive rate during the
 24 first quarter of 1974 was attributed to the
 25 introduction of a modified version of the AusRIA test;

5

1 as noted previously, the test modification, involving
 2 shorter incubation periods at elevated temperature,
 3 greatly increased the test of specificity. Again,
 4 after the first few months of test introduction during
 5 which time previously unidentified HBsAg positive
 6 donors were excluded from the plasmapheresis program,
 7 the incidence of hepatitis B antigenemia in the donor
 8 population stabilised. The introduction of the
 9 AusRIA-II test, in February 1975, has allowed the most
 10 sensitive detection of antigen-positive donations."
 11 Pausing there, sir, the story is one of the new
 12 test being introduced, there being an increase in the
 13 return of positive donations, because the new test is
 14 more sensitive, those donors being excluded, and
 15 therefore the figures becoming more stabilised as time
 16 went on.
 17 **SIR BRIAN LANGSTAFF:** I don't quite understand the
 18 reference in the article to the introduction of the
 19 AusRIA-I having a greatly increased specificity. That
 20 wouldn't explain a higher reactive rate, would it?
 21 Because the reactive rate is sensitivity, isn't it?
 22 **MR HILL:** The distinction, as I understand it, between
 23 sensitivity and specificity --
 24 **SIR BRIAN LANGSTAFF:** Sensitivity may lead to a number of
 25 false positives. It eliminates false negatives.

6

1 Specificity is the other way around.
 2 **MR HILL:** Yes, but as I understand it -- perhaps --
 3 **SIR BRIAN LANGSTAFF:** You can come back to me on that.
 4 **MR HILL:** I think that it may be that it -- the term
 5 "sensitivity" isn't necessarily being used in
 6 contradistinction to "specificity" in this article.
 7 It may be that it is -- (overspeaking) --
 8 **SIR BRIAN LANGSTAFF:** So they're not using the lingo that
 9 we're used to from our experts?
 10 **MR HILL:** I suspect that is right.
 11 **SIR BRIAN LANGSTAFF:** Right.
 12 **MR HILL:** And I think it should be read as meaning that
 13 this test is better at detecting hepatitis B surface
 14 antigen than the previous test.
 15 **SIR BRIAN LANGSTAFF:** So it should be "sensitivity" rather
 16 than "specificity"?
 17 **MR HILL:** Certainly that would be the --
 18 **SIR BRIAN LANGSTAFF:** That seems to be the sense of it but
 19 it's just the word which puzzles me.
 20 **MR HILL:** Yes. I haven't seen the word "specificity" used
 21 in this article.
 22 **SIR BRIAN LANGSTAFF:** If, in the course of the next day or
 23 so, anyone gives you a better suggestion for what it
 24 means, then let me know.
 25 **MR HILL:** I will do.

7

1 In the discussion section the authors go on to
 2 say -- this at the bottom of page 5:
 3 "In reviewing the reactive donation rate [on to
 4 the next column], it is essential to take into account
 5 the test turn-around time. Until the use of the
 6 courier service was introduced in September 1975,
 7 there was a one-week turn-around time in the
 8 radioimmunoassay testing program. Because
 9 a plasmapheresis donor may contribute plasma twice
 10 weekly, the [hepatitis B surface antigen] reactive
 11 donor contributed an average of 1.7 donations before
 12 being excluded from the plasmapheresis program (as
 13 noted previously, all reactive donations are excluded
 14 from the manufacturing process)."
 15 The authors, sir, are raising this to explain
 16 the statistical steps that they took in the article to
 17 account for this lag in time, but I flag it to you,
 18 sir, for the different purpose of indicating that, up
 19 until September 1975, when a donor was found to be
 20 hepatitis B surface antigen positive, on average that
 21 donor would have given 1.6 donations before being
 22 excluded from the programme. There is nothing in the
 23 article to suggest that retrospective steps were taken
 24 to remove that donor's previous donations from the
 25 plasma pool. It is prospective that the donor is

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1 thereafter excluded.
 2 From September 1975, there was a quicker
 3 turnaround.
 4 If we could go down to about two-thirds of the
 5 way down that right-hand column, the sentence
 6 beginning "During the period", the final paragraph.
 7 Thank you.
 8 So, second sentence into this paragraph:
 9 "During the period of
 10 counterimmunoelectrophoresis testing, the average
 11 annual reactive rates per 1,000 donations were 2.1
 12 (January through December 1971) and 2.4 (January
 13 through March 1973). From April through
 14 December 1973, concomitant with the introduction of
 15 radioimmunoassay testing the reactive rate increased
 16 to an annual average of 9.0 per 1,000 donations,
 17 reflecting a peak of 31.7 per 1,000, stabilising to
 18 4.0 per 1,000 by the last third of the year."
 19 If we go over to page 6, please, on the
 20 left-hand screen -- I think actually we can take the
 21 graph down, and we can just, sorry, go to page 7. My
 22 error. Page 7:
 23 "This marked increase represents the detection
 24 of formally unidentified [hepatitis B surface antigen]
 25 reactive donors ..."

1 1,000, which the Alpha Therapeutic Corporation's
 2 plasmapheresis program has maintained since April 1974
 3 [and I pause to note this article is now 1979, so
 4 a 5-year period], is comparable to the rate of 1.5 per
 5 1,000 reported for a volunteer whole blood donation
 6 program."
 7 And it cites couple of sources in respect of
 8 that figure, and says:
 9 "Thus the comparative reactive donor rates
 10 indicate that in a well-run commercial plasmapheresis
 11 program the incidence of HBsAg reactive donors is not
 12 significantly different from that reported in
 13 a volunteer whole blood donation program."
 14 The reference to the volunteer program is to the
 15 US volunteer program.
 16 The point made previously in that paragraph is
 17 that 90 per cent of the positive donations are for new
 18 donors who are excluded and therefore haven't entered
 19 into the Alpha or the Abbott process. But 10 per cent
 20 are previous donors.
 21 That is all that I take from that article, sir,
 22 but you will be aware, of course, that you have heard
 23 considerable evidence from individuals about they were
 24 infected with hepatitis B and non-A, non-B hepatitis
 25 during the 1970s as a result of the use of blood

1 **SIR BRIAN LANGSTAFF:** Thank you.
 2 **MR HILL:** "... in addition to antigen reactive new
 3 donors."
 4 So if I pause there, the RIA test, as one would
 5 expect, is picking up both new donors who are
 6 hepatitis B surface antigen and who will be excluded
 7 from the programme, and donors who had previously
 8 donated who were hepatitis B surface antigen positive
 9 but had not been detected by the previous test.
 10 Returning to the article, and I quote:
 11 "Since the implementation of the modified AusRIA
 12 procedures, the corrected annual reactive rates per
 13 1,000 donors have stabilised at 1.2 to 1.4.
 14 "In good agreement with the new donor reactive
 15 rate observed in community service volunteer blood
 16 centres, nearly 90% of Alpha Therapeutic Corporation's
 17 reactive donations are attributed to new donors.
 18 These donations were never used in the manufacture of
 19 plasma products and, as mentioned previously, these
 20 donors were summarily excluded from the plasmapheresis
 21 program. Thus the reactive rate within Alpha
 22 Therapeutic Corporation's continually tested
 23 plasmapheresis donor population may be estimated as
 24 0.12 to 0.14 per 1,000.
 25 "The reactive donation rate of 1.2 to 1.4 per

1 products.
 2 A further point to be made about that article is
 3 that it concerns plasmapheresis centres that were run
 4 by Alpha and, as we have seen and will see, Alpha also
 5 used plasma that was obtained from contractors and
 6 also used plasma which was recovered from whole blood
 7 donations in the voluntary sector, although whether or
 8 not that plasma went into blood products that were
 9 used to treat Factor VIII patients in the UK is
 10 a different matter.
 11 We don't have much further evidence about the
 12 available sources of Abbott's US plasma in the 1970s
 13 but there is one document which indicates that Abbott
 14 had received plasma from Central America, specifically
 15 Nicaragua, during that period. If we could have
 16 BAYP0003777, this is a letter dated 15 October 1975,
 17 and it comes from the plasmapheresis, the Centro
 18 Americana de Plasmapheresis company in Nicaragua and
 19 it's sent by Guillermo B Castro, his position title is
 20 "Responsible Head", and it is sent to the Director of
 21 the Bureau of Biologics in the United States. The
 22 letter states this:
 23 "We hereby request authorization to ship
 24 15,434 liters of Fresh Frozen (Human) Plasma,
 25 collected from normal donors to, Cutter Laboratories,

1 [in California].
 2 "The use of this plasma will be for
 3 manufacturing purposes into Human Injectable
 4 Materials. The tentative point of entry of this
 5 product shall be San Francisco, California [through]
 6 (air freight)."
 7 This is the paragraph for our purposes, and I
 8 quote:
 9 "We already have been authorized by you to make
 10 this SAME SHIPMENT to Abbott Laboratories with
 11 tentative port of entry Los Angeles, California.
 12 (Kindly see attached copy of your letter of
 13 authorization dated July 31, 1975). We wish to inform
 14 you that such shipment did not take place as Abbott
 15 Laboratories informed us at the time, they were
 16 overstock."
 17 The letter to which reference was made is at
 18 page 2 -- apologies, that is not the letter. But the
 19 point of this paragraph is that Abbott had made
 20 an arrangement to obtain blood -- or obtain plasma
 21 from Nicaragua. They hadn't, in the event, gone
 22 through with it on that instance because they were
 23 overstocked. We don't know whether or not a shipment
 24 was made at another time nor do we know to what
 25 purpose any plasma from Nicaragua was put.

1 necessary to increase the proportion of the population
 2 voluntarily donating from 3 per cent to 19 per cent.
 3 Mr Drees points out the difficulties that the US
 4 Red Cross have had in publicising and attracting
 5 donors, and goes on to say, this is at the top of
 6 page 3, the first full sentence there, please:
 7 "I submit this is impossible, and the effort
 8 would not be worth the cost to the American public for
 9 a phony moral issue. A true moral issue in paid vs
 10 volunteer blood is simply: is there an adequate, safe,
 11 cost effective supply of blood and plasma? If the
 12 controversy reduces the supply, then the cause of the
 13 controversy is immoral."
 14 That was the position put by Mr Drees. If we
 15 could turn to page 4 of this document, just on
 16 a slightly different point but one of interest, he
 17 addresses the suggestion which seems to have been made
 18 in the United States at the time that exporting
 19 anti-haemophilic fractions caused high prices in the
 20 US, a source of concern for patients within the US.
 21 Mr Drees denies that this is the case and says
 22 actually the higher prices which were obtainable
 23 overseas, in effect, subsidised the cost in the
 24 United States.
 25 He gives some prices, we can see that on the

1 As you will recall, sir, from the UK licences,
 2 the application of August 1974 expressly stated that
 3 the blood used was obtained from plasmapheresis of
 4 commercial donors at eight centres within the
 5 United States, and there was a variation application
 6 in January 1975, that added a further nine centres,
 7 all within the United States. Now, of those 17
 8 centres it seems that 16 were identified as being part
 9 of the company that Alpha itself owned and ran but one
 10 centre was part of a different company and we don't
 11 know who had control of that company, or the extent of
 12 any influence that Alpha had over it.

13 Turning to the 1980s, the president of Alpha
 14 gave a speech or a talk in February 1980, a man called
 15 Thomas C Drees, and if we could have IPSN0000328_008,
 16 this -- we don't have much context for when this talk
 17 was given but the principal purpose of it was
 18 a discussion of the plasma industry worldwide and
 19 obtaining data about it. I won't go into that.

20 What I will draw your attention to is the second
 21 section of the speech on page 2, please, which talks
 22 about "Can the volunteer blood system replace the paid
 23 plasma system?" A series of calculations are given in
 24 the speech, the nub of which is that, in order to
 25 replace paid plasma in the United States, it would be

1 second paragraph. He refers to the high prices in
 2 West Germany, 43 cents; Japan, 40 cents; it's written
 3 "US" but I think this must be a reference to the UK,
 4 UK, 17 cents; Sweden, 60 cents; Italy, 35 cents; and
 5 Spain, 43 cents. Those all subsidise the low prices
 6 in the US of 12 cents.

7 If I'm correct in thinking that there is
 8 a typographical error and the first reference to the
 9 US is to the UK, we can see that that figure is of
 10 course higher than the 12 cents of the United States
 11 but significantly lower than the prices in West
 12 Germany, Japan, Sweden, Italy and Spain.

13 I turn now to the subject of advertisements and
 14 efforts to recruit gay donors. We have discussed this
 15 over the last couple of weeks and the significance of
 16 gay donors for providing hepatitis B immune globulin,
 17 the question of whether or not plasma obtained from
 18 those donors was also used in the manufacture of
 19 Factor VIII.

20 If we could have on screen please UCSF0000058,
 21 please, Soumik. This the front cover of a magazine
 22 called Advocate, which describes itself as "the
 23 national gay news magazine". This, as we understand
 24 it, is an edition from 9 July 1981. If we could go,
 25 please, to page 4 of the document, on the left-hand

1 side the second entry down, headlined "Every healthy
2 adult should be a plasma donor", we can see that this
3 is an advert placed by Alpha Plasma Centers, you can
4 see that at the bottom left-hand corner, and the
5 advert says this, and I quote:
6 "Help us help people who need plasma.
7 "Every healthy adult should be a plasma donor.
8 "It's a two-way street. You help us meet the
9 growing demand for plasma and we'll help you earn
10 extra income.
11 "Join us ... Be a plasma donor.
12 "Did you know that plasma is desperately needed
13 by the sick and injured every day?
14 "For burn, shock, and accident victims,
15 haemophiliacs, and others, plasma can mean the
16 difference between life and death."
17 The address of a plasma centre is given,
18 973 Mission, San Francisco. Then it says:
19 "Bring this add for new donor bonus!"
20 So plainly an advertisement directed at gay
21 donors, from 1981.
22 If we could go over to page 6, please. Another
23 advert which we understand to be from the same
24 publication, and the advert this time reads -- it's
25 the one in the top right-hand corner, this time it

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1 Then a list of Alpha Plasma Centers with contact
2 details, including phone numbers, is given.
3 Finally, if we could have CGRA0000294_074. This
4 advert reads as follows:
5 "Hepatitis 'B'
6 "Have you ever had Hepatitis 'B' or a positive
7 test?
8 "Your blood may be valuable for making a new
9 vaccine.
10 "Cash paid per donation.
11 "Free confidential testing available.
12 "For more information, contact the nearest Alpha
13 Plasma Center."
14 Then five centres are listed there in different
15 cities in Texas.
16 As we have previously seen and discussed, in
17 August 1982, Dr Dennis Donohue, of the Office of
18 Biologics of the FDA, approached commercial
19 fractionators to seek a voluntary agreement to cease
20 using plasma collected from the targeted gay donors in
21 the production of Factor VIII concentrate.
22 If we could have BAUM0000008, please, on screen.
23 This is a document that we have looked at before. It
24 is dated 30 August 1982. It is a Cutter document,
25 which is referring to Dr Donohue's requests to Cutter,

19

1 reads:
2 "Chances are.
3 "You've got hepatitis
4 "Or were exposed to it.
5 "If you're an active Gay, you have an extremely
6 high chance of getting Hepatitis. This disease can
7 cripple you for months. It can hurt you, and everyone
8 around you, for a lifetime. It might even kill you.
9 "Yes, Hepatitis is a serious disease. But now
10 there is something you can do to stop it.
11 "Help develop the anti-hepatitis vaccine.
12 "At Alpha Plasma Centers we are collecting
13 plasma for use in the development of a hepatitis
14 vaccine, that may one day stop Hepatitis dead in its
15 tracks.
16 "You, or anyone you know who's had Hepatitis,
17 can help in our research by contacting an Alpha Plasma
18 Center. At Alpha, giving this plasma is fast, easy
19 and safe. We'll pay you cash if your plasma is
20 acceptable. We will give you a free blood test to
21 find out if you qualify.
22 "Please, consider the danger of Hepatitis in our
23 community. Your blood may hold the factors we're
24 searching for, so contact your Alpha Plasma Center
25 today."

18

1 which has also been made to other pharmaceutical
2 companies, and it is recording what appear to be
3 discussions with others at other pharmaceutical
4 companies about what their position is. So it is
5 Cutter's understanding of what is happening at Hyland
6 and at Alpha. We looked at the Hyland section before,
7 and what the document records in the second paragraph
8 is this:
9 "Hyland (Mike Rodell) has had a policy that any
10 plasma collected from a donor having a history of
11 hepatitis (the disease, [hepatitis B surface antigen]
12 positive, or in close association with others having
13 the disease) are excluded from use in the manufacture
14 of [anti-haemophilic fraction]. Currently Hyland
15 collects plasma from homosexuals for anti-HBs but does
16 not use it in their fractionation, it is sold to
17 Alpha. Mike has told Donohue that he thinks Hyland
18 excludes homosexual plasma from AHF but he wanted to
19 check their procedures before making a solid voluntary
20 commitment. My guess is that Hyland will make the
21 commitment."
22 The memorandum goes on:
23 "Alpha Therapeutics, (Penny Carr) has just
24 returned from Washington and had not met with her
25 management (Hartin and Drees). She will make the

20

1 recommendation that they voluntarily exclude all
 2 anti-HBs plasma (almost exclusively collected from
 3 homosexuals) from coagulation components. Penny
 4 believes that the commitment should be 'voluntary'
 5 rather than via a written request from BoB [Bureau of
 6 Biologics] because the latter, could have political
 7 repercussions, could be difficult to amend, and would
 8 ultimately create concerns and problems with both the
 9 homosexual and haemophilic populations."

10 So there is an expectation in that document that
 11 Alpha are going to give a voluntary commitment that
 12 the document doesn't necessarily address what Alpha
 13 was doing in the past, save that it notes that Hyland
 14 appear to be selling plasma from gay donors to Alpha.
 15 If we could now turn please to CGRA000027, this is
 16 a letter from Marietta Carr, Vice President of
 17 Regulatory Affairs, presumably the Penny Carr who was
 18 referred to in the previous document, which was sent
 19 to Harry M Meyer, the Director of the National Center
 20 for Drugs and Biologics in the FDA. The letter is
 21 dated 30 August 1982.

22 What it states is this, and I quote:

23 "The purpose of this letter is to inform you
 24 that until further notice Alpha Therapeutic
 25 Corporation will not be using the cryoprecipitated

1 material from plasma from hepatitis B surface antibody
 2 donors in the manufacture of Anti-haemophilic Factor
 3 (Human). Such plasma is used by Alpha in the
 4 manufacture of Hepatitis B Immune Globulin (Human)."

5 So a prospective commitment not to do it until
 6 further notice but no comment on what was done before.

7 If we could have CGRA0000657, please, it is
 8 a further letter from Marietta Carr, again to
 9 Mr Meyer, dated 7 September 1982. In this letter
 10 Marietta Carr states:

11 "We are in receipt of the Office of Biologics'
 12 August 20, 1982 letter approving our procedure for the
 13 immunization of donors with licensed hepatitis B
 14 vaccine. This letter stated that plasma obtained from
 15 donors with a history of hepatitis may be used only
 16 for the production of Hepatitis B Immune Globulin or
 17 in-vitro diagnostics."

18 So that's using it to diagnose infections in
 19 a laboratory setting. Going back to the letter,
 20 I quote:

21 "As we stated in an August 30, 1982 letter to
 22 you, we have voluntarily suspended until further
 23 notice the use of cryoprecipitated material from
 24 hepatitis B surface antibody donors in the manufacture
 25 of Anti-haemophilic Factor (Human). However, we know

1 of no reason why plasma from such donors should not
 2 continue to be [used] in the manufacture of Normal
 3 Serum Albumin (Human) or Plasma Protein Fraction
 4 (Human). Therefore, we will continue to utilize
 5 plasma from hepatitis B surface antigen donors in the
 6 manufacture of Normal Serum Albumin ... or Plasma
 7 Protein Fraction ..."

8 So the plasma from donors, particularly gay
 9 donors who have been targeted in order to make the
 10 hepatitis B immune globulin, will continue to be used,
 11 suggesting that it has been used before, in albumin
 12 and plasma protein fraction, presumably on the basis
 13 that there are viral inactivation techniques connected
 14 with those products. The use in anti-haemophilic
 15 factors, so Factor VIII and Factor IX, is stated to be
 16 suspended.

17 Can we have, please, CGRA0000262. This a letter
 18 from Thomas C Drees, the man whose speech we looked at
 19 a little while ago, and it was sent to the National
 20 Hemophilia Foundation, the -- at that time -- major
 21 haemophilia charity in the United States.

22 What Dr Drees says is this, and it is sent
 23 specifically to Mr Charles J Carman the Chairman of
 24 the Board, and Mr Louis Aledort, the Medical
 25 Co-Director of the National Hemophilia Foundation.

1 What the letter says is this, and I quote:

2 "Gentlemen:

3 "I was pleased to receive your recent letter of
 4 November 2, 1982, but was distressed with the bad
 5 news. Alpha has never used plasma from homosexuals,
 6 intravenous drug abusers or recent Haitian emigres.
 7 We have no centers in Florida, New York, Los Angeles
 8 or San Francisco, and do not buy plasma from these
 9 areas. We have always avoided drug abusers, and while
 10 we have purchased some plasma collected from
 11 homosexuals for Hepatitis B Gamma and Vaccine, we have
 12 never used it to make [anti-haemophilic faction]. We
 13 also think that plasma from prisons should be
 14 avoided."

15 It goes on to say that they agree with the
 16 proposed restrictions that have been suggested by the
 17 National Hemophilia Foundation.

18 **SIR BRIAN LANGSTAFF:** If one just goes back for a moment,
 19 bearing in mind that it says, "We have no centers in
 20 Florida, New York, Los Angeles or San Francisco", to
 21 something you showed me a moment or two ago,
 22 UCSF0000058, page 4, the address says 973 Mission,
 23 San Francisco.

24 **MR HILL:** It does, sir. We understand that comes from
 25 July 1981.

1 **SIR BRIAN LANGSTAFF:** Yes, the centre may have closed in
 2 between, but this is certainly is targeting people in
 3 San Francisco to give their plasma, and it was
 4 a centre in San Francisco, just in case it might be
 5 thought that the letter was suggesting there never had
 6 been plasma in the system which came from those
 7 centres.
 8 **MR HILL:** That's correct, sir. If we could go to page 6,
 9 I don't know -- my copy won't allow me to see where
 10 the listed centres are, but if you go to page 6 of
 11 that document --
 12 **SIR BRIAN LANGSTAFF:** It refers to the 973 Mission,
 13 San Francisco. You can work it out looking at the
 14 fourth line up.
 15 **MR HILL:** Yes, San Francisco.
 16 **SIR BRIAN LANGSTAFF:** 973 Mission Street, San Francisco,
 17 CA.
 18 **MR HILL:** I'm afraid my eyesight won't allow me to pick
 19 out --
 20 **SIR BRIAN LANGSTAFF:** It's not very clear but that,
 21 I think, is what it says.
 22 **MR HILL:** Yes, I'm very confident about that one because
 23 we have the previous address. I was just seeing, as
 24 I scanned down, whether or not there is any reference
 25 to centres in Florida, New York, or Los Angeles. I'm

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1 afraid I can't make out clearly what the other centres
 2 are.
 3 **SIR BRIAN LANGSTAFF:** It's very difficult to work that
 4 out. The head office was in Los Angeles, wasn't it?
 5 **MR HILL:** Yes, but whether or not that also meant there
 6 was a plasma centre --
 7 **SIR BRIAN LANGSTAFF:** It may not have been a collection
 8 centre but it certainly was the head office.
 9 **MR HILL:** Yes. But certainly those two adverts
 10 demonstrate that, as of 1981, there was a centre that
 11 was in San Francisco.
 12 **SIR BRIAN LANGSTAFF:** Yes. And that it was active or
 13 intended to be active at the time.
 14 **MR HILL:** Yes, yes. The phrasing of Dr Drees' letters is
 15 "We have no centers in Florida, New York, Los Angeles
 16 or San Francisco" as of 9 November 1982.
 17 **SIR BRIAN LANGSTAFF:** Yes.
 18 **MR HILL:** Trying to bring together those documents, it's
 19 not possible to give you a comprehensive picture, I'm
 20 afraid, but there does seem to be evidence of the
 21 following.
 22 First, Alpha actively advertised for gay donors
 23 and, as we have seen, that included in the
 24 San Francisco area.
 25 Second, plasma from those donors was used in the

26

1 products of hepatitis B immune globulin, and this was
 2 approved by the FDA.
 3 Third, there is evidence that Alpha also
 4 purchased plasma from gay donors from Hyland.
 5 Fourth, that as of August and September 1982,
 6 Alpha gave a prospective commitment not to use plasma
 7 in the manufacture of Factor VIII and Factor IX
 8 concentrates.
 9 However, fifth, they reserved the right to use
 10 it an albumin or plasma protein fraction products.
 11 And sixth, the president of the company informed
 12 the National Hemophilia Foundation in November 1982
 13 that Alpha had never used such plasma in
 14 anti-haemophilia fractions.
 15 That sir, I'm afraid, is as far as we are able
 16 to take it at this stage.
 17 **SIR BRIAN LANGSTAFF:** Thank you.
 18 **MR HILL:** Turning to prisons, the document that we have
 19 just looked at from Dr Drees contained the sentence:
 20 "We also think that plasma from prisons should
 21 be avoided."
 22 That is from 9 November 1982.
 23 If we could have on screen, please, CGRA0000376.
 24 This is a document dated 15 December 1982, and it is
 25 directed from the sales department of Alpha to its

27

1 sales force regional managers, and it is a document
 2 which is about AIDS and gives some facts that the
 3 regional managers should know. We will be coming
 4 back, of course, to the question of how the company
 5 and other companies responded to the threat of AIDS in
 6 November.
 7 For present purposes, the second point down in
 8 the "Some facts you should know" is the relevant one.
 9 It states:
 10 "There is a large homosexual population in the
 11 penal institutions. Alpha does not collect plasma
 12 from penal institutions."
 13 The present tense is used there, sir. I don't
 14 know if that has any significance, I'm afraid.
 15 On 22 December 1982, Alpha's US medical
 16 director, Dr Clyde McAuley, wrote to US haemophilia
 17 centres regarding AIDS.
 18 This is at CGRA0000265, please.
 19 You can see the date there, 22 December 1982,
 20 and the addressees.
 21 If we go down, please, to the third paragraph,
 22 the underlined section there. Dr McAuley said, and
 23 I quote:
 24 "We do not operate prison donor centers which
 25 have a large high risk population, nor do we purchase

28

1 plasma from prisons."
 2 Again, the present tense is used. I don't know
 3 if there is a significance to that.
 4 While we are on this document, if we could just
 5 go to the previous paragraph, it gives us some insight
 6 into how Alpha had approached its donor checks before.
 7 Dr McAuley wrote, and I quote:
 8 "Alpha has always checked potential donors for
 9 temperature, fever, weight loss and other physical
 10 signs which now are suspected of being symptomatic of
 11 AIDS. Wherever we find a potential risk factor, we
 12 will decline to accept plasma from that donor. This
 13 action is consistent with our policy to do all we can
 14 to ensure patient safety in using our plasma
 15 products."
 16 That is the information that we have, sir, about
 17 the use of prison plasma.
 18 In November, we will hear more about the steps
 19 that were taken by Alpha and other pharmaceutical
 20 companies in response to the threat of AIDS.
 21 Alpha were one of the first companies to
 22 instigate a donor screening programme specifically
 23 addressing some of the risk factors of AIDS and
 24 seeking to exclude high-risk donors. They did that
 25 from December 1982. It may be that they were the

1 that is CGRA0000665_001.
 2 What those figures don't tell us is how many of
 3 those donors were first-time donors and how many had
 4 given previous donations.
 5 If we could have on screen, please, CGRA0000241.
 6 This is on a slightly different but related point.
 7 This is an Alpha memorandum from 25 January 1983.
 8 It's entitled "AIDS - Plasma Risk". It's from
 9 Bob Rivett and sent to Dave Gury. It provides an
 10 overview of the sources of the company's expected
 11 plasma collection in 1983. It's helpful for our
 12 purposes to see where they were getting their plasma
 13 from. Although I stress that the fact that the
 14 company was obtaining plasma from a particular source
 15 does not mean that that plasma was necessarily being
 16 used in the production of Factor VIII products. Still
 17 less that it was being used in Factor VIII products
 18 that were all marketed in the United Kingdom. But it
 19 does help us to understand where the company was
 20 getting its plasma at that time.
 21 What is recorded in this memorandum is this, at
 22 point 1:
 23 "1. We will receive 900,000 Kgs of plasma from
 24 Alpha donor centres. At 666ml/donation this
 25 represents about 1,350,000 donations."

1 first company to do that.
 2 Of interest for present purposes is the effect
 3 of that donor screening programme. On 14 January 1983
 4 an Alpha representative, or several representatives,
 5 attended a large National Hemophilia Foundation
 6 meeting, alongside other pharmaceutical manufacturers.
 7 The note of this meeting -- I won't take you to it but
 8 the reference is CGRA0000327 -- recorded that in the
 9 first three weeks of Alpha's new screening process,
 10 308 people had been excluded. That screening process
 11 was focused on male donors who had had sexual contact
 12 with a man, people from Haiti, and those who used
 13 intravenous drugs.
 14 According to the Krever Report, those 308 Alpha
 15 donors who had been excluded as a result of the
 16 answers they had given to questions in the donor
 17 screening programme, came from a total of 6,000-7,000
 18 donors who had been questioned during approximately
 19 three weeks about high risk behaviour. So 308 out of
 20 about 6,000-7,000.
 21 Alpha published newsletters periodically, and
 22 the summer 1983 newsletter stated that in the first
 23 six months of the donor screening programme,
 24 800 potential donors had voluntarily disqualified
 25 themselves from the donor pool. The reference to

1 "2. We will receive 200,000 Kgs from contract
 2 centers or about 300,000 donations.
 3 "3. In the above cases, the average donor
 4 donates 15 times per year.
 5 "4. The annual donor population at Alpha is
 6 89,000 individuals and in contract centers 20,000."
 7 "5. We are planning to receive 100,000 Kgs of
 8 Recovered Fresh Frozen Plasma (RFFP) from Blood Banks.
 9 At 250ml per donation, this represents 400,000
 10 individuals, since there are few repeat donations."
 11 "This results in the following picture:
 12 "Source."
 13 And we can see the table here. "Source" is in
 14 the left-hand column, and then "Kgs" provided of
 15 plasma. The number of "Donations" in the next column,
 16 and the number of "Donors" in the column that follows,
 17 and the "[Percentage] of donors". So we can see that
 18 there are three sources: the Alpha centres, contract
 19 centres, and recovered fresh frozen plasma from blood
 20 banks.
 21 The biggest per volume, by some distance, is the
 22 900,000 kilograms obtained at Alpha centres compared
 23 to 200,000 in contract centres and 100,000 from
 24 recovered fresh frozen plasma. That was also
 25 reflected in the number of donations at the Alpha

1 centres, 1.35 million, compared to 300,000 and 400,000
2 from the contract and the recovered fresh frozen
3 plasma.

4 But the "Donors" figure shows that 89,000 donors
5 provided the 1.35 million donations at the Alpha
6 centres, so that's 17.5 per cent of the donors.
7 3.5 per cent of the donors contributed to the contract
8 plasma. 78.6 per cent of the donors contributed to
9 the recovered fresh frozen plasma. The reasons for
10 that are that the donations are smaller,
11 250 millilitres per donation, and there are few repeat
12 donations, which I understand to mean that people who
13 go to the blood banks tend to donate once per year,
14 rather than the 15 times per year that those at the
15 Alpha centre on average provide.

16 The final paragraph of the memorandum states
17 this:

18 "It would appear that if the assumptions are
19 correct, we will have 78.6% of our total donors
20 contributing to only 10% of our plasma. One could
21 conclude that it is important to take all steps
22 possible to ensure that this large segment be
23 carefully screened to avoid including plasma from
24 'high risk' individuals."

25 That is the end of the memorandum. It is

1 written of course at a time when Alpha had introduced
2 its screening programmes within its own centres. The
3 memorandum appears to be pointing out the danger, the
4 risk involved in the fact that a large number of
5 donors, the 78.6 per cent of the donors, weren't
6 coming from Alpha centres but were coming from blood
7 banks, and, in addition, 3.5 per cent were coming from
8 contractors.

9 Could we have on screen, please,
10 BPLL0001351_122. This document we believe dates from
11 31 May 1983, and it is from David J Gury, who was the
12 recipient of the previous memorandum. And it is sent
13 to Joe Kimoto, of the Green Cross Corporation in
14 Osaka, Japan, the ultimate owner of Alpha. It is
15 entitled "AIDS Report - For Discussion with the
16 Japanese Ministry of Health June 6, 1983", which is
17 why we believe it comes from May 1983. I won't take
18 you through the whole document, maybe one that we will
19 return to in November.

20 For present purposes, it's just page 4, item 3,
21 to which I will draw your attention. What Mr Gury
22 wrote there, and I quote, is:

23 "For plasma obtained from blood banks, Alpha's
24 specifications were changed" --

25 **SIR BRIAN LANGSTAFF:** It is probably "requiring", is it?

1 **MR HILL:** I suspect it is "requiring":
2 "... [requiring] that plasma collected after
3 January 1, 1983, be from donors screened in the [same]
4 manner as those at Alpha's Plasma Centers. (At first
5 this was applied to all plasma. Later in January, it
6 was reduced to apply only to plasma to be used in the
7 manufacturing of AHF since other products are subject
8 to heat treatment."

9 "The result of this requirement was a severe
10 reduction in plasma procurement from blood banks as
11 blood banks, at this point in time, refused to follow
12 Alpha's lead and would not follow the screening
13 requirements until forced to by regulations from the
14 Office of Biologics on March 24, 1983."

15 Recommendations we will come back to in due
16 course. What can be taken from this in terms of what
17 was done before January 1, 1983 would be -- or at
18 least the inference that I take from it is that Alpha
19 did not control the processes that were being used in
20 the blood banks for donor screening before that time,
21 and when they introduced or required that similar
22 processes be introduced in January 1983, the
23 contributions from blood banks dropped off.

24 **SIR BRIAN LANGSTAFF:** Just going back to the letter which
25 Mr Drees wrote to the National Hemophilia Foundation

1 on 9 November 1982, CGRA0000262:

2 "Alpha has never used plasma from homosexuals,
3 intravenous drug abusers or recent Haitian emigrees."

4 If at that time Alpha was receiving fresh frozen
5 plasma from blood banks, recovered fresh frozen
6 plasma, then they would have no way of knowing.

7 **MR HILL:** They would have no way of knowing, save for
8 whatever information was provided by the blood banks
9 to them, but the large scale of donations and
10 donors --

11 **SIR BRIAN LANGSTAFF:** And if blood banks were supplying
12 them then in the same manner as they had been applying
13 in early January through to March of '83, the
14 implication from the letter you've just shown me, at
15 BPLL -- on the AIDS report, essentially -- is that
16 there were a number of potentially high risk groups
17 the blood banks weren't prepared to ask and find out.

18 **MR HILL:** Yes. I would point out that in his letter,
19 Dr Drees says that the specific groups highlighted,
20 the Haitians, gay donors, prison donors, weren't used
21 in the production of anti-haemophilic fraction, but
22 the letter that I have read says that first the
23 requirements that were placed on the blood banks were
24 applied to all plasma, but later in January it was
25 reduced to apply only to plasma to be used in the

1 manufacturing of anti-haemophilic fraction. So it
 2 does appear that, as of January 1983, blood bank
 3 plasma was being used in the production of
 4 anti-haemophilic fraction.

5 **SIR BRIAN LANGSTAFF:** Yes, the result of this requirement
 6 was a severe reduction.

7 **MR HILL:** Yes. Yes.

8 **SIR BRIAN LANGSTAFF:** But what you don't have the
 9 documents to show me is the extent to which, prior to
 10 January 1, 1983, Alpha was taking from blood banks?

11 **MR HILL:** No. I would note that the previous document
 12 that I showed you, which showed the figures, the
 13 anticipated figures for 1983, made no reference to any
 14 dramatic changes that were anticipated in the supply
 15 at that time.

16 **SIR BRIAN LANGSTAFF:** Thank you.

17 **MR HILL:** The further point that I don't have information
 18 on, save for the documents were provided with the
 19 licence applications in 1974 and 1975, is whether the
 20 plasma that was obtained from blood banks was used in
 21 Factor VIII products that were provided to the
 22 UK market. Certainly the applications in 1974 and
 23 1975 would indicate that it was not and, if the
 24 licence were granted on that basis, then, unless the
 25 licence was varied, it would not have been open to the

37

1 company to have used plasma from -- other than the 17
 2 centres that were listed in such production.

3 But we don't have a full set of all of the
 4 licensing documentation regarding Profilate.

5 Sir, that is all I intend to say for now about
 6 the issue of donors. There may be -- I understand
 7 that a document has been forwarded to us while I have
 8 been speaking and I will look at that during the break
 9 to see if it sheds any more light, particularly on the
 10 San Francisco centres.

11 **SIR BRIAN LANGSTAFF:** Yes, I think there is a reference
 12 somewhere to the recently closed San Francisco centre.

13 **MR HILL:** That is the document which has been forwarded to
 14 me.

15 **SIR BRIAN LANGSTAFF:** That may be CGRA0000599.

16 **MR HILL:** 15 December 1982 from E Healey -- Mealey,
 17 perhaps -- PhD, an Alpha employee, sent to the
 18 Executive Committee. We can see Dr Drees' name there,
 19 copied to others including Mr Gury and Penny Carr, and
 20 it's "Re: AIDS Meeting December 15, 1982". So point
 21 1.C:
 22 "If plasma is on hand from our recently closed
 23 San Francisco center there is no reason it should not
 24 be used."

25 **SIR BRIAN LANGSTAFF:** Yes.

38

1 **MR HILL:** 15 December, 1982. Thank you, Soumik.
 2 A few further references, sir, to give you about
 3 Alpha, Abbott. I won't bring any of these documents
 4 up. There is some evidence that Alpha and Green Cross
 5 expressed an interest in establishing a fractionation
 6 plant in the United Kingdom in circa 1979 to 1980. We
 7 have seen similar documents from other companies. The
 8 references are DHSC0002197_170, and the same stem
 9 _166, and _164, and we know, of course, that
 10 ultimately that wasn't pursued.

11 Then a couple of documents on financial
 12 donations to finish with. The minutes of 14
 13 April 1986 Reference Centre Directors meeting note
 14 that Alpha had agreed to provide funds for the
 15 October 1986 annual general meeting of Haemophilia
 16 Centre Directors Organisation but no figure was given
 17 in those minutes. The reference is HCDO0000420.

18 We also have an undated letter regarding funding
 19 by pharmaceutical companies in the 1970s and 1980s
 20 which appears to relate to the Lothian Health Board.
 21 That records a donation of £6,500 from Alpha in 1986
 22 to 1987 and another of £1,000 in 1987 to 1988. Those
 23 references are STHB0000220. Finally, from June 2002,
 24 Dr Hill wrote to Ian Marshall of Alpha UK on behalf of
 25 the UKHCDO, seeking a donation towards the

39

1 organisation's database and that reference is
 2 HCDO0000264_057.

3 That, sir, concludes the presentation on Alpha,
 4 Abbott and Grifols for the present time, and that
 5 concludes this round of presentations on
 6 pharmaceutical companies. As you know, we will be
 7 coming back in November to look at the response to
 8 risk of those companies and, in particular, the
 9 response to the risk of AIDS. There are, of course,
 10 many other issues arising from the pharmaceutical
 11 companies that we will keep in mind and may explore
 12 further as the Inquiry progresses.

13 **SIR BRIAN LANGSTAFF:** Thank you.

14 **MR HILL:** The next course is to turn to some presentations
 15 from Ms Richards on various haemophilia centres.
 16 I note the time, sir, and wonder whether --

17 **SIR BRIAN LANGSTAFF:** Well, we will do that after we've
 18 had a break, and starting at 20 to 12. 20 to 12.

19 (11.10 am)

20 (A short break)

21 (11.41 am)

22 **Presentation by Counsel to The Inquiry on smaller
 23 haemophilia centres**

24 **MS RICHARDS:** Good morning, sir. There are a number of
 25 centres that we'll be covering today tomorrow and

40

1 Friday.
 2 I'm going to list them so that anyone listening
 3 can understand which centres will be covered this
 4 week. I am going to start with a brief update in
 5 relation to Alder Hey. I am then going to go today to
 6 a number of London centres, Great Ormond Street,
 7 Charing Cross, Westminster, St Mary's, UCH,
 8 Hammersmith, Middlesex, Northwick Park, Edgware,
 9 Hillingdon, Guy's, Lewisham and King's.
 10 If time permits, I'm then going to deal with two
 11 Haemophilia Centres which we didn't manage to get to
 12 in June, and that's Southampton and Truro.
 13 Then possibly late this afternoon but probably
 14 more realistically tomorrow morning, I'll then pick up
 15 on the south/south-west centres, and we'll be looking
 16 not necessarily in this precise order but at this
 17 cohort of centres: Bournemouth, Plymouth, Exeter,
 18 Taunton, Bath, Salisbury and Winchester.
 19 There is then a number of East Anglian centres
 20 to consider: Norfolk and Norwich, and Cambridge --
 21 both of which we had scheduled for the June hearing
 22 but didn't get to -- Ipswich, Bury St Edmunds and
 23 Peterborough.
 24 Then the remaining centres that will be covered
 25 this week are Bangor, Derby, York, Coventry,

41

1 Wolverhampton, Stoke, Shrewsbury, Hereford and
 2 Worcester.
 3 There will remain some individual Haemophilia
 4 Centres after that that we haven't looked at, but it
 5 is our intention to undertake the same exercise, in
 6 terms of looking at documents and seeing what
 7 questions we can answer, in relation to product usage,
 8 treatment policies, and so on, and we will be
 9 producing written presentations in relation to all the
 10 remaining Haemophilia Centres, which will be both
 11 disclosed to Core Participants and published on the
 12 Inquiry's website but that time hasn't permitted
 13 covering every single remaining Haemophilia Centre
 14 this week orally.
 15 **SIR BRIAN LANGSTAFF:** With that number of Haemophilia
 16 Centres, plainly what you're going to have to do is
 17 highlight the main points.
 18 **MS RICHARDS:** Yes, absolutely. So for some centres, there
 19 are almost no documents at all.
 20 For some there are quite a lot, for most there
 21 are at the very least annual returns, which assist in
 22 understanding what products were being used, although
 23 not necessarily for which categories of patients or
 24 why.
 25 We will be able to identify for the most part

42

1 who the relevant Centre Directors were at different
 2 points in time and so on. But I will be being
 3 selective in terms of the documents that we look at in
 4 the course of the hearing. The presentations notes
 5 themselves, both for the centres I cover this week and
 6 for the centres that won't get covered this week, are
 7 much more detailed than the oral presentation, so we
 8 will look at as much of the available documentation as
 9 we can uncover.
 10 **SIR BRIAN LANGSTAFF:** So, in essence, what you'll be
 11 giving me in open session will be the highlights.
 12 **MS RICHARDS:** Yes.
 13 **SIR BRIAN LANGSTAFF:** And both myself and anyone else who
 14 wishes the detail will have to go and look at the
 15 presentation?
 16 **MS RICHARDS:** Yes. And I think so far the presentation
 17 notes have been disclosed to Core Participants but
 18 haven't yet been published on the Inquiry's website,
 19 but the intention is, over the coming weeks, to
 20 publish all the presentation notes, including those
 21 delivered as long ago as last autumn, on the Inquiry's
 22 website, so that those who are not Core Participants
 23 can nonetheless see the material themselves.
 24 **SIR BRIAN LANGSTAFF:** Yes.
 25 **MS RICHARDS:** Sir, as I said, I will just start with

43

1 a brief update in relation to Alder Hey. You will,
 2 I know, recall the evidence in relation to Alder Hey
 3 Hospital from the summer, and you will recall in
 4 particular that we had two medicolegal reports,
 5 a report from Dr Savidge and a report from Dr Ludlam,
 6 looking at aspects of the treatment given to various
 7 patients at Alder Hey, in terms that I think could
 8 uncontroversially be described as critical.
 9 Reference was made to a witness statement from
 10 Dr John Martin, who was the relevant consultant and
 11 Centre Director at the most material time, and we now
 12 have that statement. We may always have had, it is
 13 possible, but the volume of material that the Inquiry
 14 has is such that certainly I didn't have it in the
 15 summer, but we have got it now and I just wanted to
 16 show the statement and just read aloud some parts
 17 of it to add to the picture in relation to Alder Hey.
 18 Soumik, it's DHSC0043164_070.
 19 Sir, you will see it is a statement from
 20 John Martin, Alder Hey Children's Hospital. He sets
 21 out his background and experience in paragraph 1, and
 22 you'll see he explains he came as a consultant
 23 paediatrician to Alder Hey in 1967 and he took over
 24 the care then of children with bleeding disorders.
 25 If we pick it up in paragraph 2, about five

44

1 lines down, he says:
 2 "In addition [so that's in addition to other
 3 work including paediatric oncology] I had
 4 responsibility for the Associate Haemophilia Centre at
 5 Alder Hey. There were no other consultants to assist
 6 me in this work. However, I received help from
 7 a Senior Registrar in Haematology. I also had a half
 8 share time of a Paediatric Registrar."

9 If we go over the page to paragraph 4, you will
 10 see he says:

11 "It was not my practice to give new members of
 12 my team a talk in relation to haemophilia care
 13 specifically. The Senior Registrars would have been
 14 reasonably knowledgeable in any event. Senior House
 15 Officers did receive some instruction from me, as
 16 necessary, and I was also able to rely upon the Senior
 17 Ward Sister, who was extremely knowledgeable on
 18 matters concerning haemophilia. However, I made sure
 19 that I was on call as much as possible so that I could
 20 advise, if necessary."

21 The next paragraph he says:

22 "5. Although at any one time we might have
 23 between 30 and 50 patients with blood coagulation
 24 disorders on our lists, we would treat in any one year
 25 no more than about 20 patients."

45

1 no instruction to use cryoprecipitate for mild
 2 haemophiliacs or that it should be the treatment of
 3 choice in particular circumstances, and as can be
 4 seen, cryoprecipitate had been phased out in the early
 5 1980s and was not generally available in the hospital.
 6 Equally I placed no restrictions on my staff
 7 concerning the use of cryo. If any member of my staff
 8 wished to use cryo on any particular occasions,
 9 subject to its availability, I felt that that was
 10 a matter for his/her judgment and I would not make it
 11 my practice to interfere. However, I took the view
 12 that Factor VIII concentrate was a lot more acceptable
 13 to all concerned: staff, children and their families.
 14 My aim was to keep children out of hospital as much as
 15 possible.

16 "8. I was on the mailing list for Haemophilia
 17 Centre Director minutes and meetings and certainly
 18 received information supplied from the Oxford
 19 Secretariat and we filled in annual returns."

20 Paragraph 9:

21 "Because of my other clinical responsibilities
 22 in the Hospital I did not attend Haemophilia
 23 Directors' meetings. I tried to keep up with
 24 developments in the medical literature."

25 Then he deals with hepatitis in paragraph 10:

47

1 Then paragraph 6 -- and you may want to read
 2 this, sir, in light of paragraph 4, where he says it
 3 wasn't his practice to give new members of his team
 4 a talk in relation to haemophilia -- he says in the
 5 second sentence of paragraph 6:

6 "The day to day care of the haemophilia patients
 7 was delegated to my staff in accordance with their
 8 various experience. If the parents brought their
 9 child into the ward during the day, then it is likely
 10 that they would have been seen by a Medical Officer,
 11 from the Paediatric, Haematology and Oncology Unit but
 12 at night time, the treatment would have been given
 13 either by my [SHO] or by the [SHO] on duty. If they
 14 felt unable to deal with the problem they consulted
 15 me. As I have said, I made it my practice to be
 16 available for as much of the time as I reasonably
 17 could and although I would have seen the patients only
 18 occasionally, I obviously had overall clinical control
 19 of their care."

20 Then he continues:

21 "7. At no [time] did I lay down a particular
 22 treatment regime to the clinical staff. Clinical
 23 judgments were made depending on presentation. No one
 24 would treat any patient with any blood product unless
 25 it was deemed to be necessary but there was certainly

46

1 "I was aware of the risk of transmission of
 2 Hepatitis through blood products from a theoretical
 3 point of view during the 1970s, however from the
 4 clinical experience at this Hospital we had little or
 5 no problem with Hepatitis being transmitted through
 6 blood products and I did not regard Hepatitis as
 7 a reason to alter any treatment regime. I was aware
 8 that imported commercial concentrates would be
 9 regarded as carrying a higher risk of Hepatitis than
 10 NHS products but the supply of one product over the
 11 other was not within my control.

12 "At this time, we did not use DDAVP. I viewed
 13 this product as of limited value, and difficult to use
 14 with small children. In the early days of DDAVP
 15 usage, there was a certain amount of disquiet over its
 16 potential side-effects especially disturbance of fluid
 17 balance in young children.

18 "We did not have many older children who
 19 required haemophilia care and therefore I did not have
 20 to consider DDAVP for use in such cases. I made
 21 a conscious decision that it was not to be used for
 22 smaller children although it was available at the
 23 hospital since it is used to treat other disorders of
 24 fluid balance, eg some forms of diabetes. The reason
 25 for my decision is that we had an established form of

48

1 treatment in place which I felt, at the time, to be
 2 safe and there was no reason to change my treatment
 3 methods. Another reason for not using DDAVP was that
 4 most children were treated as out-patients and DDAVP
 5 requires in-patient admission, something neither the
 6 children nor their parents relished. I was however
 7 aware that DDAVP could be suitable in some cases for
 8 adults who had mild haemophilia."

9 He then, in paragraph 13, describes the
 10 treatment of haemophiliacs in 1967 -- which is when,
 11 as he said, he arrives at the hospital -- as
 12 relatively straightforward. He used cryoprecipitate,
 13 essentially.

14 In paragraph 14, he says this:

15 "The development and availability of freeze
 16 dried Factor VIII concentrate revolutionised the
 17 treatment of haemophilia patients. It enabled home
 18 treatment to become more widely available and also for
 19 surgery to be considered more readily.

20 "Cryoprecipitate was supplied direct from the
 21 BTS [the Blood Transfusion Service] and we always
 22 found this to be a good and reliable source of supply.

23 However, it was largely phased out in 1980 and we
 24 went on to use concentrate."

25 Then he sets out over the next page information

1 from the annual returns, which we looked at last time
 2 and I don't propose to repeat.

3 If we then go to the bottom of the page,
 4 paragraph 16:

5 "Because of the considerable expense of
 6 Factor VIII concentrates, the Area and subsequently
 7 District Health Authority decided to purchase the
 8 commercial Factor VIII concentrate that was necessary
 9 via the Royal Liverpool Hospital (RLH). This made
 10 sense for a number of reasons. First, RLH was
 11 a Haemophilia Centre whilst Alder Hey was only an
 12 associate centre. They had greater medical expertise
 13 with a Consultant Haematologist. Indeed at the time,
 14 Alder Hey did not have the facilities to perform
 15 Factor VIII levels on our patients and we used to have
 16 these done at RLH. They were therefore in a better
 17 position to assess what products to purchase. I did
 18 not at any stage object to this system for the
 19 acquiring of Factor VIII concentrate for our needs.
 20 The RLH would then send the concentrate that we
 21 required to us.

22 "A further reason for obtaining concentrate
 23 through RLH is that a better price per unit was
 24 achieved by buying in bulk. Both hospitals were under
 25 the management of the same District Health Authority

1 and it therefore did not matter which hospital paid
 2 for the supplies."

3 If we then go to paragraph 19, please -- sorry,
 4 I should say in paragraph 18, he says that:

5 "... the specific commercial product that was
 6 bought was chosen by RLH. The commercial Factor VIII
 7 was normally Armour. During the whole of the relevant
 8 period there was never enough NHS/Elstree Factor VIII
 9 available."

10 Sir, just pausing there, the system he
 11 described, whereby products were purchased by RLH,
 12 which obviously was dealing predominantly with adult
 13 patients, and then those products were provided to
 14 Alder Hey, might suggest -- it'll be a matter for
 15 you in due course, and indeed for submission -- that
 16 consideration was not given to what might be the
 17 different treatment needs or different appropriate
 18 policies for treatment of children rather than adults.

19 That's relevant when we look at the next
 20 paragraph, where he says:

21 "I cannot recall specifically receiving the
 22 letter from the Haemophilia Centre Directors
 23 Organisation dated 24th June 1983 with recommendations
 24 as to treatment of children and mild haemophiliacs
 25 because of the potential implications for AIDS. As

1 I was on the mailing list, I am sure that I would have
 2 received it. There was no alteration in the treatment
 3 regime at this time as a result of the letter.

4 I understood the RLH was obtaining as much of the
 5 scarce NHS Factor VIII as possible."

6 Sir, I know we've looked at it on a number of
 7 occasions previously but if we can just put that
 8 24 June letter up on screen. Soumik, I hope you have
 9 it. It's HCDO000270_004.

10 Sir, you will recall the recommendations set out
 11 in the paragraphs numbered 1 and 2. 2 relates to the
 12 treatment of children, which would, of course, have to
 13 be of direct and immediate relevance to Alder Hey:

14 "For treatment of children and mildly affected
 15 patients or patients unexposed to imported
 16 concentrates, many Directors already reserve supplies
 17 of NHS concentrates (cryoprecipitate or freeze-dried)
 18 and it would be circumspect to continue this policy."

19 Reading that together with what we see Dr Martin
 20 says about the lack of any change in the approach to
 21 treatment at Alder Hey, following that letter, might
 22 give rise to two matters for your consideration and
 23 for submission in due course. The first is, would
 24 a more powerful and directive recommendation from
 25 UKHCDO, not something which has been described by more

1 than one witness as being a weak recommendation,
 2 potentially have had greater effect and led to
 3 clinicians, such as Dr Martin, taking more notice and
 4 changing the treatment plan?
 5 Secondly, even with such a "weak" recommendation
 6 as we see set out in this letter, should Alder Hey
 7 nonetheless have been alerted to the need to consider
 8 changing its treatment plan on receipt of this letter?
 9 That same question would apply to any clinician
 10 treating children or treating mildly affected patients
 11 or treating patients previously unexposed to imported
 12 concentrates.
 13 Soumik, if we can then go back to Dr Martin's
 14 statement, DHSC00 -- thank you, and go to page 6.
 15 Bottom of the page, he then deals with heat-treated
 16 products:
 17 "I was aware in December 1984 of the development
 18 of heat treated products and that they should be used
 19 from this time onwards. However, I do not
 20 specifically recall receiving the December 1984
 21 recommendation. Supplies of heat treated concentrate
 22 were inadequate initially and it was some time before
 23 we were able to obtain these easily. Heat treated
 24 products were sent to us by RLH. As I did not
 25 purchase the blood products I did not have any direct

1 occasions, dealing with contemplated surgery, where
 2 those risks might then be discussed.
 3 Again, whether that was an adequate way of
 4 dealing with the matter is no doubt a matter you will
 5 wish to consider in due course. Then, in relation to
 6 AIDS, he says this:
 7 "When I first became aware of the AIDS problem
 8 I did not wish to worry parents with what at first
 9 seemed to be a tenuous link. It was important that
 10 their children continued to receive treatment and
 11 I made a judgment based on what I felt to be in their
 12 best interests. If a parent, usually the mother,
 13 asked about AIDS, I said that there was a risk but
 14 that there were also risks associated with non
 15 treatment and that in my judgment the child should
 16 continue to receive treatment."
 17 He then turns to the individual claims, which
 18 I'm not going to go through because, again, we
 19 looked at information in relation to those -- the
 20 treatment of those individual children in the
 21 medicolegal reports which we examined in the summer.
 22 If we go to the top of the next page, however,
 23 we can pick up, by reference to what Dr Martin says
 24 about the treatment of one particular child, something
 25 about his general practice. He says -- sorry, the

1 control over the concentrates available to us."
 2 So that is potentially consistent with what we
 3 saw from the material we examined in the summer in
 4 relation to Alder Hey, which suggested that children
 5 continued to be treated with unheated concentrates
 6 after December 1984.
 7 He then goes on to deal with the question of
 8 information provided or not provided to patients and
 9 their families. He says this at paragraph 21:
 10 "I did not make it my practice to raise the
 11 hepatitis issue with families since my experience of
 12 it as a problem at Alder Hey was limited. If the
 13 parents wanted their child to undergo elective or
 14 unnecessary surgery I would try to dissuade them. In
 15 those circumstances I would quite often raise the
 16 risks associated with the use of blood products, in
 17 terms of risk of infection, including hepatitis."
 18 So it would appear from that that those who were
 19 routinely receiving blood products as part of
 20 treatment for their haemophilia care were not told of
 21 the risks of hepatitis, which is again consistent with
 22 the evidence the Inquiry has received from the
 23 families of those whose children were treated at
 24 Alder Hey. But in the circumstances then described by
 25 Dr Martin in paragraph 21, there were specific

1 very last word on the previous page -- we don't need
 2 to go back to the previous page, Soumik -- is
 3 "although". So:
 4 "Although not recorded in the notes I suspect
 5 this treatment was with commercial Factor VIII because
 6 in the annual returns it is suggested that he was
 7 given commercial Factor VIII in 1983 only. His
 8 treatment was consistent with the standard treatment
 9 being given to patients at the time."
 10 So children in 1983 treated with commercial
 11 concentrates.
 12 Then if we go to the last paragraph, this is
 13 just in relation to how parents learnt that their
 14 children had been infected with HIV.
 15 "In relation to both children, we arranged for
 16 HIV tests to be conducted on their blood samples in
 17 August 1985 and the samples were positive. I then
 18 sent out a letter ... explaining my current state of
 19 knowledge regarding the virus and arranging for
 20 counselling with the parents."
 21 So it would appear there to be consistent again
 22 with the broader evidence the Inquiry received, that
 23 parents whose children had been found to be positive
 24 for HTLV-III were told that diagnosis by letter.
 25 Sir, that is an additional document for you to

1 consider more broadly with the material relating to
2 Alder Hey, which we looked at earlier in the year.
3 Sir, I'm going to turn now to the various London
4 haemophilia centres and start with Great Ormond Street
5 Hospital. There is comparatively little documentation
6 available in relation to Great Ormond Street for
7 reasons that I'll come to in a moment.

8 In terms of the directors of the Haemophilia
9 Centre, the director during the 1970s through -- in
10 fact, I think from 1968 through to 1987 was professor
11 Roger Hardisty. He was then succeeded in 1987 by
12 Professor Ian Hann, and you heard oral evidence from
13 Professor Hann in December of last year. I am not
14 going to go to his statement again, which for the most
15 part, in fact, deals with his experiences in Scotland,
16 rather than at Great Ormond Street, but the reference,
17 for the benefit of the transcript, is, I think,
18 WITN3497005.

19 We also have a statement from Dr Lynne Ball.
20 Dr Ball's evidence largely pertains, in fact, to
21 Alder Hey and I referred to that in the summer. Her
22 statement is WITN -- again, we don't need to show it
23 at the moment -- 4739001, but she was also Honorary
24 Senior Registrar at the Great Ormond Street Hospital
25 between March 1986 and March 1988, and she has

57

1 Then there is reference in the next paragraph to
2 holding one file of documentation relevant to the 2004
3 vCJD notification exercise.

4 So that's the position in relation to
5 contemporaneous documentation from Great Ormond
6 Street. There is comparatively little directly held
7 by the Hospital Trust now, and we have received
8 also -- I don't propose to display it -- but we have
9 received a description from the Chief Executive of
10 Great Ormond Street setting out what searches were
11 undertaken, both, I think, physical and electronic, by
12 Great Ormond Street in response to the Inquiry's
13 request for data.

14 So we have had to piece together information
15 from other sources and, as indeed with most of the
16 centres, the picture is inevitably an incomplete one,
17 looked at at this distance in time from the events
18 with which we are most directly concerned.

19 We will see, from some of the documents, Great
20 Ormond Street Hospital was formerly known as the
21 Hospital for Sick Children. The haemophilia centre
22 there was based at the Department of Haematology at
23 Great Ormond Street Hospital, in Great Ormond Street
24 in London.

25 If we go to -- forgive me for a moment whilst

59

1 provided some background information in relation to
2 Great Ormond Street at that time in her statement.

3 In terms of the paucity of documentation
4 relating to Great Ormond Street, Soumik, could we have
5 WITN3774003, please. This is a letter dated
6 10 September 2018 from Great Ormond Street, from its
7 Chief Executive and from the Current Haemophilia
8 Centre Director, in relation to documentation and the
9 Inquiry's request that Great Ormond Street provide
10 documentation that holds relevant to the Inquiry's
11 terms of reference.

12 They say, in the third line:

13 "... we have been unable to locate any stored
14 relevant documentation from the 1970s/80s except
15 individual patient hospital records scanned onto our
16 electronic database and handwritten treatment ledgers
17 dated from November 1984 listing each treatment given
18 to named patients including batch numbers of the
19 products given. Since the 1980s the hospital has
20 undergone many structural changes and the haemophilia
21 centre and offices have moved location several times.
22 The physician in charge of the haemophilia centre in
23 the 1970s and 1980s -- Professor Roger Hardisty -- is
24 deceased and there is no personal paperwork from that
25 time to be found in storage."

58

1 I get the reference -- DHSC0100026_009. We see here
2 a letter written by the DHSS in December 1969 in
3 relation to Haemophilia Centres in London and it's
4 a standard letter that went to the 13 then designated
5 Haemophilia Centres in London and then we'll look --
6 as we look at the various centres, we'll look at the
7 responses that were received.

8 Sir, this is from a medical officer, Mr Obank or
9 Dr Obank, in the Department of Health and Social
10 Security:

11 "As you will know there are 13 designated
12 Haemophilia Centres in the London area dealing with
13 the diagnosis and normal care of patients suffering
14 from haemophilia and related conditions. In order to
15 enable the Department to consider what provisions are
16 required for the future development of this service
17 I am writing to all the directors of centres in the
18 area, in order to obtain an indication of the work
19 which each centre has undertaken during the period
20 since the issue of HM(68)8."

21 That was, I think, a department circular.

22 "I should therefore be obliged if you would let
23 me have information on the following points for your
24 own centre for the year ending 30 September 1969."

25 Then there are number of questions:

60

1 "The number of cases of registered with your
 2 centre as of 30 September 1969.
 3 "The number of incidents of haemorrhage at which
 4 the patients have attended at the centre for treatment
 5 during the year ...
 6 "The number of haemophiliac patients not
 7 registered with your centre who have attended there
 8 for treatment.
 9 "The number of incidents of severe bleeding in
 10 patients attending your centre.
 11 "The number of major surgical operations
 12 undertaken in patients registered with your centre
 13 during the year.
 14 "The number of patients from categories 4 and 5
 15 above who have been transferred to the Special
 16 Treatment Centre at Oxford (if patients have been
 17 referred to any of the other Special Treatment Centres
 18 please give a note of the circumstances)."
 19 Then 7:
 20 "Any general or specific comments on how the
 21 provisions of HM(68)8 are working out so far as they
 22 affect the London area."
 23 The answers that were given in relation to the
 24 various of the 13 centres therefore provide a snapshot
 25 of the picture of haemophilia care and numbers of

61

1 haemophilia patients as at the very end of 1969.
 2 If we turn to Professor Hardisty's response,
 3 it's DHSC0100026_011, we can see he explains 89 cases
 4 registered with the Centre; 527 incidents of
 5 haemorrhage; five is the number of patients who have
 6 attended there not registered with the Centre.
 7 Then I don't think we need to go through the
 8 detail of his answer to 4, but he raises the question
 9 as to what is meant by severe bleeding.
 10 Then you will see at paragraph 7, he refers to
 11 a joint memorandum from Dr Dormandy -- who you will
 12 recall was director of the Royal Free Haemophilia
 13 Centre -- Dr Ingram -- I think I'm right in saying who
 14 was at St Thomas's at the time, I'll double check my
 15 notes -- and himself.
 16 If we go just to that memorandum, again it
 17 provides a picture of haemophilia care in London.
 18 DHSC0100026_026.
 19 We will see that they explain that:
 20 "This memorandum is intended as a basis for
 21 discussion of the need to improve existing facilities
 22 for the care of patients with haemophilia and related
 23 disorders in and around London."
 24 Then says this in relation to cryoprecipitate:
 25 "With the increasing availability of

62

1 cryoprecipitate, a much more active approach can and
 2 should be taken to the treatment of minor bleeding
 3 episodes."
 4 Then goes on to talk about the functions of
 5 a Haemophilia Centre in the London area. I don't
 6 think we need to look at that.
 7 But if we go to page 4, we can then pick up some
 8 data in relation to Great Ormond Street.
 9 Sir, this is a table describing current workload
 10 at Great Ormond Street, the Royal Free, and St
 11 Thomas', and we are concerned only with Great Ormond
 12 Street for present purposes, so if we look at the
 13 right-hand column:
 14 "No. of patients under supervision ... 90
 15 "No. of patients treated ... 61"
 16 Then we have numbers of treatments: 396 is
 17 inpatients, 498 is outpatients.
 18 "Average no. of treatments per patient treated
 19 ... 14.6."
 20 Then if we go to the next page, we can see the
 21 distribution of patients at Great Ormond Street. So,
 22 in terms of haemophilia -- and it doesn't here
 23 distinguish between mild, moderate and severe
 24 haemophilia, but I take that as a reference to
 25 haemophilia A -- we see 59 patients registered, 46

63

1 treated in that January-October period. Christmas
 2 Disease, so haemophilia B: 20 registered, 11 treated.
 3 Von Willebrand's: eight registered, two treated and
 4 then miscellaneous: two registered and two treated.
 5 Then if we go to the next page, we can just pick
 6 up at the bottom of the page, under the heading "Great
 7 Ormond Street", it explains:
 8 "The number of patients registered has increased
 9 from about 60 to 90 during the last 5 years, despite
 10 the referral of patients to adult hospitals ... on
 11 attaining the age of about 12-13 years. Although
 12 figures for the number of treatments in past years are
 13 not readily accessible, it can be confidently stated
 14 that the availability of cryoprecipitate has led to a
 15 very great increase in this respect during the last
 16 2-3 years."
 17 So that's the picture as at really the beginning
 18 of the 1970s.
 19 Then if we go to DHSC0100026_084, this is,
 20 I think, a Department of Health note of a meeting held
 21 to discuss the organisation of haemophilia care in
 22 London.
 23 Again, we don't need to look at much of the
 24 detail of it. You'll note Dr Yellowlees in
 25 attendance. At this point in time, February 1970, he

64

1 was, as I understand it, the Deputy Chief Medical
2 Officer.

3 If we go over to the second page, paragraph 8,
4 which is the bottom half of the page, we can pick up,
5 in relation to Great Ormond Street, Professor Hardisty
6 describing the approach there:

7 "Professor Hardisty explained that at Great
8 Ormond Street the emphasis was on the early treatment
9 of minor bleeds in children to prevent crippling. The
10 increase in workload derived from the larger number of
11 treatments being given per patients rather than
12 increase in the number of patients. At his centre,
13 some 50% of the 89 registered patients attended
14 frequently or fairly often."

15 Then if we go to the next page, we can just see,
16 under the heading "Availability of haemophilic
17 material", paragraph 12 -- I'm sorry, Soumik,
18 I think -- yes, it's there.

19 "Dr Ingram stressed the need for additional
20 material if therapeutic treatment of haemophiliacs was
21 to continue and to expand. Dr Maycock outlined the
22 measures which had been taken to increase production
23 of this material; it was expected that in 3-4 years
24 good supplies of cryoprecipitate etc would be
25 available."

65

1 treatment of haemophiliacs had changed quite markedly
2 during the past 3-4 years due mainly to the increasing
3 availability of cryoprecipitate."

4 Pausing there, sir, I draw these materials to
5 your attention and the attention of those listening,
6 because obviously we've heard a lot about what was
7 said to be the revolutionary effect of factor
8 concentrates, but it is perhaps important to
9 understand what was said to be the very dramatic or
10 significant effect of the availability and
11 introduction of cryoprecipitate more widely in terms
12 of improving the lives of people with bleeding
13 disorders.

14 So the minute or the notes continue:

15 "This had allowed a much more active approach to
16 be taken in the treatment of minor episodes of
17 bleeding which in turn had encouraged the greater use
18 of other facilities, (eg physiotherapy and orthopaedic
19 surgery), in the prevention of crippling lesions from
20 which haemophilic patients had suffered in the past.
21 The concept of an adequate therapeutic service had
22 therefore altered radically and its provision demanded
23 much greater resources of experienced staff as well as
24 therapeutic materials. It had been suggested that
25 a Haemophilia Centre should be able to provide skilled

67

1 Then just picking up on "Conclusions" at the
2 bottom of the page, you can see it says at
3 paragraph 16:

4 "It seemed likely that St Thomas' and the
5 Royal Free would in time naturally evolve as the main
6 Haemophilia Centres [in relation to London, of
7 course]. Great Ormond Street should also remain in
8 view of its special nature and possibly Hammersmith."

9 And we will pick up the picture in relation to
10 Hammersmith later in the course of the day.

11 If we then look at OXUH0003597, we can see
12 a meeting later in 1970, so this is 15 October 1970,
13 and there are now representatives more broadly from
14 centres across London -- so not limited to
15 Dr Dormandy, Professor Hardisty and Dr Ingram -- and
16 we will see representatives there from various of the
17 Haemophilia Centres, which we'll be exploring in the
18 course of the day. I just want to pick up, towards
19 the bottom of this page, what's said as the view of
20 the department but also more broadly about the
21 approach to haemophilia care, and this really has
22 resonance not just for Great Ormond Street or London
23 but more generally.

24 "Dr Lees [that's the chair of the meeting and
25 a representative of the DHSS] said that the pattern of

66

1 treatment on demand at any time of day or night and
2 this implied having staff always available who were
3 experienced in treating these patients. The Centre
4 should also provide cover for emergency surgery and
5 should be able to undertake the assay of Factor VIII
6 potency of cryoprecipitate made at the Regional Blood
7 Transfusion Centre."

8 Then there were further discussions in the
9 document relating to the organisation of haemophilia
10 care in London more generally which I won't take time
11 going to now.

12 We can take that document down, thank you.

13 Without then going through -- repetitively
14 through lots of documents, in the course of around
15 1976 there were discussions about the organisation of
16 haemophilia care within London, and indeed within the
17 East Anglian region, as well. And this was part of
18 what was called the south-east supra-region, and it
19 was decided that overall responsibility would be split
20 as between Dr Dormandy and Professor Ingram
21 effectively along the Thames, so that for the most
22 part Haemophilia Centres north of the Thames would be
23 the overarching responsibility of Dr Dormandy and
24 south of the Thames, the overarching responsibility of
25 Professor Ingram, and Great Ormond Street appears to

68

1 have been regarded as part of the Northeast Thames
2 region.

3 However, if we go to CBLA0000510, this is
4 a document from December of 1976 and it's in relation
5 to the allocation of NHS Factor VIII concentrate to
6 regional blood transfusion centres. So the
7 arrangement within this south-eastern supra-region was
8 effectively that NHS concentrates would be distributed
9 through the blood transfusion centres -- there were,
10 I think, three blood transfusion centres within that
11 region -- and then they would be distributed according
12 to the 1974 annual returns. And we can see here now
13 that the Hospital for Sick Children -- Great Ormond
14 Street, as it became -- is regarded, for the purposes
15 of the distribution of the NHS concentrate, as being
16 within the North Thames Regional Health Authority, and
17 you can see there a reference to a distribution of
18 62 bottles a month, or an allocation of 62 bottles
19 a month of NHS factor concentrates.

20 If we then pick matters up at CBLA0000533, we
21 can see this matter, this question of how NHS
22 concentrates were going to be allocated within the
23 region, was discussed at a meeting on
24 15 December 1976, and we can see the range of
25 attendees. We will come back to some of these names

69

1 arrangements with the Department of Health, home
2 treatment using commercial concentrates.

3 Then:

4 "... (b) patients came from any of the 4 regions
5 ... and that if a different system of allocating
6 concentrate for each region had to be used, this would
7 become very complicated and therefore dangerous. As
8 far as he was concerned, it was only feasible to
9 supply concentrate to the patient or his parents or to
10 the hospital concerned with the care of the patient."

11 Then there's reference two paragraphs further
12 down to the chair, who was Dr Donald Carmichael,
13 I think, pointing out that:

14 "... the Hospital for Sick Children was in
15 a unique situation because it was a supra-regional
16 children's hospital. He asked if it could be accepted
17 in principle that the Hospital for Sick Children
18 should retain its individual status, and this was
19 agreed."

20 There are various other meetings of this
21 supra-regional entity. We'll look at them to the
22 extent that they cast any light on the individual
23 London haemophilia centres as we go through those
24 centres in the course of the day.

25 If we just look at one further document from

71

1 again when we look at some of the other London
2 centres. But we can pick up what was happening in
3 terms of the allocation of NHS Factor VIII concentrate
4 at the bottom of the page.

5 "Dr Dormandy explained that as from
6 December 1st, 1976, NHS F.VIII had been delivered to
7 the Regional Blood Transfusion Centres ... and that
8 the amount going to each was a proportion of the total
9 availability based on the number of patients reported
10 to have been treated at the Haemophilia Centres of
11 that region in 1974."

12 Then there's a discussion about this
13 distribution with the Thames as a dividing line
14 between an area for which Dr Dormandy was responsible
15 and an area for which Professor Ingram was
16 responsible.

17 If we then go on to page 4, however, we can pick
18 up the particular picture in relation to Great Ormond
19 Street. Second paragraph:

20 "Professor Hardisty said that (a) all his
21 patients on home treatment were on commercial F.VIII
22 for which the Hospital for Sick Children had a special
23 allocation from the DHSS ..."

24 That's the picture as at December 1976 with the
25 children at Great Ormond Street. Pursuant to specific

70

1 this time period, it's at BART0000689.

2 This is a meeting again of the same, I think,
3 group of individuals:

4 "... Second Meeting of Directors of Haemophilia,
5 Associate Haemophilia Society and Blood Transfusion
6 Centres, in [the Regional Health Authority areas] 04,
7 05 & 06, 23rd September 1977."

8 Professor Hardisty and -- I think it's Sieff --
9 Dr Sieff from the Hospital for Sick Children sent
10 their apologies but if we go to the bottom of the
11 second page we can see that Dr Sieff had provided
12 a letter which was then read to the meeting by
13 Dr Dormandy, and it is summarised as follows:

14 "Despite their allocation of 30 bottles NHS
15 [concentrate per] month they had needed to buy more
16 commercial [concentrate] from January to August 1977,
17 (235,000 [units]) than over the same period in 1976
18 (185,000 [units])."

19 So we see a picture in 1977 or towards the
20 autumn of 1977 of increased use of commercial
21 concentrates at Great Ormond Street Hospital.

22 I won't go to it now, but there's a further
23 meeting, the third meeting, I think, of this
24 particular group, in September 1978. For the benefit
25 of the transcript, the reference is CBLA0000838.

72

1 Again, Professor Hardisty sent his apologies and
2 Dr Rankin attended in his stead, and again, the issue
3 of shortage of concentrates was raised as a general
4 issue.

5 We will look at the actual usage of concentrates
6 at Great Ormond Street in a moment from the annual
7 returns, but before we do so can I just then pick up
8 a picture in relation to supply of NHS concentrates
9 and heat-treated concentrates, now in December of
10 1984, at CBLA0001945. And again, it gives a snapshot
11 in terms of the position by the end of '84.

12 It's a letter from Dr Evans, lecturer in
13 haematology at the Great Ormond Hospital, to Mr Pettit
14 at BPL. He says:

15 "... I am writing to you about supply of [NHS]
16 factor VIII for the haemophilia children at [Great
17 Ormond Street]. As you are aware my initial reason
18 for contacting you was because of the difficulties in
19 obtaining a sufficient amount of NHS concentrate to
20 treat our patients this month.

21 "On reviewing the records of our patients we
22 have four patients who have never received any
23 commercial concentrate but who are currently receiving
24 regular treatment with NHS factor VIII concentrate
25 ..."

73

1 requiring concentrate who we would like to have
2 heat-treated Lister ...
3 "Our present supplies from Edgware and Brentwood
4 certainly do not seem enough for our needs at the
5 moment."

6 So those are snapshots at different points in
7 time, but it would appear a common theme -- at least
8 in relation to those periods for which we have
9 documents -- a common theme in terms of insufficiency
10 of NHS supply, and supplementing that by the use of
11 commercial concentrates.

12 We can then pick that up by reference, in
13 a moment, to the annual returns. Before we do that,
14 however, I should just show you one letter, again from
15 the early 1970s, which may assist in understanding
16 Professor Hardisty's approach to treatment.

17 CBLA0008794.
18 Sir, we are now in November 1972. We looked at
19 those materials from 1969 and 1970 which suggested an
20 enthusiasm for cryoprecipitate. Here, in his letter
21 to Dr Maycock, Professor Hardisty says in the second
22 paragraph:

23 "Our present usage of cryoprecipitate is not
24 restricted by shortage, but is undoubtedly excessive,
25 since we have to compensate for the low potency of the

75

1 And then reference is made to those patients.
2 Then picking it up below the list of patients:
3 "We discussed the possibility of treating these
4 patients with either a small pool plasmapheresis
5 factor VIII concentrate or alternatively a small pool
6 heat treated concentrate. We would be interested and
7 willing to co-operate in a clinical trial of these
8 products in these particular patients."

9 Then picking it up at the bottom of the page:
10 "As you are well aware, our reason for
11 approaching you initially is that we would really like
12 to treat all the children with NHS concentrate."

13 And then the last sentence of that page:
14 "I am sure it will come as no surprise to you
15 that many of the parents of the children we treat here
16 are very anxious about the use of commercial
17 concentrate in use by their offspring."

18 That, of course, as at December 1984, will come
19 as no surprise.

20 That Great Ormond Street continued to experience
21 difficulties in terms of supply into 1985 appears from
22 CBLA0002160. This is from May of 1985. It's from the
23 haemophilia sister again to Mr Pettit at BPL. It
24 refers to:

25 "... a lost of most of our severe haemophiliacs

74

1 material we receive ... For this reason it would
2 presumably be economical of material if we were to
3 switch to Factor VIII concentrate, and I should
4 certainly prefer to use the latter material ..."

5 "To use" is crossed out I think.

6 "... for its significantly greater reliability.
7 On the other hand, since we treat most of our
8 haemophiliacs as outpatients, it is important that we
9 should be able to administer replacement therapy by
10 syringe rather than by drip; for this reason
11 cryoprecipitate of reliable potency would presumably
12 be preferred to the Factor VIII concentrate supplied
13 at present, since it could be given in a smaller
14 volume. [However], I should certainly much prefer to
15 be able to use concentrates with a higher potency than
16 those at present made, and perhaps the yield in this
17 case would not be significantly less than in the
18 cryoprecipitate we are currently receiving."

19 So if we then look at the annual returns, and
20 I won't go through all of them, we can get a sense of
21 both product usage and numbers of patients treated if
22 we look at some of them.

23 The annual return for 1976 is at HCDO0001077.

24 Sir, we can see for 1976 the total number of
25 haemophilic patients treated during the year described

76

1 as 38, Christmas Disease patients, 12.
 2 Then we can see the amount used. So
 3 cryoprecipitate still in 1976 in very considerable
 4 usage, 229,320 units; very, very modest amount of NHS
 5 Factor VIII concentrate; and then a range of different
 6 commercial concentrates used, predominantly the Armour
 7 product, Factorate, and the Immuno product, Kryobulin,
 8 but also some usage of Profilate, Koate to a very
 9 small extent, and Hemofil, and the NHS Factor IX
 10 concentrate for those treated for haemophilia B.

11 I won't go through the detail of the other
 12 documents supplied with the annual returns, but we see
 13 from them that there were 14 patients at that point in
 14 time on regular home therapy.

15 If we pick the picture up in 1977 at
 16 HCDO0001160, we can see a significant reduction in the
 17 usage of cryoprecipitate. So still used to a not
 18 insignificant extent, to approximately the same volume
 19 used as NHS Factor VIII concentrate, but rather less
 20 than the previous year, and then a significant
 21 increase in relation to some of the commercial
 22 concentrates with the largest share that year being
 23 the Cutter product Koate, at 223,000 odd.

24 Then -- sorry, I should say, just within that,
 25 if we go to page 3, please. Sir, we have seen these

77

1 kind of documents as part of the annual returns before
 2 and they show the individual treatment administered to
 3 individual patients, obviously the patient details are
 4 redacted. But what you'll see from the ticks on the
 5 right-hand side indicates that a number of patients at
 6 least, not all, received more than one, and indeed, in
 7 a number of cases, three different types of commercial
 8 concentrate in that year alone.

9 So it does not appear as though there was, at
 10 that point in time, any policy of restricting or
 11 trying to keep patients on one type of commercial
 12 concentrate, still less presumably one batch
 13 dedication at any particular point in time.

14 I won't then go through all of the remaining
 15 returns but we've set out in the presentation note in
 16 detail what the returns show.

17 Broadly speaking, 1978 shows an increase in the
 18 use of NHS concentrates but, again, the majority of
 19 concentrates in use being commercial concentrates, in
 20 particular for that year the Armour product Factorate.

21 There's a similar picture for 1979, and there's
 22 also there reference to use of the porcine product for
 23 an inhibitor patient. Then in 1980, again, it's
 24 a majority Factorate, the Armour product, that emerges
 25 from the annual returns with the next greatest in

78

1 volume being the NHS and then Kryobulin.
 2 We don't have the annual return for 1981. If we
 3 pick the picture up then, in terms of looking at the
 4 documents, in 1982, at HCDO0001620, we can see there,
 5 if we look at the handwritten entries on the
 6 right-hand side of the table, very limited usage of
 7 cryoprecipitate. Some NHS factor concentrate in usage
 8 but, by far and away, the majority of treatment is
 9 with the Armour product Factorate. So it looks like
 10 nearly a million units for home treatment and over
 11 400,000 units for hospital treatment of that Armour
 12 product.

13 Then the picture in 1983, HCDO0001717, does show
 14 increased use of NHS concentrate, and we have the
 15 figures there. We can still see the Armour product
 16 Factorate being used to a considerable extent for home
 17 treatment, albeit not in the same volume as
 18 previously.

19 Cryoprecipitate, again, is used only to a very
 20 limited extent.

21 The picture for 1984, HCDO0001812, is a little
 22 different. It's not entirely easy to work out what
 23 that handwriting for cryoprecipitate is intended to
 24 convey.

25 **SIR BRIAN LANGSTAFF:** Which?

79

1 **MS RICHARDS:** The cryoprecipitate -- obviously for
 2 von Willebrand's it's fairly straightforward with
 3 39 bags, but in terms of haemophilia A patients, we've
 4 got a figure for bags which has been written over.

5 **SIR BRIAN LANGSTAFF:** Yes, that looks like 710 bags.

6 **MS RICHARDS:** It does. And then --

7 **SIR BRIAN LANGSTAFF:** That then would translate at roughly
 8 70 units per bag to the figure which is above.

9 **MS RICHARDS:** Yes. That -- certainly, it's increased
 10 usage, albeit it's still not the majority, by any
 11 stretch of the imagination, but an increase on
 12 previous years.

13 Then we can see NHS concentrate being used, it
 14 would appear in 1984, as the main product for
 15 treatment, and a significant reduction in the use of
 16 commercial concentrates in terms of volume, and the
 17 note at the bottom seems to suggest that the Armour
 18 product that was being used was heat-treated,
 19 presumably towards the tail end of the year.

20 **SIR BRIAN LANGSTAFF:** One of the features of those last
 21 two years you've shown me may be the overall total
 22 used, by comparison with 1982. Can we just go back to
 23 HCDO0001620, and look at 1982. 43 haemophilia A
 24 patients, and it's well over 1 million units used for
 25 home treatment, and just over half or well over --

80

1 well, a bit over 500,000 in patient. Can we have
 2 a look again at 0001717?
 3 **MS RICHARDS:** Slightly fewer patients but not a huge
 4 difference.
 5 **SIR BRIAN LANGSTAFF:** No, seven less.
 6 **MS RICHARDS:** Yes.
 7 **SIR BRIAN LANGSTAFF:** So roughly a fifth less. But the
 8 usage has drop off there. It may be down to one or
 9 two patients, of course, but it's repeated, I think in
 10 1984, again.
 11 **MS RICHARDS:** Yes. We don't have -- we do for 1983. If
 12 we go on to page 4, we do have these individual
 13 sheets. Of course, I don't think they tell us volumes
 14 but we can see there a number to patients being
 15 treated with Armour but we don't have the same
 16 widespread use of multiple commercial concentrates in
 17 a given year for an individual patient that we had
 18 previously.
 19 **SIR BRIAN LANGSTAFF:** In due course, it may be that
 20 someone can have a quick look and just see if the
 21 total usage has dropped off or if there may be
 22 particular individual features that one can derive
 23 from the paperwork which shows that it might just be
 24 an individual moving on to some other hospital because
 25 of age, or other reasons.

81

1 **MS RICHARDS:** Yes. I'm not sure that we will know the
 2 answer to that. We have the data in relation to
 3 antibodies and that doesn't suggest that that is the
 4 cause. We've got the returns in relation obviously to
 5 Christmas Disease and haemophilia B. We see, as was
 6 the norm, I think, the sole usage being Factor IX
 7 concentrates. I don't think we have the individual
 8 patient data that will enable us to answer that
 9 question but we will have a look and see.
 10 **SIR BRIAN LANGSTAFF:** But there is no -- or did you come
 11 across any reflection in the documents which might
 12 have suggested that a response to the possible threat
 13 of AIDS was to reduce the total amount of any product
 14 given?
 15 **MS RICHARDS:** I'm afraid we just don't know because we
 16 don't have anything from Professor Hardisty, and we
 17 don't have any -- or we have very few internal Great
 18 Ormond Street documents. The documents we have, we
 19 have because they were correspondence to others or
 20 minutes kept by the Department of Health, rather than
 21 being Great Ormond Street documents. So there's
 22 nothing, I'm afraid, that I've seen that answers that
 23 question but, obviously, if we do find anything, we
 24 will let you know.
 25 **SIR BRIAN LANGSTAFF:** Thank you.

82

1 **MS RICHARDS:** Again, I'm not going to take time now with
 2 referring to what was set out in individual statements
 3 that we have received from patients who were treated
 4 at Great Ormond Street or from the families of
 5 children who were treated at Great Ormond Street, but
 6 the Inquiry has received a range of statements, which
 7 I know you have read and indeed have heard oral
 8 evidence, and we have summarised some of that in the
 9 written presentation note.
 10 If I turn then to the question of to what we can
 11 say was or might have been known about the risks of
 12 hepatitis and HIV, again, there's no real
 13 contemporaneous documentation that we can point to you
 14 to say this shows exactly what Professor Hardisty knew
 15 as at 1980 or 1983. What we can say is that Professor
 16 Hardisty was a regular attendee at UKHCDO meetings.
 17 We've listed in the presentation note the meetings at
 18 which we can identify him attending in person. On
 19 a number of other occasions, when he is not there,
 20 a colleague at Great Ormond Street attends on his
 21 behalf. So it can perhaps reasonably be assumed that
 22 he would be up to date at the very least with what was
 23 being discussed at the UKHCDO meetings.
 24 Again, I'm not going to go to it but you'll
 25 recall, I am sure, the oral evidence of Della

83

1 Ryness-Hirsch recalling her discussions with
 2 Professor Hardisty at Great Ormond Street in the early
 3 1980s about her concerns regarding the safety of
 4 imported factor concentrates and her sense that those
 5 concerns were not being taken seriously.
 6 Again, we have set out those references in our
 7 written note but that's all evidence that you have
 8 heard.
 9 Again, the evidence that the Inquiry has
 10 received from individuals paints a picture similar,
 11 I'm afraid, to the picture painted in relation to the
 12 other Haemophilia Centres, of patients not being given
 13 information, warnings, advice about the risks of viral
 14 infection associated either with the use of factor
 15 concentrates in general or with any enhanced risk
 16 arising from the use of imported concentrates. That's
 17 the picture that emerges fairly consistently from the
 18 individual accounts that the Inquiry has received.
 19 Dr Ball and Professor Hann, in their statements,
 20 have described their knowledge of hepatitis risks,
 21 their knowledge in relation to HTLV-III, HIV, AIDS,
 22 and of course you had also the oral evidence of
 23 Professor Hann but, in relation to Great Ormond
 24 Street, they only arrive on the scene in the second
 25 half of the 1980s. So, again, that doesn't assist in

84

1 understanding or providing any direct evidence as to
 2 what was or might have been known by
 3 Professor Hardisty and his colleagues at Great Ormond
 4 Street in the 1970s and 1980s.

5 Again, there's an absence of documentation from
 6 the hospital on the question of the process of testing
 7 patients for HTLV-III and informing them of their
 8 diagnosis and so the best evidence you have, sir, in
 9 relation to that again are the individual accounts
 10 that you have received, either from patients or from
 11 families of patients, which certainly record patients
 12 being tested for HTLV-III, as far as they were
 13 concerned, without their knowledge, and therefore
 14 without their consent.

15 In terms of how patients were told of positive
 16 diagnoses or what information they were given, Dr Ball
 17 and Dr Hann again, by the time they came on the scene,
 18 their understanding was that that process had been
 19 undertaken and so they were not able to cast much
 20 light on it. Dr Hann said he had limited memories but
 21 he did say in his statement, and you may recall, that
 22 by the time he arrived at Great Ormond Street there
 23 had been a realisation that consent processes had not
 24 been adequately applied.

25 In terms of the numbers of patients of the

1 haemophilia centre at Great Ormond Street who were
 2 infected with HIV, Dr Ball couldn't recall. She had
 3 a clearer recollection in relation to Alder Hey. She
 4 had estimated six boys and she didn't recollect any
 5 attempt to document dates of seroconversion, and she
 6 was not aware of there being stored serum samples that
 7 would have allowed a retrospective analysis to be
 8 undertaken.

9 You will recall, sir, that UKHCDO has provided
 10 the Inquiry with a table setting out from its records
 11 the data it holds in relation to numbers of patients
 12 infected. That table, again, I'll give the reference,
 13 I'm not going to go to it now -- is INQY0000250. That
 14 table suggests 11 patients infected with HIV at Great
 15 Ormond Street and it suggests one testing positive in
 16 1984, eight in 1985, two in 1987. That may reflect
 17 dates upon which patients arrived at the centre
 18 however, so isn't necessarily a completely reliable
 19 guide to the number of patients infected as a result
 20 of their treatment at the centre; but it's the best
 21 information we have.

22 In relation to hepatitis C, we don't have even
 23 that degree of information, I'm afraid. Dr Ball could
 24 not recall. Dr Hann recollected that some patients
 25 were indeed confirmed to have hepatitis C. He thought

1 that testing began soon after or, indeed, I think his
 2 statement says, immediately after validated tests
 3 became available. He says, in relation to hepatitis C
 4 and unlike his understanding of the position with HIV,
 5 patients were informed why the test was being done and
 6 that they would be called back to clinical daycare
 7 appointments to be provided with the test result
 8 rather than communicating it by letter or by
 9 telephone.

10 Of course, a number of patients -- because
 11 people transferred at a point in their teens from
 12 Great Ormond Street to the care of other hospitals,
 13 a number of patients who may have been infected with
 14 hepatitis C as a result of their treatment at Great
 15 Ormond Street may, because of the passage of time and
 16 having been transferred to an adult centre, learnt
 17 their diagnosis not from Great Ormond Street itself
 18 but from the adult centre to which they were
 19 transferred.

20 More broadly, in terms of the arrangements for
 21 care at Great Ormond Street for those infected with
 22 HIV and hepatitis C, we have some accounts from
 23 individuals in their statements, and we have referred
 24 to some of that in the written presentation note.

25 Dr Ball said this about the 1980s more

1 generally: there were no specialists in AIDS care for
 2 children with haemophilia. She says Great Ormond
 3 Street did have the advantage of the availability of
 4 other paediatric specialists, including immunologists,
 5 infectious disease specialists, and so on, and she
 6 would actively seek support from specialists caring
 7 for young adult HIV patients.

8 Dr Hann's recollection, again to similar effect,
 9 was that specialist counselling and diagnostic
 10 services became available at Great Ormond Street in
 11 due course, in collaboration with the infectious
 12 diseases and immunology teams.

13 He drew a contrast between what was available at
 14 Great Ormond Street, which had on-site access to this
 15 range of paediatric expertise, with what was available
 16 or might have been available at other centres.

17 Sir, that's an overview of the picture in
 18 relation to Great Ormond Street. As I say,
 19 notwithstanding its significance as a hospital and the
 20 relatively large number of patients it treated, we do
 21 have a paucity of documentation and limited
 22 information about the particular approach of its
 23 Haemophilia Centre Director in the 1970s and 1980s.

24 I'm going to turn next to Charing Cross
 25 Hospital. The documents that we have identify various

1 doctors associated with the Haemophilia Centre at
2 Charing Cross Hospital during the 1970s and 1980s. We
3 can see included on various annual returns the names
4 of Dr Mitchell, Dr Haworth, Dr Ranasinghe and
5 Dr Kendra.

6 We have a statement from Dr Samson, who was not
7 a director of the Haemophilia Centre but a senior
8 lecturer on haematology and worked at Charing Cross
9 Hospital in the 1980s and 1990s, from I think autumn
10 1983 until 1995.

11 Charing Cross was one of three Haemophilia
12 Centres under the umbrella of one the medical schools,
13 the Charing Cross and Westminster Medical School, and
14 the other two hospitals under that same umbrella was
15 Westminster and Queen Mary's, which I'll come on to
16 during the course of the day.

17 There were, according to Dr Samson, very limited
18 facilities for haemophilia care at Charing Cross
19 Hospital. She says it was a very small centre
20 treating only a very few patients and there was no
21 physical entity designated the Haemophilia Centre.
22 The evidence we have suggests that Charing Cross
23 treated both adults and children and, you may recall,
24 sir, evidence heard early in the Inquiry's oral
25 hearings from a witness, Mrs C, who had sons treated

89

1 Northwest Thames region, and it received its blood and
2 its cryoprecipitate -- the picture is slightly less
3 clear in relation to any commercial concentrates, but
4 its blood, its cryoprecipitate and its NHS
5 concentrates, from the North London blood transfusion
6 centre in Edgware.

7 It also had links with St Thomas' and, later on
8 in the course of the 1980s, it would appear that
9 patients who were infected with HIV were transferred
10 from Charing Cross to St Thomas'.

11 There were also links, and Dr Samson in her
12 statement has described these -- again, from her
13 perspective, from the eighties onwards -- links with
14 the Royal Free Hospital.

15 The evidence we have from those treated at the
16 hospital is limited, and our best evidence is indeed
17 the written and oral account of Mrs C, who says that
18 no warnings or advice or information about the risks
19 of treatment with Factor VIII concentrates were
20 provided to her. She told you, sir, that she was just
21 told that Factor VIII was an amazing thing.

22 In terms of product usage and numbers of
23 patients, we don't need to go to the document, but
24 I will read it for the transcript. It is
25 HCDO0000039_001. It's a note of a telephone call with

91

1 at Charing Cross, and she described how there wasn't
2 a haemophilia ward so you'd have to wait until the
3 treatment was sent down to the ward, the general ward
4 for the children.

5 In terms of its location, the Haemophilia
6 Centre, such as it was, was based at Charing Cross
7 Hospital on the Fulham Palace Road. It was formerly
8 designated an associate Haemophilia Centre later
9 in 1976, and we can pick that up if we go to
10 CBLA0000533.

11 So these are the minutes of the meeting we
12 looked at in relation to Great Ormond Street.

13 If we can pick the picture up insofar as
14 Charing Cross is concerned at page 5, halfway down the
15 page, under the heading "Organisation of Haemophilia
16 Care ... Centres", it refers, at (iii):

17 "... that Dr Mitchell (Charing Cross Hospital)
18 had asked if they could be an Associate Centre
19 although they were only 2 miles from Hammersmith, as
20 some of the consultants who looked after haemophiliacs
21 attending Charing Cross were anxious to continue to
22 look after them."

23 Again, I don't think we need to go to the
24 documents, the underlying documents at the time. But
25 we know from it that Charing Cross was part of the

90

1 Dr Mitchell in 1977 which gives a flavour of the small
2 size of the centre. It suggests one patient with
3 haemophilia was treated with cryoprecipitate and one
4 patient with von Willebrand's disease, who was
5 a visitor to the United Kingdom, was treated with
6 cryoprecipitate. So a very small centre indeed.

7 I won't, therefore, take you through most of the
8 annual returns but we'll just summarise what they tell
9 us.

10 The 1977 return shows the treatment of two
11 patients with haemophilia A with cryoprecipitate, and
12 one patient with haemophilia B with NHS Factor IX
13 concentrate. There were no commercial concentrates
14 used.

15 1978 shows five haemophilia A patients being
16 treated, predominantly with cryoprecipitate, but we
17 see the introduction of a commercial concentrate in
18 that year. A small amount of the Hyland product,
19 Hemofil, was used for treatment.

20 1979, cryoprecipitate still in use, six patients
21 treated. There are just over 40,000 units of
22 cryoprecipitate were used. A very small amount of the
23 Abbott product, Profilate, but Hyland Hemofil again
24 used, now to a greater extent, just under
25 35,000 units.

92

1 If we then, just in terms of looking at any
2 returns, pick the picture up in 1981, at HCDO0001506,
3 we can see this identifies the director in that year,
4 Dr Ranasinghe. Total number of haemophilia A patients
5 treated during the year: 7 and then, if we look at the
6 figures, we can see cryoprecipitate in use only to
7 a very limited extent, some use of NHS concentrates,
8 some use of the Armour product Factorate, the Hyland
9 product Hemofil, and the Immuno product Kryobulin.

10 There is, I think, a similar picture in 1982.
11 Again, I won't go to it, but we set out the precise
12 figures in the written note.

13 If we then just pick the picture up in 1983, at
14 HCDO0001705, we see a slightly different picture
15 emerging here for what's said to be the treatment of
16 four patients during the year. It's NHS concentrates
17 and the Armour product only, but a greater volume of
18 Armour product being used, so just under 95,000 in
19 hospital and just over 50,000 for home treatment.

20 And that, I think, is the first year for which
21 we have data suggesting that a home treatment
22 programme was under way.

23 In 1984 again, the picture is treatment with
24 NHS concentrate and with Armour concentrate.

25 Then, in relation to 1985, there's just

93

1 She couldn't recall any specific policies in
2 relation to prophylactic treatment or any specific
3 policies in relation to the treatment of children.
4 But if we go to CBLA0002018, we can see this is
5 a letter of February 1985. It's from the Charing
6 Cross Hospital to Dr Snape at BPL and it's in relation
7 to a request for heat-treated NHS concentrates to be
8 supplied from BPL. We can see there it refers to
9 three children, all of whom received prophylactic
10 Factor VIII.

11 So there clearly was a prophylactic treatment
12 policy in place at the time, and we see all three of
13 those children were on home therapy.

14 Sir, if I may, I'll just finish the picture in
15 relation to Charing Cross before we break for lunch,
16 if people don't mind a further five minutes or so.
17 There isn't an enormous amount of other documentation.

18 Again, we've no real direct information as to
19 the particular knowledge of risk of infection of any
20 of the doctors or directors at the Charing Cross
21 Haemophilia Centre. We do know that Dr Mitchell
22 attended, in the capacity of director of the
23 Haemophilia Centre at Charing Cross, several UKHCDO
24 meetings, including in 1978 and 1979. And on
25 occasions others, including Dr Ranasinghe, attended in

95

1 a correction to our presentation note. We gave
2 a figure for usage of cryoprecipitate of 71,000 units,
3 that should be NHS concentrates.

4 So, again, in 1985, we see the mix of NHS
5 concentrates and Armour concentrates being used. It
6 may be, of course, by 1985 that the Armour concentrate
7 may have been heat-treated concentrate, and we know
8 the additional complications that arose in relation to
9 the Armour heat-treated concentrates.

10 In terms of how the decisions were made as to
11 what concentrates to treat individual patients with,
12 I'm afraid we don't really have any information.
13 Dr Samson, who, as I say, came on the scene in the
14 autumn of 1983 at Charing Cross, couldn't recall how
15 or on what basis decisions were made.

16 Her recollection was that DDAVP and
17 cryoprecipitate were both available, although she
18 expressed the view in her statement that
19 cryoprecipitate wasn't really suitable for home
20 treatment. Her recollection -- and this was based
21 upon a recollection of an individual patient -- was
22 that DDAVP came to be used in preference to anything
23 else for patients with mild to moderate haemophilia
24 after the problem of HIV became apparent in around,
25 she says, 1984.

94

1 his place.

2 Dr Samson attended a number of UKHCDO meetings
3 on behalf of Northwick Park Hospital, where she worked
4 at the time, and then, at a later stage, attended some
5 UKHCDO meetings from the perspective of Charing Cross.

6 Then we can see others, Drs -- Dr Haworth for
7 example, and Dr Desai attending on behalf of Charing
8 Cross Hospital. So, although there doesn't appear to
9 be a consistent picture of attendance by one
10 clinician, it does appear that, for the most part,
11 most UKHCDO annual meetings were attended by somebody
12 on behalf of Charing Cross Hospital.

13 In terms of knowledge of risk of infection, I'll
14 pick up what Dr Samson recalls about her state of
15 knowledge when we look at Northwick Park this
16 afternoon, but she does say that she didn't know in
17 1983 that HIV could be transmitted by blood and blood
18 products. She says that really became apparent in
19 1984.

20 She does say, in relation to hepatitis, that it
21 was known that both hepatitis B and non-A, non-B
22 hepatitis could be transmitted by blood products when
23 she was working at Charing Cross, but that it wasn't
24 appreciated that non-A, non-B hepatitis could lead to
25 chronic liver disease. She can't say with any

96

1 confidence when she became aware that there was
2 a significant risk of serious liver disease.

3 Her recollection in relation to the process of
4 testing the small number of patients at Charing Cross
5 for HTLV-III was that patients wouldn't have been
6 tested without their consent but she can't recall what
7 the process was for obtaining consent.

8 Mrs C's evidence, as you'll recall, who had two
9 children under the care of Charing Cross Hospital, was
10 that she did not give her consent to treatment and
11 wasn't aware of the children being test for HTLV-III.

12 In terms of hepatitis C, Dr Samson did not
13 recall when testing began or whether any haemophilia
14 patients were tested for hepatitis C. That may be
15 a reflection of the very small numbers who were being
16 treated under the auspices of the Haemophilia Centre.

17 We don't, I'm afraid, have, therefore, any clear
18 picture as to the precise numbers of patients infected
19 with hepatitis C or HIV in consequence of their
20 treatment for their haemophilia care. The table we
21 received from UKHCDO doesn't contain any information
22 regarding Charing Cross Hospital, in terms of HIV.
23 Dr Samson, however, recalled two children being
24 infected with HIV at Charing Cross Hospital.

25 Their treatment was, as far as she recalls, then

97

1 was the director in 1968 to 1979; succeeded by
2 Dr Barrett, who was director from around 1979 to 1988;
3 and then Dr Costello took over as director from, we
4 understand, 1989.

5 Dr Giangrande, who, of course, you heard from in
6 connection with his later work at the Oxford
7 Haemophilia Centre, was a registrar at the Westminster
8 Hospital under Professor Barrett for a period of time
9 late 1983 to late 1984.

10 His recollection in terms of the staffing and
11 facilities as at the autumn of 1983, in Westminster,
12 was that there were two consultants, three junior
13 doctors, a transfusion laboratory, a small research
14 laboratory, and two clinic rooms where outpatients
15 could be treated. That was in terms of a general
16 haematology department, not specifically dedicated to
17 the Haemophilia Centre.

18 It was based, the Westminster Hospital, in Dean
19 Ryle Street in London, and it was one of the 13
20 designated Haemophilia Centres in the London area as
21 at 1970.

22 Westminster fell within the Northwest Thames
23 region, so in terms of Regional Health Authority
24 responsibilities, that's region 5. In terms of
25 distribution of NHS concentrates, we have seen

99

1 transferred to the Haemophilia Centre at St Thomas's
2 Hospital and there was no or little ongoing
3 involvement from Charing Cross, and that's consistent
4 with the individual evidence that we received. That's
5 the extent of the picture we currently have, sir, in
6 relation to Charing Cross Hospital .

7 We can pick up Westminster Hospital after the
8 break.

9 **SIR BRIAN LANGSTAFF:** Very well. Well, let's take a break
10 then now until 2.05. 2.05.

11 (1.05 pm)

(The luncheon adjournment)

12 (2.05 pm)

13 **MS RICHARDS:** Sir, before I turn to Westminster Hospital's
14 Haemophilia Centre, this morning when I referred to
15 the table of data which provides information about the
16 numbers of cases of HIV associated with particular
17 Haemophilia Centres, which was INQY0000250 -- we don't
18 need to put it up, Soumik -- I think I said it was
19 provided by UKHCDO. The table itself was not provided
20 by UKHCDO, it was compiled by the Inquiry on the basis
21 of the data supplied by UKHCDO. So I just wanted to
22 make that clear.

23 So, I turn to consider now the Haemophilia
24 Centre at the Westminster Hospital; Professor Humble
25

98

1 documents which suggest that, as at 1976, six bottles
2 of NHS Factor VIII were allocated to Westminster
3 Hospital.

4 But in fact, if we look at CBLA --

5 **SIR BRIAN LANGSTAFF:** Is that per month?

6 **MS RICHARDS:** Per month, sorry, yes.

7 If we look at CBLA0000657, this is one of the
8 meetings of haemophilia directors, associate
9 haemophilia directors, and directors of blood
10 transfusion centres from the regional health authority
11 areas, areas 4, 5 and 6. This meeting is
12 23 September 1977.

13 If we go to page 4, we can see towards the
14 bottom of the page, there's a reference there to
15 Professor Humble. So although Westminster, as I
16 understand it, notionally fell within the Northwest
17 Thames region, it actually received its allocation
18 from the south London blood transfusion centre, and we
19 can see that from:

20 "Professor Humble ..."

21 So two entries up from the bottom of the page:

22 "... (Westminster): NHS [concentrate] was
23 supplied by Dr Rogers, South London BTC [so blood
24 transfusion centre] and the allocation was
25 satisfactory. No commercial [concentrate] had been

100

1 bought."
 2 So that's the picture as at September 1977.
 3 In terms of numbers of patients treated at the
 4 Centre, we don't need to go to the underlying
 5 documents but again we have a snapshot as at the end
 6 of 1969, beginning of 1970 in a letter from
 7 Professor Humble to the Department of Health.
 8 I'll just give the reference for the benefit of
 9 the transcript. It's DHSC0100026_024. We don't need
 10 to go to it but it shows that at that point in time
 11 there were 13 registered patients at the Centre, there
 12 had been 14 incidences of haemorrhage for which
 13 patients had attended, and there were no patients who
 14 had attended for severe bleeding.
 15 If we look at BPLL0008111, please, you'll see
 16 this was a survey undertaken by Dr Maycock at BPL in
 17 or around November 1972, and there are pages for
 18 a range of different Haemophilia Centres.
 19 For present purposes, the relevant page is
 20 page 32. And we can see this is the letter that was
 21 addressed -- sorry, if we just look at the very top
 22 left-hand corner -- to Dr Humble, haematology
 23 department, Westminster Hospital. The letter is
 24 headed "Factor VIII Concentrate for treatment of
 25 Haemophilia", and it says:

1 "Factor VIII concentrate is supplied as
 2 a freeze-dried preparation in bottles containing from
 3 400 to 600 units. At present the supply is
 4 insufficient for all needs."
 5 Then Dr Maycock addressed a number of questions
 6 to a range of Haemophilia Centres which were the
 7 recipients of this letter:
 8 "How many patients with haemophilia do you treat
 9 regularly?"
 10 We will see the answer in relation to
 11 Westminster as at the end of 1972 was three.
 12 Then there is a question:
 13 "Would you prefer to use for the treatment of
 14 your patients
 15 "(a) Cryoprecipitate?
 16 "(b) Freeze-dried concentrate?"
 17 Or:
 18 "(c) Some cryoprecipitate and some freeze-dried
 19 concentrate?"
 20 You can see that Dr Humble's preference was for
 21 freeze-dried concentrate. He answered "Yes," to
 22 question 2(b) and "No" to questions 2(a) and (c).
 23 Then, if we go further down the page, Dr Maycock
 24 was asking for estimates in terms of how many bottles
 25 would be needed annually.

1 So that's Dr Humble's preference as at the end
 2 of 1972.
 3 In terms, then, of what the returns show as to
 4 the numbers of patients treated, I won't go through
 5 all the returns. Broadly speaking, we have the
 6 returns from 1976 through to 1986, and we've
 7 summarised what they show in our written presentation
 8 note.
 9 There are perhaps up to four patients with
 10 haemophilia A treated on an annual basis on average --
 11 or, sorry, at a maximum. I think, some years it's one
 12 or two patients treated. Usually one patient with
 13 haemophilia B, one patient with von Willebrand's
 14 disease. That's the kind of figures that emerge from
 15 the annual returns.
 16 If we then look at what the returns show in
 17 terms of the products that were used for the treatment
 18 of that small cohort of patients, 1976 shows
 19 cryoprecipitate being used to be for the treatment of
 20 haemophilia A, and NHS Factor IX concentrate for the
 21 treatment of haemophilia B. Plasma and
 22 cryoprecipitate for the treatment of von Willebrand's
 23 disease.
 24 1977 shows cryoprecipitate and NHS concentrate
 25 being used for the treatment of haemophilia A and NHS

1 Factor IX concentrate for the treatment of
 2 haemophilia B. So there were no commercial
 3 concentrates in use in 1976 or 1977.
 4 The first use of commercial concentrates emerges
 5 in 1979, when we see 40,000 units of the Immuno
 6 concentrate, Kryobulin, appearing for the first time
 7 on the annual return.
 8 In 1980, we see, again, usage of Kryobulin, but
 9 also the Armour product, Factorate, and the NHS
 10 Factor VIII concentrate all being used for the
 11 treatment of patients with haemophilia A. Again, the
 12 pattern in relation to the haemophilia B patient is
 13 NHS Factor IX concentrate, and in relation to
 14 von Willebrand's, it's a mixed picture that emerges
 15 from the returns. In that particular year, Armour
 16 product is in fact used to treat the von Willebrand's
 17 patient.
 18 1981 shows some cryoprecipitate being used but
 19 also NHS Factor VIII concentrate and the Armour
 20 product. Likewise, 1982, no cryoprecipitate in use
 21 but NHS Factor VIII concentrate and the Armour
 22 Factorate concentrate.
 23 Again, the volumes for all these returns are
 24 relatively small, reflecting the small number of
 25 patients.

1 In relation to 1983, again we see a combination
2 of NHS Factor VIII concentrates and Armour concentrate
3 being used in relation to haemophilia A, the fairly
4 usual picture of NHS Factor IX concentrate being used
5 for the treatment of haemophilia B.

6 So it's a mix of NHS and commercial concentrates
7 in relatively small volumes until 1984.

8 In 1984, six haemophilia A patients were
9 treated. The only treatment identified in the annual
10 returns in 1984 is NHS Factor VIII concentrate. And
11 that's a similar picture for the patients with
12 von Willebrand's who were treated that year with some
13 cryoprecipitate and with some NHS Factor VIII
14 concentrate.

15 In terms of knowledge of risk of hepatitis or
16 knowledge of risk of HTLV-III/AIDS on the part of the
17 clinicians at Westminster, there's no contemporaneous
18 direct material that the Inquiry has, so again it may
19 be a question of drawing inference from attendance at
20 or receipt of UKHCDO minutes.

21 Professor Humble was not a regular attender
22 at UKHCDO meetings, although the minutes do record his
23 formal apologies on a number of occasions, and it may
24 be a reasonable assumption that he would have received
25 the minutes of the meetings.

105

1 author of a textbook called Blood Transfusion in
2 Clinical Medicine, and he was a member of a number of
3 committees relating to blood products, blood and
4 transfusions, and we will no doubt come across his
5 name again when our hearings move to consider the role
6 of the blood services and the --

7 **SIR BRIAN LANGSTAFF:** Just for the sake of the transcript,
8 I think that was 1966, was it?

9 **MS RICHARDS:** From around 1968 to 1979.

10 **SIR BRIAN LANGSTAFF:** 1968?

11 **MS RICHARDS:** Yes.

12 **SIR BRIAN LANGSTAFF:** Yes, because I think you may have
13 said '86.

14 **MS RICHARDS:** Oh, I'm sorry.

15 **SIR BRIAN LANGSTAFF:** Thank you.

16 **MS RICHARDS:** He was then succeeded by Professor
17 Wickramesinghe and Dr Dodsworth, who were co-directors
18 of the centre at St Mary's from 1979 and through into
19 the 1980s.

20 We know from material that the Inquiry has that
21 Dr Dodsworth was a member of a working group on trends
22 in the demands for blood products in the course of
23 1977.

24 In terms of other personnel at St Mary's
25 Hospital more broadly, Dr Anthony Pinching was an

107

1 From time to time other clinicians attend the
2 meetings on his behalf. And that's true of a number
3 of meetings in the course of the 1970s and the early
4 1980s, including, on occasion, Dr Giangrande, as you
5 may recall from his oral evidence. But that, I'm
6 afraid, is the limit of the direct evidence we have --
7 or, indeed, the indirect evidence we have in relation
8 to developing knowledge of risk.

9 We don't have any information about, amongst the
10 small cohort of patients, the number infected with
11 hepatitis C. The data that we received from UKHCDO
12 indicates one patient infected with HIV, testing
13 positive in 1985.

14 And we don't, I'm afraid, have information about
15 what the arrangements were for testing that small
16 number of patients or how diagnosis/test results were
17 communicated to patients or what the arrangements were
18 for their treatment and care. So a relatively limited
19 picture regarding Westminster, but perhaps
20 unsurprising given the small size of the Haemophilia
21 Centre there.

22 We turn then next to St Mary's Hospital,
23 Paddington. In terms of the directors of the centre,
24 Professor Mollison was director of the centre from
25 1986 (sic) or thereabouts until 1979. He was the lead

106

1 immunologist at St Mary's who was heavily involved in
2 early development in the course of the 1980s in
3 relation to AIDS, and we've certainly seen his name
4 more generally come up in a number of documents. So
5 not based at the Haemophilia Centre, but a source of
6 information in relation to AIDS potentially at the
7 hospital more generally.

8 St Mary's Haemophilia Centre was based at
9 St Mary's Hospital in Paddington in London. Again, it
10 was one of the 13 designated Haemophilia Centres in
11 the London area identified and listed in 1970.

12 It was part of the Northwest Thames region,
13 region 5, but it received its Factor VIII concentrate,
14 and no doubt presumably also its cryoprecipitate, from
15 the North London blood transfusion centre in Edgware.

16 The allocation as at late 1976 within the
17 Northwest Thames region of NHS concentrate provided
18 for 15 bottles per month to be made available to
19 St Mary's Hospital.

20 And we have the minutes of a meeting at
21 CBLA0000657 -- we don't need to turn this up, Soumik,
22 it is really just for the benefit of the transcript --
23 in September 1977. It is one of those meetings of
24 directors of Haemophilia Centres, associate centres,
25 and blood transfusion centres that we've already

108

1 looked at.
 2 It records Dr Dodsworth at St Mary's saying that
 3 they wanted to start two patients on home therapy, and
 4 that they required for that purpose an allocation of
 5 NHS concentrate.

6 So that gives us a snapshot of the picture in
 7 terms of September 1977. It might suggest that home
 8 therapy had not been instituted before that.

9 If we then, again, just in terms of the
 10 relatively limited available information we have about
 11 St Mary's, turn to DHSC0100026_014.

12 This is a letter of 23 September 1969 from
 13 St Mary's department of haematology, to Dr Obank at
 14 the DHSS and you'll recall we looked this morning, in
 15 relation to Great Ormond Street, at the text of
 16 Dr Obank's letter asking a number of questions sent
 17 out to the various Haemophilia Centres, and the
 18 St Mary's response to that is set out here. It tells
 19 us that there were 16 cases registered at the centre,
 20 there were 84 incidents of haemorrhage for which
 21 patients attended the centre for treatment -- that's
 22 in the year ending 30 September 1969 -- two incidents
 23 of severe bleeding, no major surgical operations
 24 undertaken.

25 For the benefit of the transcript, that's

1 a response to the letter from Dr Obank that appears at
 2 DHSC0100026_009.

3 So not as small a Centre as some of the others
 4 that we have looked at but not a large centre.

5 If we look at BPLL0008111 -- again, this is the
 6 document we looked at a few minutes ago in relation to
 7 Westminster -- and we go to page 21 this time, we'll
 8 see here Professor Mollison's response on behalf of
 9 the Haemophilia Centre at St Mary's in November 1972
 10 to Dr Maycock's questionnaire:

11 "How many patients with haemophilia do you treat
 12 regularly? 13."

13 Then, in answer to the question about preference
 14 for the treatment of patients, he says "No" to
 15 cryoprecipitate, "No" to a mix of cryoprecipitate and
 16 freeze-dried concentrate, and "Yes" to freeze-dried
 17 concentrate. So the preference there being expressed
 18 was for concentrates.

19 And if we just look further down the page, we
 20 can see the estimated usage there set out by
 21 Professor Mollison.

22 In terms of the information from the annual
 23 returns, we've summarised in the written note what the
 24 annual returns show for each year from 1976 through to
 25 1988.

1 Sticking with the period from 1976 to 1986 for
 2 present purposes, what they show in terms of the
 3 number of patients treated are as follows: between
 4 five and twelve patients with haemophilia A -- so the
 5 figures range, depending on the particular year, but
 6 that's an indication of the magnitude; up to five
 7 haemophilia B patients; and occasionally one patient
 8 with von Willebrand's, treated on an annual basis.

9 We have no direct evidence in relation to
 10 treatment policies, again, and, sir we can look only
 11 at the annual returns and what they tell us about
 12 blood product usage.

13 1976, for example, shows cryoprecipitate and NHS
 14 concentrate in use. The first commercial concentrate
 15 appears to have been used in 1979 and, if we just look
 16 at that, it's HCDO0001373, please.

17 We can see this is the return completed for
 18 St Mary's by Dr Dodsworth, nine patients with
 19 haemophilia treated in that year -- with haemophilia
 20 A, I should say. Four patients with haemophilia B.

21 We can see there usage of cryoprecipitate, the
 22 estimate is 69,200 units of cryoprecipitate. Use of
 23 NHS factor concentrates just over 40,000. And then we
 24 can see some commercial products being used. So
 25 a relatively small amount of the Armour product,

1 Factorate, just over 7,000 units, and a larger volume
 2 of the Immuno product Kryobulin, 34,335 units.

3 So that's the beginning of the use of commercial
 4 concentrates at St Mary's.

5 There's a similar picture in 1980, I won't take
 6 you to that. It shows some use of cryoprecipitate
 7 still, usage of NHS factor concentrate, and then use
 8 of the Armour and the Immuno products.

9 The 1981 annual return again shows use of
 10 cryoprecipitate, NHS Factor VIII concentrate, Armour's
 11 Factorate and Immuno's Kryobulin. But the precise
 12 figures are too faint to read with any confidence.

13 Again, a similar picture emerging in 1982, in
 14 terms of the commercial concentrates used. Armour's
 15 product is used, Immuno's is used, NHS Factor VIII
 16 concentrate is used. No cryoprecipitate appears to be
 17 used in that year except for the treatment of patients
 18 with von Willebrand's and for the treatment of the
 19 patient with Factor VIII antibodies.

20 If then we pick the picture up in relation to
 21 1983, and the reference there is HCDO0001766, please,
 22 Soumik. We can see there seven, and then it's crossed
 23 out, "?6" patients treated during the year with
 24 haemophilia A, one von Willebrand's.

25 Then if we look at the figures, what they appear

1 to indicate for that year is significantly more NHS
 2 concentrate used than commercial concentrate. Again,
 3 it's not possible -- because all we have are the
 4 returns -- not possible to know the reason for that
 5 and whether that reflects a conscious decision on
 6 grounds of safety or for some other reason, or whether
 7 it's simply reflective of what was made available to
 8 the Centre.

9 **SIR BRIAN LANGSTAFF:** So the -- one of the -- the one that
 10 you last showed me with Armour and Immuno and NHS
 11 concentrate, they were about 50 per cent each of the
 12 total concentrate. This is about 2:1.

13 **MS RICHARDS:** Yes.
 14 Then there's a slight oddity with the annual
 15 return for 1984, which is probably easiest to explain
 16 by looking at it. So it's HCDO0001860.
 17 If we just look at the top of the page, we can
 18 see we're talking about St Mary's, eight haemophilia A
 19 patients treated, one von Willebrand's patient, and
 20 someone's written at the top:
 21 "It's very difficult to distinguish between in
 22 and outpatient use."
 23 But if we then look at the figures, they appear
 24 to be implausibly high, given the number of patients
 25 treated. They bear no resemblance in terms of volume

113

1 to figures in previous years.
 2 Figure for the use of NHS concentrate, for
 3 example, seems to be 1.8 million.

4 **SIR BRIAN LANGSTAFF:** Is that that's the -- is that the
 5 addition? It's the addition, I think, of the two. If
 6 you add --

7 **MS RICHARDS:** That looks about right, yes.

8 **SIR BRIAN LANGSTAFF:** -- 826 and 986 you get -- and 035,
 9 650, you get 1,812,685. So I think it's using the
 10 total.

11 **MS RICHARDS:** I think that's right.
 12 Again, it seems to bear no relationship with the
 13 number of patients treated or with the usage in
 14 previous years, where I haven't gone through each of
 15 the returns but the magnitude is in the tens of
 16 thousands rather than the hundreds of thousands.

17 **SIR BRIAN LANGSTAFF:** It's staggering higher than the
 18 commercial.

19 **MS RICHARDS:** Yes. So probably not a reliable piece of
 20 data but I wanted to display it on screen so you could
 21 see for yourself what was there set out. As I say, it
 22 seems implausibly high.

23 **SIR BRIAN LANGSTAFF:** Does it say "estimate" there?

24 **MS RICHARDS:** It does say "estimate" and it refers to
 25 a letter of 23 April 1985, but I don't think we have

114

1 traced that letter. In any event, as an estimate, it
 2 still wouldn't seem to make sense, because one would
 3 have thought if one was going to estimate one would
 4 estimate, in part, based on previous usage and
 5 conscious of the number of patients likely to be
 6 treated in the course of the year, which was always
 7 consistently a low number.

8 **SIR BRIAN LANGSTAFF:** Hmm.

9 **MS RICHARDS:** In any event, it is what it is. The 1985
 10 annual return shows the use only of NHS concentrates,
 11 both Factor VIII for haemophilia A and Factor IX for
 12 haemophilia B.
 13 In terms of --

14 **SIR BRIAN LANGSTAFF:** In 1985 they managed to get NHS
 15 Factor IX?

16 **MS RICHARDS:** Yes, I'm pretty sure that's right. Let me
 17 check, HCDO00001955. So that's haemophilia A. You'll
 18 see there only NHS concentrates. If we go over the
 19 page, haemophilia B, three patients treated, and
 20 you'll see it's home treatment, and it's entirely NHS
 21 Factor IX concentrate apparently.
 22 Of course, that may mean that it was not heated.

23 **SIR BRIAN LANGSTAFF:** Yes.

24 **MS RICHARDS:** In terms then of knowledge of risk, again
 25 our only real guide is attendance at UKHCDO meetings,

115

1 receipt of UKHCDO minutes. So even prior to becoming
 2 director of the centre, Dr Dodsworth attended meetings
 3 on behalf of Professor Mollison on a number of
 4 occasions throughout the 1970s. There's no record of
 5 Professor Mollison himself attending in person the
 6 UKHCDO meetings.
 7 Then Dr Dodsworth attends in her capacity as
 8 director, again on a fairly regular basis from 1979
 9 onwards. There is one document with Dr Mollison that
 10 it may be worth looking at on this issue. It's
 11 PRSE0001960. These are the minutes of a meeting at
 12 the Medical Research Council on 12 February 1979.
 13 We've looked at the minutes of this meeting for
 14 different purposes on an earlier occasion, and we can
 15 see that the list of attendees identify there
 16 Professor Mollison as being the chair, and then there
 17 are a number of other, one might say, distinguished
 18 attendees so we've got Dr Craske, we've got
 19 Professor Sherlock, we've got Professor Zuckerman,
 20 we've got Sir William Maycock all in attendance.
 21 We can see from the second paragraph that there
 22 is then a discussion initiated by the chair, so
 23 initiated by Professor Mollison, about non-A, non-B
 24 hepatitis.
 25 Again, I won't go through it in detail because,

116

1 as I say, we've looked at it previously but, for
2 present purposes, if we just go over the page, picking
3 it up in the second line, we see there
4 Professor Zuckerman pointing out that:

5 "... much non-A non-B associated
6 [post-transfusion hepatitis, that's PTH] might be
7 anicteric, and that the risk of progression to chronic
8 liver disease remained, however mild the initial
9 infection."

10 Then it records:

11 "Professor Sherlock, agreeing with Dr Cleghorn
12 that PTH was rare in the [UK but] was nevertheless
13 concerned about the continued use here of blood
14 products of commercial origin. Many of these products
15 were prepared in the United States, using blood from
16 professional donors, and they carried a high risk of
17 transmitting non-A, non-B hepatitis."

18 Then the discussion continues.

19 So, although Professor Mollison was not
20 a regular attendee at UKHCDO meetings, he was a member
21 of various committees in which issues such as non-A,
22 non-B hepatitis and risks from transfusion were
23 discussed, and we see there one such example.

24 Then just picking matters up with Dr Dodsworth's
25 later reflections, this is on the question of supply

117

1 of concentrates more generally, if we go to
2 RLIT000022. This is a document we've looked at again
3 on a number of occasions in relation to contributions
4 from different clinicians. It was a seminar held at
5 the Wellcome Institute in February 1988 -- sorry,
6 1998, and the topic was "Haemophilia: Recent History
7 of Clinical Management".

8 Dr Dodsworth was one of the participants in the
9 seminar. Although she doesn't say an awful lot in
10 comparison to some of the other contributors, we don't
11 have very much so it is worth looking at what she does
12 say. If we go, first of all, to page 39, please.

13 We see there the entry "Dr Helen Dodsworth", she
14 says:

15 "I used to work at St Mary's Hospital, London
16 after working in Manchester, alongside Dr David Evans.
17 May I say briefly something about the availability of
18 factor VIII concentrate? Although the manufacturing
19 process was discovered in the early 1950s, there was
20 never adequate provision for manufacture of
21 factor VIII concentrate in this country until the
22 early 1970s."

23 Then she refers to the MRC unit on the Elstree
24 site, in the early 1970s.

25 Then the next paragraph, she says this:

118

1 "In 1976 Pat Mollison, for whom I was working at
2 the time, asked me to represent him on a committee
3 convened to advise the Department of Health on how
4 much factor VIII concentrate and albumin were needed
5 to treat patients in the UK."

6 That's the Committee on Trends or the Working
7 Group on Trends in Usage of Blood Products that I
8 referred to a few minutes ago.

9 "Our spokesman, Dr Tovey, the director of the
10 Bristol Transfusion Centre, had been through a similar
11 exercise for the World Health Organisation in Geneva.
12 He persuaded us that if we wanted to treat our
13 patients adequately, it would be necessary to
14 fractionate at least 80 per cent of the blood that was
15 donated. At this point the Government decided that
16 money was available for neither extending the
17 fractionation unit at Elstree nor for equipping the
18 transfusion centres to separate yet more plasma from
19 donor units. So this is really why we found ourselves
20 buying large quantities of factor VIII concentrate
21 from America, and why we infected so many of our
22 patients with HIV."

23 Then I won't take you to it, but her second
24 contribution to the seminar is at page 71, and she
25 talks there about there being insufficient plasma for

119

1 fractionation as a further problem.

2 In terms of numbers of patients treated at
3 St Mary's at the Haemophilia Centre and infected with
4 HIV, the data the Inquiry has received from UKHCDO
5 suggests three patients testing positive for HIV: one
6 recorded in 1984, that may be an indication of
7 a relatively early testing or may be a test on stored
8 sera, we don't know which; and two patients in 1985.

9 There are also documents which show Dr Dodsworth
10 reporting to Ms Spooner at Oxford in 1990 and in 1993,
11 cases of hepatitis. The 1990 case is described as
12 a case of non-B hepatitis in a patient with
13 von Willebrand's disease, who is recorded as having
14 received buckets of cryo plus some Factor VIII
15 concentrate, and the 1993 case is described as a case
16 of hepatitis C in one of the patients of the
17 Haemophilia Centre at St Mary's.

18 So that's the available information again in
19 a snapshot, in relation to the Haemophilia Centre at
20 St Mary's.

21 Sir, I'm going to turn next, sir, to consider
22 University College Hospital, UCH. So the information
23 that we have in relation to the identity of the
24 directors of the Haemophilia Centre at UCH, during the
25 1970s and 1980s are Professor Pranker, from around

120

1 1968 to 1977, and then Dr Richards from around 1977 to
2 at least 1989.

3 We also have some evidence relevant to UCH from
4 Dr Paula Bolton-Maggs, who was a registrar at UCH for
5 periods in the 1980s. She describes the facilities in
6 her statement and I won't put the statement up but let
7 me just read the reference. It's WITN416001, and she
8 describes the facilities at UCH as follows:

9 "The haemophilia patients would usually be seen
10 as outpatients in the haematology department. As far
11 as I recall, there was no formal Haemophilia Centre at
12 UCH."

13 The haematology department at UCH was based at
14 Gower Street in London and, again, UCH is one of those
15 13 Haemophilia Centres in the London area designated
16 as such in or by 1970. It formed part of the
17 Northeast Thames region, so that's region 6, as
18 identified in various contemporaneous documents. If
19 we look at CBLA0000533, we can see again, this is one
20 of the sets of minutes of meetings of Directors of
21 Haemophilia Centres and Blood Transfusion Centres for
22 the Regional Health Authorities covering regions 4, 5
23 and 6, the date of this meeting is 15 December 1976.

24 If we go to the bottom of the second page, this
25 is in the context of a discussion about allocation and

121

1 might have fallen within a certain -- sorry, to
2 centres that might have fallen within a certain
3 Regional Health Authority area but didn't fall within
4 what the blood transfusion centre regarded as its
5 geographical or territorial remit.

6 Then we see at these regular meetings, or these
7 annual meetings, attendance usually by somebody on
8 behalf of University College Hospital. If we pick the
9 picture up at the 1977 meeting CBLA0000657, this is
10 the meeting on 23 September 1977.

11 If we go to the second page the list of
12 attendees, the name is about 15 or 20 names down,
13 shows Dr McVerry, who obviously we've come across in
14 relation to other Haemophilia Centres later, attending
15 for Professor Pranker, representing University
16 College Hospital. If we go to the bottom of the next
17 page, we look at the last few lines, it records
18 Dr McVerry saying this:

19 "UCH needed 40-45 bottles NHS [concentrate
20 a month] as they now had 3 more patients on HT [home
21 treatment]. They were currently purchasing 20-25
22 bottles ... of Hemofil [a month] to make good this
23 shortfall. They wanted 20-25 extra bottles of NHS
24 [concentrate a month]."

25 Then there's a response from Dr Dormandy which

123

1 which blood transfusion centre would supply which
2 Haemophilia Centres with NHS concentrates or
3 cryoprecipitate. If we pick it up towards the bottom
4 of the page, we can see there reference to "RHA 06
5 [North-East] Thames", and it says here:

6 "The distribution area of the Brentwood
7 [Regional Blood Transfusion Centre], 'the Brentwood
8 Parish', does not include the whole NET 'North East
9 Thames' region. There are 3 Haemophilia Centres and 4
10 Associate Centres in RHA 06. Only one of these
11 Haemophilia Centres (the London hospital) and all 4
12 Associate Centres are in the Brentwood Parish. The
13 RFH [presumably the Royal Free Hospital] and UCH
14 [University College Hospital] are both in the
15 [North-East Thames Regional Health Authority] but
16 outside the Brentwood Parish. Adjustments need to be
17 made to the allocation of NHS [Factor] VIII
18 concentrate to Brentwood and Edgware if each Director
19 is to supply only his own 'parish'."

20 So you see there a parochial -- is probably
21 precisely the accurate term -- a perhaps parochial
22 attitude on the part of the directors of the Regional
23 Blood Transfusion Centres, not wanting to be in
24 a position of having to supply cryoprecipitate
25 possibly or certainly NHS concentrates to areas that

122

1 says that the addresses of the patients should be
2 taken into account in deciding whether Brentwood or
3 Edgware should supply the extra needed.

4 So we can see there, in any event, UCH reporting
5 a shortfall in NHS concentrates which they were making
6 good through the purchase of commercial concentrates.

7 That issue of shortfall was raised again at the
8 annual meeting the following year, of the same group
9 of directors, in September 1978. We don't need to go
10 to it, but the reference, for the transcript, is
11 CBLA0000838.

12 Again, just looking at a snapshot, as at the
13 beginning of the 1970s, if we go to DHSC0100026_014,
14 we have ... I'm sorry, that's the wrong reference.
15 That's the reference again to St Mary's.

16 I will try and find the correct reference for
17 the transcript but I will just tell you what the
18 answers were from Professor Pranker.

19 Sorry, Soumik, we can take that down.

20 So the snapshot given by Professor Pranker was
21 29 cases registered at the Centre. There had been in
22 the year with which the request was concerned,
23 32 incidents of haemorrhage, four incidents of severe
24 bleeding, four major surgical operations undertaken in
25 patients registered with the centre. So that's the

124

1 picture as at the beginning of the 1970s.
 2 If we then go to BPLL0008111, again this is
 3 Dr Maycock's questionnaire and the UCH response is at
 4 page 30. We can see, heading, top left of the page
 5 "Professor Prankerd ... University College Hospital".
 6 He responds as at late 1972, indicating that there are
 7 eight patients with haemophilia regularly treated.
 8 Again, you can see his expressed preference for the
 9 treatment of patients is freeze-dried concentrate,
 10 rather than cryo or a combination of cryo and
 11 concentrate.

12 In terms of the number of patients treated at
 13 UCH, in the 1970s and 1980s, this information is drawn
 14 from the annual returns. I think the return for 1978
 15 might be missing. But what the returns for that
 16 period indicate is usually a relatively small number
 17 of patients treated, between three and 12
 18 haemophilia A patients, up to four patients with
 19 haemophilia B, up to five patients with
 20 von Willebrand's, in some years rather less.

21 To get a sense of treatment policies, again, I'm
 22 afraid, it's really only the annual returns that
 23 provide any kind of guide. If we look at the 1976
 24 return at HCDO0001124.

25 We've got the number of patients treated in that

125

1 particular year, 12. We can see there that
 2 cryoprecipitate is the main product in use for
 3 treatment but that, as early as 1976, a range of
 4 different concentrates were being used. So we've got
 5 NHS concentrate, Hyland's product Hemofil, Immuno's
 6 product Kryobulin, all in use, although in relatively
 7 small numbers.

8 There's again reasonably significant volume of
 9 cryoprecipitate used in 1977, approximately 105,000
 10 units of cryoprecipitate, just under 68,000 units of
 11 NHS concentrate. But we then see by 1979
 12 a significant decline in the usage of cryoprecipitate,
 13 so if we go to the 1979 return, at HCDO0001381, we can
 14 see by now cryoprecipitate is used only in the volume
 15 of 4,200 units. NHS concentrates used 60,000 units,
 16 and the product in greatest usage is the Hyland
 17 product Hemofil, at 126,000 units.

18 In 1980, again the main forms of treatment are
 19 with NHS concentrates and with Hyland but there is the
 20 introduction of the Immuno product, Kryobulin, used in
 21 very small amount in 1980.

22 In 1981, there is again usage of
 23 cryoprecipitate, and the usage has crept up slightly
 24 to around 67,000 units, NHS factor concentrates are
 25 used, and the main commercial concentrate used in 1981

126

1 was Kryobulin.

2 Again, a similar pattern in 1982: some
 3 cryoprecipitate but predominantly NHS Factor VIII
 4 concentrates and Kryobulin.

5 If we then pick the picture up in 1983 at
 6 HCDO0001775, we can see here that, in the course of
 7 1983, we have five haemophilia A patients treated, one
 8 haemophilia A carrier, eight von Willebrand's patients
 9 treated. Then no cryoprecipitate in use for
 10 haemophilia A patients, it is used for the
 11 von Willebrand's patients, and then NHS concentrates
 12 in fairly substantial usage: 145,000 hospital,
 13 125,000-odd home treatment. A small amount of the
 14 Armour product now, 2,000 in hospital, and then
 15 Immuno's Kryobulin, again relatively substantial use
 16 but not as much in that year as the NHS factor
 17 concentrates.

18 Then, just to complete the picture, 1984, is at
 19 HCDO0001869. We're told there seven haemophilia A
 20 patients treated, one carrier and then six
 21 von Willebrand's patients.

22 Then we can see there is some use of
 23 cryoprecipitate for haemophilia A patients. The main
 24 product, however, in use is the NHS Factor VIII
 25 concentrate for the haemophilia A patients. There's

127

1 a reference then towards the bottom -- in terms of the
 2 only commercial concentrate, there's reference to
 3 what's called "Kryoglobulin" there, "HT", presumably
 4 heat treated, and reference to the use of DDAVP, looks
 5 like that is for treatment of a carrier of
 6 haemophilia A, and that writing, I think, is the first
 7 reference in the returns to DDAVP.

8 **SIR BRIAN LANGSTAFF:** The use of cryo there, what is it,
 9 about 50,000 units roughly?

10 **MS RICHARDS:** Yes, it's relatively substantial.

11 **SIR BRIAN LANGSTAFF:** Yes. It's -- the NHS supplies, one
 12 way or the other, are -- hugely outnumber the
 13 commercial, and the commercial is heat-treated.

14 **MS RICHARDS:** Yes. Whether that reflects a conscious
 15 decision by this point in time to try to avoid the use
 16 of unheated commercial concentrates, and therefore we
 17 see, for example, the usage of DDAVP, or whether,
 18 again, it reflects what happened to be available, I'm
 19 afraid we've no way of knowing.

20 Without the need to go to it, the correct
 21 reference for the letter from Professor Prankerd from
 22 1970 -- and this is just for the sake of the
 23 transcript -- is DHSC0100026_016.

24 Dr Bolton-Maggs in her statement provided some
 25 insight into products used at UCH where she first

128

1 began work as a part-time registrar in 1980. She
 2 referred to DDAVP being introduced in preference to
 3 concentrate for mild haemophilia and mild
 4 von Willebrand's. She also refers to recalling the
 5 use of cryoprecipitate but she doesn't recall the
 6 policy; in other words, she doesn't recall why
 7 particular products might be used for particular
 8 cohorts of patients. She says:
 9 "Concentrates were introduced once they were
 10 available and this policy was not decided by me."
 11 And as a part-time registrar at the time no
 12 doubt that's correct.
 13 In terms of knowledge of risk of hepatitis or
 14 HIV, again, there's little by way of direct evidence.
 15 Professor Pranker was often represented by a clinical
 16 colleague at UKHCDO meetings. And we see, for
 17 example, a number of names, including Dr Richards, who
 18 took over as director, or Dr McVerry attending from
 19 time to time, as well as others.
 20 Then, once Dr Richards took over as director, we
 21 see him attending at various UKHCDO meetings in his
 22 own right as director, including in the early 1980s.
 23 Again, he didn't attend all of them and sent his
 24 apologies for some meetings, but it may be reasonable
 25 to assume he would have received the minutes of those

129

1 In relation to the arrangements for testing for
 2 HIV, again, Dr Bolton-Maggs has endeavoured to assist.
 3 She indicated in her statement that testing became
 4 available at UCH in around 1984, using
 5 Dr Richard Tedder's laboratory. She could not
 6 remember herself the details of discussing AIDS with
 7 any patients, but again, that may be a reflection of
 8 the relatively junior position she held at the time.
 9 She did say that she thought at UCH patients
 10 would have been told their test results in person.
 11 She did not have any information about the numbers of
 12 infected patients at UCH. The data which the UKHCDO
 13 has provided to the Inquiry suggests five patients
 14 positive for HIV: one patient identified as positive
 15 in 1982, that is presumably a reference to
 16 a retrospective testing of a stored sera example from
 17 1982; one in 1984; and three testing positive in 1985.
 18 Insofar as hepatitis C is concerned,
 19 Dr Bolton-Maggs believed that that would have become
 20 available in the early 1990s but she, by that time,
 21 had moved to a different hospital and so was not able
 22 to cast any further light upon what the position was
 23 in terms of the arrangements for either testing or for
 24 the treatment of patients with hepatitis C at UCH.
 25 So that, sir, is the overview in relation to

131

1 meetings and had some awareness of the discussions
 2 being undertaken.
 3 Dr Bolton-Maggs has in her statement described
 4 her understanding of the nature and severity of
 5 different forms of hepatitis. She said in her
 6 statement the impact of non-A, non-B hepatitis was not
 7 fully appreciated for some time and that it became
 8 apparent that a number of patients with non-A, non-B
 9 hepatitis developed evidence of chronic liver damage.
 10 In relation to HIV, she said this:
 11 "It was known before the virus was identified
 12 that the condition could be transmitted by blood
 13 transfusion, so it was not surprising to find evidence
 14 of immune dysfunction and illness in haemophilia
 15 patients in the early 1980s before the virus was
 16 identified, in 1983-4, and the test developed, in
 17 1984-86. Understanding and knowledge of HIV and AIDS
 18 evolved as further research was published and
 19 information shared at the UKHCDO and other meetings."
 20 Dr Bolton-Maggs was not able to provide us with
 21 details of what information might have been given to
 22 patients regarding the risks of hepatitis or HIV. And
 23 she couldn't recall whether, for example,
 24 cryoprecipitate was used as an alternative to
 25 concentrates in response to the risk of infection.

130

1 UCH. If I can move to the Hammersmith Hospital, there
 2 are a number of names which appear in documents
 3 relating to the Hammersmith in terms of clinicians.
 4 It would appear Professor Dacie, D-A-C-I-E, may have
 5 been director of the centre from around 1968 to '70,
 6 that Dr Mibashan was director at Hammersmith from 1970
 7 to 1976. He then moved to King's College.
 8 Dr Crawford may have been director, or at least
 9 have acted in that capacity, in 1977, a Dr Hilgard,
 10 '78 to '79.
 11 Dr Chipping, Dr Patricia Chipping, is identified
 12 as the clinician on annual returns in 1970 (*sic*), '80
 13 and '81, but she has provided the Inquiry with
 14 a statement that says she was not the director of the
 15 Haemophilia Centre, and her role at the Hammersmith,
 16 she says, was as a registrar and senior registrar in
 17 haematology, and then a locum consultant in blood
 18 transfusion from 1980 to 1982.
 19 The statement we have from Dr Chipping, I'll
 20 just give the reference, is WITN4567001. We also have
 21 a statement from Dr Hows, who's identified as the
 22 director of the Centre '84 to '86 in the annual
 23 returns, and the reference for her statement is
 24 WITN3779001.
 25 Then we have a statement from Dr Michael Laffan,

132

1 who took over as the director of the Hammersmith
2 centre in 1992, and the reference for his statement is
3 WITN37089003.

4 In terms of facilities at the Hammersmith
5 Hospital, Dr Chipping describes them as follows:

6 "Haemophilia patients at the Hammersmith were
7 treated in a side room adjacent to the blood
8 transfusion department. This was essentially for ease
9 of access as blood products were stored in the blood
10 transfusion department. The coagulation department
11 was housed in a separate building in the Royal
12 Post-graduate Medical School."

13 Dr Laffan is then able to describe the
14 arrangements for haemophilia care in the second half
15 of the eighties, when he was a registrar. He says
16 there was a treatment room, supplies of therapeutic
17 products, staff of the haematology department. Then
18 his statement relays a number of other changes to the
19 way in which haemophilia care was delivered at the
20 Hammersmith, culminating in there being a more
21 structured approach in 1992.

22 Again, the Hammersmith was one of the
23 13 designated Haemophilia Centres in the London area
24 as at 1970. It was part of the Northwest Thames
25 region, so region 5., and was supplied by the North

133

1 transcript, we don't need to go to it -- is at
2 DHSC0100026_019. That indicates that there were
3 43 cases registered at the centre, 242 incidents of
4 haemorrhage for which patients had attended the centre
5 in the relevant year, four incidents of severe
6 bleeding in patients attending the centre.

7 If we go, however, to BPLL0008111 -- so this is
8 the response to Dr Maycock's questionnaire again --
9 and I'm afraid I've failed to mark which page it is,
10 so if you just give me a moment I'll find the
11 Hammersmith entry. Yes, it's page 24.

12 So this is Dr Mibashan's response, 30 patients
13 treated with haemophilia regularly:

14 "Would you prefer to use for the patients of
15 your patients

16 "... [Cryo]? No.

17 "... Freeze-dried concentrate? Yes.

18 "... Some [cryo] and some freeze-dried
19 concentrate? No."

20 Again, an estimate is given as to what would
21 ideally be needed in terms of supply.

22 In terms of the annual returns and numbers of
23 patients treated, for the period 1976 to 1985, the
24 returns suggest between about 28 patients and
25 36 patients with haemophilia A being treated on an

135

1 London blood transfusion centre in Edgware, with blood
2 and blood products.

3 The 1976 allocation identifies 55 bottles per
4 month as the allocation for Hammersmith Hospital of
5 NHS Factor VIII concentrate. I'm not going to go back
6 to the various minutes of the meetings of directors of
7 haemophilia centres and associate centres and blood
8 transfusion centres, that we've now looked at on
9 a number of occasions, which took place in 1976, 1977
10 and 1978. But the 1977 minutes record a Dr Bateman
11 attending on behalf of the Hammersmith Hospital and
12 reporting that there was a significant shortfall in
13 NHS concentrate, and that a large amount of commercial
14 concentrate was being purchased for patients on home
15 therapy and for use in hospital and that's reported in
16 the meeting on 23 September 1977 at BART0000689.

17 There is also some evidence to suggest that
18 there may have been supplies of some products made
19 available directly from BPL to the Hammersmith. But
20 that may have been in relation to albumin rather than
21 factor concentrates.

22 The snapshot from the end of 1969, end of 1970,
23 that is provided by the Hammersmith's response to
24 Dr Obank of the DHSS's letter, is at -- and I'm just
25 going to read the transcript again -- read it for the

134

1 annual basis, up to eight von Willebrand's patients,
2 between one and five haemophilia B patients, and in
3 some years one or two carriers of haemophilia A.

4 So not a huge centre but a bigger centre than
5 some of the other London centres that we have
6 looked at.

7 There is also evidence to suggest, both from
8 Dr Chipping but perhaps more pertinently directly from
9 patients who were treated at the hospital, that
10 children as well as adults were treated at the
11 Hammersmith centre.

12 The Inquiry has received a number of statements
13 from individuals treated with blood products at the
14 centre or from their families. We referred to some of
15 them in our presentation note and you, sir, have heard
16 oral evidence from a number of them. I won't go
17 through the details but again the themes that emerge
18 are no advice or warnings or information about the
19 risks of viral transmission in concentrates, a switch
20 from cryoprecipitate to Factor VIII concentrates.
21 Again, they are main issues that emerge in terms of
22 product usage.

23 The annual returns, again, we'll just look at
24 a handful of them, starting with 1976,
25 HCDO0000088_002. If we go to page 4 we can see, in

136

1 1976, 30 haemophilia A patients treated, five
2 haemophilia B patients treated and then, if we look at
3 the products in use, cryoprecipitate used to a
4 considerable extent, 392,000 units. Also, NHS factor
5 concentrates, 206,000-odd. But a range, albeit in
6 smaller volumes, of commercial concentrates being
7 used, Koate, Hemofil, and Kryobulin, all in use in
8 1976.

9 1977, likewise shows continuing significant use
10 of cryoprecipitate. The figure from the annual
11 returns is just under 418,000 units for cryo. But
12 also NHS concentrate, Koate and Hemofil all being
13 used, with Hemofil being just under 200,000 units used
14 in the course of 1977.

15 1978 also shows cryoprecipitate still being used
16 in quite large measure, 338,000 odd units of
17 cryoprecipitate used. But also Armour's product,
18 Factorate, used, just 350,000 units, and some NHS
19 concentrates being used.

20 1979, again, still shows cryoprecipitate in
21 extensive use, but an increase in the usage of the
22 Armour product, so over half a million units of Armour
23 used in 1979, and approximately 325,000 units of
24 cryoprecipitate, just over 100,000 units of
25 NHS concentrates.

137

1 concentrate. So a significant number of the patients
2 are shown as receiving, for example, both the Armour
3 product and the Immuno product, and that pattern
4 continues on the following page.

5 So that is the picture for 1982. 1983 shows
6 little cryoprecipitate, an increase in NHS concentrate
7 but, again, the main product in use in 1983 is the
8 Armour product, and the same picture emerges in
9 relation to 1984.

10 Dr Chipping, in her statement, recalls supplies
11 to the Hammersmith Hospital coming from the North
12 London Blood Transfusion Centre, and she says that:

13 "Decisions about ordering were made on the basis
14 of clinical need but issue of product depended on
15 their availability at the Regional Transfusion
16 Centre."

17 She said this:

18 "Whilst we ordered British produced factor
19 concentrates on the basis that we were aware the
20 commercial products might contain plasma from paid
21 donors, supplies of Factor VIII concentrate from BPL
22 were limited and until well into the 1980s it was
23 unusual to receive what we had ordered. Substitution
24 being made with commercial Factor VIII, a supply was
25 via the RTCs."

139

1 If we then pick the picture up in 1980, at
2 HCDO0001423, we see a different picture emerging. So
3 33 patients of haemophilia A treated that year, five
4 von Willebrand's.

5 Then if we look at the figures, we can see very
6 small amounts of cryoprecipitate in use, reasonably
7 significant volume of NHS concentrates being used, but
8 by far and away the product in greatest use is the
9 Armour product Factorate, over 700,000 units at
10 hospital and just over 500,000 units for home
11 treatment.

12 Although the figure for cryoprecipitate goes up
13 in 1981, Armour was still the product in greatest use
14 in 1981.

15 Then if we just go to 1982 -- and if I may,
16 I will complete the position in relation to
17 Hammersmith before we break -- it's HCDO0001624, we
18 can see there a small amount of cryoprecipitate being
19 used, just under 20,000, NHS concentrate being used,
20 the Armour product again being used, and now Kryobulin
21 also in fairly extensive usage.

22 And if we go to page 4 we see the entries per
23 patient that you're very familiar with seeing now, and
24 we can see from them that there isn't an obvious
25 attempt to keep patients to one type of commercial

138

1 She says, however, that financial considerations
2 were not a factor in decision making, so dictated, she
3 suggests to some extent, by what was available. She
4 doesn't recall DDAVP being available as an alternative
5 treatment when she was at the Hammersmith Hospital and
6 she doesn't recall cryoprecipitate in routine use for
7 the treatment of haemophilia A.

8 Dr Laffan's statement talks about the centre's
9 treatment policy but that, again, is in the second
10 half of the 1980s, and specifically, in relation to
11 the period from 1985 to 1987, he says patients were
12 treated with non-concentrate therapies whenever
13 possible and whenever it was judged safe from
14 a haemostatic point of view.

15 He talks also about a preference for UK
16 concentrate when it was thought essential to use
17 a concentrate to achieve haemostasis.

18 In terms of knowledge of risk of hepatitis,
19 response to risk, again we're dependent largely upon
20 attendance at meetings. Dr Mibashan was a regular
21 attendee at UKHCDO meetings, or somebody attended from
22 the Hammersmith on his behalf. We see, for example,
23 also Dr Chipping attending, and others.

24 Dr Chipping has set out in her statement her
25 general understanding in relation to hepatitis.

140

1 Dr Laffan has done likewise in his statement, picking
2 up the picture from 1985 when he first started working
3 at the Hammersmith. He says at that point in time the
4 principal concern was the transmission of HIV. He
5 says:

6 "There were no additional measures taken at that
7 point in time for hepatitis."

8 In terms of testing, his recollection is, by the
9 time he joined Hammersmith Hospital in 1985, most
10 patients had been tested and already knew the results
11 of their test. He describes it being routine practice
12 for the virology laboratory to retain stored samples
13 of sera.

14 Again, sir, you will wish to consider when
15 you're looking at the Hammersmith the evidence you
16 have heard from individuals who were treated there.
17 You've heard accounts of patients not being told that
18 they were being tested or HIV or indeed for
19 hepatitis B, and having certainly no concerns about
20 the way in which HIV test results were communicated.

21 The information that we have from UKHCDO as to
22 the numbers of patients infected with HIV at the
23 Hammersmith Hospital Haemophilia Centre suggests 26
24 patients, which obviously is a fairly high proportion
25 of the number of patients who were treated.

141

1 infection were referred to a dedicated HIV clinic.

2 So, sir, that's the position, then, again by way
3 of overview and highlight of the documentation we have
4 available relating to the Hammersmith Hospital, and
5 that's probably a good point to break.

6 **SIR BRIAN LANGSTAFF:** Yes, well, we will take a break now
7 until ten to four. Ten to four.

8 **(3.20 pm)**

9 **(A short break)**

10 **(3.50 pm)**

11 **MS RICHARDS:** Sir, I turn next to the Middlesex Hospital.

12 The directors of the Haemophilia Centre at the
13 Middlesex Hospital were Professor Stewart until 1984,
14 when Dr Machin took over as director. Of course we
15 will have seen numerous references to the
16 Middlesex Hospital in a range of records to Dr Tedder,
17 and to Dr Tedder's role, and in particular the role in
18 relation to testing for HTLV-III is something we will
19 explore perhaps in more detail in later hearings.

20 The Middlesex was also one of the 13 designated
21 Haemophilia Centres in London as at 1970, and it fell
22 within the North-West Thames region, and was supplied
23 with products by the North London blood transfusion
24 centre in Edgware. Its 1976 allocation of NHS
25 Factor VIII concentrate was 22 bottles per month.

143

1 In terms of hepatitis C, Dr Laffan's statement
2 suggests that 64 patients at the centre were found to
3 have evidence of hepatitis C infection. His
4 recollection is that testing at the Hammersmith for
5 hepatitis C began before 1992, and he says he would
6 tell patients usually in clinic, and it wasn't the
7 policy to inform patients by phone or by letter. He
8 says this:

9 "[He] tried to ensure that all patients who had
10 received blood or blood products were tested for
11 hepatitis C antibodies. Later it became possible to
12 test for hepatitis C virus by PCR and this was also
13 done. However, this was not done systematically.
14 A systematic review to ensure that all patients who
15 received any blood products were tested was carried
16 out in 2010 and followed up in 2017 under direction of
17 UKHCDO."

18 Again, both Dr Laffan's statement and some of
19 the evidence that you've received from witnesses
20 provides, in broad terms, a description of the
21 treatment arrangements for hepatitis and for HIV at
22 the Hammersmith. Dr Laffan said he would refer
23 patients with evidence of hepatitis C infection to the
24 hepatology department for management and that, by the
25 time he was director in 1992, patients with HIV

142

1 If we then go to BPLL0008111 and go to page 28,
2 please -- and again these are the responses to
3 Dr Maycock's questionnaire -- page 28 is the response
4 on behalf of the Middlesex Hospital as at the
5 beginning of 1973:

6 "How many patients with haemophilia do you treat
7 regularly? 21."

8 Then, in terms of the preference for products,
9 the preference expressed by Professor Stewart in his
10 response was for some cryoprecipitate and some
11 freeze-dried concentrate, so not just concentrate as
12 the earlier responses we looked at were.

13 In terms of numbers of patients treated at the
14 Middlesex Hospital, the annual returns for 1976
15 through to 1985 give a range of between eight and 22
16 patients with haemophilia A, between two and nine
17 patients with von Willebrand's disease, and between
18 one and five patients with haemophilia B.

19 The annual returns themselves, beginning in
20 1976, in terms of products show relatively early use
21 of commercial concentrate, so both Hemofil and
22 Kryobulin were used in 1976, albeit the main treatment
23 in 1976, by some considerable margin, was
24 cryoprecipitate. No NHS concentrates are recorded as
25 used on the 1976 annual return.

144

1 1977, the pattern is similar, the main treatment
2 is with cryoprecipitate. There's a small amount of
3 NHS concentrate used and a small amount of Kryobulin
4 used.

5 1978, again mainly cryoprecipitate, some NHS
6 concentrate, and a small amount of the Hyland product
7 Hemofil.

8 1979, still mostly cryoprecipitate, some NHS
9 factor concentrates, some Hemofil and a very small
10 amount of the Armour product Factorate introduced in
11 1979.

12 The picture then shifts a little in 1980, and so
13 if we go to the annual return for 1980, which is
14 HCDO0001450, this shows 16 haemophilia A patients
15 treated during the year, seven von Willebrand's. Then
16 if we look at the figures, we can see
17 cryoprecipitate -- it looks like 4,000 bags. And then
18 NHS concentrate, 2,000, and then 12,000 units. And
19 then the Hemofil, 20,000 units and 14,700 units.

20 So that's the picture as of 1980.

21 **SIR BRIAN LANGSTAFF:** So that would equate, in the usual
22 conversion, to 28,000 units of cryo?

23 **MS RICHARDS:** Yes, which is a significant reduction
24 compared to the previous years. But still not
25 cryoprecipitate as a marginal source of treatment,

145

1 So that's the picture then for 1982,
2 cryoprecipitate usage drops.

3 Then, if we pick it up in 1983, HCDO0001747, we
4 see there the predominant picture is of treatment with
5 NHS factor concentrates. So comparatively little
6 commercial usage, although still 10,000-odd units of
7 Koate. Cryoprecipitate usage just under 25,000. But
8 roughly 250,000 units of NHS factor concentrates.

9 Again, whether that simply reflects issues of
10 supply or whether it reflects conscious
11 decision-making is not something we are able to detect
12 from the returns.

13 Then I think finally, for present purposes, the
14 1984 return, which is HCDO0001841.

15 The figures for commercial concentrates have
16 gone up, so we've got Profilate being used, just under
17 52,000. Factor VIII, 15,600. But again, the main
18 product in use is NHS Factor VIII concentrate, and
19 with some usage of cryoprecipitate.

20 Just in terms of relations with pharmaceutical
21 companies, there is a document in relation to the
22 Middlesex that may be worth looking at. It's
23 BAYP0000009_603. It is a letter from Linda Frith,
24 sales development manager with Cutter, and it's dated
25 November '86. She refers to having met Dr Machin and

147

1 which is what we've seen with some of the other
2 centres.

3 **SIR BRIAN LANGSTAFF:** Well, it's the biggest product used
4 per unit in hospital.

5 **MS RICHARDS:** Yes, not used for home treatment.

6 Then if we pick the picture up in 1981.

7 I'm sorry! HCDO0001551. It would help if
8 I gave you the reference, Soumik.

9 We've got 18 haemophilia A patients treated and
10 seven von Willebrand's, two carriers.

11 We can see there that bags of cryoprecipitate is
12 now 759. I'm just looking, for present purposes, at
13 the haemophilia A patients.

14 NHS concentrate used, 10,000, and then
15 16,500 units for home treatment.

16 Then we can see a range of commercial
17 concentrates being used, Koate, Hemofil, Kryobulin and
18 Humanate, in different proportions, but all four in
19 use, as well as of the NHS concentrates.

20 Then if we go to 1982, which is HCDO0001650, we
21 can see now cryoprecipitate is used to a lesser
22 extent, the figure there given is roughly 10,500
23 units. Roughly 100,000 units of NHS concentrate.
24 Koate is used, roughly 74,000 units. Then Kryobulin,
25 around 11,000 units.

146

1 colleagues "at the Haemostasis and Thrombosis Club
2 meeting". There's reference in the second paragraph
3 to cheques being paid for travelling expenses and
4 other expenses relating to a meeting. And then
5 there's a discussion then, offers of selling Cutter's
6 Gamimune product.

7 Then if we go over the page, there's
8 a discussion in the top product about Koate-HT, so the
9 heat-treated Koate product offered by Cutter's at the
10 time, and then this in the last paragraph:

11 "I would like to confirm that Cutter will be
12 able to provide funds to your department of £5,000.
13 I would like to do this in one payment before the end
14 of this year. Would you be able to provide me with
15 a letter saying what the funds would be used for, eg
16 to help support a research project or a researcher,
17 etc."

18 I should perhaps, in fairness, indicate that
19 the -- actually, I don't think we have the
20 1987 return, sir, sorry. The 1986 return doesn't show
21 any purchases from Cutter, but I'm afraid I don't have
22 the 1987 return to check.

23 Again, our information in relation to knowledge
24 of risks of hepatitis or HIV really depends upon
25 inferences to be drawn from attendance at meetings.

148

1 Professor Stewart was a regular attendee at UKHCDO
2 meetings throughout the 1970s. Dr Machin would attend
3 either in his own right or in place of
4 Professor Stewart or sometimes in place of Dr Tedder
5 at meetings in the course of the 1980s.

6 The evidence you've received from the patients
7 who were treated at or family members of patients who
8 were treated at the hospital indicate no information,
9 advice or warnings being provided in relation to the
10 risks of infection.

11 I should say that Dr Machin has provided
12 a statement in response to specific criticisms
13 contained in the statement of one patient's mother, in
14 which he said it would be normal practice for patients
15 in '84, '85, to have discussions about the dangers of
16 infections, particularly hepatitis, HIV, and any other
17 form of hepatitis from any blood products provided.

18 He says:

19 "I would expect for this to have occurred with
20 the patient's mother although not necessarily directly
21 with me."

22 Then he refers to the fact that the records
23 don't show whether any such discussions took place or
24 not.

25 The information the Inquiry has from UKHCDO in

149

1 terms of infections indicates one patient testing
2 positive for HTLV-III from the Middlesex Haemophilia
3 Centre in 1985.

4 Again, the evidence the Inquiry has received
5 from a patient treated at of the hospital or the
6 parent of a patient treated at the hospital gives an
7 account of being tested for HIV without the knowledge
8 or consent of the parent.

9 We've little information, I'm afraid, about
10 HCV -- in fact I think no information about HCV,
11 either in terms of numbers or in terms of what the
12 arrangements were for treatment of any patients
13 infected with hepatitis C.

14 Can I then turn to Northwick Park. The centre
15 at Northwick Park again was a small centre in terms of
16 the number of patients treated. Dr Chanarin was the
17 director of the centre in the course of the 1970s. We
18 then have two statements from doctors who were
19 subsequently involved.

20 Dr Samson has provided a statement to the
21 Inquiry. We don't need to put it up on the screen,
22 but it's WITN4673001. She was a consultant
23 haematologist at Northwick Park from 1977 to 1983 and
24 she sometimes completed the centre's annual returns.

25 Then Dr Reid has also provided a statement to

150

1 the Inquiry. Again, for the benefit of the transcript
2 it's WITN5248001. He was registrar and senior
3 registrar in haematology at Northwick Park from 1977
4 to 1982 and then took over a consultant role in 1983
5 at Northwick Park, I think when Dr Samson moved on,
6 and he remained at Northwick Park I think for the
7 majority of the rest of his medical career.

8 In terms of facilities at Northwick Park,
9 Dr Samson's description is that:

10 "There was no physical entity designated
11 'Haemophilia Centre' and [there were] no dedicated
12 [haemophilia centre] staff."

13 Dr Reid's description is to similar effect. He
14 says:

15 "[The centre] was comprised of myself and the
16 other haematology consultants ... and junior staff ...
17 at Northwick Park hospital. There were no dedicated
18 nursing or other ancillary staff dedicated to these
19 patients."

20 I should say Northwick Park Hospital was also
21 the home to the Medical Research Council's Clinical
22 Research Centre. Certainly I think Dr Samson I think
23 was involved with the Clinical Research Centre at
24 Northwick Park.

25 Northwick Park was designated a haemophilia

151

1 centre with associate status, so an associate
2 haemophilia centre, in 1976. We have, I think,
3 comparatively little information about the
4 arrangements for the provision of supplies to it in
5 terms of contemporaneous documentation.

6 I referred to it earlier as a very small centre,
7 and that's borne out by the figures on the annual
8 returns, which indicate in the period '76 to '86 up to
9 five haemophilia A patients treated in a year, and
10 then very occasionally a patient with von Willebrand's
11 disease or a patient with haemophilia B.

12 In terms of product usage, most years show
13 either -- or show a combination of cryoprecipitate and
14 NHS factor concentrates.

15 So that's the position in 1976, cryo and NHS
16 concentrates. In 1979, cryo and NHS concentrates. In
17 1980, cryo and NHS concentrates. Likewise in 1981 and
18 in 1983, 4 and 5.

19 There are two years, 1978 and 1982, in which the
20 annual returns show a relatively small amount of the
21 Armour product Factorate in use. So in 1978, what's
22 described as 11 bottles or 2,640 units of Armour was
23 used, and in 1982, there's reference to I think
24 837 units of Armour Factorate.

25 So those are the years for which that commercial

152

1 concentrate is identified, and the significance of
 2 that will become apparent in a moment.
 3 In terms of treatment policies and approach, we
 4 do, as I say, have a statement from Dr Reid, and he
 5 has said this: his recollection -- and I think it's
 6 fair to point out that he didn't, I think, have all
 7 the annual returns when he made his statement -- his
 8 recollection was that:
 9 "Until the advent of the NHS 8Y product in 1985,
 10 cryoprecipitate was used in most or all cases."
 11 His statement indicates that:
 12 "Patients were not consulted over decisions as
 13 to which products to use but concerns may have been
 14 discussed with them."
 15 And he says this in his statement:
 16 "Our product policy was determined by what we
 17 perceived to be in the best interests of our patients.
 18 I do not recall consulting with them over our
 19 decisions but that does not mean that we did not
 20 discuss any of their concerns with them."
 21 Then he says this:
 22 "Until the NHS heat-treated products came along
 23 I was unhappy and did not consider using any other
 24 alternative except for DDAVP in mildly affected cases
 25 or in von Willebrand's disease."

1 cryoprecipitate and unusually the doctors agreed to
 2 allow me to continue with the treatment, despite the
 3 fact it was uncommon for haemophilia patients to be
 4 allowed to elect their treatment. They were very
 5 helpful and, like all of us, uncertain of the scale
 6 and threat posed by HIV.
 7 "My doctors provided me with a steady supply of
 8 circa 20 units of cryoprecipitate to keep in the
 9 freezer to treat bloods on demand."
 10 That patient did, in fact, contract both HIV and
 11 HCV but the evidence suggests that that was because of
 12 treatment at a different hospital in London, out of
 13 hours treatment, in which he was treated with
 14 a commercial concentrate which infected him with HIV.
 15 However, there's a different picture that
 16 emerges in the statement of, again an anonymous --
 17 a parent whose son was treated at Northwick Park
 18 Hospital. She describes this:
 19 "He was treated for the first 4 years of his
 20 life with cryoprecipitate but from 1978 onwards he was
 21 transferred to Factor VIII concentrate. I was advised
 22 by the hospital that the use of Factor VIII would be
 23 a great improvement in his care, allowing us to
 24 eventually go on home treatment. I was never asked if
 25 I was agreeable to the change and I was never informed

1 Dr Reid also says this:
 2 "I remember not being convinced of the safety of
 3 early commercial preparations because of their
 4 American provenance and what I understood about their
 5 donor pool. I was happier, therefore, to persist with
 6 cryoprecipitate until the UK product became available.
 7 Although I note we used Profilate in 1986, I cannot
 8 recall the reason for this at the time."
 9 As I say, he did not, I think, have access to
 10 all the earlier annual returns when he gave his
 11 statement.
 12 The Inquiry has evidence from or about two
 13 patients treated at Northwick Park, both anonymous, so
 14 I'm going to be careful in terms of what I say. We
 15 have evidence from an anonymous witness with severe
 16 haemophilia A treated at the haemophilia centre. He
 17 describes in his statement being treated initially
 18 with fresh frozen plasma and then cryoprecipitate.
 19 Then he describes a move towards treatment with factor
 20 concentrates and his statement says this:
 21 "I was not comfortable changing my treatment
 22 from cryoprecipitate to Factor VIII and sat down with
 23 my doctors at Northwick Park Hospital in Harrow and
 24 told them that I did not want to be treated with
 25 Factor VIII. I felt relatively safe using

1 that there was a risk of viruses being carried in the
 2 blood product. The hospital said that the Factor VIII
 3 was purer. I was told it would make life simpler and
 4 easier for us and that the home treatment would reduce
 5 the number of hospital visits and this disruption to
 6 our home life."
 7 You will recall, sir, that I mentioned those
 8 small amounts of Armour product appearing in the 1978
 9 and 1982 returns.
 10 Unhappily, the UKHCDO records in relation to the
 11 child treated at Northwick Park indicate that he was
 12 the recipient of Armour Factorate in 1978 and in 1982
 13 from Northwick Park.
 14 The patient's mother's statement to you, sir,
 15 continues:
 16 "In 1983 HIV was a hot topic in the news and
 17 there were suggestions that haemophiliacs were
 18 susceptible."
 19 She describes contacting Northwick Park, being
 20 told to carry on her son's home treatment as normal as
 21 the risk of him contracting an infection was minimal.
 22 She was not given an option for her son to revert to
 23 cryoprecipitate. She says in her statement:
 24 "Mostly the treatment was NHS Factor VIII but if
 25 they were running low he would be given commercial

1 products."

2 As I say, the UKHCDO records confirm that.

3 I should also say that her statement describes

4 being informed of her son's HIV positive test result

5 by a letter from Northwick Park.

6 You will see, sir, the picture that emerges

7 there, you may think, is somewhat different from the

8 account in the witness statements from clinicians that

9 the Inquiry has received.

10 I have referred in relation to an earlier centre

11 to some of the evidence of Dr Samson and her

12 recollection that it wasn't until a later stage that

13 the severity of non-A, non-B hepatitis was

14 appreciated. She says in her statement, and this is

15 describing, I think, the position as at summer of

16 1983:

17 "We felt blood products were very safe."

18 She talks about becoming aware only of the risks

19 in relation to HIV when she moved from Northwick Park

20 to Charing Cross Hospital in 1984.

21 We don't know what the reasons were for there

22 being some use of the commercial concentrate at

23 Northwick Park in '78 and '82 as described. Dr Reid's

24 recollection was that supply was not an issue and that

25 they could get unlimited amounts of cryoprecipitate.

157

1 But, as I say, it's right to point out that he did not

2 have either the information from the full returns or,

3 indeed, the statement from the patient's mother, to

4 which I've referred.

5 In terms of the arrangements for testing for

6 HTLV-III, Dr Reid recalled arrangements being made to

7 test for three haemophilia A patients in 1985 at the

8 time of trying to make the arrangements to obtain heat

9 treated concentrate.

10 We can see, if we go to -- forgive me while

11 I check the reference. Yes, CBLA0002033. This is

12 a letter that Dr Reid wrote to Dr Snape at BPL in

13 February 1985 asking for heat-treated concentrates to

14 be made available, and he identifies there three

15 patients for whom heat-treated concentrates were being

16 sought.

17 Sir, you may wish to ignore what's written in

18 handwriting on the right-hand side because we know

19 that that's not entirely accurate. So there's what's

20 recorded there for the second identified patient as

21 negative, we know that that's the child who, later in

22 1985, was found to be positive for HTLV-III. So we

23 don't know who wrote that but that's not accurate.

24 But you will see that what's then said at the

25 end of the letter is:

158

1 "... in the meantime we're conducting

2 investigations to ascertain their HTLV-3 status."

3 Certainly, in relation to the child to whom I've

4 referred, it was around September 1985 when the letter

5 was sent communicating the HTLV-III positive test

6 result.

7 The evidence that the Inquiry has then received

8 in that regard from the parent of the patient treated

9 there is consistent with the data that UKHCDO had

10 supplied to the Inquiry, which suggested one patient

11 testing positive for HIV at Northwick Park in 1985.

12 There is, I'm afraid, no real information in

13 terms of hepatitis C. Dr Reid's recollection was that

14 testing and monitoring for hepatitis C would have been

15 undertaken at the Royal Free Hospital, which became

16 the comprehensive treatment centre from the 1990s

17 onwards, but he was unable to cast any further light

18 on any issues relating to hepatitis C.

19 Sir, that is the picture in relation to

20 Northwick Park. A small centre, a small number of

21 patients, but perhaps really quite revealing in terms

22 of what it tells us about relative risks and, indeed,

23 practices in terms of the provision or non-provision

24 of information and advice to patients.

25 Can I then turn to Edgware. The haemophilia

159

1 centre at Edgware Hospital was led in terms of

2 directorship by Dr Ardeman from 1977, certainly until

3 1990, possibly later. Edgware was designated as

4 an associate centre in later 1976, it was part of the

5 North-West Thames region, so Region 05 and received,

6 at least at that point in the 1970s, its NHS

7 concentrates from the North London Blood Transfusion

8 Centre in Edgware.

9 Dr Ardeman attended some of the meetings of

10 directors of centres and blood transfusion centres

11 that we have looked at, '76, '77 and '78. I am not

12 going to go to those meetings again, largely because,

13 although Dr Ardeman made contributions at the meetings

14 they were contributions which related more generally

15 to the supply arrangements in the Regional Health

16 Authority area, rather than anything specific to the

17 needs of or usage of products at the Edgware

18 haemophilia centre.

19 Again, it was a very small centre. The number

20 of the patients taken from the annual returns from

21 1976 to '86 suggests between one and four

22 haemophilia A patients, two von Willebrand's and no

23 haemophilia B patients treated.

24 The picture from the returns, in terms of the

25 products that were used is as follows: only

160

1 cryoprecipitate in 1976 and 1977. In 1978,
2 cryoprecipitate, NHS Factor VIII concentrate and the
3 Hyland product Hemofil. The factor -- sorry, the
4 product used most in that year was the NHS Factor VIII
5 concentrate.

6 1979 shows usage of both the NHS Factor VIII
7 concentrate and Kryobulin. That was for the treatment
8 of a single patient in that year. In 1980, we can't
9 discern the figures from the return, but the products
10 that were used were cryoprecipitate, NHS concentrate
11 and Hyland product, in relation to the treatment of
12 haemophilia A.

13 1981 again shows continuing use of
14 cryoprecipitate, the figures are all relatively small
15 because of the small numbers of patients, but also use
16 of NHS Factor VIII concentrate, Hemofil and Kryobulin.
17 In 1982, again it's cryoprecipitate, NHS concentrate
18 and Hemofil, no Kryobulin in that year.

19 In 1983, there's only one haemophilia A patient
20 treated so it may be difficult to make any particular
21 deductions, but it's treatment with cryoprecipitate
22 only, and it looks like it's for home treatment.
23 There doesn't appear to have been any Factor VIII
24 concentrate whether NHS or commercial used in Edgware
25 in 1983.

161

1 We don't, I think, have the return for 1984.
2 1985, again, shows the treatment of only one
3 patient and that was with a commercial product, the
4 Armour product, Factorate, and that's in hospital, no
5 home treatment appears to have taken place in 1985.
6 1986, and this again shows the size of the
7 centre, no patients treated and no blood products
8 therefore used.

9 We've no direct information again about the
10 knowledge of risks on the part of Dr Ardeman. He did
11 attend UKHCDO meetings on occasions, so '77, '81 and
12 '82, which are fairly important meetings, and he sent
13 his apologies on a number of other occasions, and
14 again it may be reasonable to assume that he would
15 have received the minutes of those meetings.

16 The data that the Inquiry has received from
17 UKHCDO suggests that there were no patients infected
18 with HIV in the Edgware Hospital, but there's evidence
19 to suggest two patients were tested to see whether
20 they were HTLV-III positive but no positive test
21 results. We have, I'm afraid, no information at all
22 in relation to hepatitis C.

23 The next London centre that I wanted to look at
24 is the haemophilia centre at the Hillingdon Hospital.
25 The director there during the 1970s and 1980s was

162

1 Dr Britt. Again, it was an associate centre,
2 designated as such in late 1976, and supplied with NHS
3 concentrates by the North London Blood Transfusion
4 Centre in Edgware.

5 You'll recall we looked this morning at
6 a document which showed allocations as at 1976 of
7 Factor VIII concentrate, numbers of bottles per month
8 to certain centres. But the documents show no
9 allocation to Edgware, presumably -- sorry, to
10 Hillingdon, presumably because it was a newly
11 designated associate centre so there was no
12 established pattern of usage.

13 The annual returns show in terms of numbers of
14 patients treated two patients with haemophilia A and
15 one with Christmas Disease in 1976 and then, over the
16 years that follow, the numbers remain small. I think
17 the largest number treated in a given year with
18 haemophilia A is six. Occasionally, a patient with
19 von Willebrand's disease was treated and,
20 occasionally, a patient with haemophilia B was
21 treated.

22 I can again take the product usage from the
23 annual returns, I think, by way of summary.
24 Cryoprecipitate only in 1976 and 1977. In 1978,
25 cryoprecipitate and NHS concentrates. In 1979,

163

1 cryoprecipitate and NHS concentrates but also Armour
2 Factorate. Again, the volumes used are all small
3 because the number of patients being treated was very
4 small, but we see that commercial product being used
5 in 1979.

6 1980, again, is a mixture of cryoprecipitate,
7 NHS Factor VIII concentrates and Armour's Factorate,
8 to treat two patients in hospital.

9 1981 seems to suggest no NHS concentrates used.
10 There was a small amount of cryoprecipitate used, and
11 then the treatment was with the Armour product and
12 with Immuno's Kryobulin. Again, relatively small
13 amounts in terms of overall usage.

14 1982 shows a slightly larger volume of
15 concentrate being used, so roughly 70,000 units of
16 Factorate, the Armour product, and just under 21,000
17 units of Kryobulin. Cryoprecipitate was used but only
18 for the treatment of von Willebrand's disease in that
19 year.

20 1983 shows cryoprecipitate being used in that
21 year for the treatment of haemophilia A patients, but
22 also NHS concentrates and just under 53,000 units of
23 the Armour product used in 1983.

24 1984 shows cryoprecipitate and NHS concentrates.
25 No commercial concentrates appear to have been used.

164

1 There's not much by way of evidence of Dr Britt
 2 himself attending UKHCDO meetings. He largely seemed
 3 to send his apologies, but there were clinicians from
 4 Hillingdon Hospital recorded as attending UKHCDO
 5 meetings on Dr Britt's behalf in 1977, '79, '81,
 6 '83 and '85. Again, it may be reasonable to infer
 7 that he would have been sent copies of the minutes and
 8 would have had available to him the discussions
 9 recorded in the minutes about hepatitis and HIV.

10 The data received by the Inquiry from UKHCDO
 11 suggests no patients at Hillingdon tested positive
 12 for HIV.

13 There's no information, I'm afraid, that we've
 14 unearthed from the hospital in relation to infection
 15 with hepatitis C for patients of the haemophilia
 16 centre. There is evidence in relation to patients
 17 infected with hepatitis C by way of transfusion, and
 18 of course those are issues that we will be exploring
 19 in more detail in later hearings.

20 I'm just going to read out the reference for
 21 a letter from a patient who was the subject of an
 22 operation at the Hillingdon Hospital in June 1991 --
 23 and the significance of the date is apparent, it's
 24 shortly before the introduction of hepatitis C
 25 screening in the autumn of 1991 -- who was then

1 identified on a look-back exercise in late '95 early
 2 '96.

3 It's a very powerful and telling account in
 4 a letter he wrote to his local MP. And for the
 5 transcript, it's DHSC0004728_180.

6 There is some important information in relation
 7 to Hillingdon in relation to infection by way of
 8 transfusion with hepatitis C but nothing from the
 9 documentation in relation to the position of
 10 haemophilia patients and the extent to which they were
 11 infected with hepatitis C.

12 Sir, I note the time. I've got three more
 13 London hospitals to cover but I don't think I can do
 14 justice to them in the matter of a few minutes, so
 15 perhaps we could pick those up at 10 o'clock tomorrow
 16 morning.

17 **SIR BRIAN LANGSTAFF:** Yes, well, let's do that, then.

18 Ten o'clock tomorrow morning to complete London, and
 19 then move into what, the south-west?

20 **MS RICHARDS:** South and south-west, and then East Anglia.

21 **SIR BRIAN LANGSTAFF:** Ten o'clock.

22 **(4.29 pm)**

23 **(The hearing adjourned until 10.00 am the following day)**

24
 25

1	INDEX	
2	Presentation by Counsel to The Inquiry on the Pharmaceutical Companies (continued)	1
3		
4	Presentation by Counsel to The Inquiry on smaller haemophilia centres	40
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

<p>MR HILL: [30] 1/5 6/22 7/2 7/4 7/10 7/12 7/17 7/20 7/25 10/2 24/24 25/8 25/15 25/18 25/22 26/5 26/9 26/14 26/18 27/18 35/1 36/7 36/18 37/7 37/11 37/17 38/13 38/16 39/1 40/14 MS RICHARDS: [34] 40/24 42/18 43/12 43/16 43/25 80/1 80/6 80/9 81/3 81/6 81/11 82/1 82/15 83/1 98/14 100/6 107/9 107/11 107/14 107/16 113/13 114/7 114/11 114/19 114/24 115/9 115/16 115/24 128/10 128/14 143/11 145/23 146/5 166/20 SIR BRIAN LANGSTAFF: [64] 6/17 6/24 7/3 7/8 7/11 7/15 7/18 7/22 10/1 24/18 25/1 25/12 25/16 25/20 26/3 26/7 26/12 26/17 27/17 34/25 35/24 36/11 37/5 37/8 37/16 38/11 38/15 38/25 40/13 40/17 42/15 43/10 43/13 43/24 79/25 80/5 80/7 80/20 81/5 81/7 81/19 82/10 82/25 98/9 100/5 107/7 107/10 107/12 107/15 113/9 114/4 114/8 114/17 114/23 115/8 115/14 115/23 128/8 128/11 143/6 145/21 146/3 166/17 166/21</p> <hr/> <p>'70 [1] 132/5 '76 [2] 152/8 160/11 '76 to [1] 152/8 '77 [2] 160/11 162/11 '78 [3] 132/10 157/23 160/11 '78 and [1] 157/23 '79 [2] 132/10 165/5 '80 [1] 132/12 '81 [3] 132/13 162/11 165/5 '82 [2] 157/23 162/12 '82 as [1] 157/23 '83 [2] 36/13 165/6 '83 and [1] 165/6</p>	<p>'84 [3] 73/11 132/22 149/15 '84 to [1] 132/22 '85 [2] 149/15 165/6 '86 [5] 107/13 132/22 147/25 152/8 160/21 '95 [1] 166/1 '95 early [1] 166/1 '96 [1] 166/2 'B' [2] 19/5 19/6 'Haemophilia [1] 151/11 'high [1] 33/24 'North [1] 122/8 'parish' [1] 122/19 'the [1] 122/7 'voluntary' [1] 21/4</p> <hr/> <p>- -- and [1] 1/23</p> <hr/> <p>0 0.12 [1] 10/24 0.14 [1] 10/24 0001717 [1] 81/2 001 [3] 2/13 31/1 91/25 002 [1] 136/25 003 [1] 3/9 004 [1] 52/9 008 [1] 14/15 009 [2] 60/1 110/2 011 [1] 62/3 014 [2] 109/11 124/13 016 [1] 128/23 019 [1] 135/2 024 [1] 101/9 026 [1] 62/18 035 [1] 114/8 04 [1] 72/6 05 [2] 72/7 160/5 050 [1] 2/9 057 [1] 40/2 06 [3] 72/7 122/4 122/10 070 [1] 44/18 074 [1] 19/3 084 [1] 64/19</p> <hr/> <p>1 1 million [1] 80/24 1,000 [10] 4/18 9/11 9/16 9/17 9/18 10/13 10/24 11/1 11/5 39/22 1,350,000 donations [1] 31/25 1,812,685 [1] 114/9 1.05 [1] 98/11 1.2 [2] 10/13 10/25 1.35 million [2] 33/1 33/5 1.4 [2] 10/13 10/25</p>	<p>1.5 [1] 11/4 1.6 donations [1] 8/21 1.7 donations [1] 8/11 1.8 million [1] 114/3 1.C [1] 38/21 10 [3] 11/19 33/20 47/25 10 o'clock [1] 166/15 10 September 2018 [1] 58/6 10,000 [1] 146/14 10,000-odd [1] 147/6 10,500 [1] 146/22 10.00 [2] 1/2 166/23 100,000 [3] 32/23 137/24 146/23 100,000 Kgs [1] 32/7 105,000 [1] 126/9 11 [1] 64/2 11 bottles [1] 152/22 11 patients [1] 86/14 11,000 units [1] 146/25 11.10 [1] 40/19 11.41 [1] 40/21 12 [9] 16/6 16/10 40/18 40/18 65/17 77/1 116/12 125/17 126/1 12,000 [1] 145/18 12-13 years [1] 64/11 122 [1] 34/10 125,000-odd [1] 127/13 126,000 [1] 126/17 13 [7] 49/9 60/4 60/11 61/24 99/19 110/12 143/20 13 designated [2] 108/10 133/23 13 Haemophilia [1] 121/15 13 registered [1] 101/11 14 [2] 39/12 49/14 14 incidences [1] 101/12 14 January 1983 [1] 30/3 14 patients [1] 77/13 14,700 [1] 145/19 14.6 [1] 63/19 145,000 [1] 127/12 15 [2] 38/20 123/12 15 bottles [1] 108/18 15 December [1] 39/1 15 December 1976 [2] 69/24 121/23 15 December 1982 [2] 27/24 38/16 15 October 1970 [1] 66/12</p>	<p>15 October 1975 [1] 12/16 15 times [2] 32/4 33/14 15,434 liters [1] 12/24 15,600 [1] 147/17 16 [3] 14/8 50/4 66/3 16 cases [1] 109/19 16 haemophilia A [1] 145/14 16,500 units [1] 146/15 164 [1] 39/9 166 [1] 39/9 17 [2] 14/7 38/1 17 cents [1] 16/4 17.5 [1] 33/6 170 [1] 39/8 18 [2] 51/4 146/9 180 [1] 166/5 185,000 [1] 72/18 19 [2] 15/2 51/3 1950s [1] 118/19 1966 [1] 107/8 1967 [2] 44/23 49/10 1968 [6] 57/10 99/1 107/9 107/10 121/1 132/5 1969 [9] 60/2 60/24 61/2 62/1 75/19 101/6 109/12 109/22 134/22 1970 [14] 64/25 66/12 66/12 75/19 99/21 101/6 108/11 121/16 128/22 132/6 132/12 133/24 134/22 143/21 1970s [24] 3/7 11/25 12/12 39/19 48/3 57/9 58/23 64/18 75/15 85/4 88/23 89/2 106/3 116/4 118/22 118/24 120/25 124/13 125/1 125/13 149/2 150/17 160/6 162/25 1970s/80s [1] 58/14 1971 [4] 3/19 4/20 5/10 9/12 1972 [7] 5/11 75/18 101/17 102/11 103/2 110/9 125/6 1973 [7] 4/1 4/7 5/14 5/18 9/13 9/14 144/5 1974 [7] 5/24 11/2 14/2 37/19 37/22 69/12 70/11 1975 [10] 4/9 6/9 8/6 8/19 9/2 12/16 13/13 14/6 37/19 37/23 1976 [44] 68/15 69/4 69/24 70/6 70/24 72/17 76/23 76/24 77/3 90/9 100/1 103/6</p>	<p>103/18 104/3 108/16 110/24 111/1 111/13 119/1 121/23 125/23 126/3 132/7 134/3 134/9 135/23 136/24 137/1 137/8 143/24 144/14 144/20 144/22 144/23 144/25 152/2 152/15 160/4 160/21 161/1 163/2 163/6 163/15 163/24 1977 [31] 72/7 72/16 72/19 72/20 77/15 92/1 92/10 100/12 101/2 103/24 104/3 107/23 108/23 109/7 121/1 121/1 123/9 123/10 126/9 132/9 134/9 134/16 137/9 137/14 145/1 150/23 151/3 160/2 161/1 163/24 165/5 1977 minutes [1] 134/10 1978 [16] 72/24 78/17 92/15 95/24 124/9 125/14 134/10 137/15 145/5 152/19 152/21 155/20 156/8 156/12 161/1 163/24 1979 [27] 3/6 3/11 4/21 11/3 39/6 78/21 92/20 95/24 99/1 99/2 104/5 106/25 107/9 107/18 111/15 116/8 116/12 126/11 126/13 137/20 137/23 145/8 145/11 152/16 161/6 163/25 164/5 1980 [18] 14/14 39/6 49/23 78/23 83/15 104/8 112/5 126/18 126/21 129/1 132/18 138/1 145/12 145/13 145/20 152/17 161/8 164/6 1980s [25] 14/13 39/19 47/5 58/19 58/23 84/3 84/25 85/4 87/25 88/23 89/2 89/9 91/8 106/4 107/19 108/2 120/25 121/5 125/13 129/22 130/15 139/22 140/10 149/5 162/25 1981 [16] 16/24 17/21 24/25 26/10 79/2 93/2 104/18 112/9 126/22 126/25 138/13 138/14 146/6 152/17 161/13 164/9 1982 [41] 2/14 19/17</p>	<p>19/24 21/21 22/9 22/12 22/21 24/4 26/16 27/5 27/12 27/22 27/24 28/15 28/19 29/25 36/1 38/16 38/20 39/1 79/4 80/22 80/23 93/10 104/20 112/13 127/2 131/15 131/17 132/18 138/15 139/5 146/20 147/1 151/4 152/19 152/23 156/9 156/12 161/17 164/14 1983 [42] 30/3 30/22 31/7 31/11 34/11 34/16 34/17 35/3 35/14 35/17 35/22 37/2 37/10 37/13 51/23 56/7 56/10 79/13 81/11 83/15 89/10 93/13 94/14 96/17 99/9 99/11 105/1 112/21 127/5 127/7 139/5 139/7 147/3 150/23 151/4 152/18 156/16 157/16 161/19 161/25 164/20 164/23 1983-4 [1] 130/16 1984 [30] 1/11 1/20 2/1 53/17 53/20 54/6 58/17 73/10 74/18 79/21 80/14 81/10 86/16 93/23 94/25 96/19 99/9 105/7 105/8 105/10 113/15 120/6 127/18 131/4 131/17 139/9 143/13 157/20 162/1 164/24 1984 return [1] 147/14 1984-86 [1] 130/17 1985 [33] 1/12 2/2 2/5 2/9 2/11 56/17 74/21 74/22 86/16 93/25 94/4 94/6 95/5 106/13 114/25 115/9 115/14 120/8 131/17 135/23 140/11 141/2 141/9 144/15 150/3 153/9 158/7 158/13 158/22 159/4 159/11 162/2 162/5 1986 [10] 39/13 39/15 39/21 57/25 103/6 106/25 111/1 148/20 154/7 162/6 1987 [7] 39/22 39/22 57/10 57/11 86/16 140/11 148/22 1987 return [1] 148/20</p>
--	--	--	---	---	--

1 1988 [5] 39/22 57/25 99/2 110/25 118/5 1989 [2] 99/4 121/2 1990 [4] 2/10 120/10 120/11 160/3 1990s [3] 89/9 131/20 159/16 1991 [2] 165/22 165/25 1992 [4] 133/2 133/21 142/5 142/25 1993 [2] 120/10 120/15 1995 [1] 89/10 1998 [1] 118/6 1st [1] 70/6	235,000 [1] 72/17 23rd September 1977 [1] 72/7 24 [2] 35/14 135/11 24 June [1] 52/8 242 [1] 135/3 24th June 1983 [1] 51/23 25 [2] 123/21 123/23 25 January 1983 [1] 31/7 25,000 [1] 147/7 250 millilitres [1] 33/11 250,000 [1] 147/8 250ml [1] 32/9 26 [1] 141/23 28 [2] 144/1 144/3 28 patients [1] 135/24 28,000 units [1] 145/22 29 cases [1] 124/21 2:1 [1] 113/12	392,000 [1] 137/4 396 [1] 63/16	4 4 years [1] 155/19 4,000 [1] 145/17 4,200 units [1] 126/15 4.0 [1] 9/18 4.29 [1] 166/22 40 [1] 16/2 40,000 [3] 92/21 104/5 111/23 40-45 [1] 123/19 400 [1] 102/3 400,000 [3] 32/9 33/1 79/11 418,000 units [1] 137/11 43 [3] 16/2 16/5 80/23 43 cases [1] 135/3 45 [1] 123/19 46 [1] 63/25 4739001 [1] 57/23 498 [1] 63/17	5 5 years [1] 64/9 5,000 [1] 148/12 50 [3] 45/23 65/13 113/11 50,000 [1] 93/19 50,000 units [1] 128/9 500,000 [2] 81/1 138/10 52,000 [1] 147/17 527 [1] 62/4 53,000 units [1] 164/22 55 bottles [1] 134/3 59 patients [1] 63/25	6 6 October 2021 [1] 1/1 6,000-7,000 [2] 30/17 30/20 6,500 [1] 39/21 60 [2] 16/4 64/9 60,000 [1] 126/15 600 [1] 102/3 603 [1] 147/23 61 [1] 63/15 62 [1] 69/18 62 bottles [1] 69/18 64 [1] 142/2 650 [1] 114/9 666ml/donation [1] 31/24 67,000 units [1] 126/24 68 [2] 60/20 61/21 68,000 [1] 126/10	69,200 units [1] 111/22	7 7 May 1985 [1] 2/2 7 September 1982 [1] 22/9 7,000 [3] 30/17 30/20 112/1 70 [1] 80/8 70,000 [1] 164/15 700,000 [1] 138/9 71 [1] 119/24 71,000 [1] 94/2 710 [1] 80/5 74,000 [1] 146/24 756 [1] 1/18 759 [1] 146/12 78.6 [2] 33/8 33/19 78.6 per cent [1] 34/5	8 80 [1] 119/14 800 potential [1] 30/24 80s [1] 58/14 826 [1] 114/8 837 units [1] 152/24 84 incidents [1] 109/20 86 [1] 130/17 89 [1] 62/3 89 registered [1] 65/13 89,000 [2] 32/6 33/4 8Y [1] 153/9	9 9 July 1981 [1] 16/24 9 November 1982 [2] 26/16 36/1 9.0 [1] 9/16 90 [4] 10/16 11/17 63/14 64/9 900,000 Kgs [1] 31/23 900,000 kilograms [1] 32/22 95,000 [1] 93/18 973 [2] 25/12 25/16 973 Mission [2] 17/18 24/22 986 [1] 114/8	130/20 131/21 133/13 147/11 148/12 148/14 about [75] 2/22 9/4 11/23 12/2 12/11 14/19 14/22 20/4 25/22 28/2 29/16 29/18 30/19 30/20 31/25 32/2 38/5 39/2 44/25 45/25 52/20 55/13 55/24 55/25 63/4 64/9 64/11 66/20 67/6 68/15 70/12 73/15 74/16 83/11 84/3 84/13 87/25 88/22 91/18 96/14 98/16 106/9 106/14 109/10 110/13 111/11 113/11 113/12 113/18 114/7 116/23 117/13 118/17 119/25 121/25 123/12 128/9 131/11 135/24 136/18 139/13 140/8 140/15 141/19 148/8 149/15 150/9 150/10 152/3 154/4 154/12 157/18 159/22 162/9 165/9 above [3] 32/3 61/15 80/8 absence [1] 85/5 absolutely [1] 42/18 abusers [3] 24/6 24/9 36/3 accept [1] 29/12 acceptable [2] 18/20 47/12 accepted [1] 71/16 access [3] 88/14 133/9 154/9 accessible [1] 64/13 accident [1] 17/14 accordance [1] 46/7 according [4] 4/22 30/14 69/11 89/17 account [7] 8/4 8/17 91/17 124/2 150/7 157/8 166/3 accounts [4] 84/18 85/9 87/22 141/17 accurate [3] 122/21 158/19 158/23 achieve [1] 140/17 achieved [1] 50/24 acquiring [1] 50/19 across [4] 66/14 82/11 107/4 123/13 acted [1] 132/9 action [1] 29/13 active [5] 18/5 26/12 26/13 63/1 67/15 actively [2] 26/22 88/6	actual [1] 73/5 actually [4] 9/20 15/22 100/17 148/19 add [3] 17/19 44/17 114/6 added [1] 14/6 addition [6] 10/2 34/7 45/2 45/2 114/5 114/5 additional [4] 56/25 65/19 94/8 141/6 address [4] 17/17 21/12 24/22 25/23 addressed [2] 101/21 102/5 addressees [1] 28/20 addresses [2] 15/17 124/1 addressing [1] 29/23 adequate [4] 15/10 55/3 67/21 118/20 adequately [2] 85/24 119/13 adjacent [1] 133/7 adjourned [1] 166/23 adjournment [1] 98/12 Adjustments [1] 122/16 administer [1] 76/9 administered [1] 78/2 admission [1] 49/5 adult [7] 17/2 17/7 51/12 64/10 87/16 87/18 88/7 adults [4] 49/8 51/18 89/23 136/10 advantage [1] 88/3 advent [1] 153/9 advert [5] 17/3 17/5 17/23 17/24 19/4 advertised [1] 26/22 advertisement [1] 17/20 advertisements [1] 16/13 advert [1] 26/9 advice [5] 84/13 91/18 136/18 149/9 159/24 advise [2] 45/20 119/3 advised [1] 155/21 Advocate [1] 16/22 Affairs [1] 21/17 affect [1] 61/22 affected [3] 52/14 53/10 153/24 afraid [21] 25/18 26/1 26/20 27/15 28/14 82/15 82/22 84/11 86/23 94/12 97/17 106/6 106/14 125/22
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<p>A</p> <p>afraid... [7] 128/19 135/9 148/21 150/9 159/12 162/21 165/13</p> <p>after [12] 6/4 35/2 40/17 42/4 54/6 87/1 87/2 90/20 90/22 94/24 98/7 118/16</p> <p>afternoon [2] 41/13 96/16</p> <p>again [117] 6/3 22/8 29/2 54/21 55/3 55/18 56/21 57/14 57/22 62/16 64/23 70/1 72/2 73/1 73/2 73/10 74/23 75/14 78/18 78/23 79/19 81/2 81/10 83/1 83/12 83/24 84/6 84/9 84/25 85/5 85/9 85/17 86/12 88/8 90/23 91/12 92/23 93/11 93/23 94/4 95/18 101/5 104/8 104/11 104/23 105/1 105/18 107/5 108/9 109/9 110/5 111/10 112/9 112/13 113/2 114/12 115/24 116/8 116/25 118/2 120/18 121/14 121/19 124/7 124/12 124/15 125/2 125/8 125/21 126/8 126/18 126/22 127/2 127/15 128/18 129/14 129/23 131/2 131/7 133/22 134/25 135/8 135/20 136/17 136/21 136/23 137/20 138/20 139/7 140/9 140/19 141/14 142/18 143/2 144/2 145/5 147/9 147/17 148/23 150/4 150/15 151/1 155/16 160/12 160/19 161/13 161/17 162/2 162/6 162/9 162/14 163/1 163/22 164/2 164/6 164/12 165/6</p> <p>age [2] 64/11 81/25</p> <p>ago [5] 23/19 24/21 43/21 110/6 119/8</p> <p>agree [1] 24/15</p> <p>agreeable [1] 155/25</p> <p>agreed [3] 39/14 71/19 155/1</p> <p>agreeing [1] 117/11</p> <p>agreement [2] 10/14 19/19</p> <p>AHF [2] 20/18 35/7</p> <p>AIDS [23] 28/2 28/5 28/17 29/11 29/20</p>	<p>29/23 31/8 34/15 36/15 38/20 40/9 51/25 55/6 55/7 55/13 82/13 84/21 88/1 105/16 108/3 108/6 130/17 131/6</p> <p>aim [1] 47/14</p> <p>air [1] 13/6</p> <p>albeit [4] 79/17 80/10 137/5 144/22</p> <p>albumin [6] 23/3 23/6 23/11 27/10 119/4 134/20</p> <p>Alder [20] 41/5 44/1 44/2 44/7 44/17 44/20 44/23 45/5 50/11 50/14 51/14 52/13 52/21 53/6 54/4 54/12 54/24 57/2 57/21 86/3</p> <p>Alder Hey [19] 41/5 44/1 44/2 44/7 44/17 44/20 44/23 50/11 50/14 51/14 52/13 52/21 53/6 54/4 54/12 54/24 57/2 57/21 86/3</p> <p>Aledort [1] 23/24</p> <p>alerted [1] 53/7</p> <p>all [48] 3/17 8/13 11/21 14/7 16/5 21/1 29/13 31/18 33/21 35/5 36/24 38/3 38/5 42/9 42/19 43/20 47/13 60/17 70/20 74/12 76/20 78/6 78/14 84/7 95/9 95/12 102/4 103/5 104/10 104/23 113/3 116/20 118/12 122/11 126/6 129/23 137/7 137/12 142/9 142/14 146/18 153/6 153/10 154/10 155/5 161/14 162/21 164/2</p> <p>allocated [2] 69/22 100/2</p> <p>allocating [1] 71/5</p> <p>allocation [15] 69/5 69/18 70/3 70/23 72/14 100/17 100/24 108/16 109/4 121/25 122/17 134/3 134/4 143/24 163/9</p> <p>allocations [1] 163/6</p> <p>allow [3] 25/9 25/18 155/2</p> <p>allowed [4] 6/9 67/15 86/7 155/4</p> <p>allowing [1] 155/23</p> <p>almost [2] 21/2 42/19</p> <p>alone [1] 78/8</p> <p>along [2] 68/21 153/22</p>	<p>alongside [2] 30/6 118/16</p> <p>aloud [1] 44/16</p> <p>Alpha [71] 1/6 1/7 1/19 2/6 2/14 3/6 3/12 3/16 3/17 3/21 4/2 10/16 10/21 11/1 11/19 12/4 12/4 14/9 14/12 14/13 17/3 18/12 18/17 18/18 18/24 19/1 19/12 20/6 20/17 20/23 21/11 21/12 21/14 21/24 22/3 24/5 26/22 27/3 27/6 27/13 27/25 28/11 29/6 29/8 29/19 29/21 30/4 30/14 30/21 31/7 31/24 32/5 32/18 32/22 32/25 33/5 33/15 34/1 34/6 34/14 35/18 36/2 36/4 37/10 38/17 39/3 39/4 39/14 39/21 39/24 40/3</p> <p>Alpha's [6] 2/3 28/15 30/9 34/23 35/4 35/12</p> <p>AlphaNine [1] 2/16</p> <p>already [5] 1/23 13/9 52/16 108/25 141/10</p> <p>also [50] 12/4 12/6 16/18 20/1 24/13 26/5 27/3 27/20 32/24 39/18 45/7 45/16 49/18 55/14 57/19 57/23 59/8 66/7 66/20 68/4 77/8 78/22 84/22 91/7 91/11 104/9 104/19 108/14 120/9 121/3 129/4 132/20 134/17 136/7 137/4 137/12 137/15 137/17 138/21 140/15 140/23 142/12 143/20 150/25 151/20 154/1 157/3 161/15 164/1 164/22</p> <p>alter [1] 48/7</p> <p>alteration [1] 52/2</p> <p>altered [1] 67/22</p> <p>alternative [3] 130/24 140/4 153/24</p> <p>alternatively [1] 74/5</p> <p>although [23] 12/7 31/13 42/22 45/22 46/17 48/22 56/3 56/4 64/11 90/19 94/17 96/8 100/15 105/22 117/19 118/9 118/18 126/6 138/12 147/6 149/20 154/7 160/13</p> <p>always [6] 24/9 29/8 44/12 49/21 68/2 115/6</p>	<p>am [13] 1/2 40/19 40/21 41/4 41/5 52/1 57/13 60/17 73/15 74/14 83/25 160/11 166/23</p> <p>amazing [1] 91/21</p> <p>amend [1] 21/7</p> <p>America [2] 12/14 119/21</p> <p>American [2] 15/8 154/4</p> <p>Americana [1] 12/18</p> <p>amongst [1] 106/9</p> <p>amount [20] 48/15 70/8 73/19 77/2 77/4 82/13 92/18 92/22 95/17 111/25 126/21 127/13 134/13 138/18 145/2 145/3 145/6 145/10 152/20 164/10</p> <p>amounts [4] 138/6 156/8 157/25 164/13</p> <p>an absence [1] 85/5</p> <p>an adequate [1] 55/3</p> <p>an adult [1] 87/16</p> <p>an advertisement [1] 17/20</p> <p>an alternative [1] 140/4</p> <p>an anonymous [2] 154/15 155/16</p> <p>an arrangement [1] 13/20</p> <p>an associate [3] 90/8 160/4 163/1</p> <p>an August 30 [1] 22/21</p> <p>an earlier [2] 116/14 157/10</p> <p>an edition [1] 16/24</p> <p>an established [1] 48/25</p> <p>an estimate [1] 115/1</p> <p>an expectation [1] 21/10</p> <p>an extremely [1] 18/5</p> <p>an incomplete [1] 59/16</p> <p>an increase [3] 78/17 80/11 139/6</p> <p>an individual [1] 81/17</p> <p>an inhibitor [1] 78/23</p> <p>an interest [1] 39/5</p> <p>an issue [1] 157/24</p> <p>an option [1] 156/22</p> <p>an undated [1] 39/18</p> <p>analysis [1] 86/7</p> <p>ancillary [1] 151/18</p> <p>Angeles [6] 13/11 24/7 24/20 25/25 26/4 26/15</p>	<p>Anglia [1] 166/20</p> <p>Anglian [2] 41/19 68/17</p> <p>anicteric [1] 117/7</p> <p>annual [54] 9/11 9/16 10/12 32/5 39/15 42/21 47/19 50/1 56/6 69/12 73/6 75/13 76/19 76/23 77/12 78/1 78/25 79/2 89/3 92/8 96/11 103/10 103/15 104/7 105/9 110/22 110/24 111/8 111/11 112/9 113/14 115/10 123/7 124/8 125/14 125/22 132/12 132/22 135/22 136/1 136/23 137/10 144/14 144/19 144/25 145/13 150/24 152/7 152/20 153/7 154/10 160/20 163/13 163/23</p> <p>annually [1] 102/25</p> <p>anonymous [3] 154/13 154/15 155/16</p> <p>another [4] 13/24 17/22 39/22 49/3</p> <p>answer [6] 42/7 62/8 82/2 82/8 102/10 110/13</p> <p>answered [1] 102/21</p> <p>answers [4] 30/16 61/23 82/22 124/18</p> <p>Anthony [1] 107/25</p> <p>anti [13] 15/19 18/11 20/14 20/15 21/2 22/2 22/25 23/14 24/12 27/14 36/21 37/1 37/4</p> <p>anti-haemophilia [1] 27/14</p> <p>anti-haemophilic [9] 15/19 20/14 22/2 22/25 23/14 24/12 36/21 37/1 37/4</p> <p>anti-HBs [2] 20/15 21/2</p> <p>anti-hepatitis [1] 18/11</p> <p>antibodies [3] 82/3 112/19 142/11</p> <p>antibody [2] 22/1 22/24</p> <p>anticipated [2] 37/13 37/14</p> <p>antigen [13] 3/8 3/18 5/16 6/10 7/14 8/10 8/20 9/24 10/2 10/6 10/8 20/11 23/5</p> <p>antigen-positive [2] 5/16 6/10</p> <p>antigenemia [1] 6/7</p> <p>anxious [2] 74/16</p>	<p>90/21</p> <p>any [68] 1/9 13/25 14/12 20/9 25/24 28/14 37/13 38/9 39/3 45/14 45/22 45/24 46/24 46/24 47/7 47/8 48/7 50/18 52/20 53/9 53/25 58/13 61/17 61/20 68/1 71/4 71/22 73/22 78/10 78/13 80/10 82/11 82/13 82/17 84/15 85/1 86/4 91/3 93/1 94/12 95/1 95/2 95/19 96/25 97/13 97/17 97/21 106/9 112/12 115/1 115/9 124/4 125/23 131/7 131/11 131/22 142/15 148/21 149/16 149/17 149/23 150/12 153/20 153/23 159/17 159/18 161/20 161/23</p> <p>anyone [4] 7/23 18/16 41/2 43/13</p> <p>anything [5] 2/21 82/16 82/23 94/22 160/16</p> <p>apologies [7] 13/18 72/10 73/1 105/23 129/24 162/13 165/3</p> <p>apparent [5] 94/24 96/18 130/8 153/2 165/23</p> <p>apparently [1] 115/21</p> <p>appear [18] 20/2 21/14 33/18 37/2 54/18 56/21 75/7 78/9 80/14 91/8 96/8 96/10 112/25 113/23 132/2 132/4 161/23 164/25</p> <p>appearing [2] 104/6 156/8</p> <p>appears [8] 34/3 39/20 68/25 74/21 110/1 111/15 112/16 162/5</p> <p>application [2] 14/2 14/5</p> <p>applications [2] 37/19 37/22</p> <p>applied [4] 2/14 35/5 36/24 85/24</p> <p>apply [3] 35/6 36/25 53/9</p> <p>applying [1] 36/12</p> <p>appointments [1] 87/7</p> <p>appreciated [3] 96/24 130/7 157/14</p> <p>approach [9] 52/20 63/1 65/6 66/21 67/15 75/16 88/22 133/21</p>
--	---	---	---	---	--

(45) afraid... - approach

<p>A</p> <p>approach... [1] 153/3</p> <p>approached [2] 19/18 29/6</p> <p>approaching [1] 74/11</p> <p>appropriate [1] 51/17</p> <p>approved [1] 27/2</p> <p>approving [1] 22/12</p> <p>approximately [4] 30/18 77/18 126/9 137/23</p> <p>April [8] 4/1 4/7 5/14 5/18 9/13 11/2 39/13 114/25</p> <p>April 1973 [3] 4/1 4/7 5/18</p> <p>April 1974 [1] 11/2</p> <p>April 1986 [1] 39/13</p> <p>Ardeman [4] 160/2 160/9 160/13 162/10</p> <p>are [91] 1/5 3/2 4/22 8/13 8/15 10/5 10/17 11/17 11/18 11/20 14/23 18/2 18/12 19/14 20/13 21/11 22/11 23/13 25/10 26/2 27/15 29/4 29/10 32/7 32/10 32/18 33/10 33/10 33/11 33/18 35/7 39/8 39/23 40/9 40/24 41/25 42/19 42/20 42/21 43/6 43/22 59/18 60/11 60/15 60/25 61/21 63/11 64/12 66/13 71/20 73/17 73/23 74/10 74/16 75/6 75/18 76/18 78/3 85/9 90/11 92/21 101/17 103/9 104/23 111/3 112/12 113/3 116/11 116/17 120/9 120/25 122/9 122/12 122/14 125/6 126/18 126/24 128/12 132/2 136/18 136/21 139/2 144/2 144/24 147/11 152/19 152/25 161/14 162/12 164/2 165/18</p> <p>area [15] 26/24 50/6 60/12 60/18 61/22 63/5 70/14 70/15 99/20 108/11 121/15 122/6 123/3 133/23 160/16</p> <p>areas [5] 24/9 72/6 100/11 100/11 122/25</p> <p>arising [2] 40/10 84/16</p> <p>Armour [43] 51/7 77/6</p>	<p>78/20 78/24 79/9 79/11 79/15 80/17 81/15 93/8 93/17 93/18 93/24 94/5 94/6 94/9 104/9 104/15 104/19 104/21 105/2 111/25 112/8 113/10 127/14 137/22 137/22 138/9 138/13 138/20 139/2 139/8 145/10 152/21 152/22 152/24 156/8 156/12 162/4 164/1 164/11 164/16 164/23</p> <p>Armour's [4] 112/10 112/14 137/17 164/7</p> <p>arose [1] 94/8</p> <p>around [17] 7/1 8/5 8/7 18/8 62/23 68/14 94/24 99/2 101/17 107/9 120/25 121/1 126/24 131/4 132/5 146/25 159/4</p> <p>arranged [1] 56/15</p> <p>arrangement [2] 13/20 69/7</p> <p>arrangements [14] 71/1 87/20 106/15 106/17 131/1 131/23 133/14 142/21 150/12 152/4 158/5 158/6 158/8 160/15</p> <p>arranging [1] 56/19</p> <p>arrive [1] 84/24</p> <p>arrived [2] 85/22 86/17</p> <p>arrives [1] 49/11</p> <p>article [16] 3/5 3/10 3/15 3/25 4/10 4/15 5/5 6/18 7/6 7/21 8/16 8/23 10/10 11/3 11/21 12/2</p> <p>as [223]</p> <p>ascertain [1] 159/2</p> <p>ask [2] 4/13 36/17</p> <p>asked [5] 55/13 71/16 90/18 119/2 155/24</p> <p>asking [3] 102/24 109/16 158/13</p> <p>aspects [1] 44/6</p> <p>assay [1] 68/5</p> <p>assess [1] 50/17</p> <p>assist [5] 42/21 45/5 75/15 84/25 131/2</p> <p>associate [15] 45/4 50/12 72/5 90/8 90/18 100/8 108/24 122/10 122/12 134/7 152/1 152/1 160/4 163/1 163/11</p> <p>associated [6] 54/16 55/14 84/14 89/1</p>	<p>98/17 117/5</p> <p>association [1] 20/12</p> <p>assume [2] 129/25 162/14</p> <p>assumed [1] 83/21</p> <p>assumption [1] 105/24</p> <p>assumptions [1] 33/18</p> <p>attached [1] 13/12</p> <p>attaining [1] 64/11</p> <p>attempt [2] 86/5 138/25</p> <p>attend [5] 47/22 106/1 129/23 149/2 162/11</p> <p>attendance [8] 64/25 96/9 105/19 115/25 116/20 123/7 140/20 148/25</p> <p>attended [18] 30/5 61/4 61/7 62/6 65/13 73/2 95/22 95/25 96/2 96/4 96/11 101/13 101/14 109/21 116/2 135/4 140/21 160/9</p> <p>attendee [3] 83/16 117/20 149/1</p> <p>attendees [4] 69/25 116/15 116/18 123/12</p> <p>attender [2] 105/21 140/21</p> <p>attending [13] 61/10 83/18 90/21 96/7 116/5 123/14 129/18 129/21 134/11 135/6 140/23 165/2 165/4</p> <p>attends [2] 83/20 116/7</p> <p>attention [5] 3/4 14/20 34/21 67/5 67/5</p> <p>attitude [1] 122/22</p> <p>attracting [1] 15/4</p> <p>attributed [2] 5/24 10/17</p> <p>August [9] 14/2 19/17 19/24 21/21 22/12 22/21 27/5 56/17 72/16</p> <p>August 1977 [1] 72/16</p> <p>August 1982 [1] 19/17</p> <p>August 1985 [1] 56/17</p> <p>August 20 [1] 22/12</p> <p>auspices [1] 97/16</p> <p>AusRIA [8] 4/6 4/8 4/25 5/1 5/25 6/9 6/19 10/11</p> <p>AusRIA I first [1] 4/25</p> <p>AusRIA-I [2] 4/6 6/19</p> <p>AusRIA-II [3] 4/8 5/1</p>	<p>6/9</p> <p>author [1] 107/1</p> <p>Authorities [1] 121/22</p> <p>authority [9] 50/7 50/25 69/16 72/6 99/23 100/10 122/15 123/3 160/16</p> <p>authorization [2] 12/23 13/13</p> <p>authorized [1] 13/9</p> <p>authors [3] 5/7 8/1 8/15</p> <p>autumn [6] 43/21 72/20 89/9 94/14 99/11 165/25</p> <p>availability [11] 47/9 49/15 62/25 64/14 65/16 67/3 67/10 70/9 88/3 118/17 139/15</p> <p>available [36] 1/20 2/12 12/12 19/11 43/8 46/16 47/5 48/22 49/18 51/9 54/1 57/6 65/25 68/2 87/3 88/10 88/13 88/15 88/16 94/17 108/18 109/10 113/7 119/16 120/18 128/18 129/10 131/4 131/20 134/19 140/3 140/4 143/4 154/6 158/14 165/8</p> <p>average [8] 8/11 8/20 9/10 9/16 32/3 33/15 63/18 103/10</p> <p>avoid [2] 33/23 128/15</p> <p>avoided [3] 24/9 24/14 27/21</p> <p>aware [13] 11/22 48/1 48/7 49/7 53/17 55/7 73/17 74/10 86/6 97/1 97/11 139/19 157/18</p> <p>awareness [1] 130/1</p> <p>away [2] 79/8 138/8</p> <p>awful [1] 118/9</p> <p>axis [2] 4/18 4/19</p> <p>B</p> <p>back [15] 3/6 7/3 22/19 24/18 28/4 35/15 35/24 40/7 53/13 56/2 69/25 80/22 87/6 134/5 166/1</p> <p>background [2] 44/21 58/1</p> <p>bad [1] 24/4</p> <p>bag [1] 80/8</p> <p>bags [5] 80/3 80/4 80/5 145/17 146/11</p> <p>balance [2] 48/17 48/24</p>	<p>Ball [6] 57/19 84/19 85/16 86/2 86/23 87/25</p> <p>Ball's [1] 57/20</p> <p>Bangor [1] 41/25</p> <p>bank [1] 37/2</p> <p>banks [16] 32/8 32/20 33/13 34/7 34/23 35/10 35/11 35/20 35/23 36/5 36/8 36/11 36/17 36/23 37/10 37/20</p> <p>Barrett [2] 99/2 99/8</p> <p>BART0000689 [2] 72/1 134/16</p> <p>based [10] 55/11 59/22 70/9 90/6 94/20 99/18 108/5 108/8 115/4 121/13</p> <p>basis [11] 23/12 37/24 62/20 94/15 98/21 103/10 111/8 116/8 136/1 139/13 139/19</p> <p>batch [2] 58/18 78/12</p> <p>batches [1] 2/7</p> <p>Bateman [1] 134/10</p> <p>Bath [1] 41/18</p> <p>BAUM0000008 [1] 19/22</p> <p>BAYP0000009 [1] 147/23</p> <p>BAYP0000021 [1] 3/9</p> <p>BAYP0003777 [1] 12/16</p> <p>be [171]</p> <p>bear [2] 113/25 114/12</p> <p>bearing [1] 24/19</p> <p>became [12] 55/7 69/14 87/3 88/10 94/24 96/18 97/1 130/7 131/3 142/11 154/6 159/15</p> <p>because [31] 1/16 6/13 6/21 8/8 13/22 21/6 25/22 47/21 50/5 51/25 55/18 56/5 67/6 71/15 73/18 81/24 82/15 82/19 87/10 87/15 107/12 113/3 115/2 116/25 154/3 155/11 158/18 160/12 161/15 163/10 164/3</p> <p>become [4] 49/18 71/7 131/19 153/2</p> <p>becoming [3] 6/15 116/1 157/18</p> <p>been [65] 2/17 10/9 13/9 15/17 20/1 23/9 23/11 24/16 25/6 26/7 30/10 30/15 30/18</p>	<p>36/12 37/25 38/7 38/8 38/13 43/17 43/18 45/13 46/10 46/12 47/4 52/25 53/7 56/14 56/23 58/13 61/15 61/16 65/22 67/24 69/1 70/6 70/10 80/4 83/11 85/2 85/18 85/23 85/24 87/13 87/16 88/16 94/7 97/5 100/25 101/12 109/8 111/15 119/10 124/21 130/21 131/10 132/5 132/8 134/18 134/20 141/10 153/13 159/14 161/23 164/25 165/7</p> <p>before [24] 3/23 8/11 8/21 19/23 20/6 20/19 22/6 23/11 29/6 35/17 35/20 53/22 73/7 75/13 78/1 95/15 98/14 109/8 130/11 130/15 138/17 142/5 148/13 165/24</p> <p>began [4] 87/1 97/13 129/1 142/5</p> <p>begin [1] 3/5</p> <p>beginning [8] 9/6 64/17 101/6 112/3 124/13 125/1 144/5 144/19</p> <p>behalf [13] 39/24 83/21 96/3 96/7 96/12 106/2 110/8 116/3 123/8 134/11 140/22 144/4 165/5</p> <p>behaviour [1] 30/19</p> <p>being [87] 6/12 6/12 6/14 7/5 8/12 8/21 14/8 29/10 31/15 31/17 35/19 37/3 42/22 43/2 48/5 53/1 56/9 65/11 69/15 77/22 78/19 79/1 79/16 80/13 80/18 81/14 82/6 82/21 83/23 84/5 84/12 85/12 86/6 87/5 92/15 93/18 94/5 97/11 97/15 97/23 103/19 103/25 104/10 104/18 105/3 105/4 110/17 111/24 116/16 119/25 126/4 129/2 130/2 133/20 134/14 135/25 137/6 137/12 137/13 137/15 137/19 138/7 138/18 138/19 138/20 139/24 140/4 141/11 141/17 141/18 146/17 147/16 148/3 149/9 150/7 154/2 154/17</p>
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<p>B</p> <p>being... [10] 156/1 156/19 157/4 157/22 158/6 158/15 164/3 164/4 164/15 164/20</p> <p>believe [2] 34/10 34/17</p> <p>believed [1] 131/19</p> <p>believes [1] 21/4</p> <p>Bell [1] 3/19</p> <p>below [1] 74/2</p> <p>benefit [6] 57/17 72/24 101/8 108/22 109/25 151/1</p> <p>best [5] 55/12 85/8 86/20 91/16 153/17</p> <p>better [4] 71/3 7/23 50/16 50/23</p> <p>between [19] 2/8 6/22 17/16 25/2 45/23 57/25 63/23 68/20 70/14 88/13 111/3 113/21 125/17 135/24 136/2 144/15 144/16 144/17 160/21</p> <p>bigger [1] 136/4</p> <p>biggest [2] 32/21 146/3</p> <p>Biologics [5] 12/21 19/18 21/6 21/20 35/14</p> <p>Biologics' [1] 22/11</p> <p>bit [1] 81/1</p> <p>bleeding [10] 44/24 61/9 62/9 63/2 67/12 67/17 101/14 109/23 124/24 135/6</p> <p>bleeds [1] 65/9</p> <p>block [1] 4/24</p> <p>blood [94] 10/15 11/5 11/13 11/25 12/6 12/8 13/20 14/3 14/22 15/10 15/11 18/20 18/23 19/8 32/8 32/19 33/13 34/6 34/23 35/10 35/11 35/20 35/23 36/5 36/8 36/11 36/17 36/23 37/2 37/10 37/20 45/23 46/24 48/2 48/6 49/21 53/25 54/16 54/19 56/16 68/6 69/6 69/9 69/10 70/7 72/5 91/1 91/4 91/5 96/17 96/17 96/22 100/9 100/18 100/23 107/1 107/3 107/3 107/6 107/22 108/15 108/25 111/12 117/13 117/15 119/7 119/14 121/21 122/1 122/7 122/23 123/4</p>	<p>130/12 132/17 133/7 133/9 133/9 134/1 134/1 134/2 134/7 136/13 139/12 142/10 142/10 142/15 143/23 149/17 156/2 157/17 160/7 160/10 162/7 163/3</p> <p>bloods [1] 155/9</p> <p>Bloom [1] 2/6</p> <p>BoB [2] 23/24 39/20</p> <p>BoB [2] 21/5 31/9</p> <p>Bob Rivett [1] 31/9</p> <p>Bolton [6] 121/4 128/24 130/3 130/20 131/2 131/19</p> <p>Bolton-Maggs [1] 121/4</p> <p>bonus [1] 17/19</p> <p>borne [1] 152/7</p> <p>both [24] 4/11 4/13 10/5 21/8 41/21 42/10 43/5 43/13 50/24 56/15 59/11 76/21 89/23 94/17 96/21 115/11 122/14 136/7 139/2 142/18 144/21 154/13 155/10 161/6</p> <p>bottles [14] 69/18 69/18 72/14 100/1 102/2 102/24 108/18 123/19 123/22 123/23 134/3 143/25 152/22 163/7</p> <p>bottom [18] 8/2 17/4 50/3 53/15 64/6 65/4 66/2 66/19 70/4 72/10 74/9 80/17 100/14 100/21 121/24 122/3 123/16 128/1</p> <p>bought [2] 51/6 101/1</p> <p>Bournemouth [1] 41/17</p> <p>boys [1] 86/4</p> <p>BPL [8] 73/14 74/23 95/6 95/8 101/16 134/19 139/21 158/12</p> <p>BPLL [1] 36/15</p> <p>BPLL0001351 [1] 34/10</p> <p>BPLL0008111 [5] 101/15 110/5 125/2 135/7 144/1</p> <p>break [10] 38/8 40/18 40/20 95/15 98/8 98/9 138/17 143/5 143/6 143/9</p> <p>Brentwood [7] 75/3 122/6 122/7 122/12 122/16 122/18 124/2</p> <p>brief [2] 41/4 44/1</p> <p>briefly [1] 118/17</p>	<p>bring [4] 3/25 17/19 26/18 39/3</p> <p>Bristol [1] 119/10</p> <p>British [1] 139/18</p> <p>Britt [2] 163/1 165/1</p> <p>Britt's [1] 165/5</p> <p>broad [1] 142/20</p> <p>broader [1] 56/22</p> <p>broadly [7] 57/1 66/13 66/20 78/17 87/20 103/5 107/25</p> <p>brought [1] 46/8</p> <p>BTC [1] 100/23</p> <p>BTS [1] 49/21</p> <p>buckets [1] 120/14</p> <p>building [1] 133/11</p> <p>bulk [1] 50/24</p> <p>Bureau [2] 12/21 21/5</p> <p>burn [1] 17/14</p> <p>Bury [1] 41/22</p> <p>Bury St Edmunds [1] 41/22</p> <p>but [188]</p> <p>buy [2] 24/8 72/15</p> <p>buying [2] 50/24 119/20</p> <p>by [122] 1/3 1/7 1/16 3/12 3/16 3/21 3/22 3/23 3/24 4/11 4/24 4/25 5/1 5/15 9/18 10/9 12/4 12/19 13/9 15/14 17/3 17/13 18/17 22/3 24/16 27/2 29/19 32/21 35/13 36/8 39/19 40/22 46/10 46/13 46/13 50/24 51/6 51/11 52/25 53/24 54/24 55/23 56/24 57/11 59/7 59/11 60/2 62/9 72/12 73/11 74/17 75/10 75/12 75/24 76/9 76/10 79/8 80/10 80/22 82/20 85/2 85/17 85/22 87/8 87/8 94/6 96/9 96/11 96/17 96/22 98/20 98/21 98/21 98/22 99/1 100/23 101/16 107/16 110/20 111/18 113/16 116/22 116/23 121/16 123/7 124/20 126/11 126/14 128/15 129/10 129/14 129/15 130/12 131/20 133/25 134/23 138/8 140/3 141/8 142/7 142/7 142/12 142/24 143/2 143/23 144/9 144/23 148/9 152/7 153/16 155/6 155/22 157/5 160/2 163/3 163/23 165/1</p>	<p>165/10 165/17 166/7 167/2 167/4</p> <p>C</p> <p>C's [1] 97/8</p> <p>CA [1] 25/17</p> <p>calculations [1] 14/23</p> <p>California [3] 13/1 13/5 13/11</p> <p>call [2] 45/19 91/25</p> <p>called [6] 14/14 16/22 68/18 87/6 107/1 128/3</p> <p>Cambridge [1] 41/20</p> <p>came [8] 25/6 30/17 44/22 71/4 85/17 94/13 94/22 153/22</p> <p>can [116] 4/16 4/18 4/22 5/5 7/3 9/20 9/21 14/22 15/25 16/9 17/2 17/3 17/15 18/6 18/7 18/10 18/17 23/17 25/13 28/19 29/13 32/13 32/17 35/16 38/18 41/3 42/7 43/9 43/23 47/3 52/7 53/13 55/23 62/3 63/1 63/7 63/20 64/5 64/13 65/4 65/15 66/2 66/11 68/12 69/12 69/17 69/21 69/24 70/2 70/17 72/11 73/7 75/12 76/20 76/24 77/2 77/16 79/4 79/15 80/13 80/22 81/1 81/14 81/20 81/22 83/10 83/13 83/15 83/18 83/21 89/3 90/9 90/13 93/3 93/6 95/4 95/8 96/6 98/7 100/13 100/19 101/20 102/20 110/20 111/10 111/17 111/21 111/24 112/22 113/17 116/14 116/21 121/19 122/4 124/4 124/19 125/4 125/8 126/1 126/13 127/6 127/22 132/1 136/25 138/5 138/18 138/24 145/16 146/11 146/16 146/21 150/14 158/10 159/25 163/22 166/13</p> <p>can't [4] 26/1 96/25 97/6 161/8</p> <p>cannot [2] 51/21 154/7</p> <p>capacity [3] 95/22 116/7 132/9</p> <p>Cardiff [1] 2/7</p> <p>care [26] 44/24 45/12 46/6 46/19 48/19 54/20 60/13 61/25</p>	<p>62/17 62/22 64/21 66/21 68/10 68/16 71/10 87/12 87/21 88/1 89/18 90/16 97/9 97/20 106/18 133/14 133/19 155/23</p> <p>career [1] 151/7</p> <p>careful [1] 154/14</p> <p>carefully [1] 33/23</p> <p>caran [1] 88/6</p> <p>Carman [1] 23/23</p> <p>Carmichael [1] 71/12</p> <p>Carr [6] 20/23 21/16 21/17 22/8 22/10 38/19</p> <p>carried [3] 117/16 142/15 156/1</p> <p>carrier [3] 127/8 127/20 128/5</p> <p>carriers [2] 136/3 146/10</p> <p>carry [1] 156/20</p> <p>carrying [1] 48/9</p> <p>case [7] 15/21 25/4 76/17 120/11 120/12 120/15 120/15</p> <p>cases [13] 32/3 48/20 49/7 61/1 62/3 78/7 98/17 109/19 120/11 124/21 135/3 153/10 153/24</p> <p>cash [2] 18/19 19/10</p> <p>cast [4] 71/22 85/19 131/22 159/17</p> <p>Castro [1] 12/19</p> <p>categories [2] 42/23 61/14</p> <p>cause [2] 15/12 82/4</p> <p>caused [1] 15/19</p> <p>CBLA [1] 100/4</p> <p>CBLA0000510 [1] 69/3</p> <p>CBLA0000533 [3] 69/20 90/10 121/19</p> <p>CBLA0000657 [3] 100/7 108/21 123/9</p> <p>CBLA0000838 [2] 72/25 124/11</p> <p>CBLA0001945 [1] 73/10</p> <p>CBLA0002018 [1] 95/4</p> <p>CBLA0002033 [1] 158/11</p> <p>CBLA0002159 [1] 2/4</p> <p>CBLA0002160 [1] 74/22</p> <p>CBLA0008794 [1] 75/17</p> <p>cease [1] 19/19</p> <p>cent [11] 11/17 11/19 15/2 15/2 33/6 33/7</p>	<p>33/8 34/5 34/7 113/11 119/14</p> <p>center [5] 18/18 18/24 19/13 21/19 38/23</p> <p>centers [10] 17/3 18/12 19/1 24/7 24/19 26/15 28/24 32/2 32/6 35/4</p> <p>Central [1] 12/14</p> <p>centre [140] 2/7 2/10 14/10 17/17 25/1 25/4 26/6 26/8 26/10 33/15 38/12 39/13 39/16 42/13 43/1 44/11 45/4 47/17 50/11 50/12 51/22 57/9 58/8 58/21 58/22 59/21 60/19 60/24 61/2 61/4 61/7 61/10 61/12 61/16 62/4 62/6 62/13 63/5 65/12 67/25 68/3 68/7 86/1 86/17 86/20 87/16 87/18 88/23 89/1 89/7 89/19 89/21 90/6 90/8 90/18 91/6 92/2 92/6 95/21 95/23 97/16 98/1 98/15 98/25 99/7 99/17 100/18 100/24 101/4 101/11 106/21 106/23 106/24 107/18 108/5 108/8 108/15 109/19 109/21 110/3 110/4 110/9 113/8 116/2 119/10 120/3 120/17 120/19 120/24 121/11 122/1 122/7 123/4 124/21 124/25 132/5 132/15 132/22 133/2 134/1 135/3 135/4 135/6 136/4 136/4 136/11 136/14 139/12 139/16 141/23 142/2 143/12 143/24 150/3 150/14 150/15 150/17 151/12 151/15 151/22 151/23 152/1 152/2 152/6 154/16 157/10 159/16 159/20 160/1 160/4 160/8 160/18 160/19 162/7 162/23 162/24 163/1 163/4 163/11 165/16</p> <p>Centre' [1] 151/11</p> <p>centre's [2] 140/8 150/24</p> <p>centres [97] 10/16 12/3 14/4 14/6 14/8 19/14 25/7 25/10 25/25 26/1 28/17 31/24 32/18 32/19 32/22 32/23 33/1 33/6</p>
--	---	--	---	---	--

<p>C</p> <p>centres... [79] 34/2 34/6 38/2 38/10 40/15 40/23 40/25 41/3 41/6 41/11 41/15 41/17 41/19 41/24 42/4 42/10 42/16 42/18 43/5 43/6 57/4 59/16 60/3 60/5 60/6 60/12 60/17 61/17 61/24 66/6 66/14 66/17 68/22 69/6 69/9 69/10 70/2 70/7 70/10 71/23 71/24 72/6 84/12 88/16 89/12 90/16 98/18 99/20 100/10 101/18 102/6 108/10 108/24 108/24 108/25 109/17 119/18 121/15 121/21 121/21 122/2 122/9 122/10 122/11 122/12 122/23 123/2 123/14 133/23 134/7 134/7 134/8 136/5 143/21 146/2 160/10 160/10 163/8 167/5</p> <p>Centro [1] 12/17</p> <p>cents [8] 16/2 16/2 16/4 16/4 16/4 16/5 16/6 16/10</p> <p>CEP [1] 4/23</p> <p>certain [4] 48/15 123/1 123/2 163/8</p> <p>certainly [19] 7/17 25/2 26/8 26/9 37/22 44/14 46/25 47/17 75/4 76/4 76/14 80/9 85/11 108/3 122/25 141/19 151/22 159/3 160/2</p> <p>CGRA0000241 [1] 31/5</p> <p>CGRA0000262 [2] 23/17 36/1</p> <p>CGRA0000265 [1] 28/18</p> <p>CGRA000027 [1] 21/15</p> <p>CGRA0000294 [1] 19/3</p> <p>CGRA0000327 [1] 30/8</p> <p>CGRA0000376 [1] 27/23</p> <p>CGRA0000599 [1] 38/15</p> <p>CGRA0000657 [1] 22/7</p> <p>CGRA0000665 [1] 31/1</p> <p>chair [4] 66/24 71/12</p>	<p>116/16 116/22</p> <p>Chairman [1] 23/23</p> <p>Chanarin [1] 150/16</p> <p>chance [1] 18/6</p> <p>Chances [1] 18/2</p> <p>change [3] 49/2 52/20 155/25</p> <p>changed [2] 34/24 67/1</p> <p>changes [3] 37/14 58/20 133/18</p> <p>changing [3] 53/4 53/8 154/21</p> <p>charge [1] 58/22</p> <p>Charing [31] 41/7 88/24 89/2 89/8 89/11 89/13 89/18 89/22 90/1 90/6 90/14 90/17 90/21 90/25 91/10 94/14 95/5 95/15 95/20 95/23 96/5 96/7 96/12 96/23 97/4 97/9 97/22 97/24 98/3 98/6 157/20</p> <p>Charing Cross [5] 41/7 89/11 89/22 90/1 90/14</p> <p>charity [1] 23/21</p> <p>Charles [1] 23/23</p> <p>check [5] 20/19 62/14 115/17 148/22 158/11</p> <p>checked [1] 29/8</p> <p>checks [1] 29/6</p> <p>cheques [1] 148/3</p> <p>Chief [3] 58/7 59/9 65/1</p> <p>child [7] 46/9 54/13 55/15 55/24 156/11 158/21 159/3</p> <p>children [44] 44/24 47/13 47/14 48/14 48/17 48/18 48/22 49/4 49/6 51/18 51/24 52/12 52/14 53/10 54/4 54/23 55/10 55/20 56/10 56/14 56/15 56/23 59/21 65/9 69/13 70/22 70/25 71/14 71/17 72/9 73/16 74/12 74/15 83/5 88/2 89/23 90/4 95/3 95/9 95/13 97/9 97/11 97/23 136/10</p> <p>children's [2] 44/20 71/16</p> <p>Chipping [8] 132/11 132/11 132/19 133/5 136/8 139/10 140/23 140/24</p> <p>choice [1] 47/3</p> <p>chosen [1] 51/6</p>	<p>Christmas [4] 64/1 77/1 82/5 163/15</p> <p>chronic [3] 96/25 117/7 130/9</p> <p>circa [2] 39/6 155/8</p> <p>circular [1] 60/21</p> <p>circumspect [1] 52/18</p> <p>circumstances [4] 47/3 54/15 54/24 61/18</p> <p>cites [1] 11/7</p> <p>cities [1] 19/15</p> <p>claims [1] 55/17</p> <p>clear [4] 25/20 91/3 97/17 98/23</p> <p>clearer [1] 86/3</p> <p>clearly [2] 26/1 95/11</p> <p>Cleghorn [1] 117/11</p> <p>clinic [3] 99/14 142/6 143/1</p> <p>clinical [14] 3/10 46/18 46/22 46/22 47/21 48/4 74/7 87/6 107/2 118/7 129/15 139/14 151/21 151/23</p> <p>clinician [3] 53/9 96/10 132/12</p> <p>clinicians [8] 1/16 53/3 105/17 106/1 118/4 132/3 157/8 165/3</p> <p>close [1] 20/12</p> <p>closed [3] 25/1 38/12 38/22</p> <p>Club [1] 148/1</p> <p>Clyde [2] 3/12 28/16</p> <p>Clyde McAuley [1] 3/12</p> <p>co [3] 23/25 74/7 107/17</p> <p>Co-Director [1] 23/25</p> <p>co-directors [1] 107/17</p> <p>co-operate [1] 74/7</p> <p>coagulation [3] 21/3 45/23 133/10</p> <p>cohort [3] 41/17 103/18 106/10</p> <p>cohorts [1] 129/8</p> <p>collaboration [1] 88/11</p> <p>colleague [2] 83/20 129/16</p> <p>colleagues [2] 85/3 148/1</p> <p>collect [1] 28/11</p> <p>collected [6] 12/25 19/20 20/10 21/2 24/10 35/2</p> <p>collecting [1] 18/12</p> <p>collection [2] 26/7 31/11</p>	<p>collects [1] 20/15</p> <p>College [6] 120/22 122/14 123/8 123/16 125/5 132/7</p> <p>column [6] 8/4 9/5 32/14 32/15 32/16 63/13</p> <p>combination [3] 105/1 125/10 152/13</p> <p>come [11] 7/3 35/15 57/7 69/25 74/14 74/18 82/10 89/15 107/4 108/4 123/13</p> <p>comes [4] 3/10 12/17 24/24 34/17</p> <p>comfortable [1] 154/21</p> <p>coming [7] 28/3 34/6 34/6 34/7 40/7 43/19 139/11</p> <p>comment [1] 22/6</p> <p>comments [1] 61/20</p> <p>commercial [63] 3/13 11/10 14/4 19/18 48/8 50/8 51/5 51/6 56/5 56/7 56/10 70/21 71/2 72/16 72/20 73/23 74/16 75/11 77/6 77/21 78/7 78/11 78/19 80/16 81/16 91/3 92/13 92/17 100/25 104/2 104/4 105/6 111/14 111/24 112/3 112/14 113/2 114/18 117/14 124/6 126/25 128/2 128/13 128/13 128/16 134/13 137/6 138/25 139/20 139/24 144/21 146/16 147/6 147/15 152/25 154/3 155/14 156/25 157/22 161/24 162/3 164/4 164/25</p> <p>commitment [6] 20/20 20/21 21/4 21/11 22/5 27/6</p> <p>committee [3] 38/18 119/2 119/6</p> <p>committees [2] 107/3 117/21</p> <p>common [2] 75/7 75/9</p> <p>communicated [2] 106/17 141/20</p> <p>communicating [2] 87/8 159/5</p> <p>community [2] 10/15 18/23</p> <p>companies [13] 1/4 20/2 20/4 28/5 29/20 29/21 39/7 39/19 40/6 40/8 40/11 147/21 167/3</p>	<p>company [10] 12/18 14/9 14/10 14/11 27/11 28/4 30/1 31/14 31/19 38/1</p> <p>company's [1] 31/10</p> <p>comparable [1] 11/4</p> <p>comparative [1] 11/9</p> <p>comparatively [4] 57/5 59/6 147/5 152/3</p> <p>compared [3] 32/22 33/1 145/24</p> <p>comparison [2] 80/22 118/10</p> <p>compensate [1] 75/25</p> <p>compiled [1] 98/21</p> <p>complete [3] 127/18 138/16 166/18</p> <p>completed [2] 111/17 150/24</p> <p>completely [1] 86/18</p> <p>complicated [1] 71/7</p> <p>complications [1] 94/8</p> <p>components [1] 21/3</p> <p>comprehensive [2] 26/19 159/16</p> <p>comprised [1] 151/15</p> <p>concentrate [129] 19/21 47/12 49/16 49/24 50/8 50/19 50/20 50/22 53/21 69/5 69/15 70/3 71/6 71/9 72/15 72/16 73/19 73/23 73/24 74/5 74/6 74/12 74/17 75/1 76/3 76/12 77/5 77/10 77/19 78/8 78/12 79/7 79/14 80/13 92/13 92/17 93/24 93/24 94/6 94/7 100/22 100/25 101/24 102/1 102/16 102/19 102/21 103/20 103/24 104/1 104/6 104/10 104/13 104/19 104/21 104/22 105/2 105/4 105/10 105/14 108/13 108/17 109/5 110/16 110/17 111/14 111/14 112/7 112/10 112/16 113/2 113/2 113/11 113/12 114/2 115/21 118/18 118/21 119/4 119/20 120/15 122/18 123/19 123/24 125/9 125/11 126/5 126/11 126/25 127/25 128/2 129/3 134/5 134/13 134/14 135/17 135/19 137/12 138/19 139/1 139/6 139/21 140/12 140/16 140/17 143/25</p>	<p>144/11 144/11 144/21 145/3 145/6 145/18 146/14 146/23 147/18 153/1 155/14 155/21 157/22 158/9 161/2 161/5 161/7 161/10 161/16 161/17 161/24 163/7 164/15</p> <p>concentrates [102] 27/8 48/8 50/6 52/16 52/17 53/12 54/1 54/5 56/11 67/8 69/8 69/19 69/22 71/2 72/21 73/3 73/5 73/8 73/9 75/11 76/15 77/6 77/22 78/18 78/19 78/19 80/16 81/16 82/7 84/4 84/15 84/16 91/3 91/5 91/19 92/13 93/7 93/16 94/3 94/5 94/5 94/9 94/11 95/7 99/25 104/3 104/4 105/2 105/6 110/18 111/23 112/4 112/14 115/10 115/18 118/1 122/2 122/25 124/5 124/6 126/4 126/15 126/19 126/24 127/4 127/11 127/17 128/16 129/9 130/25 134/21 136/19 136/20 137/5 137/6 137/19 137/25 138/7 139/19 144/24 145/9 146/17 146/19 147/5 147/8 147/15 152/14 152/16 152/16 152/17 154/20 158/13 158/15 160/7 163/3 163/25 164/1 164/7 164/9 164/22 164/24 164/25</p> <p>concept [1] 67/21</p> <p>concern [2] 15/20 141/4</p> <p>concerned [10] 47/13 59/18 63/11 71/8 71/10 85/13 90/14 117/13 124/22 131/18</p> <p>concerning [2] 45/18 47/7</p> <p>concerns [7] 12/3 21/8 84/3 84/5 141/19 153/13 153/20</p> <p>conclude [1] 33/21</p> <p>concludes [2] 40/3 40/5</p> <p>Conclusions [1] 66/1</p> <p>concomitant [1] 9/14</p> <p>condition [1] 130/12</p> <p>conditions [2] 2/20 60/14</p> <p>conducted [1] 56/16</p> <p>conducting [1] 159/1</p>
--	--	--	---	---	---

<p>C</p> <p>confidence [2] 97/1 112/12</p> <p>confident [1] 25/22</p> <p>confidential [1] 19/11</p> <p>confidentially [1] 64/13</p> <p>confirm [2] 148/11 157/2</p> <p>confirmed [1] 86/25</p> <p>connected [1] 23/13</p> <p>connection [1] 99/6</p> <p>conscious [5] 48/21 113/5 115/5 128/14 147/10</p> <p>consent [6] 85/14 85/23 97/6 97/7 97/10 150/8</p> <p>consequence [1] 97/19</p> <p>consider [12] 18/22 41/20 48/20 53/7 55/5 57/1 60/15 98/24 107/5 120/21 141/14 153/23</p> <p>considerable [6] 11/23 50/5 77/3 79/16 137/4 144/23</p> <p>consideration [2] 51/16 52/22</p> <p>considerations [1] 140/1</p> <p>considered [1] 49/19</p> <p>consistent [9] 5/20 29/13 54/2 54/21 56/8 56/21 96/9 98/3 159/9</p> <p>consistently [2] 84/17 115/7</p> <p>consultant [6] 44/10 44/22 50/13 132/17 150/22 151/4</p> <p>consultants [4] 45/5 90/20 99/12 151/16</p> <p>consulted [2] 46/14 153/12</p> <p>consulting [1] 153/18</p> <p>contact [4] 18/24 19/1 19/12 30/11</p> <p>contacting [3] 18/17 73/18 156/19</p> <p>contain [2] 97/21 139/20</p> <p>contained [2] 27/19 149/13</p> <p>containing [1] 102/2</p> <p>contemplated [1] 55/1</p> <p>contemporaneous [5] 59/5 83/13 105/17 121/18 152/5</p> <p>context [2] 14/16 121/25</p>	<p>continually [1] 10/22</p> <p>continue [9] 23/2 23/4 23/10 52/18 55/16 65/21 67/14 90/21 155/2</p> <p>continued [6] 1/4 54/5 55/10 74/20 117/13 167/3</p> <p>continues [4] 46/20 117/18 139/4 156/15</p> <p>continuing [3] 1/5 137/9 161/13</p> <p>contract [7] 32/1 32/6 32/18 32/23 33/2 33/7 155/10</p> <p>contracting [1] 156/21</p> <p>contractors [2] 12/5 34/8</p> <p>contradistinction [1] 7/6</p> <p>contrast [1] 88/13</p> <p>contribute [1] 8/9</p> <p>contributed [3] 8/11 33/7 33/8</p> <p>contributing [1] 33/20</p> <p>contribution [1] 119/24</p> <p>contributions [4] 35/23 118/3 160/13 160/14</p> <p>contributors [1] 118/10</p> <p>control [5] 14/11 35/19 46/18 48/11 54/1</p> <p>controversy [2] 15/12 15/13</p> <p>convened [1] 119/3</p> <p>conversion [1] 145/22</p> <p>convey [1] 79/24</p> <p>convinced [1] 154/2</p> <p>copied [1] 38/19</p> <p>copies [1] 165/7</p> <p>copy [2] 13/12 25/9</p> <p>Core [3] 42/11 43/17 43/22</p> <p>corner [3] 17/4 17/25 101/22</p> <p>Corporation [3] 4/2 21/25 34/13</p> <p>Corporation's [3] 10/16 10/22 11/1</p> <p>correct [6] 16/7 25/8 33/19 124/16 128/20 129/12</p> <p>corrected [1] 10/12</p> <p>correction [1] 94/1</p> <p>correspondence [1] 82/19</p> <p>cost [3] 15/8 15/11 15/23</p>	<p>Costello [1] 99/3</p> <p>could [41] 3/5 4/13 4/14 5/3 9/4 12/15 14/15 15/15 16/20 16/24 17/22 19/3 19/22 21/6 21/7 21/15 22/7 25/8 27/23 29/4 31/5 33/20 34/9 44/7 45/19 46/17 49/7 58/4 71/16 76/13 86/23 90/18 96/17 96/22 96/24 99/15 114/20 130/12 131/5 157/25 166/15</p> <p>couldn't [4] 86/2 94/14 95/1 130/23</p> <p>Council [1] 116/12</p> <p>Council's [1] 151/21</p> <p>Counsel [4] 1/3 40/22 167/2 167/4</p> <p>counselling [2] 56/20 88/9</p> <p>counterimmunoelctrophoresis [4] 4/5 5/10 5/13 9/10</p> <p>country [1] 118/21</p> <p>couple [3] 11/7 16/15 39/11</p> <p>courier [1] 8/6</p> <p>course [42] 3/22 7/22 11/22 16/10 28/4 34/1 35/16 39/9 40/9 40/14 43/4 51/15 52/12 52/23 55/5 66/7 66/10 66/18 68/14 71/24 74/18 81/9 81/13 81/19 84/22 87/10 88/11 89/16 91/8 94/6 99/5 106/3 107/22 108/2 115/6 115/22 127/6 137/14 143/14 149/5 150/17 165/18</p> <p>Coventry [1] 41/25</p> <p>cover [4] 16/21 43/5 68/4 166/13</p> <p>covered [4] 2/24 41/3 41/24 43/6</p> <p>covering [3] 40/25 42/13 121/22</p> <p>Craske [1] 116/18</p> <p>Crawford [1] 132/8</p> <p>create [1] 21/8</p> <p>crept [1] 126/23</p> <p>cripple [1] 18/7</p> <p>crippling [2] 65/9 67/19</p> <p>critical [1] 44/8</p> <p>criticisms [1] 149/12</p> <p>cross [35] 5/1 15/4 34/13 39/4 41/7 88/24 89/2 89/8 89/11 89/13 89/18 89/22 90/1 90/6</p>	<p>90/14 90/17 90/21 90/25 91/10 94/14 95/6 95/15 95/20 95/23 96/5 96/8 96/12 96/23 97/4 97/9 97/22 97/24 98/3 98/6 157/20</p> <p>crossed [2] 76/5 112/22</p> <p>cryo [13] 47/7 47/8 120/14 125/10 125/10 128/8 135/16 135/18 137/11 145/22 152/15 152/16 152/17</p> <p>cryoprecipitate [112] 47/1 47/4 49/12 49/20 52/17 62/24 63/1 64/14 65/24 67/3 67/11 68/6 75/20 75/23 76/11 76/18 77/3 77/17 79/7 79/19 79/23 80/1 91/2 91/4 92/3 92/6 92/11 92/16 92/20 92/22 93/6 94/2 94/17 94/19 102/15 102/18 103/19 103/22 103/24 104/18 104/20 105/13 108/14 110/15 110/15 111/13 111/21 111/22 112/6 112/10 112/16 122/3 122/24 126/2 126/9 126/10 126/23 127/3 127/9 127/23 129/5 130/24 136/20 137/3 137/10 137/15 137/17 137/20 137/24 138/6 138/12 138/18 139/6 140/6 144/10 144/24 145/2 145/5 145/8 145/17 145/25 146/11 146/21 147/2 147/7 147/19 152/13 153/10 154/6 154/18 154/22 155/1 155/8 155/20 156/23 157/25 161/1 161/2 161/10 161/14 161/17 161/21 163/24 163/25 164/1 164/6 164/10 164/17 164/20 164/24</p> <p>cryoprecipitated [2] 21/25 22/23</p> <p>culminating [1] 133/20</p> <p>current [3] 56/18 58/7 63/9</p> <p>currently [5] 20/14 73/23 76/18 98/5 123/21</p> <p>Cutter [7] 12/25 19/24 19/25 77/23 147/24</p>	<p>148/11 148/21</p> <p>Cutter's [3] 20/5 148/5 148/9</p> <p>CVHB0000002 [1] 2/9</p> <p>D</p> <p>D-A-C-I-E [1] 132/4</p> <p>Dacie [1] 132/4</p> <p>damage [1] 130/9</p> <p>danger [2] 18/22 34/3</p> <p>dangerous [1] 71/7</p> <p>dangers [1] 149/15</p> <p>data [16] 14/19 59/13 63/8 82/2 82/8 86/11 93/21 98/16 98/22 106/11 114/20 120/4 131/12 159/9 162/16 165/10</p> <p>database [2] 40/1 58/16</p> <p>date [4] 28/19 83/22 121/23 165/23</p> <p>dated [10] 12/16 13/13 19/24 21/21 22/9 27/24 51/23 58/5 58/17 147/24</p> <p>dates [3] 34/10 86/5 86/17</p> <p>Dave [1] 31/9</p> <p>Dave Gury [1] 31/9</p> <p>David [3] 3/19 34/11 118/16</p> <p>day [12] 7/22 17/13 18/14 46/6 46/6 46/9 66/10 66/18 68/1 71/24 89/16 166/23</p> <p>daycare [1] 87/6</p> <p>days [1] 48/14</p> <p>DDAVP [14] 48/12 48/14 48/20 49/3 49/4 49/7 94/16 94/22 128/4 128/7 128/17 129/2 140/4 153/24</p> <p>de [1] 12/18</p> <p>dead [1] 18/14</p> <p>deal [3] 41/10 46/14 54/7</p> <p>dealing [4] 51/12 55/1 55/4 60/12</p> <p>deals [3] 47/25 53/15 57/15</p> <p>Dean [1] 99/18</p> <p>death [1] 17/16</p> <p>deceased [1] 58/24</p> <p>December [21] 9/12 9/14 27/24 28/15 28/19 29/25 38/16 38/20 39/1 53/17 53/20 54/6 57/13 60/2 69/4 69/24 70/6 70/24 73/9 74/18 121/23</p> <p>December 15 [1]</p>	<p>38/20</p> <p>December 1969 [1] 60/2</p> <p>December 1971 [1] 9/12</p> <p>December 1973 [1] 9/14</p> <p>December 1976 [1] 70/24</p> <p>December 1982 [1] 29/25</p> <p>December 1984 [3] 53/17 53/20 54/6</p> <p>December 1st [1] 70/6</p> <p>decided [4] 50/7 68/19 119/15 129/10</p> <p>deciding [1] 124/2</p> <p>decision [6] 48/21 48/25 113/5 128/15 140/2 147/11</p> <p>decision-making [1] 147/11</p> <p>decisions [5] 94/10 94/15 139/13 153/12 153/19</p> <p>decline [2] 29/12 126/12</p> <p>dedicated [5] 99/16 143/1 151/11 151/17 151/18</p> <p>dedication [1] 78/13</p> <p>deductions [1] 161/21</p> <p>deemed [1] 46/25</p> <p>degree [1] 86/23</p> <p>delegated [1] 46/7</p> <p>delivered [3] 43/21 70/6 133/19</p> <p>Della [1] 83/25</p> <p>demand [3] 17/9 68/1 155/9</p> <p>demande [1] 67/22</p> <p>demands [1] 107/22</p> <p>demonstrate [1] 26/10</p> <p>denies [1] 15/21</p> <p>Dennis [1] 19/17</p> <p>department [22] 27/25 59/22 60/9 60/15 60/21 64/20 66/20 71/1 82/20 99/16 101/7 101/23 109/13 119/3 121/10 121/13 133/8 133/10 133/10 133/17 142/24 148/12</p> <p>depended [1] 139/14</p> <p>dependent [1] 140/19</p> <p>depending [2] 46/23 111/5</p> <p>depends [1] 148/24</p> <p>Deputy [1] 65/1</p>
--	---	--	---	--	--

<p>D</p> <p>Derby [1] 41/25</p> <p>derive [1] 81/22</p> <p>derived [1] 65/10</p> <p>Desai [1] 96/7</p> <p>describe [1] 133/13</p> <p>described [13] 44/8 51/11 52/25 54/24 76/25 84/20 90/1 91/12 120/11 120/15 130/3 152/22 157/23</p> <p>describes [12] 4/10 16/22 49/9 121/5 121/8 133/5 141/11 154/17 154/19 155/18 156/19 157/3</p> <p>describing [3] 63/9 65/6 157/15</p> <p>description [4] 59/9 142/20 151/9 151/13</p> <p>designated [14] 60/4 60/11 89/21 90/8 99/20 108/10 121/15 133/23 143/20 151/10 151/25 160/3 163/2 163/11</p> <p>desperately [1] 17/12</p> <p>despite [3] 64/9 72/14 155/2</p> <p>detail [9] 1/22 43/14 62/8 64/24 77/11 78/16 116/25 143/19 165/19</p> <p>detailed [1] 43/7</p> <p>details [6] 3/15 19/2 78/3 130/21 131/6 136/17</p> <p>detect [1] 147/11</p> <p>detected [2] 5/16 10/9</p> <p>detecting [1] 7/13</p> <p>detection [2] 6/10 9/23</p> <p>detergent [1] 2/15</p> <p>detergent-treated [1] 2/15</p> <p>determined [1] 153/16</p> <p>develop [1] 18/11</p> <p>developed [2] 130/9 130/16</p> <p>developing [1] 106/8</p> <p>development [6] 18/13 49/15 53/17 60/16 108/2 147/24</p> <p>developments [1] 47/24</p> <p>DHSC00 [1] 53/14</p> <p>DHSC0002197 [1] 39/8</p> <p>DHSC0004728 [1] 166/5</p>	<p>DHSC0043164 [1] 44/18</p> <p>DHSC0100026 [10] 60/1 62/3 62/18 64/19 101/9 109/11 110/2 124/13 128/23 135/2</p> <p>DHSS [4] 60/2 66/25 70/23 109/14</p> <p>DHSS's [1] 134/24</p> <p>diabetes [1] 48/24</p> <p>diagnose [1] 22/18</p> <p>diagnoses [1] 85/16</p> <p>diagnosis [5] 56/24 60/13 85/8 87/17 106/16</p> <p>diagnosis/test [1] 106/16</p> <p>diagnostic [1] 88/9</p> <p>diagnostics [1] 22/17</p> <p>diagonal [1] 4/24</p> <p>dictated [1] 140/2</p> <p>did [32] 13/14 17/12 29/24 35/19 45/15 46/21 47/22 48/6 48/12 48/18 48/19 50/14 50/17 51/1 53/24 53/25 54/10 55/8 82/10 85/21 88/3 97/10 97/12 131/9 131/11 153/19 153/23 154/9 154/24 155/10 158/1 162/10</p> <p>didn't [8] 41/11 41/22 44/14 86/4 96/16 123/3 129/23 153/6</p> <p>difference [2] 17/16 81/4</p> <p>different [29] 3/15 4/20 8/18 11/12 12/10 14/10 15/16 19/14 31/6 43/1 51/17 51/17 71/5 75/6 77/5 78/7 79/22 93/14 101/18 116/14 118/4 126/4 130/5 131/21 138/2 146/18 155/12 155/15 157/7</p> <p>difficult [5] 21/7 26/3 48/13 113/21 161/20</p> <p>difficulties [3] 15/3 73/18 74/21</p> <p>direct [10] 49/20 52/13 53/25 85/1 95/18 105/18 106/6 111/9 129/14 162/9</p> <p>directed [2] 17/20 27/25</p> <p>direction [1] 142/16</p> <p>directive [1] 52/24</p> <p>directly [5] 59/6 59/18 134/19 136/8 149/20</p> <p>director [34] 12/20</p>	<p>21/19 23/25 28/16 44/11 47/17 57/9 58/8 62/12 88/23 89/7 93/3 95/22 99/1 99/2 99/3 106/24 116/2 116/8 119/9 122/18 129/18 129/20 129/22 132/5 132/6 132/8 132/14 132/22 133/1 142/25 143/14 150/17 162/25</p> <p>directors [22] 39/13 39/16 43/1 51/22 52/16 57/8 60/17 72/4 95/20 100/8 100/9 100/9 106/23 107/17 108/24 120/24 121/20 122/22 124/9 134/6 143/12 160/10</p> <p>Directors' [1] 47/23</p> <p>directorship [1] 160/2</p> <p>discern [1] 161/9</p> <p>disclosed [2] 42/11 43/17</p> <p>discovered [1] 118/19</p> <p>discuss [2] 64/21 153/20</p> <p>discussed [8] 16/14 19/16 55/2 69/23 74/3 83/23 117/23 153/14</p> <p>discussing [1] 131/6</p> <p>discussion [10] 8/1 14/18 34/15 62/21 70/12 116/22 117/18 121/25 148/5 148/8</p> <p>discussions [8] 20/3 68/8 68/15 84/1 130/1 149/15 149/23 165/8</p> <p>disease [21] 18/6 18/9 20/11 20/13 64/2 77/1 82/5 88/5 92/4 96/25 97/2 103/14 103/23 117/8 120/13 144/17 152/11 153/25 163/15 163/19 164/18</p> <p>diseases [1] 88/12</p> <p>disorders [5] 44/24 45/24 48/23 62/23 67/13</p> <p>display [2] 59/8 114/20</p> <p>disqualified [1] 30/24</p> <p>disquiet [1] 48/15</p> <p>disruption [1] 156/5</p> <p>dissuade [1] 54/14</p> <p>distance [2] 32/21 59/17</p> <p>distinction [1] 6/22</p> <p>distinguish [2] 63/23 113/21</p> <p>distinguished [1] 116/17</p> <p>distressed [1] 24/4</p>	<p>distributed [2] 69/8 69/11</p> <p>distribution [6] 63/21 69/15 69/17 70/13 99/25 122/6</p> <p>District [2] 50/7 50/25</p> <p>disturbance [1] 48/16</p> <p>dividing [1] 70/13</p> <p>do [29] 7/25 13/24 18/10 22/5 24/8 28/24 28/25 29/13 30/1 40/17 42/16 53/19 73/7 75/4 75/13 81/11 81/12 82/23 88/20 95/21 102/8 105/22 110/11 144/6 148/13 153/4 153/18 166/13 166/17</p> <p>doctors [7] 89/1 95/20 99/13 150/18 154/23 155/1 155/7</p> <p>document [32] 2/10 12/13 15/15 16/25 19/23 19/24 20/7 21/10 21/12 21/18 25/11 27/18 27/24 28/1 29/4 34/10 34/18 37/11 38/7 38/13 56/25 68/9 68/12 69/4 71/25 86/5 91/23 110/6 116/9 118/2 147/21 163/6</p> <p>documentation [16] 38/4 43/8 57/5 58/3 58/8 58/10 58/14 59/2 59/5 83/13 85/5 88/21 95/17 143/3 152/5 166/9</p> <p>documents [33] 1/9 2/19 2/25 3/3 26/18 37/9 37/18 39/3 39/7 39/11 42/6 42/19 43/3 59/19 68/14 75/9 77/12 78/1 79/4 82/11 82/18 82/18 82/21 88/25 90/24 90/24 100/1 101/5 108/4 120/9 121/18 132/2 163/8</p> <p>Dodsworth [9] 107/17 107/21 109/2 111/18 116/2 116/7 118/8 118/13 120/9</p> <p>Dodsworth's [1] 117/24</p> <p>does [19] 4/11 20/15 24/24 26/20 28/11 31/15 31/19 37/2 78/9 79/13 80/6 96/10 96/16 96/20 114/23 114/24 118/11 122/8 153/19</p>	<p>does it [1] 4/11</p> <p>doesn't [13] 21/12 63/22 82/3 84/25 96/8 97/21 118/9 129/5 129/6 140/4 140/6 148/20 161/23</p> <p>doing [1] 21/13</p> <p>don't [53] 2/21 6/17 12/11 13/23 14/10 14/16 25/9 28/13 29/2 31/2 37/8 37/17 38/3 50/2 56/1 57/22 59/8 62/7 63/5 64/23 79/2 81/11 81/13 81/15 82/7 82/15 82/16 82/17 86/22 90/23 91/23 94/12 95/16 97/17 98/18 101/4 101/9 106/9 106/14 108/21 114/25 118/10 120/8 124/9 135/1 148/19 148/21 149/23 150/21 157/21 158/23 162/1 166/13</p> <p>Donald [1] 71/12</p> <p>donate [1] 33/13</p> <p>donated [2] 10/8 119/15</p> <p>donates [1] 32/4</p> <p>donating [1] 15/2</p> <p>donation [10] 8/3 10/25 11/5 11/13 19/10 31/24 32/9 33/11 39/21 39/25</p> <p>donations [26] 3/18 4/19 5/16 6/10 6/13 8/11 8/13 8/21 8/24 9/11 9/16 10/17 10/18 11/17 12/7 31/4 31/25 32/2 32/10 32/15 32/25 33/5 33/10 33/12 36/9 39/12</p> <p>done [10] 3/6 3/21 3/23 22/6 35/17 50/16 87/5 141/11 142/13 142/13</p> <p>Donohue [2] 19/17 20/17</p> <p>Donohue's [1] 19/25</p> <p>donor [30] 3/1 5/11 6/7 8/9 8/11 8/19 8/21 8/25 10/14 10/23 11/9 17/2 17/7 17/11 17/19 20/10 28/24 29/6 29/12 29/22 30/3 30/16 30/23 30/25 31/24 32/3 32/5 35/20 119/19 154/5</p> <p>donor's [1] 8/24</p> <p>donors [60] 2/23 3/4 5/22 6/6 6/14 9/25 10/3 10/5 10/7 10/13</p>	<p>10/17 10/20 11/11 11/18 11/20 12/25 14/4 15/5 16/14 16/16 16/18 17/21 19/20 21/14 22/2 22/13 22/15 22/24 23/1 23/5 23/8 23/9 26/22 26/25 27/4 29/8 29/24 30/11 30/15 30/18 30/24 31/3 31/3 32/16 32/17 33/4 33/4 33/6 33/7 33/8 33/19 34/5 34/5 35/3 36/10 36/20 36/20 38/6 117/16 139/21</p> <p>Dormandy [8] 62/11 66/15 68/20 68/23 70/5 70/14 72/13 123/25</p> <p>dots [1] 5/1</p> <p>double [1] 62/14</p> <p>doubt [4] 55/4 107/4 108/14 129/12</p> <p>down [20] 5/7 9/4 9/5 9/21 17/1 25/24 28/7 28/21 45/1 46/21 68/12 71/12 81/8 90/3 90/14 102/23 110/19 123/12 124/19 154/22</p> <p>Dr [174]</p> <p>Dr Anthony Pinching [1] 107/25</p> <p>Dr Ardeman [4] 160/2 160/9 160/13 162/10</p> <p>Dr Ball [5] 84/19 85/16 86/2 86/23 87/25</p> <p>Dr Ball's [1] 57/20</p> <p>Dr Barrett [1] 99/2</p> <p>Dr Bolton-Maggs [5] 128/24 130/3 130/20 131/2 131/19</p> <p>Dr Britt [2] 163/1 165/1</p> <p>Dr Britt's [1] 165/5</p> <p>Dr Chanarin [1] 150/16</p> <p>Dr Chipping [7] 132/11 132/19 133/5 136/8 139/10 140/23 140/24</p> <p>Dr Cleghorn [1] 117/11</p> <p>Dr Clyde McAuley [1] 28/16</p> <p>Dr Costello [1] 99/3</p> <p>Dr Craske [1] 116/18</p> <p>Dr Crawford [1] 132/8</p> <p>Dr David [1] 118/16</p> <p>Dr Dennis Donohue [1] 19/17</p> <p>Dr Desai [1] 96/7</p>
--	--	---	--	--	--

<p>D</p> <p>Dr Dodsworth [8] 107/17 107/21 109/2 111/18 116/2 116/7 118/8 120/9</p> <p>Dr Dodsworth's [1] 117/24</p> <p>Dr Donald [1] 71/12</p> <p>Dr Donohue's [1] 19/25</p> <p>Dr Dormandy [8] 62/11 66/15 68/20 68/23 70/5 70/14 72/13 123/25</p> <p>Dr Drees [3] 23/22 27/19 36/19</p> <p>Dr Drees' [2] 26/14 38/18</p> <p>Dr Evans [1] 73/12</p> <p>Dr Giangrande [2] 99/5 106/4</p> <p>Dr Hann [3] 85/17 85/20 86/24</p> <p>Dr Hann's [1] 88/8</p> <p>Dr Haworth [2] 89/4 96/6</p> <p>Dr Helen [1] 118/13</p> <p>Dr Hill [1] 39/24</p> <p>Dr Hows [1] 132/21</p> <p>Dr Humble [1] 101/22</p> <p>Dr Humble's [2] 102/20 103/1</p> <p>Dr Ingram [3] 62/13 65/19 66/15</p> <p>Dr John Martin [1] 44/10</p> <p>Dr Jones [1] 2/9</p> <p>Dr Kendra [1] 89/5</p> <p>Dr Kernoff [1] 2/2</p> <p>Dr Laffan [3] 133/13 141/1 142/22</p> <p>Dr Laffan's [3] 140/8 142/1 142/18</p> <p>Dr Lane [1] 2/2</p> <p>Dr Lees [1] 66/24</p> <p>Dr Ludlam [1] 44/5</p> <p>Dr Lynne Ball [1] 57/19</p> <p>Dr Machin [4] 143/14 147/25 149/2 149/11</p> <p>Dr Martin [4] 52/19 53/3 54/25 55/23</p> <p>Dr Martin's [1] 53/13</p> <p>Dr Maycock [5] 65/21 75/21 101/16 102/5 102/23</p> <p>Dr Maycock's [4] 110/10 125/3 135/8 144/3</p> <p>Dr McAuley [2] 28/22 29/7</p>	<p>Dr McVerry [3] 123/13 123/18 129/18</p> <p>Dr Mibashan [2] 132/6 140/20</p> <p>Dr Mibashan's [1] 135/12</p> <p>Dr Michael Laffan [1] 132/25</p> <p>Dr Mitchell [4] 89/4 90/17 92/1 95/21</p> <p>Dr Mollison [1] 116/9</p> <p>Dr Obank [4] 60/9 109/13 110/1 134/24</p> <p>Dr Obank's [1] 109/16</p> <p>Dr Paula [1] 121/4</p> <p>Dr Ranasinghe [3] 89/4 93/4 95/25</p> <p>Dr Rankin [1] 73/2</p> <p>Dr Reid [5] 150/25 153/4 154/1 158/6 158/12</p> <p>Dr Reid's [3] 151/13 157/23 159/13</p> <p>Dr Richard Tedder's [1] 131/5</p> <p>Dr Richards [3] 121/1 129/17 129/20</p> <p>Dr Rogers [1] 100/23</p> <p>Dr Samson [12] 89/6 89/17 91/11 94/13 96/2 96/14 97/12 97/23 150/20 151/5 151/22 157/11</p> <p>Dr Samson's [1] 151/9</p> <p>Dr Savidge [1] 44/5</p> <p>Dr Seiff [1] 72/11</p> <p>Dr Sieff [1] 72/9</p> <p>Dr Snape [2] 95/6 158/12</p> <p>Dr Tedder [2] 143/16 149/4</p> <p>Dr Tedder's [1] 143/17</p> <p>Dr Tovey [1] 119/9</p> <p>Dr Winter's [1] 1/24</p> <p>Dr Yellowlees [1] 64/24</p> <p>dramatic [2] 37/14 67/9</p> <p>draw [4] 3/3 14/20 34/21 67/4</p> <p>drawing [1] 105/19</p> <p>drawn [2] 125/13 148/25</p> <p>Drees [10] 14/15 15/3 15/14 15/21 20/25 23/18 23/22 27/19 35/25 36/19</p> <p>Drees' [2] 26/14 38/18</p> <p>drew [1] 88/13</p> <p>dried [12] 49/16 52/17</p>	<p>102/2 102/16 102/18 102/21 110/16 110/16 125/9 135/17 135/18 144/11</p> <p>drip [1] 76/10</p> <p>drop [1] 81/8</p> <p>dropped [2] 35/23 81/21</p> <p>drops [1] 147/2</p> <p>Drs [1] 96/6</p> <p>drug [3] 24/6 24/9 36/3</p> <p>drugs [2] 21/20 30/13</p> <p>due [7] 35/15 51/15 52/23 55/5 67/2 81/19 88/11</p> <p>during [30] 1/10 3/16 5/10 5/23 6/4 9/6 9/9 11/25 12/15 30/18 38/8 46/9 48/3 51/7 57/9 60/19 61/5 61/13 64/9 64/15 67/2 76/25 89/2 89/16 93/5 93/16 112/23 120/24 145/15 162/25</p> <p>duty [1] 46/13</p> <p>dysfunction [1] 130/14</p>	<p>143/24 159/25 160/1 160/3 160/8 160/17 161/24 162/18 163/4 163/9</p> <p>edition [1] 16/24</p> <p>Edmunds [1] 41/22</p> <p>effect [8] 4/10 15/23 30/2 53/2 67/7 67/10 88/8 151/13</p> <p>effective [1] 15/11</p> <p>effectively [2] 68/21 69/8</p> <p>effects [1] 48/16</p> <p>effort [1] 15/7</p> <p>efforts [1] 16/14</p> <p>eg [3] 48/24 67/18 148/15</p> <p>eight [8] 14/4 64/3 86/16 113/18 125/7 127/8 136/1 144/15</p> <p>eighties [3] 1/8 91/13 133/15</p> <p>either [9] 46/13 74/4 84/14 85/10 131/23 149/3 150/11 152/13 158/2</p> <p>elect [1] 155/4</p> <p>elective [1] 54/13</p> <p>electronic [2] 58/16 59/11</p> <p>elevated [1] 6/2</p> <p>eliminates [1] 6/25</p> <p>else [2] 43/13 94/23</p> <p>Elstree [3] 51/8 118/23 119/17</p> <p>emerge [3] 103/14 136/17 136/21</p> <p>emergency [1] 68/4</p> <p>emerges [7] 78/24 84/17 104/4 104/14 139/8 155/16 157/6</p> <p>emerging [3] 93/15 112/13 138/2</p> <p>emigrees [2] 24/6 36/3</p> <p>emphasis [1] 65/8</p> <p>employee [1] 38/17</p> <p>enable [2] 60/15 82/8</p> <p>enabled [1] 49/17</p> <p>encouraged [1] 67/17</p> <p>end [11] 33/25 62/1 73/11 80/19 101/5 102/11 103/1 134/22 134/22 148/13 158/25</p> <p>endeavoured [1] 131/2</p> <p>ending [2] 60/24 109/22</p> <p>enhanced [1] 84/15</p> <p>enormous [2] 5/15 95/17</p> <p>enough [2] 51/8 75/4</p>	<p>ensuing [1] 5/22</p> <p>ensure [4] 29/14 33/22 142/9 142/14</p> <p>entered [1] 11/18</p> <p>enthusiasm [1] 75/20</p> <p>entirely [3] 79/22 115/20 158/19</p> <p>entitled [3] 3/13 31/8 34/15</p> <p>entity [3] 71/21 89/21 151/10</p> <p>entries [3] 79/5 100/21 138/22</p> <p>entry [5] 13/4 13/11 17/1 118/13 135/11</p> <p>episodes [2] 63/3 67/16</p> <p>Equally [1] 47/6</p> <p>equate [1] 145/21</p> <p>equipping [1] 119/17</p> <p>equivalent [1] 1/17</p> <p>error [2] 9/22 16/8</p> <p>especially [1] 48/16</p> <p>essence [1] 43/10</p> <p>essential [2] 8/4 140/16</p> <p>essentially [3] 36/15 49/13 133/8</p> <p>established [2] 48/25 163/12</p> <p>establishing [1] 39/5</p> <p>estimate [7] 111/22 114/23 114/24 115/1 115/3 115/4 135/20</p> <p>estimated [3] 10/23 86/4 110/20</p> <p>estimates [1] 102/24</p> <p>etc [2] 65/24 148/17</p> <p>evaluating [1] 2/3</p> <p>Evans [2] 73/12 118/16</p> <p>even [4] 18/8 53/5 86/22 116/1</p> <p>event [5] 13/21 45/14 115/1 115/9 124/4</p> <p>events [1] 59/17</p> <p>eventually [1] 155/24</p> <p>ever [1] 19/6</p> <p>every [4] 17/1 17/7 17/13 42/13</p> <p>everyone [1] 18/7</p> <p>evidence [52] 1/11 1/15 1/22 1/24 11/23 12/11 26/20 27/3 39/4 44/2 54/22 56/22 57/12 57/20 83/8 83/25 84/7 84/9 84/22 85/1 85/8 89/22 89/24 91/15 91/16 97/8 98/4 106/5 106/6 106/7 111/9 121/3 129/14 130/9 130/13 134/17</p>	<p>136/7 136/16 141/15 142/3 142/19 142/23 149/6 150/4 154/12 154/15 155/11 157/11 159/7 162/18 165/1 165/16</p> <p>evolve [1] 66/5</p> <p>evolved [1] 130/18</p> <p>exactly [1] 83/14</p> <p>examined [2] 54/3 55/21</p> <p>example [11] 3/1 96/7 111/13 114/3 117/23 128/17 129/17 130/23 131/16 139/2 140/22</p> <p>except [3] 58/14 112/17 153/24</p> <p>excessive [1] 75/24</p> <p>exclude [2] 21/1 29/24</p> <p>excluded [12] 6/6 6/14 8/12 8/13 8/22 9/1 10/6 10/20 11/18 20/13 30/10 30/15</p> <p>excludes [1] 20/18</p> <p>exclusively [1] 21/2</p> <p>Executive [3] 38/18 58/7 59/9</p> <p>exercise [4] 42/5 59/3 119/11 166/1</p> <p>Exeter [1] 41/17</p> <p>existing [1] 62/21</p> <p>expand [1] 65/21</p> <p>expect [2] 10/5 149/19</p> <p>expectation [1] 21/10</p> <p>expected [2] 31/10 65/23</p> <p>expense [1] 50/5</p> <p>expenses [2] 148/3 148/4</p> <p>experience [5] 44/21 46/8 48/4 54/11 74/20</p> <p>experienced [2] 67/23 68/3</p> <p>experiences [1] 57/15</p> <p>expertise [2] 50/12 88/15</p> <p>experts [1] 7/9</p> <p>explain [4] 6/20 8/15 62/19 113/15</p> <p>explained [2] 65/7 70/5</p> <p>explaining [1] 56/18</p> <p>explains [3] 44/22 62/3 64/7</p> <p>explore [2] 40/11 143/19</p> <p>exploring [2] 66/17 165/18</p> <p>exporting [1] 15/18</p> <p>exposed [1] 18/4</p>
---	--	--	--	---	--

<p>E</p> <p>expressed [5] 39/5 94/18 110/17 125/8 144/9</p> <p>expressly [1] 14/2</p> <p>extending [1] 119/16</p> <p>extensive [2] 137/21 138/21</p> <p>extent [14] 14/11 37/9 71/22 77/9 77/18 79/16 79/20 92/24 93/7 98/5 137/4 140/3 146/22 166/10</p> <p>extra [3] 17/10 123/23 124/3</p> <p>extremely [2] 18/5 45/17</p> <p>eyesight [1] 25/18</p>	<p>152/14 154/19 154/22 154/25 155/21 155/22 156/2 156/24 161/2 161/3 161/4 161/6 161/16 161/23 163/7 164/7</p> <p>Factor IX [17] 1/6 1/19 2/1 2/4 2/15 2/22 27/7 77/9 82/6 92/12 103/20 104/1 104/13 105/4 115/11 115/15 115/21</p> <p>factor VIII [70] 1/13 1/25 12/9 16/19 19/21 23/15 27/7 31/16 31/17 37/21 47/12 49/16 50/6 50/8 50/15 50/19 51/6 51/8 52/5 56/7 68/5 69/5 70/3 73/16 73/24 76/3 76/12 77/5 77/19 91/19 91/21 95/10 100/2 101/24 102/1 104/10 104/19 104/21 105/10 105/13 108/13 112/10 112/15 112/19 115/11 118/18 118/21 119/4 119/20 120/14 127/3 127/24 136/20 139/21 143/25 147/17 147/18 154/22 154/25 155/21 155/22 156/2 156/24 161/2 161/4 161/6 161/16 161/23 163/7 164/7</p> <p>Factorate [20] 77/7 78/20 78/24 79/9 79/16 93/8 104/9 104/22 112/1 112/11 137/18 138/9 145/10 152/21 152/24 156/12 162/4 164/2 164/7 164/16</p> <p>factors [3] 18/23 23/15 29/23</p> <p>facts [2] 28/2 28/8</p> <p>failed [1] 135/9</p> <p>faint [1] 112/12</p> <p>fair [1] 153/6</p> <p>fairly [9] 65/14 80/2 84/17 105/3 116/8 127/12 138/21 141/24 162/12</p> <p>fairness [1] 148/18</p> <p>fall [1] 123/3</p> <p>fallen [2] 123/1 123/2</p> <p>false [2] 6/25 6/25</p> <p>familiar [1] 138/23</p> <p>families [7] 47/13 54/9 54/11 54/23 83/4 85/11 136/14</p> <p>family [1] 149/7</p>	<p>far [9] 27/15 43/16 61/21 71/8 79/8 85/12 97/25 121/10 138/8</p> <p>fast [1] 18/18</p> <p>FDA [4] 3/24 19/18 21/20 27/2</p> <p>feasible [1] 71/8</p> <p>features [2] 80/20 81/22</p> <p>February [9] 3/20 4/9 6/9 14/14 64/25 95/5 116/12 118/5 158/13</p> <p>February 1970 [1] 64/25</p> <p>February 1975 [1] 4/9</p> <p>February 1979 [1] 116/12</p> <p>February 1985 [2] 95/5 158/13</p> <p>February 1988 [1] 118/5</p> <p>fell [3] 99/22 100/16 143/21</p> <p>felt [6] 46/14 47/9 49/1 55/11 154/25 157/17</p> <p>fever [1] 29/9</p> <p>few [10] 6/4 32/10 33/11 39/2 82/17 89/20 110/6 119/8 123/17 166/14</p> <p>fewer [1] 81/3</p> <p>fifth [2] 27/9 81/7</p> <p>figure [14] 4/12 4/17 5/18 11/8 16/9 33/4 39/16 80/4 80/8 94/2 114/2 137/10 138/12 146/22</p> <p>figures [20] 6/15 31/2 37/12 37/13 64/12 79/15 93/6 93/12 103/14 111/5 112/12 112/25 113/23 114/1 138/5 145/16 147/15 152/7 161/9 161/14</p> <p>file [1] 59/2</p> <p>filled [1] 47/19</p> <p>final [2] 9/6 33/16</p> <p>finally [3] 19/3 39/23 147/13</p> <p>financial [2] 39/11 140/1</p> <p>find [7] 18/21 29/11 36/17 82/23 124/16 130/13 135/10</p> <p>finish [2] 39/12 95/14</p> <p>first [30] 4/5 4/23 4/24 4/25 5/9 5/24 6/4 15/6 16/8 26/22 29/21 30/1 30/9 30/22 31/3 35/4 36/22 50/10 52/23 55/7 55/8 93/20 104/4</p>	<p>104/6 111/14 118/12 128/6 128/25 141/2 155/19</p> <p>first-time [1] 31/3</p> <p>five [16] 5/22 19/14 44/25 62/5 92/15 95/16 111/4 111/6 125/19 127/7 131/13 136/2 137/1 138/3 144/18 152/9</p> <p>flag [1] 8/17</p> <p>flavour [1] 92/1</p> <p>Florida [4] 24/7 24/20 25/25 26/15</p> <p>fluid [2] 48/16 48/24</p> <p>focused [1] 30/11</p> <p>follow [3] 35/11 35/12 163/16</p> <p>followed [1] 142/16</p> <p>following [7] 26/21 32/11 52/21 60/23 124/8 139/4 166/23</p> <p>follows [7] 19/4 32/16 72/13 111/3 121/8 133/5 160/25</p> <p>force [1] 28/1</p> <p>forced [1] 35/13</p> <p>forgive [2] 59/25 158/10</p> <p>form [3] 1/12 48/25 149/17</p> <p>formal [2] 105/23 121/11</p> <p>formally [1] 9/24</p> <p>formed [1] 121/16</p> <p>formerly [2] 59/20 90/7</p> <p>forms [3] 48/24 126/18 130/5</p> <p>forwarded [2] 38/7 38/13</p> <p>found [7] 8/19 49/22 56/23 58/25 119/19 142/2 158/22</p> <p>Foundation [6] 23/20 23/25 24/17 27/12 30/5 35/25</p> <p>four [12] 73/22 93/16 103/9 111/20 124/23 124/24 125/18 135/5 143/7 143/7 146/18 160/21</p> <p>four patients [1] 93/16</p> <p>fourth [2] 25/14 27/5</p> <p>fraction [8] 20/14 23/3 23/7 23/12 27/10 36/21 37/1 37/4</p> <p>fractionate [1] 119/14</p> <p>fractionation [4] 20/16 39/5 119/17 120/1</p>	<p>fractionators [1] 19/19</p> <p>fractions [1] 27/14</p> <p>Francisco [16] 13/5 17/18 24/8 24/20 24/23 25/3 25/4 25/13 25/15 25/16 26/11 26/16 26/24 38/10 38/12 38/23</p> <p>free [9] 2/3 18/20 19/11 62/12 63/10 66/5 91/14 122/13 159/15</p> <p>freeze [12] 49/15 52/17 102/2 102/16 102/18 102/21 110/16 110/16 125/9 135/17 135/18 144/11</p> <p>freeze-dried [10] 52/17 102/16 102/18 102/21 110/16 110/16 125/9 135/17 135/18 144/11</p> <p>freezer [1] 155/9</p> <p>freight [1] 13/6</p> <p>frequently [1] 65/14</p> <p>fresh [9] 12/24 32/8 32/19 32/24 33/2 33/9 36/4 36/5 154/18</p> <p>Friday [1] 41/1</p> <p>Frith [1] 147/23</p> <p>from [314]</p> <p>front [1] 16/21</p> <p>frozen [9] 12/24 32/8 32/19 32/24 33/2 33/9 36/4 36/5 154/18</p> <p>Fulham [1] 90/7</p> <p>full [3] 15/6 38/3 158/2</p> <p>fully [1] 130/7</p> <p>functions [1] 63/4</p> <p>funding [1] 39/18</p> <p>funds [3] 39/14 148/12 148/15</p> <p>further [22] 12/2 12/11 14/6 21/24 22/6 22/8 22/22 37/17 39/2 40/12 50/22 68/8 71/11 71/25 72/22 95/16 102/23 110/19 120/1 130/18 131/22 159/17</p> <p>future [1] 60/16</p>	<p>26/22 27/4 36/20</p> <p>general [8] 39/15 55/25 61/20 73/3 84/15 90/3 99/15 140/25</p> <p>generally [8] 47/5 66/23 68/10 88/1 108/4 108/7 118/1 160/14</p> <p>generation [4] 4/6 4/8 4/23 4/25</p> <p>Geneva [1] 119/11</p> <p>Gentlemen [1] 24/2</p> <p>geographical [1] 123/5</p> <p>Germany [2] 16/2 16/12</p> <p>get [10] 41/11 41/22 43/6 60/1 76/20 114/8 114/9 115/14 125/21 157/25</p> <p>getting [3] 18/6 31/12 31/20</p> <p>Giangrande [2] 99/5 106/4</p> <p>give [15] 18/20 21/11 25/3 26/19 39/2 45/11 46/3 52/22 61/18 86/12 97/10 101/8 132/20 135/10 144/15</p> <p>given [32] 1/23 8/21 14/17 14/23 17/17 19/2 30/16 31/4 39/16 44/6 46/12 51/16 56/7 56/9 58/17 58/19 61/23 65/11 76/13 81/17 82/14 84/12 85/16 106/20 113/24 124/20 130/21 135/20 146/22 156/22 156/25 163/17</p> <p>gives [8] 7/23 15/25 28/2 29/5 73/10 92/1 109/6 150/6</p> <p>giving [2] 18/18 43/11</p> <p>globulin [5] 16/16 22/4 22/16 23/10 27/1</p> <p>go [86] 1/22 8/1 9/4 9/19 9/21 14/19 16/24 17/22 25/8 25/10 28/21 29/5 33/13 41/5 43/14 45/9 50/3 51/3 53/13 53/14 55/18 55/22 56/2 56/12 57/14 59/25 62/7 62/16 63/7 63/20 64/5 64/19 65/3 65/15 69/3 70/17 71/23 72/10 72/22 76/20 77/11 77/25 78/14 80/22 81/12 83/24 86/13 90/9 90/23 91/23</p>
--	---	--	--	--	---

<p>G</p> <p>go... [36] 93/11 95/4 100/13 101/4 101/10 102/23 103/4 110/7 115/18 116/25 117/2 118/1 118/12 121/24 123/11 123/16 124/9 124/13 125/2 126/13 128/20 134/5 135/1 135/7 136/16 136/25 138/15 138/22 144/1 144/1 145/13 146/20 148/7 155/24 158/10 160/12</p> <p>goes [8] 3/25 15/5 20/22 24/15 24/18 54/7 63/4 138/12</p> <p>going [28] 4/13 4/20 21/11 22/19 35/24 41/2 41/4 41/5 41/10 42/16 55/18 57/3 57/14 68/11 68/13 69/22 70/8 83/1 83/24 86/13 88/24 115/3 120/21 134/5 134/25 154/14 160/12 165/20</p> <p>gone [3] 13/21 114/14 147/16</p> <p>good [7] 10/14 40/24 49/22 65/24 123/22 124/6 143/5</p> <p>got [13] 18/3 44/15 80/4 82/4 116/18 116/18 116/19 116/20 125/25 126/4 146/9 147/16 166/12</p> <p>Government [1] 119/15</p> <p>Gower [1] 121/14</p> <p>graduate [1] 133/12</p> <p>granted [2] 2/20 37/24</p> <p>graph [5] 4/12 4/16 5/5 5/19 9/21</p> <p>great [56] 41/6 57/4 57/6 57/16 57/24 58/2 58/4 58/6 58/9 59/5 59/10 59/12 59/19 59/23 59/23 63/8 63/10 63/11 63/21 64/6 64/15 65/5 65/7 66/7 66/22 68/25 69/13 70/18 70/25 72/21 73/6 73/13 73/16 74/20 82/17 82/21 83/4 83/5 83/20 84/2 84/23 85/3 85/22 86/1 86/14 87/12 87/14 87/17 87/21 88/2 88/10 88/14 88/18 90/12 109/15 155/23</p>	<p>greater [7] 50/12 53/2 67/17 67/23 76/6 92/24 93/17</p> <p>greatest [4] 78/25 126/16 138/8 138/13</p> <p>greatly [2] 6/3 6/19</p> <p>Green [2] 34/13 39/4</p> <p>Grifols [2] 1/6 40/4</p> <p>ground [1] 2/24</p> <p>grounds [1] 113/6</p> <p>group [5] 72/3 72/24 107/21 119/7 124/8</p> <p>groups [2] 36/16 36/19</p> <p>growing [1] 17/9</p> <p>guess [1] 20/20</p> <p>guide [3] 86/19 115/25 125/23</p> <p>Guillermo [1] 12/19</p> <p>Gury [4] 31/9 34/11 34/21 38/19</p> <p>Guy's [1] 41/9</p>	<p>H</p> <p>had [87] 2/7 2/11 2/17 3/6 4/11 10/7 10/9 12/14 13/19 14/11 14/12 15/4 18/16 19/6 20/9 20/24 25/5 27/13 29/6 30/10 30/11 30/11 30/15 30/16 30/18 30/24 31/3 34/1 36/12 39/14 40/18 41/21 44/4 44/12 45/3 45/7 46/18 47/4 48/4 48/25 49/8 50/12 53/2 56/14 56/23 59/14 65/22 67/1 67/15 67/17 67/20 67/21 67/24 70/6 70/22 71/6 72/11 72/15 81/17 84/22 85/18 85/20 85/23 85/23 86/2 86/4 88/14 89/25 90/18 91/7 97/8 100/25 101/12 101/13 101/14 109/8 119/10 123/20 124/21 130/1 131/21 135/4 139/23 141/10 142/9 159/9 165/8</p> <p>hadn't [1] 13/21</p> <p>haematologist [2] 50/13 150/23</p> <p>haematology [14] 45/7 46/11 59/22 73/13 89/8 99/16 101/22 109/13 121/10 121/13 132/17 133/17 151/3 151/16</p> <p>haemophilia [201]</p> <p>haemophilia A [28] 92/15 105/3 105/8</p>	<p>113/18 125/18 127/7 127/8 127/10 127/19 127/23 127/25 128/6 135/25 136/3 138/3 140/7 144/16 146/9 146/13 152/9 154/16 158/7 160/22 161/12 161/19 163/14 163/18 164/21</p> <p>haemophilia B [6] 77/10 92/12 103/13 104/2 104/12 105/5</p> <p>haemophiliac [3] 61/6 65/16 67/20</p> <p>haemophiliacs [10] 17/15 47/2 49/10 51/24 65/20 67/1 74/25 76/8 90/20 156/17</p> <p>haemophilic [11] 15/19 20/14 21/9 22/2 22/25 23/14 24/12 36/21 37/1 37/4 76/25</p> <p>haemorrhage [6] 61/3 62/5 101/12 109/20 124/23 135/4</p> <p>haemostasis [2] 140/17 148/1</p> <p>haemostatic [1] 140/14</p> <p>Haiti [1] 30/12</p> <p>Haitian [2] 24/6 36/3</p> <p>Haitians [1] 36/20</p> <p>half [7] 45/7 65/4 80/25 84/25 133/14 137/22 140/10</p> <p>halfway [1] 90/14</p> <p>Hammersmith [29] 41/8 66/8 66/10 90/19 132/1 132/3 132/6 132/15 133/1 133/4 133/6 133/20 133/22 134/4 134/11 134/19 135/11 136/11 138/17 139/11 140/5 140/22 141/3 141/9 141/15 141/23 142/4 142/22 143/4</p> <p>Hammersmith's [1] 134/23</p> <p>hand [15] 4/17 4/17 9/5 9/20 16/25 17/4 17/25 32/14 38/22 63/13 76/7 78/5 79/6 101/22 158/18</p> <p>handful [1] 136/24</p> <p>handwriting [2] 79/23 158/18</p> <p>handwritten [2] 58/16 79/5</p> <p>Hann [7] 57/12 57/13 84/19 84/23 85/17</p>	<p>85/20 86/24</p> <p>Hann's [1] 88/8</p> <p>happened [1] 128/18</p> <p>happening [2] 20/5 70/2</p> <p>happier [1] 154/5</p> <p>Hardisty [14] 57/11 58/23 65/5 65/7 66/15 70/20 72/8 73/1 75/21 82/16 83/14 83/16 84/2 85/3</p> <p>Hardisty's [2] 62/2 75/16</p> <p>Harrow [1] 154/23</p> <p>Harry [1] 21/19</p> <p>Harry M [1] 21/19</p> <p>Hartin [1] 20/25</p> <p>has [52] 1/8 6/9 11/2 20/1 20/9 20/17 20/23 23/11 24/5 28/14 29/8 36/2 38/7 38/13 44/14 52/25 54/22 57/25 58/19 60/19 64/8 64/14 66/21 80/4 81/8 81/21 83/6 84/9 84/18 86/9 91/12 105/18 107/20 120/4 126/23 130/3 131/2 131/13 132/13 136/12 140/24 141/1 149/11 149/25 150/4 150/20 150/25 153/5 154/12 157/9 159/7 162/16</p> <p>hasn't [1] 42/12</p> <p>hatching [1] 5/2</p> <p>have [219]</p> <p>haven't [5] 7/20 11/18 42/4 43/18 114/14</p> <p>having [9] 6/19 20/10 20/12 68/2 87/16 120/13 122/24 141/19 147/25</p> <p>Haworth [2] 89/4 96/6</p> <p>HBs [2] 20/15 21/2</p> <p>HBsAg [3] 3/13 6/5 11/11</p> <p>HCDO000039 [1] 91/25</p> <p>HCDO0000088 [1] 136/25</p> <p>HCDO00001955 [1] 115/17</p> <p>HCDO0000264 [1] 40/2</p> <p>HCDO0000270 [1] 52/9</p> <p>HCDO0000420 [1] 39/17</p> <p>HCDO0001077 [1] 76/23</p> <p>HCDO0001124 [1] 125/24</p>	<p>HCDO0001160 [1] 77/16</p> <p>HCDO0001373 [1] 111/16</p> <p>HCDO0001381 [1] 126/13</p> <p>HCDO0001423 [1] 138/2</p> <p>HCDO0001450 [1] 145/14</p> <p>HCDO0001506 [1] 93/2</p> <p>HCDO0001551 [1] 146/7</p> <p>HCDO0001620 [2] 79/4 80/23</p> <p>HCDO0001624 [1] 138/17</p> <p>HCDO0001650 [1] 146/20</p> <p>HCDO0001705 [1] 93/14</p> <p>HCDO0001717 [1] 79/13</p> <p>HCDO0001747 [1] 147/3</p> <p>HCDO0001766 [1] 112/21</p> <p>HCDO0001775 [1] 127/6</p> <p>HCDO0001812 [1] 79/21</p> <p>HCDO0001841 [1] 147/14</p> <p>HCDO0001860 [1] 113/16</p> <p>HCDO0001869 [1] 127/19</p> <p>HCV [3] 150/10 150/10 155/11</p> <p>he [107] 1/25 2/11 3/22 15/16 15/25 16/1 20/17 20/18 44/20 44/22 44/22 44/23 45/1 45/10 45/21 46/2 46/4 46/20 47/25 49/9 49/11 49/11 49/12 49/14 49/25 51/4 51/10 51/20 53/15 54/7 54/9 55/6 55/17 55/25 56/6 57/11 62/3 62/8 62/10 64/25 71/8 71/16 73/14 83/19 83/22 85/20 85/21 85/22 86/25 87/3 88/13 102/21 105/24 106/25 107/2 107/16 110/14 117/20 119/12 125/6 129/23 129/25 132/7 133/15 133/15 140/11 140/15 141/2 141/3 141/4 141/9</p>	<p>141/11 142/5 142/5 142/7 142/9 142/22 142/25 149/14 149/18 149/22 151/2 151/6 151/13 153/4 153/6 153/7 153/15 153/21 154/9 154/10 154/16 154/19 155/13 155/19 155/20 156/11 156/25 158/1 158/14 159/17 162/10 162/12 162/14 165/2 165/7 166/4</p> <p>head [3] 12/20 26/4 26/8</p> <p>headed [1] 101/24</p> <p>heading [4] 64/6 65/16 90/15 125/4</p> <p>headlined [1] 17/1</p> <p>Healey [1] 38/16</p> <p>health [19] 34/16 39/20 50/7 50/25 60/9 64/20 69/16 71/1 72/6 82/20 99/23 100/10 101/7 119/3 119/11 121/22 122/15 123/3 160/15</p> <p>healthy [2] 17/1 17/7</p> <p>hear [1] 29/18</p> <p>heard [11] 1/23 11/22 57/12 67/6 83/7 84/8 89/24 99/5 136/15 141/16 141/17</p> <p>hearing [3] 41/21 43/4 166/23</p> <p>hearings [4] 89/25 107/5 143/19 165/19</p> <p>heat [26] 1/12 1/17 1/19 1/25 2/3 2/8 2/12 35/8 53/15 53/18 53/21 53/23 73/9 74/6 75/2 80/18 94/7 94/9 95/7 128/4 128/13 148/9 153/22 158/8 158/13 158/15</p> <p>heat-treated [19] 1/12 1/17 1/19 1/25 2/3 2/8 2/12 53/15 73/9 75/2 80/18 94/7 94/9 95/7 128/13 148/9 153/22 158/13 158/15</p> <p>heated [2] 1/12 115/22</p> <p>heavily [1] 108/1</p> <p>held [4] 59/6 64/20 118/4 131/8</p> <p>Helen [1] 118/13</p> <p>help [10] 17/6 17/6 17/8 17/9 18/11 18/17 31/19 45/6 146/7 148/16</p> <p>helpful [2] 31/11 155/5</p>
---	--	---	--	--	--	--

<p>H</p> <p>Hemofil [18] 77/9 92/19 92/23 93/9 123/22 126/5 126/17 137/7 137/12 137/13 144/21 145/7 145/9 145/19 146/17 161/3 161/16 161/18</p> <p>Hemophilia [6] 23/20 23/25 24/17 27/12 30/5 35/25</p> <p>hepatitis [98] 3/8 3/18 6/7 7/13 8/10 8/20 9/24 10/6 10/8 11/24 11/24 16/16 18/3 18/6 18/9 18/11 18/13 18/14 18/16 18/22 19/5 19/6 20/11 20/11 22/1 22/4 22/13 22/15 22/16 22/24 23/5 23/10 24/11 27/1 47/25 48/2 48/5 48/6 48/9 54/11 54/17 54/21 83/12 84/20 86/22 86/25 87/3 87/14 87/22 96/20 96/21 96/22 96/24 97/12 97/14 97/19 105/15 106/11 116/24 117/6 117/17 117/22 120/11 120/12 120/16 129/13 130/5 130/6 130/9 130/22 131/18 131/24 140/18 140/25 141/7 141/19 142/1 142/3 142/5 142/11 142/12 142/21 142/23 148/24 149/16 149/17 150/13 157/13 159/13 159/14 159/18 162/22 165/9 165/15 165/17 165/24 166/8 166/11</p> <p>Hepatitis 'B' [1] 19/5</p> <p>hepatitis B [23] 3/8 3/18 6/7 7/13 8/10 8/20 9/24 10/6 10/8 11/24 16/16 20/11 22/1 22/4 22/13 22/16 22/24 23/5 23/10 24/11 27/1 96/21 141/19</p> <p>hepatitis C [27] 86/22 86/25 87/3 87/14 87/22 97/12 97/14 97/19 106/11 120/16 131/18 131/24 142/1 142/3 142/5 142/11 142/12 142/23 150/13 159/13 159/14 159/18 162/22 165/15 165/24 166/8 166/11</p>	<p>hepatitis C by [1] 165/17</p> <p>hepatology [1] 142/24</p> <p>heptane [1] 1/14</p> <p>her [36] 20/24 47/10 57/21 58/2 84/1 84/3 84/4 91/11 91/12 91/20 94/16 94/18 94/20 96/14 97/3 97/10 116/7 119/23 121/6 128/24 130/3 130/4 130/5 131/3 132/15 132/23 139/10 140/24 140/24 156/20 156/22 156/23 157/3 157/4 157/11 157/14</p> <p>here [12] 32/13 60/1 63/22 69/12 74/15 75/20 93/15 109/18 110/8 117/13 122/5 127/6</p> <p>hereby [1] 12/23</p> <p>Hereford [1] 42/1</p> <p>herself [1] 131/6</p> <p>Hey [20] 41/5 44/1 44/2 44/7 44/17 44/20 44/23 45/5 50/11 50/14 51/14 52/13 52/21 53/6 54/4 54/12 54/24 57/2 57/21 86/3</p> <p>high [11] 15/19 16/1 18/6 28/25 29/24 30/19 36/16 113/24 114/22 117/16 141/24</p> <p>high-risk [1] 29/24</p> <p>higher [6] 6/20 15/22 16/10 48/9 76/15 114/17</p> <p>highlight [2] 42/17 143/3</p> <p>highlighted [1] 36/19</p> <p>highlights [1] 43/11</p> <p>Hilgard [1] 132/9</p> <p>Hill [1] 39/24</p> <p>Hillingdon [7] 41/9 162/24 163/10 165/4 165/11 165/22 166/7</p> <p>him [6] 83/18 119/2 129/21 155/14 156/21 165/8</p> <p>himself [3] 62/15 116/5 165/2</p> <p>Hirsch [1] 84/1</p> <p>his [58] 2/1 3/19 12/19 36/18 44/21 46/3 46/3 47/10 55/25 56/7 57/14 57/15 62/8 65/12 70/20 71/9 73/1 73/2 75/20 83/20 85/3 85/21 87/1 87/4 96/1 99/6 99/10 105/22 106/2 106/5 107/4</p>	<p>108/3 122/19 125/8 129/21 129/23 133/2 133/18 140/22 141/1 141/8 142/3 144/9 149/3 151/7 153/5 153/7 153/7 153/11 153/15 154/10 154/17 154/20 155/19 155/23 162/13 165/3 166/4</p> <p>his/her [1] 47/10</p> <p>history [3] 20/10 22/15 118/6</p> <p>HIV [46] 56/14 56/16 83/12 84/21 86/2 86/14 87/4 87/22 88/7 91/9 94/24 96/17 97/19 97/22 97/24 98/17 106/12 119/22 120/4 120/5 129/14 130/10 130/17 130/22 131/2 131/14 141/4 141/18 141/20 141/22 142/21 142/25 143/1 148/24 149/16 150/7 155/6 155/10 155/14 156/16 157/4 157/19 159/11 162/18 165/9 165/12</p> <p>HM [2] 60/20 61/21</p> <p>Hmm [1] 115/8</p> <p>hold [1] 18/23</p> <p>holding [1] 59/2</p> <p>holds [2] 58/10 86/11</p> <p>home [27] 49/17 70/21 71/1 77/14 79/10 79/16 80/25 93/19 93/21 94/19 95/13 109/3 109/7 115/20 123/20 127/13 134/14 138/10 146/5 146/15 151/21 155/24 156/4 156/6 156/20 161/22 162/5</p> <p>homosexual [3] 20/18 21/9 28/10</p> <p>homosexuals [5] 20/15 21/3 24/5 24/11 36/2</p> <p>Honorary [1] 57/23</p> <p>hope [1] 52/8</p> <p>horizontal [1] 4/19</p> <p>hospital [110] 44/3 44/20 47/5 47/14 47/22 48/4 48/23 49/11 50/9 51/1 57/5 57/24 58/15 58/19 59/7 59/20 59/21 59/23 69/13 70/22 71/10 71/14 71/16 71/17 72/9 72/21 73/13 79/11 81/24 85/6 88/19 88/25 89/2</p>	<p>89/9 89/19 90/7 90/17 91/14 91/16 93/19 95/6 96/3 96/8 96/12 97/9 97/22 97/24 98/2 98/6 98/7 98/25 99/8 99/18 100/3 101/23 106/22 107/25 108/7 108/9 108/19 118/15 120/22 122/11 122/13 122/14 123/8 123/16 125/5 127/12 127/14 131/21 132/1 133/5 134/4 134/11 134/15 136/9 138/10 139/11 140/5 141/9 141/23 143/4 143/11 143/13 143/16 144/4 144/14 146/4 149/8 150/5 150/6 151/17 151/20 154/23 155/12 155/18 155/22 156/2 156/5 157/20 159/15 160/1 162/4 162/18 162/24 164/8 165/4 165/14 165/22</p> <p>Hospital's [1] 98/14</p> <p>hospitals [5] 50/24 64/10 87/12 89/14 166/13</p> <p>hot [1] 156/16</p> <p>hours [1] 155/13</p> <p>House [1] 45/14</p> <p>housed [1] 133/11</p> <p>how [18] 4/22 28/4 29/6 31/2 31/3 56/13 61/20 69/21 85/15 90/1 94/10 94/14 102/8 102/24 106/16 110/11 119/3 144/6</p> <p>however [22] 22/25 27/9 45/6 45/18 47/11 48/3 49/6 49/23 53/19 55/22 69/3 70/17 75/14 76/14 86/18 97/23 117/8 127/24 135/7 140/1 142/13 155/15</p> <p>Hows [1] 132/21</p> <p>HT [3] 123/20 128/3 148/8</p> <p>HTLV [14] 56/24 84/21 85/7 85/12 97/5 97/11 105/16 143/18 150/2 158/6 158/22 159/2 159/5 162/20</p> <p>HTLV-3 [1] 159/2</p> <p>HTLV-III [12] 56/24 84/21 85/7 85/12 97/5 97/11 143/18 150/2 158/6 158/22 159/5 162/20</p> <p>HTLV-III/AIDS [1]</p>	<p>105/16</p> <p>huge [2] 81/3 136/4</p> <p>hugely [1] 128/12</p> <p>Human [7] 12/24 13/3 22/3 22/4 22/25 23/3 23/4</p> <p>Humanate [1] 146/18</p> <p>Humble [6] 98/25 100/15 100/20 101/7 101/22 105/21</p> <p>Humble's [2] 102/20 103/1</p> <p>hundreds [1] 114/16</p> <p>hurt [1] 18/7</p> <p>Hyland [16] 20/5 20/6 20/9 20/14 20/17 20/20 21/13 27/4 92/18 92/23 93/8 126/16 126/19 145/6 161/3 161/11</p> <p>Hyland's [1] 126/5</p> <hr/> <p>I</p> <p>I also [1] 45/7</p> <p>I am [7] 41/4 41/5 52/1 57/13 60/17 83/25 160/11</p> <p>I can [3] 132/1 163/22 166/13</p> <p>I can't [1] 26/1</p> <p>I cannot [2] 51/21 154/7</p> <p>I check [1] 158/11</p> <p>I cover [1] 43/5</p> <p>I did [8] 47/22 48/6 48/19 50/17 53/24 53/25 54/10 55/8</p> <p>I didn't [1] 44/14</p> <p>I do [1] 153/18</p> <p>I don't [15] 6/17 25/9 28/13 29/2 50/2 59/8 62/7 63/5 81/13 82/7 90/23 114/25 148/19 148/21 166/13</p> <p>I felt [4] 47/9 49/1 55/11 154/25</p> <p>I first [1] 55/7</p> <p>I flag [1] 8/17</p> <p>I gave [1] 146/8</p> <p>I get [1] 60/1</p> <p>I had [1] 45/3</p> <p>I have [4] 36/22 38/7 46/15 157/10</p> <p>I haven't [2] 7/20 114/14</p> <p>I hope [1] 52/8</p> <p>I intend [1] 38/5</p> <p>I just [4] 44/15 66/18 73/7 98/22</p> <p>I know [3] 44/2 52/6 83/7</p> <p>I lay [1] 46/21</p>	<p>I made [2] 48/20 55/11</p> <p>I may [2] 95/14 138/15</p> <p>I note [2] 40/16 154/7</p> <p>I obviously [1] 46/18</p> <p>I pause [3] 5/17 10/4 11/3</p> <p>I placed [1] 47/6</p> <p>I quote [9] 5/8 10/10 17/5 21/22 22/20 24/1 28/23 29/7 34/22</p> <p>I reasonably [1] 46/16</p> <p>I recall [1] 121/11</p> <p>I received [1] 45/6</p> <p>I referred [3] 57/21 98/15 152/6</p> <p>I remember [1] 154/2</p> <p>I said [4] 3/21 43/25 55/13 98/19</p> <p>I say [10] 88/18 94/13 114/21 117/1 118/17 153/4 154/9 154/14 157/2 158/1</p> <p>I scanned [1] 25/24</p> <p>I should [11] 51/4 60/22 75/14 76/3 76/14 77/24 111/20 148/18 149/11 151/20 157/3</p> <p>I stress [1] 31/13</p> <p>I submit [1] 15/7</p> <p>I suspect [3] 7/10 35/1 56/4</p> <p>I take [2] 11/21 63/24</p> <p>I then [1] 56/17</p> <p>I think [51] 2/16 4/2 7/4 9/20 16/3 25/21 38/11 43/16 44/7 57/10 57/17 59/11 60/21 62/13 64/20 65/18 69/10 71/13 72/2 72/8 72/23 76/5 81/9 87/1 89/9 93/10 93/20 98/19 103/11 107/8 107/12 114/5 114/9 114/11 125/14 128/6 147/13 150/10 151/5 151/6 151/22 151/22 152/2 152/23 153/5 153/6 154/9 157/15 162/1 163/16 163/23</p> <p>I took [1] 47/11</p> <p>I tried [1] 47/23</p> <p>I turn [5] 16/13 83/10 98/14 98/24 143/11</p> <p>I understand [4] 7/2 33/12 38/6 65/1</p> <p>I understood [2] 52/4 154/4</p> <p>I used [1] 118/15</p>
--	--	--	---	--	--

<p>I</p> <p>I viewed [1] 48/12</p> <p>I wanted [1] 114/20</p> <p>I was [18] 24/3 25/23 45/16 47/16 48/1 48/7 49/6 52/1 53/17 119/1 153/23 154/5 154/21 155/21 155/24 155/25 155/25 156/3</p> <p>I will [10] 7/25 14/20 34/21 38/8 43/2 43/25 91/24 124/16 124/17 138/16</p> <p>I won't [17] 1/22 3/25 14/19 30/7 34/17 68/10 72/22 76/20 77/11 78/14 92/7 93/11 103/4 112/5 119/23 121/6 136/16</p> <p>I would [9] 3/3 36/18 37/11 46/17 47/10 54/14 54/15 148/13 149/19</p> <p>I'll [10] 41/14 57/7 62/14 86/12 89/15 95/14 96/13 101/8 132/19 135/10</p> <p>I'm [45] 4/13 16/7 25/18 25/22 25/25 26/19 27/15 28/14 41/2 41/10 55/18 57/3 62/13 65/17 82/1 82/15 82/22 83/1 83/24 84/11 86/13 86/23 88/24 94/12 97/17 106/5 106/14 107/14 115/16 120/21 124/14 125/21 128/18 134/5 134/24 135/9 146/7 146/12 148/21 150/9 154/14 159/12 162/21 165/13 165/20</p> <p>I'm afraid [1] 94/12</p> <p>I've [6] 1/23 82/22 135/9 158/4 159/3 166/12</p> <p>Ian [2] 39/24 57/12</p> <p>ideally [1] 135/21</p> <p>identified [13] 1/9 14/8 105/9 108/11 121/18 130/11 130/16 131/14 132/11 132/21 153/1 158/20 166/1</p> <p>identifies [3] 93/3 134/3 158/14</p> <p>identify [4] 42/25 83/18 88/25 116/15</p> <p>identity [1] 120/23</p> <p>if [150] 3/5 4/13 4/14 5/3 7/22 9/4 9/19 10/4 12/15 14/15 15/11</p>	<p>15/14 16/7 16/20 16/24 17/22 18/5 18/19 18/21 19/3 19/22 21/15 22/7 24/18 25/8 25/10 27/23 28/14 28/21 29/3 29/4 31/5 33/18 36/4 36/11 37/23 38/9 38/22 41/10 44/25 45/9 45/20 46/8 46/13 47/7 50/3 51/3 52/7 53/13 54/12 55/12 55/22 56/12 59/25 60/22 61/16 62/2 62/16 63/7 63/12 63/20 64/5 64/19 65/3 65/15 65/20 66/11 69/3 69/20 70/17 71/5 71/16 71/25 72/10 76/2 76/19 76/21 77/15 77/25 79/2 79/5 81/11 81/20 81/21 82/23 83/10 90/9 90/13 90/18 93/1 93/5 93/13 95/4 95/14 95/16 100/4 100/7 100/13 101/15 101/21 102/23 103/16 109/9 110/5 110/19 111/15 112/20 112/25 113/17 113/23 114/5 115/3 115/18 117/2 118/1 118/12 119/12 121/18 121/24 122/3 122/18 123/8 123/11 123/16 124/13 125/2 125/23 126/13 127/5 132/1 135/7 135/10 136/25 137/2 138/1 138/5 138/15 138/15 138/22 144/1 145/13 145/16 146/6 146/7 146/20 147/3 148/7 155/24 156/24 158/10</p> <p>ignore [1] 158/17</p> <p>II [3] 4/8 5/1 6/9</p> <p>iii [14] 56/24 84/21 85/7 85/12 90/16 97/5 97/11 105/16 143/18 150/2 158/6 158/22 159/5 162/20</p> <p>illness [1] 130/14</p> <p>imagination [1] 80/11</p> <p>immediate [1] 52/13</p> <p>immediately [1] 87/2</p> <p>immoral [1] 15/13</p> <p>immune [6] 16/16 22/4 22/16 23/10 27/1 130/14</p> <p>immunization [1] 22/13</p> <p>Immuno [8] 77/7 93/9</p>	<p>104/5 112/2 112/8 113/10 126/20 139/3</p> <p>Immuno's [5] 112/11 112/15 126/5 127/15 164/12</p> <p>immunologist [1] 108/1</p> <p>immunologists [1] 88/4</p> <p>immunology [1] 88/12</p> <p>impact [1] 130/6</p> <p>implausibly [2] 113/24 114/22</p> <p>implementation [1] 10/11</p> <p>implication [1] 36/14</p> <p>implications [1] 51/25</p> <p>implied [1] 68/2</p> <p>important [6] 33/21 55/9 67/8 76/8 162/12 166/6</p> <p>imported [5] 48/8 52/15 53/11 84/4 84/16</p> <p>impossible [1] 15/7</p> <p>improve [1] 62/21</p> <p>improvement [1] 155/23</p> <p>improving [1] 67/12</p> <p>inactivation [2] 2/25 23/13</p> <p>inadequate [1] 53/22</p> <p>incidence [2] 6/7 11/11</p> <p>incidences [1] 101/12</p> <p>incidents [9] 61/3 61/9 62/4 109/20 109/22 124/23 124/23 135/3 135/5</p> <p>include [1] 122/8</p> <p>included [2] 26/23 89/3</p> <p>including [13] 19/2 33/23 38/19 43/20 45/3 54/17 58/18 88/4 95/24 95/25 106/4 129/17 129/22</p> <p>income [1] 17/10</p> <p>incomplete [1] 59/16</p> <p>increase [13] 5/15 6/12 9/23 15/1 64/15 65/10 65/12 65/22 77/21 78/17 80/11 137/21 139/6</p> <p>increased [8] 5/20 6/3 6/19 9/15 64/8 72/20 79/14 80/9</p> <p>increasing [2] 62/25 67/2</p> <p>incubation [1] 6/2</p> <p>indeed [14] 50/13</p>	<p>51/15 59/15 68/16 78/6 83/7 86/25 87/1 91/16 92/6 106/7 141/18 158/3 159/22</p> <p>indicate [8] 11/10 37/23 113/1 125/16 148/18 149/8 152/8 156/11</p> <p>indicated [2] 5/11 131/3</p> <p>indicates [6] 12/13 78/5 106/12 135/2 150/1 153/11</p> <p>indicating [2] 8/18 125/6</p> <p>indication [3] 60/18 111/6 120/6</p> <p>indirect [1] 106/7</p> <p>individual [19] 42/3 55/17 55/20 58/15 71/18 71/22 78/2 78/3 81/12 81/17 81/22 81/24 82/7 83/2 84/18 85/9 94/11 94/21 98/4</p> <p>individuals [9] 11/23 32/6 32/10 33/24 72/3 84/10 87/23 136/13 141/16</p> <p>industry [1] 14/18</p> <p>inevitably [1] 59/16</p> <p>infected [22] 11/24 56/14 86/2 86/12 86/14 86/19 87/13 87/21 91/9 97/18 97/24 106/10 106/12 119/21 120/3 131/12 141/22 150/13 155/14 162/17 165/17 166/11</p> <p>infection [13] 54/17 84/14 95/19 96/13 117/9 130/25 142/3 142/23 143/1 149/10 156/21 165/14 166/7</p> <p>infections [3] 22/18 149/16 150/1</p> <p>infectious [2] 88/5 88/11</p> <p>infer [1] 165/6</p> <p>inference [2] 35/18 105/19</p> <p>inferences [1] 148/25</p> <p>influence [1] 14/12</p> <p>inform [3] 13/13 21/23 142/7</p> <p>information [47] 19/12 29/16 36/8 37/17 47/18 49/25 54/8 55/19 58/1 59/14 60/23 84/13 85/16 86/21 86/23 88/22 91/18 94/12 95/18 97/21 98/16 106/9</p>	<p>106/14 108/6 109/10 110/22 120/18 120/22 125/13 130/19 130/21 131/11 136/18 141/21 148/23 149/8 149/25 150/9 150/10 152/3 158/2 159/12 159/24 162/9 162/21 165/13 166/6</p> <p>informed [5] 13/15 27/11 87/5 155/25 157/4</p> <p>informing [1] 85/7</p> <p>Ingram [6] 62/13 65/19 66/15 68/20 68/25 70/15</p> <p>inhibitor [1] 78/23</p> <p>initial [3] 4/4 73/17 117/8</p> <p>initially [3] 53/22 74/11 154/17</p> <p>initiated [2] 116/22 116/23</p> <p>Injectable [1] 13/3</p> <p>injured [1] 17/13</p> <p>inpatients [1] 63/17</p> <p>Inquiry [31] 1/3 1/8 1/24 40/12 40/22 44/13 54/22 56/22 83/6 84/9 84/18 86/10 98/21 105/18 107/20 120/4 131/13 132/13 136/12 149/25 150/4 150/21 151/1 154/12 157/9 159/7 159/10 162/16 165/10 167/2 167/4</p> <p>Inquiry's [7] 42/12 43/18 43/21 58/9 58/10 59/12 89/24</p> <p>INQY0000250 [2] 86/13 98/18</p> <p>insight [2] 29/5 128/25</p> <p>insignificant [1] 77/18</p> <p>insofar [2] 90/13 131/18</p> <p>instance [1] 13/22</p> <p>instigate [1] 29/22</p> <p>Institute [1] 118/5</p> <p>instituted [1] 109/8</p> <p>institutions [2] 28/11 28/12</p> <p>instruction [2] 45/15 47/1</p> <p>insufficiency [1] 75/9</p> <p>insufficient [2] 102/4 119/25</p> <p>intend [2] 2/21 38/5</p> <p>intended [3] 26/13 62/20 79/23</p> <p>intention [2] 42/5</p>	<p>43/19</p> <p>interest [3] 15/16 30/2 39/5</p> <p>interested [1] 74/6</p> <p>interests [2] 55/12 153/17</p> <p>interfere [1] 47/11</p> <p>internal [1] 82/17</p> <p>into [14] 8/4 9/8 11/19 12/8 13/3 14/19 29/6 46/9 74/21 107/18 124/2 128/25 139/22 166/19</p> <p>intravenous [3] 24/6 30/13 36/3</p> <p>introduced [11] 3/16 3/17 4/9 6/12 8/6 34/1 35/21 35/22 129/2 129/9 145/10</p> <p>introduction [10] 3/2 5/25 6/4 6/8 6/18 9/14 67/11 92/17 126/20 165/24</p> <p>investigations [1] 159/2</p> <p>involved [4] 34/4 108/1 150/19 151/23</p> <p>involvement [1] 98/3</p> <p>involving [1] 6/1</p> <p>IPSN0000328 [1] 14/15</p> <p>Ipswich [1] 41/22</p> <p>isn't [5] 6/21 7/5 86/18 95/17 138/24</p> <p>issue [11] 15/9 15/9 38/6 54/11 60/20 73/2 73/4 116/10 124/7 139/14 157/24</p> <p>issues [6] 40/10 117/21 136/21 147/9 159/18 165/18</p> <p>it'll [1] 51/14</p> <p>it's [71] 4/1 7/19 12/19 16/2 17/8 17/24 25/20 26/3 26/18 31/8 31/8 31/11 34/20 38/20 44/18 52/9 60/3 62/3 65/18 69/4 72/1 72/8 73/12 74/22 78/23 79/22 80/2 80/9 80/10 80/24 81/9 86/20 91/25 93/16 95/5 95/6 101/9 103/11 104/14 105/6 111/16 112/22 113/3 113/7 113/16 113/21 114/5 114/9 114/17 115/20 115/20 116/10 121/7 125/22 128/10 128/11 135/11 138/17 146/3 147/22 147/24 150/22 151/2 153/5 158/1 161/17</p>
---	--	---	---	--	---

<p>I</p> <p>it's... [5] 161/21 161/22 165/23 166/3 166/5</p> <p>it's Sieff [1] 72/8</p> <p>Italy [2] 16/4 16/12</p> <p>item [1] 34/20</p> <p>item 3 [1] 34/20</p> <p>its [31] 1/12 5/3 18/14 27/25 29/6 31/20 34/2 34/2 47/9 48/15 53/8 58/6 66/8 67/22 71/18 76/6 86/10 88/19 88/22 90/5 91/1 91/2 91/4 91/4 91/4 100/17 108/13 108/14 123/4 143/24 160/6</p> <p>itself [4] 14/9 16/22 87/17 98/20</p> <p>IX [18] 1/6 1/19 2/1 2/4 2/15 2/22 23/15 27/7 77/9 82/6 92/12 103/20 104/1 104/13 105/4 115/11 115/15 115/21</p> <p>J</p> <p>January [16] 3/19 9/12 9/12 14/6 30/3 31/7 35/3 35/5 35/17 35/22 36/13 36/24 37/2 37/10 64/1 72/16</p> <p>January 1 [3] 35/3 35/17 37/10</p> <p>January 1971 [1] 3/19</p> <p>January 1975 [1] 14/6</p> <p>January 1983 [2] 35/22 37/2</p> <p>January-October [1] 64/1</p> <p>Japan [3] 16/2 16/12 34/14</p> <p>Japanese [1] 34/16</p> <p>Joe [1] 34/13</p> <p>Joe Kimoto [1] 34/13</p> <p>John [2] 44/10 44/20</p> <p>John Martin [1] 44/20</p> <p>Join [1] 17/11</p> <p>joined [1] 141/9</p> <p>joint [1] 62/11</p> <p>Jones [1] 2/9</p> <p>judged [1] 140/13</p> <p>judgment [3] 47/10 55/11 55/15</p> <p>judgments [1] 46/23</p> <p>July [3] 13/13 16/24 24/25</p> <p>July 1981 [1] 24/25</p> <p>July 31 [1] 13/13</p> <p>June [8] 2/8 34/16 39/23 41/12 41/21</p>	<p>51/23 52/8 165/22</p> <p>June 1991 [1] 165/22</p> <p>June 2002 [1] 39/23</p> <p>June 6 [1] 34/16</p> <p>junior [3] 99/12 131/8 151/16</p> <p>just [81] 7/19 9/21 15/15 20/23 24/18 25/4 25/23 27/19 29/4 34/20 35/24 36/14 43/25 44/15 44/16 51/10 52/7 56/13 62/16 64/5 65/15 66/1 66/18 66/22 71/25 73/7 75/14 77/24 80/22 80/25 81/20 81/23 82/15 91/20 92/8 92/21 92/24 93/1 93/13 93/18 93/19 93/25 95/14 98/22 101/8 101/21 107/7 108/22 109/9 110/19 111/15 111/23 112/1 113/17 117/2 117/24 121/7 124/12 124/17 126/10 127/18 128/22 132/20 134/24 135/10 136/23 137/11 137/13 137/18 137/24 138/10 138/15 138/19 144/11 146/12 147/7 147/16 147/20 164/16 164/22 165/20</p> <p>justice [1] 166/14</p> <p>K</p> <p>Kay [1] 3/12</p> <p>keep [6] 40/11 47/14 47/23 78/11 138/25 155/8</p> <p>Kendra [1] 89/5</p> <p>kept [1] 82/20</p> <p>Kernoff [1] 2/2</p> <p>Kgs [4] 31/23 32/1 32/7 32/14</p> <p>kill [1] 18/8</p> <p>kilograms [1] 32/22</p> <p>Kimoto [1] 34/13</p> <p>kind [3] 78/1 103/14 125/23</p> <p>Kindly [1] 13/12</p> <p>King's [2] 41/9 132/7</p> <p>Kingdom [3] 31/18 39/6 92/5</p> <p>knew [2] 83/14 141/10</p> <p>know [32] 7/24 13/23 13/24 14/11 17/12 18/16 22/25 25/9 28/3 28/8 28/14 29/2 39/9 40/6 44/2 52/6 60/11 82/1 82/15 82/24 83/7 90/25 94/7 95/21</p>	<p>96/16 107/20 113/4 120/8 157/21 158/18 158/21 158/23</p> <p>knowing [3] 36/6 36/7 128/19</p> <p>knowledge [17] 56/19 84/20 84/21 85/13 95/19 96/13 96/15 105/15 105/16 106/8 115/24 129/13 130/17 140/18 148/23 150/7 162/10</p> <p>knowledgeable [2] 45/14 45/17</p> <p>known [6] 2/16 59/20 83/11 85/2 96/21 130/11</p> <p>Koate [9] 77/8 77/23 137/7 137/12 146/17 146/24 147/7 148/8 148/9</p> <p>Koate-HT [1] 148/8</p> <p>Konyne [1] 2/11</p> <p>Krever [2] 1/18 30/14</p> <p>Kryobulin [23] 77/7 79/1 93/9 104/6 104/8 112/2 112/11 126/6 126/20 127/1 127/4 127/15 137/7 138/20 144/22 145/3 146/17 146/24 161/7 161/16 161/18 164/12 164/17</p> <p>Kryoglobulin [1] 128/3</p> <p>L</p> <p>Laboratories [3] 12/25 13/10 13/15</p> <p>laboratory [5] 22/19 99/13 99/14 131/5 141/12</p> <p>lack [1] 52/20</p> <p>Laffan [4] 132/25 133/13 141/1 142/22</p> <p>Laffan's [3] 140/8 142/1 142/18</p> <p>lag [1] 8/17</p> <p>Lane [1] 2/2</p> <p>large [11] 28/10 28/25 30/5 33/22 34/4 36/9 88/20 110/4 119/20 134/13 137/16</p> <p>largely [5] 49/23 57/20 140/19 160/12 165/2</p> <p>larger [3] 65/10 112/1 164/14</p> <p>largest [2] 77/22 163/17</p> <p>last [14] 9/18 16/15 43/21 50/1 56/1 56/12 57/13 64/9 64/15</p>	<p>74/13 80/20 113/10 123/17 148/10</p> <p>late [8] 1/20 41/13 99/9 99/9 108/16 125/6 163/2 166/1</p> <p>later [18] 2/6 35/5 36/24 66/10 66/12 90/8 91/7 96/4 99/6 117/25 123/14 142/11 143/19 157/12 158/21 160/3 160/4 165/19</p> <p>latter [2] 21/6 76/4</p> <p>lay [1] 46/21</p> <p>lead [4] 6/24 35/12 96/24 106/25</p> <p>learnt [2] 56/13 87/16</p> <p>least [10] 1/20 35/18 42/21 75/7 78/6 83/22 119/14 121/2 132/8 160/6</p> <p>lecturer [2] 73/12 89/8</p> <p>led [3] 53/2 64/14 160/1</p> <p>ledgers [1] 58/16</p> <p>Lees [1] 66/24</p> <p>left [8] 4/17 4/17 9/20 16/25 17/4 32/14 101/22 125/4</p> <p>left-hand [7] 4/17 4/17 9/20 16/25 17/4 32/14 101/22</p> <p>lesions [1] 67/19</p> <p>less [8] 31/17 76/17 77/19 78/12 81/5 81/7 91/2 125/20</p> <p>lesser [1] 146/21</p> <p>let [5] 7/24 60/22 82/24 115/16 121/6</p> <p>let's [2] 98/9 166/17</p> <p>letter [61] 2/6 12/16 12/22 13/12 13/17 13/18 21/16 21/9 21/23 22/8 22/9 22/12 22/14 22/19 22/21 23/17 24/1 24/3 25/5 35/24 36/14 36/18 36/22 39/18 51/22 52/3 52/8 52/21 53/6 53/8 56/18 56/24 58/5 60/2 60/4 72/12 73/12 75/14 75/20 87/8 95/5 101/6 101/20 101/23 102/7 109/12 109/16 110/1 114/25 115/1 128/21 134/24 142/7 147/23 148/15 157/5 158/12 158/25 159/4 165/21 166/4</p> <p>letters [1] 26/14</p> <p>levels [1] 50/15</p> <p>Lewisham [1] 41/9</p> <p>licence [6] 1/10 2/14</p>	<p>2/19 37/19 37/24 37/25</p> <p>licences [1] 14/1</p> <p>licensed [1] 22/13</p> <p>licensing [2] 2/25 38/4</p> <p>life [4] 17/16 155/20 156/3 156/6</p> <p>lifetime [1] 18/8</p> <p>light [6] 38/9 46/2 71/22 85/20 131/22 159/17</p> <p>like [11] 3/3 74/11 75/1 79/9 80/5 128/5 145/17 148/11 148/13 155/5 161/22</p> <p>likely [3] 46/9 66/4 115/5</p> <p>likewise [4] 104/20 137/9 141/1 152/17</p> <p>limit [1] 106/6</p> <p>limited [13] 48/13 54/12 66/14 79/6 79/20 85/20 88/21 89/17 91/16 93/7 106/18 109/10 139/22</p> <p>Linda [1] 147/23</p> <p>line [4] 25/14 58/12 70/13 117/3</p> <p>lines [3] 4/24 45/1 123/17</p> <p>lingo [1] 7/8</p> <p>link [1] 55/9</p> <p>links [3] 91/7 91/11 91/13</p> <p>list [7] 19/1 41/2 47/16 52/1 74/2 116/15 123/11</p> <p>listed [5] 19/14 25/10 38/2 83/17 108/11</p> <p>listening [2] 41/2 67/5</p> <p>Lister [1] 75/2</p> <p>listing [1] 58/17</p> <p>lists [1] 45/24</p> <p>literature [1] 47/24</p> <p>liters [1] 12/24</p> <p>little [12] 23/19 48/4 57/5 59/6 79/21 98/2 129/14 139/6 145/12 147/5 150/9 152/3</p> <p>liver [4] 96/25 97/2 117/8 130/9</p> <p>Liverpool [1] 50/9</p> <p>lives [1] 67/12</p> <p>local [1] 166/4</p> <p>locate [1] 58/13</p> <p>location [2] 58/21 90/5</p> <p>locum [1] 132/17</p> <p>London [42] 41/6 57/3 59/24 60/3 60/5 60/12 61/22 62/17 62/23</p>	<p>63/5 64/22 66/6 66/14 66/22 68/10 68/16 70/1 71/23 91/5 99/19 99/20 100/18 100/23 108/9 108/11 108/15 118/15 121/14 121/15 122/11 133/23 134/1 136/5 139/12 143/21 143/23 155/12 160/7 162/23 163/3 166/13 166/18</p> <p>long [1] 43/21</p> <p>look [49] 5/5 38/8 40/7 43/3 43/8 43/14 51/19 60/5 60/6 60/6 63/6 63/12 64/23 66/11 70/1 71/21 71/25 73/5 76/19 76/22 79/5 80/23 81/2 81/20 82/9 90/22 93/5 96/15 100/4 100/7 101/15 101/21 103/16 110/5 110/19 111/10 111/15 112/25 113/17 113/23 121/19 123/17 125/23 136/23 137/2 138/5 145/16 162/23 166/1</p> <p>looked [25] 19/23 20/6 23/18 27/19 42/4 50/1 52/6 55/19 57/2 59/17 75/18 90/12 90/20 109/1 109/14 110/4 110/6 116/13 117/1 118/2 134/8 136/6 144/12 160/11 163/5</p> <p>looked at [18] 19/23 27/19 50/1 52/6 55/19 57/2 59/17 75/18 90/12 109/1 110/4 110/6 117/1 118/2 134/8 136/6 144/12 160/11</p> <p>looking [14] 3/6 25/13 41/15 42/6 44/6 79/3 93/1 113/16 116/10 118/11 124/12 141/15 146/12 147/22</p> <p>looks [6] 79/9 80/5 114/7 128/4 145/17 161/22</p> <p>Los [6] 13/11 24/7 24/20 25/25 26/4 26/15</p> <p>Los Angeles [6] 13/11 24/7 24/20 25/25 26/4 26/15</p> <p>loss [1] 29/9</p> <p>lost [1] 74/25</p> <p>lot [4] 42/20 47/12 67/6 118/9</p>
---	--	---	--	---	--

<p>L</p> <p>Lothian [1] 39/20</p> <p>lots [1] 68/14</p> <p>Louis [1] 23/24</p> <p>low [4] 16/5 75/25 115/7 156/25</p> <p>lower [1] 16/11</p> <p>Ludlam [1] 44/5</p> <p>lunch [1] 95/15</p> <p>luncheon [1] 98/12</p> <p>Lynne [1] 57/19</p>	<p>managers [2] 28/1 28/3</p> <p>Manchester [1] 118/16</p> <p>mandated [1] 3/23</p> <p>manner [2] 35/4 36/12</p> <p>manufacture [10] 10/18 16/18 20/13 22/2 22/4 22/24 23/2 23/6 27/7 118/20</p> <p>manufacturers [1] 30/6</p> <p>manufacturing [5] 8/14 13/3 35/7 37/1 118/18</p> <p>many [13] 31/2 31/3 40/10 48/18 52/16 58/20 74/15 102/8 102/24 110/11 117/14 119/21 144/6</p> <p>March [5] 9/13 35/14 36/13 57/25 57/25</p> <p>March 1973 [1] 9/13</p> <p>March 24 [1] 35/14</p> <p>margin [2] 4/17 144/23</p> <p>marginal [1] 145/25</p> <p>Marietta [3] 21/16 22/8 22/10</p> <p>mark [1] 135/9</p> <p>marked [4] 4/24 4/25 5/14 9/23</p> <p>markedly [1] 67/1</p> <p>market [1] 37/22</p> <p>marketed [1] 31/18</p> <p>Marshall [1] 39/24</p> <p>Martin [6] 44/10 44/20 52/19 53/3 54/25 55/23</p> <p>Martin's [1] 53/13</p> <p>Mary's [22] 41/7 89/15 106/22 107/18 107/24 108/1 108/8 108/9 108/19 109/2 109/11 109/13 109/18 110/9 111/18 112/4 113/18 118/15 120/3 120/17 120/20 124/15</p> <p>material [15] 22/1 22/23 43/23 44/11 44/13 54/3 57/1 65/17 65/20 65/23 76/1 76/2 76/4 105/18 107/20</p> <p>materials [4] 13/4 67/4 67/24 75/19</p> <p>matter [8] 12/10 47/10 51/1 51/14 55/4 55/4 69/21 166/14</p> <p>matters [4] 45/18 52/22 69/20 117/24</p> <p>maximum [1] 103/11</p> <p>may [60] 2/2 2/5 2/14</p>	<p>6/24 7/4 7/7 8/9 10/23 18/14 18/23 19/8 22/15 25/1 26/7 29/25 34/11 34/17 38/6 38/15 40/11 44/12 46/1 74/22 75/15 80/21 81/8 81/19 81/21 85/21 86/16 87/13 87/15 89/23 94/6 94/7 95/14 97/14 105/18 105/23 106/5 107/12 115/22 116/10 118/17 120/6 120/7 129/24 131/7 132/4 132/8 134/18 134/20 138/15 147/22 153/13 157/7 158/17 161/20 162/14 165/6</p> <p>May 1982 [1] 2/14</p> <p>May 1983 [1] 34/17</p> <p>May 1985 [1] 2/5</p> <p>maybe [1] 34/18</p> <p>Maycock [6] 65/21 75/21 101/16 102/5 102/23 116/20</p> <p>Maycock's [4] 110/10 125/3 135/8 144/3</p> <p>McAuley [4] 3/12 28/16 28/22 29/7</p> <p>McVerry [3] 123/13 123/18 129/18</p> <p>me [27] 7/3 7/19 7/24 24/21 25/9 25/18 36/14 37/9 38/14 43/11 45/6 45/15 46/15 59/25 60/23 80/21 113/10 115/16 119/2 121/7 129/10 135/10 148/14 149/21 155/2 155/7 158/10</p> <p>Mealey [1] 38/16</p> <p>mean [6] 4/3 17/15 31/15 33/12 115/22 153/19</p> <p>meaning [1] 7/12</p> <p>means [1] 7/24</p> <p>meant [2] 26/5 62/9</p> <p>meantime [1] 159/1</p> <p>measure [1] 137/16</p> <p>measures [2] 65/22 141/6</p> <p>medical [13] 23/24 28/15 46/10 47/24 50/12 60/8 65/1 89/12 89/13 116/12 133/12 151/7 151/21</p> <p>Medicine [1] 107/2</p> <p>medicolegal [2] 44/4 55/21</p> <p>meet [1] 17/8</p> <p>meeting [26] 30/6 30/7 38/20 39/13</p>	<p>39/15 64/20 66/12 66/24 69/23 72/2 72/4 72/12 72/23 72/23 90/11 100/11 108/20 116/11 116/13 121/23 123/9 123/10 124/8 134/16 148/2 148/4</p> <p>meetings [42] 47/17 47/23 71/20 83/16 83/17 83/23 95/24 96/2 96/5 96/11 100/8 105/22 105/25 106/2 106/3 108/23 115/25 116/2 116/6 117/20 121/20 123/6 123/7 129/16 129/21 129/24 130/1 130/19 134/6 140/20 140/21 148/25 149/2 149/5 160/9 160/12 160/13 162/11 162/12 162/15 165/2 165/5</p> <p>member [4] 47/7 107/2 107/21 117/20</p> <p>members [3] 45/11 46/3 149/7</p> <p>memo [1] 2/1</p> <p>memorandum [10] 20/22 31/7 31/21 33/16 33/25 34/3 34/12 62/11 62/16 62/20</p> <p>memories [1] 85/20</p> <p>mentioned [2] 10/19 156/7</p> <p>met [2] 20/24 147/25</p> <p>methods [1] 49/3</p> <p>Meyer [2] 21/19 22/9</p> <p>MHRA0007149 [1] 2/21</p> <p>MHRA0007156 [1] 2/20</p> <p>Mibashan [2] 132/6 140/20</p> <p>Mibashan's [1] 135/12</p> <p>Michael [1] 132/25</p> <p>Middlesex [9] 41/8 143/11 143/13 143/16 143/20 144/4 144/14 147/22 150/2</p> <p>Middlesex Hospital [5] 143/11 143/13 143/16 144/4 144/14</p> <p>might [21] 18/8 25/4 45/22 51/14 51/16 52/21 55/2 81/23 82/11 83/11 85/2 88/16 109/7 116/17 117/6 123/1 123/2 125/15 129/7 130/21 139/20</p>	<p>Mike [2] 20/9 20/17</p> <p>mild [8] 47/1 49/8 51/24 63/23 94/23 117/8 129/3 129/3</p> <p>mildly [3] 52/14 53/10 153/24</p> <p>miles [1] 90/19</p> <p>millilitres [1] 33/11</p> <p>million [6] 33/1 33/5 79/10 80/24 114/3 137/22</p> <p>mind [3] 24/19 40/11 95/16</p> <p>minimal [1] 156/21</p> <p>Ministry [1] 34/16</p> <p>minor [3] 63/2 65/9 67/16</p> <p>minute [1] 67/14</p> <p>minutes [23] 39/12 39/17 47/17 82/20 90/11 95/16 105/20 105/22 105/25 108/20 110/6 116/1 116/11 116/13 119/8 121/20 129/25 134/6 134/10 162/15 165/7 165/9 166/14</p> <p>miscellaneous [1] 64/4</p> <p>missing [1] 125/15</p> <p>Mission [4] 17/18 24/22 25/12 25/16</p> <p>Mitchell [4] 89/4 90/17 92/1 95/21</p> <p>mix [3] 94/4 105/6 110/15</p> <p>mixed [1] 104/14</p> <p>mixture [1] 164/6</p> <p>moderate [2] 63/23 94/23</p> <p>modest [1] 77/4</p> <p>modification [1] 6/1</p> <p>modified [2] 5/25 10/11</p> <p>Mollison [9] 106/24 110/21 116/3 116/5 116/9 116/16 116/23 117/19 119/1</p> <p>Mollison's [1] 110/8</p> <p>moment [10] 24/18 24/21 57/7 57/23 59/25 73/6 75/5 75/13 135/10 153/2</p> <p>money [1] 119/16</p> <p>monitoring [1] 159/14</p> <p>month [13] 69/18 69/19 72/15 73/20 100/5 100/6 108/18 123/20 123/22 123/24 134/4 143/25 163/7</p> <p>months [4] 5/22 6/4 18/7 30/23</p>	<p>moral [2] 15/9 15/9</p> <p>more [40] 2/21 6/14 6/15 19/12 29/18 38/9 41/14 43/7 45/25 47/12 49/18 49/19 52/24 52/25 53/3 57/1 63/1 66/13 66/20 66/23 67/11 67/15 68/10 72/15 78/6 87/20 87/25 107/25 108/4 108/7 113/1 118/1 119/18 123/20 133/20 136/8 143/19 160/14 165/19 166/12</p> <p>morning [7] 40/24 41/14 98/15 109/14 163/5 166/16 166/18</p> <p>most [18] 6/9 42/20 42/25 44/11 49/4 57/14 59/15 59/18 68/21 74/25 76/7 92/7 96/10 96/11 141/9 152/12 153/10 161/4</p> <p>mostly [2] 145/8 156/24</p> <p>mother [4] 55/12 149/13 149/20 158/3</p> <p>mother's [1] 156/14</p> <p>move [4] 107/5 132/1 154/19 166/19</p> <p>moved [5] 58/21 131/21 132/7 151/5 157/19</p> <p>moving [1] 81/24</p> <p>MP [1] 166/4</p> <p>Mr [12] 15/3 15/14 15/21 22/9 23/23 23/24 34/21 35/25 38/19 60/8 73/13 74/23</p> <p>Mr Charles J Carman [1] 23/23</p> <p>Mr Drees [4] 15/3 15/14 15/21 35/25</p> <p>Mr Gury [2] 34/21 38/19</p> <p>Mr Louis [1] 23/24</p> <p>Mr Meyer [1] 22/9</p> <p>Mr Obank [1] 60/8</p> <p>Mr Pettit [1] 73/13</p> <p>MRC [1] 118/23</p> <p>Mrs [3] 89/25 91/17 97/8</p> <p>Mrs C [2] 89/25 91/17</p> <p>Mrs C's [1] 97/8</p> <p>Ms [2] 40/15 120/10</p> <p>Ms Richards [1] 40/15</p> <p>Ms Spooner [1] 120/10</p> <p>much [19] 12/11 14/16 43/7 43/8 45/19</p>
---	---	---	---	--	---

<p>M</p> <p>much... [14] 46/16 47/14 52/4 63/1 64/23 67/15 67/23 76/14 85/19 117/5 118/11 119/4 127/16 165/1</p> <p>multiple [1] 81/16</p> <p>must [1] 16/3</p> <p>my [26] 9/21 20/20 25/9 25/18 45/11 45/12 46/7 46/13 46/15 47/6 47/7 47/11 47/14 47/21 48/11 48/25 49/2 54/10 54/11 55/15 56/18 62/14 73/17 154/21 154/23 155/7</p> <p>myself [2] 43/13 151/15</p>	<p>nevertheless [1] 117/12</p> <p>new [16] 6/11 6/13 10/2 10/5 10/14 10/17 11/17 17/19 19/8 24/7 24/20 25/25 26/15 30/9 45/11 46/3</p> <p>New York [4] 24/7 24/20 25/25 26/15</p> <p>Newcastle [1] 2/10</p> <p>newly [1] 163/10</p> <p>news [3] 16/23 24/5 156/16</p> <p>newsletter [1] 30/22</p> <p>newsletters [1] 30/21</p> <p>next [20] 7/22 8/4 32/15 40/14 45/21 49/25 51/19 55/22 59/1 63/20 64/5 65/15 78/25 88/24 106/22 118/25 120/21 123/16 143/11 162/23</p> <p>NHS [125] 1/16 1/17 2/12 48/10 51/8 52/5 52/17 69/5 69/8 69/15 69/19 69/21 70/3 70/6 72/14 73/8 73/15 73/19 73/24 74/12 75/10 77/4 77/9 77/19 78/18 79/1 79/7 79/14 80/13 91/4 92/12 93/7 93/16 93/24 94/3 94/4 95/7 99/25 100/2 100/22 103/20 103/24 103/25 104/9 104/13 104/19 104/21 105/2 105/4 105/6 105/10 105/13 108/17 109/5 111/13 111/23 112/7 112/10 112/15 113/1 113/10 114/2 115/10 115/14 115/18 115/20 122/2 122/17 122/25 123/19 123/23 124/5 126/5 126/11 126/15 126/19 126/24 127/3 127/11 127/16 127/24 128/11 134/5 134/13 137/4 137/12 137/18 137/25 138/7 138/19 139/6 143/24 144/24 145/3 145/5 145/8 145/18 146/14 146/19 146/23 147/5 147/8 147/18 152/14 152/15 152/16 152/17 153/9 153/22 156/24 160/6 161/2 161/4 161/6 161/10 161/16 161/17 161/24 163/2 163/25 164/1 164/7 164/9 164/22 164/24</p>	<p>NHS 8Y [1] 153/9</p> <p>NHS concentrate [2] 69/15 93/24</p> <p>NHS concentrates [1] 137/25</p> <p>NHS factor [1] 147/5</p> <p>NHS Factor VIII [2] 105/2 134/5</p> <p>NHS/Elstree [1] 51/8</p> <p>Nicaragua [4] 12/15 12/18 13/21 13/25</p> <p>night [2] 46/12 68/1</p> <p>nine [4] 2/17 14/6 111/18 144/16</p> <p>no [85] 2/11 22/6 23/1 24/7 24/19 26/15 36/6 36/7 37/11 37/13 38/23 39/16 42/19 45/5 45/25 46/21 46/23 47/1 47/6 48/5 49/2 52/2 55/4 58/24 63/14 63/15 63/18 74/14 74/19 81/5 82/10 83/12 88/1 89/20 91/18 92/13 95/18 98/2 100/25 101/13 102/22 104/2 104/20 105/17 107/4 108/14 109/23 110/14 110/15 111/9 112/16 113/25 114/12 116/4 121/11 127/9 128/19 129/11 135/16 135/19 136/18 141/6 141/19 144/24 149/8 150/10 151/10 151/11 151/17 159/12 160/22 161/18 162/4 162/7 162/7 162/9 162/17 162/20 162/21 163/8 163/11 164/9 164/25 165/11 165/13</p> <p>Noel [1] 3/12</p> <p>non [24] 11/24 11/24 55/14 96/21 96/21 96/24 96/24 116/23 116/23 117/5 117/5 117/17 117/17 117/21 117/22 120/12 130/6 130/6 130/8 130/8 140/12 157/13 157/13 159/23</p> <p>non-A [10] 11/24 96/21 96/24 116/23 117/5 117/17 117/21 130/6 130/8 157/13</p> <p>non-B [11] 11/24 96/21 96/24 116/23 117/5 117/17 117/22 120/12 130/6 130/8 157/13</p> <p>non-concentrate [1] 140/12</p>	<p>non-provision [1] 159/23</p> <p>nonetheless [2] 43/23 53/7</p> <p>nor [4] 13/24 28/25 49/6 119/17</p> <p>Norfolk [1] 41/20</p> <p>norm [1] 82/6</p> <p>normal [6] 12/25 23/2 23/6 60/13 149/14 156/20</p> <p>normally [1] 51/7</p> <p>north [13] 68/22 69/16 91/5 108/15 122/5 122/15 133/25 139/11 143/22 143/23 160/5 160/7 163/3</p> <p>North-East [2] 122/5 122/15</p> <p>North-West [2] 143/22 160/5</p> <p>Northeast [2] 69/1 121/17</p> <p>Northwest [6] 91/1 99/22 100/16 108/12 108/17 133/24</p> <p>Northwick [25] 41/8 96/3 96/15 150/14 150/15 150/23 151/3 151/5 151/6 151/8 151/17 151/20 151/24 151/25 154/13 154/23 155/17 156/11 156/13 156/19 157/5 157/19 157/23 159/11 159/20</p> <p>Northwick Park [25] 41/8 96/3 96/15 150/14 150/15 150/23 151/3 151/5 151/6 151/8 151/17 151/20 151/24 151/25 154/13 154/23 155/17 156/11 156/13 156/19 157/5 157/19 157/23 159/11 159/20</p> <p>Norwich [1] 41/20</p> <p>not [139] 1/9 7/8 10/9 11/11 12/8 13/14 13/18 13/23 15/8 16/17 20/16 20/24 21/25 22/5 23/1 24/8 25/20 25/24 26/5 26/7 26/19 27/6 28/11 28/24 31/15 35/12 35/19 37/23 37/25 38/23 41/16 42/23 43/22 45/11 47/5 47/10 47/22 48/6 48/11 48/12 48/18 48/19 48/21 49/3 50/14 50/18 51/1</p>	<p>51/16 52/25 53/19 53/24 53/25 54/8 54/10 54/20 55/8 55/18 56/4 57/13 61/6 62/6 64/13 66/14 66/22 75/4 75/23 76/17 77/17 78/6 78/9 79/17 79/22 80/10 81/3 82/1 83/1 83/19 83/24 84/5 84/12 85/19 85/23 86/6 86/13 86/24 87/17 89/6 97/10 97/12 98/20 99/16 105/21 108/5 109/8 110/3 110/4 113/3 113/4 114/19 115/22 117/19 122/8 122/23 127/16 129/10 130/6 130/13 130/20 131/5 131/11 131/21 132/14 134/5 136/4 140/2 141/17 142/13 144/11 145/24 146/5 147/11 149/20 149/24 153/12 153/18 153/19 153/19 153/23 154/2 154/9 154/21 154/24 156/22 157/24 158/1 158/19 158/23 160/11 165/1</p> <p>note [22] 11/3 30/7 37/11 39/13 40/16 61/18 64/20 64/24 78/15 80/17 83/9 83/17 84/7 87/24 91/25 93/12 94/1 103/8 110/23 136/15 154/7 166/12</p> <p>noted [3] 2/2 6/1 8/13</p> <p>notes [8] 3/16 21/13 43/4 43/17 43/20 56/4 62/15 67/14</p> <p>nothing [3] 8/22 82/22 166/8</p> <p>notice [4] 21/24 22/6 22/23 53/3</p> <p>notification [1] 59/3</p> <p>notionally [1] 100/16</p> <p>notwithstanding [1] 88/19</p> <p>November [14] 24/4 26/16 27/12 27/22 28/6 29/18 34/19 36/1 40/7 58/17 75/18 101/17 110/9 147/25</p> <p>November '86 [1] 147/25</p> <p>November 1972 [3] 75/18 101/17 110/9</p> <p>November 1982 [2] 27/12 27/22</p> <p>November 1984 [1]</p>	<p>58/17</p> <p>November 2 [1] 24/4</p> <p>now [31] 11/3 14/7 16/13 18/9 21/15 29/10 38/5 44/11 44/15 57/3 59/7 66/13 68/11 69/12 72/22 73/9 75/18 83/1 86/13 92/24 98/10 98/24 123/20 126/14 127/14 134/8 138/20 138/23 143/6 146/12 146/21</p> <p>now 759 [1] 146/12</p> <p>nub [1] 14/24</p> <p>number [76] 3/11 5/15 5/21 6/24 32/15 32/16 32/25 34/4 36/16 40/24 41/6 41/19 42/15 50/10 52/6 60/25 61/1 61/3 61/6 61/9 61/11 61/14 62/5 64/8 64/12 65/10 65/12 70/9 76/24 78/5 78/7 81/14 83/19 86/19 87/10 87/13 88/20 93/4 96/2 97/4 102/5 104/24 105/23 106/2 106/10 106/16 107/2 108/4 109/16 111/3 113/24 114/13 115/5 115/7 116/3 116/17 118/3 125/12 125/16 125/25 129/17 130/8 132/2 133/18 134/9 136/12 136/16 139/1 141/25 150/16 156/5 159/20 160/19 162/13 163/17 164/3</p> <p>number 5 [1] 3/11</p> <p>numbered [1] 52/11</p> <p>numbers [24] 19/2 58/18 61/25 63/16 76/21 85/25 86/11 91/22 97/15 97/18 98/17 101/3 103/4 120/2 126/7 131/11 135/22 141/22 144/13 150/11 161/15 163/7 163/13 163/16</p> <p>numerous [1] 143/15</p> <p>nursing [1] 151/18</p>
					<p>O</p> <p>o'clock [3] 166/15 166/18 166/21</p> <p>Obank [5] 60/8 60/9 109/13 110/1 134/24</p> <p>Obank's [1] 109/16</p> <p>object [1] 50/18</p> <p>obliged [1] 60/22</p> <p>observed [1] 10/15</p> <p>obtain [5] 13/20 13/20</p>

<p>O</p> <p>obtain... [3] 53/23 60/18 158/8</p> <p>obtainable [1] 15/22</p> <p>obtained [7] 12/5 14/3 16/17 22/14 32/22 34/23 37/20</p> <p>obtaining [6] 14/19 31/14 50/22 52/4 73/19 97/7</p> <p>obvious [1] 138/24</p> <p>obviously [9] 46/18 51/12 67/6 78/3 80/1 82/4 82/23 123/13 141/24</p> <p>occasion [2] 106/4 116/14</p> <p>occasionally [5] 46/18 111/7 152/10 163/18 163/20</p> <p>occasions [11] 47/8 52/7 55/1 83/19 95/25 105/23 116/4 118/3 134/9 162/11 162/13</p> <p>occurred [1] 149/19</p> <p>October [7] 1/1 1/20 2/9 12/16 39/15 64/1 66/12</p> <p>October 1985 [1] 2/9</p> <p>October 1986 [1] 39/15</p> <p>odd [5] 77/23 127/13 137/5 137/16 147/6</p> <p>oddity [1] 113/14</p> <p>off [3] 35/23 81/8 81/21</p> <p>offered [1] 148/9</p> <p>offers [1] 148/5</p> <p>office [5] 19/17 22/11 26/4 26/8 35/14</p> <p>officer [3] 46/10 60/8 65/2</p> <p>Officers [1] 45/15</p> <p>offices [1] 58/21</p> <p>offspring [1] 74/17</p> <p>often [3] 54/15 65/14 129/15</p> <p>Oh [1] 107/14</p> <p>older [1] 48/18</p> <p>once [3] 33/13 129/9 129/20</p> <p>oncology [2] 45/3 46/11</p> <p>one [82] 4/15 6/11 8/7 10/4 12/13 14/9 15/16 17/25 18/14 24/18 25/22 28/8 29/21 33/20 34/18 45/22 45/24 46/23 48/10 53/1 55/24 59/2 59/16 71/25 75/14 78/6</p>	<p>78/11 78/12 80/20 81/8 81/22 86/15 89/11 89/12 92/2 92/3 92/12 96/9 99/19 100/7 103/11 103/12 103/13 106/12 108/10 108/23 111/7 112/24 113/9 113/9 113/19 115/2 115/3 115/3 116/9 116/17 117/23 118/8 120/5 120/16 121/14 121/19 122/10 127/7 127/20 128/11 131/14 131/17 133/22 136/2 136/3 138/25 143/20 144/18 148/13 149/13 150/1 159/10 160/21 161/19 162/2 163/15</p> <p>one of [1] 6/11</p> <p>ongoing [1] 98/2</p> <p>only [32] 22/15 33/20 35/6 36/25 46/17 50/11 56/7 63/11 71/8 79/19 84/24 89/20 90/19 93/6 93/17 105/9 111/10 115/10 115/18 115/25 122/10 122/19 125/22 126/14 128/2 157/18 160/25 161/19 161/22 162/2 163/24 164/17</p> <p>onto [1] 58/15</p> <p>onwards [5] 53/19 91/13 116/9 155/20 159/17</p> <p>open [2] 37/25 43/11</p> <p>operate [2] 28/24 74/7</p> <p>operation [1] 165/22</p> <p>operations [3] 61/11 109/23 124/24</p> <p>option [1] 156/22</p> <p>or [144] 4/16 7/22 11/19 12/7 13/20 13/23 14/11 14/14 16/17 18/4 18/16 19/6 20/12 22/16 23/3 23/6 24/6 24/8 24/20 24/21 25/24 25/25 26/5 26/12 26/16 27/10 30/4 32/2 35/17 35/21 36/3 42/23 46/13 47/2 48/4 51/17 52/15 52/17 53/10 53/11 54/8 54/13 60/8 61/20 65/14 66/22 67/9 67/14 68/1 69/18 71/9 71/9 72/19 74/5 78/10 80/25 81/8 81/21 81/25 82/10 82/17 82/19 83/4 83/11 83/15 84/15 85/1 85/2</p>	<p>85/10 85/16 87/1 87/8 88/16 91/18 91/18 94/15 95/2 95/16 95/20 97/13 97/19 98/2 101/17 102/17 103/11 103/12 104/3 105/15 105/20 106/7 106/16 106/17 106/25 113/6 113/6 114/13 119/6 120/7 121/16 122/2 122/25 123/5 123/6 123/12 124/2 125/10 128/12 128/17 129/13 129/18 130/22 131/23 132/8 136/3 136/14 136/18 136/18 140/21 141/18 141/18 142/7 142/10 147/10 148/16 148/24 149/3 149/4 149/7 149/9 149/23 150/5 150/8 150/11 151/18 152/11 152/13 152/22 153/10 153/25 154/12 158/2 159/23 160/17 161/24</p> <p>oral [9] 43/7 57/12 83/7 83/25 84/22 89/24 91/17 106/5 136/16</p> <p>orally [1] 42/14</p> <p>order [5] 14/24 23/9 41/16 60/14 60/18</p> <p>ordered [2] 139/18 139/23</p> <p>ordering [1] 139/13</p> <p>organisation [7] 39/16 51/23 64/21 68/9 68/15 90/15 119/11</p> <p>organisation's [1] 40/1</p> <p>origin [1] 117/14</p> <p>Ormond [54] 41/6 57/4 57/6 57/16 57/24 58/2 58/4 58/6 58/9 59/5 59/10 59/12 59/20 59/23 59/23 63/8 63/10 63/11 63/21 64/7 65/5 65/8 66/7 66/22 68/25 69/13 70/18 70/25 72/21 73/6 73/13 73/17 74/20 82/18 82/21 83/4 83/5 83/20 84/2 84/23 85/3 85/22 86/1 86/15 87/12 87/15 87/17 87/21 88/2 88/10 88/14 88/18 90/12 109/15</p> <p>orthopaedic [1] 67/18</p> <p>Osaka [1] 34/14</p> <p>other [53] 3/3 4/16 7/1</p>	<p>20/1 20/3 26/1 28/5 29/9 29/19 30/6 35/7 38/1 39/7 40/10 45/2 45/5 47/21 48/11 48/23 59/15 61/17 67/18 70/1 71/20 76/7 77/11 81/24 81/25 83/19 84/12 87/12 88/4 88/16 89/14 95/17 106/1 107/24 113/6 116/17 118/10 123/14 128/12 129/6 130/19 133/18 136/5 146/1 148/4 149/16 151/16 151/18 153/23 162/13</p> <p>others [10] 17/15 20/3 20/12 38/19 82/19 95/25 96/6 110/3 129/19 140/23</p> <p>our [39] 7/9 13/7 18/17 18/22 22/12 29/13 29/14 31/11 33/19 33/20 38/22 42/5 45/24 50/15 50/19 58/15 73/20 73/21 74/10 74/25 75/3 75/4 75/23 76/7 84/6 91/16 94/1 103/7 107/5 115/25 119/9 119/12 119/21 136/15 148/23 153/16 153/17 153/18 156/6</p> <p>ourselves [1] 119/19</p> <p>out [42] 15/3 18/21 25/13 25/19 26/1 26/4 30/19 34/3 36/17 36/18 44/21 47/4 47/14 49/4 49/23 49/25 52/10 53/6 56/18 59/10 61/21 71/13 76/5 78/15 79/22 83/2 84/6 86/10 93/11 109/17 109/18 110/20 112/23 114/21 117/4 140/24 142/16 152/7 153/6 155/12 158/1 165/20</p> <p>out-patients [1] 49/4</p> <p>outlined [1] 65/21</p> <p>outnumber [1] 128/12</p> <p>outpatient [1] 113/22</p> <p>outpatients [4] 63/17 76/8 99/14 121/10</p> <p>outside [1] 122/16</p> <p>over [39] 9/19 14/12 16/15 17/22 43/19 44/23 45/9 48/10 48/15 49/25 54/1 65/3 72/17 79/10 80/4 80/24 80/25 80/25 81/1 92/21 93/19 99/3</p>	<p>111/23 112/1 115/18 117/2 129/18 129/20 133/1 137/22 137/24 138/9 138/10 143/14 148/7 151/4 153/12 153/18 163/15</p> <p>overall [4] 46/18 68/19 80/21 164/13</p> <p>overarching [2] 68/23 68/24</p> <p>overseas [1] 15/23</p> <p>overspeaking [1] 7/7</p> <p>overstock [1] 13/16</p> <p>overstocked [1] 13/23</p> <p>overview [4] 31/10 88/17 131/25 143/3</p> <p>own [5] 34/2 60/24 122/19 129/22 149/3</p> <p>owned [1] 14/9</p> <p>owner [1] 34/14</p> <p>Oxford [4] 47/18 61/16 99/6 120/10</p> <p>OXUH0003597 [1] 66/11</p>	<p>page 30 [1] 125/4</p> <p>page 32 [1] 101/20</p> <p>page 39 [1] 118/12</p> <p>page 4 [11] 4/1 15/15 16/25 24/22 34/20 63/7 70/17 81/12 100/13 136/25 138/22</p> <p>page 5 [4] 4/14 5/7 8/2 90/14</p> <p>page 6 [5] 4/15 9/19 17/22 25/8 53/14</p> <p>page 7 [2] 9/21 9/22</p> <p>page 71 [1] 119/24</p> <p>page 756 [1] 1/18</p> <p>pages [1] 101/17</p> <p>paid [7] 14/22 14/25 15/9 19/10 51/1 139/20 148/3</p> <p>painted [1] 84/11</p> <p>paints [1] 84/10</p> <p>Palace [1] 90/7</p> <p>pane [1] 5/3</p> <p>paperwork [2] 58/24 81/23</p> <p>paragraph [40] 5/7 9/6 9/8 11/16 13/7 13/19 16/1 20/7 28/21 29/5 33/16 44/21 44/25 45/9 45/21 46/1 46/2 46/5 47/20 47/25 49/9 49/14 50/4 51/3 51/4 51/20 54/9 54/25 56/12 59/1 62/10 65/3 65/17 66/3 70/19 75/22 116/21 118/25 148/2 148/10</p> <p>paragraph 1 [1] 44/21</p> <p>paragraph 10 [1] 47/25</p> <p>paragraph 12 [1] 65/17</p> <p>paragraph 13 [1] 49/9</p> <p>paragraph 14 [1] 49/14</p> <p>paragraph 16 [2] 50/4 66/3</p> <p>paragraph 18 [1] 51/4</p> <p>paragraph 19 [1] 51/3</p> <p>paragraph 2 [1] 44/25</p> <p>paragraph 21 [2] 54/9 54/25</p> <p>paragraph 4 [2] 45/9 46/2</p> <p>paragraph 6 [2] 46/1 46/5</p> <p>paragraph 8 [1] 65/3</p> <p>Paragraph 9 [1] 47/20</p> <p>paragraphs [2] 52/11 71/11</p> <p>parent [5] 55/12 150/6 150/8 155/17 159/8</p> <p>parents [9] 46/8 49/6</p>
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(59) obtain... - parents

<p>P</p> <p>parents... [7] 54/13 55/8 56/13 56/20 56/23 71/9 74/15</p> <p>Parish [2] 122/12 122/16</p> <p>Parish' [1] 122/8</p> <p>Park [25] 41/8 96/3 96/15 150/14 150/15 150/23 151/3 151/5 151/6 151/8 151/17 151/20 151/24 151/25 154/13 154/23 155/17 156/11 156/13 156/19 157/5 157/19 157/23 159/11 159/20</p> <p>parochial [2] 122/20 122/21</p> <p>part [21] 14/8 14/10 42/25 54/19 57/15 68/17 68/22 69/1 78/1 90/25 96/10 105/16 108/12 115/4 121/16 122/22 129/1 129/11 133/24 160/4 162/10</p> <p>participants [4] 42/11 43/17 43/22 118/8</p> <p>particular [26] 1/15 3/7 5/6 31/14 40/8 44/4 46/21 47/3 47/8 55/24 70/18 72/24 74/8 78/13 78/20 81/22 88/22 95/19 98/17 104/15 111/5 126/1 129/7 129/7 143/17 161/20</p> <p>particularly [3] 23/8 38/9 149/16</p> <p>parts [1] 44/16</p> <p>passage [1] 87/15</p> <p>past [4] 21/13 64/12 67/2 67/20</p> <p>Pat [1] 119/1</p> <p>patient [42] 29/14 46/24 49/5 58/15 63/18 71/9 71/10 78/3 78/23 81/1 81/17 82/8 92/2 92/4 92/12 94/21 103/12 103/13 104/12 104/17 106/12 111/7 112/19 113/19 120/12 131/14 138/23 150/1 150/5 150/6 152/10 152/11 155/10 158/20 159/8 159/10 161/8 161/19 162/3 163/18 163/20 165/21</p> <p>patient's [4] 149/13 149/20 156/14 158/3</p> <p>patients [234]</p> <p>Patricia [1] 132/11</p>	<p>Patricia Chipping [1] 132/11</p> <p>pattern [6] 66/25 104/12 127/2 139/3 145/1 163/12</p> <p>paucity [2] 58/3 88/21</p> <p>Paula [1] 121/4</p> <p>pause [3] 5/17 10/4 11/3</p> <p>pausing [3] 6/11 51/10 67/4</p> <p>pay [1] 18/19</p> <p>payment [1] 148/13</p> <p>PCR [1] 142/12</p> <p>peak [1] 9/17</p> <p>penal [2] 28/11 28/12</p> <p>Penny [4] 20/23 21/3 21/17 38/19</p> <p>people [9] 5/5 17/6 25/2 30/10 30/12 33/12 67/12 87/11 95/16</p> <p>per [40] 4/18 9/11 9/16 9/17 9/18 10/12 10/24 10/25 11/4 11/17 11/19 15/2 15/2 19/10 32/4 32/9 32/21 33/6 33/7 33/8 33/11 33/13 33/14 34/5 34/7 50/23 63/18 65/11 72/15 80/8 100/5 100/6 108/18 113/11 119/14 134/3 138/22 143/25 146/4 163/7</p> <p>perceived [1] 153/17</p> <p>Percentage [1] 32/17</p> <p>perform [1] 50/14</p> <p>perhaps [14] 5/5 7/2 38/17 67/8 76/16 83/21 103/9 106/19 122/21 136/8 143/19 148/18 159/21 166/15</p> <p>period [16] 5/9 9/6 9/9 11/4 12/15 51/8 60/19 64/1 72/1 72/17 99/8 111/1 125/16 135/23 140/11 152/8</p> <p>periodically [1] 30/21</p> <p>periods [3] 6/2 75/8 121/5</p> <p>permits [1] 41/10</p> <p>permitted [1] 42/12</p> <p>persist [1] 154/5</p> <p>person [3] 83/18 116/5 131/10</p> <p>personal [1] 58/24</p> <p>personnel [1] 107/24</p> <p>perspective [2] 91/13 96/5</p> <p>persuaded [1] 119/12</p> <p>pertains [1] 57/20</p> <p>pertinently [1] 136/8</p>	<p>Peterborough [1] 41/23</p> <p>Pettit [2] 73/13 74/23</p> <p>PGON0000104 [1] 2/13</p> <p>pharmaceutical [10] 1/4 20/1 20/3 29/19 30/6 39/19 40/6 40/10 147/20 167/2</p> <p>phased [2] 47/4 49/23</p> <p>PhD [1] 38/17</p> <p>phone [2] 19/2 142/7</p> <p>phony [1] 15/9</p> <p>phrasing [1] 26/14</p> <p>physical [4] 29/9 59/11 89/21 151/10</p> <p>physician [1] 58/22</p> <p>physiotherapy [1] 67/18</p> <p>pick [30] 25/18 41/14 44/25 55/23 63/7 64/5 65/4 66/9 66/18 69/20 70/2 70/17 73/7 75/12 77/15 79/3 90/9 90/13 93/2 93/13 96/14 98/7 112/20 122/3 123/8 127/5 138/1 146/6 147/3 166/15</p> <p>picking [7] 10/5 66/1 74/2 74/9 117/2 117/24 141/1</p> <p>picture [59] 26/19 32/11 44/17 59/16 61/25 62/17 64/17 66/9 70/18 70/24 72/19 73/8 77/15 78/21 79/3 79/13 79/21 84/10 84/11 84/17 88/17 90/13 91/2 93/2 93/10 93/13 93/14 93/23 95/14 96/9 97/18 98/5 101/2 104/14 105/4 105/11 106/19 109/6 112/5 112/13 112/20 123/9 125/1 127/5 127/18 138/1 138/2 139/5 139/8 141/2 145/12 145/20 146/6 147/1 147/4 155/15 157/6 159/19 160/24</p> <p>piece [2] 59/14 114/19</p> <p>Pinching [1] 107/25</p> <p>place [9] 13/14 49/1 95/12 96/1 134/9 149/3 149/4 149/23 162/5</p> <p>placed [3] 17/3 36/23 47/6</p> <p>plainly [2] 17/20 42/16</p>	<p>plan [2] 53/4 53/8</p> <p>planning [1] 32/7</p> <p>plant [1] 39/6</p> <p>plasma [107] 2/23 2/23 3/4 3/17 8/9 8/25 10/19 12/5 12/6 12/8 12/12 12/14 12/24 13/2 13/20 13/25 14/18 14/23 14/25 15/11 16/17 17/2 17/3 17/6 17/7 17/9 17/11 17/12 17/15 17/17 18/12 18/13 18/17 18/18 18/19 18/24 19/1 19/13 19/20 20/10 20/15 20/18 21/2 21/14 22/1 22/3 22/14 23/1 23/3 23/5 23/6 23/8 23/12 24/5 24/8 24/10 24/13 25/3 25/6 26/6 26/25 27/4 27/6 27/10 27/13 27/20 28/11 29/1 29/12 29/14 29/17 31/8 31/11 31/12 31/14 31/15 31/20 31/23 32/8 32/15 32/19 32/24 33/3 33/8 33/9 33/20 33/23 34/23 35/2 35/4 35/5 35/6 35/10 36/2 36/5 36/6 36/24 36/25 37/3 37/20 38/1 38/22 103/21 119/18 119/25 139/20 154/18</p> <p>plasmapheresis [13] 3/14 6/6 8/9 8/12 10/20 10/23 11/2 11/10 12/3 12/17 12/18 14/3 74/4</p> <p>please [27] 4/14 9/19 14/21 15/6 16/20 16/21 16/25 17/22 18/22 19/22 21/15 22/7 23/17 27/23 28/18 28/21 31/5 34/9 51/3 58/5 61/18 77/25 101/15 111/16 112/21 118/12 144/2</p> <p>pleased [1] 24/3</p> <p>plus [1] 120/14</p> <p>Plymouth [1] 41/17</p> <p>pm [5] 98/11 98/13 143/8 143/10 166/22</p> <p>point [30] 5/18 11/16 12/2 13/4 13/19 15/16 28/7 31/6 31/22 35/11 36/18 37/17 38/20 48/3 64/25 77/13 78/10 78/13 83/13 87/11 101/10 119/15 128/15 140/14 141/3</p>	<p>141/7 143/5 153/6 158/1 160/6</p> <p>pointing [3] 34/3 71/13 117/4</p> <p>points [5] 15/3 42/17 43/2 60/23 75/6</p> <p>policies [7] 42/8 51/18 95/1 95/3 111/10 125/21 153/3</p> <p>policy [10] 20/9 29/13 52/18 78/10 95/12 129/6 129/10 140/9 142/7 153/16</p> <p>political [1] 21/6</p> <p>pool [6] 3/1 8/25 30/25 74/4 74/5 154/5</p> <p>population [7] 5/12 6/8 10/23 15/1 28/10 28/25 32/5</p> <p>populations [1] 21/9</p> <p>porcine [1] 78/22</p> <p>port [1] 13/11</p> <p>posed [1] 155/6</p> <p>position [15] 12/19 15/14 20/4 50/17 59/4 73/11 87/4 122/24 131/8 131/22 138/16 143/2 152/15 157/15 166/9</p> <p>positive [26] 5/16 6/5 6/10 6/13 8/20 10/8 11/17 19/6 20/12 56/17 56/23 85/15 86/15 106/13 120/5 131/14 131/14 131/17 150/2 157/4 158/22 159/5 159/11 162/20 162/20 165/11</p> <p>positives [1] 6/25</p> <p>possibility [1] 74/3</p> <p>possible [11] 26/19 33/22 44/13 45/19 47/15 52/5 82/12 113/3 113/4 140/13 142/11</p> <p>possibly [4] 41/13 66/8 122/25 160/3</p> <p>post [2] 117/6 133/12</p> <p>Post-graduate [1] 133/12</p> <p>post-transfusion [1] 117/6</p> <p>potency [4] 68/6 75/25 76/11 76/15</p> <p>potential [5] 29/8 29/11 30/24 48/16 51/25</p> <p>potentially [4] 36/16 53/2 54/2 108/6</p> <p>powerful [2] 52/24 166/3</p> <p>practice [8] 45/11</p>	<p>46/3 46/15 47/11 54/10 55/25 141/11 149/14</p> <p>practices [1] 159/23</p> <p>Prankerd [7] 120/25 123/15 124/18 124/20 125/5 128/21 129/15</p> <p>precise [4] 41/16 93/11 97/18 112/11</p> <p>precisely [1] 122/21</p> <p>predominant [1] 147/4</p> <p>predominantly [4] 51/12 77/6 92/16 127/3</p> <p>prefer [4] 76/4 76/14 102/13 135/14</p> <p>preference [10] 94/22 102/20 103/1 110/13 110/17 125/8 129/2 140/15 144/8 144/9</p> <p>preferred [2] 2/17 76/12</p> <p>preparation [1] 102/2</p> <p>preparations [1] 154/3</p> <p>prepared [2] 36/17 117/15</p> <p>present [17] 28/7 28/13 29/2 30/2 34/20 40/4 63/12 75/3 75/23 76/13 76/16 101/19 102/3 111/2 117/2 146/12 147/13</p> <p>presentation [18] 1/3 1/5 40/3 40/22 43/7 43/15 43/16 43/20 46/23 78/15 83/9 83/17 87/24 94/1 103/7 136/15 167/2 167/4</p> <p>presentations [4] 40/5 40/14 42/9 43/4</p> <p>present [3] 14/13 21/16 27/11</p> <p>presumably [12] 21/17 23/12 76/2 76/11 78/12 80/19 108/14 122/13 128/3 131/15 163/9 163/10</p> <p>pretty [1] 115/16</p> <p>prevent [1] 65/9</p> <p>prevention [1] 67/19</p> <p>previous [18] 7/14 8/24 10/9 11/20 21/18 25/23 29/5 31/4 34/12 37/11 56/1 56/2 77/20 80/12 114/1 114/14 115/4 145/24</p> <p>previously [13] 2/17 6/1 6/5 8/13 10/7 10/19 11/16 19/16</p>
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(60) parents... - previously

<p>P</p> <p>previously... [5] 52/7 53/11 79/18 81/18 117/1</p> <p>price [1] 50/23</p> <p>prices [6] 15/19 15/22 15/25 16/1 16/5 16/11</p> <p>principal [2] 14/17 141/4</p> <p>principle [1] 71/17</p> <p>prior [2] 37/9 116/1</p> <p>prison [3] 28/24 29/17 36/20</p> <p>prisons [4] 24/13 27/18 27/20 29/1</p> <p>probably [6] 34/25 41/13 113/15 114/19 122/20 143/5</p> <p>problem [6] 46/14 48/5 54/12 55/7 94/24 120/1</p> <p>problems [1] 21/8</p> <p>procedure [1] 22/12</p> <p>procedures [2] 10/12 20/19</p> <p>process [9] 8/14 11/19 30/9 30/10 85/6 85/18 97/3 97/7 118/19</p> <p>processes [3] 35/19 35/22 85/23</p> <p>procurement [1] 35/10</p> <p>produced [2] 1/7 139/18</p> <p>producing [1] 42/9</p> <p>product [88] 1/7 1/10 1/10 1/13 1/16 1/17 1/19 2/12 2/14 2/15 13/5 42/7 46/24 48/10 48/13 51/5 76/21 77/7 77/7 77/23 78/20 78/22 78/24 79/9 79/12 79/15 80/14 80/18 82/13 91/22 92/18 92/23 93/8 93/9 93/9 93/17 93/18 104/9 104/16 104/20 111/12 111/25 112/2 112/15 126/2 126/5 126/6 126/16 126/17 126/20 127/14 127/24 136/22 137/17 137/22 138/8 138/9 138/13 138/20 139/3 139/3 139/7 139/8 139/14 145/6 145/10 146/3 147/18 148/6 148/8 148/9 152/12 152/21 153/9 153/16 154/6 156/2 156/8 161/3</p>	<p>161/4 161/11 162/3 162/4 163/22 164/4 164/11 164/16 164/23</p> <p>production [7] 19/21 22/16 31/16 36/21 37/3 38/2 65/22</p> <p>products [60] 2/22 10/19 12/1 12/8 23/14 27/1 27/10 29/15 31/16 31/17 35/7 37/21 42/22 48/2 48/6 48/10 50/17 51/11 51/13 53/16 53/18 53/24 53/25 54/16 54/19 58/19 74/8 96/18 96/22 103/17 107/3 107/22 111/24 112/8 117/14 117/14 119/7 128/25 129/7 133/9 133/17 134/2 134/18 136/13 137/3 139/20 142/10 142/15 143/23 144/8 144/20 149/17 153/13 153/22 157/1 157/17 160/17 160/25 161/9 162/7</p> <p>professional [1] 117/16</p> <p>professor [55] 2/6 57/10 57/12 57/13 58/23 62/2 65/5 65/7 66/15 68/20 68/25 70/15 70/20 72/8 73/1 75/16 75/21 82/16 83/14 83/15 84/2 84/19 84/23 85/3 98/25 99/8 100/15 100/20 101/7 105/21 106/24 107/16 110/8 110/21 116/3 116/5 116/19 116/16 116/19 116/19 116/19 116/23 117/4 117/11 117/19 120/25 123/15 124/18 124/20 125/5 128/21 129/15 132/4 143/13 144/9 149/1 149/4</p> <p>Professor Barrett [1] 99/8</p> <p>Professor Bloom [1] 2/6</p> <p>Professor Dacie [1] 132/4</p> <p>Professor Hann [3] 57/13 84/19 84/23</p> <p>Professor Hardisty [11] 65/5 65/7 66/15 70/20 72/8 73/1 75/21 82/16 83/14 84/2 85/3</p> <p>Professor Hardisty's [2] 62/2 75/16</p> <p>Professor Humble [5]</p>	<p>98/25 100/15 100/20 101/7 105/21</p> <p>Professor Ian [1] 57/12</p> <p>Professor Ingram [3] 68/20 68/25 70/15</p> <p>Professor Mollison [7] 106/24 110/21 116/3 116/5 116/16 116/23 117/19</p> <p>Professor Mollison's [1] 110/8</p> <p>Professor Pranker [7] 120/25 123/15 124/18 124/20 125/5 128/21 129/15</p> <p>Professor Roger [1] 58/23</p> <p>Professor Sherlock [2] 116/19 117/11</p> <p>Professor Stewart [4] 143/13 144/9 149/1 149/4</p> <p>Professor Zuckerman [2] 116/19 117/4</p> <p>Profilate [5] 38/4 77/8 92/23 147/16 154/7</p> <p>Profiline [3] 1/7 2/8 2/11</p> <p>program [10] 6/6 8/8 8/12 10/21 11/2 11/6 11/11 11/13 11/14 11/15</p> <p>programme [7] 8/22 10/7 29/22 30/3 30/17 30/23 93/22</p> <p>programmes [1] 34/2</p> <p>progresses [1] 40/12</p> <p>progression [1] 117/7</p> <p>project [1] 148/16</p> <p>prophylactic [3] 95/2 95/9 95/11</p> <p>proportion [3] 15/1 70/8 141/24</p> <p>proportions [1] 146/18</p> <p>propose [2] 50/2 59/8</p> <p>proposed [1] 24/16</p> <p>prose [1] 4/11</p> <p>prospective [3] 8/25 22/5 27/6</p> <p>protein [4] 23/3 23/7 23/12 27/10</p> <p>provenance [1] 154/4</p> <p>provide [10] 33/15 39/14 58/9 61/24 67/25 68/4 125/23 130/20 148/12 148/14</p> <p>provided [26] 32/14 33/5 36/8 37/18 37/21 51/13 54/8 54/8 58/1 72/11 86/9 87/7 91/20</p>	<p>98/20 98/20 108/17 128/24 131/13 132/13 134/23 149/9 149/11 149/17 150/20 150/25 155/7</p> <p>provides [4] 31/9 62/17 98/16 142/20</p> <p>providing [2] 16/16 85/1</p> <p>provision [5] 67/22 118/20 152/4 159/23 159/23</p> <p>provisions [2] 60/15 61/21</p> <p>PRSE0001960 [1] 116/11</p> <p>PTH [2] 117/6 117/12</p> <p>public [1] 15/8</p> <p>publication [2] 3/10 17/24</p> <p>publicising [1] 15/4</p> <p>publish [1] 43/20</p> <p>published [5] 3/5 30/21 42/11 43/18 130/18</p> <p>purchase [5] 28/25 50/7 50/17 53/25 124/6</p> <p>purchased [4] 24/10 27/4 51/11 134/14</p> <p>purchases [1] 148/21</p> <p>purchasing [1] 123/21</p> <p>Pure [1] 2/17</p> <p>purifier [1] 156/3</p> <p>purpose [5] 8/18 13/25 14/17 21/23 109/4</p> <p>purposes [14] 13/3 13/7 28/7 30/2 31/12 34/20 63/12 69/14 101/19 111/2 116/14 117/2 146/12 147/13</p> <p>Pursuant [1] 70/25</p> <p>pursued [1] 39/10</p> <p>put [6] 13/25 15/14 52/7 98/19 121/6 150/21</p> <p>puzzles [1] 7/19</p>	<p>questionnaire [4] 110/10 125/3 135/8 144/3</p> <p>questions [6] 30/16 42/7 60/25 102/5 102/22 109/16</p> <p>quick [1] 81/20</p> <p>quicker [1] 9/2</p> <p>quite [6] 6/17 42/20 54/15 67/1 137/16 159/21</p> <p>quote [10] 5/8 10/10 13/8 17/5 21/22 22/20 24/1 28/23 29/7 34/22</p>	<p>115/25 159/12</p> <p>realisation [1] 85/23</p> <p>realistically [1] 41/14</p> <p>really [11] 64/17 66/21 74/11 94/12 94/19 96/18 108/22 119/19 125/22 148/24 159/21</p> <p>reason [14] 23/1 38/23 48/7 48/24 49/2 49/3 50/22 73/17 74/10 76/1 76/10 113/4 113/6 154/8</p> <p>reasonable [4] 105/24 129/24 162/14 165/6</p> <p>reasonably [5] 45/14 46/16 83/21 126/8 138/6</p> <p>reasons [5] 33/9 50/10 57/7 81/25 157/21</p> <p>recall [30] 14/1 44/2 44/3 51/21 52/10 53/20 62/12 83/25 85/21 86/2 86/9 86/24 89/23 94/14 95/1 97/6 97/8 97/13 106/5 109/14 121/11 129/5 129/6 130/23 140/4 140/6 153/18 154/8 156/7 163/5</p> <p>recalled [2] 97/23 158/6</p> <p>recalling [2] 84/1 129/4</p> <p>recalls [3] 96/14 97/25 139/10</p> <p>receipt [4] 22/11 53/8 105/20 116/1</p> <p>receive [9] 24/3 31/23 32/1 32/7 45/15 55/10 55/16 76/1 139/23</p> <p>received [40] 2/7 12/14 45/6 47/18 52/2 54/22 56/22 59/7 59/9 60/7 73/22 78/6 83/3 83/6 84/10 84/18 85/10 91/1 95/9 97/21 98/4 100/17 105/24 106/11 108/13 120/4 120/14 129/25 136/12 142/10 142/15 142/19 149/6 150/4 157/9 159/7 160/5 162/15 162/16 165/10</p> <p>receiving [7] 36/4 51/21 53/20 54/19 73/23 76/18 139/2</p> <p>recent [4] 24/3 24/6 36/3 118/6</p> <p>recently [2] 38/12 38/22</p>
<p style="text-align: right;">(61) previously... - recently</p>					

<p>R</p> <p>recipient [2] 34/12 156/12</p> <p>recipients [1] 102/7</p> <p>recollect [1] 86/4</p> <p>recollected [1] 86/24</p> <p>recollection [14] 86/3 88/8 94/16 94/20 94/21 97/3 99/10 141/8 142/4 153/5 153/8 157/12 157/24 159/13</p> <p>recommendation [5] 21/1 52/24 53/1 53/5 53/21</p> <p>recommendations [3] 35/15 51/23 52/10</p> <p>record [4] 85/11 105/22 116/4 134/10</p> <p>recorded [10] 2/7 30/8 31/21 56/4 120/6 120/13 144/24 158/20 165/4 165/9</p> <p>recording [1] 20/2</p> <p>records [12] 20/7 39/21 58/15 73/21 86/10 109/2 117/10 123/17 143/16 149/22 156/10 157/2</p> <p>recovered [7] 12/6 32/8 32/19 32/24 33/2 33/9 36/5</p> <p>recruit [1] 16/14</p> <p>Red [1] 15/4</p> <p>redacted [1] 78/4</p> <p>reduce [2] 82/13 156/4</p> <p>reduced [2] 35/6 36/25</p> <p>reduces [1] 15/12</p> <p>reduction [5] 35/10 37/6 77/16 80/15 145/23</p> <p>refer [1] 142/22</p> <p>reference [53] 2/4 3/9 4/12 6/18 11/14 13/17 16/3 16/8 25/24 30/8 30/25 37/13 38/11 39/13 39/17 40/1 44/9 55/23 57/16 58/11 59/1 60/1 63/24 69/17 71/11 72/25 74/1 75/12 78/22 86/12 100/14 101/8 112/21 121/7 122/4 124/10 124/14 124/15 124/16 128/1 128/2 128/4 128/7 128/21 131/15 132/20 132/23 133/2 146/8 148/2 152/23 158/11 165/20</p>	<p>references [6] 1/24 39/2 39/8 39/23 84/6 143/15</p> <p>referral [1] 64/10</p> <p>referred [14] 3/20 21/18 57/21 61/17 87/23 98/15 119/8 129/2 136/14 143/1 152/6 157/10 158/4 159/4</p> <p>referring [3] 5/6 19/25 83/2</p> <p>refers [11] 16/1 25/12 62/10 74/24 90/16 95/8 114/24 118/23 129/4 147/25 149/22</p> <p>reflect [1] 86/16</p> <p>reflected [1] 32/25</p> <p>reflecting [2] 9/17 104/24</p> <p>reflection [3] 82/11 97/15 131/7</p> <p>reflections [1] 117/25</p> <p>reflective [1] 113/7</p> <p>reflects [5] 113/5 128/14 128/18 147/9 147/10</p> <p>refused [1] 35/11</p> <p>regard [2] 48/6 159/8</p> <p>regarded [4] 48/9 69/1 69/14 123/4</p> <p>regarding [8] 28/17 38/4 39/18 56/19 84/3 97/22 106/19 130/22</p> <p>regime [3] 46/22 48/7 52/3</p> <p>region [23] 68/17 68/18 69/2 69/7 69/11 69/23 70/11 71/6 91/1 99/23 99/24 100/17 108/12 108/13 108/17 121/17 121/17 122/9 133/25 133/25 143/22 160/5 160/5</p> <p>region 5 [2] 99/24 108/13</p> <p>regional [18] 28/1 28/3 68/6 69/6 69/16 70/7 71/15 71/21 72/6 99/23 100/10 121/22 122/7 122/15 122/22 123/3 139/15 160/15</p> <p>regions [2] 71/4 121/22</p> <p>registered [16] 61/1 61/7 61/12 62/4 62/6 63/25 64/2 64/3 64/4 64/8 65/13 101/11 109/19 124/21 124/25 135/3</p> <p>registrar [12] 45/7 45/8 57/24 99/7 121/4</p>	<p>129/1 129/11 132/16 132/16 133/15 151/2 151/3</p> <p>Registrars [1] 45/13</p> <p>regular [9] 73/24 77/14 83/16 105/21 116/8 117/20 123/6 140/20 149/1</p> <p>regularly [5] 102/9 110/12 125/7 135/13 144/7</p> <p>regulations [1] 35/13</p> <p>Regulatory [1] 21/17</p> <p>Reid [5] 150/25 153/4 154/1 158/6 158/12</p> <p>Reid's [3] 151/13 157/23 159/13</p> <p>rejected [1] 5/22</p> <p>relate [1] 39/20</p> <p>related [4] 31/6 60/14 62/22 160/14</p> <p>relates [1] 52/11</p> <p>relating [8] 57/1 58/4 68/9 107/3 132/3 143/4 148/4 159/18</p> <p>relation [91] 41/5 42/7 42/9 44/1 44/2 44/17 45/12 46/4 54/4 55/5 55/19 56/13 56/15 57/6 58/1 58/8 59/4 60/3 61/23 62/24 63/8 65/5 66/6 66/9 69/4 70/18 73/8 75/8 77/21 82/2 82/4 84/11 84/21 84/23 85/9 86/3 86/11 86/22 87/3 88/18 90/12 91/3 93/25 94/8 95/2 95/3 95/6 95/15 96/20 97/3 98/6 102/10 104/12 104/13 105/1 105/3 106/7 108/3 108/6 109/15 110/6 111/9 112/20 118/3 120/19 120/23 123/14 130/10 131/1 131/25 134/20 138/16 139/9 140/10 140/25 143/18 147/21 148/23 149/9 156/10 157/10 157/19 159/3 159/19 161/11 162/22 165/14 165/16 166/6 166/7 166/9</p> <p>relations [1] 147/20</p> <p>relationship [1] 114/12</p> <p>relative [1] 159/22</p> <p>relatively [19] 5/11 49/12 88/20 104/24 105/7 106/18 109/10 111/25 120/7 125/16 126/6 127/15 128/10</p>	<p>131/8 144/20 152/20 154/25 161/14 164/12</p> <p>relays [1] 133/18</p> <p>relevance [1] 52/13</p> <p>relevant [11] 28/8 43/1 44/10 51/7 51/19 58/10 58/14 59/2 101/19 121/3 135/5</p> <p>reliability [1] 76/6</p> <p>reliable [4] 49/22 76/11 86/18 114/19</p> <p>relished [1] 49/6</p> <p>rely [1] 45/16</p> <p>remain [3] 42/3 66/7 163/16</p> <p>remained [2] 117/8 151/6</p> <p>remaining [4] 41/24 42/10 42/13 78/14</p> <p>remember [2] 131/6 154/2</p> <p>remit [1] 123/5</p> <p>remove [1] 8/24</p> <p>repeat [3] 32/10 33/11 50/2</p> <p>repeated [1] 81/9</p> <p>repercussions [1] 21/7</p> <p>repetitively [1] 68/13</p> <p>replace [2] 14/22 14/25</p> <p>replaced [1] 4/3</p> <p>replacement [1] 76/9</p> <p>report [6] 1/18 30/14 34/15 36/15 44/5 44/5</p> <p>reported [4] 11/5 11/12 70/9 134/15</p> <p>reporting [3] 120/10 124/4 134/12</p> <p>reports [2] 44/4 55/21</p> <p>represent [1] 119/2</p> <p>representative [2] 30/4 66/25</p> <p>representatives [3] 30/4 66/13 66/16</p> <p>represented [1] 129/15</p> <p>representing [1] 123/15</p> <p>represents [3] 9/23 31/25 32/9</p> <p>request [6] 12/23 21/5 58/9 59/13 95/7 124/22</p> <p>requests [1] 19/25</p> <p>required [5] 35/21 48/19 50/21 60/16 109/4</p> <p>requirement [2] 35/9 37/5</p> <p>requirements [2] 35/13 36/23</p>	<p>requires [1] 49/5</p> <p>requiring [4] 34/25 35/1 35/2 75/1</p> <p>research [8] 18/17 99/13 116/12 130/18 148/16 151/21 151/22 151/23</p> <p>researcher [1] 148/16</p> <p>resemblance [1] 113/25</p> <p>reserve [1] 52/16</p> <p>reserved [1] 27/9</p> <p>resonance [1] 66/22</p> <p>resources [1] 67/23</p> <p>respect [2] 11/7 64/15</p> <p>respect of [1] 11/7</p> <p>responded [1] 28/5</p> <p>responds [1] 125/6</p> <p>response [19] 29/20 40/7 40/9 59/12 62/2 82/12 109/18 110/1 110/8 123/25 125/3 130/25 134/23 135/8 135/12 140/19 144/3 144/10 149/12</p> <p>responses [3] 60/7 144/2 144/12</p> <p>responsibilities [2] 47/21 99/24</p> <p>responsibility [4] 45/4 68/19 68/23 68/24</p> <p>responsible [3] 12/20 70/14 70/16</p> <p>rest [1] 151/7</p> <p>restricted [1] 75/24</p> <p>restricting [1] 78/10</p> <p>restrictions [2] 24/16 47/6</p> <p>result [10] 11/25 30/15 35/9 37/5 52/3 86/19 87/7 87/14 157/4 159/6</p> <p>results [6] 32/11 106/16 131/10 141/10 141/20 162/21</p> <p>retain [2] 71/18 141/12</p> <p>retrospective [3] 8/23 86/7 131/16</p> <p>return [22] 5/3 6/13 34/19 76/23 79/2 92/10 104/7 111/17 112/9 113/15 115/10 125/14 125/24 126/13 144/25 145/13 147/14 148/20 148/20 148/22 161/9 162/1</p> <p>returned [1] 20/24</p> <p>Returning [1] 10/10</p> <p>returns [54] 42/21 47/19 50/1 56/6 69/12</p>	<p>73/7 75/13 76/19 77/12 78/1 78/15 78/16 78/25 82/4 89/3 92/8 93/2 103/3 103/5 103/6 103/15 103/16 104/15 104/23 105/10 110/23 110/24 111/11 113/4 114/15 125/14 125/15 125/22 128/7 132/12 132/23 135/22 135/24 136/23 137/11 144/14 144/19 147/12 150/24 152/8 152/20 153/7 154/10 156/9 158/2 160/20 160/24 163/13 163/23</p> <p>revealing [1] 159/21</p> <p>revert [1] 156/22</p> <p>review [1] 142/14</p> <p>reviewing [2] 8/3 73/21</p> <p>revolutionary [1] 67/7</p> <p>revolutionised [1] 49/16</p> <p>RFFP [1] 32/8</p> <p>RFH [1] 122/13</p> <p>RHA [2] 122/4 122/10</p> <p>RIA [3] 4/6 4/25 10/4</p> <p>Richard [1] 131/5</p> <p>Richards [4] 40/15 121/1 129/17 129/20</p> <p>right [16] 7/10 7/11 9/5 17/25 27/9 62/13 63/13 78/5 79/6 114/7 114/11 115/16 129/22 149/3 158/1 158/18</p> <p>right-hand [6] 9/5 17/25 63/13 78/5 79/6 158/18</p> <p>rise [2] 5/23 52/22</p> <p>risk [30] 28/25 29/11 29/23 29/24 30/19 31/8 34/4 36/16 40/8 40/9 48/1 48/9 54/17 55/13 84/15 95/19 96/13 97/2 105/15 105/16 106/8 115/24 117/7 117/16 129/13 130/25 140/18 140/19 156/1 156/21</p> <p>risk' [1] 33/24</p> <p>risks [16] 54/16 54/21 55/2 55/14 83/11 84/13 84/20 91/18 117/22 130/22 136/19 148/24 149/10 157/18 159/22 162/10</p> <p>Rivett [1] 31/9</p> <p>RLH [9] 50/9 50/10 50/16 50/20 50/23 51/6 51/11 52/4 53/24</p> <p>RLIT0000022 [1]</p>
---	---	--	---	---	---

<p>R</p> <p>RLIT0000022... [1] 118/2</p> <p>Road [1] 90/7</p> <p>Rodell [1] 20/9</p> <p>Roger [2] 57/11 58/23</p> <p>Roger Hardisty [1] 57/11</p> <p>Rogers [1] 100/23</p> <p>role [5] 107/5 132/15 143/17 143/17 151/4</p> <p>room [2] 133/7 133/16</p> <p>rooms [1] 99/14</p> <p>roughly [8] 80/7 81/7 128/9 146/22 146/23 146/24 147/8 164/15</p> <p>round [1] 40/5</p> <p>routine [2] 140/6 141/11</p> <p>routinely [1] 54/19</p> <p>Royal [9] 2/3 50/9 62/12 63/10 66/5 91/14 122/13 133/11 159/15</p> <p>Royal Free [4] 2/3 62/12 63/10 66/5</p> <p>RTCs [1] 139/25</p> <p>run [2] 11/10 12/3</p> <p>running [1] 156/25</p> <p>Ryle [1] 99/19</p> <p>Ryness [1] 84/1</p> <p>Ryness-Hirsch [1] 84/1</p>	<p>Samson [12] 89/6 89/17 91/11 94/13 96/2 96/14 97/12 97/23 150/20 151/5 151/22 157/11</p> <p>Samson's [1] 151/9</p> <p>San [16] 13/5 17/18 24/8 24/20 24/23 25/3 25/4 25/13 25/15 25/16 26/11 26/16 26/24 38/10 38/12 38/23</p> <p>San Francisco [16] 13/5 17/18 24/8 24/20 24/23 25/3 25/4 25/13 25/15 25/16 26/11 26/16 26/24 38/10 38/12 38/23</p> <p>sat [1] 154/22</p> <p>satisfactory [1] 100/25</p> <p>save [3] 21/13 36/7 37/18</p> <p>Savidge [1] 44/5</p> <p>saw [1] 54/3</p> <p>say [36] 2/21 3/25 8/2 15/5 24/15 38/5 51/4 58/12 77/24 83/11 83/14 83/15 85/21 88/18 94/13 96/16 96/20 96/25 111/20 114/21 114/23 114/24 116/17 117/1 118/9 118/12 118/17 131/9 149/11 151/20 153/4 154/9 154/14 157/2 157/3 158/1</p> <p>saying [4] 62/13 109/2 123/18 148/15</p> <p>says [63] 3/22 4/1 4/18 11/8 15/21 17/5 17/18 23/22 24/1 24/19 24/22 25/21 36/19 36/22 45/1 45/10 45/21 46/2 46/4 49/14 51/4 51/20 52/20 54/9 55/6 55/23 55/25 62/24 66/2 73/14 75/21 87/2 87/3 88/2 89/19 91/17 94/25 96/18 101/25 110/14 118/14 118/25 122/5 124/1 129/8 132/14 132/16 133/15 139/12 140/1 140/11 141/3 141/5 142/5 142/8 149/18 151/14 153/15 153/21 154/1 154/20 156/23 157/14</p> <p>scale [2] 36/9 155/5</p> <p>scanned [2] 25/24 58/15</p>	<p>scarce [1] 52/5</p> <p>scene [3] 84/24 85/17 94/13</p> <p>scheduled [1] 41/21</p> <p>School [2] 89/13 133/12</p> <p>schools [1] 89/12</p> <p>Scotland [1] 57/15</p> <p>screen [11] 4/14 4/15 9/20 16/20 19/22 27/23 31/5 34/9 52/8 114/20 150/21</p> <p>screened [2] 33/23 35/3</p> <p>screening [11] 3/17 29/22 30/3 30/9 30/10 30/17 30/23 34/2 35/12 35/20 165/25</p> <p>searches [1] 59/10</p> <p>searching [1] 18/24</p> <p>second [25] 4/8 5/7 9/8 14/20 16/1 17/1 20/7 26/25 28/7 46/5 65/3 70/19 72/4 72/11 75/21 84/24 116/21 117/3 119/23 121/24 123/11 133/14 140/9 148/2 158/20</p> <p>Secondly [1] 53/5</p> <p>Secretariat [1] 47/19</p> <p>section [4] 8/1 14/21 20/6 28/22</p> <p>sector [1] 12/7</p> <p>Security [1] 60/10</p> <p>see [118] 4/16 4/18 4/22 5/6 12/4 13/12 15/25 16/9 17/2 17/4 25/9 28/19 31/12 32/13 32/17 38/9 38/18 43/23 44/19 44/22 45/10 52/19 53/6 59/19 60/1 62/3 62/10 62/19 63/20 63/25 65/15 66/2 66/11 66/16 69/12 69/17 69/21 69/24 72/11 72/19 76/24 77/2 77/12 77/16 78/4 79/4 79/15 80/13 81/14 81/20 82/5 82/9 89/3 92/17 93/3 93/6 93/14 94/4 95/4 95/8 95/12 96/6 100/13 100/19 101/15 101/20 102/10 102/20 104/5 104/8 105/1 110/8 110/20 111/17 111/21 111/24 112/22 113/18 114/21 115/18 115/20 116/15 116/21 117/3 117/23 118/13 121/19 122/4 122/20 123/6</p>	<p>124/4 125/4 125/8 126/1 126/11 126/14 127/6 127/22 128/17 129/16 129/21 136/25 138/2 138/5 138/18 138/22 138/24 140/22 145/16 146/11 146/16 146/21 147/4 157/6 158/10 158/24 162/19 164/4</p> <p>seeing [3] 25/23 42/6 138/23</p> <p>seek [2] 19/19 88/6</p> <p>seeking [2] 29/24 39/25</p> <p>seem [3] 26/20 75/4 115/2</p> <p>seemed [3] 55/9 66/4 165/2</p> <p>seems [8] 7/18 14/8 15/17 80/17 114/3 114/12 114/22 164/9</p> <p>seen [15] 7/20 12/4 19/16 26/23 39/7 46/10 46/17 47/4 77/25 82/22 99/25 108/3 121/9 143/15 146/1</p> <p>segment [1] 33/22</p> <p>Seiff [1] 72/11</p> <p>selective [1] 43/3</p> <p>selling [2] 21/14 148/5</p> <p>seminar [3] 118/4 118/9 119/24</p> <p>send [2] 50/20 165/3</p> <p>senior [8] 45/7 45/13 45/14 45/16 57/24 89/7 132/16 151/2</p> <p>sense [6] 7/18 50/10 76/20 84/4 115/2 125/21</p> <p>sensitive [2] 6/10 6/14</p> <p>sensitivity [6] 5/20 6/21 6/23 6/24 7/5 7/15</p> <p>sent [18] 12/19 12/20 21/18 23/19 23/22 31/9 34/12 38/17 53/24 56/18 72/9 73/1 90/3 109/16 129/23 159/5 162/12 165/7</p> <p>sentence [6] 9/5 9/8 15/6 27/19 46/5 74/13</p> <p>separate [2] 119/18 133/11</p> <p>September [20] 8/6 8/19 9/2 22/9 27/5 58/6 60/24 61/2 72/7 72/24 100/12 101/2 108/23 109/7 109/12</p>	<p>109/22 123/10 124/9 134/16 159/4</p> <p>September 1975 [3] 8/6 8/19 9/2</p> <p>September 1977 [3] 101/2 108/23 109/7</p> <p>September 1978 [2] 72/24 124/9</p> <p>September 1982 [1] 27/5</p> <p>sera [3] 120/8 131/16 141/13</p> <p>series [1] 14/23</p> <p>serious [2] 18/9 97/2</p> <p>seriously [1] 84/5</p> <p>seroconversion [1] 86/5</p> <p>serum [3] 23/3 23/6 86/6</p> <p>service [5] 8/6 10/15 49/21 60/16 67/21</p> <p>services [2] 88/10 107/6</p> <p>session [1] 43/11</p> <p>set [11] 38/3 52/10 53/6 78/15 83/2 84/6 93/11 109/18 110/20 114/21 140/24</p> <p>sets [3] 44/20 49/25 121/20</p> <p>setting [3] 22/19 59/10 86/10</p> <p>seven [5] 81/5 112/22 127/19 145/15 146/10</p> <p>seventies [2] 1/8 3/16</p> <p>several [3] 30/4 58/21 95/23</p> <p>severe [11] 35/9 37/6 61/9 62/9 63/23 74/25 101/14 109/23 124/23 135/5 154/15</p> <p>severity [2] 130/4 157/13</p> <p>sexual [1] 30/11</p> <p>shall [1] 13/5</p> <p>share [2] 45/8 77/22</p> <p>shared [1] 130/19</p> <p>she [71] 20/25 57/23 57/25 86/2 86/3 86/4 86/5 88/2 88/5 89/19 90/1 91/20 91/20 94/17 94/25 95/1 96/3 96/16 96/16 96/18 96/20 96/23 96/25 97/1 97/6 97/10 97/25 118/9 118/11 118/13 118/23 118/25 119/24 121/5 121/7 128/25 129/1 129/4 129/5 129/6 129/8 130/5 130/10 130/23 131/3 131/5 131/8 131/9</p>	<p>131/9 131/11 131/20 132/13 132/14 132/16 139/12 139/17 140/1 140/2 140/3 140/5 140/6 147/25 150/22 150/24 155/18 156/19 156/22 156/23 157/14 157/18 157/19</p> <p>sheds [1] 38/9</p> <p>sheets [1] 81/13</p> <p>Sherlock [2] 116/19 117/11</p> <p>shifts [1] 145/12</p> <p>ship [1] 12/23</p> <p>shipment [3] 13/10 13/14 13/23</p> <p>SHO [2] 46/13 46/13</p> <p>shock [1] 17/14</p> <p>short [2] 40/20 143/9</p> <p>shortage [2] 73/3 75/24</p> <p>shorter [1] 6/2</p> <p>shortfall [4] 123/23 124/5 124/7 134/12</p> <p>shortly [1] 165/24</p> <p>should [37] 4/2 7/12 7/15 17/2 17/7 21/4 23/1 24/13 27/20 28/3 28/8 38/23 47/2 51/4 53/6 53/18 55/15 60/22 63/2 66/7 67/25 68/4 68/5 71/18 75/14 76/3 76/9 76/14 77/24 94/3 111/20 124/1 124/3 148/18 149/11 151/20 157/3</p> <p>show [21] 37/9 44/16 57/22 75/14 78/2 78/16 79/13 103/3 103/7 103/16 110/24 111/2 120/9 144/20 148/20 149/23 152/12 152/13 152/20 163/8 163/13</p> <p>showed [5] 24/21 37/12 37/12 113/10 163/6</p> <p>shown [3] 36/14 80/21 139/2</p> <p>shows [27] 33/4 78/17 81/23 83/14 92/10 92/15 101/10 103/18 103/24 104/18 111/13 112/6 112/9 115/10 123/13 137/9 137/15 137/20 139/5 145/14 161/6 161/13 162/2 162/6 164/14 164/20 164/24</p> <p>Shrewsbury [1] 42/1</p> <p>sic [2] 106/25 132/12</p> <p>sick [7] 17/13 59/21</p>
--	---	--	---	--	---

(63) RLIT0000022... - sick

S sick... [5] 69/13 70/22 71/14 71/17 72/9 side [8] 4/15 4/16 17/1 48/16 78/5 79/6 133/7 158/18 side-effects [1] 48/16 Sieff [2] 72/8 72/9 significance [6] 16/15 28/14 29/3 88/19 153/1 165/23 significant [12] 67/10 77/16 77/20 80/15 97/2 126/8 126/12 134/12 137/9 138/7 139/1 145/23 significantly [5] 11/12 16/11 76/6 76/17 113/1 signs [1] 29/10 similar [13] 35/21 39/7 78/21 84/10 88/8 93/10 105/11 112/5 112/13 119/10 127/2 145/1 151/13 simpler [1] 156/3 simply [3] 15/10 113/7 147/9 since [11] 10/11 11/2 32/10 35/7 48/23 54/11 58/19 60/20 75/25 76/7 76/13 single [2] 42/13 161/8 sir [56] 1/5 2/22 5/17 6/11 8/15 8/18 11/21 14/1 24/24 25/8 27/15 28/13 29/16 38/5 39/2 40/3 40/16 40/24 43/25 44/19 46/2 51/10 52/6 52/10 56/25 57/3 60/8 63/9 67/4 75/18 76/24 77/25 85/8 86/9 88/17 89/24 91/20 95/14 98/5 98/14 111/10 116/20 120/21 120/21 131/25 136/15 141/14 143/2 143/11 148/20 156/7 156/14 157/6 158/17 159/19 166/12 sister [2] 45/17 74/23 site [2] 88/14 118/24 situation [1] 71/15 six [7] 30/23 86/4 92/20 100/1 105/8 127/20 163/18 six months [1] 30/23 sixth [1] 27/11 size [3] 92/2 106/20 162/6 sizes [1] 3/1	skilled [1] 67/25 slight [2] 5/23 113/14 slightly [7] 15/16 31/6 81/3 91/2 93/14 126/23 164/14 small [45] 48/14 74/4 74/5 77/9 89/19 92/1 92/6 92/18 92/22 97/4 97/15 99/13 103/18 104/24 104/24 105/7 106/10 106/15 106/20 110/3 111/25 125/16 126/7 126/21 127/13 138/6 138/18 145/2 145/3 145/6 145/9 150/15 152/6 152/20 156/8 159/20 159/20 160/19 161/14 161/15 163/16 164/2 164/4 164/10 164/12 smaller [6] 33/10 40/22 48/22 76/13 137/6 167/4 Snap [2] 95/6 158/12 snapshot [8] 61/24 73/10 101/5 109/6 120/19 124/12 124/20 134/22 snapshots [1] 75/6 so [151] 2/5 4/6 4/14 4/23 7/8 7/15 7/23 9/8 10/4 11/3 17/20 18/24 20/4 21/10 22/5 22/18 23/8 23/15 30/19 32/17 33/6 37/1 38/20 41/2 42/8 42/18 43/2 43/7 43/10 43/16 43/22 45/2 45/19 54/2 54/18 56/3 56/10 56/21 59/4 59/14 61/21 63/12 63/21 64/2 64/17 66/12 66/14 67/14 68/21 69/6 72/19 73/7 75/6 76/19 77/2 77/17 78/9 79/9 81/7 82/21 83/21 84/25 85/8 85/19 86/18 88/5 90/2 90/11 92/6 93/18 94/4 95/11 95/16 96/8 98/22 98/24 99/23 100/15 100/21 100/23 101/2 103/1 104/2 105/6 105/18 106/18 108/4 109/6 110/3 110/17 111/4 111/24 112/3 113/9 113/16 114/9 114/19 114/20 115/17 116/1 116/18 116/22 117/19 118/11 119/19 119/21 120/18 120/22 121/17 122/20 124/4	124/20 124/25 126/4 126/13 130/13 131/21 131/25 133/25 135/7 135/10 135/12 136/4 137/22 138/2 139/1 139/5 140/2 143/2 144/11 144/21 145/12 145/20 145/21 147/1 147/5 147/16 148/8 152/1 152/15 152/21 152/25 154/13 158/19 158/22 160/5 161/20 162/11 163/11 164/15 166/14 Social [1] 60/9 Society [1] 72/5 sold [1] 20/16 sole [1] 82/6 solid [1] 20/19 solvent [1] 2/15 some [82] 2/20 2/24 3/2 3/2 15/25 24/10 28/2 28/8 29/5 29/23 32/21 39/4 40/14 42/3 42/18 42/20 44/16 45/15 48/24 49/7 53/22 58/1 59/19 63/7 65/13 69/25 70/1 76/22 77/8 77/21 79/7 81/24 83/8 86/24 87/22 87/24 90/20 93/7 93/8 96/4 102/18 102/18 103/11 104/18 105/12 105/13 110/3 111/24 112/6 113/6 118/10 120/14 121/3 125/20 127/2 127/22 128/24 129/24 130/1 130/7 134/17 134/18 135/18 135/18 136/3 136/5 136/14 137/18 140/3 142/18 144/10 144/10 144/23 145/5 145/8 145/9 146/1 147/19 157/11 157/22 160/9 166/6 some of [2] 29/23 136/5 somebody [3] 96/11 123/7 140/21 someone [1] 81/20 someone's [1] 113/20 something [8] 18/10 24/21 49/5 52/25 55/24 118/17 143/18 147/11 sometimes [2] 149/4 150/24 somewhat [1] 157/7 somewhere [1] 38/12 son [2] 155/17 156/22 son's [2] 156/20	157/4 sons [1] 89/25 soon [1] 87/1 sorry [18] 3/21 9/21 51/3 55/25 65/17 77/24 100/6 101/21 103/11 107/14 118/5 123/1 124/14 124/19 146/7 148/20 161/3 163/9 sought [1] 158/16 Soumik [15] 4/14 5/4 16/21 39/1 44/18 52/8 53/13 56/2 58/4 65/17 98/19 108/21 112/22 124/19 146/8 source [7] 15/20 31/14 32/12 32/13 49/22 108/5 145/25 sources [7] 2/23 3/4 11/7 12/12 31/10 32/18 59/15 south [10] 41/15 41/15 68/18 68/24 69/7 100/18 100/23 166/19 166/20 166/20 south-east [1] 68/18 south-eastern [1] 69/7 south-west [2] 166/19 166/20 south/south-west [1] 41/15 Southampton [1] 41/12 Spain [2] 16/5 16/12 speaking [3] 38/8 78/17 103/5 special [4] 61/15 61/17 66/8 70/22 specialist [1] 88/9 specialists [4] 88/1 88/4 88/5 88/6 specific [9] 36/19 51/5 54/25 61/20 70/25 95/1 95/2 149/12 160/16 specifically [8] 12/14 23/23 29/22 45/13 51/21 53/20 99/16 140/10 specifications [1] 34/24 specificity [7] 6/3 6/19 6/23 7/1 7/6 7/16 7/20 speckled [1] 5/1 speech [4] 14/14 14/21 14/24 23/18 spike [1] 5/18 spikes [1] 5/6 split [2] 4/22 68/19	spokesman [1] 119/9 Spooner [1] 120/10 St [28] 41/7 41/22 62/14 63/10 66/4 91/7 91/10 98/1 106/22 107/18 107/24 108/1 108/8 108/9 108/19 109/2 109/11 109/13 109/18 110/9 111/18 112/4 113/18 118/15 120/3 120/17 120/20 124/15 St Mary's [21] 41/7 106/22 107/18 107/24 108/1 108/8 108/9 108/19 109/2 109/11 109/13 109/18 110/9 111/18 112/4 113/18 118/15 120/3 120/17 120/20 124/15 St Thomas's [1] 98/1 stabilised [4] 5/11 6/8 6/15 10/13 stabilising [1] 9/17 staff [11] 46/7 46/22 47/6 47/7 47/13 67/23 68/2 133/17 151/12 151/16 151/18 staffing [1] 99/10 stage [6] 2/4 2/16 27/16 50/18 96/4 157/12 staggering [1] 114/17 standard [2] 56/8 60/4 start [4] 4/14 43/25 57/4 109/3 started [1] 141/2 starting [3] 4/20 40/18 136/24 state [2] 56/18 96/14 stated [7] 2/10 14/2 22/14 22/21 23/15 30/22 64/13 statement [51] 3/19 44/9 44/12 44/16 44/19 53/14 57/14 57/19 57/22 58/2 85/21 87/2 89/6 91/12 94/18 121/6 121/6 128/24 130/3 130/6 131/3 132/14 132/19 132/21 132/23 132/25 133/2 133/18 139/10 140/8 140/24 141/1 142/1 142/18 149/12 149/13 150/20 150/25 153/4 153/7 153/11 153/15 154/11 154/17 154/20 155/16 156/14 156/23 157/3 157/14 158/3 statements [7] 83/2	83/6 84/19 87/23 136/12 150/18 157/8 states [15] 1/21 12/21 12/22 14/5 14/7 14/25 15/18 15/24 16/10 21/22 22/10 23/21 28/9 33/16 117/15 statistical [1] 8/16 status [3] 71/18 152/1 159/2 stead [1] 73/2 steady [1] 155/7 stem [1] 39/8 steps [4] 8/16 8/23 29/18 33/21 Stewart [4] 143/13 144/9 149/1 149/4 STHB0000220 [1] 39/23 Sticking [1] 111/1 still [15] 31/16 77/3 77/17 78/12 79/15 80/10 92/20 112/7 115/2 137/15 137/20 138/13 145/8 145/24 147/6 Stoke [1] 42/1 stop [2] 18/10 18/14 storage [1] 58/25 stored [6] 58/13 86/6 120/7 131/16 133/9 141/12 story [1] 6/11 straightforward [2] 49/12 80/2 street [57] 17/8 25/16 41/6 57/4 57/6 57/16 57/24 58/2 58/4 58/6 58/9 59/6 59/10 59/12 59/20 59/23 59/23 63/8 63/10 63/12 63/21 64/7 65/5 65/8 66/7 66/22 68/25 69/14 70/19 70/25 72/21 73/6 73/17 74/20 82/18 82/21 83/4 83/5 83/20 84/2 84/24 85/4 85/22 86/1 86/15 87/12 87/15 87/17 87/21 88/3 88/10 88/14 88/18 90/12 99/19 109/15 121/14 stress [1] 31/13 stressed [1] 65/19 stretch [1] 80/11 structural [1] 58/20 structured [1] 133/21 subject [5] 2/20 16/13 35/7 47/9 165/21 submission [2] 51/15 52/23
--	--	--	---	--	--

(64) sick... - submission

<p>S</p> <p>submit [1] 15/7</p> <p>subsequent [1] 5/23</p> <p>subsequently [2] 50/6 150/19</p> <p>subsidise [1] 16/5</p> <p>subsidised [1] 15/23</p> <p>substantial [4] 5/21 127/12 127/15 128/10</p> <p>Substitution [1] 139/23</p> <p>succeeded [3] 57/11 99/1 107/16</p> <p>such [15] 13/14 22/3 23/1 27/13 38/2 44/14 48/20 53/3 53/5 90/6 117/21 117/23 121/16 149/23 163/2</p> <p>suffered [1] 67/20</p> <p>suffering [1] 60/13</p> <p>sufficient [1] 73/19</p> <p>suggest [13] 1/9 2/19 8/23 51/14 80/17 82/3 100/1 109/7 134/17 135/24 136/7 162/19 164/9</p> <p>suggested [7] 24/16 54/4 56/6 67/24 75/19 82/12 159/10</p> <p>suggesting [3] 23/11 25/5 93/21</p> <p>suggestion [2] 7/23 15/17</p> <p>suggestions [1] 156/17</p> <p>suggests [15] 1/15 1/18 86/14 86/15 89/22 92/2 120/5 131/13 140/3 141/23 142/2 155/11 160/21 162/17 165/11</p> <p>suitable [2] 49/7 94/19</p> <p>summarily [1] 10/20</p> <p>summarise [1] 92/8</p> <p>summarised [4] 72/13 83/8 103/7 110/23</p> <p>summary [1] 163/23</p> <p>summer [7] 30/22 44/3 44/15 54/3 55/21 57/21 157/15</p> <p>supervision [1] 63/14</p> <p>supplementing [1] 75/10</p> <p>supplied [12] 47/18 49/20 76/12 77/12 95/8 98/22 100/23 102/1 133/25 143/22 159/10 163/2</p> <p>supplies [11] 51/2 52/16 53/21 65/24</p> <p>75/3 128/11 133/16 134/18 139/10 139/21 152/4</p> <p>supply [22] 15/11 15/12 37/14 48/10 49/22 71/9 73/8 73/15 74/21 75/10 102/3 117/25 122/1 122/19 122/24 124/3 135/21 139/24 147/10 155/7 157/24 160/15</p> <p>supplying [1] 36/11</p> <p>support [2] 88/6 148/16</p> <p>supra [4] 68/18 69/7 71/15 71/21</p> <p>supra-region [2] 68/18 69/7</p> <p>supra-regional [1] 71/21</p> <p>sure [6] 45/18 52/1 74/14 82/1 83/25 115/16</p> <p>surface [12] 3/8 3/18 7/13 8/10 8/20 9/24 10/6 10/8 20/11 22/1 22/24 23/5</p> <p>surgery [5] 49/19 54/14 55/1 67/19 68/4</p> <p>surgical [3] 61/11 109/23 124/24</p> <p>surprise [2] 74/14 74/19</p> <p>surprising [1] 130/13</p> <p>survey [1] 101/16</p> <p>susceptible [1] 156/18</p> <p>suspect [3] 7/10 35/1 56/4</p> <p>suspected [1] 29/10</p> <p>suspended [2] 22/22 23/16</p> <p>swension [1] 1/14</p> <p>Sweden [2] 16/4 16/12</p> <p>switch [2] 76/3 136/19</p> <p>symptomatic [1] 29/10</p> <p>syringe [1] 76/10</p> <p>system [6] 14/22 14/23 25/6 50/18 51/10 71/5</p> <p>systematic [1] 142/14</p> <p>systematically [1] 142/13</p> <hr/> <p>T</p> <p>table [9] 32/13 63/9 79/6 86/10 86/12 86/14 97/20 98/16 98/20</p> <p>tail [1] 80/19</p> <p>take [20] 8/4 9/20 11/21 13/14 27/16 30/7 33/21 34/17 35/18 63/24 68/10 68/12 83/1 92/7 98/9 112/5 119/23 124/19 143/6 163/22</p> <p>taken [11] 8/23 29/19 35/16 63/2 65/22 67/16 84/5 124/2 141/6 160/20 162/5</p> <p>taking [2] 37/10 53/3</p> <p>talk [5] 14/14 14/16 45/12 46/4 63/4</p> <p>talking [1] 113/18</p> <p>talks [5] 14/21 119/25 140/8 140/15 157/18</p> <p>targeted [2] 19/20 23/9</p> <p>targeting [1] 25/2</p> <p>Taunton [1] 41/18</p> <p>team [2] 45/12 46/3</p> <p>teams [1] 88/12</p> <p>technique [2] 5/14 5/21</p> <p>techniques [1] 23/13</p> <p>Tedder [2] 143/16 149/4</p> <p>Tedder's [2] 131/5 143/17</p> <p>teens [1] 87/11</p> <p>telephone [2] 87/9 91/25</p> <p>tell [6] 31/2 81/13 92/8 111/11 124/17 142/6</p> <p>telling [1] 166/3</p> <p>tells [2] 109/18 159/22</p> <p>temperature [2] 6/2 29/9</p> <p>ten [4] 143/7 143/7 166/18 166/21</p> <p>Ten o'clock [2] 166/18 166/21</p> <p>tend [1] 33/13</p> <p>tens [1] 114/15</p> <p>tense [2] 28/13 29/2</p> <p>tentative [2] 13/4 13/11</p> <p>tenuous [1] 55/9</p> <p>term [2] 7/4 122/21</p> <p>terms [83] 3/4 3/7 35/16 42/6 43/3 44/7 54/17 57/8 58/3 58/11 63/22 67/11 70/3 73/11 74/21 75/9 79/3 80/3 80/16 85/15 85/25 87/20 90/5 91/22 93/1 94/10 96/13 97/12 97/22 99/10 99/15 99/23</p> <p>99/24 101/3 102/24 103/3 103/17 105/15 106/23 107/24 109/7 109/9 110/22 111/2 112/14 113/25 115/13 115/24 120/2 125/12 128/1 129/13 131/23 132/3 133/4 135/21 135/22 136/21 140/18 141/8 142/1 142/20 144/8 144/13 144/20 147/20 150/1 150/11 150/11 150/15 151/8 152/5 152/12 153/3 154/14 158/5 159/13 159/21 159/23 160/1 160/24 163/13 164/13</p> <p>territorial [1] 123/5</p> <p>test [37] 4/4 4/5 4/6 4/6 4/8 4/23 4/25 5/1 5/13 5/25 6/1 6/3 6/4 6/9 6/12 6/13 7/13 7/14 8/5 10/4 10/9 18/20 19/7 87/5 87/7 97/11 106/16 120/7 130/16 131/10 141/11 141/20 142/12 157/4 158/7 159/5 162/20</p> <p>tested [11] 10/22 85/12 97/6 97/14 141/10 141/18 142/10 142/15 150/7 162/19 165/11</p> <p>testing [29] 3/2 3/7 3/13 5/10 8/8 9/10 9/15 19/11 85/6 86/15 87/1 97/4 97/13 106/12 106/15 120/5 120/7 131/1 131/3 131/16 131/17 131/23 141/8 142/4 143/18 150/1 158/5 159/11 159/14</p> <p>tests [5] 3/15 4/11 4/23 56/16 87/2</p> <p>Texas [1] 19/15</p> <p>text [1] 109/15</p> <p>textbook [1] 107/1</p> <p>Thames [17] 68/21 68/22 68/24 69/1 69/16 70/13 91/1 99/22 100/17 108/12 108/17 121/17 122/5 122/15 133/24 143/22 160/5</p> <p>Thames' [1] 122/9</p> <p>than [29] 7/14 7/16 16/10 16/11 21/5 33/14 38/1 43/7 45/25 48/9 51/18 53/1 57/16 65/11 72/17 76/10 76/15 76/17 77/20</p> <p>78/6 82/20 87/8 113/2 114/16 114/17 125/10 134/20 136/4 160/16</p> <p>thank [11] 5/3 9/7 10/1 27/17 37/16 39/1 40/13 53/14 68/12 82/25 107/15</p> <p>that [578]</p> <p>that I [9] 35/18 37/12 37/17 45/19 45/19 52/1 119/7 154/24 156/7</p> <p>that is [15] 5/17 7/10 11/21 13/18 27/22 29/16 31/1 33/25 38/5 54/2 56/25 109/18 128/5 131/15 159/19</p> <p>that retrospective [1] 8/23</p> <p>That was [1] 32/24</p> <p>that's [50] 2/5 2/12 22/18 25/8 33/6 41/12 45/2 51/19 59/4 64/17 66/24 70/24 84/7 84/16 88/17 98/3 98/4 99/24 101/2 103/1 103/14 105/11 106/2 109/21 109/25 111/6 112/3 114/4 114/11 115/16 115/17 117/6 119/6 120/18 121/17 124/14 124/15 124/25 129/12 134/15 143/2 143/5 145/20 147/1 152/7 152/15 158/19 158/21 158/23 162/4</p> <p>their [46] 20/4 20/16 20/19 25/3 31/12 46/7 46/8 46/19 47/13 49/6 54/9 54/13 54/20 55/10 55/11 56/13 56/16 72/10 72/14 74/17 84/19 84/20 84/21 85/7 85/13 85/14 85/18 86/20 87/11 87/14 87/17 87/23 97/6 97/19 97/20 97/25 106/18 131/10 136/14 139/15 141/11 153/20 154/3 154/4 155/4 159/2</p> <p>them [21] 36/9 36/12 41/2 54/14 71/21 76/20 76/22 77/13 85/7 90/22 129/23 133/5 136/15 136/16 136/24 138/24 153/14 153/18 153/20 154/24 166/14</p> <p>theme [2] 75/7 75/9</p> <p>themes [1] 136/17</p> <p>themselves [4] 30/25</p> <p>43/5 43/23 144/19</p> <p>then [183]</p> <p>theoretical [1] 48/2</p> <p>therapeutic [9] 4/2 10/16 10/22 11/1 21/24 65/20 67/21 67/24 133/16</p> <p>Therapeutics [2] 3/11 20/23</p> <p>therapies [1] 140/12</p> <p>therapy [6] 76/9 77/14 95/13 109/3 109/8 134/15</p> <p>there [186]</p> <p>there's [30] 70/12 71/11 72/22 78/21 78/21 82/21 83/12 85/5 93/25 100/14 105/17 112/5 113/14 116/4 123/25 126/8 127/25 128/2 129/14 145/2 148/2 148/5 148/7 152/23 155/15 158/19 161/19 162/18 165/1 165/13</p> <p>thereabouts [1] 106/25</p> <p>thereafter [1] 9/1</p> <p>therefore [16] 6/15 11/18 23/4 48/19 50/16 51/1 60/22 61/24 67/22 71/7 85/13 92/7 97/17 128/16 154/5 162/8</p> <p>these [25] 4/10 10/18 10/19 24/8 39/3 50/16 53/23 67/4 68/3 69/25 74/3 74/7 74/8 77/25 81/12 90/11 91/12 104/23 116/11 117/14 122/10 123/6 123/6 144/2 151/18</p> <p>they [65] 8/16 11/23 13/15 13/21 13/22 21/1 24/15 27/9 29/24 29/25 30/16 31/12 35/21 36/6 36/7 36/12 46/10 46/13 46/14 50/12 50/16 53/18 58/12 61/21 62/19 69/11 71/22 72/15 78/2 81/13 82/19 84/24 85/12 85/16 85/17 85/19 87/6 87/18 90/18 90/19 92/8 103/7 109/3 109/4 111/2 111/11 112/25 113/11 113/23 113/25 115/14 117/16 123/20 123/21 123/23 124/5 129/9 136/21 141/18 155/4 156/25</p>

T	114/16 threat [4] 28/5 29/20 82/12 155/6 three [17] 30/9 30/19 32/18 69/10 78/7 89/11 95/9 95/12 99/12 102/11 115/19 120/5 125/17 131/17 158/7 158/14 166/12 Thrombosis [1] 148/1 through [36] 1/13 1/22 2/24 5/4 9/12 9/13 9/13 13/5 13/22 34/18 36/13 48/2 48/5 50/23 55/18 57/9 57/10 62/7 68/13 68/14 69/9 71/23 76/20 77/11 78/14 92/7 103/4 103/6 107/18 110/24 114/14 116/25 119/10 124/6 136/17 144/15 throughout [2] 116/4 149/2 Thus [2] 10/21 11/9 ticks [1] 78/4 time [86] 1/10 1/18 3/22 4/3 6/5 6/15 8/5 8/7 8/17 13/15 13/24 15/18 17/24 17/25 23/20 26/13 31/3 31/20 34/1 35/11 35/20 36/4 37/15 40/4 40/16 41/10 42/12 43/2 44/11 45/8 45/22 46/12 46/16 46/21 48/12 49/1 50/1 50/13 52/3 53/19 53/22 56/9 58/2 58/25 59/17 62/14 64/25 66/5 68/1 68/10 72/1 75/7 77/14 78/10 78/13 83/1 85/17 85/22 87/15 90/24 95/12 96/4 99/8 101/10 104/6 106/1 106/1 110/7 119/2 128/15 129/1 129/11 129/11 129/19 129/19 130/7 131/8 131/20 141/3 141/7 141/9 142/25 148/10 154/8 158/8 166/12 times [3] 32/4 33/14 58/21 title [1] 12/19 to [924] today [3] 18/25 40/25 41/5 together [3] 26/18 52/19 59/14 told [12] 20/17 54/20 56/24 85/15 91/20	91/21 127/19 131/10 141/17 154/24 156/3 156/20 tomorrow [4] 40/25 41/14 166/15 166/18 too [1] 112/12 took [11] 8/16 44/23 47/11 99/3 129/18 129/20 133/1 134/9 143/14 149/23 151/4 top [8] 15/5 17/25 55/22 101/21 113/17 113/20 125/4 148/8 topic [2] 118/6 156/16 total [10] 30/17 33/19 70/8 76/24 80/21 81/21 82/13 93/4 113/12 114/10 Tovey [1] 119/9 towards [8] 39/25 66/18 72/19 80/19 100/13 122/3 128/1 154/19 traced [1] 115/1 tracks [1] 18/15 transcript [14] 57/17 72/25 91/24 101/9 107/7 108/22 109/25 124/10 124/17 128/23 134/25 135/1 151/1 166/5 transferred [7] 61/15 87/11 87/16 87/19 91/9 98/1 155/21 transfusion [38] 49/21 68/7 69/6 69/9 69/10 70/7 72/5 91/5 99/13 100/10 100/18 100/24 107/1 108/15 108/25 117/6 117/22 119/10 119/18 121/21 122/1 122/7 122/23 123/4 130/13 132/18 133/8 133/10 134/1 134/8 139/12 139/15 143/23 160/7 160/10 163/3 165/17 166/8 transfusions [1] 107/4 Transition [1] 5/12 translate [1] 80/7 transmission [3] 48/1 136/19 141/4 transmitted [4] 48/5 96/17 96/22 130/12 transmitting [1] 117/17 travelling [1] 148/3 treat [17] 12/9 45/24 46/24 48/23 73/20 74/12 74/15 76/7 94/11 102/8 104/16	110/11 119/5 119/12 144/6 155/9 164/8 treated [116] 1/12 1/17 1/19 1/25 2/3 2/8 2/12 2/15 49/4 53/15 53/18 53/21 53/23 54/5 54/23 56/10 63/15 63/18 64/1 64/2 64/3 64/4 70/10 73/9 74/6 75/2 76/21 76/25 77/10 80/18 81/15 83/3 83/5 88/20 89/23 89/25 91/15 92/3 92/5 92/16 92/21 93/5 94/7 94/9 95/7 97/16 99/15 101/3 103/4 103/10 103/12 105/9 105/12 111/3 111/8 111/19 112/23 113/19 113/25 114/13 115/6 115/19 120/2 125/7 125/12 125/17 125/25 127/7 127/9 127/20 128/4 128/13 133/7 135/13 135/23 135/25 136/9 136/10 136/13 137/1 137/2 138/3 140/12 141/16 141/25 144/13 145/15 146/9 148/9 149/7 149/8 150/5 150/6 150/16 152/9 153/22 154/13 154/16 154/17 154/24 155/13 155/17 155/19 156/11 158/9 158/13 158/15 159/8 160/23 161/20 162/7 163/14 163/17 163/19 163/21 164/3 treating [6] 53/10 53/10 53/11 68/3 74/3 89/20 treatment [130] 35/8 42/8 44/6 46/12 46/22 47/2 48/7 49/1 49/2 49/10 49/17 49/18 51/17 51/18 51/24 52/2 52/12 52/14 52/21 53/4 53/8 54/20 55/10 55/15 55/16 55/20 55/24 56/5 56/8 56/8 58/16 58/17 61/4 61/8 61/16 61/17 63/2 65/8 65/20 67/1 67/16 68/1 70/21 71/2 73/24 75/16 78/2 79/8 79/10 79/11 79/17 80/15 80/25 86/20 87/14 90/3 91/19 92/10 92/19 93/15 93/19 93/21 93/23 94/20 95/2 95/3 95/11 97/10 97/20 97/25 101/24	102/13 103/17 103/19 103/21 103/22 103/25 104/1 104/11 105/5 105/9 106/18 109/21 110/14 111/10 112/17 112/18 115/20 123/21 125/9 125/21 126/3 126/18 127/13 128/5 131/24 133/16 138/11 140/5 140/7 140/9 142/21 144/22 145/1 145/25 146/5 146/15 147/4 150/12 153/3 154/19 154/21 155/2 155/4 155/12 155/13 155/24 156/4 156/20 156/24 159/16 161/7 161/11 161/21 161/22 162/2 162/5 164/11 164/18 164/21 treatments [3] 63/18 64/12 65/11 treatments: [1] 63/16 treatments: 396 [1] 63/16 trends [3] 107/21 119/6 119/7 trial [1] 74/7 tried [2] 47/23 142/9 true [2] 15/9 106/2 Truro [1] 41/12 Trust [1] 59/7 try [3] 54/14 124/16 128/15 trying [3] 26/18 78/11 158/8 turn [20] 8/5 8/7 15/15 16/13 21/15 40/14 57/3 62/2 67/17 83/10 88/24 98/14 98/24 106/22 108/21 109/11 120/21 143/11 150/14 159/25 turn-around [2] 8/5 8/7 turnaround [1] 9/3 turning [4] 1/6 2/23 14/13 27/18 turns [1] 55/17 twelve [1] 111/4 twice [1] 8/9 two [36] 9/4 17/8 24/21 26/9 41/10 44/4 52/22 64/3 64/4 64/4 71/11 80/21 81/9 86/16 89/14 92/10 97/8 97/23 99/12 99/14 100/21 103/12 109/3 109/22 114/5 120/8 136/3 144/16 146/10 150/18 152/19 154/12 160/22 162/19	163/14 164/8 two paragraphs [1] 71/11 two years [1] 152/19 two-thirds [1] 9/4 type [2] 78/11 138/25 types [1] 78/7 typographical [1] 16/8
U					
	UCH [20] 41/7 120/22 120/24 121/3 121/4 121/8 121/12 121/13 121/14 122/13 123/19 124/4 125/3 125/13 128/25 131/4 131/9 131/12 131/24 132/1 UCSF0000058 [2] 16/20 24/22 UK [11] 12/9 14/1 16/3 16/4 16/9 37/22 39/24 117/12 119/5 140/15 154/6 UK market [1] 37/22 UKHCDO [38] 39/25 52/25 83/16 83/23 86/9 95/23 96/2 96/5 96/11 97/21 98/20 98/21 98/22 105/20 105/22 106/11 115/25 116/1 116/6 117/20 120/4 129/16 129/21 130/19 131/12 140/21 141/21 142/17 149/1 149/25 156/10 157/2 159/9 162/11 162/17 165/2 165/4 165/10 ultimate [1] 34/14 ultimately [2] 21/8 39/10 umbrella [2] 89/12 89/14 unable [3] 46/14 58/13 159/17 uncertain [1] 155/5 uncommon [1] 155/3 uncontroversially [1] 44/8 uncover [1] 43/9 undated [1] 39/18 under [22] 50/24 63/14 64/6 65/16 89/12 89/14 90/15 92/24 93/18 93/22 97/9 97/16 99/8 126/10 137/11 137/13 138/19 142/16 147/7 147/16 164/16 164/22 undergo [1] 54/13 undergone [1] 58/20 underlined [1] 28/22				

(66) they... - underlined

<p>U</p> <p>underlying [2] 90/24 101/4</p> <p>understand [15] 4/3 6/17 6/22 7/2 16/23 17/23 24/24 31/19 33/12 38/6 41/3 65/1 67/9 99/4 100/16</p> <p>understanding [9] 20/5 42/22 75/15 85/1 85/18 87/4 130/4 130/17 140/25</p> <p>understood [2] 52/4 154/4</p> <p>undertake [2] 42/5 68/5</p> <p>undertaken [10] 59/11 60/19 61/12 85/19 86/8 101/16 109/24 124/24 130/2 159/15</p> <p>undoubtedly [1] 75/24</p> <p>unearthed [1] 165/14</p> <p>unexposed [2] 52/15 53/11</p> <p>Unhappily [1] 156/10</p> <p>unhappy [1] 153/23</p> <p>unheated [2] 54/5 128/16</p> <p>unidentified [2] 6/5 9/24</p> <p>unique [1] 71/15</p> <p>unit [5] 46/11 50/23 118/23 119/17 146/4</p> <p>United [12] 12/21 14/5 14/7 14/25 15/18 15/24 16/10 23/21 31/18 39/6 92/5 117/15</p> <p>United Kingdom [3] 31/18 39/6 92/5</p> <p>United States [7] 12/21 14/5 14/7 14/25 15/24 16/10 117/15</p> <p>units [50] 72/17 72/18 77/4 79/10 79/11 80/8 80/24 92/21 92/25 94/2 102/3 104/5 111/22 112/1 112/2 119/19 126/10 126/10 126/15 126/15 126/17 126/24 128/9 137/4 137/11 137/13 137/16 137/18 137/22 137/23 137/24 138/9 138/10 145/18 145/19 145/19 145/22 146/15 146/23 146/23 146/24 146/25 147/6 147/8 152/22 152/24 155/8 164/15</p>	<p>164/17 164/22</p> <p>University [5] 120/22 122/14 123/8 123/15 125/5</p> <p>unless [2] 37/24 46/24</p> <p>unlike [1] 87/4</p> <p>unlimited [1] 157/25</p> <p>unnecessary [1] 54/14</p> <p>unsurprising [1] 106/20</p> <p>until [21] 8/5 8/19 21/24 22/5 22/22 35/13 89/10 90/2 98/10 105/7 106/25 118/21 139/22 143/7 143/13 153/9 153/22 154/6 157/12 160/2 166/23</p> <p>unusual [1] 139/23</p> <p>unusually [1] 155/1</p> <p>up [61] 4/1 4/20 4/22 8/18 10/5 25/14 39/4 41/14 44/25 47/23 52/8 55/23 63/7 64/6 65/4 66/1 66/9 66/18 69/20 70/2 70/18 73/7 74/2 74/9 75/12 77/15 79/3 83/22 90/9 90/13 93/2 93/13 96/14 98/7 98/19 100/21 103/9 108/4 108/21 111/6 112/20 117/3 117/24 121/6 122/3 123/9 125/18 125/19 126/23 127/5 136/1 138/1 138/12 141/2 142/16 146/6 147/3 147/16 150/21 152/8 166/15</p> <p>update [2] 41/4 44/1</p> <p>upon [6] 45/16 86/17 94/21 131/22 140/19 148/24</p> <p>us [33] 11/15 12/12 13/15 15/3 15/20 15/20 16/3 16/6 16/9 17/6 17/8 17/11 28/15 28/16 29/5 31/2 31/19 38/7 50/21 53/24 54/1 81/13 82/8 92/9 109/6 109/19 111/11 119/12 130/20 155/5 155/23 156/4 159/22</p> <p>US volunteer [1] 11/15</p> <p>usage [43] 42/7 48/15 73/5 75/23 76/21 77/4 77/8 77/17 79/6 79/7 80/10 81/8 81/21 82/6 91/22 94/2 104/8 110/20 111/12 111/21</p>	<p>112/7 114/13 115/4 119/7 126/12 126/16 126/22 126/23 127/12 128/17 136/22 137/21 138/21 147/2 147/6 147/7 147/19 152/12 160/17 161/6 163/12 163/22 164/13</p> <p>use [85] 1/13 8/5 11/25 13/2 18/13 20/13 20/16 22/23 23/14 27/6 27/9 29/17 47/1 47/7 47/8 48/12 48/13 48/20 49/24 54/16 67/17 72/20 74/16 74/17 75/10 76/4 76/5 76/15 78/18 78/19 78/22 79/14 80/15 81/16 84/14 84/16 92/20 93/6 93/7 93/8 102/13 104/3 104/4 104/20 111/14 111/22 112/3 112/6 112/7 112/9 113/22 114/2 115/10 117/13 126/2 126/6 127/9 127/15 127/22 127/24 128/4 128/8 128/15 129/5 134/15 135/14 137/3 137/7 137/9 137/21 138/6 138/8 138/13 139/7 140/6 140/16 144/20 146/19 147/18 152/21 153/13 155/22 157/22 161/13 161/15</p> <p>used [129] 1/11 1/16 2/11 7/5 7/9 7/20 10/18 12/5 12/6 12/9 14/3 16/18 22/3 22/15 23/2 23/10 23/11 24/5 24/12 26/25 27/13 28/13 29/2 30/12 31/16 31/17 35/6 35/19 36/2 36/20 36/25 37/3 37/20 38/1 38/24 42/22 48/21 48/23 49/12 50/15 53/18 71/6 77/2 77/6 77/17 77/19 79/16 79/19 80/13 80/18 80/22 80/24 92/14 92/19 92/22 92/24 93/18 94/5 94/22</p> <p>103/17 103/19 103/25 104/10 104/16 104/18 105/3 105/4 111/15 111/24 112/14 112/15 112/15 112/16 112/17 113/2 118/15 126/4 126/9 126/14 126/15 126/20 126/25 126/25</p>	<p>127/10 128/25 129/7 130/24 137/3 137/7 137/13 137/13 137/15 137/17 137/18 137/19 137/23 138/7 138/19 138/19 138/20 144/22 144/25 145/3 145/4 146/3 146/5 146/14 146/17 146/21 146/24 147/16 148/15 152/23 153/10 154/7 160/25 161/4 161/10 161/24 162/8 164/2 164/4 164/9 164/10 164/15 164/17 164/20 164/23 164/25</p> <p>using [13] 1/25 7/8 19/20 21/25 22/18 29/14 49/3 71/2 114/9 117/15 131/4 153/23 154/25</p> <p>usual [2] 105/4 145/21</p> <p>usually [6] 55/12 103/12 121/9 123/7 125/16 142/6</p> <p>utilize [1] 23/4</p>	<p>view [6] 47/11 48/3 66/8 66/19 94/18 140/14</p> <p>viewed [1] 48/12</p> <p>VIII [76] 1/13 1/25 12/9 16/19 19/21 23/15 27/7 31/16 31/17 37/21 47/12 49/16 50/6 50/8 50/15 50/19 51/6 51/8 52/5 56/5 56/7 68/5 69/5 70/3 73/16 73/24 74/5 76/3 76/12 77/5 77/19 91/19 91/21 95/10 100/2 101/24 102/1 104/10 104/19 104/21 105/2 105/10 105/13 108/13 112/10 112/15 112/19 115/11 118/18 118/21 119/4 119/20 120/14 122/17 127/3 127/24 134/5 136/20 139/21 139/24 143/25 147/17 147/18 154/22 154/25 155/21 155/22 156/2 156/24 161/2 161/4 161/6 161/16 161/23 163/7 164/7</p> <p>viral [4] 2/25 23/13 84/13 136/19</p> <p>virology [1] 141/12</p> <p>virus [4] 56/19 130/11 130/15 142/12</p> <p>viruses [1] 156/1</p> <p>visible [1] 5/17</p> <p>visitor [1] 92/5</p> <p>visits [1] 156/5</p> <p>vitro [1] 22/17</p> <p>volume [15] 3/11 32/21 44/13 76/14 77/18 79/1 79/17 80/16 93/17 112/1 113/25 126/8 126/14 138/7 164/14</p> <p>volume 2 [1] 3/11</p> <p>volumes [5] 81/13 104/23 105/7 137/6 164/2</p> <p>voluntarily [4] 15/2 21/1 22/22 30/24</p> <p>voluntary [4] 12/7 19/19 20/19 21/11</p> <p>volunteer [7] 10/15 11/5 11/13 11/14 11/15 14/22 15/10</p> <p>von [28] 64/3 80/2 92/4 103/13 103/22 104/14 104/16 105/12 111/8 112/18 112/24 113/19 120/13 125/20 127/8 127/11 127/21 129/4 136/1 138/4</p>	<p>144/17 145/15 146/10 152/10 153/25 160/22 163/19 164/18</p> <p>von Willebrand's [28] 64/3 80/2 92/4 103/13 103/22 104/14 104/16 105/12 111/8 112/18 112/24 113/19 120/13 125/20 127/8 127/11 127/21 129/4 136/1 138/4 144/17 145/15 146/10 152/10 153/25 160/22 163/19 164/18</p> <p>vs [1] 15/9</p>
W					
<p>wait [1] 90/2</p> <p>want [3] 46/1 66/18 154/24</p> <p>wanted [9] 20/18 44/15 54/13 98/22 109/3 114/20 119/12 123/23 162/23</p> <p>wanting [1] 122/23</p> <p>ward [5] 45/17 46/9 90/2 90/3 90/3</p> <p>warnings [4] 84/13 91/18 136/18 149/9</p> <p>was [360]</p> <p>was also [1] 143/20</p> <p>was made [1] 113/7</p> <p>Washington [1] 20/24</p> <p>wasn't [10] 1/17 26/4 39/10 46/3 90/1 94/19 96/23 97/11 142/6 157/12</p> <p>way [18] 1/12 7/1 9/5 17/8 36/6 36/7 55/3 93/22 128/12 128/19 129/14 133/19 141/20 143/2 163/23 165/1 165/17 166/7</p> <p>we [472]</p> <p>we'll [11] 17/9 18/19 40/25 41/15 60/5 60/6 66/17 71/21 92/8 110/7 136/23</p> <p>we're [6] 7/9 18/23 113/18 127/19 140/19 159/1</p> <p>we've [30] 40/17 52/6 67/6 78/15 80/3 82/4 83/17 95/18 103/6 108/3 108/25 110/23 116/13 116/18 116/18 116/19 116/20 117/1 118/2 123/13 125/25 126/4 128/19 134/8 146/1 146/9 147/16 150/9 162/9 165/13</p> <p>weak [2] 53/1 53/5</p> <p>website [3] 42/12</p>					

W	142/15 143/1 143/13 144/12 144/22 149/7 149/8 150/12 150/18 151/11 151/17 153/12 155/4 156/17 156/17 156/25 157/17 157/21 158/15 160/14 160/25 161/10 161/10 162/17 162/19 162/20 165/3 166/10	whenever [2] 140/12 140/13 where [10] 25/9 31/12 31/19 46/2 51/20 55/1 96/3 99/14 114/14 128/25 whereby [1] 51/11 Wherever [1] 29/11 whether [20] 12/7 13/23 16/17 25/24 26/5 37/19 40/16 55/3 97/13 113/5 113/6 124/2 128/14 128/17 130/23 147/9 147/10 149/23 161/24 162/19 which [124] 1/25 2/16 3/3 3/20 4/4 6/5 7/19 11/1 12/6 12/13 13/17 14/21 14/24 15/17 15/22 16/22 17/23 19/25 20/1 21/18 25/6 28/2 28/24 29/10 33/12 34/16 34/21 35/24 37/9 37/12 38/13 39/20 41/3 41/11 41/21 42/10 42/21 42/23 49/1 49/10 50/1 51/1 51/12 52/12 52/25 54/4 54/21 55/17 55/21 57/2 57/14 59/18 60/19 61/3 65/4 65/22 66/17 67/17 67/20 68/10 70/14 70/15 70/22 72/12 75/8 75/15 75/19 79/25 80/4 80/8 81/23 82/11 83/6 83/18 85/11 86/17 87/18 88/14 89/15 92/1 93/20 98/16 98/18 100/1 101/12 102/6 109/20 113/15 115/6 117/21 120/8 120/9 122/1 122/1 123/25 124/5 124/22 131/12 132/2 133/19 134/9 135/4 135/9 141/20 141/24 145/13 145/23 146/1 146/20 147/14 149/14 152/8 152/19 152/25 153/13 155/13 155/14 158/4 159/10 159/15 160/14 162/12 163/6 166/10 while [5] 23/19 24/9 29/4 38/7 158/10 whilst [3] 50/11 59/25 139/18 who [69] 10/5 10/6 10/7 10/8 11/18 14/11 17/6 21/17 23/9 30/11	30/12 30/15 30/18 33/12 34/11 43/1 43/13 43/22 44/10 45/17 48/18 49/8 54/18 61/7 61/15 62/5 62/11 62/13 68/2 71/12 73/22 73/23 75/1 83/3 83/5 86/1 87/13 89/6 89/25 90/20 91/9 91/17 92/4 94/13 97/8 97/15 99/2 99/5 101/13 105/12 107/17 108/1 120/13 121/4 123/13 129/17 133/1 136/9 141/16 141/25 142/9 142/14 149/7 149/7 150/18 158/21 158/23 165/21 165/25 who's [2] 18/16 132/21 whole [6] 11/5 11/13 12/6 34/18 51/7 122/8 whom [4] 95/9 119/1 158/15 159/3 whose [4] 23/18 54/23 56/23 155/17 why [7] 23/1 34/17 42/24 87/5 119/19 119/21 129/6 Wickramesinghe [1] 107/17 widely [2] 49/18 67/11 widespread [1] 81/16 will [76] 5/4 7/25 10/6 11/22 12/4 13/2 14/1 14/20 18/20 20/20 20/25 21/25 23/4 23/10 28/3 29/12 29/18 31/23 32/1 33/19 34/18 34/21 35/15 38/8 40/6 40/11 40/17 41/3 41/24 42/3 42/8 42/10 42/25 43/2 43/8 43/11 43/14 43/25 44/1 44/3 44/19 45/9 52/10 55/4 59/19 60/11 62/10 62/11 62/19 66/9 66/16 69/25 73/5 74/14 74/18 82/1 82/8 82/9 82/24 86/9 91/24 102/10 107/4 124/16 124/17 138/16 141/14 143/6 143/15 143/18 148/11 153/2 156/7 157/6 158/24 165/18 Willebrand's [28] 64/3 80/2 92/4 103/13 103/22 104/14 104/16 105/12 111/8 112/18 112/24 113/19 120/13	125/20 127/8 127/11 127/21 129/4 136/1 138/4 144/17 145/15 146/10 152/10 153/25 160/22 163/19 164/18 William [1] 116/20 willing [1] 74/7 Winchester [1] 41/18 Winter's [1] 1/24 wish [5] 13/13 55/5 55/8 141/14 158/17 wished [1] 47/8 wishes [1] 43/14 with [234] with me [1] 149/21 within [20] 10/21 14/4 14/7 15/20 34/2 48/11 68/16 68/16 69/7 69/10 69/16 69/22 77/24 99/22 100/16 108/16 123/1 123/2 123/3 143/22 without [6] 68/13 85/13 85/14 97/6 128/20 150/7 WITN [1] 57/22 WITN3497005 [1] 57/18 WITN37089003 [1] 133/3 WITN3774003 [1] 58/5 WITN3779001 [1] 132/24 WITN416001 [1] 121/7 WITN4567001 [1] 132/20 WITN4673001 [1] 150/22 WITN5248001 [1] 151/2 witness [6] 3/19 44/9 53/1 89/25 154/15 157/8 witnesses [1] 142/19 Wolverhampton [1] 42/1 won't [22] 1/22 3/25 14/19 25/9 25/18 30/7 34/17 39/3 43/6 68/10 72/22 76/20 77/11 78/14 92/7 93/11 103/4 112/5 116/25 119/23 121/6 136/16 wonder [1] 40/16 Worcester [1] 42/2 word [3] 7/19 7/20 56/1 words [1] 129/6 work [9] 25/13 26/3 45/3 45/6 60/18 79/22 99/6 118/15 129/1 worked [2] 89/8 96/3	working [7] 61/21 96/23 107/21 118/16 119/1 119/6 141/2 workload [2] 63/9 65/10 World [1] 119/11 worldwide [1] 14/18 worry [1] 55/8 worth [4] 15/8 116/10 118/11 147/22 would [90] 3/3 6/20 7/17 8/21 10/4 14/25 15/8 21/7 33/18 35/12 35/17 36/6 36/7 36/18 37/11 37/23 37/25 45/13 45/24 46/10 46/12 46/17 46/24 47/10 48/8 50/20 52/1 52/12 52/18 52/23 53/9 54/14 54/15 54/18 56/21 60/22 65/24 66/5 68/19 68/22 69/8 69/11 71/6 74/6 74/11 75/1 75/7 76/1 76/11 76/17 80/7 80/14 83/22 86/7 87/6 88/6 91/8 102/13 102/25 105/24 115/2 115/3 119/13 121/9 122/1 129/25 131/10 131/19 132/4 135/14 135/20 142/5 142/22 145/21 146/7 148/11 148/13 148/14 148/15 149/2 149/14 149/19 155/22 156/3 156/4 156/25 159/14 162/14 165/7 165/8 wouldn't [3] 6/20 97/5 115/2 write [1] 5/8 writing [3] 60/17 73/15 128/6 written [16] 3/12 16/2 21/5 34/1 42/9 60/2 80/4 83/9 84/7 87/24 91/17 93/12 103/7 110/23 113/20 158/17 wrong [1] 124/14 wrote [8] 28/16 29/7 34/22 35/25 39/24 158/12 158/23 166/4
				Y	
				year [48] 3/23 9/18 11/4 32/4 33/13 33/14 45/24 57/2 57/13 60/24 61/5 61/13 76/25 77/20 77/22 78/8 78/20 80/19 81/17 92/18 93/3 93/16 93/20 104/15	

<p>Y</p> <p>year... [24] 105/12 109/22 110/24 111/5 111/19 112/17 112/23 113/1 115/6 124/8 124/22 126/1 127/16 135/5 138/3 145/15 148/14 152/9 161/4 161/8 161/18 163/17 164/19 164/21</p> <p>year: [1] 93/5</p> <p>year: 7 [1] 93/5</p> <p>years [21] 4/20 4/22 64/9 64/11 64/12 64/16 65/23 67/2 80/12 80/21 103/11 114/1 114/14 125/20 136/3 145/24 152/12 152/19 152/25 155/19 163/16</p> <p>Yellowlees [1] 64/24</p> <p>yes [48] 7/2 7/20 18/9 25/1 25/15 25/22 26/5 26/9 26/12 26/14 26/14 26/17 36/18 37/5 37/7 37/7 38/11 38/25 42/18 43/12 43/16 43/24 65/18 80/5 80/9 81/6 81/11 82/1 100/6 102/21 107/11 107/12 110/16 113/13 114/7 114/19 115/16 115/23 128/10 128/11 128/14 135/11 135/17 143/6 145/23 146/5 158/11 166/17</p> <p>yesterday [2] 3/1 3/20</p> <p>yet [2] 43/18 119/18</p> <p>yield [1] 76/16</p> <p>York [5] 24/7 24/20 25/25 26/15 41/25</p> <p>you [120] 1/23 4/19 4/22 5/3 7/3 7/23 8/17 9/7 10/1 11/22 11/22 13/9 13/14 14/1 17/3 17/8 17/9 17/12 18/5 18/7 18/7 18/8 18/8 18/10 18/16 18/16 18/19 18/20 18/21 19/6 21/23 22/22 24/21 25/10 25/13 26/19 27/17 28/8 28/19 30/7 34/18 37/8 37/12 37/16 39/1 39/2 40/6 40/13 44/1 44/3 44/19 45/9 46/1 51/15 52/8 52/10 53/14 55/4 56/25 57/12 60/11 60/22 62/10 62/11 66/2 68/12 69/17 73/15 73/17 73/18</p>	<p>74/10 74/11 74/14 75/14 82/10 82/24 82/25 83/7 83/13 84/7 84/22 85/8 85/10 85/21 86/9 89/23 91/20 92/7 99/5 102/8 102/13 102/20 106/4 107/12 107/15 110/11 112/6 113/10 114/6 114/8 114/9 114/20 119/23 122/20 124/17 125/8 135/10 135/14 136/15 141/14 141/15 144/6 146/8 148/14 156/7 156/14 157/6 157/7 158/17 158/24</p> <p>you'd [1] 90/2</p> <p>you'll [11] 43/10 44/22 64/24 78/4 83/24 97/8 101/15 109/14 115/17 115/20 163/5</p> <p>you're [4] 18/5 42/16 138/23 141/15</p> <p>you've [6] 18/3 36/14 80/21 141/17 142/19 149/6</p> <p>young [2] 48/17 88/7</p> <p>your [19] 3/3 13/12 14/20 18/19 18/23 18/24 19/8 24/3 34/21 52/22 60/23 61/1 61/7 61/10 61/12 67/5 102/14 135/15 148/12</p> <p>yourself [1] 114/21</p> <p>Z</p> <p>Zuckerman [2] 116/19 117/4</p>				
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