

Friday, 1 April 2022

(10.00 am)

DR ROBERT PERRY (continued)

Questioned by MS RICHARDS (continued)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Dr Perry, we had started talking yesterday afternoon about product warnings and that's the topic I want to pick up this morning.

A. Okay.

Q. We will see shortly how the terms of the leaflet or insert were submitted with the licence application to the licensing authority. Once the product licence had been granted, and presumably the form of wording approved, was there any system within PFC for reviewing what was said on the labels or the leaflets during the duration of the product licence, or was it a question of, "Well, it has been approved, we have got our product licence, we will look at it again when the licence comes up for renewal"?

A. I can't describe the details of a system but certainly when significant changes to the product specification -- and the best example of that is introduction of heat treatment -- was arrived at, then, yes, the labelling and the leaflet would have been reviewed. In some cases it remained unchanged

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licensing authority that we had done that.

Q. I think you have said in one of your statements to the Penrose Inquiry that the wording that was used in relation to hepatitis was the wording -- I think you used the words "prescribed by the British Pharmacopoeia". We will look in a moment both at the wording used and at the wording in the British Pharmacopoeia.

Was it your understanding that the pharmacopoeia actually prescribed what had to be on the labels or that it laid down a minimum requirement or minimum recommendation?

A. I'm not absolutely clear after the passage of time whether it was a requirement to slavishly adhere to the wording that the pharmacopoeia had used but I think we took the view that the product that we made was presented as human anti-haemophilic factor. BP, then -- which is typical of some pharmaceuticals, you put "BPR", which means it has been made in accordance with the specifications of the pharmacopoeia. I think in that circumstance we fairly consistently applied the wording that had been prescribed by the pharmacopoeia.

I think there was freedom for manufacturers to diverge from that, but it is always a problem with

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but in other cases, modifications would have been brought about, and I believe those modifications would have been notified to the licensing authority.

Q. So would it be right to understand, and I appreciate I'm asking you about events, obviously, a number of years ago, but do you think it is more likely that there wasn't a systematic process for re-examining the contents of the label but an *ad hoc* process, that as and when things came to PFC's attention or changes were made to the products, that the matter would be looked at?

A. I don't think -- I wouldn't describe it as "*ad hoc*". But it was clearly evident, certainly to myself and others, that when significant changes had occurred to the product and, if necessary -- and some review or labelling.

The first example we had of this was when we introduced the first generation heat-treated Factor VIII product, where we really didn't have the opportunity, because we wanted to do it so quickly, to substantially change the wording on the leaflets or the wordings on the label. So what we used in that situation was we simply over-stuck the packaging with notifications that this product had been heat treated and so on. My recollection is that we advised the

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small vials of product, how much wording you can actually put on a label or in a product insert leaflet.

Q. I'm going to ask you to look at the leaflets and some of the information submitted to the licensing authority and also some of the labels. We did look at these with Dr Foster, but I'm conscious that there may be those listening who wouldn't have seen this material, so I'm going to take a little time going through it again Dr Perry.

If we start at PRSE0002726 and if we go over to page 5, I think, Sully. No, I had this last time. Try page 10. I think there are blank pages in the middle. Thank you.

This is the licence application submitted by Mr Watt in March 1978 for PFC's Factor VIII product, is that right?

A. Yes, yes.

Q. If we go to the second page and we look at the bottom half of the page, there's the -- sorry just up a little further, please.

So we have got the:

"Contra-indications.

"Precautions and Warnings."

We see it is written:

4

1 "... no contra-indications. Warnings include
2 storage below 5°C, reconstitution by addition of pyrogen
3 free distilled water, the material should not be infused
4 if a gel forms on solution and should be discarded if it
5 is not used within three hours of preparation of
6 solution. Product may carry the risk of transmitting
7 serum hepatitis."

8 So that is the information in the application
9 form.

10 If we go over to the next page, please, Sully,
11 or, if it is blank, go two pages. Yes, thank you.

12 So we can see this is then, as I understand it,
13 appended to the licence application form and it is
14 PFC's proposed draft package leaflet insert, is that
15 right?

16 **A.** For the 1978 application.

17 **Q.** For the 1978 application, yes.

18 Then if we go on to the next page, please. We
19 can see in the second paragraph, as part of the
20 description, it refers to:

21 "All plasma used for preparation of factor VIII
22 concentrate is derived from blood collected from
23 volunteer donors has been screened for the presence of
24 the HB surface antigen ..."

25 And details given of the test:

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1 **A.** So it was -- my understanding is that this would have
2 been a more -- perhaps a more sensitive assay, using
3 more sophisticated extraction techniques for the
4 product which may have picked up or had the capability
5 of picking up much lower levels of contamination that
6 could be detected by routine assay. That is my
7 understanding, although I don't have on a clear view
8 on it. And I'm not sure what Mr Watt meant in 1978
9 but that's my interpretation of his meaning.

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

11 **MS RICHARDS:** The leaflet continues:

12 "Nevertheless none of these tests are of sufficient
13 sensitivity to eliminate the possibility of transmitting
14 hepatitis. Methods for examination of this product
15 continue to be developed but the risk of transmission
16 cannot be disregarded."

17 That's part of the description.

18 Then over the page, under the heading "Side
19 Effects", towards the bottom of the page:

20 "Complications in the use of factor VIII concentrate
21 are rare. Apart from the general complications of
22 hepatitis and intravascular haemolysis (see above) some
23 patients may occasionally experience slight irritation
24 at the site of the injection."

25 Then there is reference to transitory headache

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1 "... preparation has also been examined by more
2 searching techniques applied in at least two
3 laboratories external to the laboratory of manufacture."

4 Do you know what that's a reference to?

5 **A.** No, but there would have been reference laboratories
6 in both Scotland and England that had perhaps more
7 sensitive assays available, and my predecessor Mr Watt
8 I think always took the advantage of accessing those
9 to -- either to confirm the results that PFC was
10 getting or he was interested in a technique which
11 could be more searching. I don't think they were
12 routinely applied to every batch.

13 **Q.** Then it continues --

14 **SIR BRIAN LANGSTAFF:** Just one moment.

15 Do you actually know of a test being used in
16 1978 which was more searching than radioimmunoassay?
17 I can understand that RIAs is and was thought to be at
18 the time more searching than RPH, but RIA itself, more
19 searching than that?

20 **A.** There may have been versions of it and different
21 extraction techniques which increased the sensitivity.

22 I think it is simply implying that. I don't think --
23 there was nothing like nucleic acid amplification
24 technology then.

25 **SIR BRIAN LANGSTAFF:** No.

6

1 or nausea being reported.

2 That is the information as at 1978. If we then
3 go over the page to the application made also in '78,
4 but I think in October '78, for Factor IX.

5 Can we go to the next page, please, Sully.

6 We can see at the bottom of the page, we see in
7 the licence application form a similar heading
8 "Contra-indications, Precautions and Warnings",
9 similar to what's said in relation to Factor VIII, and
10 then:

11 "Product may carry the risk of transmitting
12 serum hepatitis."

13 Then there is reference to a "slight generic
14 risk of diffuse intravascular thrombosis".

15 If we go to the next page we can see similarly
16 we have an appendix CONTAINING the proposed package
17 insert leaflet for the -- DEFIX, the Factor IX
18 concentrate.

19 If we go to the next page. I won't read it
20 fully aloud, but we have, in the second paragraph
21 under the heading "Description", a similar
22 explanation, recording in the penultimate sentence:

23 "... none of these tests are of sufficient
24 sensitivity to eliminate the possibility of transmitting
25 hepatitis ... the risk of transmission cannot be

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1 disregarded."
2 Then if we go over the page to "Side Effects",
3 it suggests complications in the use of the Factor IX
4 concentrate DEFIX are rare.

5 Then there is the reference to the general
6 complications of hepatitis and then it goes on to talk
7 about intravascular coagulation or thrombosis as
8 a potential side effect of Factor IX.

9 Can we go to the next page, then, please.

10 If we zoom in on this, is this, as far as you
11 understand it, the final version of the leaflet,
12 Dr Perry?

13 **A.** Unfortunately it hasn't got a date reference, but it's
14 prior -- it's a leaflet that was used prior to the
15 introduction of heat treatment. So I believe this is
16 a faithful copy of the leaflet which was included with
17 the product.

18 **Q.** So this is Factor VIII, and we can see in the second
19 paragraph, under the heading "Description" --
20 I haven't checked word for word to see if it is
21 identical to the form submitted to the licensing
22 authority, but it certainly seems to be largely the
23 same in relation to what's said about hepatitis, and
24 under the heading "Side Effects", again, it seems to
25 follow or be very similar to the language in the draft

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1 **A.** Yes.

2 **Q.** We can see the second paragraph -- sorry, under the
3 heading "Description" refers to a collection from
4 volunteer donors, screening for hepatitis B surface
5 antigen using radioimmunoassay. So just the RIA test.
6 Reference again to the more sensitive techniques. And
7 then:

8 "The product has been heat treated at 68°C for
9 twenty-four hours in the dried state but it cannot be
10 assumed that the product is non-infective."

11 I think this is right, in this section, there is
12 not any express reference to serum hepatitis or
13 hepatitis beyond the hepatitis B surface antigen
14 testing?

15 **A.** No, there is no explicit reference to any particular
16 infectivity risk. And my recollection is that I think
17 in discussions with Professor Cash, and probably the
18 Haemophilia Centre Directors as well, we chose to give
19 a more generic expression of "non-infective", which
20 was intended to imply that there could be a risk of
21 other viruses as well. So I think we moved from
22 a situation where we were only referencing hepatitis
23 and this was intended to include, particularly at this
24 time, HIV as well.

25 **Q.** But I think it is clear on the face of it, there is no

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1 submitted to the licensing authority. So reference
2 there, do you see, to the general complications of
3 hepatitis?

4 Then, next page, we have, as I understand it
5 now, the leaflet in relation to Factor VIII heat
6 treated. Is that right?

7 **A.** Yes.

8 **Q.** Would this then be a leaflet that would have been
9 produced from -- well, are you able to assist us with
10 when? There is a date in the bottom right which looks
11 like it is April 1985, "5/4/85".

12 **A.** Yes, I think this is a date reference for this
13 particular leaflet.

14 **Q.** Do you know what was done between December 1984 and
15 April 1985 in terms of information provided with the
16 heat-treated product?

17 **A.** I'm not sure what information was provided in addition
18 to the leaflet. As I mentioned a few minutes ago, the
19 action that we took as a result of introducing our
20 first generation heat-treated product was simply to
21 apply over-stick labels to the existing labelling.
22 That was seen as the most efficient and quick way of
23 getting the product to issue.

24 **Q.** In any event, by April 1985 we have this as the
25 leaflet for the heat-treated Factor VIII?

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1 express reference to HTLV-III or AIDS?

2 **A.** No. I think that was by design, at that stage.

3 **Q.** Yes, I will come back to -- once we have looked at the
4 actual documents as to why that might be the case.
5 There is reference under the heading "Side Effects" to
6 general complications of hepatitis, and we can see
7 that in the second sentence there.

8 Then, if we go to the next page --

9 **SIR BRIAN LANGSTAFF:** May I just ask, the references here,
10 the references 1 and 2, at the bottom, they are copied
11 over from the previous document. I think reference
12 number 3, "MMWR Vol 33 No. 42 1984", is a new one.
13 And if I'm --

14 **A.** Yes.

15 **SIR BRIAN LANGSTAFF:** I imagine, though I haven't checked,
16 that may be the MMWR that spoke about the likely
17 efficacy about heat treatment.

18 **MS RICHARDS:** The timing would be right but I haven't
19 checked either, sir. I will do so.

20 **SIR BRIAN LANGSTAFF:** That can be checked and confirmed in
21 due course.

22 **A.** The timing is certainly consistent, I agree.

23 **MS RICHARDS:** Then if we go to the next page, we've got
24 what looks like the issued leaflet in relation to the
25 unheated Factor IX concentrate.

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1 A. Yes.
 2 Q. And the description contains in the second paragraph
 3 a similar narrative to that in the draft leaflet
 4 submitted in 1978 with the licence application, and
 5 then if we look at "side effects", there is reference
 6 there in the second sentence again to general
 7 complications of hepatitis.
 8 Then, the next page is the heat-treated
 9 Factor IX. Now, if we just look a little more
 10 closely, first of all, to the left-hand side, please,
 11 Sully. Thank you. If we look at the second paragraph
 12 under the heading "description", it reads:
 13 "All plasma used for the preparation of Factor IX
 14 concentrate as derived from blood collected by volunteer
 15 donors has been screened for the presence of the
 16 hepatitis B surface antigen using a radioimmunoassay.
 17 The preparation has also been examined for this antigen
 18 by more searching techniques applied in at least two
 19 laboratories."
 20 So that's similar to what had been in the
 21 earlier leaflets from 1978.
 22 A. Yes, yes.
 23 Q. "In addition, product plasma pools and individual
 24 plasma donations are tested for the presence of
 25 antibody to HTLV-III. The product has been heat

1 in Scotland until the autumn of 1985 because of our
 2 experiments and studies and to ensure that it didn't
 3 have any risk of thrombosis associated with it.
 4 So, by that time we knew we were testing --
 5 well, we were. We were testing individual donations
 6 and plasma pools for HIV.
 7 Q. Which was, I think, the middle of October 1985?
 8 A. Which was middle of October 1985, yes.
 9 Q. This is autumn or end of 1985, this leaflet?
 10 A. So the opportunity presented itself to update that
 11 leaflet but that opportunity didn't exist with
 12 Factor VIII which was introduced in -- the 24 hour
 13 heated product wasn't introduced -- it was introduced
 14 much sooner than that in manufacture in early 1985 and
 15 HIV testing hadn't been introduced then.
 16 Q. Then if we just go to the next page, I'm not going to
 17 try and read this because we looked at it with
 18 Dr Foster and he helpfully reminded us that there were
 19 colour copies available which are easier for us to
 20 read. We can see these are vial labels.
 21 A. Yes.
 22 Q. If we go to CBCA0000065_010, I hope we will have
 23 a clearer -- yes, this is slightly easier to read. If
 24 we look first of all at the top label which is
 25 "unheated Factor VIII", I don't think again we have

1 treated at 80 degrees C for 72 hours in the freeze
 2 dried state. This treatment is expected to inactivate
 3 viruses associated with the acquired immune deficiency
 4 syndrome (HTLV-III, LAV, ARV). The effect of this
 5 heat treatment of hepatitis B and hepatitis non-A,
 6 non-B has still to be elucidated and therefore this
 7 product cannot be assumed to be non-infective with
 8 regard to the hepatitis viruses."
 9 Then, before I ask you about that, if we just
 10 look at side effects, we can see it records:
 11 "Apart from the general complications of virus
 12 transmission (discussed above) ..."
 13 Then it goes on to talk about the risks of
 14 intravascular coagulation or thrombosis.
 15 Now, I don't think this leaflet is dated. Can
 16 we just go back to the whole leaflet, Sully. We don't
 17 appear to have a date on it in the way that we had for
 18 the heat-treated Factor VIII but does the reference to
 19 plasma pools and individual plasma donations being
 20 tested and the reference to the heat treatment
 21 programme enable you to tell us roughly when this
 22 would have been produced?
 23 A. Yes. We may come on to discuss this, but the
 24 Factor IX product was not introduced -- the
 25 heat-treated DEFIX was not introduced for routine use

1 a date. There's an expiry for this particular vial
 2 presumably, this particular batch, which looks like --
 3 well, I'm not quite sure, 84?
 4 SIR BRIAN LANGSTAFF: It looks like 12/84.
 5 A. I'm sorry where are we?
 6 MS RICHARDS: So the expiry date in the bottom right-hand
 7 corner of that label.
 8 SIR BRIAN LANGSTAFF: SLC -- was it 2575m/12/84? It looks
 9 like 12/84. It looks as though there might be the
 10 operative date.
 11 A. Yes. It seems a strange way of expressing the expiry
 12 date which is usually just a -- so I can't quite
 13 explain that, but it could well have been a sample
 14 label from a batch which did expire in December 1984.
 15 SIR BRIAN LANGSTAFF: Well, whoever was using it would
 16 have to know when it was past its use by date.
 17 A. Absolutely.
 18 MS RICHARDS: In any event, we're told, and I think it is
 19 apparent from the label, that this is for Factor VIII
 20 and it's clear it's for the non-heat-treated
 21 Factor VIII. So it's for the product that was being
 22 used by PFC up until the end of 1984.
 23 A. Yes.
 24 Q. And we can see the label contains instructions about
 25 reconstitution and so on, and then says:

1 "This preparation is of human origin and cannot be
2 assumed free of hepatitis virus."

3 **A.** Yes.

4 **Q.** And that is what I think we'll see potentially echoes
5 the language of the British Pharmacopoeia. If we then
6 just go to the next label, so this is the heat-treated
7 Factor VIII and, again, looking at the expiry date it
8 looks to me as though it's a date in 1985.

9 **A.** Yes.

10 **SIR BRIAN LANGSTAFF:** It looks like 2/85.

11 **A.** Yes, it's February '85 yes.

12 **MS RICHARDS:** Again, the label has instructions in
13 relation to reconstitution, and then the last sentence
14 says:

15 "The freeze-dried product has been heat treated but
16 cannot be assumed to be non-infective."

17 So that echoes, I think, the term that PFC have
18 chosen to use in the leaflet: not referencing
19 hepatitis, not referencing AIDS or HTLV-III --

20 **A.** Yes but --

21 **Q.** -- using the terminology "non-infective"?

22 **A.** But recognising there were risks other than hepatitis
23 by then. I think this curious reference in the expiry
24 date actually is just a label-dating reference for
25 when the label was drafted. I think typically under

17

1 **Q.** Only on the Factor IX there's an explicit reference to
2 acquired immune deficiency syndrome and HTLV-III LAV.

3 **A.** And the confidence that the product is likely to be
4 free of that particular -- of HIV risk, yes.

5 **Q.** Would you also accept, looking at this material,
6 there's nothing which would inform a reader of what
7 I think you yourself have described and others have
8 described as the almost inevitability of infection or
9 transmission of non-A, non-B hepatitis, even with NHS
10 products?

11 **A.** No, there's not. There's not an extended narrative on
12 those risks but I think as -- we may come onto discuss
13 the purpose of these -- these were prescription-only
14 medicines. The labelling, the leaflets and so on were
15 primarily targeted at the prescribing doctor and, in
16 a sense, they had a much closer working knowledge of
17 risks of hepatitis non-A, non-B, hepatitis B and,
18 latterly, HIV than the manufacturer of the products.
19 So none of this information would have been a surprise
20 to a treating doctor.

21 **Q.** Yes. I may come back to that, Dr Perry. But before
22 I do that, just to complete the factual picture, the
23 British Pharmacopoeia -- and we have extracts only for
24 present purposes at SBTS0002189. So these are
25 extracts provided by SNBTS and we'll obviously want to

19

1 the Factor VIII, the lot number and expires, there
2 would have been a much clearer expression alongside.
3 These are blank labels. So I think that reference
4 down there, which is a bit curious, is a label version
5 reference.

6 **Q.** Thank you. Understood.

7 Then if we look at the last of the labels, which
8 is for the unheated Factor IX concentrate, we can see
9 again it has instructions in relation to usage and
10 then it says:

11 "This preparation is of human origin and cannot be
12 assumed free of hepatitis virus."

13 So I think we can see from the material that
14 we've looked at, Dr Perry, there's no express
15 reference to non-A, non-B hepatitis in any of the
16 material until we get to the heated Factor IX at the
17 end of 1985.

18 **A.** Yes, that's right, yes.

19 **Q.** There is no particular description or account of
20 either -- the seriousness of hepatitis, is there?

21 **A.** No, there's not.

22 **Q.** There's no reference to HTLV-III or AIDS again until
23 we get to the heat-treated Factor IX towards the end
24 of 1985?

25 **A.** Yes, but not an explicit reference to it. It's in --

18

1 look at the fuller pharmacopoeia in due course. We
2 can see these are extracts related to Factor VIII,
3 rather than Factor IX.

4 If we go to the next page, please, Sully.

5 So this is the extract. We're told at the top
6 of the page it's from the British Pharmacopoeia for
7 1973. Then if we look down the bottom of the page to
8 the heading "Dried Human Antihæmophilic Fraction",
9 there's a description that I'm not going to read
10 through.

11 If we go to the next page, if we look at the
12 right-hand column, top half of the page, there's
13 a heading "Labelling". We can see what's written here
14 is:

15 "The label on the container states ..."

16 Now, just pausing there, this isn't,
17 therefore -- is this right -- prescribing what should
18 be in the package insert or leaflet? This is
19 concerned only with what should be on the container
20 itself?

21 **A.** Precisely, yes.

22 **Q.** And then we can see this is what the pharmacopoeia is
23 contemplating, that the label will state: the number
24 of units contained in it; equivalence to the
25 anti-hæmophilic activity of normal plasma; amounts of

20

1 fibrinogen; sodium ions; citrate ions, other added
2 substances; point 5 is about reconstitution, as is 6,
3 7, 8. Then point 9 is:

4 "The number of donations in the pool from which the
5 preparation was obtained."

6 So that's -- and then 10, 11, and 12 is about
7 expiry, storage and use.

8 So it would appear from the British
9 Pharmacopoeia extract, 1973, that we've got here,
10 there isn't any express reference to hepatitis there
11 but there is a requirement or a recommendation or
12 an expectation that the label will state the number of
13 donations in the pool?

14 **A.** Yes, clearly. I think that subsequently disappeared
15 in the subsequent monographs.

16 **Q.** Yes, absolutely right. Yes, that is correct as far as
17 I understand at least these extracts and that's why
18 I wanted to go through them with you with some care.

19 If we go over the page, you'll see someone's
20 written at the top there:

21 "British Pharmacopoeia 1973, Addendum 1977."

22 There's nothing of particular significance in
23 the passage in the addendum relating to
24 anti-haemophilic fraction. It is the one paragraph on
25 the page that hasn't been crossed through. Then if we

21

1 "dried human anti-haemophilic fraction", we can see
2 there is a narrative here which refers to donor
3 selection and donor screening in relation to
4 hepatitis B. It says:

5 "Blood to be used for preparing ... Fraction is
6 obtained from human subjects (a) who are, as far as can
7 be ascertained by a registered medical practitioner
8 after simple clinical examination and consideration of
9 their medical history, free from disease transmissible
10 by blood transfusion ..."

11 (b) there refers to testing for syphilis. (c)
12 then refers to testing for hepatitis B antigen. Then
13 I don't think I need to read any of the remainder.

14 Then if we go over the page and we look in the
15 bottom right-hand part of the page, we have got the
16 heading "Labelling".

17 Thank you, Sully.

18 Here we have got what's recommended for
19 inclusion on the label: (1) number of units; (2)
20 concerns concentration of protein, sodium ions and
21 citrate ions, (3) any other substances contained in
22 it. (4), (5), (6) and (7) are concerned with matters
23 relating to reconstitution of the product. And then
24 (8):

25 "... that the preparation is of human origin and

23

1 go to the next page, someone has written at the top
2 there:

3 "British Pharmacopoeia 1973, Addendum 1978,
4 Pages 11-12."

5 Just before we look at the text, I don't know
6 whether you can assist with this, Dr Perry. Is this
7 right: there was a principal version of the
8 pharmacopoeia produced periodically and then there
9 would be, was it every year there was an addendum
10 produced or ...?

11 **A.** I can't confirm whether or not that's the case but
12 that was certainly the way they managed changes in
13 pharmaceutical development if there was a -- because
14 the pharmacopoeia, if you've ever seen these things,
15 they're enormous volumes --

16 **Q.** Yes.

17 **A.** -- and republishing to make minor changes to certain
18 monographs just simply wouldn't be possible. Well, it
19 would be possible but at enormous cost and
20 inconvenience to everybody, I think. So the system
21 was that they would put out regular updates in the
22 form of addenda, which were formal documents.

23 **Q.** Yes. Then we can see -- so this is recorded as being
24 the addendum from 1978 and, if we go to the bottom
25 right-hand part of the page then, under the heading

22

1 cannot be assumed to be free of hepatitis virus ..."

2 So that's the language which is similar to the
3 language used on the PFC labels, is that right?

4 **A.** That is correct, yes.

5 **Q.** Then (9) is date, (10) and (11) concern storage and
6 use.

7 So it would appear from this that between 1973
8 and 1978 -- or, sorry, by 1978, the British
9 Pharmacopoeia recommendation that the label includes
10 a description of the number of donations has
11 disappeared?

12 **A.** It has. And they have added hepatitis risks.

13 **Q.** Yes, in the terms that we see here.

14 If we go to the next page, someone has written
15 at the top:

16 "British Pharmacopoeia 1980."

17 Now the Inquiry will be checking this for itself
18 and we hope, sir, to obtain full copies of the
19 relevant pharmacopoeias, but this would tend to
20 suggest that in 1980 a whole new pharmacopoeia was
21 issued. So we had the 1973 one, then we had addendums
22 being published, and then in 1980 there is a new
23 version.

24 We can see bottom of the page refers to the
25 dried Factor VIII fraction.

24

1 If we go over the page to "Labelling", top
2 left-hand corner of the page, I don't, I think, need
3 to read through all of them. Again, it echoes what we
4 saw from the previous addendum from 1978, so there's
5 no reference to number of donations and then point (8)
6 is the terminology of "the preparation is of human
7 origin and cannot be assumed to be free of hepatitis
8 virus".

9 So that is 1980. If we go to the next page,
10 someone has written on the top there:

11 "British Pharmacopoeia 1980. Addendum 1986."

12 Do you know, Dr Perry, bearing in mind that this
13 was provided by SNBTS, whether there were any addenda
14 issued between 1980 and 1986 that related to
15 Factor VIII concentrate?

16 **A.** I don't know.

17 **Q.** Well, again, sir, the Inquiry will be endeavouring to
18 check all of the originals and find out for ourselves.

19 Bottom right-hand corner, in any event, we see
20 the start of the monograph for "Dried Factor VIII
21 Fraction". If we go over the page -- actually, no,
22 can I -- sorry, Sully -- if we stay on the page that
23 we were -- look at the bottom right-hand corner. It
24 says:

25 "Dried Factor VIII Fraction is prepared from human

25

1 So it doesn't appear, as at the addendum of
2 1986, at least from these extracts, that there's any
3 reference in the British Pharmacopoeia to HTLV-III or
4 AIDS?

5 **A.** No, I don't think -- there is no reference to AIDS at
6 this stage. This is 1983?

7 **Q.** This is 1986.

8 **A.** Oh, 1986. Okay. No, there is no reference by that
9 time.

10 **Q.** Then the next extract we have is from 1988, which is
11 the next page.

12 We will see in the description in the first
13 paragraph on the left-hand side -- if we just go
14 closer in to that, please -- again, there is reference
15 to preparation from human plasma, and then it says:

16 "The examinations and tests to be carried out are
17 decided by the appropriate national authority; in
18 particular, tests for hepatitis B surface antigen and
19 for HIV antibodies are carried out by suitably sensitive
20 methods and give negative results in both cases."

21 Then if we go over the page, please, to the
22 "Labelling".

23 So if we can just zoom in on the paragraph on
24 the left-hand side, please, Sully. "Labelling", top
25 half of the page. Thank you.

27

1 plasma obtained from blood from more than ten healthy
2 donors who must, as far as can be ascertained after
3 clinical examination, laboratory tests on their blood
4 and a study of their medical history, be free from
5 disease transmissible by transfusion of blood or blood
6 derivatives."

7 Then there is reference to how it is prepared
8 and so on.

9 Then if we go back to the whole page, Sully,
10 "Labelling" is bottom right-hand corner of the page.

11 So here we have, as at 1986:

12 "The label on the container and the label of the
13 package state ..."

14 Then I think I can skip over the first few -- well,
15 in fact, no, actually I won't:

16 "... the label on the container and the label on the
17 package state ..."

18 Then there are number of units, protein,
19 heparin, information about preparation. Then the
20 second paragraph says:

21 "The label on the container or a leaflet
22 accompanying the package states ..."

23 Then we have the reference at (3) to "the
24 preparation cannot be assumed free of hepatitis
25 virus".

26

1 So we can see what's stipulated there for the
2 label: number of units, concentration of protein,
3 fibrinogen, heparin, other substances, volume of
4 water, expiry dates, conditions for storage, and so
5 on.

6 So there's no reference here to the label
7 stating anything about infection?

8 **A.** No, no.

9 **Q.** Do you know why that might have been the case as at
10 1988? Is that reflecting the belief that products --
11 Factor VIII concentrates had been successfully
12 inactivated?

13 **A.** I think so. I would make the general observation that
14 pharmacopoeia monographs always tended to be produced
15 after a significant period of time. You know, they
16 weren't prospective; they were retrospective
17 documents, reflecting best practice and developments
18 and so on. My explanation, I think, is not dissimilar
19 to yours: that it was -- by that time there was
20 an expectation that clotting factor products should
21 not transmit HTLV-III -- or HIV as it was then.

22 **Q.** Or non-A, non-B hepatitis?

23 **A.** Or perhaps non-A, non-B, but I think it is a little
24 early for that. It is interesting that there is no
25 reference to hepatitis virus because there were

28

1 products still transmitting non-A, non-B hepatitis at
2 that time.

3 **Q.** Dr Perry, do you know from your own knowledge anything
4 about how the British Pharmacopoeia in the 1970s and
5 1980s was compiled or who by?

6 **A.** Well, I did actually sit for a brief period, a few
7 years, on the British Pharmacopoeia Commission
8 subgroup on biologicals, and it met very infrequently
9 and often by correspondence, and, as I have described,
10 it was a highly retrospective exercise and prescribed
11 absolute minimum standards. For instance, it talks
12 about 10 donors, a minimum of 10 donors. Well, I know
13 of no organisation that produced Factor VIII from
14 10 donors. But it was a document and a system that
15 was widely used beyond the UK. So it was targeted, as
16 well as at developed countries, at developing
17 countries as well, so it could give them some guidance
18 on how to make these products.

19 **SIR BRIAN LANGSTAFF:** On that point, it was plainly -- if
20 we just go back to the start of this particular
21 document -- thank you. The previous page.

22 It is the first paragraph. About halfway down:

23 "The examinations and tests to be carried out are
24 decided by the appropriate national authority."

25 So it looks from that that this was designed to

29

1 the next page, please, Sully.

2 The very last words, which are not apparently to
3 be put on the label as -- or not prescribed as minimum
4 for the label, are repeated from edition to edition:

5 "Dried Factor VIII Fraction [which is what this is],
6 after constitution, should be administered only with
7 equipment that includes a filter."

8 **A.** Yes.

9 **SIR BRIAN LANGSTAFF:** It is not simply a question of
10 reconstituting and putting into a syringe, there has
11 to be a filter somewhere in the --

12 **A.** Yes, I think the conventional practice, as
13 I understand it, and we introduced this in our
14 products latterly, that the product and the insert
15 leaflet and the outer package would contain a filter
16 needle. So you would take the -- you would aspirate
17 the reconstituted product into the syringe, you
18 would -- and then attach a filter needle prior to
19 infusion.

20 **SIR BRIAN LANGSTAFF:** I see. So that's how it would --

21 **A.** It wasn't a big sophisticated filtered giving set, it
22 was a simple filter needle that took out any
23 particulate matter that might be there.

24 **SIR BRIAN LANGSTAFF:** And that would be why it didn't need
25 to be put on the label, is it?

31

1 deal with any Factor VIII fraction, whether it was of
2 origin at the PFC or BPL, but also origin elsewhere --
3 **A.** Or any other country.

4 **SIR BRIAN LANGSTAFF:** -- that was being sold or
5 distributed in the UK through pharmacies or through
6 hospitals. And that might explain or fit with the
7 reference to 10 you are mentioning possibly.

8 **A.** Absolutely. I recall being involved in discussions on
9 some monographs and -- well, it was more than
10 a tendency. It was a requirement to provide -- it
11 provided a minimum specification for these products.
12 It wasn't designed to be a state of the art document.
13 It was designed, as I say, for other countries, and
14 many other countries did use the British Pharmacopoeia
15 as a reference document or a reference specification
16 for products that they wished to make, not only plasma
17 products but many other pharmaceuticals as well. So
18 it was a -- I think it was an attempt to provide
19 a useful body of knowledge for organisations that
20 wished to produce products but for whatever reason
21 couldn't -- were not able to provide state of the art
22 pharmaceuticals, as it were.

23 **SIR BRIAN LANGSTAFF:** Just one further slightly different
24 point in respect of these labels.

25 If we go to the very end of this document, so

30

1 **A.** Yes, yes.

2 **MS RICHARDS:** As you have explained, Dr Perry, these
3 effectively then were minimum expectations. So there
4 was nothing that would prevent someone producing
5 Factor VIII, whether it is PFC or BPL or a commercial
6 pharmaceutical company, from setting out more
7 information, particularly in the package inserts and
8 leaflets?

9 **A.** No, that's right. I think that's absolutely right.

10 **Q.** Can I then just look at some of the evidence you have
11 given on this topic to the Penrose Inquiry, when you
12 were asked to explain PFC's approach.

13 If we start with PRSE0002620.

14 This is a statement provided by you. I don't
15 think it's -- oh, yes, it's the end of 2011.

16 If we go to the second page, I just want to pick
17 it up -- so you've set out an extract from a range of
18 the materials. We have looked at the originals so
19 I don't need to trouble you with that. And then you
20 say this:

21 "The above statements are designed to comply with
22 regulatory and pharmacopoeial standards and to provide
23 a warning to expert and experienced prescribers of the
24 product (ie Haemophilia Doctors) of the generally
25 recognised and understood infectivity risks associated

32

1 with the use of these products. It was reasonable to
 2 assume that these expert users would understand that
 3 these risks included NANBH. Explanation of such risks
 4 to patients was exclusively the responsibility of
 5 Haemophilia doctors.

6 "Notwithstanding that some patients (eg patients on
 7 home treatment) would have cited the information
 8 provided by the manufacturer this was not the target
 9 audience for the technical information which was
 10 required to be included."

11 Then you refer -- I think you gave evidence on
 12 this yesterday afternoon -- to a change in the 1990s
 13 when there was a specific requirement for patient
 14 information leaflets.

15 I think in fairness I should also read the third
 16 paragraph:

17 "Examples of leaflets held by SNBTS other
 18 manufacturers suggest that the statements included with
 19 PFC products were typical of products at that time."

20 I just wanted to go back to the first of those
 21 paragraphs that I read, Dr Perry, so the paragraph
 22 beginning "The above statements were designed".

23 Can we just have that? Thank you, Sully.

24 So, as I understand it, the explanation that
 25 you're giving here, Dr Perry, is that it was

33

1 or hepatologists, or discuss with them what
 2 information they were providing about non-A, non-B
 3 hepatitis to their patients?

4 **A.** No, I think, if anything, the flow of information was
 5 in the other direction. They would inform us on risks
 6 of hepatitis in their patients or incidents of
 7 transmissions and so on, but to the best of my
 8 recollection -- we would periodically, including
 9 myself, Dr Foster, others, Professor Cash, we would
 10 give talks, lectures, presentations on products and
 11 refer to matters such as hepatitis, but I don't think
 12 it was ever a view that the SNBTS was an expert on
 13 non-A, non-B hepatitis and, as you say, all
 14 haemophilia doctors are haematologists by trade but
 15 they do have, and increasingly had, an expert
 16 knowledge on hepatitis and its transmission and its
 17 implications for patients.

18 **Q.** Is it right to put it this way, that the PFC in taking
 19 its decisions about what it included on leaflets and
 20 so on acted on an assumption that information about
 21 non-A, non-B hepatitis was being provided to patients
 22 by clinicians without any actual knowledge itself that
 23 that was taking place?

24 **A.** Well, I think it's more than an assumption. I think
 25 it was an evidence-based belief that they knew the

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1 reasonable not to have an express reference to non-A,
 2 non-B hepatitis because haemophilia clinicians would
 3 have that knowledge themselves?

4 **A.** I think that was the prevailing view, yes. In fact,
 5 the products that PFC made only went to five
 6 individual centres in -- Factor VIII products to five
 7 individual centres and haemophilia doctors are, you
 8 know, much more knowledgeable about the risks of
 9 coagulation factors with respect to non-A, non-B
 10 hepatitis, and it was certainly the case that the
 11 belief -- and that's not just my belief, that's the
 12 belief of RTC medical colleagues and so on -- that
 13 conveying and providing a detailed narrative and
 14 understanding of the risk associated with products was
 15 not the responsibility of the manufacturer. It was
 16 the responsibility of the prescribing doctor.

17 **Q.** On that basis, why say anything about hepatitis at
 18 all? Haemophilia clinicians would be even more
 19 familiar perhaps with hepatitis B.

20 **A.** Because that's what the regulation and the reference
 21 documents required us to do.

22 **Q.** Did PFC, as far as you know, ever actually discuss
 23 with haemophilia clinicians using its products (a)
 24 what their knowledge of non-A, non-B hepatitis was,
 25 because they're haematologists rather than virologists

34

1 risks of treatment with these products. They talked
 2 to us about it. They delivered publications. They
 3 studied groups of patients and so on.

4 **Q.** The "they" you're talking about there are the
 5 haemophilia clinicians?

6 **A.** I'm talking about haemophilia clinicians, yes.

7 **Q.** My question was slightly different. Forgive me.

8 **A.** Sorry.

9 **Q.** No, no, the fault's mine. Did PFC essentially assume
 10 that PFC, as the product manufacturer, did not need to
 11 spell out risks relating to non-A, non-B hepatitis
 12 because PFC assumed that clinicians would be spelling
 13 out those risks to their patients?

14 **A.** I think clinicians, as I understand it, would be
 15 trained in their requirement to have a sufficient
 16 knowledge of the risks associated with treatment, so
 17 that they could convey that to patients. And, like
 18 all other manufacturers, we were quite limited in the
 19 amount of information that it was appropriate to give
 20 to doctors or -- and certainly to patients.

21 So I think your assumption is -- it is
 22 an assumption but it's one based on a good knowledge
 23 of the people that we were working with and providing
 24 the products to.

25 **Q.** Looking at it now, and with the knowledge that,

36

1 certainly by a date in the early 1980s -- you referred
2 yesterday to, I think, the Kernoff publication, it may
3 have been the Fletcher publication you had in mind,
4 but in any event a publication in 1983 which suggested
5 a high risk of infectivity with non-A, non-B hepatitis
6 from NHS concentrates and not just commercial
7 concentrates?

8 **A.** Yes.

9 **Q.** So looking -- knowing that as at 1983 if not earlier,
10 do you think PFC, rather than saying, "This product
11 can't be assumed to be free of hepatitis viruses",
12 that rather understated the risk, and there was a case
13 for saying, "This product is likely to transmit
14 hepatitis virus", because that was the state of
15 knowledge, at least by 1983, wasn't it?

16 **A.** I think by 1983 there was increasing knowledge that
17 the NHS products and commercial products did transmit
18 non-A, non-B hepatitis in close to 100 per cent of
19 recipients over a period of time. But the information
20 that we gained or that our knowledge, actually, for
21 instance, from that key publication from
22 Peter Kernoff -- he was a member of the UKHCDO. These
23 were topics that routinely and regularly were
24 discussed by haemophilia doctors. So, in a sense, we
25 got that information from publications provided by

37

1 hepatitis, it could well have been that the regulatory
2 authorities said, "No, you can't say that". They
3 might say, "It is not absolutely proven, so you cannot
4 state something that's not absolutely proven
5 scientifically and enjoys a large consensus."

6 **Q.** That, I think, is -- and I don't mean this as
7 a criticism, but that's -- I think that is a degree of
8 speculation on your part --

9 **A.** Absolutely.

10 **Q.** -- because, as I understand it, that conversation
11 never took place. PFC didn't ask the licensing
12 authorities for its view on whether there should be
13 any explicit statement about either non-A, non-B
14 hepatitis or about the likelihood of infection of
15 non-A, non-B hepatitis?

16 **A.** No, that is right. That is right.

17 I do remember, and I think this has been raised
18 somewhere in the evidence that's provided to the
19 Inquiry, perhaps by Dr Foster, that he recalls
20 a conversation either with Professor Cash or Dr Ludlam
21 where we did suggest that we should be much more
22 explicit about the risk of HIV in our products, and my
23 understanding is that Professor Ludlam and his
24 colleagues expressed concern at making such
25 a statement. Not that he wanted to hide it but he

39

1 experts dealing with haemophilia patients. And
2 I think, to be honest, we didn't feel the need,
3 certainly at PFC, to elaborate on that information.
4 We would just be reflecting back to them the
5 information that they provided to us.

6 **Q.** Looking at it now -- and I ask this question because
7 this may be a submission made in due course to the
8 chair, and it will be a matter for the chair obviously
9 to decide. Looking at it now, do you think PFC made
10 the wrong call in not stating sufficiently clearly
11 the risks of non-A, non-B hepatitis on its product
12 information?

13 **A.** No, I don't. I think PFC reflected the wider practice
14 through the industry. We had many -- we used to have
15 discussions with Haemophilia Directors on a frequent
16 basis, and there was a legitimate concern that we
17 should neither under-exaggerate or over-exaggerate
18 the risks associated with the product. So the wording
19 that was used was not just the wording that PFC
20 developed, it was informed by our medical advisers,
21 Professor Cash, RTC colleagues, haemophilia doctors
22 and so on, plus satisfying the requirements of the
23 regulatory authorities. And it may well have been, if
24 we had been more explicit in saying we want now to say
25 that this product will transmit non-A, non-B

38

1 felt the wording had to be very, very carefully
2 considered.

3 **Q.** Yes. I will check that. I think there certainly is
4 a reference to a conversation with Professor Cash in
5 the evidence somewhere. Whether it referenced
6 Dr Ludlam or not we will check.

7 **A.** I'm not sure whether there is any documented evidence
8 of this conversation, no.

9 **Q.** That leads then to the question of warnings about AIDS
10 or HTLV-III.

11 If we could perhaps just look at PRSE0001885 --
12 no, in fact, I don't need to because you were just
13 summarising in that document what wasn't in the
14 leaflets about -- and we have looked at the leaflets
15 themselves.

16 Can I take you to some of your evidence to the
17 Penrose Inquiry on the issue of warnings in relation
18 to AIDS.

19 PRSE0006038, please.

20 So this is your evidence on 24 June 2011.

21 Sully, can you go to page 98, please.

22 So you were asked at line 4 this question:

23 "I just wanted to ask you whether consideration had
24 been given within PFC to include in the text information
25 about the risks of AIDS or HIV from the products at any

40

1 stage in 1983 or 1984?"
2 Your answer was no. Then you go on to explain
3 why that might have been the case.

4 Can I just ask you to confirm that that's
5 correct. I think you say it elsewhere in the evidence
6 as well -- you say it elsewhere in your evidence to
7 Penrose -- that you don't recall there being any
8 express discussion within PFC of the issue of adding
9 information about AIDS risks in '83 or '84?

10 **A.** No, other than that which we just mentioned, about the
11 possible conversation with Professor Cash and his
12 proposal to Professor Ludlam. So I think the views
13 expressed in that answer to the Penrose Inquiry
14 I would still -- I still think are my views today.

15 **Q.** If we just read then what you gave as the reasoning
16 there. You say:

17 "I think at that stage, with the state of scientific
18 knowledge, it would have been highly improper for any
19 manufacturer of a pharmaceutical product without good
20 reason and without good evidence that the product may
21 present a risk of HIV -- The sort of information that's
22 provided in these package insert leaflets is highly
23 controlled and highly regulated and I think in the
24 absence of any information, the control authorities
25 would have taken grave exception to us intimating

41

1 regulatory authorities work. They are very careful
2 and very clear on what can and should be communicated
3 to patients. And the manner in which it is
4 communicated.

5 **Q.** It may be, I hope, that we will hear evidence from --
6 or hear or receive evidence from regulatory
7 authorities in due course in relation to what their
8 approach was at the time.

9 But is this right, then, your evidence is that
10 you think that if a pharmaceutical manufacturer went
11 to the regulatory authorities in the United Kingdom in
12 the 1980s and said, "We think it is likely that
13 HTLV-III -- or that AIDS is transmissible through
14 factor concentrates" -- because that was, certainly by
15 1984, the belief?

16 **A.** Sure.

17 **Q.** It was, I think, the belief probably pretty early on
18 in 1983, not proven but the belief?

19 **A.** Yes.

20 **Q.** "And we would like to say something about that in
21 our -- not necessarily on the label, but in our
22 leaflets", you think the regulatory authorities would
23 turn to a pharmaceutical company and say, "No, you
24 can't say that"?

25 **A.** I'd think they would want to see the evidence for the

43

1 without any evidence on -- that this was the case. I'm
2 not suggesting that there was no evidence. I know there
3 was a body of evidence growing and so on but not to the
4 extent that allowed one to place this as a standard
5 warning in a pharmaceutical product."

6 Again, is it right to understand that there was
7 no conversation with the regulatory authorities about
8 this in 83/84?

9 **A.** Not that I was aware of. It may have been discussed,
10 I don't know, on the Biologicals Committee on the
11 Committee on Safety of Medicines, which Mr Watt was
12 a member of at that time, in 1983 and 1984, but
13 I don't remember personally having any direct
14 conversation with the regulatory authorities about
15 these issues. And indeed, I think my speculation
16 there on what the regulatory authorities might have
17 thought I think is still valid. Certainly in 1983 and
18 1984 we were aware of HIV and its risks but, at that
19 stage, there was no evidence that our products were
20 transmitting at that stage. And, therefore, to put in
21 a leaflet that "this product may transmit", I think
22 the regulatory authorities would have come back and
23 asked for evidence of that. And at that stage there
24 was no evidence.

25 This sounds very pedantic but this is how the

42

1 statement that you are making. And in the same way
2 that pharmaceutical companies, in the documentation
3 that they provide, the insert leaflets and so on, they
4 are certainly not permitted to make claims for
5 benefits without evidence, and I think the converse of
6 that is true as well, that they shouldn't be
7 pronouncing risks where a sufficient body of evidence
8 doesn't exist.

9 Now, that might sound a little complacent by the
10 system, but that's my understanding of how it worked.

11 **Q.** As I say, it may be that we will have to try to pick
12 that up with evidence in relation to the approach of
13 the licensing authorities.

14 Can I then -- just continuing with evidence on
15 this theme to the Penrose Inquiry, if we go to
16 PRSE0001324, please.

17 Now this is another written statement to the
18 Penrose Inquiry from you. If we go over to the bottom
19 of the page -- sorry, bottom of the next page, my
20 apologies, Sully.

21 You were asked by the Penrose Inquiry, the
22 question of:

23 "What discussions were there amongst the staff
24 of the PFC of the possibility of including reference
25 to the risk of HIV transmission on package

44

1 inserts ..."

2 Your answer was there you can't recall whether

3 or not in '82 or '83 you had any discussions with the

4 PFC director, Mr Watt, concerning the inclusion of

5 AIDS warnings, and you don't know if Mr Watt discussed

6 the possibility with others including Dr Cash, as

7 national medical director.

8 That's obviously the period prior to you taking

9 up the directorship?

10 **A.** Sure.

11 **Q.** But you were -- I think, as quality control inspector,

12 liaising with regulatory authorities, content of

13 leaflets and so on was part of your role?

14 **A.** It was, it was.

15 **Q.** Then if we go to the next page. You say this:

16 "However I did lead a review of the packaging

17 systems for PFC FVIII and FIX products during this

18 period which resulted in the introduction of new

19 multi-vial packaging. Product warnings on both product

20 packaging and leaflets remained unchanged and continued

21 to relate only to a hepatitis risk."

22 Just pausing there. Although we know there was

23 no change in the product warnings, you say so there

24 and we have looked at the underlying documents, what

25 did the review that you describe there entail?

45

1 Subcommittee. Of course, if that issue had been

2 discussed as part of the proceedings of the Biological

3 Subcommittee, Mr Watt wouldn't have been able to pass

4 that on because those meetings were confidential?

5 **A.** It is a very good point, but he may have found a way

6 to communicate that this was an emerging view.

7 **Q.** And then if we continue -- in any event, you have no

8 recollection that he -- of him saying anything of the

9 kind?

10 **A.** No, no, he didn't.

11 **Q.** Then if we continue with this passage you say:

12 "I cannot recall whether or not in 1984 (following

13 my appointment as Director) I discussed with others in

14 PFC or elsewhere the possibility or desirability of

15 modifying our 'warnings' to include AIDS. I think it is

16 possible that such discussions took place with eg

17 Dr Cash, Dr Boulton and the Haemophilia Directors."

18 This, I think, is the reference that you were

19 making earlier, Dr Perry:

20 "For example Dr Foster has advised me that he

21 recalls that in late 1983 the SNBTS (Professor Cash)

22 suggested, at a meeting between SNBTS and Haemophilia

23 Directors, the inclusion of an AIDS warning but that

24 this suggestion was rejected by those present in the

25 belief that such action might cause patients unnecessary

47

1 **A.** Well, I think the review was a response to feedback

2 that we were getting that the existing presentation of

3 the product in individual boxes was not the most

4 convenient, particularly for patients increasingly

5 being transferred onto home therapy. So we produced,

6 as it is described there, a multi-vial. It was

7 a small box with ten vials of products and ten vials

8 of water for reconstitution, product insert leaflets

9 and so on. And as part of that process, I think

10 I also carried out a review of the -- because it was

11 an appropriate time to do it, because we were making

12 a change to the packaging, to check that the wording

13 that was used particularly on the outer box packaging

14 and on the vial label was still accurate and

15 reflecting the current position. And during that

16 process, as I think I have described there, Mr Watt

17 was on the Committee on Safety of Medicines. He would

18 have looked at these things on a number of occasions,

19 and I don't recall him suggesting that we needed to

20 change the warnings -- or, indeed, Professor Cash,

21 because he would have also been involved in just

22 checking the documentation and leaflets and the

23 packaging and so on.

24 **Q.** Can I just pick up on the point you make about Mr Watt

25 by reference to his membership of the Biological

46

1 anxiety. However the SNBTS has been unable to find any

2 record of this."

3 Then if we look at the next sentence, please,

4 Sully:

5 "In any event no action was taken to include any

6 specific reference to AIDS or HIV until [heat-treated]

7 DEFIX was issued in September 1985."

8 **A.** That is correct.

9 **Q.** Can we then just go over the page and I will just go

10 through this with you before we break.

11 You say:

12 "However I am unable to find any reference to or

13 evidence of a process which led any individual(s) to

14 recommend in favour or against the introduction of AIDS

15 warnings for FVIII products.

16 "Prior to 1985, product information supplied by

17 PFC/SNBTS reflected the background of knowledge and

18 guidance available between 1982 and 1984 ie ..."

19 Then you have set out here a series of six

20 points and I just wanted to, really in fairness to

21 you, just go through those. The first is:

22 "... no requirement or advice from the UK licensing

23 authority to include such warnings for products used in

24 the UK."

25 Now, leave aside the British Pharmacopoeia

48

1 because we have already discussed those tended to be
2 minimum recommendations or stipulations and after the
3 event rather than being proactive.

4 **A.** Yes.

5 **Q.** So you are talking here about the UK licensing
6 authority, essentially the medicines division of the
7 Department of Health, is that really what you have in
8 mind here?

9 **A.** Yes, the Medicines Control Agency, yes.

10 **Q.** Yes. I'm not sure it was called that then, but in
11 any -- it may have been.

12 **A.** I think it was.

13 **Q.** You may well be right. You are talking about, in any
14 event, something coming from the medicines division or
15 from the Committee on Safety of Medicines or the
16 Biological Subcommittee, some manifestation of the
17 licensing authorities?

18 **A.** Yes.

19 **Q.** Other than through the process of submitting licence
20 applications and having them approved, which would
21 have involved, obviously, a degree of dialogue with
22 the licensing authority -- and we have seen you would
23 submit your proposed draft leaflet package insert to
24 the licensing authority. So that was obviously one
25 means whereby the licensing authority could give you

49

1 issued a warning, perhaps to all manufacturers, to
2 either keep an eye out for a particular new adverse
3 event or if there was a requirement to change the
4 specification of a product as a result of clinical
5 experience, then, yes, they would have put out
6 warnings or notifications and so on. I can't remember
7 the detail of how it happened but it was -- I think
8 there almost certainly was a formal system for
9 maintaining an open dialogue between the regulatory
10 authorities, the licensing authority, and the licence
11 holders.

12 **Q.** In any event, is this right, that there was neither an
13 approach by PFC to the licensing authority for advice
14 nor anything issued by the licensing authority to PFC
15 or anyone else, to your knowledge, about it?

16 **A.** I can't remember. I can't remember any such approach.

17 **Q.** The second point you make in this part of your --

18 **A.** Sorry. I would say that Mr Watt regularly attended
19 meetings of the licensing authority on the Biological
20 Subcommittee and there would have been opportunity at
21 those meetings for him to discuss these issues with
22 the secretariat of the Biological Subcommittee. But
23 I have no record of him coming back and saying this is
24 a topic which has emerged in discussion.

25 **Q.** Do you mean informal opportunities?

51

1 its views.

2 **A.** Yes.

3 **Q.** But that would only happen at application or renewal
4 time. Was there -- did the licensing authority issue
5 advice or requirements other than during the licence
6 application process?

7 **A.** If there was a key development for any pharmaceutical
8 that required them to provide an update or a revision,
9 then they would have done that spontaneously. But
10 they also -- if there had been an approach to the
11 licensing authority, they would have responded, an
12 approach by a manufacturer. For instance, it wanted
13 to change its leaflet or it wanted to change its
14 packaging or it wanted to change risk warnings, as
15 you've discussed, then I think there was a mechanism
16 for dialogue between manufacturers and the licensing
17 authority.

18 **Q.** We know that no such approach was made by PFC, so my
19 question was more really did the licensing authority
20 proactively issue advice outside of dialogue with an
21 individual manufacturer?

22 **A.** Generic guidance or industry --

23 **Q.** Generic guidance or advice in the early '80s?

24 **A.** I can't remember. If there was a particular risk
25 arising from a particular drug, then it would have

50

1 **A.** Informal opportunities, yes.

2 **Q.** The second bullet point is this:

3 "In contrast to products imported from the USA prior
4 to October '84, there was no evidence that products
5 manufactured from UK plasma had transmitted HTLV-III."

6 Now, I just wanted to explore with you whether
7 you maintain that was a sufficient reason or a good
8 reason not to include any warnings on PFC products.
9 If you wait until a UK product has transmitted
10 HTLV-III, isn't that rather too late?

11 **A.** I understand the question. But, again, in terms of
12 the formal documentation that went out with our
13 products, as I have said before, I think as far as the
14 very formal and limited information that we provided
15 with the products, and the requirement to get
16 regulatory approval for that, there would have been at
17 least disquiet that we were issuing a warning for
18 which there was no evidence. But we didn't test that
19 in practice.

20 **Q.** The next bullet point is:

21 "Prior to 1984 no consensus on the causal
22 relationship between AIDS and treatment with
23 coagulation factor products."

24 Is that essentially this -- is that a different
25 point to the point you've already made?

52

- 1 A. No, I think it's slightly different. I think it's an
2 arguable statement. I would acknowledge, and I think
3 many would say, that there was consensus on the causal
4 relationship but there were legitimate scientists and
5 experts expressing slightly different views at that
6 time.
- 7 Q. Do you need a consensus in order to be able to include
8 a warning if you, as the manufacturer, believe that
9 the risk is real?
- 10 A. Well, the only way the manufacturer knows whether the
11 risk is real is by talking to the people that
12 prescribed the products because that's where the
13 information comes back from and so, in terms of its
14 routine scanning of the environment in which it
15 operates, it can only get the information that it
16 needs to make statements from the people that are
17 using the products and the publications that they
18 make. So I'm not sure whether that answers the
19 question.
- 20 Q. Well, that may be a matter for the Chair. But that
21 leads to the next point, which is, you say:
22 "PFC and NBTS received no request or advice from
23 haemophilia directors to receive such warning."
24 So just pausing there, I certainly think we've
25 seen no evidence of that; so you may be right. But

53

- 1 communicated to individual patients. And that was
2 a clear view.
- 3 **SIR BRIAN LANGSTAFF:** Can you help me with this,
4 particularly the reference that you've just made to
5 what Professor Cash may have thought.
6 A few minutes ago we were talking about
7 Professor Cash having had a conversation in which he
8 was suggesting there might be a warning in respect of
9 AIDS to SNBTS and clinicians, who were persuading him
10 that he shouldn't do so, not because there were no
11 risks or because a warning might not in itself be
12 justified, but because it might cause unnecessary
13 distress or anxiety amongst the patients who might be
14 receiving it.
- 15 A. Yes.
- 16 **SIR BRIAN LANGSTAFF:** How does that fit with what you're
17 saying here?
- 18 A. If I understand the question correctly, I think what
19 I'm saying here is that this is an example of the
20 clear demarcation which existed between the SNBTS and
21 those that prescribed our products and Professor Cash
22 was always emphasising the importance of not -- of the
23 SNBTS, as a manufacturer, not trying to influence
24 product use and so on. So I'm not sure I'm answering
25 your question, sir.

55

- 1 you then say this:
2 "It is highly unlikely that PFC would have included
3 AIDS warnings without their express agreement and
4 support."
5 A. That's right.
6 Q. Why was the agreement and support of the treating
7 clinicians a prerequisite to putting information on
8 a product?
9 A. Because they -- I think there was an understandable
10 sensitivity in this area. Well, it was an
11 extraordinarily difficult period of time in which
12 everyone operated, and I think we may well have
13 discussed with haemophilia doctors whether we wanted
14 to -- whether we should put more explicit warnings and
15 I think the feedback that we got was that their
16 preference was to be cautious.
17 I think certainly our view and Professor Cash's
18 view would have been that it's no business of the
19 manufacturer and the supplier to provide such direct
20 warnings. Those sort of nuanced discussions, which
21 are not absolutely clear, was the business of the
22 doctor that's treating the patients, and our job was
23 to provide as much information to the prescribing
24 doctor and it is then for the doctor to prescribe what
25 is known and what is best communicated and not

54

- 1 But the emphasis for the PFC and for the wider
2 SNBTS through its medical colleagues, Dr Boulton and
3 Professor Cash and others, was to provide the best
4 possible information we could to the haemophilia
5 directors. One of the advantages of the SNBTS system
6 of manufacture and supply is that it was a very
7 collegiate group of people involving Regional
8 Transfusion Centres, PFC as the operational
9 manufacturing unit, and haemophilia doctors, and
10 I think many of these discussions about developments
11 certainly in the early and mid-80s, leading up to and
12 during these terrible events, were always conducted
13 collegiately.
14 So there would be an instinctive tendency in
15 SNBTS to consult with haemophilia doctors so that they
16 could judge whether, if the manufacturer put out
17 a warning, a formal warning, on a particular product,
18 whether the haemophilia directors would be able to
19 support that or whether that would be consistent with
20 the information they wanted to give to their patients.
- 21 Q. The reference to a concern about causing distress or
22 anxiety, about there being a lot of sensitivity about
23 this issue, I think it is picked up in the next bullet
24 point where you say:
25 "There would need to be some measure of evidence

56

1 a genuine risk existed. It would be inappropriate for
2 a manufacturer to provide warnings which could cause
3 anxiety and alarm to patients and which might cause
4 patients to reject life-saving treatment."

5 Would it be right to understand the evidence
6 that you've given over the last few minutes and what
7 we see reflected here as indicating that the message
8 that was coming back to PFC or SNBTS from the
9 haemophilia clinicians in Scotland was a message of
10 "we don't want patients to be alarmed, we don't want
11 patients to be caused anxiety, we don't want patients
12 to be put off from accepting factor concentrates"?

13 A. I don't think I can say that that was their position.

14 Q. Was that the PFC's perception?

15 A. The PFC's perception was that it was our job and our
16 duty to consult with haemophilia directors, which we
17 did on a whole range of issues, and this was one of
18 them and we would accept the advice and the feedback
19 that we got, unless it contravened a particular
20 regulatory requirement.

21 And there are other -- I don't think this was
22 just a feature of SNBTS or Scotland. There are
23 a number of examples throughout the world where there
24 was a late reference to HTLV-III and AIDS in package
25 inserts. The most striking example that I've seen

57

1 as you have suggested it might have been. But there
2 was no absence of discussion and there were certainly
3 alarm bells ringing throughout this period. They were
4 very loud and they were very persistent. But I can
5 only repeat what I've said, that we did -- we
6 consulted on this, we asked for their views and their
7 feedback. Perhaps it is an issue that haemophilia
8 doctors need to respond on how they were managing that
9 important interface with their patients.

10 Q. They certainly have been asked those questions,
11 Dr Perry.

12 Just the last, then, question on this point.
13 I'm conscious we have gone into a time that would
14 normally be for a break.

15 It might be said that there is something
16 profoundly paternalistic about a system which says: we
17 are not going to include information about a potential
18 risk of a fatal virus because we don't want to cause
19 alarm and anxiety.

20 Do you have any comment on that?

21 A. Well, only -- I'm not a medical doctor, I had no
22 direct dealings with patients in terms of their
23 treatment. And I think, by today's standards, it was
24 as you describe it: it was a much more paternalistic
25 system and the actions and inactions at that time were

59

1 recently, or certainly reminded myself about recently,
2 was the products that were supplied to Canada, where
3 commercial manufacturers in -- they obtained their
4 supplies of product from commercial suppliers from the
5 US, and I think at some stage the commercial products
6 did include perhaps AIDS warnings, but the Canadian
7 authorities, who were supplying plasma for
8 fractionation on a contract basis to America, said,
9 "We don't want to include that warning". Now, I'm not
10 saying that's the right outcome. But it's another
11 example of this difficult area of what the
12 manufacturer should say to the user of its products.

13 Q. It might be said, Dr Perry, that if the feeling that
14 is coming from the Haemophilia Centre Directors is,
15 "We don't want to cause undue anxiety to our patients
16 by having some reference to AIDS on the products",
17 that that should be ringing alarm bells for SNBTS and
18 PFC that information about AIDS is not being passed on
19 in practice to patients, which might reinforce the
20 importance of you, as a manufacturer, setting it out
21 when you release your product, because you can't have
22 the confidence that the clinicians are actually, in
23 their real life discussions with patients, providing
24 that information?

25 A. Well, yes. And as I have described, the outcome isn't

58

1 quite different to those that you would expect today.

2 I'm not sure if -- god forbid -- another virus
3 should enter the blood supply that there wouldn't be
4 similar considerations, about: how sure we are of
5 this? Do we know what the clinical outcome of this
6 is? Do we know what the long-term sequelae are to the
7 infections with this product? They are always
8 difficult decisions. And I think, in that
9 environment, the PFC, as a manufacturer of the
10 products, put out the best information that it thought
11 it was justified in doing.

12 MS RICHARDS: Sir, that completes my questioning on this
13 topic, and I'm conscious I have gone 15 minutes over,
14 into what would normally be everybody's break. So
15 perhaps we could take the break now.

16 SIR BRIAN LANGSTAFF: Yes. It was just quite right that
17 you should do so. We will take a break now until
18 12 o'clock. 12 o'clock.

19 (11.30 am)

(A short break)

21 (12.00 pm)

22 MS RICHARDS: Dr Perry, I'm going to ask you to look at
23 a different aspect now of the evidence you gave to the
24 Penrose Inquiry.

25 PRSE0001258, please, Sully, page 3.

60

1 So this is part of -- one of your statements on
2 the topic of viral inactivation '85 to '87. Can
3 I just pick up what you say on this page. At the top
4 of the page:

5 "When it became known in 1984 that coagulation
6 factor concentrates were implicated in transmission of
7 HIV ... the SNBTS and Haemophilia Centre Directors'
8 strategy to protect patients from infection with HIV
9 included the following key elements ..."

10 You then set out three key elements. The first
11 was:

12 "[Avoiding] the need to import commercial
13 products through the already established programme to
14 achieve and maintain 'self sufficiency'."

15 So that is essentially a continuation of what
16 you were already doing?

17 **A.** Yes.

18 **Q.** The second was:

19 "... rapid and progressive development of
20 manufacturing processes capable of inactivating HIV
21 following the announcement that HIV could be
22 inactivated by heat treatment."

23 I will come on to that in a little while. Then
24 the third key element was:

25 "The development and implementation of a system of

61

1 Health Service Haemophilia Centre/Transfusion Service
2 Directors' Meeting. February 1984". So prepared by
3 him in anticipation of the meeting that was going to
4 take place the following month.

5 **A.** The annual meeting, yes, of that group.

6 **Q.** Do you know, was that Dr Cash's practice, to prepare
7 something in advance of the meeting --

8 **A.** Yes, he would always prepare a -- a briefing document,
9 effectively, and also raising issues that he thought
10 were important. So that was his practice, yes.

11 **Q.** And so if we can go on to page 4, under the heading
12 "AIDS", so bottom half of the page.

13 He refers, first of all, to the introduction of
14 the leaflet for donors, and then he says this:

15 "Clinical colleagues' attention is drawn to
16 a leading article, published in the BMJ ... by
17 Dr Peter Jones ... Dr Jones concludes ... 'For the
18 moment, however, it seems sensible to treat very young
19 severely affected children with cryoprecipitate rather
20 than concentrates'. The SNBTS Directors would welcome
21 comments on this proposal."

22 Then the next paragraph:

23 "It is noted that cryoprecipitate is no longer
24 issued for haemophilia care at the Inverness and
25 Aberdeen Centres and the size of current intermediate

63

1 'batch dedication' to reduce the exposure of patients to
2 multiple batches ... Introduced in early 1985 ..."

3 Again, I will come on to that in a little more
4 detail in a little while.

5 If we go back to the whole paragraph, please,
6 Sully.

7 Now, it is right to say you were describing this
8 as a strategy that included those key elements. You
9 weren't suggesting this was the only thing that was
10 under contemplation. But is it right to understand
11 that the strategy within Scotland to protect patients
12 from infection with HIV did not include a reversion to
13 cryoprecipitate?

14 **A.** I don't recall there being -- from my perspective at
15 least, I don't recall there being a significant
16 reversion to the use of cryoprecipitate. I think it
17 would almost certainly have been discussed at various
18 levels and at various times but I don't think that
19 actually occurred.

20 **Q.** I then just want to show you I think three documents
21 where there is a discussion in the course of 1984 of
22 the issue and invite your perspective. The first is
23 PRSE0004741.

24 Now, these are notes prepared in January 1984 by
25 Dr Cash, and we can see they are notes for "Scottish

62

1 stocks would normally lead to the consideration with the
2 SNBTS of the introduction of similar practices in other
3 regions."

4 Now, just if I may try and unpick that with you,
5 obviously the paragraph referring to Dr Jones is
6 self-evident and as I understand it, but Dr Cash is
7 inviting the views of SNBTS directors on the proposal
8 of cryoprecipitate for children.

9 **A.** And haemophilia directors.

10 **Q.** Yes. Then there is reference to two of the centres no
11 longer issuing cryoprecipitate, one assumes at all.
12 But it is that last part of the second -- of that last
13 paragraph that I wanted your help with. "The size of
14 current intermediate stocks", is that a reference to
15 the volume of intermediate purity factor concentrate
16 that's been built up?

17 **A.** I'm not with you.

18 **Q.** It is the paragraph --

19 **A.** The last paragraph in the AIDS --

20 **Q.** Yes, sorry, Dr Perry.

21 **A.** I can only try to construct a view on what
22 Professor Cash meant by that. I think what he is
23 actually signaling is that there are large stocks of
24 intermediate -- I'm not sure whether -- what the
25 stocks he is talking about actually:

64

1 "... the size of current intermediate stocks
2 would normally lead to the consideration with the
3 SNBTS of the introduction of similar practices in
4 other regions."

5 I'm not sure I can help you. I was going to say
6 that he was making the point that we have high stocks
7 of a Factor VIII concentrate, which in normal
8 circumstances would lead to a discontinued use of
9 cryoprecipitate --

10 Q. That's what I wondered --

11 A. -- but I'm not sure he is saying that, because you
12 wouldn't describe the stock of Factor VIII
13 concentrates, national stocks of Factor VIII
14 concentrates, as "current intermediate stocks". That
15 would be a curious way of expressing it.

16 Q. If we go over two pages then. If we look at the
17 bottom half of the page you will see the heading
18 "Limitation of batch exposure to individual patients".
19 I'm not going to read through the detail of that, but
20 if we look just at the very bottom of the page he
21 says:

22 "It is suggested to Directors that in view of the
23 current significant national reserves of SNBTS
24 intermediate factor VIII ..."

25 Top of the next page:

65

1 which was:

2 "Members discussed the suggestion that the
3 production of cryoprecipitate could now be reduced.
4 Dr Ludlam said that cryoprecipitate was preferred in the
5 treatment of children at present, because of the new
6 danger of AIDS. Dr Hann concurred. A policy seemed to
7 be emerging however to use less cryo for haemophilia A
8 patients. It was agreed that a certain minimal amount
9 of cryo was required and Dr Cash pointed out that TDs
10 [Transfusion Directors I assume] could produce it in
11 emergencies."

12 Dr Foster told us his recollection of the
13 discussion about cryoprecipitate at that meeting. Do
14 you have any recollection of the discussion and what
15 the views were that were being expressed or what
16 Dr Cash's position was?

17 A. I don't have any recollection from my memory. I can
18 only interpret what is probably meant here, and it
19 seems to me that what was agreed was that there was
20 clearly an ongoing need for cryoprecipitate for
21 treatment of some groups of patients, but it wasn't
22 signaling a large increase, for example. But
23 Professor Cash also made the point that if there was
24 a large increase in the need for cryoprecipitate for
25 children or other groups of patients then it can be

67

1 "... that the time is opportune to direct efforts
2 towards reducing the number of batch exposures per
3 patient per year."

4 Is that Dr Cash, in January 1984, identifying
5 the possibility of having a batch dedication system or
6 policy introduced?

7 A. Yes, I think so. I think he wrote to -- as we saw
8 yesterday, he wrote a letter to regional transfusion
9 centre directors in late 1983 asking for updated
10 information on product stocks but also their views and
11 ideas on a batch dedication type of system. So, yes.
12 He was reiterating that here.

13 Q. If we then move to the actual meeting for which the
14 document was prepared.

15 PRSE0001556, please.

16 So we can see it is meetings of directors of
17 SNBTS and Haemophilia Directors, 2 February 1984. We
18 can see that you were present.

19 If we go over the page, point 5 is headed
20 "Review paper from SNBTS", and there's reference to
21 Dr Cash introducing the paper he had prepared, which
22 I take is a reference to the document we've just
23 looked at?

24 A. Yes.

25 Q. Then, we see the discussion on cryoprecipitate at (ii)

66

1 produced at relatively short notice.

2 Q. Then just still on the topic of cryoprecipitate, if we
3 can go to SBTS0000615_042, please.

4 Now, this is a few days later in 1984,
5 7 February, and it is a special meeting of the
6 coordinating group.

7 Can you just remind us what the coordinating
8 group was?

9 A. I think the title of the meeting, which was
10 established in the late 1970s -- or in the 1970s under
11 Dr Cash's predecessor, and its role was -- it
12 reflected the fact that he was not in charge but he
13 had a specific role to coordinate the activities of
14 the individual operation centres within the SNBTS. So
15 this was a meeting -- I think it was held every three
16 months or maybe more frequently -- for general
17 discussion of topics that were important to the SNBTS.

18 Q. We can pick up the discussion on AIDS at page 4 of the
19 minutes. Towards the bottom of the page we have the
20 heading "AIDS". There is a reference to a report
21 being circulated by Dr McClelland and then a number of
22 matters being agreed. The first that Dr Cash will
23 write recommending a single UK working group, with
24 Scottish representation. The second refers to
25 revisions to the donor leaflet.

68

1 If we go over the page to the top of the next
 2 page, please. If we just zoom in on the top half of
 3 the page, thanks, we don't need to zoom in any
 4 further.

5 There is then a reference to donor screening
 6 studies, a plasma processing policy, auto transfusion.
 7 Then this at (f):
 8 "Small pool [Factor] VIII
 9 "It was noted that small pool freeze dried
 10 [cryoprecipitate] for haemophilia therapy may have to be
 11 reassessed."

12 Just before we look at the next sentence, is it
 13 right to understand that's referring to the type of
 14 cryoprecipitate that had been manufactured in that
 15 project at the Law Hospital?
 16 **A.** In the west of Scotland, yes.
 17 **Q.** Which had then been abandoned --
 18 **A.** That's my understanding.
 19 **Q.** Then it says:
 20 "Dr Perry said he could manufacture such a product
 21 (given the appropriate resources)."
 22 **A.** Yes.
 23 **Q.** Can you recall anything further about that discussion
 24 and assist us in understanding what the appropriate
 25 resources would have been?

69

1 recollection of the first time I heard this was on --
 2 which may be wrong, because I think there is some
 3 evidence, though not conclusive, that it was known
 4 before this date -- but my recollection is that
 5 I learnt about this for the first time on my return
 6 from the meeting in Groningen, the conference in
 7 Groningen, on 5 November. But it may have been
 8 because the very early information that came
 9 through -- that Dr Foster has described, and he has
 10 a good memory of things, and he has kept scrupulous
 11 diaries -- is that the earliest information that the
 12 PFC might have known about it was as a result of
 13 a telephone call to Dr Cuthbertson. But that may have
 14 been about the very earliest reports of three patients
 15 having what he thought -- which may have -- three
 16 patients who may have antibodies to HTLV-III.
 17 But I think at that stage, for those three
 18 patients, Professor Ludlam was looking for
 19 a confirmation of that because the assays that were
 20 being used were research assays. They weren't
 21 established, fully validated assays. So I think he --
 22 he wanted -- but my memory is that the first time
 23 I heard about it was when I returned from the
 24 Groningen conference.
 25 **Q.** Whatever the precise date, can you remember your

71

1 **A.** I think I was simply signaling if that's what the
 2 service required, ie the haemophilia directors, if
 3 a decision -- by that stage I thought the discussion
 4 about freeze-dried cryoprecipitate was finished and
 5 the idea of producing it had been discontinued in
 6 1983. I think I was simply signaling that if there is
 7 a reversal of that decision and there is a clinical
 8 consensus that we would need freeze-dried
 9 cryoprecipitate as a treatment option, then the PFC
 10 could produce that product but it would need, as
 11 I described yesterday, quite extensive re-configuring
 12 of the production facilities at PFC.
 13 **Q.** Is it right to understand that this idea was never
 14 taken any further?
 15 **A.** I'm not aware of freeze-dried cryoprecipitate emerging
 16 as a product from SNBTS.
 17 **Q.** Can I then move to later in 1984 and the discovery of
 18 HTLV-III seroconversion in a group of Dr Ludlam's
 19 patients.
 20 We can take the document down, Sully, thank you.
 21 What's your best recollection of how and when
 22 you learnt of the first news that a PFC product may
 23 have transmitted HIV?
 24 **A.** Well, clearly, this was a major and devastating event
 25 for SNBTS, and obviously for patients. My

70

1 reaction and the reaction within PFC?
 2 **A.** Difficult to describe it actually. It was a very
 3 shocking and devastating news. Not shock in terms of
 4 a major surprise (how could this ever have happened?)
 5 but it had a profound impact throughout the centre and
 6 that that point forward there was very little
 7 discussed in PFC other than its programme of work to
 8 actually deal with this.
 9 **Q.** Would it be right to understand that in a sense it was
 10 not unexpected? I think Dr Foster had told us or we
 11 looked at some evidence Dr Foster had given to the
 12 Lindsay Tribunal reflecting the idea it was really
 13 only a matter of time. Do you remember that being the
 14 sense at the time?
 15 **A.** I think that was a perfectly legitimate view and
 16 probably a view that I held myself. There was another
 17 view that the epidemiology of HTLV-III was still
 18 focused and concentrated in the United States and
 19 maybe it was more a hope than an evidence-based
 20 conclusion but that it had yet to enter in any
 21 significant way into the UK blood supply.
 22 **Q.** Do you remember how and when you learnt of the
 23 possible -- any similar events having taken place in
 24 England?
 25 **A.** No.

72

1 Q. If we just go then, just to pick up on a handful of
2 dates to PRSE0000828, please, Sully.
3 This is a memo that Dr McClelland wrote to you,
4 20 November 1984, setting out events leading up to the
5 recall of Factor VIII batch 023110090.

6 A. Yes.

7 Q. We can just see some of the staging posts along the
8 way to the decision in principle to recall. So
9 paragraph 1 refers to Dr Ludlam phoning Dr McClelland
10 in the evening of 26 October, reporting six
11 haemophilic patients having developed antibody to
12 HTLV-III, three of whom he thought could be
13 attributable to PFC products.

14 Sorry, Sully, could we have the whole section on
15 the screen. It's slightly easier, thank you.

16 Point 2 refers to Dr McClelland just reporting
17 that to Dr Cash on the Saturday. It says:

18 "We were both agreed that the information was
19 insufficient to require any recall of PFC products."

20 Now, I appreciate that Dr Cash obviously was the
21 overall director of SNBTS, but there doesn't appear to
22 be recorded there any communication with you or with
23 Dr Cuthbertson or anyone else directly at PFC at that
24 early stage. Is that your recollection as well?

25 A. That's my recollection. I think that's right. At

73

1 know of the action that had been taken.

2 Do you know, would that have been Dr Cuthbertson
3 at that stage?

4 A. I think that would have been Dr Cuthbertson.

5 Q. Were you in Groningen at that time?

6 A. I was in Groningen at that time, yes. Well, that's my
7 recollection. I was certainly at the meeting, so
8 I would have been in Groningen.

9 Q. So it's just over a week from Dr Ludlam first
10 contacting Dr McClelland to Dr Boulton and
11 Dr McClelland notifying the Regional Transfusion
12 Centres that that particular batch should be recalled.

13 Did you think it was, from your perspective as
14 director of the PFC, that that was done quickly enough
15 or whether it could have been done any quicker?

16 A. The only delay that was injected into the overall
17 timescale from the initial results was the need to
18 analyse effectively manually, because there were no
19 computers around at that time, the batch to try and
20 identify which patients had received what batches and
21 then come to a conclusion as to which might be the
22 implicated batches because there were many, many
23 batches that had been used to treat those patients.
24 And that would clearly take, yes, a matter of days to
25 collect the data from patient records and so on.

75

1 that stage all that was known was that were three
2 patients that had produced this positive result in
3 a research HTLV-III assay run by Dr Tedder and I don't
4 think PFC had any further information. At that stage,
5 the analysis of the batch consumption hadn't been
6 done, so there was actually -- there was no idea which
7 batches might be implicated. That work was carried on
8 over the weekend and on 29th and 30th October,
9 I think.

10 Q. We can then see on the Friday of 2 November
11 (so essentially a week later) there's a reference to
12 Dr Ludlam telephoning Dr McClelland at home, having
13 received further data from Dr Tedder, and
14 Dr McClelland records that:

15 "An initial look at these data indicated that
16 either 15 or 16 of these patients had received the
17 above batch."

18 Then paragraph 5 says "October 3rd". I think
19 someone has written: "I am sure this should be
20 November!", so I'll assume that's right, I think.
21 November 3 records Dr Boulton and Dr McClelland
22 contacting all the Scottish transfusion centres and
23 the Northern Ireland transfusion centre to notify them
24 "that the above batch should be immediately recalled".
25 Also contacting the duty officer at the PFC to let him

74

1 Q. If we then go to LOTH0000005_052, please. This is
2 a letter from Dr McClelland on 15 November 1984 to
3 Dr Cash. The first paragraph says:

4 "I have had several discussions with Dr Christopher
5 Ludlam following the discovery that some recipients of
6 PFC Factor VIII have developed antibodies to HTLVIII ...
7 which must at present be attributed to infusions of PFC
8 product. I spent several hours this morning with
9 Dr Ludlam and Dr Perry ... reviewing the data and write
10 now to report to you, as National Medical Director on
11 our conclusions."

12 Can you recall that meeting and what the process
13 was that was being undertaken?

14 A. What was the date of this letter?

15 Q. 15 November.

16 A. 15 November. I think it was a meeting with Dr Ludlam,
17 myself and Dr McClelland really just going over again
18 the -- I have a faint memory and recollection of
19 sitting down and examining not the individual patient
20 records, but an analysis of the patient exposures to
21 different batches and the rationale for concluding
22 that it was batch 3-009 which was the most likely
23 candidate batch that had transmitted HTLV-III.

24 Q. We can see from the third paragraph the analysis had
25 been that all but one of the patients had received

76

1 that batch. There's then a description of looking at
2 batches received -- sorry -- yes, batches received
3 by -- other batches received by the patients.

4 **A.** Yes.

5 **Q.** If we go over the page, just picking it up below the
6 paragraph numbered 6, it refers to one patient who
7 didn't receive the implicated batch and was not known
8 to have other risk factors.

9 Now, obviously we're not going to say anything
10 which potentially identifies any individual patient
11 and you, I suspect, probably wouldn't have that
12 information to hand anyway.

13 **A.** Of course.

14 **Q.** It is right, isn't it, I think, that it was never
15 established how that one patient who hadn't received
16 that batch had been infected?

17 **A.** I'm not absolutely clear on the final outcome. What
18 I do know is in subsequent analysis of data, there was
19 found to be a total of 18 patients in Scotland.

20 **Q.** Yes.

21 **A.** And I think our conclusion from the analysis that was
22 done by Dr Cuthbertson and others of the detailed
23 information we had was that there were probably three
24 batches that had -- that could be described as being
25 suspect for the transmission of HTLV-III.

77

1 **A.** I can't describe the details of the process other than
2 to say that when we initiated the recall or we
3 instructed the Regional Transfusion Centres, they were
4 already aware of this issue, of course, and the
5 instruction was to recall product held in the Regional
6 Transfusion Centres, to recall product that may have
7 been held in haematology departments or haemophilia
8 directors or in haemophilia centres and also from
9 patients' home stocks as well. So it was an in-depth
10 recall.

11 **Q.** Was it a formal product recall or was it essentially
12 a product exchange programme whereby people were asked
13 to bring in such stocks that they had? I'm thinking
14 in terms of the patients here. Sorry, I should have
15 made that --

16 **A.** I hope I've not lost the thread here. Are we talking
17 about the recall of batch 3-009?

18 **Q.** No, I'm sorry --

19 **A.** Oh, you're talking about the exchange of --

20 **Q.** Yes.

21 **A.** I'm sorry.

22 **Q.** We'll leave aside that batch because you're absolutely
23 right as to what happened in relation to that batch.
24 Edinburgh had used up all of it, as I understand the
25 position. Aberdeen had not. There was a formal

79

1 I don't think any of those three still account
2 for the sixteenth patient in that patient cohort.

3 **Q.** So potentially there may have been a fourth batch
4 but --

5 **A.** There may have been a fourth batch, yes, or a ...

6 **Q.** At this point in time there were no other batches that
7 were withdrawn?

8 **A.** No, it was only batch 3-009.

9 **Q.** We can take that down.

10 **A.** Well, batch 3-009 had been consumed. It had all been
11 used up in Edinburgh, and there were about 40 or
12 45 vials left in Aberdeen.

13 **Q.** Yes.

14 **A.** So the only physical material that came back was from
15 Aberdeen.

16 **Q.** Was the Aberdeen.

17 Now, we know that from your evidence and the
18 evidence of others that what happened over the
19 following weeks was a process of heating, dry heating,
20 the stock of Factor VIII concentrates that the PFC had
21 built up with a view to issuing that then to patients
22 from, I think, late -- from a date in December 1984?

23 **A.** 10 December.

24 **Q.** Can you recall what the process was for receiving back
25 in from centres or patients unheated concentrate?

78

1 recall of the remaining vials from Aberdeen.

2 No, I'm talking about what happened in order to
3 give effect to the decision to now issue only heated
4 product.

5 **A.** Yes, I understand.

6 **Q.** What was the process that was undertaken to try and
7 get back as much unheated product and replace it with
8 heated product?

9 **A.** Well, it was not -- in all practical respects. It was
10 a recall but we described it as a "product exchange"
11 because recalls are usually associated with a known
12 defect or a known issue and so on and, other than the
13 batch that we recalled, there was no reason to suspect
14 these other batches or the rest of the stock.

15 So we called it or we have subsequently
16 described it more as a product exchange and the
17 process was very similar to that which we used for any
18 recall, except on this occasion we once again drilled
19 down into the detail of the supply chain and, as far
20 as I recall, the instruction was that, coordinated by
21 Regional Transfusion Centre staff because they were
22 responsible for distribution, they should recover
23 stocks from Haemophilia Centres, haematology, any
24 stock, any place where the product was stocked and
25 also from the stocks held by patients in their homes.

80

- 1 **Q.** So in terms of the process of getting any stocks held
2 by patients in their homes, do you know whether that
3 was coordinated or was it intended to be coordinated
4 by the transfusion centres or by the haemophilia
5 centres?
6 **A.** Well, it would have been coordinated by the
7 transfusion centres but they would have clearly
8 corresponded or discussed the requirements with the
9 haemophilia directors and it would be for the
10 haemophilia directors then to speak to their
11 individual patients. To the best of my knowledge,
12 that process worked perfectly well. We didn't get
13 any, for instance, late returns of product that should
14 have been sent back.
15 The intention -- the system was set up so that
16 by 10 December every patient in Scotland and
17 Northern Ireland should have access to heat-treated
18 Factor VIII and, to the best of my knowledge, that was
19 achieved.
20 **Q.** Can we then just look at --
21 **A.** Sorry, I've slightly misled you. The recall that I've
22 described didn't take place until January.
23 **Q.** That makes a little more sense.
24 **A.** Clearly you can't do the two things simultaneously;
25 you can't fully recall and issue new stock at the same

81

- 1 any recollection of this:
2 "Views were exchanged on the very difficult ethical
3 problems which had arisen. These included whether
4 patients and patients' relatives should be informed and
5 perhaps subjected to needless worry; whether publicity
6 additional to that already provided should be given, and
7 how directors should respond to direct enquiries or
8 requests for advice. The chairman advised members that
9 ministers had been informed and that SIO had been
10 briefed. While a press statement would not be issued by
11 the Department at present any enquiries would be
12 answered. It was agreed that every effort should be
13 made for patients to have the situation explained to
14 them before the impending publicity."
15 Now, I'm not suggesting that informing patients
16 was the responsibility of PFC, Dr Perry, but you were
17 present at this meeting and it appears to be suggested
18 that there was some question mark over whether
19 patients and their relatives should be told or not,
20 and this was described as a very difficult ethical
21 problem. It might be thought fairly obvious that they
22 should be told. Do you have any reflection or any
23 recollection of that discussion?
24 **A.** I don't have a detailed recollection. My focus and
25 emphasis at the time, and probably during this

83

- 1 time. It would have been too confusing. So we put
2 a hold on all use of -- the first step was to issue
3 product that had been heat treated to every centre in
4 Scotland so that that could be distributed throughout
5 the centres and, where necessary, to patients' homes.
6 When that was complete and we'd built up further
7 stocks of heat-treated products, we then did the
8 formal recall in early January.
9 **Q.** Can we then just look at one further meeting at this
10 time which is PRSE0002066.
11 So this is a meeting of haemophilia directors
12 and SNBTS directors, 29 November '84. You were
13 present. We can see from paragraph 2 the purpose of
14 the meeting:
15 "... convened to discuss the implications of the
16 recent finding of HTLV III antibodies in Scottish
17 haemophiliacs ..."
18 Then, if we go over the page, there is an update
19 in paragraph 6 from you of what's being done by PFC in
20 terms of heat treatment. And it is explained that the
21 measure that was being implemented in terms of heat
22 treatment of existing stocks at 68 degrees for
23 two hours.
24 If we then go further down the page, I just
25 wanted to pick up on paragraph 8 and whether you have

82

- 1 meeting, was making sure I clearly communicated what
2 the PFC was doing in its response. I think I would
3 have regarded this very much the business of
4 haemophilia directors in describing the issues that
5 arises in terms of their conversations with patients.
6 And I would have noted it, I would have understood it,
7 I would have understood their concerns, but I would
8 not have had any further input into that particular
9 decision.
10 **Q.** We know a meeting took place, a group meeting, at the
11 Edinburgh Royal Infirmary in December. We heard
12 evidence about that from Dr Ludlam and from attendees
13 at the meeting. Were you present at that meeting?
14 **A.** No, I wasn't. Dr McClelland, from South East Scotland
15 BTS, and I think the haemophilia director from Glasgow
16 also attended. I think that was Dr Forbes at that
17 time.
18 **Q.** But you did not?
19 **A.** I didn't attend it, no.
20 **Q.** Then I won't ask you anything further in relation to
21 that.
22 Can I just ask you to look then at one document
23 from the evidence submitted to Penrose.
24 PRSE0002801, please.
25 I'm not proposing to go through the detail of

84

1 this. It is a report describing actions surrounding
 2 batch 3-009. If we go to page 5.
 3 We will see that there is a fairly detailed
 4 narrative of the actions taken. Over the page.
 5 There's then a description of the history of this
 6 particular batch, when it was manufactured and so on.
 7 I'm not going to ask you about the detail of
 8 that because we have got it set out in the report.
 9 But there's just one passage I wanted to ask you
 10 about, if we go to page 10. It is this, under the
 11 heading "Introduction of Heat Treatment", it says
 12 this:
 13 "It should be noted that the finding of HIV
 14 infection in Scottish haemophiliacs was unexpected,
 15 since until that time, the belief was that the
 16 infection was largely confined to donors in the USA."
 17 I don't know whether you were an author or
 18 co-author of this particular paper, Dr Perry, but if
 19 I can perhaps ask you more generally, do you agree
 20 with that sentence that it was unexpected?
 21 **A.** I didn't author this paper, although I think I was
 22 involved and I had input into it. It is probably not
 23 the word I would use now. I think it was perhaps (and
 24 Dr Foster has explained and, to an extent, I would
 25 agree with him) that it was just a matter of time.

85

1 Donor selection.
 2 But I'm afraid I can't recall any specific
 3 issues. I think at that stage it was -- although what
 4 you have described as the potential risk factors of
 5 drug use and so on and it being a fairly international
 6 city, at least for one month in the year, I think the
 7 general view was that we simply didn't know the nature
 8 of the epidemiology of HIV at that time. There were
 9 no assays. The diagnosis was only available through
 10 patients presenting with clear signs of AIDS.
 11 **Q.** Then just going briefly back to the implicated batch
 12 from the autumn of 1984, is this right, that it was
 13 possible to identify from records all the donors who
 14 had contributed to that batch, which was I think
 15 approximately 4,000?
 16 **A.** About 4,000, yes.
 17 **Q.** But it was never established which particular donor or
 18 donors had transmitted HIV?
 19 **A.** That was certainly my understanding when I left the
 20 SNBTS and I don't think there's been any further
 21 clarity on that using the assay systems that were
 22 available at the time -- none of the donors. And,
 23 yes, I think, as you probably already know, the PFC
 24 had a complete traceability system associated with
 25 these products.

87

1 I think it was unexpected in the sense that we did
 2 believe or at least we had an evidence-based hope that
 3 the epidemic was mainly confined to the US at that
 4 time.
 5 **Q.** One of the issues explored with Dr McClelland,
 6 Dr Brian McClelland, when he gave evidence to this
 7 Inquiry, was whether there were particular risk
 8 factors perhaps associated with Edinburgh in terms of
 9 high-risk donors.
 10 **A.** Yes.
 11 **Q.** As a centre of international travel, location of the
 12 Edinburgh Festival, population in terms of drug use,
 13 and so on?
 14 **A.** Yes.
 15 **Q.** Do you remember that being something that was
 16 explicitly discussed back in '83/'84? So prior to the
 17 October '84 discovery of the seroconversion of this
 18 particular cohort of patients, do you recall PFC ever
 19 giving any particular thought to that or there being
 20 any discussions between PFC and SEBTS?
 21 **A.** There could well have been discussions. It would have
 22 been -- the discussions would have taken place at the
 23 coordinating group or directors' meetings because they
 24 were the people involved in the interface with donors
 25 and so these issues were constantly on the agenda.

86

1 **Q.** Yes. Then just a handful of further questions about
 2 seroconversions if I may.
 3 Can we just start, first of all, at CBLA0001919.
 4 Now, this is not a meeting in which you were
 5 involved, Dr Perry. It's a meeting of the Central
 6 Committee for Research and Development in Blood
 7 Transfusion, November 1984 -- 9 November 1984 -- but
 8 you will see Dr Brian McClelland was there.
 9 **A.** Yes.
 10 **Q.** If we go over the page, the third paragraph, under the
 11 heading "Developments with respect to AIDS", says
 12 this, and this is a particular point I've been asked
 13 to see whether you can help us understand or clarify,
 14 Dr Perry:
 15 "Dr McClelland referred to a batch of
 16 Factor VIII in Scotland, fractionated in November,
 17 1983, which was discovered to contain anti-HTLV3 in
 18 August, 1984."
 19 Then there's reference to the remainder of the
 20 product having been withdrawn:
 21 "... but the incident served to highlight the
 22 difficulties which lay ahead ..."
 23 Was there a discovery in August 1984 or is that,
 24 to the best of your knowledge, simply an error in the
 25 minutes?

88

1 A. I think it must be an error in the recording of the
2 minute. We had no knowledge of HTLV-III being in any
3 batch of PFC product in August 1984.

4 Q. Thank you. That's what I wanted to check with you.

5 A. I don't know the genesis of that statement. It seems
6 like it is just an error of reporting.

7 Q. Now, the next document, please, is at BNOR000177. If
8 we go to the second page, please.

9 So this is a letter from Dr Snape at BPL to
10 Dr Jean Harrison, the Northeast Thames Regional
11 Transfusion Centre, 26 July 1985, and we can see from
12 the bottom right-hand corner, it was copied to you.

13 If we then just go up the page, please. We can
14 see it is headed "Advice of Transfusion Incident and
15 Product Recall Notice". Then there is a reference to
16 a BPL product and then PFC 795. Then the letter says
17 that:

18 "[Dr Snape] has been informed by Dr Craske ...
19 that a patient treated at the London Hospital ... has
20 developed ..."

21 An illness consistent with HTLV-III infection.

22 "The batches implicated are HLA and HLB3185 and
23 [then] PFC batch 795."

24 It's described that the Regional Transfusion
25 Centre had received 947 vials of PFC 795 as their

89

1 February 1986, referring to having become aware of
2 three seroconversions in the past year in patients
3 receiving blood products. And then there's, I think,
4 a follow-up letter if we go to MACK0001870_01.

5 You then wrote to Dr Madhok in Glasgow in July
6 of the same year:

7 "HTLV III seroconversions in west of Scotland
8 haemophiliacs.

9 "You will recall our discussions regarding the
10 seroconversions of 2 haemophiliacs in your region.

11 "I can now enclose a brief report on our findings
12 which attempts to relate these 2 incidents to the
13 seroconversions in Edinburgh. As you will see, we can
14 draw no definite conclusions."

15 Then I think the report that is referred to in
16 this letter is at PRSE0003506.

17 And we can see it is headed "HTLVIII
18 seroconversions related to SNBTS [Factor] VIII,
19 An interim report". The first paragraph refers to the
20 Edinburgh seroconversions and then the second
21 paragraph says:

22 "Follow-up of West of Scotland haemophiliacs,
23 has revealed two patients receiving SNBTS
24 [Factor] VIII who seroconverted in 1983 and 1985
25 respectively."

91

1 September allocation.

2 Now that presumably is a reference to the
3 distribution of PFC products when you were sending
4 part of the stockpile or surplus to BPL which we
5 looked at yesterday. That would be consistent with
6 the timing?

7 A. That is right.

8 Q. Do you know what, if any, follow up was done or what,
9 if any, investigation was done into PFC 795?

10 A. No. I think just for clarification, where it
11 describes the batches implicated doesn't necessarily
12 imply that there's a causal association with batch 795
13 or any of the other batches. It's just a description
14 of what the patient's received.

15 I'm afraid I only -- I think this -- I only saw
16 this letter again recently in the bundle of results,
17 so I haven't had the opportunity of researching it.
18 I can only say that when that was received at PFC,
19 that would certainly have been subject to evaluation
20 and follow up and so on. But I don't think batch 795
21 was ever identified as a batch that either contained
22 an HIV positive donation or not.

23 Q. Then if we go to PRSE00001773, please. There is an
24 exchange of correspondence here between -- this
25 particular letter is Dr Forbes to Dr Cash,

90

1 Then we can skip over the details of the two
2 patients. It then says:

3 "The batches of product received by the South-East
4 and West of Scotland seroconverters are summarised in
5 the Table."

6 Point 1:

7 "Neither of the West of Scotland patients received
8 the batch ... implicated in the South-East Scotland
9 seroconversions.

10 "2. No batch is common to the two West of Scotland
11 seroconversions.

12 "3. If SNBTS FVIII was responsible for each of the
13 18 seroconversions, then at least three contaminated
14 batches must have been issued."

15 There is then an identification of batches
16 common to both seroconversions.

17 Then, if we go over the page, it says:

18 "5. None of the batches received by any of the
19 seroconverters are known to have contained an HTLV-III
20 positive donations."

21 "Further action:

22 "At this time, no information is available (at PFC)
23 on the quantities of each batch received by the two West
24 of Scotland seroconverters."

25 Do you know -- other than identifying that there

92

1 were potentially at least three contaminated batches
2 that must have been issued from PFC on the basis of
3 the information you had about those seroconverted, do
4 you know whether there was any particular follow-up to
5 this investigation or whether any conclusions were
6 reached as to which other batches and how many were
7 implicated?

8 **A.** I have no recollection of any additional data or
9 evidence coming to light beyond that which has been
10 reported here. My memory is that there were -- it was
11 established fairly early on that there were at least
12 three batches, but I don't think there are -- I think
13 we requested further information from Dr Madhok in my
14 letter. I'm not sure whether that was received or
15 whether it was significant.

16 **Q.** Then finally on this topic, can we go to
17 MACK0002301_022, please.

18 This was an email from Dr Foster to you,
19 January 2000. I don't need to go through the detail
20 of most of it. If we go to the bottom half of the
21 page, you'll see there's a list of pharmaceutical
22 companies and viral transmissions reported.

23 In relation to Armour it refers to there being:
24 "18 HIV transmissions published in 1988 & 1990
25 (+ 2 in Scotland not published) ..."

93

1 **A.** Okay, thank you.

2 **Q.** The next topic I wanted to move to is just batch
3 dedication. We saw it touched on in that report from
4 Dr Cash, January 1984 --

5 **A.** Yes.

6 **Q.** -- for the February 1984 SNBTS and Haemophilia Centre
7 Directors' meeting.

8 Now, the evidence shows -- your own evidence
9 explains this -- the batch dedication system was
10 introduced from early 1985.

11 **A.** That's correct.

12 **Q.** Can you assist us, first of all, by explaining how the
13 particular batch dedication system introduced worked?

14 **A.** When it was fully implemented?

15 **Q.** Yes.

16 **A.** It was a system whereby -- and it was predicated and
17 necessary to have large stocks of product to make such
18 a system work, and it involved dividing the patients,
19 all the patients in Scotland who were treated with
20 Factor VIII, into patient groups on a regional basis.
21 So there might have been three patient groups in
22 Edinburgh, six patient groups in Glasgow, one in
23 Aberdeen, Dundee, Inverness and so on, and I think we
24 called them "lanes", patient "lanes". They were
25 allocated, I think, simply on the basis of their

95

1 And, if we go to the very bottom of the page, it
2 says -- it's referring to, I think, Dr Mike McGovern
3 here:

4 "... Mike seems not to be aware that Armour's FVIII
5 was withdrawn from the UK ... following HIV
6 transmissions in the UK (4 cases in Birmingham and 2 in
7 Glasgow's Royal Hospital for Sick Children)."

8 Then it refers to that product also transmitting
9 HIV in the USA and Canada. I appreciate that this is
10 not talking about SNBTS product, it's talking about
11 seroconversions from the heat-treated Armour
12 Factor VIII --

13 **A.** Yes.

14 **Q.** -- said to be two in the Royal Hospital for Sick
15 Children. But do you have any further knowledge about
16 those seroconversions?

17 **A.** I don't think I do. I would have probably had more
18 knowledge and recollection closer to the time but
19 after the passage of time. I'm aware, of course, that
20 there were reports of commercial products in
21 particular continuing to transmit HIV. But I can't
22 recall who Mike McGovern was.

23 **Q.** Based, I think, at the Department of Health.

24 **A.** Oh, okay.

25 **Q.** I think that's right.

94

1 alphabetical surnames. And the PFC's role in the
2 batch dedication system was to provide these so-called
3 lanes with whole batches of product.

4 The patients, when they received their product
5 for treatment from the Haemophilia Centres, would draw
6 upon the stocks that had been particularly -- from the
7 lane that they had been allocated and when that lane
8 was empty, ie the patients had used up all the product
9 in that lane, that batch would be replenished with
10 another whole batch.

11 I'm not sure how many patients were in each
12 patient group but I would estimate it would be in the
13 region of 20 or so, maybe more, depending how many
14 lanes had been established and that system was
15 designed to minimise patient exposure to donors. It
16 worked very well. Once it was implemented, it worked
17 very well.

18 **Q.** There are various documents and correspondence
19 relating to it but I don't think we probably need to
20 go to those, but can you assist with this: why was
21 a system only introduced in early 1985 (at which time
22 you've got a product which, in fact, inactivates
23 HTLV-III, albeit not non-A, non-B hepatitis), given
24 that it was certainly under contemplation beginning of
25 the previous year and presumably is something that

96

1 could have been thought about earlier even than 1984?
2 Wasn't it done really too late?

3 **A.** Well, I don't think it was done too late but I think,
4 you know, as perhaps an opening comment I think this
5 is a topic that could have been addressed earlier.
6 I've thought quite extensively about this particular
7 topic because it's become an important issue.

8 I think my conclusions are that it was perhaps
9 not well defined who was -- where the centre of
10 responsibility or the leadership for such a process
11 existed. The operation of it was primarily dependent
12 on the Regional Transfusion Centres and the
13 Haemophilia Centre Directors identifying the patient
14 groups and setting up the operational systems for
15 making sure that individual patients only got the
16 batch that they were allocated to, and the PFC had no
17 involvement or role in that. The PFC's role was
18 simply to provide the number of batches necessary to
19 sustain the system.

20 So it was never quite clear, I think, even in
21 the minutes of the annual meeting of Haemophilia
22 Centre Directors and Transfusion Directors, that it
23 was -- that it was not defined who, if anybody, should
24 take the lead in that. It was a sort of call to arms
25 I think, in some respects, to begin thinking about

97

1 (1.00 pm)

(Luncheon adjournment)

2 (2.00 pm)

3 **MS RICHARDS:** Dr Perry, I'm going to move to the question
4 of viral inactivation now, heat treatment work.

5 This has been largely covered in the evidence of
6 Dr Peter Foster so I'm not going to go through the
7 detail of it at all with you. I've a handful of
8 general questions which reflect, I think it's probably
9 fair to say, concerns of some Core Participants or
10 issues which some Core Participants have asked to
11 raise.

12 So the first question is this: what was your
13 understanding of the weight attached to viral
14 inactivation as a research and development goal for
15 PFC in 1981/1982? In other words, how much of
16 a priority was it for the PFC at that stage?

17 **A.** I think it was top priority by '81/'82.

18 **Q.** In terms of the establishment of the Factor VIII study
19 group, do you know of any reasons why that couldn't
20 have been set up earlier than it was?

21 **A.** No, I don't think there's a particularly good reason
22 why it couldn't have been set up sooner. I think it
23 was set up when I think the body of evidence and
24 opinion and so on drew us to the conclusion that it

99

1 this and determine its feasibility.

2 My analysis of the situation is that it
3 certainly had the product stocks in 1984. And I think
4 it is fair to say that had it been identified as a --
5 I had only just become acting director at that stage
6 and I think my priorities lay elsewhere at that time,
7 but had it been identified as a high priority topic by
8 transfusion centres or haemophilia directors or indeed
9 myself, then, I think it could have been introduced
10 earlier.

11 What I'm not clear on though is whether, had it
12 been introduced in 1984, the infective batch that we
13 have just talked about would have been included in one
14 of the patient lanes for a batch dedication system in
15 1984. And so there would have still been a tragic
16 outcome. Whether it would have resulted in more
17 patients being infected or less patients being
18 infected, I'm not sure, but I think I have described
19 it in my witness statement as a lost opportunity. We
20 could and should have done it sooner.

21 **MS RICHARDS:** Sir, I'm going to move on to another topic
22 now. Given the time, perhaps we could pick that up at
23 2 o'clock.

24 **SIR BRIAN LANGSTAFF:** Yes, let's do that. 2 o'clock.

25 **MS RICHARDS:** Thank you, sir.

98

1 was necessary and it was necessary to draw upon, not
2 just PFC resources, but the wider resources of SNBTS
3 to address the issues. And it wasn't just about virus
4 inactivation, the Factor VIII study group, it was
5 about maintaining self-sufficiency as well.

6 **Q.** Can I then ask you about one passage in your witness
7 statement, WITN69200001, and if we could go to
8 page 37, please, Sully. So, in paragraph 106, having
9 referred to the work of the Factor VIII study group,
10 you say that PFC continued to research and progress
11 methods for pasteurisation of Factor VIII as its
12 preferred option. You refer to the development of
13 in-house methods for testing the efficacy of
14 inactivation processes and then say this:

15 "However there remained concern, including
16 internationally, that the modification of [Factor] VIII
17 manufacturing processes to include steps for virus
18 inactivation could lead to the development of inhibitors
19 in recipient patients, leading to potentially
20 catastrophic consequences for the treatment of
21 haemophilia."

22 The question arising out of that, Dr Perry, is
23 this: what weight was given to that hypothetical
24 theory as opposed to the known real risk of hepatitis
25 which, equally, could lead to catastrophic

100

1 consequences?
 2 **A.** I think there was very significant weight. It wasn't
 3 completely hypothetical, either. I think it was based
 4 on admittedly rather scant knowledge of the
 5 Factor VIII molecule and what heat might do to it, and
 6 the consequences that it might have in invoking or
 7 potentiating inhibitors in patients.

8 It was a very serious risk. I wouldn't describe
 9 it as a hypothetical risk. Indeed, latterly, there
 10 were a couple of organisations, I think the Dutch Red
 11 Cross (the CLB, as it was then) and Octapharma did
 12 actually produce heat-treated product which generated
 13 very high levels of inhibitors in a large number of
 14 patients. So it was a very real risk. I think that
 15 postdated '81/'82 but it was still -- it has still
 16 been identified as a risk then, and I think part of
 17 the Factor VIII study group actually tried to develop
 18 ways of examining whether there was any physical
 19 damage to Factor VIII after it had been subjected to
 20 a heat treatment process.

21 **Q.** Now, more generally, it might be said in relation to
 22 the work of PFL and BPL, having regard to the evidence
 23 the Inquiry's examined from Dr Smith and Dr Lane, that
 24 the work on heat treatment, whether pasteurised or dry
 25 heat, which had been started because of a desire to

101

1 during -- if we talk about the period of 1984, for
 2 instance, leading up to the patient cohort in
 3 Edinburgh, there was -- I think, as I say, there are
 4 a number of factors.

5 We didn't -- nobody knew what the -- it hadn't
 6 been discovered or identified or isolated, the HIV
 7 virus or the HTLV-III virus. We didn't know its
 8 physical characteristics. We didn't know whether heat
 9 treatment would do anything for it at all. There was
 10 the risk of inhibitors, which was very real, and we
 11 had correspondence, or Professor Cash certainly had
 12 correspondence, with a number of haemophilia doctors
 13 who advised him that they were very concerned
 14 (Professor Ludlam was one of them) about the risk of
 15 inhibitors following the application of heat treatment
 16 and, indeed, for really quite extensive, and probably
 17 quite lengthy, clinical trials before it was
 18 introduced.

19 So I think those two main factors -- and I think
 20 had we suggested -- this is my own view -- had it been
 21 proposed to introduce heat treatment in 1984, for
 22 instance, at the beginning of 1984, in a similar way
 23 to which we did in late 1984, I'm far from convinced
 24 that would have enjoyed the support of haemophilia
 25 doctors, because I think they may have regarded it as

103

1 address non-A, non-B hepatitis, was really given
 2 urgency, galvanised by the advent of AIDS and it was
 3 that which injected a greater sense of urgency into
 4 the work that was being undertaken. That might be
 5 a submission that's advanced.

6 Is the same point applicable to the work of the
 7 PFC, that it was AIDS that injected the real sense of
 8 urgency, and at a relatively late stage, and perhaps
 9 a greater sense of urgency having been engendered by
 10 non-A, non-B?

11 **A.** It was certainly the case that the major concern when
 12 this group was set up in 1982 was how to address the
 13 universal risk of non-A, non-B hepatitis by its
 14 coagulation factors and I think it's probably true to
 15 say that, following the events in late 1984, it did
 16 inject a much ... I don't know how best to express
 17 it -- a substantially greater sense of urgency and
 18 also a slight change of direction. This became the
 19 target HIV, not non-A, non-B hepatitis anymore.

20 **Q.** Again, this is a question I've particularly been asked
 21 to put to you, Dr Perry. Why did it take patients in
 22 Scotland being infected with HIV to bring about this
 23 change of direction and this greater sense of urgency?

24 **A.** I think there are a number of reasons. I think our
 25 work on non-A, non-B hepatitis was still very valid

102

1 premature. They had no evidence that patients were or
 2 had been infected with HIV at that stage.

3 **Q.** And then can I ask you to help with one particular
 4 document from November 1984.

5 PRSE0004148.

6 So it's a meeting chaired by you, Dr Perry, on
 7 13 November 1984.

8 **A.** Yes.

9 **Q.** Minutes of a meeting of heads of department/section
 10 managers. So it's an internal PFC meeting; is that
 11 right?

12 **A.** It's a local management team meeting, yes.

13 **Q.** If we go to the second page, towards the top of the
 14 page, under the heading "AIDS Minute", the minutes
 15 record as follows:

16 "Dr Perry advised the meeting that as a result of
 17 the amount of information being publicised through the
 18 press on the subject of AIDS, there was an immediate
 19 requirement for PFC to render all [Factor] VIII free
 20 from HTLV III virus."

21 Then there is an explanation of the work that
 22 was being undertaken to that end.

23 **A.** Yes.

24 **Q.** Now that might be said to read as though this sense of
 25 urgency, this change of direction in the autumn of

104

1 1984 is because of publicity. That's how it reads.
 2 Are you able to assist us with that?
 3 **A.** I agree it could be interpreted like that. I didn't
 4 write the minute of the meeting, but I would have
 5 approved them. I think the minutes tended to be
 6 written by the head of the administration department
 7 in PFC.
 8 But it is certainly the case that the impetus
 9 and the momentum and the requirement for inactivation
 10 wasn't simply to do with publicity. It was, as I say,
 11 the devastating news received earlier that month of
 12 the transmission episode.
 13 **Q.** I then want to move beyond 1984 into 1985, and in
 14 particular 1986. If we get to, as it were, 1986,
 15 I think it is right to say that, in terms of domestic
 16 Factor VIII concentrates, there are two products, both
 17 of which inactivate HIV, that is BPL 8Y's product and
 18 PFC's NY product?
 19 **A.** Yes.
 20 **Q.** 8Y inactivated non-A, non-B hepatitis. NY did not.
 21 That is correct, isn't it? I leave aside the question
 22 of when that became known.
 23 **A.** I don't think it was certain at that beginning of '86
 24 that 8Y was effective against non-A, non-B, but there
 25 was the early -- there was reason for optimism,

105

1 I think.
 2 **Q.** Yes, I will come on to, as it were, date of knowledge
 3 in the moment. On any view, that's correct as
 4 a matter of fact, I think, 8Y had that advantage over
 5 NY?
 6 **A.** At that point in time, yes. Yes.
 7 **Q.** Obviously PFC then introduced Z8 in 1987, and Z8 did
 8 inactivate non-A, non-B hepatitis?
 9 **A.** But that conclusion can only be drawn with hindsight,
 10 as it were.
 11 **Q.** What I want to do is just look at what was known and
 12 what was happening at the time then, so that we avoid
 13 hindsight.
 14 So if we just perhaps pick it up at PRSE0001258.
 15 So we can see this is, again, one of your
 16 statements to the Penrose Inquiry.
 17 If we just go a little further down the page,
 18 please, Sully. So below the passage, or the question
 19 in italics, you say:
 20 "I am unable to precisely identify the date on which
 21 the SNBTS/PFC first became aware of the BPL/PFL 8Y
 22 development."
 23 Then you refer to a paper put together by
 24 Dr Foster which you say:
 25 "... indicates that we were first briefed by

106

1 Dr JK Smith ... on their 8Y developments in
 2 February 1985."
 3 If we then go over the page. You refer to the
 4 clinical trial of 8Y commencing around April 1985.
 5 Then, if we pick it up in the second paragraph, you
 6 say this:
 7 "Therefore, although early results in a relatively
 8 small group of patients were reported by Dr Rizza as
 9 encouraging ..."
 10 Just pausing there. Can you recall when that
 11 was being reported by Dr Rizza?
 12 **A.** No, I can't recall the date, but it would have
 13 obviously pre-dated 1986. It might have been late
 14 1985.
 15 **Q.** My understanding is it was 1985, but I'm afraid I've
 16 mislaid the reference that gave me a precise date.
 17 **A.** It was probably in a study that didn't quite meet the
 18 international guidelines for conducting these studies.
 19 **Q.** I am sure we can check that in any event. You then
 20 continue:
 21 "... it was not until the interim review point in
 22 this study (March 1986), reported in October 1986, to
 23 the UKHCDO, that the freedom of NANBH ..."
 24 I will skip over hepatitis B or HTLV-III:
 25 "... would have been described as likely."

107

1 Now that, at first blush, makes it sound as
 2 though the point in time at which it would have been
 3 regarded that 8Y was likely not to transmit
 4 non A, non B hepatitis was when the results were
 5 published, in October 1986. But I think it is right
 6 that you would have been aware of the interim results
 7 in March of 1986, is that correct?
 8 **A.** I think so, yes, absolutely.
 9 **Q.** And I think we can just look briefly at the meeting.
 10 PRSE0003764.
 11 Sir, it is a note of a meeting held at PFC on
 12 17 March at 1986. We can see that there are a range
 13 of representatives from BPL and a range of
 14 representatives from SNBTS present.
 15 If we go to the third page, please, Sully.
 16 We can see this is your note of a meeting,
 17 24 March 1986, and it is paragraph 5 on this page in
 18 which we see:
 19 "Dr Smith outlined clinical trial results of the
 20 8Y [Factor] VIII products so far. While results
 21 cannot be considered conclusive at this stage, he
 22 indicated that no cases of virus infection have
 23 occurred (attributable to 8Y material) after 12 months
 24 experience of 8Y in virgin haemophiliacs."
 25 That is the significance, I think, of

108

- 1 March 1986; is that right?
- 2 **A.** I think that is correct.
- 3 **Q.** The earlier indications had been promising but this
4 was a greater degree of confirmation, albeit it
5 obviously fell short of conclusive --
- 6 **A.** Yes, I think it became likely at this stage, I think.
7 I think my view of these reports was more optimistic
8 than Dr Smith's actually. He was always very cautious
9 not to overestimate or be too optimistic about
10 outcomes before the data was confirming it.
- 11 **Q.** So by March 1986, or by the date of this meeting, by
12 the time of this meeting in March 1986, you and your
13 colleagues, within Scotland -- if we just go back to
14 the list of attenders on the first page.
- 15 So we have a range of colleagues there, although
16 I'm not sure whether we can tell if all of them were
17 present for the whole of the meeting -- sorry, for the
18 relevant part of the meeting.
- 19 But, in any event, you and your colleagues would
20 know that there was a good chance, if I can put it
21 that way, that 8Y was successful in terms of not
22 transmitting non-A, non-B hepatitis?
- 23 **A.** Yes.
- 24 **Q.** And at that time, in terms of NY, the feeling was it
25 did transmit non-A, non-B hepatitis?

109

- 1 **Q.** And then if we go to PRSE0003030, please.
2 You responded to Dr Boulton on 2 July 1986. If
3 we look at the text of the letter, you don't deal with
4 the particular case that has been flagged up but you
5 say, in the second and third paragraphs, that the PFC
6 is, you say, "poised to introduce ... another
7 [Factor] VIII product". I'm not sure whether --
8 I think it's April 1987 by which time you were
9 actually --
- 10 **A.** I think our expectation in our plan at that time was
11 it should have been -- it would have been available by
12 September, I think.
- 13 **Q.** But, in any event, what you're doing is flagging up
14 that there will be a PFC product --
- 15 **A.** A comparable product --
- 16 **Q.** -- equivalent to 8Y in due course?
- 17 **A.** Yes.
- 18 **Q.** If we then go, please, to PRSE0001784.
19 We can see Dr Boulton wrote to you on
20 4 July 1986, and it reflects -- or refers to
21 a telephone conversation that the two of you had had
22 the previous day. And then the attached record of the
23 conversation is actually on a different reference.
24 PRSE0002783. If we turn the document round,
25 please.

111

- 1 **A.** I'm not sure that we had any data on that but we had
2 no reason to expect 24 hours at 68 degrees to
3 inactivate non-A, non-B hepatitis.
- 4 **Q.** What I want to do next then is just go through a chain
5 of correspondence in June, July and August involving
6 the efforts made to obtain some 8Y from BPL for use in
7 virgin haemophiliacs or minimally treated patients.
8 If we start with PRSE0003845.
9 What I'm going to do, Dr Perry, is go through
10 the correspondence and then ask you some questions
11 about it.
12 We can see this is Dr Boulton to you,
13 27 June 1986 passing on some comments from Dr Ludlam,
14 and the first main paragraph reads -- sorry, it's the
15 second paragraph:
16 "A young haemophiliac who previously had minimal
17 therapy with factor VIII received an infusion of the
18 current heat-treated product a month ago. He now shows
19 signs of liver enzyme rises indicating non-A, non-B
20 hepatitis. Christopher is a bit ruthless with his own
21 staff about this because he feels that this patient
22 should have received VIIIY or an equivalent product."
23 I think that's the first communication with you
24 on this particular issue.
- 25 **A.** On this topic, yes.

110

- 1 Now I think most of this page, as I understand
2 it, Dr Perry, is describing the intended progression
3 towards the release of the PFC's own new product, Z8;
4 is that right?
- 5 **A.** Yes. I think the phase 2 product refers to the
6 68 degrees for 24 hours and phase 3 refers to Z8.
- 7 **Q.** Yes. And so we can see a timescale being given in
8 relation to that which I don't need to trouble you
9 with. But the bottom of the page says this:
10 "In the meantime any Edinburgh 'virgin'
11 haemophiliacs requiring therapy could be given BPL 8Y."
12 Is it right to understand from this note you and
13 Dr Boulton have had a conversation on 3 July, and part
14 of the conversation involves a plan for 8Y to be given
15 to any virgin haemophiliacs who may require treatment?
- 16 **A.** Yes.
- 17 **Q.** So I think we see that then picked up next in a letter
18 at PRSE0004097.
19 This is again Dr Boulton to you, 7 July:
20 "Sorry to be pestering you again.
21 "Last week Dr Ludlam wrote to Brian ..."
22 That's presumably Dr McClelland?
- 23 **A.** Dr McClelland, yes.
- 24 **Q.** "... asking you if it would be possible to obtain some
25 of the BPL products for use if a previously untreated

112

1 haemophilic presented for replacement therapy."
 2 Then the letter continues by a discussion of how
 3 much and Dr Boulton says he thinks the amount that
 4 Dr Ludlam had suggested might be too much,
 5 essentially.

6 If we just look at the whole letter, please,
 7 Sully.

8 In the last paragraph, Dr Boulton says to you:
 9 "... would it be possible for you to obtain perhaps
 10 10,000 units -- ie 50 vials ..."

11 **A.** Yes.

12 **Q.** So that's 7 July.

13 Then if we go to PRSE0003814.

14 We can see a letter of the same date from you
 15 back to Dr Boulton, and you're responding, I think, to
 16 the note, the handwritten note, I'm assuming is what's
 17 referred to in the first paragraph. And then you say
 18 in paragraph (b):

19 "While there will be no PFC product virucidally
 20 comparable to 8Y until September '86 ..."

21 Then you refer to the Phase III product. Then you
 22 say this:

23 "However, in the immediate future
 24 (July-September '86), we could probably get supplies of
 25 8Y for special cases. It would of course be preferable

113

1 **Q.** If we then go, please, to PRSE0004383.

2 We can see that you wrote on 10 July to
 3 Mr Pettet at BPL. The first paragraph of the letter
 4 refers to:

5 "Very occasionally a haemophiliac without previous
 6 exposure to Factor VIII Concentrate presents in Scotland
 7 for treatment."

8 You refer to one such patient presenting very
 9 recently being:

10 "... treated with our current product ... and
 11 subsequently developed markers for NANB hepatitis ..."

12 You then refer to the intention to introduce PFC's
 13 own product in due course.

14 Then the second paragraph:

15 "Pending the introduction of this product in
 16 Scotland and Northern Ireland, I write to ask if it
 17 would be possible for you to supply PFC with a very
 18 modest quantity of 8Y (50 vials) to cover the treatment
 19 of similar virgin patients who may appear between now
 20 and September. This request originated from our own
 21 Haemophilia Directors and, in the light of our imminent
 22 introduction of a product comparable to 8Y, does not
 23 seem unreasonable and should not place an overwhelming
 24 burden on your supply."

25 I think that's you to Mr Pettet on 10 July.

115

1 if these were obtained and supplied through PFC."

2 Why would it be preferable for them to be
 3 obtained and supplied through PFC?

4 **A.** With hindsight, I'm not sure actually. Perhaps I felt
 5 that it would have -- it would just have fitted in
 6 with the distribution system and we could have held
 7 the stock at PFC.

8 **Q.** In any event, is it right to understand that this is
 9 a suggestion that in the intervening period before the
 10 PFC equivalent is capable of being available, rolled
 11 out, you think you'll be able to get supplies of 8Y
 12 for what's described as "special cases"?

13 **A.** In response to a specific request by a haemophilia
 14 director, yes.

15 **Q.** And by "special cases", I assume that's meaning
 16 minimally or previously untreated patients?

17 **A.** I think it would be, yes, exactly those two categories
 18 of patients, yes.

19 **Q.** If we --

20 **A.** If -- my understanding is the guidance produced by
 21 UKHCDO at that time did have a prescribed policy for
 22 minimally treated patients or previously untreated
 23 patients, which was the use of cryoprecipitate. So
 24 that was the standard treatment for those groups of
 25 patients. That's my understanding.

114

1 Then, if we go to PRSE0001397.

2 It appears you wrote to Dr Smith at PFL on
 3 24 July, referring to a discussion you'd had and
 4 asking for a supply of 50 vials of 8Y as a contingency
 5 in the event that a virgin haemophiliac presents for
 6 treatment. You say it:

7 "... will be issued on condition that [the]
 8 clinical trial protocol is observed."

9 What would that entail, the clinical trial
 10 protocol?

11 **A.** I think there's a little correspondence in between
 12 this where Mr Pettet wrote back to me and said he'd
 13 discussed it with Dr Lane and he'd discussed it with
 14 Dr Smith, this was an unlicensed product, and they
 15 could assist, they thought it was a reasonable
 16 request, but what they would prefer was a slightly
 17 more win-win situation where, if we did have
 18 a previously untreated patient, they could be entered
 19 into the trial, the clinical trial of 8Y, which was
 20 ongoing, to study the absence of infectivity in that
 21 product.

22 **Q.** I think that's probably a reference to a letter of the
 23 same date, but it essentially crossed with yours, from
 24 Mr Pettet to you, PRSE0003693, where he says:

25 "Following your letter on your requirements for

116

1 'virgin' haemophiliacs in Scotland and Northern
2 Ireland, I tried to contact you by telephone last
3 Thursday in order to begin supplies as soon as
4 possible."

5 The next paragraph refers to Dr Lane's
6 agreement:

7 "... I had spoken to Jim Smith and he hoped to see
8 you last Friday with a novel proposal: perhaps Scotland
9 would like to participate in our trial of Factor VIII Y!

10 "Provided that you were agreeable that the patients
11 met the criteria, and given agreement by the Haemophilia
12 Directors involved, Jim can provide 8Y from batches set
13 aside for trial purposes."

14 The next paragraph says:

15 "In case there are some patients who do not strictly
16 meet the criteria for trial, now or in the future,
17 I have put aside some 8Y for immediate despatch to PFC
18 (or any other destination), if you require it. I can
19 arrange same day delivery if necessary. Would you like
20 this additional product to be sent to PFC now, or have
21 you made adequate arrangements for cover with Jim?"

22 That letter reads as though saying there are two
23 routes to getting a small supply of 8Y for Scotland.
24 There's the proposal that any Scottish or Northern
25 Irish patient who might need it could be entered in

117

1 You're writing on 28 July. You confirm -- if we just
2 zoom in on the text, Sully, thank you -- that you've
3 spoken to Jim Smith. You've confirmed locally that
4 the supplies of 8Y should be conditional on users
5 participating in the clinical trial, and you've asked
6 if someone can send -- sorry, if Jim can:

7 "... send (immediately) 50 vials ... as
8 a contingency stock of non-infective material in the
9 unlikely event that a virgin haemophiliac presents for
10 treatment in the near future."

11 Then we can see, if we then go to PRSE0002616,
12 here's Dr Smith sending 50 vials of 8Y on
13 1 August 1986 to you.

14 Then PRSE0002643, we can see on 5 August you
15 wrote to Dr Boulton. You told him the 8Y had arrived
16 and you've sent 20 vials to the Regional Transfusion
17 Centre in Edinburgh. And you say:

18 "There is more here if [you] need it."

19 Now, is it fair to say, having regard to that
20 correspondence, that certainly once the issue had been
21 raised with you, it was fairly simple and
22 straightforward for you to obtain a supply of 8Y from
23 BPL?

24 **A.** I think the incident that triggered this was the one
25 that you've described -- or the one that was described

119

1 the trial and get 8Y that way?

2 **A.** Yes.

3 **Q.** And then Mr Pettet saying, "But we can also put aside
4 some 8Y for you and send it to you by same-day
5 delivery"?

6 **A.** Yes. If there were similar patients that didn't quite
7 meet the criteria for entry into the trial, they
8 weren't going to be too rigid about which in patients
9 it should be useful.

10 **Q.** Then we can see at PRSE0003143 -- now, you wouldn't
11 have received the letter we just looked at because
12 these are all letters written on the same date, so
13 I suspect you wouldn't --

14 **A.** Okay.

15 **Q.** You might have had the earlier letters. But this is
16 you writing to Dr Boulton, 24 July:

17 "I have now confirmed that BPL are happy to supply
18 50 vials of 8Y to PFC on the understanding that, in the
19 event that the material is used in suitable virgin
20 patients, appropriate serial samples would be taken to
21 contribute to their overall infectivity study."

22 That is 24 July.

23 Then, just to complete the chain of
24 correspondence, if we go to PRSE0004146, this is you
25 now responding to Mr Pettet's letter of 24 July.

118

1 in Dr Boulton's original letter, and I guess I set out
2 on this short journey not necessarily with
3 an expectation it would be successful. I think
4 Factor VIII was in short supply in England and
5 50 vials for Scotland would mean 50 vials less for
6 England and those sorts of considerations.

7 So I was quite surprised, but also delighted,
8 when they responded so positively and I guess, in
9 Jim Smith's usual way, he found quite an elegant way
10 of dealing with this, which was providing product and
11 if it was a previously untreated patient or somebody
12 that met the criteria for entry into the trial, then
13 it would be a good way of meeting the clinical need
14 but also supplementing the data that they had for
15 their clinical study.

16 **Q.** Now, we can see from this, and indeed from the
17 document on screen, having received the 50 vials from
18 England, you sent out 20 to Edinburgh and obviously
19 Dr Boulton knew what the plan was because you'd been
20 having these earlier discussions with him --

21 **A.** Sure.

22 **Q.** -- and we saw the handwritten note of your
23 conversation in early July. Did you notify other
24 regions that there was a small supply of 8Y in stock
25 in case they had a virgin haemophiliac or minimally

120

1 treated haemophiliac?
 2 **A.** No, I didn't.
 3 **Q.** Should you have done?
 4 **A.** This topic was discussed in the Penrose Inquiry -- and
 5 I'm not suggesting that's not a reason to discuss it
 6 here. I think my understanding and my response to
 7 this particular request was that we were responding to
 8 a specific request from a specific haemophilia
 9 director and, although I framed the correspondence
 10 with BPL to reflect a Scotland-wide potential
 11 requirement, it was designed to maximise the chances
 12 of success of getting this product for Scotland.

13 I think, with hindsight, what should have
 14 happened -- or maybe I can go on to explain why
 15 I didn't.

16 It was not a licensed product. I think if
 17 another haemophilia director in Scotland had requested
 18 a similar product for treatment, then I would have
 19 acted in the same way and sought further supplies.
 20 But my view at that time, which wasn't an overly hard
 21 view, but it was that the fractionator or the
 22 manufacturer has no business in selecting products for
 23 treating specific groups of patients; that's
 24 a doctor's job. And what I was doing on this occasion
 25 was responding to a legitimate request from a close

121

1 identifying -- for any patients in the UK that were
 2 appropriate, that were previously untreated, whether
 3 they were in Scotland, Northern Ireland, Wales or
 4 England, to access 8Y. And an operational arrangement
 5 could have been made so that the 8Y that was used (for
 6 instance, for treatment of patients in Scotland) could
 7 have been replaced with some PFC product for routinely
 8 treated severe haemophiliacs in England.

9 I think that would have been possible, I think,
 10 a bit like the batch dedication, it was a lost
 11 opportunity. It would have only appropriately come,
 12 I think, from the haemophilia doctors' organisation,
 13 because they had the knowledge, they knew how many
 14 patients there were likely to be, and I think that
 15 would have been well received. As it was, my response
 16 was limited to a particular response to a particular
 17 request from a doctor.

18 I think the other big centre in Scotland where
 19 it was likely that a previously untreated patient
 20 would emerge was in Glasgow, in the West of Scotland,
 21 and Dr Forbes, I think, was the director of that
 22 centre at the time, and he was chairman of the UKHCDO
 23 at that time as well. So he would also have been very
 24 aware of the data on 8Y and could, and perhaps should,
 25 have made a similar request, but in the event he

123

1 haemophilia director colleague and there, for me,
 2 I think the matter rested.

3 And also the issue about not being seen to
 4 promote unlicensed products, and if I'd have started
 5 broadcasting to all the haemophilia directors in
 6 Scotland that, "We have this product available should
 7 you need it", that could be interpreted as promotion
 8 of a particular product, an unlicensed product.

9 My view with hindsight, and I've reflected not
 10 only during the Penrose Inquiry but subsequently on
 11 this topic, because it started out as a relatively
 12 small -- a response to an individual request from
 13 a haemophilia doctor. It was not a major issue for
 14 me. And, you're right, it went very smoothly in the
 15 end.

16 I think what should have happened or what could
 17 have happened is -- on a UK-wide basis, because there
 18 was this difference in availability -- or 8Y was
 19 proving to be a world-class product capable of
 20 inactivating not only HIV but non-A, non-B hepatitis,
 21 it seems to me -- and this is with hindsight but it's
 22 still a valid view -- that the UKHCDO organisation, if
 23 they'd have recognised that, it would not have been
 24 difficult for them to come up with a policy, which may
 25 have had to involve discussions with PFC and BPL, for

122

1 didn't. It could be that he chose to continue using
 2 cryoprecipitate for such cases, because that was the
 3 official UKHCDO guideline at the time I think.

4 **Q.** Did you have any direct discussions with Dr Ludlam
 5 yourself on this issue in 1986?

6 **A.** I don't think I did. I think it was -- it wasn't
 7 always done like this but I think this arrangement was
 8 brought about via Dr Boulton. He was, if you like,
 9 the go-between between Professor Ludlam and myself.

10 **Q.** Does that reflect, I think, what you told us
 11 yesterday, Dr Cash's preference that the Haemophilia
 12 Centre Directors would liaise with the RTCs rather
 13 than directly with PFC?

14 **A.** Yes, yes.

15 **Q.** So there was this slightly cumbersome route of
 16 Dr Ludlam going to Dr Boulton, who came to you and you
 17 went to Dr Smith or Mr Pettet?

18 **A.** Yes, yes, that's right.

19 **Q.** Leaving aside the question of whose individual
 20 responsibility it might have been, who should have
 21 come up with the idea --

22 **A.** Yes.

23 **Q.** -- would you accept this as a general proposition,
 24 that it should have been apparent to somebody, to the
 25 appropriate bodies in Scotland, and whether that's

124

1 just the Haemophilia Centre Directors or SNBTS or
2 both, by March of 1986 -- leave aside for present
3 purposes the earlier period and Dr Rizza's early
4 promising signs, but by March 1986 it was known that
5 there was this disparity between, or that there was
6 likely to be a disparity between, 8Y and NY. It must
7 have been capable of being foreseen that minimally
8 treated or virgin haemophiliacs might present for
9 treatment and that therefore somebody, maybe the
10 Haemophilia Centre Directors, should have taken the
11 lead, but somebody should have thought about this
12 rather than for the solution to be triggered by the
13 actual infection of a patient?

14 **A.** Well, I think I would probably agree with you, which
15 is why, with hindsight, I think the ideal outcome
16 would have been for the UK Haemophilia Centre
17 Directors organisation to -- in the knowledge that
18 they had a product which was likely to be
19 non-infective with respect to non-A, non-B, there was
20 an opportunity for wider UK co-operation between
21 Scotland, England, Northern Ireland and Wales, and
22 on -- and that could have been fairly simply put in
23 place.

24 I'm not trying to distance myself. I was in
25 a position perhaps to create more influence or to

125

1 should have.

2 **A.** Well, yes, but only in the context of the short
3 discussion we've just had. Again, I'm really not
4 trying to distance myself from this, but for me to say
5 that Professor Forbes should have done something in
6 terms of selection of products for his patients is
7 really not my --

8 **SIR BRIAN LANGSTAFF:** I appreciate there are a number of
9 people who might have done something. You happen to
10 be a person who had realised there was something
11 perhaps to be done because of the position that
12 Dr Ludlam had put you in. Plainly, it was a matter
13 for him to raise too should he wish to do so. And you
14 could have perhaps spoken informally to Dr Forbes
15 because of his position in the UKHCDO and said, "Have
16 you thought of this? It's not my position really to
17 mention it but, you know, we're talking about children
18 here. They're the likeliest people to come forward as
19 newly diagnosed people with haemophilia. Perhaps you
20 might want to discuss whether something can be done
21 about it?"

22 **A.** Yes, indeed, that is the case. I could have done
23 that. I wouldn't want to --

24 **SIR BRIAN LANGSTAFF:** And you didn't.

25 **A.** I wouldn't distance myself from that and I didn't do

127

1 drive this forward but, as I say, these decisions on
2 choice of product for patients were quite well
3 defined, for good reason, and, as I say, I don't think
4 it was at the front of my mind that it was a PFC
5 responsibility to then circulate a proposal to the
6 Haemophilia Centres in Scotland that they might want
7 to -- they might wish to consider using 8Y for the
8 treatment of previously untreated patients. That's
9 their business.

10 Professor Cash also took the view that this was
11 perhaps was not an appropriate thing to be doing
12 anyway. England and Wales were so short of
13 Factor VIII from the NHS that I think he perhaps --
14 I'm not sure why, but he took the view that we
15 shouldn't be stealing resources from England and
16 Wales. Which was a slightly extreme view, I think,
17 for the relatively small quantities involved.

18 So that's my view now, and I think it sort of
19 concurs with your view that somebody or some
20 organisation or some part of the network of care for
21 haemophilia could have identified this as
22 an opportunity.

23 **SIR BRIAN LANGSTAFF:** And the way you put it just a little
24 while ago in your evidence, talking about
25 Professor Forbes, was that he could have and perhaps

126

1 that. But I think what I -- my more likely position
2 would have been that Dr Ludlam, who had succeeded in
3 obtaining this product through the good offices of
4 PFC, if you like, and via BPL, I would have thought
5 would have communicated to his fellow haemophilia
6 directors in Scotland because they met regularly, they
7 discussed issues regularly, they had common problems
8 in terms of previously untreated patients and how best
9 to treat them and so on.

10 So that seemed to me at the time, or subsequent
11 to this issue, a more likely and appropriate mechanism
12 for wider use of this product. I think, in the event,
13 the product that we did get never got used for
14 previously untreated patients. I think it was
15 ultimately used for a patient under Dr Ludlam's care
16 who had an allergic reaction to some other products
17 and 8Y didn't produce that allergic reaction. So it
18 never got used because previously untreated patients
19 didn't come up very often.

20 And the other factor is that this was only -- it
21 was only envisaged at the time of it taking place to
22 be in place for about two or three months because the
23 PFC equivalent product would have been available then.
24 In the event, it was delayed for reasons of clinical
25 trials and so on.

128

1 **MS RICHARDS:** I'm going to move now, Dr Perry, to
2 a completely different topic. I just want to ask you
3 very briefly, first of all, about your role on the
4 Biological Subcommittee on the Committee on Safety of
5 Medicines.

6 I'm not asking you about any particular aspect
7 of the decisions or the Committee meetings that you
8 attended between 1986 to 1990. It's just really to
9 ask you to illuminate the process a little.

10 First of all, the confidentiality of meetings of
11 the Biological Subcommittee, I think described by you
12 in your Penrose evidence as "rigorous and formal". So
13 members of the committee were expected not to share
14 information about committee meetings --

15 **A.** This is the Committee on Safety of Medicines?

16 **Q.** Committee on Safety of Medicines, that's right. So
17 there was a high expectation of confidentiality?

18 **A.** I think I had to sign a formal document declaring that
19 I would keep the contents of the meeting and the
20 discussions strictly confidential.

21 **Q.** Can you recall how potentially conflicts of interest
22 were managed because you were and Mr Watt had been
23 effectively fractionators, producers of blood
24 products, at the time of sitting on the meetings.
25 That could be said to give rise to a potential

129

1 committee, made a very real contribution to the work
2 of the committee.

3 **Q.** And in terms of the issues that were considered at
4 meetings, would it be right to understand that the
5 majority of the consideration would be of actual
6 licence applications or licence renewal applications?
7 Was that most --

8 **A.** Yes, the way the system worked was perhaps a month
9 before the meeting, a very large bag would arrive at
10 my house, or it may have come to PFC as the point of
11 delivery, containing the full dossiers that had been
12 submitted by product licence holders and the job was
13 to go through those and then present any views that we
14 might have on safety or quality issues to the
15 Committee when it met.

16 **Q.** Were there ever, as far as you can recall,
17 subcommittee meetings which were looking -- in which
18 *ad hoc* advice was sought on issues other than licence
19 applications or licence renewal?

20 **A.** A generic issue?

21 **Q.** Yes.

22 **A.** No, but I think they did take place. I think they did
23 occur. I can't give any really meaningful examples
24 during my tenure, but they may well have done. But
25 the bulk of the work was to address specific licence

131

1 conflict of interest when considering applications or
2 issues relating to similar products produced
3 elsewhere. But was there a system for managing that?

4 **A.** The solution to that very real problem that you
5 described was fairly simple and straightforward, that
6 both myself and Dr Snape, who was on the committee at
7 the same time, were asked if we would care to resign
8 because of potential conflict of interest.

9 So when that was recognised I think it was
10 following the removal of Crown immunity. I think
11 prior to that date, I think the Committee on Safety of
12 Medicines, the Biological Subcommittee, felt that they
13 needed people who had expertise in fractionation to
14 advise the secretariat and the people that assessed
15 product licence applications from other organisations
16 to be part of that decision-making process.

17 I think I was always aware of the conflict of
18 interest and I was extremely rigorous about never
19 divulging any information or knowledge that I gained
20 from reading a manufacturer's licence application.
21 But I think, with hindsight, it was probably the
22 correct outcome, that it was a conflict of interest
23 but during our -- certainly during my time on the
24 Committee on Safety of Medicines, I think both
25 Dr Snape and Dr Lane, who preceded Dr Snape on the

130

1 applications and so on, but nothing comes to mind
2 regarding more generic considerations.

3 **Q.** Now, the next and the sort of final main topic I want
4 to turn to is your role on the Advisory Committee for
5 the Virological Safety of Blood and its consideration
6 of issues relating to the introduction of hepatitis C
7 screening.

8 I just want to ask you before we look at any
9 particular documents just for some general assistance
10 with this particular committee. You were on it from
11 its inception and the first meeting was April 1989.
12 Did you gain any understanding or sense of why it
13 hadn't been set up earlier than 1989?

14 **A.** Not really. I think it was -- my understanding, and
15 I'm not sure I have a good evidence base for this
16 understanding, but it was a result of some disquiet
17 over the processes that were in place during the
18 implementation of HIV testing in blood because it
19 wasn't a straightforward process and it was -- there
20 were multiple organisations involved in policy-making
21 and so on and, as with so many things in government,
22 it took them a few years to actually find the solution
23 to this, which was to create an advisory committee
24 whose purpose was to advise ministers on this.

25 **Q.** And it's right to understand, I think, that was

132

1 precisely its role. You would advise -- when I say
2 "you", the Committee would advise -- the Department of
3 Health through -- I think there's a suggestion in one
4 of the documents it would go first to the Chief
5 Medical Officer, but leave that aside, and then for
6 Ministers to take the final decisions?

7 **A.** Maybe it's the passage of time but I'm not sure I know
8 of the precise mechanism. It was certainly
9 an advisory committee to advise Ministers. Whether it
10 got -- whether the decisions and the considerations
11 were passed through the Department of Health, I'm
12 not sure. But it was always chaired by the Deputy
13 Chief Medical Officer. So it was a fairly senior
14 official within the Department of Health and, indeed,
15 the other four territorial countries, as they were
16 called, had representation on the Committee as
17 observers.

18 **Q.** Around the same time, there was another committee
19 formed which was the Advisory Committee on Transfusion
20 Transmitted Diseases. What was your understanding of
21 the different roles or respective roles and remits of
22 the two bodies?

23 **A.** Well, the ACVSB was set up to advise ministers on
24 policy and I think that was emphasised. Its stated
25 aim was not to get involved in detailed operational

133

1 Dr Metters ..."

2 He was the Deputy Chief Medical Officer, I think --

3 **A.** He was.

4 **Q.** -- who took over from Dr Harris, who chaired the first
5 three meetings?

6 **A.** Yes, that's right.

7 **Q.** "... always emphasised that the views of the committee
8 were advisory. It was an advisory committee and it
9 didn't have the final say. So it always carried the
10 caveat that ministers may or may not agree."

11 And that was your understanding at the time?

12 **A.** That was my understanding at the time, yes.

13 **Q.** Then, if we just go, by way of example --

14 **A.** I can't actually recall any instance where a carefully
15 worked out strategy or policy presented to ministers
16 was rejected, I think. By and large, at least in 99%
17 of the time, the advice was accepted.

18 **Q.** Now, if we can go to the minutes of the second
19 meeting, which was 22 May 1989. And it is
20 NHBT0005019, please.

21 We see there the membership of the committee.

22 We have got still Dr Harris here, before Dr Metters
23 takes over. We have then got a number of members
24 listed, yourself included, a number of names familiar
25 to the Inquiry: Professor Zuckerman, Dr Tedder,

135

1 issues, however important, these were matters for the
2 professional services, the blood services and public
3 health organisations to deal with. And ACTTD, the
4 Advisory Committee on Transfusion Transmitted
5 Diseases, was set up within or amongst the four blood
6 services within the UK to consider those operational
7 details. But also to advise the ACVSB on particular
8 issues. And Dr Gunson, who chaired the ACTTD, sat on
9 both committees, so there was overlap, but it was
10 always reinforced at the meetings that I went to of
11 ACVSB and also NSBT that it was their role to create
12 policy and to decide policy, not the ACTTD.

13 So there was a little tension between the two
14 committees but they worked very well together overall.

15 **Q.** You told the Penrose Inquiry when you gave evidence on
16 this topic that the agendas for ACVSB meetings would
17 be put together by the Department of Health
18 secretariat, is that right?

19 **A.** Yes.

20 **Q.** If we can just pick up your Penrose evidence at
21 PRSE0006068, please. If we go to page 116.

22 This is evidence given in November 2011.

23 So page 116, please, Sully. Bottom of the page.

24 You say this:

25 "It was always the case at these meetings that

134

1 Dr Tuddenham, Dr Mitchell, Dr Mortimer, Dr Lane,
2 Dr Minor, who I think represented NIBSC?

3 **A.** Yes, he was a well known and respected virologist at
4 NIBSC.

5 **Q.** Then we have the secretariat, Dr Rejman, Mr Canavan,
6 so they're from the Department of Health. Then we
7 have observers, of whom I think, on the left-hand side
8 of the observers, Dr Pickles, Dr Rotblat, Dr Purves,
9 are from the Department of Health?

10 **A.** Dr Pickles was from the Department of Health.

11 Dr Rotblat was a medical assessor for the Medicines
12 Control Agency. And Dr Purves was a pharmaceutical
13 assessor for the Medicines Control Agency.

14 **Q.** Then the other observers we have listed represented
15 Scotland, Wales and Northern Ireland. I might have
16 got the Northern Ireland and Wales the wrong way
17 round, I'll need to double-check --

18 **A.** Yes, Dr McIntyre was the Scottish representative and
19 I think Dr George was the Northern Ireland
20 representative and Dr Flett perhaps from Wales, but
21 I can't be sure.

22 **Q.** Now, you said in your Penrose -- or it was put to you
23 in your evidence to the Penrose Inquiry, and you
24 agreed, looking back, that there may have been
25 insufficient public health expertise or perspective in

136

1 terms of the membership of the ACVSB; is that right?

2 **A.** This was in a briefing note I supplied to

3 Professor Cash, wasn't it? Is that where that came

4 from? Or is it in my evidence?

5 **Q.** It is in your evidence. I think if we go to

6 PRSE0006068.

7 **SIR BRIAN LANGSTAFF:** That's it on the screen, I think.

8 **MS RICHARDS:** No, PRSE0006068. Oh, my screen still has

9 the minutes.

10 **SIR BRIAN LANGSTAFF:** -- (overspeaking) -- 5019 on the

11 screen I think.

12 **MS RICHARDS:** I don't have the transcript on the screen.

13 Thank you.

14 Page 137. I should perhaps just pick it up on

15 the previous page, 136, just so that we can see the

16 context in which you then give an answer. So

17 Professor James in the Penrose Inquiry explores with

18 you issues about the composition of the committee. He

19 says -- he suggested it:

20 "... didn't contain enough sharp end

21 transfusionists ... and they were outnumbered by

22 strong-minded and authoritative 'virologists' for

23 example, so that the committee might have paid rather

24 more cognisance, in that important period in 1990 in

25 particular, and the beginning of 1991, to the

137

1 that basis alone, that was a reasonable justification

2 for implementing the Phase I test rather than delaying

3 it by a further year.

4 **Q.** Then if we go to page 14, please, of this transcript.

5 If I can pick it up from line 10 onwards, you

6 were asked about the contribution of the secretariat

7 to the meetings. Did they contribute to meetings,

8 those individuals? And your answer:

9 "Yes, there were -- certainly Dr Rejman and

10 Dr Pickles -- and I'm trying to recall if there were

11 others ..."

12 Then you refer to Dr Purves.

13 Then line 18:

14 "Yes, periodically they were called upon

15 specifically to report on a particular issue, but also

16 took a full part in the discussions of the committee."

17 So that is your recollection of the role of the

18 Department of Health secretariat, that they weren't

19 simply there to put together the agenda and take

20 a note; they participated actively in the discussions?

21 **A.** No, they had quite senior medical officers from the

22 Department of Health that were part of the committee.

23 They weren't full members of the committee, but then

24 it wasn't a voting committee. It didn't used to vote

25 on issues and so on. There was a process that I never

139

1 virology, as against the public health/needs of the

2 screening service."

3 I want to remind you of your answer, which is at

4 the top of the next page. You say:

5 "**Answer:** ... I think I agree with your analysis to

6 an extent, and the reason I was hesitating was because

7 this was something that I considered before I wrote my

8 statement. I thought composition of the committee was,

9 perhaps with hindsight, unduly biased to the science,

10 the expert virologists, who are very authoritative

11 people. I have to say this, it is not a criticism of

12 them. But, standing back, and perhaps 20 or 30 years

13 on, the public health perspective was not as dominant in

14 fact as it possibly could have been."

15 Does that remain your view, again, looking back?

16 **A.** Yes, I think it does. Well, I would just underline,

17 this is not a criticism of the virologists but it

18 seemed to me that the best became the enemy of the

19 good, as it were, as the expression goes. That they

20 were searching for perfect outcomes rather than good

21 outcomes that could meet a public health need. And

22 that was -- for me, that came to the fore when data

23 was presented that said the first generation

24 hepatitis C antibody test would have picked up 60% of

25 HCV positive donors. And I thought that's -- just on

138

1 really understood what the detail was, and we would

2 have the discussions at the meeting and then those

3 discussions would get taken away to the Department of

4 Health for further consideration and perhaps a revised

5 position might come back from the Department of Health

6 for consideration. So they were very much an integral

7 part of the process as far as I recall.

8 **Q.** Then you continue:

9 "I think that was probably less the case with the

10 Welsh, the Northern Irish and the Scottish departmental

11 representatives, who tended to be, as they were

12 described there, more observers than participants."

13 **A.** That's my impression, yes.

14 **Q.** Now, confidentiality, I don't think we need to look at

15 the minutes to see this, but in -- a number of the

16 minutes record the chair, so the deputy CMO,

17 emphasising the confidentiality of the proceedings.

18 If we go to page 16, please.

19 I want to pick up the way in which you put it in

20 your Penrose evidence. At line 6, you were -- so your

21 attention was drawn to the minutes referring to

22 confidentiality, and then you said this:

23 "Yes, I think the minutes slightly understate what

24 was actually said at the meeting and I remember this --

25 there are a few moments in one's life that you do

140

1 remember and I think Ed Harris, who was the deputy chief
2 medical officer at the time, did really underline and
3 emphasis this point, almost threatening you with the
4 tower of London if you were to breach that
5 confidentiality."

6 So it was expected that members of the committee
7 would keep what was being discussed absolutely
8 confidential and secret?

9 **A.** That was certainly the message that was delivered very
10 forcefully at the first meeting and subsequently
11 underlined periodically. There wasn't a -- it wasn't
12 reinforced vigorously at each meeting but we were
13 reminded that discussions were confidential and if
14 there was a particularly controversial topic or
15 a topic with a very wide and active public health
16 interest associated with it, which was controversial,
17 then we were always advised that the discussions of
18 the meeting should remain confidential.

19 That was always a problem, of course, because
20 some of the discussions had really quite short-term
21 impacts on the work of the transfusion services. So
22 I think I did find ways of communicating some points
23 of information that I gleaned from the meeting to
24 senior colleagues. But it was never a satisfactory
25 process. The minutes were never released to a wider

141

1 about than England, of course. So, yes, it did
2 concern me.

3 But the process as prescribed by the committee
4 was that the -- nothing can be said to anybody until
5 the formal position had been solidified and approved
6 and so on.

7 **Q.** Can I suggest to you for your comment two problems
8 that might arise as a consequence of the requirement
9 of confidentiality. The first, which I think you have
10 already alluded to, is that it means you, as a member
11 of the committee, or any other members of the
12 committee, could not report back to others and share
13 with them information which might be highly relevant
14 to what others are doing --

15 **A.** Yes.

16 **Q.** -- or might need to know?

17 **A.** Or equally, because I was a representative,
18 effectively, I was on the committee because I was part
19 of the SNBTS, but, equally, colleagues from SNBTS
20 could inform my views much more substantially if
21 I knew there was a particular topic on the agenda, but
22 I couldn't go to them and say, "This particular topic
23 is coming up on the agenda, can you please brief me?"

24 **Q.** I think that essentially picks up on what I was going
25 to suggest was the second problem, which --

143

1 audience.

2 **Q.** You say later in your Penrose evidence, I don't think
3 we need to go to it, but it is the same transcript, at
4 page 141, you said:

5 "... there was undue emphasis on this [that's
6 the confidentiality requirement], for reasons which
7 were never really clear."

8 Is that right?

9 Sorry, it is a different page. I can take you
10 to it.

11 Page 141, please, Sully.

12 Bottom of the page, line 21, you were being
13 asked about confidentiality, and you say:

14 "I think there was undue emphasis on this, for
15 reasons that were never really clear."

16 So is that right, it was never really explained
17 to you as a member why there was this requirement of
18 confidentiality?

19 **A.** I think the world was generally much more confidential
20 then, and perhaps less transparent than it's required
21 to be now. But periodically it did concern me that
22 some of the issues that were being discussed I knew
23 would be very important to those planning the work of
24 the transfusion services back in the Regional
25 Transfusion Centres in Scotland, which I knew more

142

1 **A.** I think I found ways of managing around that, but it
2 was a constraint, yes.

3 **Q.** Because if you have minutes that are publicly
4 accessible and can be shared, it means that those who
5 are not the eight, nine or however many members of the
6 committee, but who might have a great deal of informed
7 opinion and expertise to bear, they are not in
8 a position to influence or inform or shape the
9 decision-making, are they?

10 **A.** No.

11 **Q.** Because they simply don't know what's being considered
12 and why?

13 **A.** Yes, that's right that is right. I think, to be fair
14 to the process, I think it over the -- as the years
15 passed, it loosened up a little in terms of ability to
16 communicate outside the Committee on particular
17 issues.

18 **Q.** Now, what I'm going to do next is -- I'm not going to
19 take you through each of the meetings. I'm going to
20 just read the references and the dates for the
21 meetings, so they're collected in one place on the
22 transcript. Then I just want to take you to just
23 a handful of observations you made either to Penrose
24 or in your statement to this Inquiry about the
25 decision-making process on hepatitis C screening.

144

1 So the dates of the meetings and their URNs are
 2 as follows: first meeting from April 1989 is
 3 NHBT0000041_003; second meeting, 22 May 1989,
 4 NHBT0005019; third meeting, 3 July 1989,
 5 NHBT0000072_025; and then, fourth meeting, 6 November
 6 1989, NHBT0005043; fifth meeting, 17 January 1990,
 7 PRSE0001477; sixth meeting, 24 April 1990,
 8 NHBT0000072_098; seventh meeting, 2 July 1990,
 9 PRSE0000976; eighth meeting, 21 November 1990,
 10 NHBT0000073_018; ninth meeting, 25 February 1991,
 11 PRSE0002280; and then tenth meeting, 21 May 1991,
 12 NHBT000042_080.

13 Now, obviously meetings continued after that
 14 date but those are the meetings at which the issue of
 15 hepatitis C screening were considered.

16 Can I then come to just a number of general
 17 matters about the decision-making process. First of
 18 all, it appears to have been understood that the
 19 ultimate decision on hepatitis C screening was going
 20 to be a decision for the Department of Health or the
 21 Secretary of State for Health?

22 A. Departments of Health.

23 Q. So for the four departments; is that your
 24 understanding?

25 A. Yes.

145

1 patients, starting to choose hospitals or where they
 2 would have their transfusion according to whether they
 3 were testing for hepatitis C.

4 So I think there was -- amongst the
 5 professionals, there was no dissent from the notion
 6 that it should all be done on a single date. I think
 7 the problem in Scotland arose when I think colleagues
 8 in Scotland felt that this process was being delayed
 9 over and over again for no good reason for us in
 10 Scotland because all the systems are in place, the
 11 funding was in place, the expertise was there, the
 12 counselling algorithms for the donors was all in
 13 place, and there was very serious concern expressed by
 14 the then general manager, Mr Mackintosh, that actually
 15 we should be implementing this. Our line of
 16 accountability is to the Secretary of State for
 17 Scotland. That was always his argument. But I think
 18 SHHD came back and said no, this is a UK-wide
 19 decision.

20 Q. Now, one of the matters which I think I know you're
 21 now aware of, because you refer either in your Penrose
 22 evidence or your evidence to the Inquiry to having
 23 read the judgment of Mr Justice Burton in *A v National*
 24 *Blood Authority*?

25 A. Yes.

147

1 Q. So it was a government decision, in any event?

2 A. I think so. And the DoH, the English Department of
 3 Health would have --

4 Q. Was in the lead?

5 A. Was very much in the lead, yes.

6 Q. The question both of whether to introduce screening,
 7 when to introduce screening, was going to be a matter
 8 centrally determined in that way?

9 A. That's my understanding of the process, yes.

10 Q. Was that just taken as read, as it were, because it
 11 might be said there was actually no real obstacle to
 12 individual transfusion services taking their own
 13 decision. They were autonomous bodies, funded in
 14 Scotland by the CSA, funded in England and Wales by
 15 their Regional Health Authorities. They didn't
 16 require the permission legally of the Departments of
 17 Health.

18 A. I can't comment on the legal aspects, but what I could
 19 say at the outset of both HIV testing and hepatitis C
 20 testing, it was a fairly consensual view that a single
 21 date for implementation of testing was desirable to
 22 avoid the situation where one hospital in a particular
 23 region was testing and another hospital was receiving
 24 untested blood. I think it would have caused really
 25 quite serious concerns and problems, not least amongst

146

1 Q. So you will know now that a number of other countries
 2 introduced hepatitis C screening significantly earlier
 3 in some cases than the United Kingdom did. The
 4 judgment lists the dates for various different
 5 countries starting, I think, with Japan in November
 6 '89.

7 There's some reference in the ACVSB minutes from
 8 time to time to the position in other countries. Do
 9 you recall that being a focus of discussion or anyone
 10 asking the question, "The States have done it,
 11 Australia's done it, France has done it, Finland's
 12 done it; Canada's done it. Why aren't we doing it?"

13 A. I think it was discussed. I can't remember the
 14 specific conversations. I can certainly remember at
 15 one point in time at one of the meetings, I think it
 16 would have been in 1990, where we learnt that the
 17 Phase I product, Phase I testing system, had been
 18 implemented in many countries (including USA, France,
 19 Finland and so on) and, whatever problems were
 20 considered to remain in the UK, many other countries,
 21 not dissimilar to ourselves, had managed to resolve
 22 these.

23 So my view was -- although I was not an expert
 24 virologist, my view was, well, if they can resolve
 25 these issues and still implement the test system, then

148

1 even with only a 60 per cent specificity rate, then
2 there's absolutely no reason why we shouldn't do that.
3 So that was my evolving view. But it was discussed
4 but perhaps not at the top of the agenda.

5 Q. Then if I can just pick up another general observation
6 you made at PRSE0006068. This is back in your oral
7 evidence, page 50.

8 Now, you were here, I think -- you were taken
9 through during your Penrose evidence a number of the
10 sets of minutes for the ACVSB. I'm not going to
11 replicate that process. I think you were here
12 commenting upon the November '89 meeting, but I'm
13 really interested in whether this is a more general
14 observation.

15 At line 10 you say this -- you talk about your
16 recollection being:

17 "... Dr Metters ... was very anxious that the
18 policy decision should not be taken until it was
19 absolutely clear that all the various details
20 associated with the test had been resolved."

21 Then you go on to say in line 17 that you
22 thought:

23 "... fairly early on in the process, that there
24 could have been a point earlier where ... the
25 Department of Health ..."

1 So WITN6920001, and if we can go to page 146,
2 please, Sully.

3 If we can pick it up towards the bottom of the
4 page, paragraph 458. I'm just going to read what you
5 say and then ask if you have any further comments.
6 You say this:

7 "In brief summary I believe there were a number of
8 shortcomings in the overall UK management process
9 ultimately leading to a relatively late implementation
10 of HCV testing in Scotland and throughout the UK. These
11 included:

12 "i. Unnecessary secrecy and confidentiality
13 associated with the considerations of ACVSB and other
14 'behind the scenes' discussions.

15 "ii. Absent or confused processes for communication
16 of ACVSB decisions to operational managers.

17 "iii. A late recommendation in principle (in my
18 view) by ACVSB and DOH for the introduction of HCV
19 testing. This appeared to be driven primarily by
20 scientific rigour rather than urgent public health
21 considerations."

22 If we go to the top of the next page, please:

23 "iv. The apparent absence of a clear plan,
24 timescale, strategy or policy guidance (from either
25 DOH or SHHD) for the introduction of testing,

1 Then I think there might be some words missing,
2 but it talks about "the testing would go ahead".

3 Then, top of the next page, I think you're
4 contrasting at the top of the next page, Dr Gunson's
5 position, "urging the government to make a policy
6 decision", with the position of the Department of
7 Health taking what you describe in line 5 as
8 "a slightly less enthusiastic view".

9 Leaving aside the particular meeting in
10 question, is that a general theme that ran through it,
11 a reluctance or anxiety on the part of Dr Metters that
12 all the details had to be got right before the bigger
13 decision could be taken?

14 A. From my perspective, that's a reasonable view. I took
15 the view I think there were three conditions that were
16 established during the work up to implementation of
17 hepatitis C that had to be satisfied. One was FDA
18 licentiateship of the test system because they licence
19 diagnostic tests in the US.

20 Satisfactory operational experience of the
21 transfusion services and a suitable confirmatory test
22 and much earlier than September 1991. Those
23 conditions had been satisfied.

24 Q. Then if I can just, to conclude this topic, go to your
25 witness statement to this Inquiry.

1 following the decision in principle by ACVSB in
2 July 1990 to introduce testing.

3 "v. The progressive (and largely unexplained)
4 deferral of the UK start date from April to July to
5 September 1991, believed to have been caused at least in
6 part by administrative and funding issues between the
7 English services and DOH rather than operational
8 readiness.

9 "vi. With hindsight, and given its readiness (both
10 operational and financial) to introduce testing in early
11 1991, the failure of SNBTS to robustly argue a case for
12 earlier introduction of testing in Scotland with
13 SHHD/Scottish Ministers including the public health
14 consequences of delays. Equally an SHHD apparent
15 reluctance to consider such an option preferring instead
16 to be guided exclusively by timescales determined by
17 DoH."

18 Now, you've set out in your Penrose evidence
19 some more detailed observations by reference to the
20 various stages of the decision-making process and, as
21 I say, I'm not going to repeat those. But does that
22 represent your considered view now as someone who was
23 a member of the ACVSB and involved in the
24 contemporaneous decision-making?

25 A. Yes, I think those observations, which are my personal

1 observations (there may be others that disagree with
2 some of those issues), but from my perspective they
3 seem to be the main problems that emerged from the
4 rather turbulent period during 1989 to 1991 when it
5 was eventually implemented and, in particular, there
6 were important meetings that were held in SNBTS and
7 they were quite robust discussions about what Scotland
8 should be doing. I certainly remember that the then
9 general manager felt very, very passionately that
10 Scotland was ready to go, so it should go. But SHHD
11 flatly refused, I think is the best way of expressing
12 it, to entertain such an event.

13 **MS RICHARDS:** Sir, just noting the time. I've probably
14 got another, I think, only five to ten minutes of my
15 own questions for Dr Perry.

16 **SIR BRIAN LANGSTAFF:** Then let's go ahead with them, shall
17 we?

18 **MS RICHARDS:** Thank you. Then we can perhaps break and
19 have the opportunity for Core Participants to suggest
20 any further questions. We can take that down, thank
21 you, Sully.

22 I just wanted to ask you next about your
23 involvement in the Better Blood Transfusion programme,
24 2005 to 2007. Can you just tell us what, in broad
25 terms, that entailed, what the objective was of the

153

1 go out and deliver training to nurse practitioners and
2 in hospitals, and so on, and to haematology
3 departments.

4 Another aspect of the programme was data
5 collection to better understand how blood was being
6 used. The Better Blood Transfusion programme was
7 really only about blood components. It was nothing to
8 do with plasma products.

9 **Q.** No, I understand.

10 **A.** So one of the key targets was understanding how much
11 blood was being used for a hip replacement or a knee
12 replacement or a standard high blood using procedure,
13 because until you have got that and were able to feed
14 that back to practicing doctors, it was very difficult
15 to control demand or to ensure appropriate demand. So
16 it sort of built as a peer review system, and I think
17 the people that used blood most extensively, certainly
18 in the surgical area, were quite interested in these
19 data because they would look at it and say, "Well, I'm
20 using twice as much blood as my colleague". And there
21 was no data before that on that particular topic.

22 So the SNBTS set up what it thought was a --
23 what it thought and I still think today is still
24 a very important programme.

25 **Q.** Was that set up in 2005 when you became involved or

155

1 Better Blood Transfusion programme in Scotland?

2 **A.** I think I can, yes. The Better Blood Transfusion
3 programme, its slogan was "Right Blood, Right Patient,
4 Right Time". It was about getting appropriate
5 prescription of blood transfusion, making sure the
6 right blood was transfused to the right patient
7 because that was always an issue. Many of the adverse
8 reactions associated with transfusion were associated
9 with mismatched blood or the wrong blood going to the
10 wrong patient, and so on.

11 But the -- so it was about clinical practice,
12 about actual delivery of blood transfusion in a safe
13 and appropriate way. But I think it also reflected
14 the increasing observation that one of the most
15 effective ways of reducing the risk of blood
16 transfusion was to reduce the use of blood in
17 inappropriate situations.

18 So if you could eliminate the use of 10 per cent
19 of the blood used in a particular procedure, then you
20 are at a stroke reducing the risk by 10 per cent.
21 That seemed to be an important reward.

22 That process was put in place. The Better Blood
23 Transfusion programme had a number of elements to it,
24 including one of the major elements was training,
25 building training programmes for specialist nurses to

154

1 had it been running before then?

2 **A.** No, it was set up before then.

3 **Q.** Do you know when it was initiated in Scotland?

4 **A.** No. Probably about 2000, maybe. 2001. Dr McClelland
5 was closely involved in this programme.

6 **Q.** Can I ask you then to look at two separate unrelated
7 documents.

8 The first is LOTH0000045_002. LOTH0000045_002.

9 This is a letter, 11 November 1991, from you to
10 Professor Cash. It picks up on a letter that
11 Dr Foster had written to Professor Cash on 5 November
12 expressing some concerns about what Dr Ludlam had said
13 at a meeting. And we looked at the letter with
14 Dr Foster when he gave his evidence.

15 I just want to ask you about what you say here.

16 You say in the second line:

17 "... I share Peter's disappointment at the
18 presentational aspects of Christopher's talk. His
19 comments seem to provide no useful purpose and have only
20 served to undermine our claims of a unique and
21 constructive relationship with our "customers".

22 "Perhaps of more concern is the effect of such
23 public statements at a time when HIV infection of
24 haemophiliacs is very much under continued public
25 scrutiny:

156

1 "Indeed, a central feature of our own position with
2 regard to the tragedy of HIV is the early introduction
3 of heat treatment and other measures such as batch
4 dedication. The scientific value of these measures
5 cannot and will not be proved but they were introduced
6 as a collective response (including Haemophilia
7 Directors) in 1984."

8 Then it is this sentence I wanted to ask you
9 about, please, Dr Perry:

10 "I think the public denial of the value of these
11 actions should be carefully considered lest we undermine
12 our collective security on this issue."

13 What does that mean, undermining our collective
14 surety on this issue?

15 **A.** I'm not sure. I think I was referring to -- oh,
16 I can't remember the detail of this little transaction
17 that occurred, but the source of it was Dr Foster
18 attending a lecture given by Professor Ludlam, where
19 I think his view was -- quite clear view -- that
20 Dr Ludlam had minimised the importance of the actions
21 that we took in response to HIV. He wasn't
22 criticising them, he was simply I think -- I might be
23 thinking about another thing now but he sort of
24 described the early PFC's product as gentle warming,
25 for instance, and --

157

1 provided, it is always possible that different experts
2 will have different opinions. I don't think we should
3 'interfere' with Terry or ask him to change his
4 statement (should there be any differences between us),
5 nor should we change ours to fit a BPL view."

6 I won't read out the rest of the email. But he
7 continues. Then if we go to the top of the page to
8 your response, you say:

9 "I disagree slightly!

10 "Not because I do not trust the competence of the
11 Tribunal to make decisions based on different witness
12 statements but because the Tribunal is a public process
13 in which perceived differences can be exploited by media
14 and other interested parties.

15 "I am not interested in spinning the two statements
16 together or ensuring that the detail is identical, but
17 I am interested in seeing that our respective positions
18 are consistent."

19 Then you say you think it would help the
20 Tribunal if any major conflict/differences were dealt
21 with beforehand.

22 Why were you keen to avoid inconsistency between
23 the picture that might be painted by the evidence of
24 Dr Snape and any evidence that might be presented to
25 the Tribunal from Dr Foster or others within SNBTS?

159

1 **Q.** You are correctly remembering, yes.

2 **A.** Is that a correct reference? Yes.

3 And I think Peter's view, and certainly mine,
4 underscored by this letter, was that making such
5 statements were not helpful to the SNBTS or, indeed,
6 for patients either. So I think it was a concern
7 about -- this was a specific concern about the
8 presentation.

9 **Q.** Then if we can look at WITN3431004.

10 This is an email exchange between you, Dr Foster
11 and Dr Douglas in July 2000 in the context of the
12 Lindsay Inquiry in Ireland.

13 Can we look at the bottom of the page, first of
14 all. So we see at the bottom an email from you to Drs
15 Douglas and Foster, 20 July:

16 "Have just heard that Terry Snape ... is acting as
17 an expert witness in the Tribunal. I think we need to
18 take steps to ensure that there is no major conflict
19 between our report of events (which will soon be in the
20 public domain) and what Terry is planning to say. He
21 has already provided written witness statement.

22 "I will contact him."

23 Then if we go up a little, we see Dr Foster
24 emailed you back, saying:

25 "Although it will be useful to learn what Terry has

158

1 **A.** I don't really know I can answer that. I certainly
2 wasn't aware of any major problems, but I think I took
3 the view that, although Dr Foster and Dr Snape were
4 both there in their personal capacities attending the
5 Tribunal, they were, in a sense, representing SNBTS
6 and BPL or at least a UK-wide position.

7 So I think both for the purposes of the Tribunal
8 itself, I thought it would be useful if there was
9 consistency between the two statements. I think the
10 outcome of this short exchange was no action was taken
11 by anybody.

12 **Q.** Yes. Was it the case that you were keen to avoid
13 there being public criticism of SNBTS?

14 **A.** No. I think it was -- well, yes, if that criticism
15 was based on an unclear comparison between England and
16 Scotland, for instance. So yes, I was concerned that
17 there could be criticism. But I think my statement
18 really is as it is. I was definitely not interested
19 in spinning the two statements together or trying to
20 influence the outcomes.

21 Dr Foster is very able and competent and
22 Dr Snape is very able and competent. But they were --
23 in a sense, Dr Foster reported to me and he was
24 representing the environment in which I was operating.
25 So at that time on that day I felt I had a legitimate

160

1 interest in what he might be saying and what Dr Snape
2 might be saying.

3 **Q.** We can take that down, thank you, Sully.
4 Just one final question then for now, Dr Perry.
5 A theme of your evidence, in particular yesterday when
6 we were looking at self-sufficiency, was the
7 importance of minimising the use of commercial
8 concentrates in Scotland because commercial
9 concentrates were seen as risky products in terms of
10 viral transmission. Is that fair?

11 **A.** Yes, I think that's fair.
12 **Q.** Do you think that may have led to a sense of or
13 a degree of complacency within SNBTS and PFC that the
14 domestic product was safe as opposed to the domestic
15 product being less risky than commercial concentrates?

16 **A.** I don't think that was a conclusion that we drew.
17 I think certainly after, as we've discussed this
18 morning, the publications by people like Peter Kernoff
19 and so on which demonstrated that UK products from
20 voluntary donors still had the capability of
21 transmitting virus to patients, and they did, it was
22 certainly not a view in my mind, or indeed other
23 people's minds, that the products were necessarily
24 safer with respect to non-A, non-B, although there was
25 still a belief that the severity of disease in the

161

1 **MS RICHARDS:** I think that will be sufficient, thank you,
2 sir.

3 **SIR BRIAN LANGSTAFF:** Let me explain to you, Dr Perry --
4 you may have heard me say this before, I don't know,
5 but I'll say it again anyway -- those who are
6 represented as Core Participants have the right,
7 through their representative, to ask counsel to put
8 questions to you. Many will have been watching
9 online. Those questions may not yet have been
10 formulated, though people may have been thinking about
11 them. Counsel must have a chance to collect those
12 questions, consider them and then put the substance of
13 them to you in due course. It takes time. That time
14 is very usefully spent having a cup of tea, so we will
15 take a tea break now and come back at 4.15 pm.

16 **A.** Thank you.
17 **(3.38 pm)**
18 **(A short break)**
19 **(4.15 pm)**
20 **SIR BRIAN LANGSTAFF:** Yes, Ms Richards.
21 **MS RICHARDS:** Dr Perry, because the questions I'm going to
22 ask you now have come from Core Participants, or their
23 legal representatives, over the break, they will leap
24 around from topic to topic a little because of the
25 multiple sources. Apologies for that.

163

1 acute phase was lower and the duration of disease was
2 lower and so on.

3 Where I think that changed dramatically was with
4 the advent of AIDS, where I think there was a very
5 clear view then that SNBTS, and indeed UK products and
6 indeed voluntary products based on the voluntary donor
7 principle, were almost certainly going to be safer in
8 terms of the number of virus-infected donations
9 entering a plasma pool. I think all the data that's
10 come out from that particular period in terms of
11 incidence of AIDS and incidence of HIV in plasma
12 donors and so on bears that out.

13 But it didn't make us complacent. It reinforced
14 the view that SNBTS products, and indeed BPL products,
15 were going to be safer. But not safe.

16 **MS RICHARDS:** Sir, those are the questions or topics I'm
17 proposing to cover with Dr Perry, but we now need to
18 give an opportunity to Core Participants to suggest
19 any further issues arising out of Dr Perry's evidence.

20 **SIR BRIAN LANGSTAFF:** Do you have any sense of how long
21 a period of break you might need?

22 **MS RICHARDS:** I don't know but I think it is probably safe
23 to ask for half an hour.

24 **SIR BRIAN LANGSTAFF:** If I was to suggest not before
25 4.15 pm?

162

1 **A.** Okay.
2 **Q.** The first question arises out of your evidence earlier
3 today when we were discussing the question of product
4 warnings and leaflets, and it is this: at the time, so
5 in the early 1980s, did you think that the PFC had
6 a responsibility to patients to provide accurate and
7 clear information about the risk of hepatitis B and
8 hepatitis non-A, non-B on its labels and leaflets, or
9 did you think the PFC had no responsibility in that
10 regard because it was the responsibility of others,
11 such as treating clinicians or the licensing
12 authority?

13 **A.** I think it was the former. I think that PFC did feel
14 it had a responsibility to provide appropriate
15 warnings but, as we discussed, I think those warnings
16 to an extent are prescribed or proscribed by the
17 regulations that we operated in.

18 So, yes, of course the PFC had a responsibility
19 to communicate to patients, although at that time
20 the communication was not directly to patients, it was
21 to the doctors that treated the patients and, as
22 I think we noted, that changed in 1994, when patient
23 information leaflets which were much clearer, much
24 more explicit of risks and so on, came into force.

25 **Q.** Did the PFC ever, to your knowledge -- again I'm

164

1 talking about really the first half of the 80s here --
 2 ever explicitly consider the position of patients on
 3 home treatment who might essentially just be taking
 4 the products home and using them there rather than
 5 having the products administered to them by their
 6 clinicians?
 7 **A.** I'm so sorry --
 8 **Q.** In the context of labels and what should be on the
 9 labels or in the leaflets.
 10 **A.** Providing special information to patients on home
 11 therapy?
 12 **Q.** Yes, or ensuring that whatever information was
 13 provided took account of patients on home therapy.
 14 **A.** It may well have been that PFC did provide information
 15 like that but never directly to patients. We may have
 16 provided background information for haemophilia
 17 doctors to decide whether they wanted to include it in
 18 information that they provided to patients, but
 19 I don't think it would be appropriate -- I would
 20 hesitate to say illegal, but I'm not sure of the
 21 formal regulatory position of a manufacturer providing
 22 detailed information to patients which could be of
 23 a clinical nature or identify risks. So we may well
 24 have produced information for home therapy -- patients
 25 on home therapy, but that would never have been

165

1 directly with patients. Nor would it be appropriate
 2 to do so now, I don't think.
 3 **Q.** You are not aware of any particular documents or
 4 discussions or meetings which canvass that issue and
 5 what might be the information requirements of home
 6 therapy patients?
 7 **A.** No, it was quite clear that if there was a requirement
 8 for such information, PFC and the wider SNBTS would
 9 have always responded positively to requests for
 10 detailed information that could then be provided by
 11 their doctors to their patients.
 12 **Q.** In broad terms, what measures were taken to protect
 13 those working at PFC, in the processing and
 14 manufacturing plants, from hepatitis?
 15 **A.** I think it was a process of just continually
 16 underlining awareness of the materials that they were
 17 dealing with that -- and I think in some of the
 18 documents that I have seen referenced by the Inquiry,
 19 there are memos that I have sent out to all staff. We
 20 had active health and safety committees. And the
 21 underlying principles of everything that we did was to
 22 assume, for the purposes of health and safety, that
 23 the plasma that we were dealing with had infectious
 24 agents in it and people should respond accordingly.
 25 Of course, systems and manufacturing

166

1 environments were made as safe as possible but
 2 nonetheless, on occasions, there were inescapable
 3 situations where you have open systems where large
 4 pools of plasma are being held.
 5 **Q.** When the risks of -- potential risks of viral
 6 infection leading to AIDS emerged, did the PFC change
 7 the measures it took to protect the plant workers?
 8 **A.** No, there wasn't much that we could do. The immediate
 9 measure that we took was to reinforce the importance
 10 of the existing practices, to further encourage staff
 11 to make comments and suggestions about safer methods
 12 of working. And the documents that -- some of the
 13 documents that were provided to staff to assist in
 14 that I think the Inquiry has access to. But there
 15 weren't any specific -- there was no vaccine, there
 16 was no way of protecting staff working at PFC from
 17 the risks of infectious agents. Although, to the very
 18 best of my knowledge, and I think it is fairly
 19 accurate, there were never any instances of
 20 transmission of either hepatitis viruses or HIV to any
 21 staff working at PFC. And probably BPL. I think we
 22 would have known about it had there been such a case.
 23 **Q.** The next question then relates to the use of red cell
 24 concentrates as part of the strategy towards
 25 self-sufficiency. Do you know how Professor Cash

167

1 managed to get clinicians to adopt a much more
 2 widespread use of red cell concentrates rather than
 3 whole blood? Was it force of personality or
 4 particular initiatives or steps that he took or both?
 5 **A.** I think it was a combination of all of those things.
 6 I think -- if I can sort of picture the scene in the
 7 late '70s when he was director of the Blood
 8 Transfusion Service in Edinburgh, I would imagine part
 9 of his working day would have been visiting, speaking
 10 to colleagues, harassing them, if you like, to
 11 actually perhaps review their clinical practice. He
 12 would have never prescribed and said you were only
 13 getting red cells. He would have done it by
 14 consensus.
 15 **Q.** I asked you yesterday about pool sizes. In relation
 16 to HIV, do you accept that pool size did matter when
 17 it came to HIV, in contrast to what you've said was
 18 the position in relation to non-A, non-B because of
 19 what you described effectively as the inevitability of
 20 infection?
 21 **A.** Yes. After so many batches, yes. I think it was
 22 a much -- it had much more significance and importance
 23 when HIV emerged.
 24 **Q.** And when HIV did emerge, HTLV-III/AIDS did emerge, end
 25 of '82 through into '83, and we heard from Dr Foster

168

1 last week about the information he gathered at the
 2 Stockholm conference in the middle of '83, was any
 3 consideration given to reducing pool sizes at that
 4 point in time, even as a temporary measure to try to
 5 reduce the risk of HIV transmission?

6 **A.** I think in all honesty there wasn't, for the reasons
 7 that I have described: reducing the pool size would
 8 have reduced the batch size, it would have reduced our
 9 capacity, output would have not met demand, and the
 10 outcome of that would have increased commercial
 11 product purchase. So that -- I don't recall any
 12 discussions being held about reducing pool size.

13 **Q.** Do you recall the context for Dr Crawford's suggestion
 14 of the creation of individual donor pools?

15 **A.** No, I don't, sorry.

16 **Q.** NIBSC, the testing that was undertaken before anti-HIV
 17 testing became available, was that focused on potency?

18 **A.** Potency and perhaps hepatitis B surface antigen
 19 testing and -- but I think it started out -- its
 20 genesis was concern that the vial potency of
 21 Factor VIII concentrates being used in the UK were
 22 particularly -- though not exclusively -- from
 23 commercial organisations, were carrying potency which
 24 didn't seem to accord with the measurements that were
 25 being made by clinicians and by NIBSC itself. So they

169

1 But there was a short period when NIBSC said, "We are
 2 too busy to handle your material", so they suspended
 3 this arrangement where we submitted batch samples for
 4 testing. But that was reintroduced about a year later
 5 I think.

6 **Q.** In terms of the accumulation of or stockpile of
 7 material at PFC, you said in your evidence you were
 8 shocked to learn that that amount had been accumulated
 9 whilst operating a pro rata distribution system. Do
 10 you know how it happened that PFC was able to
 11 accumulate such a large surplus?

12 **A.** I think it was increased plasma supply, which was
 13 going up quite steeply at that time, and it was the
 14 product of the research and the development that
 15 Dr Foster had done to increase the process yield. So
 16 I think a combination of those two factors led to
 17 an increased product stock. I was surprised that it
 18 had accumulated to such an extent and nobody had
 19 noticed.

20 **Q.** That was really going to be my next question. How was
 21 it that nobody had noticed, and could it have been
 22 noticed rather earlier than I think late 1983?

23 **A.** Yes. I think if we had had -- but that was the
 24 purpose of me introducing a different stock control
 25 system and product supply system.

171

1 set up a system of -- I think it was -- I don't
 2 know -- I'm not sure whether it was absolutely
 3 mandatory but licence manufacturers were required to
 4 submit samples and NIBSC would either confirm the
 5 potency or suggest that they assign a different
 6 potency to a particular batch.

7 **Q.** Before HIV testing became available, roughly what
 8 proportion of PFC batches were tested by NIBSC?

9 **A.** Sorry, before?

10 **Q.** Before HIV testing became available, what proportion
 11 of batches were tested?

12 **A.** Before HIV testing?

13 **Q.** And then the next question is: did it change after HIV
 14 testing became available?

15 **A.** Before HIV testing became available, there were no
 16 batches tested for HIV --

17 **Q.** No, sorry --

18 **A.** But for -- for hepatitis B surface antigen?

19 **Q.** Yes. So what proportion of PFC batches were submitted
 20 to NIBSC for whatever tests they wanted to carry out?

21 **A.** This would be prior to 1985, of course.

22 **Q.** Yes.

23 **A.** I don't think I can answer that. When we did have
 24 arrangements for NIBSC undertaking testing on our
 25 products, it would probably have been all the batches.

170

1 **Q.** Then can I just ask you to look now at PRSE0000040.
 2 This is your note of the UKHCDO meeting,
 3 17 October 1983.
 4 Yes, PRSE0000040. Bottom of the page.
 5 We looked at this passage before. It is just
 6 above the heading "Pasteurisation in Liquid State".
 7 It records you asking whether any viral inactivation
 8 data was available. Then it gives the example
 9 "vaccinia data". What is that data that you are
 10 referring to there as a possible indicator of
 11 non-infectivity?

12 **A.** Vaccinia is a virus that can be used in model -- it
 13 can be cultured in test tubes, if you like, and used
 14 to do model virus inactivation experiments. So when
 15 I say "eg vaccinia data", I think we used mumps virus
 16 and various other viruses to try to calibrate our
 17 processes using model viruses. And we did that on
 18 behalf of both BPL and PFC.

19 **Q.** If we go to your witness statement, WITN6920001.
 20 Page 37. Just looking at paragraph 106, which we
 21 looked at earlier for different purposes, where it
 22 says in the fourth line:
 23 "This included the development of in house methods
 24 for testing the efficacy of inactivation processes using
 25 'model' viruses."

172

1 My next question was going to be what were the
2 model viruses you used at PFC. I think you have just
3 referred to a couple?

4 **A.** Yes, I think we used vaccinia mumps. We also used --
5 on some occasions we used phage, which are bacterial
6 viruses which are very easily grown and utilised and
7 can be useful as models. But I -- there were others,
8 but I can't remember what they were. But they were
9 viruses that selected, especially when we were looking
10 at heat treatment, for their thermal stability. So we
11 tried to access viruses, for instance, that we knew
12 were resistant to heat treatment and use those as part
13 of a process. And then there will be other viruses
14 that selected for different processes, like
15 immunoglobulin preparation, where you wanted viruses
16 that -- in which you could demonstrate the ability of
17 low pH to inactivate viruses. So you use different
18 viruses for different circumstances.

19 **Q.** In the same document can we go to page 133. Different
20 issue.

21 Top of the page refers to a vial of the
22 particular implicated batch from autumn of 1984, NY
23 3-009, being found in 2008 and submitted to NIBSC for
24 testing.

25 How did a vial of the implicated batch come to

173

1 in vitro trials or testing of the heat-treated NY was
2 done before the rollout?

3 **A.** I don't think too much. I think it was -- I can't
4 remember exactly how many patients but they were
5 infused with the product and carefully followed up to
6 ensure there were no short-term or long-term adverse
7 events, but in one sense it was an advantage of
8 operating out of a very tightly and formally
9 controlled regulatory system, because we were able to
10 introduce developments like this very quickly.
11 I think by today's standards you would have done
12 a much more extensive study before implementing such
13 a change. But I think it is a good example of the
14 urgency with which we thought this process step was
15 required.

16 **MS RICHARDS:** Sir, those are the questions I'm proposing
17 to ask from those submitted by Core Participants.

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

19 **MS RICHARDS:** Do you have any questions?

20 **Questions from SIR BRIAN LANGSTAFF**

21 **SIR BRIAN LANGSTAFF:** Just one area really. It arises out
22 of the questions which a Core Participant invited you
23 to ask.

24 You said that, as far as protection of staff
25 were concerned, you assumed for the purposes of health

175

1 be found in 2008 do you know?

2 **A.** This postdated my retirement from SNBTS but I think
3 I'm familiar with the context from my involvement in
4 writing this particular report. It was a vial of
5 product that was sent to, at that time a close
6 colleague of PFC and SNBTS, a virologist,
7 Dr Peter Simmonds, and he was doing some work on
8 identifying HIV, and we sent him -- I think we sent
9 him some of the vials that were returned from Aberdeen
10 associated with batch 3-009. And this was when -- in
11 the run-up to the Penrose Inquiry, we knew this topic
12 was an important topic, the transmission of HIV by
13 this particular batch, and so we -- the SNBTS
14 circulated everybody it could think of who might have
15 access to any samples of this product and Dr Simmonds
16 wrote back and said, "Yes, I have found one actually".
17 It hadn't been held in appropriate storage. It had
18 been held at room temperature. But we were able to
19 gain some useful information from it.

20 **Q.** You can take that down, thank you.

21 Then, last question. In relation to the rollout
22 of heat-treated concentrates from 10 December 1984,
23 and given the potential for heat treated concentrates
24 to cause problems such as the development of
25 inhibitors that you mentioned before, what in vivo or

174

1 and safety that the products you were dealing with had
2 infectious agents in them?

3 **A.** Yes.

4 **SIR BRIAN LANGSTAFF:** Did you tell the staff of the risks
5 that there might be?

6 **A.** Yes, we did. And as soon as hepatitis B vaccination
7 came in, all staff of PFC were vaccinated for
8 hepatitis B.

9 There was little other action that was taken but
10 they were certainly informed of the risks of
11 needlestick injuries or abrasions or cuts and so on.
12 And on those occasions where staff -- and they were
13 encouraged to always report those incidents, and we
14 had the services of a GP close by who used to attend
15 the centre periodically, and the staff would be
16 injected with a dose of immunoglobulin following any
17 needlestick injury or suspected needlestick injury.

18 I'm not sure how effective that was, but that
19 was the extent to which one could make a material
20 intervention for staff that might have been exposed to
21 a virus. But I think generally staff at the centre
22 were very carefully advised and trained to -- as
23 I say -- the underlying principle of the training and
24 the behaviour control was to -- really just to
25 emphasise that they had to assume that everything was

176

1 infective, because we didn't know otherwise. We
 2 couldn't identify which batches might be infective or
 3 which particular -- so you assume everything is
 4 infective and behave accordingly.
 5 **SIR BRIAN LANGSTAFF:** They were heavily unionised.
 6 **A.** Yes.
 7 **SIR BRIAN LANGSTAFF:** So the union would have been told of
 8 the health and safety risk and pass that on as well?
 9 **A.** Yes.
 10 **SIR BRIAN LANGSTAFF:** But you didn't rely just on the
 11 union to tell them?
 12 **A.** No, we didn't rely on the union. The union -- we had
 13 all the appropriate safety committees in place and
 14 safety advisory groups and so on. But no, we always
 15 felt that it was not the business -- it was the
 16 management's responsibility to do appropriate training
 17 and information provision on health and safety issues.
 18 And I think we had a very co-operative relationship
 19 with the health and safety officers of ASTMS, I think
 20 it was at the time.
 21 **SIR BRIAN LANGSTAFF:** And although in one sense they
 22 couldn't avoid exposure to some risk because, after
 23 all, the product was there, you ensured, I take it,
 24 that their working practices were safe through
 25 standard operating procedures and that they had PPE

177

1 at that meeting was it not a topic of conversation at
 2 least around the --
 3 **A.** HIV?
 4 **SIR BRIAN LANGSTAFF:** Yes, the fact that somebody had just
 5 died, who had haemophilia.
 6 **A.** Yes, I think even at that stage, though -- I think I'm
 7 right in this but I can't be absolutely sure -- the
 8 cases of HIV in haemophilia patients in the UK at that
 9 time were, primarily or at least in the majority of,
 10 patients that had been treated with commercial
 11 Factor VIII concentrates from the US. So there was
 12 still a view at that stage that the UK plasma -- that
 13 the epidemic had yet to transmit completely to the UK.
 14 **SIR BRIAN LANGSTAFF:** Although by then, as my memory
 15 serves me right, the Terry Higgins Trust as it was
 16 first known, was established in the middle of 1982.
 17 So plainly there was some public awareness of --
 18 **A.** Of HIV --
 19 **SIR BRIAN LANGSTAFF:** -- HIV as such.
 20 **A.** Yes, yes, I think that's right. I think that's
 21 correct. It may be -- I gave the example of the memo
 22 that I wrote in mid-November 1984. It is quite
 23 possible that other communications to staff were made
 24 or the topic discussed. I think it was probably
 25 a regular topic on the agenda of the regular health

179

1 which was appropriate?
 2 **A.** They didn't have such things as -- I'm not sure
 3 whether they're called hazmat suits or -- but it was
 4 PPE. They were dressed in Tyvek suits. They had
 5 appropriate face coverings and head coverings and
 6 I think we did the best that we possibly could with
 7 the materials and products that were available.
 8 **SIR BRIAN LANGSTAFF:** Once you were aware, not of the
 9 certainty that blood products might transmit the
 10 whatever it was that was causing AIDS, but that there
 11 was a risk that it might, and you and Dr Foster both
 12 thought, as you've told us, that it was only a matter
 13 of time before what was in American pitched up in what
 14 you were dealing with in Scotland, you would have
 15 passed that on as a risk that people needed to be even
 16 more aware of and more cautious, did you?
 17 **A.** Yes. I think we saw a document that I wrote,
 18 a memorandum to all staff which was one of my methods
 19 of communicating to staff on such things, to put out
 20 a memorandum to all staff and put it on the notice
 21 board, and that certainly immediately followed
 22 (I think it was mid-November 1984) after the report of
 23 the Edinburgh cohort.
 24 **SIR BRIAN LANGSTAFF:** But you'd been a year before on
 25 17th October 1983 to the meeting of the UKHCDO. Now,

178

1 and safety meetings about safety with respect to
 2 infectivity.
 3 **SIR BRIAN LANGSTAFF:** Well, that's where these questions
 4 were leading. Presumably there was some discussion
 5 about it. Did you hold back on any of the risks which
 6 you saw because you might alarm or upset members of
 7 the staff?
 8 **A.** No. No, we explained -- people knew the environment
 9 they were working in. They knew that they had 4,000
 10 bags of plasma from 4,000 individual donors and so it
 11 was not difficult to explain the risks, and we would
 12 talk about hepatitis B, and I think increasingly we
 13 would talk about non-A, non-B as it became better
 14 understood, and certainly when HIV -- when we knew HIV
 15 was in the blood supply, as it were, we certainly
 16 included that. So no, there was no caution in
 17 presenting those risks to staff.
 18 We were concerned that staff would become
 19 extremely anxious about this but, in the event, we
 20 found they were -- they were sensible, they were
 21 co-operative, they knew the environment that they work
 22 in and they behaved accordingly. I don't think we
 23 collected any data on the number of needlestick
 24 injuries or abrasions that happened post-HIV to
 25 measure that. But I think, with hindsight, we were as

180

1 vigilant as we could be in terms of health and safety
 2 and it was always an important topic.
 3 **SIR BRIAN LANGSTAFF:** Yes, thank you very much. I don't
 4 know if any questions arise out of that at all?
 5 **MS RICHARDS:** No, sir.
 6 Dr Perry, is there anything further that you
 7 would wish to add?
 8 **A.** Well, I would just like to make a couple of final
 9 comments, if I may, just to -- in general and it's
 10 really no more than -- and I've actually just drafted
 11 a few notes to make sure I say what I need to say.
 12 I would simply like to record my acknowledgement
 13 and recognition of the scale and the depth of impact
 14 that events explored and being explored in this
 15 Inquiry have had on so many patients. And these
 16 events are even more tragic, having been caused by
 17 developments in my field of work in SNBTS which held
 18 the promise of being so transformational for the
 19 treatment of haemophilia patients but which, at the
 20 same time, we now know had such tragic consequences
 21 for so many patients and their families.
 22 My last thought is that I sincerely hope that
 23 this Inquiry will provide a complete as possible
 24 understanding of the events and the rationales for the
 25 decisions made by all those who were entrusted with

181

1 1997.
 2 Then on 12 May we will be hearing from
 3 Dr Hilary Pickles, Principal Medical Officer in the
 4 Department of Health, in particular in the Med SEB
 5 division, 1998 to 1991. Of course, both those names
 6 were mentioned in the course of the evidence this
 7 afternoon looking at the ACVSB.
 8 On 13 May, Friday of that week, we turn to the
 9 first of these witnesses concerned with CJD and, in
 10 particular, vCJD. We will be calling
 11 Professor John Collinge on 13 May, Director of the NHS
 12 National Prion Clinic and MRC Prion Clinic.
 13 In the following week, on 17 May, we will then
 14 be calling Professor James Ironside, a professor of
 15 clinical neuropathology and I think head or based at
 16 the National CJD Research and Surveillance Unit in
 17 Edinburgh.
 18 The vCJD evidence continues on 18 May, hearing
 19 first from Dr Nicky Connor, a consultant
 20 epidemiologist and head of the CJD section of the
 21 Health Protection Agency. Then we will have
 22 a presentation by counsel to the Inquiry on
 23 a chronology of key events relevant to vCJD.
 24 19 May we then return to Government evidence,
 25 where we will hear from David Mellor, Minister of

183

1 a duty of care for the patients they served.
 2 Thank you.
 3 **SIR BRIAN LANGSTAFF:** Thank you, Dr Perry. We will
 4 certainly try to get it as right as the evidence
 5 permits. Can I thank you in particular for coming.
 6 You've been here for two days. You've come down from
 7 Scotland. So, thank you for that. In many ways, it's
 8 been most informative. So thank you.
 9 If you wait there for a moment or two, we have
 10 some little business to deal with since this is the
 11 last session before we have a bit of a break from
 12 sitting.
 13 Ms Richards, we come back, do we, in May?
 14 **MS RICHARDS:** We do. Sir, we come back on 10 May.
 15 We will be publishing on the Inquiry's website
 16 imminently our proposed timetable for the rest of the
 17 year. Some of it, we're able to populate with names
 18 of witnesses. Other days or weeks we'll populate as
 19 the following weeks come on. But I just wanted to
 20 explain where we've got to so far so that those
 21 listening know who they'll be hearing from in May,
 22 June and July.
 23 So we will start on 10 May, continuing on to
 24 11 May with evidence from Dr Andrzej Rejman, Senior
 25 Medical Officer in the Department of Health 1989 to

182

1 State for Health '88 to '89 and Chief Secretary to the
 2 Treasury 1990 to 1992. And then, on 20 May, from John
 3 Patten, Lord Patten, Parliamentary Undersecretary at
 4 the Department of Health and Social Security, 1983 to
 5 1985.
 6 There will then be two weeks when the Inquiry is
 7 not sitting and the Inquiry will then resume again in
 8 the week of 6 June, calling on 7 June,
 9 Professor Sir Michael Rawlins, professor of clinical
 10 pharmacology, but particularly for our purposes,
 11 member of the Committee of the Safety of Medicines
 12 from 1980 through to 1998.
 13 On 8 June we will be calling Charles Lister,
 14 head of blood policy at the Department of Health, 1998
 15 to 2003.
 16 On 9 June we will be calling Justin Fenwick QC,
 17 who was instructed by the central defendants in the
 18 HIV Haemophilia Litigation.
 19 And on 10 June, Richard Gutowski, head of blood
 20 policy at the Department of Health, 2003 to 2005.
 21 There will then be a further two weeks when the
 22 Inquiry is not sitting, and then it will resume on
 23 27 June, and then there will be five weeks when the
 24 Inquiry sits week after week.
 25 So in the week of 27 June, we will be hearing

184

1 first from Sir John Major, Chief Secretary to the
2 Treasury, Chancellor of the Exchequer and, obviously,
3 Prime Minister.

4 On 28 June, Baroness Virginia Bottomley,
5 Minister of State at the Department of Health and
6 Secretary of State for Health the period 1989 through
7 to 1995.

8 On 29 and 30 June, we will be hearing from
9 Professor Richard Tedder, whose name obviously has
10 come up in multiple documents, in terms of his
11 involvement in relation to matters of virology in
12 particular in the 1980s.

13 Then, on 1 June we will be hearing from
14 Gloria Hooper, Baroness Hooper.

15 **SIR BRIAN LANGSTAFF:** 1 June?

16 **MS RICHARDS:** Sorry, 1 July -- who was Parliamentary
17 Undersecretary of State for Health, 1989 to 1992.

18 In the week of 4 July, we will be calling
19 William Waldegrave, Lord Waldegrave, Secretary of
20 State for Health, 1990 to 1992, Chief Secretary to the
21 Treasury, 1995 to 1997, and that will be on 5 and
22 6 July.

23 On 7 July we anticipate a counsel to the Inquiry
24 presentation on the role and the decision-making of
25 the Chief Medical Officers of the Departments of

185

1 particular on decision-making and the response of
2 governments in Scotland, Wales and Northern Ireland.

3 Again, we will need to confirm the details of
4 who will be called, but one of the witnesses will be
5 Professor Aileen Keel, Deputy Chief Medical Officer
6 for Scotland and, prior to that, a medical officer in
7 the Scottish Home and Health Department.

8 That will conclude the summer evidence, that
9 week of 25 July. The Inquiry will then resume in the
10 week of 12 September. So some of these are additional
11 weeks to those previously published on the Inquiry's
12 website. The focus of the evidence called and
13 examined in the week of 12 September will relate to
14 issues of candour, openness, cover-up and
15 recordkeeping.

16 On 12 September, so the Monday we will be
17 calling Nigel Crisp, Lord Crisp, who was permanent
18 secretary at the Department of Health from 2000 to
19 2006.

20 We will also be calling Zubeda Seedat, a civil
21 servant in the blood policy team at the Department of
22 Health.

23 On 13 September, we will be calling
24 William Connon, who was head of blood policy at the
25 Department of Health 2005 to 2009.

187

1 Health in the 1970s and the 1980s.

2 In the week of 11 July, on the Monday and
3 Tuesday of that week, so 11 and 12 July, we will be
4 calling Sir Robert Francis to talk about and answer
5 questions about his Infected Blood Compensation
6 Framework Study.

7 The witnesses for 13 and 14 July of that week
8 are yet to be confirmed and as soon as we have
9 confirmed the position those details will be published
10 on the Inquiry's website.

11 On 15 July we will be calling Andy Burnham,
12 Minister of State at the Department of Health, 2006 to
13 2007, and Secretary of State for Health, 2009 to 2010.

14 In the week of 18 July we intend calling
15 evidence relating to Government decision-making and
16 the response of governments in Scotland Wales,
17 Northern Ireland and England. We are yet to fully
18 flesh out that week.

19 We will be calling, however, in the course of
20 that week, John Reid, Lord Reid, Secretary of State
21 for Health, 2003 to 2005. Also occupied positions as
22 Secretary of State for Scotland and Northern Ireland.
23 And we will be calling Hazel Blears, Parliamentary
24 Undersecretary of State from 2001 to 2003.

25 In the week of 25 July, the focus will be in

186

1 There will then, in the afternoon of 13
2 September and 14 September, be a number of
3 presentations by counsel to the Inquiry on matters
4 relevant to transparency, cover-up and recordkeeping.

5 On 15 September, we will be calling in the
6 morning Susan Douglas who was the political
7 correspondent to the Mail On Sunday in 1983 --
8 obviously many other journalistic roles during her
9 career. Then there will be further presentations to
10 the Inquiry.

11 16 September, we'll be calling Caroline Flint,
12 Parliamentary Undersecretary for Public Health, 2005
13 to 2006, and Minister of State for Public Health 2006
14 to 2007, and there will be further presentations by
15 counsel to the Inquiry.

16 In the week of 19 September, we anticipate
17 having further evidence about government
18 decision-making and the response of governments,
19 a combination of witnesses and presentations, but we
20 do not yet know exactly what that week will comprise.

21 We then move to the week of 26 September where
22 we hope to have panels of people who were infected and
23 affected giving evidence, and the week of 3 October
24 where we will be hearing further expert evidence and
25 also panels of people infected and affected.

188

1 Currently, it's then envisaged that the weeks of
2 7 and 14 November we will hear evidence relevant to
3 the making of recommendations by the Inquiry and then
4 the indicative weeks for the making of oral
5 submissions remain as previously indicated, the weeks
6 of 28 November, 5 December and 12 December.

7 So that, I hope, is a useful update of the
8 Inquiry's future hearing plans for the remainder of
9 this calendar year.

10 **SIR BRIAN LANGSTAFF:** Thank you very much, Ms Richards.

11 Let me add a few words of my own. I know that
12 it can be all too easy to become so focused in some of
13 the detail of what we have been hearing as to lose
14 sight of how what we have already heard may fit
15 together with what we are next to hear. But witnesses
16 and topics are not heard at random. I hope you have
17 recognised that there is some pattern with what the
18 Inquiry is doing. Everything starts, everything
19 started, everything will finish with the experiences
20 of those infected by blood and blood products given to
21 them by the NHS. Building on what we heard earlier,
22 in the last six months we've heard how that blood was
23 collected, transfused, turned into blood products and
24 of blood products which were administered by the NHS
25 but came from abroad.

189

1 is needed concerning those recommendations. I shall
2 remind you again of the second deadline but I make no
3 apology for mentioning it now and that's 24 October.
4 Core Participants may address the Inquiry through
5 their representative if they have one at the end of
6 the hearings which come later. 24 October is the date
7 by which anyone taking advantage of that opportunity
8 must supply written detail of any closing arguments --
9 we've called them submissions which is a lawyer's
10 phrase -- so that anything that is said can be
11 properly focused. Now, there's further detail in the
12 statement of approach to submissions on the website.

13 Finally, and looking to the more immediate
14 future, I would like to wish everyone here and
15 everyone listening a refreshing break over Easter.
16 Thank you.

17 **(5.00 pm)**
18 **(Adjourned until 10.00 am on Tuesday, 10th May 2022)**

191

1 We have heard how palliative care, properly
2 delivered, can assist. In the next three months, as
3 you've just heard, we're turning to government, which
4 oversaw and had ultimate responsibility for what
5 happened. I'm looking forward to hearing what civil
6 servants and former government ministers have to say
7 and, like many of you, to what Sir Robert Francis will
8 have to say.

9 It is going to be an intensive timetable as we
10 get closer to the end of the hearings, but I want to
11 highlight two things which mustn't go unnoticed.
12 First, I know that some statements which are in the
13 pipeline have not yet been submitted to the Inquiry.
14 It would be of real assistance to me if those
15 statements could be provided by the end of September.
16 I'm determined to read each and every one of them.
17 Legal representatives, this is particularly for you:
18 let the Inquiry have them as and when they are ready
19 and not just in an avalanche all at once. That is
20 a firm request rather than an absolute deadline but
21 the second matter does relate to deadlines.

22 Legal representatives, please don't forget that
23 20 June is the deadline for suggesting recommendations
24 that you'd want me to consider making and this allows
25 time to consider if further evidence and, if so what,

190

INDEX

1
2 DR ROBERT PERRY (continued) 1
3 Questioned by MS RICHARDS (continued) 1
4 Questions from SIR BRIAN LANGSTAFF 175

192

<p>MS RICHARDS: [27] 1/6 7/11 12/18 12/23 16/6 16/18 17/12 32/2 60/12 60/22 98/21 98/25 99/4 129/1 137/8 137/12 153/13 153/18 162/16 162/22 163/1 163/21 175/16 175/19 181/5 182/14 185/16</p> <p>SIR BRIAN LANGSTAFF: [48] 1/5 6/14 6/25 7/10 12/9 12/15 12/20 16/4 16/8 16/15 17/10 29/19 30/4 30/23 31/9 31/20 31/24 55/3 55/16 60/16 98/24 126/23 127/8 127/24 137/7 137/10 153/16 162/20 162/24 163/3 163/20 175/18 175/21 176/4 177/5 177/7 177/10 177/21 178/8 178/24 179/4 179/14 179/19 180/3 181/3 182/3 185/15 189/10</p> <hr/> <p>'70s [1] 168/7 '78 [2] 8/3 8/4 '80s [1] 50/23 '81 [2] 99/18 101/15 '81/'82 [2] 99/18 101/15 '82 [4] 45/3 99/18 101/15 168/25 '83 [5] 41/9 45/3 86/16 168/25 169/2 '83/'84 [1] 86/16 '84 [5] 41/9 52/4 82/12 86/16 86/17 '85 [2] 17/11 61/2 '86 [3] 105/23 113/20 113/24 '87 [1] 61/2 '88 [1] 184/1 '89 [3] 148/6 149/12 184/1 'batch [1] 62/1 'behind [1] 151/14 'For [1] 63/17 'interfere' [1] 159/3 'model' [1] 172/25 'self [1] 61/14 'virgin' [2] 112/10 117/1 'virologists' [1] 137/22 'warnings' [1] 47/15</p>	<p>0 002 [2] 156/8 156/8 003 [1] 145/3 009 [7] 76/22 78/8 78/10 79/17 85/2 173/23 174/10 01 [1] 91/4 010 [1] 15/22 018 [1] 145/10 022 [1] 93/17 023110090 [1] 73/5 025 [1] 145/5 042 [1] 68/3 052 [1] 76/1 080 [1] 145/12 098 [1] 145/8</p> <hr/> <p>1 1 April 2022 [1] 1/1 1 August 1986 [1] 119/13 1 July [1] 185/16 1 June [1] 185/13 1.00 pm [1] 99/1 10 [10] 4/13 21/6 24/5 29/12 30/7 85/10 139/5 149/15 154/18 154/20 10 December [2] 78/23 81/16 10 December 1984 [1] 174/22 10 donors [2] 29/12 29/14 10 July [2] 115/2 115/25 10 June [1] 184/19 10 May [2] 182/14 182/23 10,000 units [1] 113/10 10.00 [2] 1/2 191/18 100 per cent [1] 37/18 106 [2] 100/8 172/20 10th May [1] 191/18 11 [3] 21/6 24/5 186/3 11 July [1] 186/2 11 May [1] 182/24 11 November 1991 [1] 156/9 11.30 [1] 60/19 116 [2] 134/21 134/23 12 [2] 21/6 22/4 12 December [1] 189/6 12 July [1] 186/3 12 May [1] 183/2 12 months [1] 108/23 12 o'clock [2] 60/18 60/18 12 September [3]</p>	<p>187/10 187/13 187/16 12.00 pm [1] 60/21 12/84 [2] 16/4 16/9 13 [2] 186/7 188/1 13 May [2] 183/8 183/11 13 November 1984 [1] 104/7 13 September [1] 187/23 133 [1] 173/19 136 [1] 137/15 137 [1] 137/14 14 [2] 139/4 189/2 14 July [1] 186/7 14 September [1] 188/2 141 [2] 142/4 142/11 146 [1] 151/1 15 [2] 74/16 76/16 15 July [1] 186/11 15 minutes [1] 60/13 15 November [1] 76/15 15 November 1984 [1] 76/2 15 September [1] 188/5 16 [3] 74/16 140/18 188/11 17 [1] 149/21 17 January 1990 [1] 145/6 17 March [1] 108/12 17 May [1] 183/13 17 October 1983 [1] 172/3 17th October 1983 [1] 178/25 18 [2] 77/19 139/13 18 HIV [1] 93/24 18 July [1] 186/14 18 May [1] 183/18 18 seroconversions [1] 92/13 19 May [1] 183/24 19 September [1] 188/16 1970s [4] 29/4 68/10 68/10 186/1 1973 [6] 20/7 21/9 21/21 22/3 24/7 24/21 1977 [1] 21/21 1978 [13] 4/16 5/16 5/17 6/16 7/8 8/2 13/4 13/21 22/3 22/24 24/8 24/8 25/4 1980 [7] 24/16 24/20 24/22 25/9 25/11 25/14 184/12 1980s [6] 29/5 37/1 43/12 164/5 185/12</p>	<p>186/1 1981/1982 [1] 99/16 1982 [4] 48/18 99/16 102/12 179/16 1983 [19] 27/6 37/4 37/9 37/15 37/16 41/1 42/12 42/17 43/18 47/21 66/9 70/6 88/17 91/24 171/22 172/3 178/25 184/4 188/7 1984 [48] 10/14 12/12 16/14 16/22 41/1 42/12 42/18 43/15 47/12 48/18 52/21 61/5 62/21 62/24 63/2 66/4 66/17 68/4 70/17 73/4 76/2 78/22 87/12 88/7 88/7 88/18 88/23 89/3 95/4 95/6 97/1 98/3 98/12 98/15 102/15 103/1 103/21 103/22 103/23 104/4 104/7 105/1 105/13 157/7 173/22 174/22 178/22 179/22 1985 [25] 10/11 10/15 10/24 15/1 15/7 15/8 15/9 15/14 17/8 18/17 18/24 48/7 48/16 62/2 89/11 91/24 95/10 96/21 105/13 107/2 107/4 107/14 107/15 170/21 184/5 1986 [27] 25/11 25/14 26/11 27/2 27/7 27/8 91/1 105/14 105/14 107/13 107/22 107/22 108/5 108/7 108/12 108/17 109/1 109/11 109/12 110/13 111/2 111/20 119/13 124/5 125/2 125/4 129/8 1987 [2] 106/7 111/8 1988 [3] 27/10 28/10 93/24 1989 [11] 132/11 132/13 135/19 145/2 145/3 145/4 145/6 153/4 182/25 185/6 185/17 1990 [11] 93/24 129/8 137/24 145/6 145/7 145/8 145/9 148/16 152/2 184/2 185/20 1990s [1] 33/12 1991 [9] 137/25 145/10 145/11 150/22 152/5 152/11 153/4 156/9 183/5 1992 [3] 184/2 185/17 185/20 1994 [1] 164/22</p>	<p>1995 [2] 185/7 185/21 1997 [2] 183/1 185/21 1998 [3] 183/5 184/12 184/14</p> <hr/> <p>2 2 February 1984 [1] 66/17 2 July 1986 [1] 111/2 2 July 1990 [1] 145/8 2 November [1] 74/10 2 o'clock [2] 98/23 98/24 2.00 pm [1] 99/3 2/85 [1] 17/10 20 [4] 96/13 120/18 138/12 158/15 20 June [1] 190/23 20 May [1] 184/2 20 November [1] 73/4 20 vials [1] 119/16 2000 [4] 93/19 156/4 158/11 187/18 2001 [2] 156/4 186/24 2003 [4] 184/15 184/20 186/21 186/24 2005 [6] 153/24 155/25 184/20 186/21 187/25 188/12 2006 [4] 186/12 187/19 188/13 188/13 2007 [3] 153/24 186/13 188/14 2008 [2] 173/23 174/1 186/13 187/25 2010 [1] 186/13 2011 [3] 32/15 40/20 134/22 2022 [2] 1/1 191/18 21 [1] 142/12 21 May 1991 [1] 145/11 21 November 1990 [1] 145/9 22 May 1989 [2] 135/19 145/3 24 April 1990 [1] 145/7 24 hour [1] 15/12 24 hours [2] 110/2 112/6 24 July [4] 116/3 118/16 118/22 118/25 24 June 2011 [1] 40/20 24 March 1986 [1] 108/17 24 October [2] 191/3 191/6 25 February 1991 [1] 145/10</p>	<p>25 July [2] 186/25 187/9 2575m/12/84 [1] 16/8 26 July 1985 [1] 89/11 26 October [1] 73/10 26 September [1] 188/21 27 June [2] 184/23 184/25 27 June 1986 [1] 110/13 28 July [1] 119/1 28 June [1] 185/4 28 November [1] 189/6 29 [1] 185/8 29 November [1] 82/12 29th [1] 74/8</p> <hr/> <p>3 3 July [1] 112/13 3 July 1989 [1] 145/4 3 October [1] 188/23 3-009 [4] 78/8 78/10 79/17 173/23 3.38 pm [1] 163/17 30 June [1] 185/8 30 years [1] 138/12 30th October [1] 74/8 33 [1] 12/12 37 [2] 100/8 172/20 3rd [1] 74/18</p> <hr/> <p>4 4 July [1] 185/18 4 July 1986 [1] 111/20 4,000 [4] 87/15 87/16 180/9 180/10 4.15 pm [3] 162/25 163/15 163/19 40 [1] 78/11 42 [1] 12/12 45 vials [1] 78/12 458 [1] 151/4</p> <hr/> <p>5 5 August [1] 119/14 5 December [1] 189/6 5 November [2] 71/7 156/11 5.00 pm [1] 191/17 5/4/85 [1] 10/11 50 [4] 113/10 115/18 120/17 149/7 50 vials [6] 116/4 118/18 119/7 119/12 120/5 120/5 5019 [1] 137/10</p>
--	--	---	--	--	---

<p>6</p> <p>6 June [1] 184/8</p> <p>6 November [1] 145/5</p> <p>60 [2] 138/24 149/1</p> <p>68 [1] 11/8</p> <p>68 degrees [3] 82/22 110/2 112/6</p> <hr/> <p>7</p> <p>7 and [1] 189/2</p> <p>7 February [1] 68/5</p> <p>7 July [3] 112/19 113/12 185/23</p> <p>7 June [1] 184/8</p> <p>72 hours [1] 14/1</p> <p>795 [6] 89/16 89/23 89/25 90/9 90/12 90/20</p> <hr/> <p>8</p> <p>8 June [1] 184/13</p> <p>80 [1] 14/1</p> <p>80s [2] 56/11 165/1</p> <p>83/84 [1] 42/8</p> <p>84 [5] 16/3 16/4 16/8 16/9 42/8</p> <p>85 [2] 10/11 17/10</p> <p>8Y [40] 105/20 105/24 106/4 106/21 107/1 107/4 108/3 108/20 108/23 108/24 109/21 110/6 111/16 112/11 112/14 113/20 113/25 114/11 115/18 115/22 116/4 116/19 117/12 117/17 117/23 118/1 118/4 118/18 119/4 119/12 119/15 119/22 120/24 122/18 123/4 123/5 123/24 125/6 126/7 128/17</p> <p>8Y's [1] 105/17</p> <hr/> <p>9</p> <p>9 June [1] 184/16</p> <p>9 November 1984 [1] 88/7</p> <p>947 vials [1] 89/25</p> <p>98 [1] 40/21</p> <p>99 [1] 135/16</p> <hr/> <p>A</p> <p>A, [1] 108/4</p> <p>abandoned [1] 69/17</p> <p>Aberdeen [8] 63/25 78/12 78/15 78/16 79/25 80/1 95/23 174/9</p> <p>ability [2] 144/15 173/16</p> <p>able [14] 10/9 30/21 47/3 53/7 56/18 105/2</p>	<p>114/11 155/13 160/21 160/22 171/10 174/18 175/9 182/17</p> <p>about [133] 1/7 2/2 2/5 9/7 9/23 12/16 12/17 14/9 14/13 16/24 21/2 21/6 26/19 28/7 29/4 29/12 29/22 34/8 34/17 35/2 35/19 35/20 36/2 36/4 36/6 39/13 39/14 39/22 40/9 40/14 40/25 41/9 41/10 42/7 42/14 43/20 46/24 49/5 49/13 51/15 55/6 56/10 56/21 56/22 56/22 58/1 58/18 59/16 59/17 64/25 67/13 69/23 70/4 71/5 71/12 71/14 71/23 78/11 79/17 79/19 80/2 84/12 85/7 85/10 87/16 88/1 93/3 94/10 94/10 94/15 97/1 97/6 97/25 98/13 100/3 100/5 100/6 102/22 103/1 103/14 109/9 110/11 110/21 118/8 122/3 124/8 125/11 126/24 127/17 127/21 128/22 129/3 129/6 129/14 130/18 137/18 139/6 142/13 143/1 144/24 145/17 149/15 150/2 153/7 153/22 154/4 154/11 154/12 155/7 156/4 156/12 156/15 157/9 157/23 158/7 158/7 163/10 164/7 165/1 167/11 167/22 168/15 169/1 169/12 171/4 180/1 180/5 180/12 180/13 180/19 186/4 186/5 188/17</p> <p>about: [1] 60/4</p> <p>about: how [1] 60/4</p> <p>above [7] 7/22 14/12 32/21 33/22 74/17 74/24 172/6</p> <p>abrasions [2] 176/11 180/24</p> <p>abroad [1] 189/25</p> <p>absence [4] 41/24 59/2 116/20 151/23</p> <p>Absent [1] 151/15</p> <p>absolute [2] 29/11 190/20</p> <p>absolutely [17] 3/13 16/17 21/16 30/8 32/9 39/3 39/4 39/9 54/21 77/17 79/22 108/8</p>	<p>141/7 149/2 149/19 170/2 179/7</p> <p>accept [4] 19/5 57/18 124/23 168/16</p> <p>accepted [1] 135/17</p> <p>accepting [1] 57/12</p> <p>access [5] 81/17 123/4 167/14 173/11 174/15</p> <p>access 8Y [1] 123/4</p> <p>accessible [1] 144/4</p> <p>accessing [1] 6/8</p> <p>accompanying [1] 26/22</p> <p>accord [1] 169/24</p> <p>accordance [1] 3/19</p> <p>according [1] 147/2</p> <p>accordingly [3] 166/24 177/4 180/22</p> <p>account [3] 18/19 78/1 165/13</p> <p>accountability [1] 147/16</p> <p>accumulate [1] 171/11</p> <p>accumulated [2] 171/8 171/18</p> <p>accumulation [1] 171/6</p> <p>accurate [3] 46/14 164/6 167/19</p> <p>achieve [1] 61/14</p> <p>achieved [1] 81/19</p> <p>acid [1] 6/23</p> <p>acknowledge [1] 53/2</p> <p>acknowledgement [1] 181/12</p> <p>acquired [2] 14/3 19/2</p> <p>acted [2] 35/20 121/19</p> <p>acting [2] 98/5 158/16</p> <p>action [7] 10/19 47/25 48/5 75/1 92/21 160/10 176/9</p> <p>actions [5] 59/25 85/1 85/4 157/11 157/20</p> <p>active [2] 141/15 166/20</p> <p>actively [1] 139/20</p> <p>activities [1] 68/13</p> <p>activity [1] 20/25</p> <p>ACTTD [3] 134/3 134/8 134/12</p> <p>actual [6] 12/4 35/22 66/13 125/13 131/5 154/12</p> <p>actually [30] 3/10 4/2 6/15 17/24 25/21 26/15 29/6 34/22 37/20 58/22 62/19 64/23 64/25 72/2 72/8 74/6 101/12 101/17</p>	<p>109/8 111/9 111/23 114/4 132/22 135/14 140/24 146/11 147/14 168/11 174/16 181/10</p> <p>acute [1] 162/1</p> <p>ACVSB [13] 133/23 134/7 134/11 134/16 137/1 148/7 149/10 151/13 151/16 151/18 152/1 152/23 183/7</p> <p>ad [3] 2/8 2/12 131/18</p> <p>add [2] 181/7 189/11</p> <p>added [2] 21/1 24/12</p> <p>addenda [2] 22/22 25/13</p> <p>addendum [8] 21/21 21/23 22/3 22/9 22/24 25/4 25/11 27/1</p> <p>addendums [1] 24/21</p> <p>adding [1] 41/8</p> <p>addition [3] 5/2 10/17 13/23</p> <p>additional [4] 83/6 93/8 117/20 187/10</p> <p>address [5] 100/3 102/1 102/12 131/25 191/4</p> <p>addressed [1] 97/5</p> <p>adequate [1] 117/21</p> <p>adhere [1] 3/14</p> <p>Adjourned [1] 191/18</p> <p>adjournment [1] 99/2</p> <p>administered [3] 31/6 165/5 189/24</p> <p>administration [1] 105/6</p> <p>administrative [1] 152/6</p> <p>admittedly [1] 101/4</p> <p>adopt [1] 168/1</p> <p>advance [1] 63/7</p> <p>advanced [1] 102/5</p> <p>advantage [4] 6/8 106/4 175/7 191/7</p> <p>advantages [1] 56/5</p> <p>advent [2] 102/2 162/4</p> <p>adverse [3] 51/2 154/7 175/6</p> <p>advice [11] 48/22 50/5 50/20 50/23 51/13 53/22 57/18 83/8 89/14 131/18 135/17</p> <p>advise [7] 130/14 132/24 133/1 133/2 133/9 133/23 134/7</p> <p>advised [7] 2/25 47/20 83/8 103/13 104/16 141/17 176/22</p> <p>advisers [1] 38/20</p> <p>advisory [8] 132/4</p>	<p>132/23 133/9 133/19 134/4 135/8 135/8 177/14</p> <p>affected [3] 63/19 188/23 188/25</p> <p>afraid [3] 87/2 90/15 107/15</p> <p>after [16] 3/13 23/8 26/2 28/15 31/6 49/2 94/19 101/19 108/23 145/13 161/17 168/21 170/13 177/22 178/22 184/24</p> <p>afternoon [4] 1/7 33/12 183/7 188/1</p> <p>again [31] 1/18 4/10 9/24 11/6 13/6 15/25 17/7 17/12 18/9 18/22 25/3 25/17 27/14 42/6 52/11 62/3 76/17 80/18 90/16 102/20 106/15 112/19 112/20 127/3 138/15 147/9 163/5 164/25 184/7 187/3 191/2</p> <p>against [3] 48/14 105/24 138/1</p> <p>Agency [4] 49/9 136/12 136/13 183/21</p> <p>agenda [6] 86/25 139/19 143/21 143/23 149/4 179/25</p> <p>agendas [1] 134/16</p> <p>agents [3] 166/24 167/17 176/2</p> <p>ago [5] 2/6 10/18 55/6 110/18 126/24</p> <p>agree [7] 12/22 85/19 85/25 105/3 125/14 135/10 138/5</p> <p>agreeable [1] 117/10</p> <p>agreed [6] 67/8 67/19 68/22 73/18 83/12 136/24</p> <p>agreement [4] 54/3 54/6 117/6 117/11</p> <p>ahead [3] 88/22 150/2 153/16</p> <p>AIDS [38] 12/1 17/19 18/22 27/4 27/5 40/9 40/18 40/25 41/9 43/13 45/5 47/15 47/23 48/6 48/14 52/22 54/3 55/9 57/24 58/6 58/16 58/18 63/12 64/19 67/6 68/18 68/20 87/10 88/11 102/2 102/7 104/14 104/18 162/4 162/11 167/6 168/24 178/10</p> <p>Aileen [1] 187/5</p>	<p>aim [1] 133/25</p> <p>alarm [5] 57/3 58/17 59/3 59/19 180/6</p> <p>alarmed [1] 57/10</p> <p>albeit [2] 96/23 109/4</p> <p>algorithms [1] 147/12</p> <p>all [53] 5/21 13/10 13/13 15/24 25/3 25/18 34/18 35/13 36/18 51/1 63/13 64/11 74/1 74/22 76/25 78/10 79/24 80/9 82/2 87/13 88/3 95/12 95/19 96/8 99/8 103/9 104/19 109/16 118/12 122/5 129/3 129/10 145/18 147/6 147/10 147/12 149/19 150/12 158/14 162/9 166/19 168/5 169/6 170/25 176/7 177/13 177/23 178/18 178/20 181/4 181/25 189/12 190/19</p> <p>allergic [2] 128/16 128/17</p> <p>allocated [3] 95/25 96/7 97/16</p> <p>allocation [1] 90/1</p> <p>allowed [1] 42/4</p> <p>allows [1] 190/24</p> <p>alluded [1] 143/10</p> <p>almost [5] 19/8 51/8 62/17 141/3 162/7</p> <p>alone [1] 139/1</p> <p>along [1] 73/7</p> <p>alongside [1] 18/2</p> <p>aloud [1] 8/20</p> <p>alphabetical [1] 96/1</p> <p>already [10] 49/1 52/25 61/13 61/16 79/4 83/6 87/23 143/10 158/21 189/14</p> <p>also [33] 4/6 6/1 8/3 13/17 19/5 30/2 33/15 46/10 46/21 50/10 63/9 66/10 67/23 74/25 79/8 80/25 84/16 94/8 102/18 118/3 120/7 120/14 122/3 123/23 126/10 134/7 134/11 139/15 154/13 173/4 186/21 187/20 188/25</p> <p>although [15] 7/7 45/22 85/21 87/3 107/7 109/15 121/9 148/23 158/25 160/3 161/24 164/19 167/17 177/21 179/14</p> <p>always [24] 3/25 6/8 28/14 55/22 56/12</p>
---	---	---	---	--	--

A	an expiry [1] 16/1	149/5 153/14 155/4	131/13 131/23 132/8	165/19 166/1 174/17	arising [3] 50/25
always... [19] 60/7	an explanation [1] 104/21	157/23	132/12 135/14 143/11	177/13 177/16 178/1	100/22 162/19
63/8 109/8 124/7	an explicit [2] 18/25	answer [9] 41/2 41/13	146/1 151/5 153/20	178/5	Armour [2] 93/23
130/17 133/12 134/10	19/1	45/2 137/16 138/3	159/4 159/20 159/24	appropriately [1]	94/11
134/25 135/7 135/9	an express [1] 34/1	139/8 160/1 170/23	160/2 162/19 162/20	123/11	Armour's [1] 94/4
141/17 141/19 147/17	an extended [1] 19/11	186/4	166/3 167/15 167/19	approval [1] 52/16	arms [1] 97/24
154/7 159/1 166/9	an extent [4] 85/24	answered [1] 83/12	167/20 169/2 169/11	approved [5] 1/14	arose [1] 147/7
176/13 177/14 181/2	138/6 164/16 171/18	answering [1] 55/24	172/7 174/15 175/19	1/17 49/20 105/5	around [6] 75/19
am [9] 1/2 48/12	an extract [1] 32/17	answers [1] 53/18	176/16 180/5 180/23	143/5	107/4 133/18 144/1
60/19 74/19 106/20	an eye [1] 51/2	anti [6] 3/17 20/25	181/4 191/8	approximately [1]	163/24 179/2
107/19 159/15 159/17	an HIV [1] 90/22	21/24 23/1 88/17	anybody [3] 97/23	87/15	arrange [1] 117/19
191/18	an hour [1] 162/23	169/16	143/4 160/11	April [10] 1/1 10/11	arrangement [3]
America [1] 58/8	an HTLV-III [1] 92/19	anti-haemophilic [4]	anyone [1] 102/19	10/15 10/24 107/4	123/4 124/7 171/3
American [1] 178/13	an immediate [1]	3/17 20/25 21/24 23/1	anyone [4] 51/15	111/8 132/11 145/2	arrangements [2]
amongst [5] 44/23	104/18	anti-HIV [1] 169/16	73/23 148/9 191/7	145/7 152/4	117/21 170/24
55/13 134/5 146/25	an important [4] 97/7	anti-HTLV3 [1] 88/17	anything [12] 28/7	April 1985 [4] 10/11	arrive [1] 131/9
147/4	154/21 174/12 181/2	antibodies [4] 27/19	29/3 34/17 35/4 47/8	10/15 10/24 107/4	arrived [2] 1/23
amount [5] 36/19 67/8	an increased [1]	71/16 76/6 82/16	51/14 69/23 77/9	April 1987 [1] 111/8	119/15
104/17 113/3 171/8	171/17	antibody [3] 13/25	84/20 103/9 181/6	April 1989 [2] 132/11	art [2] 30/12 30/21
amounts [1] 20/25	an individual [1]	73/11 138/24	191/10	145/2	article [1] 63/16
amplification [1] 6/23	122/12	anticipate [2] 185/23	anyway [3] 77/12	are [97] 4/13 7/12	ARV [1] 14/4
an absolute [1]	an infusion [1] 110/17	188/16	126/12 163/5	7/21 8/23 9/4 10/9	as [231]
190/20	An initial [1] 74/15	anticipation [1] 63/3	Apart [2] 7/21 14/11	12/10 13/24 15/19	ascertained [2] 23/7
an ad [1] 2/8	an instinctive [1]	antigen [9] 5/24 11/5	apologies [2] 44/20	15/20 16/5 18/3 19/24	26/2
an addendum [1]	56/14	11/13 13/16 13/17	163/25	20/2 23/6 23/22 26/18	aside [10] 48/25
22/9	an integral [1] 140/6	23/12 27/18 169/18	apology [1] 191/3	27/16 27/19 29/23	79/22 105/21 117/13
an advantage [1]	an intensive [1] 190/9	170/18	apparent [4] 16/19	30/7 31/2 31/4 32/21	117/17 118/3 124/19
175/7	An interim [1] 91/19	Antihaemophilic [1]	124/24 151/23 152/14	34/7 35/14 36/4 41/14	125/2 133/5 150/9
an advisory [2]	an internal [1] 104/10	20/8	apparently [1] 31/2	43/1 44/1 44/4 49/5	ask [32] 4/4 12/9 14/9
132/23 133/9	an issue [2] 59/7	anxiety [8] 48/1 55/13	appear [6] 14/17 21/8	49/13 53/16 54/21	38/6 39/11 40/23 41/4
an AIDS [1] 47/23	154/7	56/22 57/3 57/11	24/7 27/1 73/21	57/21 57/22 58/22	60/22 84/20 84/22
an allergic [1] 128/16	an ongoing [1] 67/20	58/15 59/19 150/11	115/19	59/17 60/4 60/6 60/7	85/7 85/9 85/19 100/6
an analysis [1] 76/20	an open [1] 51/9	anxious [2] 149/17	appeared [1] 151/19	62/24 62/25 64/23	104/3 110/10 115/16
an answer [1] 137/16	an opening [1] 97/4	180/19	appears [3] 83/17	79/16 80/11 89/22	129/2 129/9 132/8
an appendix [1] 8/16	an opportunity [3]	any [120] 1/14 10/24	116/2 145/18	92/4 92/19 93/12	151/5 153/22 156/6
an approach [1]	125/20 126/22 162/18	11/12 11/15 15/3	appended [1] 5/13	96/18 97/8 102/24	156/15 157/8 159/3
50/10	an option [1] 152/15	16/18 18/15 21/10	appendix [1] 8/16	103/3 105/2 105/16	162/23 163/7 163/22
an appropriate [2]	an overly [1] 121/20	23/13 23/21 25/13	applicable [1] 102/6	108/12 117/15 117/22	172/1 175/17 175/23
46/11 126/11	an SHHD [1] 152/14	25/19 27/2 30/1 30/3	application [13] 1/11	118/12 118/17 127/8	asked [15] 32/12
an assumption [3]	an unclear [1] 160/15	31/22 35/22 37/4	4/15 5/8 5/13 5/16	136/9 138/10 140/25	40/22 42/23 44/21
35/20 35/24 36/22	an understandable [1]	39/13 40/7 40/25 41/7	5/17 8/3 8/7 13/4 50/3	143/14 144/3 144/5	59/6 59/10 79/12
an attempt [1] 30/18	54/9	41/18 41/24 42/1	50/6 103/15 130/20	144/7 144/9 145/1	88/12 99/11 102/20
an author [1] 85/17	an unlicensed [2]	42/13 45/3 47/7 48/1	applications [7] 49/20	145/14 147/10 152/25	119/5 130/7 139/6
an avalanche [1]	116/14 122/8	48/5 48/5 48/12 48/13	130/1 130/15 131/6	154/20 158/1 159/18	142/13 168/15
190/19	an update [2] 50/8	49/11 49/13 50/7	131/6 131/19 132/1	162/16 163/5 164/16	asking [7] 2/5 66/9
an elegant [1] 120/9	82/18	51/12 51/16 52/8	applied [4] 3/21 6/2	166/3 166/19 167/4	112/24 116/4 129/6
an email [3] 93/18	analyse [1] 75/18	59/20 67/14 67/17	6/12 13/18	171/1 172/9 173/5	148/10 172/7
158/10 158/14	analysis [7] 74/5	69/3 70/14 72/20	apply [1] 10/21	173/6 175/16 181/16	aspect [3] 60/23
an emerging [1] 47/6	76/20 76/24 77/18	72/23 73/19 73/22	appointment [1]	186/8 186/17 187/10	129/6 155/4
an equivalent [1]	77/21 98/2 138/5	74/4 75/15 77/10 78/1	47/13	189/15 189/16 190/12	aspects [2] 146/18
110/22	Andrzej [1] 182/24	80/17 80/23 80/24	appreciate [4] 2/4	190/18	156/18
an error [3] 88/24	Andy [1] 186/11	81/1 81/13 83/1 83/11	73/20 94/9 127/8	area [4] 54/10 58/11	aspirate [1] 31/16
89/1 89/6	Andy Burnham [1]	83/22 83/22 84/8	approach [9] 32/12	155/18 175/21	assay [4] 7/2 7/6 74/3
an event [1] 153/12	186/11	86/19 86/20 87/2	43/8 44/12 50/10	aren't [1] 148/12	87/21
an evidence-based [3]	announcement [1]	87/20 89/2 90/8 90/9	50/12 50/18 51/13	arguable [1] 53/2	assays [5] 6/7 71/19
35/25 72/19 86/2	61/21	90/13 92/18 93/4 93/5	51/16 191/12	argue [1] 152/11	71/20 71/21 87/9
an example [1] 55/19	annual [2] 63/5 97/21	93/8 94/15 99/20	appropriate [22]	argument [1] 147/17	assessed [1] 130/14
an expectation [3]	61/21	101/18 106/3 107/19	27/17 29/24 36/19	arguments [1] 191/8	assessor [2] 136/11
21/12 28/20 120/3	another [14] 44/17	109/19 110/1 111/13	46/11 69/21 69/24	arise [2] 143/8 181/4	136/13
an expert [4] 35/12	58/10 60/2 72/16	112/10 112/15 114/8	118/20 123/2 124/25	arisen [1] 83/3	assign [1] 170/5
35/15 148/23 158/17	96/10 98/21 111/6	117/18 117/24 123/1	126/11 128/11 154/4	arises [3] 84/5 164/2	assist [9] 10/9 22/6
	121/17 133/18 146/23	124/4 129/6 130/19	154/13 155/15 164/14	175/21	69/24 95/12 96/20

<p>A</p> <p>assist... [4] 105/2 116/15 167/13 190/2</p> <p>assistance [2] 132/9 190/14</p> <p>associated [15] 14/3 15/3 32/25 34/14 36/16 38/18 80/11 86/8 87/24 141/16 149/20 151/13 154/8 154/8 174/10</p> <p>association [1] 90/12</p> <p>assume [8] 33/2 36/9 67/10 74/20 114/15 166/22 176/25 177/3</p> <p>assumed [11] 11/10 14/7 17/2 17/16 18/12 24/1 25/7 26/24 36/12 37/11 175/25</p> <p>assumes [1] 64/11</p> <p>assuming [1] 113/16</p> <p>assumption [4] 35/20 35/24 36/21 36/22</p> <p>ASTMS [1] 177/19</p> <p>attach [1] 31/18</p> <p>attached [2] 99/14 111/22</p> <p>attempt [1] 30/18</p> <p>attempts [1] 91/12</p> <p>attend [2] 84/19 176/14</p> <p>attended [3] 51/18 84/16 129/8</p> <p>attendees [1] 84/12</p> <p>attenders [1] 109/14</p> <p>attending [2] 157/18 160/4</p> <p>attention [3] 2/9 63/15 140/21</p> <p>attributable [2] 73/13 108/23</p> <p>attributed [1] 76/7</p> <p>audience [2] 33/9 142/1</p> <p>August [6] 88/18 88/23 89/3 110/5 119/13 119/14</p> <p>August 1984 [2] 88/23 89/3</p> <p>Australia's [1] 148/11</p> <p>author [3] 85/17 85/18 85/21</p> <p>authoritative [2] 137/22 138/10</p> <p>authorities [18] 38/23 39/2 39/12 41/24 42/7 42/14 42/16 42/22 43/1 43/7 43/11 43/22 44/13 45/12 49/17 51/10 58/7 146/15</p> <p>authority [23] 1/12</p>	<p>2/3 3/1 4/6 9/22 10/1 27/17 29/24 48/23 49/6 49/22 49/24 49/25 50/4 50/11 50/17 50/19 51/10 51/13 51/14 51/19 147/24 164/12</p> <p>auto [1] 69/6</p> <p>autonomous [1] 146/13</p> <p>autumn [5] 15/1 15/9 87/12 104/25 173/22</p> <p>availability [1] 122/18</p> <p>available [17] 6/7 15/19 48/18 87/9 87/22 92/22 111/11 114/10 122/6 128/23 169/17 170/7 170/10 170/14 170/15 172/8 178/7</p> <p>avalanche [1] 190/19</p> <p>avoid [5] 106/12 146/22 159/22 160/12 177/22</p> <p>Avoiding [1] 61/12</p> <p>aware [16] 42/9 42/18 70/15 79/4 91/1 94/4 94/19 106/21 108/6 123/24 130/17 147/21 160/2 166/3 178/8 178/16</p> <p>awareness [2] 166/16 179/17</p> <p>away [1] 140/3</p> <hr/> <p>B</p> <p>back [36] 12/3 14/16 19/21 26/9 29/20 33/20 38/4 42/22 51/23 53/13 57/8 62/5 78/14 78/24 80/7 81/14 86/16 87/11 109/13 113/15 116/12 136/24 138/12 138/15 140/5 142/24 143/12 147/18 149/6 155/14 158/24 163/15 174/16 180/5 182/13 182/14</p> <p>background [2] 48/17 165/16</p> <p>bacterial [1] 173/5</p> <p>bag [1] 131/9</p> <p>bags [1] 180/10</p> <p>Baroness [2] 185/4 185/14</p> <p>Baroness Hooper [1] 185/14</p> <p>base [1] 132/15</p> <p>based [10] 35/25 36/22 72/19 86/2 94/23 101/3 159/11 160/15 162/6 183/15</p>	<p>basis [8] 34/17 38/16 58/8 93/2 95/20 95/25 122/17 139/1</p> <p>batch [57] 6/12 16/2 16/14 65/18 66/2 66/5 66/11 73/5 74/5 74/17 74/24 75/12 75/19 76/22 76/23 77/1 77/7 77/16 78/3 78/5 78/8 78/10 79/17 79/22 79/23 80/13 85/2 85/6 87/11 87/14 88/15 89/3 89/23 90/12 90/20 90/21 92/8 92/10 92/23 95/2 95/9 95/13 96/2 96/9 96/10 97/16 98/12 98/14 123/10 157/3 169/8 170/6 171/3 173/22 173/25 174/10 174/13</p> <p>batch 3-009 [3] 76/22 85/2 174/10</p> <p>batches [32] 62/2 74/7 75/20 75/22 75/23 76/21 77/2 77/2 77/3 77/24 78/6 80/14 89/22 90/11 90/13 92/3 92/14 92/15 92/18 93/1 93/6 93/12 96/3 97/18 117/12 168/21 170/8 170/11 170/16 170/19 170/25 177/2</p> <p>be [284]</p> <p>be five [1] 184/23</p> <p>bear [1] 144/7</p> <p>bearing [1] 25/12</p> <p>bears [1] 162/12</p> <p>became [13] 61/5 102/18 105/22 106/21 109/6 138/18 155/25 169/17 170/7 170/10 170/14 170/15 180/13</p> <p>because [81] 2/20 15/1 15/17 22/13 28/25 34/2 34/20 34/25 36/12 37/14 38/6 39/10 40/12 43/14 46/10 46/11 46/21 47/4 49/1 53/12 54/9 55/10 55/11 55/12 58/21 59/18 65/11 67/5 71/2 71/8 71/19 75/18 75/22 79/22 80/11 80/21 85/8 86/23 97/7 101/25 103/25 105/1 110/21 118/11 120/19 122/11 122/17 123/13 124/2 127/11 127/15 128/6 128/18 128/22 129/22 130/8 132/18</p>	<p>138/6 141/19 143/17 143/18 144/3 144/11 146/10 147/10 147/21 150/18 154/7 155/13 155/19 159/10 159/12 161/8 163/21 163/24 164/10 168/18 175/9 177/1 177/22 180/6</p> <p>become [5] 91/1 97/7 98/5 180/18 189/12</p> <p>been [167] 1/13 1/17 1/25 2/1 2/3 2/24 3/19 3/22 5/23 6/1 6/5 6/20 7/2 10/8 11/8 13/15 13/17 13/20 13/25 14/22 15/15 16/13 17/15 18/2 19/19 21/25 28/9 28/11 37/3 38/23 38/24 39/1 39/17 40/24 41/3 41/18 42/9 46/21 47/1 47/3 48/1 49/11 50/10 51/20 52/16 54/18 59/1 59/10 62/17 64/16 69/14 69/17 69/25 70/5 71/7 71/14 74/5 75/1 75/2 75/4 75/8 75/15 75/23 76/25 77/16 78/3 78/5 78/10 78/10 79/7 81/6 81/14 82/1 82/3 83/9 83/9 86/21 86/22 87/20 88/12 88/20 89/18 90/19 92/14 93/2 93/9 95/21 96/6 96/7 96/14 97/1 97/5 98/4 98/7 98/9 98/12 98/13 98/15 99/6 99/21 99/23 101/16 101/19 101/25 102/9 102/20 103/6 103/20 104/2 107/13 107/25 108/2 108/6 109/3 111/4 111/11 111/11 119/20 120/19 122/23 123/5 123/7 123/9 123/15 123/23 124/20 124/24 125/7 125/16 125/22 128/2 128/23 129/22 131/11 132/13 136/24 138/14 143/5 145/18 148/16 148/17 149/20 149/24 150/23 152/5 156/1 163/8 163/9 163/10 165/14 165/25 167/22 168/9 170/25 171/8 171/21 174/17 174/18 176/20 177/7 178/24 179/10 181/16 182/6 182/8 189/13 190/13</p> <p>before [34] 14/9 19/21</p>	<p>22/5 48/10 52/13 69/12 71/4 83/14 103/17 109/10 114/9 131/9 132/8 135/22 138/7 150/12 155/21 156/1 156/2 162/24 163/4 169/16 170/7 170/9 170/10 170/12 170/15 172/5 174/25 175/2 175/12 178/13 178/24 182/11</p> <p>beforehand [1] 159/21</p> <p>begin [2] 97/25 117/3</p> <p>beginning [5] 33/22 96/24 103/22 105/23 137/25</p> <p>behalf [1] 172/18</p> <p>behave [1] 177/4</p> <p>behaved [1] 180/22</p> <p>behaviour [1] 176/24</p> <p>being [60] 6/15 8/1 14/19 16/21 22/23 24/22 30/4 30/8 35/21 41/7 46/5 49/3 56/22 58/18 62/14 62/15 67/15 68/21 68/22 71/20 72/13 76/13 77/24 82/19 82/21 86/15 86/19 87/5 89/2 93/23 98/17 98/17 102/4 102/22 104/17 104/22 107/11 112/7 114/10 115/9 122/3 125/7 141/7 142/12 142/22 144/11 147/8 148/9 149/16 155/5 155/11 160/13 161/15 167/4 169/12 169/21 169/25 173/23 181/14 181/18</p> <p>belief [11] 28/10 34/11 34/11 34/12 35/25 43/15 43/17 43/18 47/25 85/15 161/25</p> <p>believe [5] 2/2 9/15 53/8 86/2 151/7</p> <p>believed [1] 152/5</p> <p>bells [2] 58/17 59/3</p> <p>below [3] 5/2 77/5 106/18</p> <p>benefits [1] 44/5</p> <p>best [16] 1/22 28/17 35/7 54/25 56/3 60/10 70/21 81/11 81/18 88/24 102/16 128/8 138/18 153/11 167/18 178/6</p> <p>better [7] 153/23 154/1 154/2 154/22 155/5 155/6 180/13</p>	<p>between [27] 10/14 24/7 25/14 47/22 48/18 50/16 51/9 52/22 55/20 86/20 90/24 115/19 116/11 124/9 124/9 125/5 125/6 125/20 129/8 134/13 152/6 158/10 158/19 159/4 159/22 160/9 160/15</p> <p>beyond [4] 11/13 29/15 93/9 105/13</p> <p>biased [1] 138/9</p> <p>big [2] 31/21 123/18</p> <p>bigger [1] 150/12</p> <p>Biological [8] 46/25 47/2 49/16 51/19 51/22 129/4 129/11 130/12</p> <p>biologicals [2] 29/8 42/10</p> <p>Birmingham [1] 94/6</p> <p>bit [4] 18/4 110/20 123/10 182/11</p> <p>blank [3] 4/13 5/11 18/3</p> <p>Blears [1] 186/23</p> <p>blood [53] 5/22 13/14 23/5 23/10 26/1 26/3 26/5 26/5 60/3 72/21 88/6 91/3 129/23 132/5 132/18 134/2 134/5 146/24 147/24 153/23 154/1 154/2 154/3 154/5 154/6 154/9 154/9 154/12 154/15 154/16 154/19 154/22 155/5 155/6 155/7 155/11 155/12 155/17 155/20 168/3 168/7 178/9 180/15 184/14 184/19 186/5 187/21 187/24 189/20 189/20 189/22 189/23 189/24</p> <p>blush [1] 108/1</p> <p>BMJ [1] 63/16</p> <p>BNOR000177 [1] 89/7</p> <p>board [1] 178/21</p> <p>bodies [3] 124/25 133/22 146/13</p> <p>body [4] 30/19 42/3 44/7 99/24</p> <p>both [20] 3/6 6/6 27/20 45/19 73/18 92/16 105/16 125/2 130/6 130/24 134/9 146/6 146/19 152/9 160/4 160/7 168/4 172/18 178/11 183/5</p> <p>bottom [29] 4/19 7/19 8/6 10/10 12/10 16/6</p>
--	---	--	--	---	---

B	built [4] 64/16 78/21 82/6 155/16 bulk [1] 131/25 bullet [3] 52/2 52/20 56/23 bundle [1] 90/16 burden [1] 115/24 Burnham [1] 186/11 Burton [1] 147/23 business [7] 54/18 54/21 84/3 121/22 126/9 177/15 182/10 busy [1] 171/2 but [250] by [156] 1/4 3/5 3/22 4/15 5/2 6/1 7/6 10/24 12/2 13/14 13/18 15/4 16/16 16/22 17/23 19/25 23/7 23/10 24/8 25/13 26/5 27/8 27/17 27/19 28/19 29/5 29/9 29/24 32/14 33/8 33/17 35/14 35/22 37/1 37/15 37/16 37/24 37/25 38/20 39/19 43/14 44/9 44/21 46/25 47/24 48/16 50/12 50/18 51/13 51/14 53/11 58/16 59/23 61/22 62/24 63/2 63/16 64/22 68/21 70/3 74/3 77/3 77/3 77/22 80/20 80/25 81/2 81/4 81/4 81/6 81/16 82/19 83/10 89/18 92/3 92/18 92/23 95/12 98/7 99/18 102/2 102/9 102/13 104/6 105/6 106/23 106/25 107/8 107/11 109/11 109/11 109/11 111/8 111/11 113/2 114/13 114/15 114/20 117/2 117/11 118/4 125/2 125/4 125/12 129/11 131/12 133/12 134/17 135/13 135/16 137/21 139/3 143/3 146/14 146/14 147/13 151/18 151/19 152/1 152/6 152/16 152/16 152/19 154/20 157/18 158/4 159/13 159/23 160/11 161/18 164/16 165/5 166/10 166/18 168/13 169/25 169/25 170/8 174/12 175/11 175/17 176/14 179/14 181/16 181/25 183/22 184/17 188/3 188/14 189/3 189/20 189/21 189/24	190/15 191/7 192/3 C calendar [1] 189/9 calibrate [1] 172/16 call [3] 38/10 71/13 97/24 called [10] 49/10 80/15 95/24 96/2 133/16 139/14 178/3 187/4 187/12 191/9 calling [16] 183/10 183/14 184/8 184/13 184/16 185/18 186/4 186/11 186/14 186/19 186/23 187/17 187/20 187/23 188/5 188/11 came [11] 2/9 71/8 78/14 124/16 137/3 138/22 147/18 164/24 168/17 176/7 189/25 can [150] 4/1 5/12 5/19 6/17 8/5 8/6 8/15 9/9 9/18 11/2 12/6 12/20 14/10 14/15 15/20 16/24 18/8 18/13 20/2 20/13 20/22 22/6 22/23 23/1 23/6 24/24 25/22 26/2 26/14 27/23 28/1 32/10 33/23 40/16 40/21 41/4 43/2 44/14 46/24 48/9 53/15 55/3 57/13 59/4 61/2 62/25 63/11 64/21 65/5 66/16 66/18 67/17 67/25 68/3 68/7 68/18 69/23 70/17 70/20 71/25 73/7 74/10 76/12 76/24 78/9 78/24 81/20 82/9 82/13 84/22 85/19 88/3 88/13 89/11 89/13 90/18 91/11 91/13 91/17 92/1 93/16 95/12 96/20 100/6 104/3 106/9 106/15 107/10 107/19 108/9 108/12 108/16 109/16 109/20 110/12 111/19 112/7 113/14 115/2 117/12 117/18 118/3 118/10 119/6 119/6 119/11 119/14 120/16 121/14 127/20 129/21 131/16 134/20 135/18 137/15 139/5 142/9 143/4 143/7 143/23 144/4 145/16 148/14 148/24 149/5 150/24 151/1 151/3 153/18 153/20 153/24	154/2 156/6 158/9 158/13 159/13 160/1 161/3 168/6 170/23 172/1 172/12 172/13 173/7 173/19 174/20 182/5 189/12 190/2 191/10 can I [1] 25/22 can't [27] 1/20 16/12 22/11 37/11 39/2 43/24 45/2 50/24 51/6 51/16 51/16 58/21 79/1 81/24 81/25 87/2 94/21 107/12 131/23 135/14 136/21 146/18 148/13 157/16 173/8 175/3 179/7 Canada [2] 58/2 94/9 Canada's [1] 148/12 Canadian [1] 58/6 Canavan [1] 136/5 candidate [1] 76/23 candour [1] 187/14 cannot [14] 7/16 8/25 11/9 14/7 17/1 17/16 18/11 24/1 25/7 26/24 39/3 47/12 108/21 157/5 canvass [1] 166/4 capability [2] 7/4 161/20 capable [4] 61/20 114/10 122/19 125/7 capacities [1] 160/4 capacity [1] 169/9 care [7] 21/18 63/24 126/20 128/15 130/7 182/1 190/1 career [1] 188/9 careful [1] 43/1 carefully [5] 40/1 135/14 157/11 175/5 176/22 Caroline [1] 188/11 carried [6] 27/16 27/19 29/23 46/10 74/7 135/9 carry [3] 5/6 8/11 170/20 carrying [1] 169/23 case [18] 12/4 22/11 28/9 34/10 37/12 41/3 42/1 102/11 105/8 111/4 117/15 120/25 127/22 134/25 140/9 152/11 160/12 167/22 cases [11] 1/25 2/1 27/20 94/6 108/22 113/25 114/12 114/15 124/2 148/3 179/8 Cash [33] 11/17 35/9 38/21 39/20 40/4	41/11 45/6 46/20 47/17 47/21 55/5 55/7 55/21 56/3 62/25 64/6 64/22 66/4 66/21 67/9 67/23 68/22 73/17 73/20 76/3 90/25 95/4 103/11 126/10 137/3 156/10 156/11 167/25 Cash's [5] 54/17 63/6 67/16 68/11 124/11 catastrophic [2] 100/20 100/25 categories [1] 114/17 causal [3] 52/21 53/3 90/12 cause [7] 47/25 55/12 57/2 57/3 58/15 59/18 174/24 caused [4] 57/11 146/24 152/5 181/16 causing [2] 56/21 178/10 caution [1] 180/16 cautious [3] 54/16 109/8 178/16 caveat [1] 135/10 CBCA0000065 [1] 15/22 CBLA0001919 [1] 88/3 cell [2] 167/23 168/2 cells [1] 168/13 cent [4] 37/18 149/1 154/18 154/20 central [3] 88/5 157/1 184/17 centrally [1] 146/8 centre [25] 11/18 58/14 61/7 63/1 66/9 72/5 74/23 80/21 82/3 86/11 89/11 89/25 95/6 97/9 97/13 97/22 119/17 123/18 123/22 124/12 125/1 125/10 125/16 176/15 176/21 Centre/Transfusion [1] 63/1 centres [22] 34/6 34/7 56/8 63/25 64/10 68/14 74/22 75/12 78/25 79/3 79/6 79/8 80/23 81/4 81/5 81/7 82/5 96/5 97/12 98/8 126/6 142/25 certain [3] 22/17 67/8 105/23 certainly [47] 1/20 2/13 9/22 12/22 22/12 34/10 36/20 37/1 38/3 40/3 42/17 43/14 44/4 51/8 53/24 54/17 56/11 58/1 59/2 59/10	62/17 75/7 87/19 90/19 96/24 98/3 102/11 103/11 105/8 119/20 130/23 133/8 139/9 141/9 148/14 153/8 155/17 158/3 160/1 161/17 161/22 162/7 176/10 178/21 180/14 180/15 182/4 certainty [1] 178/9 chain [3] 80/19 110/4 118/23 chair [4] 38/8 38/8 53/20 140/16 chaired [4] 104/6 133/12 134/8 135/4 chairman [2] 83/8 123/22 chance [2] 109/20 163/11 Chancellor [1] 185/2 chances [1] 121/11 change [17] 2/21 33/12 45/23 46/12 46/20 50/13 50/13 50/14 51/3 102/18 102/23 104/25 159/3 159/5 167/6 170/13 175/13 changed [2] 162/3 164/22 changes [5] 1/21 2/9 2/14 22/12 22/17 characteristics [1] 103/8 charge [1] 68/12 Charles [1] 184/13 Charles Lister [1] 184/13 check [7] 25/18 40/3 40/6 46/12 89/4 107/19 136/17 checked [4] 9/20 12/15 12/19 12/20 checking [2] 24/17 46/22 chief [9] 133/4 133/13 135/2 141/1 184/1 185/1 185/20 185/25 187/5 children [7] 63/19 64/8 67/5 67/25 94/7 94/15 127/17 choice [1] 126/2 choose [1] 147/1 chose [2] 11/18 124/1 124/1 chosen [1] 17/18 Christopher [2] 76/4 110/20 Christopher's [1] 156/18 chronology [1]
----------	---	---	--	---	---

<p>C</p> <p>chronology... [1] 183/23</p> <p>circulate [1] 126/5</p> <p>circulated [2] 68/21 174/14</p> <p>circumstance [1] 3/21</p> <p>circumstances [2] 65/8 173/18</p> <p>cited [1] 33/7</p> <p>citrate [2] 21/1 23/21</p> <p>city [1] 87/6</p> <p>civil [2] 187/20 190/5</p> <p>CJD [3] 183/9 183/16 183/20</p> <p>claims [2] 44/4 156/20</p> <p>clarification [1] 90/10</p> <p>clarify [1] 88/13</p> <p>clarity [1] 87/21</p> <p>class [1] 122/19</p> <p>CLB [1] 101/11</p> <p>clear [20] 3/13 7/7 11/25 16/20 43/2 54/21 55/2 55/20 77/17 87/10 97/20 98/11 142/7 142/15 149/19 151/23 157/19 162/5 164/7 166/7</p> <p>clearer [3] 15/23 18/2 164/23</p> <p>clearly [9] 2/13 21/14 38/10 67/20 70/24 75/24 81/7 81/24 84/1</p> <p>Clinic [2] 183/12 183/12</p> <p>clinical [21] 23/8 26/3 51/4 60/5 63/15 70/7 103/17 107/4 108/19 116/8 116/9 116/19 119/5 120/13 120/15 128/24 154/11 165/23 168/11 183/15 184/9</p> <p>clinicians [16] 34/2 34/18 34/23 35/22 36/5 36/6 36/12 36/14 54/7 55/9 57/9 58/22 164/11 165/6 168/1 169/25</p> <p>close [4] 37/18 121/25 174/5 176/14</p> <p>closely [2] 13/10 156/5</p> <p>closer [4] 19/16 27/14 94/18 190/10</p> <p>closing [1] 191/8</p> <p>clotting [1] 28/20</p> <p>CMO [1] 140/16</p> <p>co [4] 85/18 125/20 177/18 180/21</p> <p>co-author [1] 85/18</p>	<p>co-operation [1] 125/20</p> <p>co-operative [2] 177/18 180/21</p> <p>coagulation [6] 9/7 14/14 34/9 52/23 61/5 102/14</p> <p>cognisance [1] 137/24</p> <p>cohort [4] 78/2 86/18 103/2 178/23</p> <p>colleague [3] 122/1 155/20 174/6</p> <p>colleagues [11] 34/12 38/21 39/24 56/2 109/13 109/15 109/19 141/24 143/19 147/7 168/10</p> <p>colleagues' [1] 63/15</p> <p>collect [2] 75/25 163/11</p> <p>collected [5] 5/22 13/14 144/21 180/23 189/23</p> <p>collection [2] 11/3 155/5</p> <p>collective [3] 157/6 157/12 157/13</p> <p>collegiate [1] 56/7</p> <p>collegiately [1] 56/13</p> <p>Collinge [1] 183/11</p> <p>colour [1] 15/19</p> <p>column [1] 20/12</p> <p>combination [3] 168/5 171/16 188/19</p> <p>come [27] 12/3 14/23 19/12 19/21 42/22 61/23 62/3 75/21 106/2 122/24 123/11 124/21 127/18 128/19 131/10 140/5 145/16 162/10 163/15 163/22 173/25 182/6 182/13 182/14 182/19 185/10 191/6</p> <p>comes [3] 1/19 53/13 132/1</p> <p>coming [7] 49/14 51/23 57/8 58/14 93/9 143/23 182/5</p> <p>commencing [1] 107/4</p> <p>comment [4] 59/20 97/4 143/7 146/18</p> <p>commenting [1] 149/12</p> <p>comments [6] 63/21 110/13 151/5 156/19 167/11 181/9</p> <p>commercial [14] 32/5 37/6 37/17 58/3 58/4 58/5 61/12 94/20</p>	<p>161/7 161/8 161/15 169/10 169/23 179/10</p> <p>Commission [1] 29/7</p> <p>committee [44] 42/10 42/11 46/17 49/15 88/6 129/4 129/7 129/13 129/14 129/15 129/16 130/6 130/11 130/24 131/1 131/2 131/15 132/4 132/10 132/23 133/2 133/9 133/16 133/18 133/19 134/4 135/7 135/8 135/21 137/18 137/23 138/8 139/16 139/22 139/23 139/24 141/6 143/3 143/11 143/12 143/18 144/6 144/16 184/11</p> <p>committees [4] 134/9 134/14 166/20 177/13</p> <p>common [3] 92/10 92/16 128/7</p> <p>communicate [3] 47/6 144/16 164/19</p> <p>communicated [6] 43/2 43/4 54/25 55/1 84/1 128/5</p> <p>communicating [2] 141/22 178/19</p> <p>communication [4] 73/22 110/23 151/15 164/20</p> <p>communications [1] 179/23</p> <p>companies [2] 44/2 93/22</p> <p>company [2] 32/6 43/23</p> <p>comparable [3] 111/15 113/20 115/22</p> <p>comparison [1] 160/15</p> <p>Compensation [1] 186/5</p> <p>competence [1] 159/10</p> <p>competent [2] 160/21 160/22</p> <p>compiled [1] 29/5</p> <p>complacency [1] 161/13</p> <p>complacent [2] 44/9 162/13</p> <p>complete [5] 19/22 82/6 87/24 118/23 181/23</p> <p>completely [3] 101/3 129/2 179/13</p> <p>completes [1] 60/12</p> <p>complications [8] 7/20 7/21 9/3 9/6 10/2</p>	<p>12/6 13/7 14/11</p> <p>comply [1] 32/21</p> <p>components [1] 155/7</p> <p>composition [2] 137/18 138/8</p> <p>comprise [1] 188/20</p> <p>computers [1] 75/19</p> <p>concentrate [12] 5/22 7/20 8/18 9/4 12/25 13/14 18/8 25/15 64/15 65/7 78/25 115/6</p> <p>concentrated [1] 72/18</p> <p>concentrates [19] 28/11 37/6 37/7 43/14 57/12 61/6 65/13 65/14 78/20 105/16 161/8 161/9 161/15 167/24 168/2 169/21 174/22 174/23 179/11</p> <p>concentrates' [1] 63/20</p> <p>concentration [2] 23/20 28/2</p> <p>concern [13] 24/5 38/16 39/24 56/21 100/15 102/11 142/21 143/2 147/13 156/22 158/6 158/7 169/20</p> <p>concerned [7] 20/19 23/22 103/13 160/16 175/25 180/18 183/9</p> <p>concerning [2] 45/4 191/1</p> <p>concerns [5] 23/20 84/7 99/10 146/25 156/12</p> <p>conclude [2] 150/24 187/8</p> <p>concludes [1] 63/17</p> <p>concluding [1] 76/21</p> <p>conclusion [6] 72/20 75/21 77/21 99/25 106/9 161/16</p> <p>conclusions [4] 76/11 91/14 93/5 97/8</p> <p>conclusive [3] 71/3 108/21 109/5</p> <p>concluded [1] 67/6</p> <p>concurr [1] 126/19</p> <p>condition [1] 116/7</p> <p>conditional [1] 119/4</p> <p>conditions [3] 28/4 150/15 150/23</p> <p>conducted [1] 56/12</p> <p>conducting [1] 107/18</p> <p>conference [3] 71/6 71/24 169/2</p> <p>confidence [2] 19/3</p>	<p>58/22</p> <p>confidential [6] 47/4 129/20 141/8 141/13 141/18 142/19</p> <p>confidentiality [11] 129/10 129/17 140/14 140/17 140/22 141/5 142/6 142/13 142/18 143/9 151/12</p> <p>configuring [1] 70/11</p> <p>confined [2] 85/16 86/3</p> <p>confirm [6] 6/9 22/11 41/4 119/1 170/4 187/3</p> <p>confirmation [2] 71/19 109/4</p> <p>confirmatory [1] 150/21</p> <p>confirmed [5] 12/20 118/17 119/3 186/8 186/9</p> <p>confirming [1] 109/10</p> <p>conflict [6] 130/1 130/8 130/17 130/22 158/18 159/20</p> <p>conflict/differences [1] 159/20</p> <p>conflicts [1] 129/21</p> <p>confused [1] 151/15</p> <p>confusing [1] 82/1</p> <p>Connon [1] 187/24</p> <p>Connor [1] 183/19</p> <p>conscious [3] 4/7 59/13 60/13</p> <p>consensual [1] 146/20</p> <p>consensus [6] 39/5 52/21 53/3 53/7 70/8 168/14</p> <p>consequence [1] 143/8</p> <p>consequences [5] 100/20 101/1 101/6 152/14 181/20</p> <p>consider [7] 126/7 134/6 152/15 163/12 165/2 190/24 190/25</p> <p>consideration [9] 23/8 40/23 64/1 65/2 131/5 132/5 140/4 140/6 169/3</p> <p>considerations [6] 60/4 120/6 132/2 133/10 151/13 151/21</p> <p>considered [9] 40/2 108/21 131/3 138/7 144/11 145/15 148/20 152/22 157/11</p> <p>considering [1] 130/1</p> <p>consistency [1] 160/9</p> <p>consistent [5] 12/22</p>	<p>56/19 89/21 90/5 159/18</p> <p>consistently [1] 3/21</p> <p>constantly [1] 86/25</p> <p>constitution [1] 31/6</p> <p>constraint [1] 144/2</p> <p>construct [1] 64/21</p> <p>constructive [1] 156/21</p> <p>consult [2] 56/15 57/16</p> <p>consultant [1] 183/19</p> <p>consulted [1] 59/6</p> <p>consumed [1] 78/10</p> <p>consumption [1] 74/5</p> <p>contact [2] 117/2 158/22</p> <p>contacting [3] 74/22 74/25 75/10</p> <p>contain [3] 31/15 88/17 137/20</p> <p>contained [4] 20/24 23/21 90/21 92/19</p> <p>container [5] 20/15 20/19 26/12 26/16 26/21</p> <p>containing [2] 8/16 131/11</p> <p>contains [2] 13/2 16/24</p> <p>contaminated [2] 92/13 93/1</p> <p>contamination [1] 7/5</p> <p>contemplating [1] 20/23</p> <p>contemplation [2] 62/10 96/24</p> <p>contemporaneous [1] 152/24</p> <p>content [1] 45/12</p> <p>contents [2] 2/8 129/19</p> <p>context [6] 127/2 137/16 158/11 165/8 169/13 174/3</p> <p>contingency [2] 116/4 119/8</p> <p>continually [1] 166/15</p> <p>continuation [1] 61/15</p> <p>continue [6] 7/15 47/7 47/11 107/20 124/1 140/8</p> <p>continued [8] 1/3 1/4 45/20 100/10 145/13 156/24 192/2 192/3</p> <p>continues [5] 6/13 7/11 113/2 159/7 183/18</p> <p>continuing [3] 44/14 94/21 182/23</p> <p>contra [3] 4/23 5/1 8/8</p>
---	---	--	---	--	---

<p>C</p> <p>contra-indications [3] 4/23 5/1 8/8</p> <p>contract [1] 58/8</p> <p>contrast [2] 52/3 168/17</p> <p>contrasting [1] 150/4</p> <p>contravened [1] 57/19</p> <p>contribute [2] 118/21 139/7</p> <p>contributed [1] 87/14</p> <p>contribution [2] 131/1 139/6</p> <p>control [8] 41/24 45/11 49/9 136/12 136/13 155/15 171/24 176/24</p> <p>controlled [2] 41/23 175/9</p> <p>controversial [2] 141/14 141/16</p> <p>convened [1] 82/15</p> <p>convenient [1] 46/4</p> <p>conventional [1] 31/12</p> <p>conversation [14] 39/10 39/20 40/4 40/8 41/11 42/7 42/14 55/7 111/21 111/23 112/13 112/14 120/23 179/1</p> <p>conversations [2] 84/5 148/14</p> <p>converse [1] 44/5</p> <p>convey [1] 36/17</p> <p>conveying [1] 34/13</p> <p>convinced [1] 103/23</p> <p>coordinate [1] 68/13</p> <p>coordinated [4] 80/20 81/3 81/3 81/6</p> <p>coordinating [3] 68/6 68/7 86/23</p> <p>copied [2] 12/10 89/12</p> <p>copies [2] 15/19 24/18</p> <p>copy [1] 9/16</p> <p>Core [9] 99/10 99/11 153/19 162/18 163/6 163/22 175/17 175/22 191/4</p> <p>corner [6] 16/7 25/2 25/19 25/23 26/10 89/12</p> <p>correct [12] 21/16 24/4 41/5 48/8 95/11 105/21 106/3 108/7 109/2 130/22 158/2 179/21</p> <p>correctly [2] 55/18 158/1</p>	<p>corresponded [1] 81/8</p> <p>correspondence [11] 29/9 90/24 96/18 103/11 103/12 110/5 110/10 116/11 118/24 119/20 121/9</p> <p>correspondent [1] 188/7</p> <p>cost [1] 22/19</p> <p>could [71] 6/11 7/6 11/20 16/13 29/17 36/17 39/1 40/11 49/25 56/4 56/16 57/2 60/15 61/21 67/3 67/10 69/20 70/10 72/4 73/12 73/14 75/15 77/24 82/4 86/21 97/1 97/5 98/9 98/20 98/22 100/7 100/18 100/25 105/3 112/11 113/24 114/6 116/15 116/18 117/25 122/7 122/16 123/5 123/6 123/24 124/1 125/22 126/21 126/25 127/14 127/22 129/25 138/14 138/21 143/12 143/20 146/18 149/24 150/13 154/18 160/17 165/22 166/10 167/8 171/21 173/16 174/14 176/19 178/6 181/1 190/15</p> <p>couldn't [6] 30/21 99/20 99/23 143/22 177/2 177/22</p> <p>counsel [6] 163/7 163/11 183/22 185/23 188/3 188/15</p> <p>counselling [1] 147/12</p> <p>countries [10] 29/16 29/17 30/13 30/14 133/15 148/1 148/5 148/8 148/18 148/20</p> <p>country [1] 30/3</p> <p>couple [3] 101/10 173/3 181/8</p> <p>course [21] 12/21 20/1 38/7 43/7 47/1 62/21 77/13 79/4 94/19 111/16 113/25 115/13 141/19 143/1 163/13 164/18 166/25 170/21 183/5 183/6 186/19</p> <p>cover [5] 115/18 117/21 162/17 187/14 188/4</p> <p>cover-up [2] 187/14 188/4</p>	<p>covered [1] 99/6</p> <p>coverings [2] 178/5 178/5</p> <p>Craske [1] 89/18</p> <p>Crawford's [1] 169/13</p> <p>create [3] 125/25 132/23 134/11</p> <p>creation [1] 169/14</p> <p>Crisp [2] 187/17 187/17</p> <p>criteria [4] 117/11 117/16 118/7 120/12</p> <p>criticising [1] 157/22</p> <p>criticism [6] 39/7 138/11 138/17 160/13 160/14 160/17</p> <p>Cross [1] 101/11</p> <p>crossed [2] 21/25 116/23</p> <p>Crown [1] 130/10</p> <p>cryo [2] 67/7 67/9</p> <p>cryoprecipitate [21] 62/13 62/16 63/19 63/23 64/8 64/11 65/9 66/25 67/3 67/4 67/13 67/20 67/24 68/2 69/10 69/14 70/4 70/9 70/15 114/23 124/2</p> <p>CSA [1] 146/14</p> <p>cultured [1] 172/13</p> <p>cumbersome [1] 124/15</p> <p>cup [1] 163/14</p> <p>curious [3] 17/23 18/4 65/15</p> <p>current [8] 46/15 63/25 64/14 65/1 65/14 65/23 110/18 115/10</p> <p>Currently [1] 189/1</p> <p>customers [1] 156/21</p> <p>Cuthbertson [5] 71/13 73/23 75/2 75/4 77/22</p> <p>cuts [1] 176/11</p>	<p>113/14 116/23 118/12 130/11 145/14 146/21 147/6 152/4 191/6</p> <p>dated [2] 14/15 107/13</p> <p>dates [5] 28/4 73/2 144/20 145/1 148/4</p> <p>dating [1] 17/24</p> <p>David [1] 183/25</p> <p>day [5] 111/22 117/19 118/4 160/25 168/9</p> <p>days [4] 68/4 75/24 182/6 182/18</p> <p>deadline [3] 190/20 190/23 191/2</p> <p>deadlines [1] 190/21</p> <p>deal [6] 30/1 72/8 111/3 134/3 144/6 182/10</p> <p>dealing [6] 38/1 120/10 166/17 166/23 176/1 178/14</p> <p>dealings [1] 59/22</p> <p>dealt [1] 159/20</p> <p>December [9] 10/14 16/14 78/22 78/23 81/16 84/11 174/22 189/6 189/6</p> <p>December 1984 [3] 10/14 16/14 78/22</p> <p>decide [3] 38/9 134/12 165/17</p> <p>decided [2] 27/17 29/24</p> <p>decision [24] 70/3 70/7 73/8 80/3 84/9 130/16 144/9 144/25 145/17 145/19 145/20 146/1 146/13 147/19 149/18 150/6 150/13 152/1 152/20 152/24 185/24 186/15 187/1 188/18</p> <p>decision-making [10] 130/16 144/9 144/25 145/17 152/20 152/24 185/24 186/15 187/1 188/18</p> <p>decisions [9] 35/19 60/8 126/1 129/7 133/6 133/10 151/16 159/11 181/25</p> <p>declaring [1] 129/18</p> <p>dedication [9] 66/5 66/11 95/3 95/9 95/13 96/2 98/14 123/10 157/4</p> <p>dedication' [1] 62/1</p> <p>defect [1] 80/12</p> <p>defendants [1] 184/17</p> <p>deferral [1] 152/4</p> <p>deficiency [2] 14/3</p>	<p>19/2</p> <p>defined [3] 97/9 97/23 126/3</p> <p>definite [1] 91/14</p> <p>definitely [1] 160/18</p> <p>DEFIX [4] 8/17 9/4 14/25 48/7</p> <p>degree [4] 39/7 49/21 109/4 161/13</p> <p>degrees [4] 14/1 82/22 110/2 112/6</p> <p>delay [1] 75/16</p> <p>delayed [2] 128/24 147/8</p> <p>delaying [1] 139/2</p> <p>delays [1] 152/14</p> <p>delighted [1] 120/7</p> <p>deliver [1] 155/1</p> <p>delivered [3] 36/2 141/9 190/2</p> <p>delivery [4] 117/19 118/5 131/11 154/12</p> <p>demand [3] 155/15 155/15 169/9</p> <p>demarcation [1] 55/20</p> <p>demonstrate [1] 173/16</p> <p>demonstrated [1] 161/19</p> <p>denial [1] 157/10</p> <p>department [31] 49/7 83/11 94/23 104/9 105/6 133/2 133/11 133/14 134/17 136/6 136/9 136/10 139/18 139/22 140/3 140/5 145/20 146/2 149/25 150/6 182/25 183/4 184/4 184/14 184/20 185/5 186/12 187/7 187/18 187/21 187/25</p> <p>department/section [1] 104/9</p> <p>departmental [1] 140/10</p> <p>departments [6] 79/7 145/22 145/23 146/16 155/3 185/25</p> <p>dependent [1] 97/11</p> <p>depending [1] 96/13</p> <p>depth [2] 79/9 181/13</p> <p>deputy [5] 133/12 135/2 140/16 141/1 187/5</p> <p>derivatives [1] 26/6</p> <p>derived [2] 5/22 13/14</p> <p>describe [9] 1/20 2/12 45/25 59/24 65/12 72/2 79/1 101/8 150/7</p> <p>described [26] 19/7 19/8 29/9 46/6 46/16</p>	<p>58/25 70/11 71/9 77/24 80/10 80/16 81/22 83/20 87/4 89/24 98/18 107/25 114/12 119/25 119/25 129/11 130/5 140/12 157/24 168/19 169/7</p> <p>describes [1] 90/11</p> <p>describing [4] 62/7 84/4 85/1 112/2</p> <p>description [14] 5/20 7/17 8/21 9/19 11/3 13/2 13/12 18/19 20/9 24/10 27/12 77/1 85/5 90/13</p> <p>design [1] 12/2</p> <p>designed [7] 29/25 30/12 30/13 32/21 33/22 96/15 121/11</p> <p>desirability [1] 47/14</p> <p>desirable [1] 146/21</p> <p>desire [1] 101/25</p> <p>despatch [1] 117/17</p> <p>destination [1] 117/18</p> <p>detail [14] 51/7 62/4 65/19 80/19 84/25 85/7 93/19 99/8 140/1 157/16 159/16 189/13 191/8 191/11</p> <p>detailed [8] 34/13 77/22 83/24 85/3 133/25 152/19 165/22 166/10</p> <p>details [9] 1/20 5/25 79/1 92/1 134/7 149/19 150/12 186/9 187/3</p> <p>detected [1] 7/6</p> <p>determine [1] 98/1</p> <p>determined [3] 146/8 152/16 190/16</p> <p>devastating [3] 70/24 72/3 105/11</p> <p>develop [1] 101/17</p> <p>developed [7] 7/15 29/16 38/20 73/11 76/6 89/20 115/11</p> <p>developing [1] 29/16</p> <p>development [12] 22/13 50/7 61/19 61/25 88/6 99/15 100/12 100/18 106/22 171/14 172/23 174/24</p> <p>developments [6] 28/17 56/10 88/11 107/1 175/10 181/17</p> <p>diagnosed [1] 127/19</p> <p>diagnosis [1] 87/9</p> <p>diagnostic [1] 150/19</p> <p>dialogue [4] 49/21 50/16 50/20 51/9</p> <p>diaries [1] 71/11</p>
--	--	--	--	---	---

<p>D</p> <p>did [63] 4/6 16/14 29/6 30/14 34/22 36/9 36/10 37/17 39/21 45/16 45/25 50/4 50/19 57/17 58/6 59/5 62/12 75/13 82/7 84/18 86/1 101/11 102/15 102/21 103/23 105/20 106/7 109/25 114/21 116/17 120/23 124/4 124/6 128/13 131/22 131/22 132/12 139/7 141/2 141/22 142/21 143/1 148/3 161/21 164/5 164/9 164/13 164/25 165/14 166/21 167/6 168/16 168/24 168/24 170/13 170/23 172/17 173/25 176/4 176/6 178/6 178/16 180/5</p> <p>didn't [37] 2/19 15/2 15/11 31/24 38/2 39/11 47/10 52/18 77/7 81/12 81/22 84/19 85/21 87/7 103/5 103/7 103/8 105/3 107/17 118/6 121/2 121/15 124/1 127/24 127/25 128/17 128/19 135/9 137/20 139/24 146/15 162/13 169/24 177/1 177/10 177/12 178/2</p> <p>died [1] 179/5</p> <p>difference [1] 122/18</p> <p>differences [3] 159/4 159/13 159/20</p> <p>different [24] 6/20 30/23 36/7 52/24 53/1 53/5 60/1 60/23 76/21 111/23 129/2 133/21 142/9 148/4 159/1 159/2 159/11 170/5 171/24 172/21 173/14 173/17 173/18 173/19</p> <p>difficult [9] 54/11 58/11 60/8 72/2 83/2 83/20 122/24 155/14 180/11</p> <p>difficulties [1] 88/22</p> <p>diffuse [1] 8/14</p> <p>direct [6] 42/13 54/19 59/22 66/1 83/7 124/4</p> <p>direction [4] 35/5 102/18 102/23 104/25</p> <p>directly [5] 73/23 124/13 164/20 165/15 166/1</p> <p>director [15] 45/4</p>	<p>45/7 47/13 73/21 75/14 76/10 84/15 98/5 114/14 121/9 121/17 122/1 123/21 168/7 183/11</p> <p>directors [38] 11/18 38/15 47/17 47/23 53/23 56/5 56/18 57/16 58/14 63/20 64/7 64/9 65/22 66/9 66/16 66/17 67/10 70/2 79/8 81/9 81/10 82/11 82/12 83/7 84/4 97/13 97/22 97/22 98/8 115/21 117/12 122/5 124/12 125/1 125/10 125/17 128/6 157/7</p> <p>directors' [4] 61/7 63/2 86/23 95/7</p> <p>directorship [1] 45/9</p> <p>disagree [2] 153/1 159/9</p> <p>disappeared [2] 21/14 24/11</p> <p>disappointment [1] 156/17</p> <p>discarded [1] 5/4</p> <p>discontinued [2] 65/8 70/5</p> <p>discovered [2] 88/17 103/6</p> <p>discovery [4] 70/17 76/5 86/17 88/23</p> <p>discuss [8] 14/23 19/12 34/22 35/1 51/21 82/15 121/5 127/20</p> <p>discussed [25] 14/12 37/24 42/9 45/5 47/2 47/13 49/1 50/15 54/13 62/17 67/2 72/7 81/8 86/16 116/13 116/13 121/4 128/7 141/7 142/22 148/13 149/3 161/17 164/15 179/24</p> <p>discussing [1] 164/3</p> <p>discussion [17] 41/8 51/24 59/2 62/21 66/25 67/13 67/14 68/17 68/18 69/23 70/3 83/23 113/2 116/3 127/3 148/9 180/4</p> <p>discussions [29] 11/17 30/8 38/15 44/23 45/3 47/16 54/20 56/10 58/23 76/4 86/20 86/21 86/22 91/9 120/20 122/25 124/4 129/20</p>	<p>139/16 139/20 140/2 140/3 141/13 141/17 141/20 151/14 153/7 166/4 169/12</p> <p>disease [4] 23/9 26/5 161/25 162/1</p> <p>Diseases [2] 133/20 134/5</p> <p>disparity [2] 125/5 125/6</p> <p>disquiet [2] 52/17 132/16</p> <p>disregarded [2] 7/16 9/1</p> <p>dissent [1] 147/5</p> <p>dissimilar [2] 28/18 148/21</p> <p>distance [3] 125/24 127/4 127/25</p> <p>distilled [1] 5/3</p> <p>distress [2] 55/13 56/21</p> <p>distributed [2] 30/5 82/4</p> <p>distribution [4] 80/22 90/3 114/6 171/9</p> <p>diverge [1] 3/25</p> <p>dividing [1] 95/18</p> <p>division [3] 49/6 49/14 183/5</p> <p>divulging [1] 130/19</p> <p>do [74] 2/6 2/20 6/4 6/15 10/2 10/14 12/19 19/22 25/12 28/9 29/3 34/21 35/15 37/10 38/9 39/17 46/11 51/25 53/7 55/10 59/20 60/5 60/6 60/17 63/6 67/13 72/13 72/22 75/2 77/18 81/2 81/24 83/22 85/19 86/15 86/18 90/8 92/25 93/3 94/15 94/17 98/24 99/20 101/5 103/9 105/10 106/11 110/4 110/9 117/15 127/13 127/25 140/25 144/18 148/8 149/2 155/8 156/3 159/10 161/12 162/20 166/2 167/8 167/25 168/16 169/13 171/9 172/14 174/1 175/19 177/16 182/13 182/14 188/20</p> <p>doctor [9] 19/15 19/20 34/16 54/22 54/24 54/24 59/21 122/13 123/17</p> <p>doctor's [1] 121/24</p> <p>doctors [17] 32/24 33/5 34/7 35/14 36/20</p>	<p>37/24 38/21 54/13 56/9 56/15 59/8 103/12 103/25 155/14 164/21 165/17 166/11</p> <p>doctors' [1] 123/12</p> <p>document [19] 12/11 29/14 29/21 30/12 30/15 30/25 40/13 63/8 66/14 66/22 70/20 84/22 89/7 104/4 111/24 120/17 129/18 173/19 178/17</p> <p>documentation [3] 44/2 46/22 52/12</p> <p>documented [1] 40/7</p> <p>documents [15] 12/4 22/22 28/17 34/21 45/24 62/20 96/18 132/9 133/4 156/7 166/3 166/18 167/12 167/13 185/10</p> <p>does [9] 14/18 55/16 115/22 124/10 138/15 138/16 152/21 157/13 190/21</p> <p>doesn't [4] 27/1 44/8 73/21 90/11</p> <p>DoH [5] 146/2 151/18 151/25 152/7 152/17</p> <p>doing [11] 60/11 61/16 84/2 111/13 121/24 126/11 143/14 148/12 153/8 174/7 189/18</p> <p>domain [1] 158/20</p> <p>domestic [3] 105/15 161/14 161/14</p> <p>dominant [1] 138/13</p> <p>don't [74] 2/12 6/11 6/22 7/7 14/15 14/16 15/25 22/5 23/13 25/2 25/16 27/5 32/14 32/19 35/11 38/13 39/6 40/12 41/7 42/10 42/13 45/5 46/19 57/10 57/10 57/11 57/13 57/21 58/9 58/15 59/18 62/14 62/15 62/18 67/17 69/3 74/3 78/1 83/24 85/17 87/20 89/5 90/20 93/12 93/19 94/17 96/19 97/3 99/22 102/16 105/23 111/3 112/8 124/6 126/3 137/12 140/14 142/2 144/11 159/2 160/1 161/16 162/22 163/4 165/19 166/2 169/11 169/15 170/1 170/23 175/3 180/22 181/3 190/22</p>	<p>donation [1] 90/22</p> <p>donations [9] 13/24 14/19 15/5 21/4 21/13 24/10 25/5 92/20 162/8</p> <p>done [31] 3/1 10/14 50/9 74/6 75/14 75/15 77/22 82/19 90/8 90/9 97/2 97/3 98/20 121/3 124/7 127/5 127/9 127/11 127/20 127/22 131/24 147/6 148/10 148/11 148/11 148/12 148/12 168/13 171/15 175/2 175/11</p> <p>done it [2] 148/11 148/12</p> <p>donor [8] 23/2 23/3 68/25 69/5 87/1 87/17 162/6 169/14</p> <p>donors [20] 5/23 11/4 13/15 26/2 29/12 29/12 29/14 63/14 85/16 86/9 86/24 87/13 87/18 87/22 96/15 138/25 147/12 161/20 162/12 180/10</p> <p>dose [1] 176/16</p> <p>dossiers [1] 131/11</p> <p>double [1] 136/17</p> <p>double-check [1] 136/17</p> <p>Douglas [3] 158/11 158/15 188/6</p> <p>down [14] 3/11 18/4 20/7 29/22 70/20 76/19 78/9 80/19 82/24 106/17 153/20 161/3 174/20 182/6</p> <p>DR [219]</p> <p>Dr Andrzej [1] 182/24</p> <p>Dr Boulton [17] 47/17 56/2 74/21 75/10 110/12 111/2 111/19 112/13 112/19 113/3 113/8 113/15 118/16 119/15 120/19 124/8 124/16</p> <p>Dr Boulton's [1] 120/1</p> <p>Dr Brian [1] 88/8</p> <p>Dr Brian McClelland [1] 86/6</p> <p>Dr Cash [13] 45/6 47/17 62/25 64/6 66/4 66/21 67/9 68/22 73/17 73/20 76/3 90/25 95/4</p> <p>Dr Cash's [4] 63/6 67/16 68/11 124/11</p> <p>Dr Christopher [1] 76/4</p>	<p>Dr Craske [1] 89/18</p> <p>Dr Crawford's [1] 169/13</p> <p>Dr Cuthbertson [5] 71/13 73/23 75/2 75/4 77/22</p> <p>Dr Douglas [1] 158/11</p> <p>Dr Flett [1] 136/20</p> <p>Dr Forbes [4] 84/16 90/25 123/21 127/14</p> <p>Dr Foster [24] 4/7 15/18 35/9 39/19 47/20 67/12 71/9 72/10 72/11 85/24 93/18 106/24 156/11 156/14 157/17 158/10 158/23 159/25 160/3 160/21 160/23 168/25 171/15 178/11</p> <p>Dr George [1] 136/19</p> <p>Dr Gunson [1] 134/8</p> <p>Dr Gunson's [1] 150/4</p> <p>Dr Hann [1] 67/6</p> <p>Dr Harris [2] 135/4 135/22</p> <p>Dr Hilary Pickles [1] 183/3</p> <p>Dr Jean Harrison [1] 89/10</p> <p>Dr JK Smith [1] 107/1</p> <p>Dr Jones [2] 63/17 64/5</p> <p>Dr Lane [4] 101/23 116/13 130/25 136/1</p> <p>Dr Lane's [1] 117/5</p> <p>Dr Ludlam [18] 39/20 40/6 67/4 73/9 74/12 75/9 76/9 76/16 84/12 110/13 112/21 113/4 124/4 124/16 127/12 128/2 156/12 157/20</p> <p>Dr Ludlam's [2] 70/18 128/15</p> <p>Dr Madhok [2] 91/5 93/13</p> <p>Dr McClelland [16] 68/21 73/3 73/9 73/16 74/12 74/14 74/21 75/10 75/11 76/2 76/17 84/14 86/5 88/15 112/22 156/4</p> <p>Dr McIntyre [1] 136/18</p> <p>Dr Metters [4] 135/1 135/22 149/17 150/11</p> <p>Dr Mike [1] 94/2</p> <p>Dr Minor [1] 136/2</p> <p>Dr Mitchell [1] 136/1</p> <p>Dr Mortimer [1] 136/1</p> <p>Dr Nicky [1] 183/19</p> <p>Dr Perry [38] 1/6 4/10</p>
---	---	---	--	--	---

D	70/4 70/8 70/15 drilled [1] 80/18 drive [1] 126/1 driven [1] 151/19 Drs [1] 158/14 drug [3] 50/25 86/12 87/5 dry [2] 78/19 101/24 due [7] 12/21 20/1 38/7 43/7 111/16 115/13 163/13 Dundee [1] 95/23 duration [2] 1/16 162/1 during [16] 1/16 45/17 46/15 50/5 56/12 83/25 103/1 122/10 130/23 130/23 131/24 132/17 149/9 150/16 153/4 188/8 Dutch [1] 101/10 duty [3] 57/16 74/25 182/1	edition [2] 31/4 31/4 effect [4] 9/8 14/4 80/3 156/22 effective [3] 105/24 154/15 176/18 effectively [6] 32/3 63/9 75/18 129/23 143/18 168/19 effects [6] 7/19 9/2 9/24 12/5 13/5 14/10 efficacy [3] 12/17 100/13 172/24 efficient [1] 10/22 effort [1] 83/12 efforts [2] 66/1 110/6 eg [3] 33/6 47/16 172/15 eg vaccinia [1] 172/15 eight [1] 144/5 eighth [1] 145/9 either [15] 6/9 12/19 18/20 39/13 39/20 51/2 74/16 90/21 101/3 144/23 147/21 151/24 158/6 167/20 170/4 elaborate [1] 38/3 elegant [1] 120/9 element [1] 61/24 elements [5] 61/9 61/10 62/8 154/23 154/24 eliminate [3] 7/13 8/24 154/18 else [2] 51/15 73/23 elsewhere [6] 30/2 41/5 41/6 47/14 98/6 130/3 elucidated [1] 14/6 email [4] 93/18 158/10 158/14 159/6 emailed [1] 158/24 emerge [3] 123/20 168/24 168/24 eliminate [4] 51/24 153/3 167/6 168/23 emergencies [1] 67/11 emerging [3] 47/6 67/7 70/15 emphasis [5] 56/1 83/25 141/3 142/5 142/14 emphasise [1] 176/25 emphasised [2] 133/24 135/7 emphasising [2] 55/22 140/17 empty [1] 96/8 enable [1] 14/21 enclose [1] 91/11	encourage [1] 167/10 encouraged [1] 176/13 encouraging [1] 107/9 end [13] 15/9 16/22 18/17 18/23 30/25 32/15 104/22 122/15 137/20 168/24 190/10 190/15 191/5 endeavouring [1] 25/17 enemy [1] 138/18 engendered [1] 102/9 England [14] 6/6 72/24 120/4 120/6 120/18 123/4 123/8 125/21 126/12 126/15 143/1 146/14 160/15 186/17 English [2] 146/2 152/7 enjoyed [1] 103/24 enjoys [1] 39/5 enormous [2] 22/15 22/19 enough [2] 75/14 137/20 enquiries [2] 83/7 83/11 ensure [4] 15/2 155/15 158/18 175/6 ensured [1] 177/23 ensuring [2] 159/16 165/12 entail [2] 45/25 116/9 entailed [1] 153/25 enter [2] 60/3 72/20 entered [2] 116/18 117/25 entering [1] 162/9 entertain [1] 153/12 enthusiastic [1] 150/8 entrusted [1] 181/25 entry [2] 118/7 120/12 environment [5] 53/14 60/9 160/24 180/8 180/21 environments [1] 167/1 envisaged [2] 128/21 189/1 enzyme [1] 110/19 epidemic [2] 86/3 179/13 epidemiologist [1] 183/20 epidemiology [2] 72/17 87/8 episode [1] 105/12 equally [4] 100/25 143/17 143/19 152/14	equipment [1] 31/7 equivalence [1] 20/24 equivalent [4] 110/22 111/16 114/10 128/23 error [3] 88/24 89/1 89/6 especially [1] 173/9 essentially [10] 36/9 49/6 52/24 61/15 74/11 79/11 113/5 116/23 143/24 165/3 established [9] 61/13 68/10 71/21 77/15 87/17 93/11 96/14 150/16 179/16 establishment [1] 99/19 estimate [1] 96/12 ethical [2] 83/2 83/20 evaluation [1] 90/19 even [9] 19/9 34/18 97/1 97/20 149/1 169/4 178/15 179/6 181/16 evening [1] 73/10 event [24] 10/24 16/18 25/19 37/4 47/7 48/5 49/3 49/14 51/3 51/12 70/24 107/19 109/19 111/13 114/8 116/5 118/19 119/9 123/25 128/12 128/24 146/1 153/12 180/19 events [11] 2/5 56/12 72/23 73/4 102/15 158/19 175/7 181/14 181/16 181/24 183/23 eventually [1] 153/5 ever [9] 22/14 34/22 35/12 72/4 86/18 90/21 131/16 164/25 165/2 every [7] 6/12 22/9 68/15 81/16 82/3 83/12 190/16 everybody [2] 22/20 174/14 everybody's [1] 60/14 everyone [3] 54/12 191/14 191/15 everything [6] 166/21 176/25 177/3 189/18 189/18 189/19 evidence [84] 32/10 33/11 35/25 39/18 40/5 40/7 40/16 40/20 41/5 41/6 41/20 42/1 42/2 42/3 42/19 42/23 42/24 43/5 43/6 43/9 43/25 44/5 44/7 44/12 44/14 48/13 52/4 52/18 53/25 56/25	57/5 60/23 71/3 72/11 72/19 78/17 78/18 84/12 84/23 86/2 86/6 93/9 95/8 95/8 99/6 99/24 101/22 104/1 126/24 129/12 132/15 134/15 134/20 134/22 136/23 137/4 137/5 140/20 142/2 147/22 147/22 149/7 149/9 152/18 156/14 159/23 159/24 161/5 162/19 164/2 171/17 182/4 182/24 183/6 183/18 183/24 186/15 187/8 187/12 188/17 188/23 188/24 189/2 190/25 evident [2] 2/13 64/6 evolving [1] 149/3 exactly [3] 114/17 175/4 188/20 exaggerate [2] 38/17 38/17 examination [3] 7/14 23/8 26/3 examinations [2] 27/16 29/23 examined [4] 6/1 13/17 101/23 187/13 examining [3] 2/7 76/19 101/18 example [12] 1/22 2/17 47/20 55/19 57/25 58/11 67/22 135/13 137/23 172/8 175/13 179/21 examples [3] 33/17 57/23 131/23 except [1] 80/18 exception [1] 41/25 exchange [7] 79/12 79/19 80/10 80/16 90/24 158/10 160/10 exchanged [1] 83/2 Exchequer [1] 185/2 exclusively [3] 33/4 152/16 169/22 exercise [1] 29/10 exist [2] 15/11 44/8 existed [3] 55/20 57/1 97/11 existing [4] 10/21 46/2 82/22 167/10 expect [2] 60/1 110/2 expectation [5] 21/12 28/20 111/10 120/3 129/17 expectations [1] 32/3 expected [3] 14/2 129/13 141/6 experience [4] 7/23 51/5 108/24 150/20
----------	--	---	---	--	--

E	extent [6] 42/4 85/24 138/6 164/16 171/18 176/19	101/19 105/16 110/17 120/4 126/13 169/21 179/11	189/11	93/4	framed [1] 121/9
experienced [1] 32/23	external [1] 6/3	Factor VIII Y [1] 117/9	fibrinogen [2] 21/1 28/3	followed [2] 175/5 178/21	Framework [1] 186/6
experiences [1] 189/19	extract [4] 20/5 21/9 27/10 32/17	factors [8] 34/9 77/8 86/8 87/4 102/14 103/4 103/19 171/16	field [1] 181/17	following [15] 47/12 61/9 61/21 63/4 76/5 78/19 94/5 102/15 103/15 116/25 130/10 152/1 176/16 182/19 183/13	France [2] 148/11 148/18
experiments [2] 15/2 172/14	extraction [2] 6/21 7/3	factitious [1] 19/22	fifth [1] 145/6	force [2] 164/24 168/3	Francis [2] 186/4 190/7
expert [8] 32/23 33/2 35/12 35/15 138/10 148/23 158/17 188/24	extracts [5] 19/23 19/25 20/2 21/17 27/2	failure [1] 152/11	filter [5] 31/7 31/11 31/15 31/18 31/22	forcefully [1] 141/10	free [11] 5/3 17/2 18/12 19/4 23/9 24/1 25/7 26/4 26/24 37/11 104/19
expertise [4] 130/13 136/25 144/7 147/11	extraordinarily [1] 54/11	faint [1] 76/18	filtered [1] 31/21	fore [1] 138/22	freedom [2] 3/24 107/23
experts [3] 38/1 53/5 159/1	extreme [1] 126/16	fair [6] 98/4 99/10 119/19 144/13 161/10 161/11	final [7] 9/11 77/17 132/3 133/6 135/9 161/4 181/8	foreseen [1] 125/7	freeze [6] 14/1 17/15 69/9 70/4 70/8 70/15
expire [1] 16/14	extremely [2] 130/18 180/19	fairly [12] 3/21 83/21 85/3 87/5 93/11 119/21 125/22 130/5 133/13 146/20 149/23 167/18	finally [2] 93/16 191/13	forbid [1] 60/2	freeze-dried [4] 17/15 70/4 70/8 70/15
expires [1] 18/1	eye [1] 51/2	faithfulness [2] 33/15 48/20	financial [1] 152/10	force [2] 164/24 168/3	frequent [1] 38/15
expiry [7] 16/1 16/6 16/11 17/7 17/23 21/7 28/4	F	faithful [1] 9/16	find [5] 25/18 48/1 48/12 132/22 141/22	fore [1] 138/22	frequently [1] 68/16
explain [8] 16/13 30/6 32/12 41/2 121/14 163/3 180/11 182/20	face [2] 11/25 178/5	familiar [3] 34/19 135/24 174/3	finding [2] 82/16 85/13	forever [1] 190/22	Friday [4] 1/1 74/10 117/8 183/8
explained [6] 32/2 82/20 83/13 85/24 142/16 180/8	facilities [1] 70/12	families [1] 181/21	findings [1] 91/11	forgive [1] 36/7	from [188] 3/25 5/22 5/22 7/21 10/9 11/3 11/21 12/11 13/14 13/21 14/11 16/14 16/19 18/13 20/6 21/4 21/8 22/24 23/6 23/9 24/7 25/4 25/4 25/25 26/1 26/1 26/4 27/2 27/10 27/15 29/3 29/13 29/25 31/4 32/6 32/17 37/6 37/21 37/21 37/25 40/25 43/5 43/6 44/18 48/22 49/14 49/15 50/25 52/3 52/5 53/13 53/16 53/22 57/8 57/12 58/4 58/4 58/14 61/8 62/12 62/14 66/20 67/17 70/16 71/6 71/23 74/13 75/9 75/13 75/17 75/25 76/2 76/24 77/21 78/14 78/17 78/22 78/22 78/25 79/8 80/1 80/23 80/25 82/13 82/19 84/12 84/12 84/14 84/15 84/23 87/12 87/13 89/9 89/11 93/2 93/13 93/18 94/5 94/11 95/3 95/10 96/5 96/6 101/23 103/23 104/4 104/20 108/13 108/14 110/6 110/13 112/12 113/14 115/20 116/23 117/12 119/22 120/16 120/16 120/17 121/8 121/25 122/12 123/12 123/17 126/13 126/15 127/4 127/25 130/15 130/20 132/10 135/4 136/6 136/9 136/10 136/20 137/4
explains [1] 95/9	fact [8] 26/15 34/4 40/12 68/12 96/22 106/4 138/14 179/4	far [13] 9/10 21/16 23/6 26/2 34/22 52/13 80/19 103/23 108/20 131/16 140/7 175/24 182/20	finished [1] 70/4	formed [1] 133/19	
explanation [5] 8/22 28/18 33/3 33/24 104/21	factor [80] 2/19 3/17 4/16 5/21 7/20 8/4 8/9 8/17 9/3 9/8 9/18 10/5 10/25 12/25 13/9 13/13 14/18 14/24 15/12 15/25 16/19 16/21 17/7 18/1 18/8 18/16 18/23 19/1 20/2 20/3 24/25 25/15 25/20 25/25 28/11 28/20 29/13 30/1 31/5 32/5 34/6 43/14 52/23 57/12 61/6 64/15 65/7 65/12 65/13 65/24 69/8 73/5 76/6 78/20 81/18 88/16 91/18 91/24 94/12 95/20 99/19 100/4 100/9 100/11 100/16 101/5 101/17 101/19 104/19 105/16 108/20 110/17 111/7 115/6 117/9 120/4 126/13 128/20 169/21 179/11	fatal [1] 59/18	firm [1] 190/20	former [2] 164/13 190/6	
explicit [8] 11/15 18/25 19/1 38/24 39/13 39/22 54/14 164/24	fatal [1] 59/18	fault's [1] 36/9	firm [1] 190/20	forms [1] 5/4	
explicitly [2] 86/16 165/2	fault's [1] 36/9	favour [1] 48/14	first [52] 2/17 2/18 10/20 13/10 15/24 26/14 27/12 29/22 33/20 48/21 61/10 62/22 63/13 68/22 70/22 71/1 71/5 71/22 75/9 76/3 82/2 88/3 91/19 95/12 99/13 106/21 106/25 108/1 109/14 110/14 110/23 113/17 115/3 129/3 129/10 132/11 133/4 135/4 138/23 141/10 143/9 145/2 145/17 156/8 158/13 164/2 165/1 179/16 183/9 183/19 185/1 190/12	formulated [1] 163/10	
exploited [1] 159/13	feature [2] 57/22 157/1	FDA [1] 150/17	first [52] 2/17 2/18 10/20 13/10 15/24 26/14 27/12 29/22 33/20 48/21 61/10 62/22 63/13 68/22 70/22 71/1 71/5 71/22 75/9 76/3 82/2 88/3 91/19 95/12 99/13 106/21 106/25 108/1 109/14 110/14 110/23 113/17 115/3 129/3 129/10 132/11 133/4 135/4 138/23 141/10 143/9 145/2 145/17 156/8 158/13 164/2 165/1 179/16 183/9 183/19 185/1 190/12	forward [4] 72/6 126/1 127/18 190/5	
explore [1] 52/6	February [8] 17/11 63/2 66/17 68/5 91/1 95/6 107/2 145/10	feasibility [1] 98/1	fit [4] 30/6 55/16 159/5 189/14	Foster [26] 4/7 15/18 35/9 39/19 47/20 67/12 71/9 72/10 72/11 85/24 93/18 99/7 106/24 156/11 156/14 157/17 158/10 158/15 158/23 159/25 160/3 160/21 160/23 168/25 171/15 178/11	
explored [3] 86/5 181/14 181/14	February 1984 [1] 95/6	feature [2] 57/22 157/1	fitted [1] 114/5	found [8] 47/5 77/19 120/9 144/1 173/23 174/1 174/16 180/20	
explores [1] 137/17	February 1985 [1] 107/2	February 1986 [1] 91/1	five [4] 34/5 34/6 153/14 184/23	four [4] 11/9 133/15 134/5 145/23	
exposed [1] 176/20	February 1986 [1] 91/1	feed [1] 155/13	flagged [1] 111/4	fourth [4] 78/3 78/5 145/5 172/22	
exposure [5] 62/1 65/18 96/15 115/6 177/22	February 1986 [1] 91/1	feedback [4] 46/1 54/15 57/18 59/7	flagging [1] 111/13	fraction [9] 20/8 21/24 23/1 23/5 24/25 25/21 25/25 30/1 31/5	
exposures [2] 66/2 76/20	February 1986 [1] 91/1	feel [2] 38/2 164/13	flatly [1] 153/11	fractionated [1] 88/16 130/13	
express [8] 11/12 12/1 18/14 21/10 34/1 41/8 54/3 102/16	Factor IX [13] 8/4 8/17 9/3 9/8 12/25 13/9 13/13 14/24 18/8 18/16 18/23 19/1 20/3	feeling [2] 58/13 109/24	flesh [1] 186/18	fractionator [1] 121/21	
expressed [4] 39/24 41/13 67/15 147/13	factor VIII [46] 2/19 4/16 5/21 7/20 8/9 9/18 10/5 10/25 14/18 15/12 15/25 16/19 16/21 17/7 18/1 20/2 24/25 25/15 25/25 28/11 29/13 30/1 31/5 32/5 34/6 65/13 65/24 73/5 78/20 81/18 88/16 94/12 95/20 99/19 100/4 100/9 100/11 101/5 101/17	feels [1] 110/21	Fletcher [1] 37/3	fractionators [1] 129/23	
expressing [5] 16/11 53/5 65/15 153/11 156/12	Factor VIII [46] 2/19 4/16 5/21 7/20 8/9 9/18 10/5 10/25 14/18 15/12 15/25 16/19 16/21 17/7 18/1 20/2 24/25 25/15 25/25 28/11 29/13 30/1 31/5 32/5 34/6 65/13 65/24 73/5 78/20 81/18 88/16 94/12 95/20 99/19 100/4 100/9 100/11 101/5 101/17	fell [1] 109/5	Flint [1] 188/11		
expression [3] 11/19 18/2 138/19	Factor VIII [46] 2/19 4/16 5/21 7/20 8/9 9/18 10/5 10/25 14/18 15/12 15/25 16/19 16/21 17/7 18/1 20/2 24/25 25/15 25/25 28/11 29/13 30/1 31/5 32/5 34/6 65/13 65/24 73/5 78/20 81/18 88/16 94/12 95/20 99/19 100/4 100/9 100/11 101/5 101/17	felt [7] 40/1 114/4 130/12 147/8 153/9 160/25 177/15	flow [1] 35/4		
extended [1] 19/11	Factor VIII [46] 2/19 4/16 5/21 7/20 8/9 9/18 10/5 10/25 14/18 15/12 15/25 16/19 16/21 17/7 18/1 20/2 24/25 25/15 25/25 28/11 29/13 30/1 31/5 32/5 34/6 65/13 65/24 73/5 78/20 81/18 88/16 94/12 95/20 99/19 100/4 100/9 100/11 101/5 101/17	Fenwick [1] 184/16	focus [4] 83/24 148/9 186/25 187/12		
extensive [3] 70/11 103/16 175/12	Factor VIII [46] 2/19 4/16 5/21 7/20 8/9 9/18 10/5 10/25 14/18 15/12 15/25 16/19 16/21 17/7 18/1 20/2 24/25 25/15 25/25 28/11 29/13 30/1 31/5 32/5 34/6 65/13 65/24 73/5 78/20 81/18 88/16 94/12 95/20 99/19 100/4 100/9 100/11 101/5 101/17	Festival [1] 86/12	focused [4] 72/18 169/17 189/12 191/11		
extensively [2] 97/6 155/17	Factor VIII [46] 2/19 4/16 5/21 7/20 8/9 9/18 10/5 10/25 14/18 15/12 15/25 16/19 16/21 17/7 18/1 20/2 24/25 25/15 25/25 28/11 29/13 30/1 31/5 32/5 34/6 65/13 65/24 73/5 78/20 81/18 88/16 94/12 95/20 99/19 100/4 100/9 100/11 101/5 101/17	few [10] 10/18 26/14 29/6 55/6 57/6 68/4 132/22 140/25 181/11	follow [6] 9/25 90/8 90/20 91/4 91/22 93/4		
			follow-up [2] 91/22		

<p>F</p> <p>from... [50] 139/5 139/21 140/5 141/23 143/19 145/2 147/5 148/7 150/14 151/24 152/4 153/2 153/3 156/9 158/14 159/25 161/19 162/10 163/22 163/24 166/14 167/16 168/25 169/22 173/22 174/2 174/3 174/9 174/19 174/22 175/17 175/20 179/11 180/10 182/6 182/11 182/21 182/24 183/2 183/19 183/25 184/2 184/12 185/1 185/8 185/13 186/24 187/18 189/25 192/4</p> <p>front [1] 126/4</p> <p>full [4] 24/18 131/11 139/16 139/23</p> <p>fuller [1] 20/1</p> <p>fully [5] 8/20 71/21 81/25 95/14 186/17</p> <p>funded [2] 146/13 146/14</p> <p>funding [2] 147/11 152/6</p> <p>further [33] 4/21 30/23 69/4 69/23 70/14 74/4 74/13 82/6 82/9 82/24 84/8 84/20 87/20 88/1 92/21 93/13 94/15 106/17 121/19 139/3 140/4 151/5 153/20 162/19 167/10 181/6 184/21 188/9 188/14 188/17 188/24 190/25 191/11</p> <p>future [5] 113/23 117/16 119/10 189/8 191/14</p> <p>FVIII [4] 45/17 48/15 92/12 94/4</p>	<p>147/14 149/5 149/13 150/10 153/9 181/9</p> <p>generally [5] 32/24 85/19 101/21 142/19 176/21</p> <p>generated [1] 101/12</p> <p>generation [3] 2/18 10/20 138/23</p> <p>generic [6] 8/13 11/19 50/22 50/23 131/20 132/2</p> <p>genesis [2] 89/5 169/20</p> <p>gentle [1] 157/24</p> <p>genuine [1] 57/1</p> <p>George [1] 136/19</p> <p>get [16] 18/16 18/23 52/15 53/15 80/7 81/12 105/14 113/24 114/11 118/1 128/13 133/25 140/3 168/1 182/4 190/10</p> <p>getting [8] 6/10 10/23 46/2 81/1 117/23 121/12 154/4 168/13</p> <p>give [12] 11/18 27/20 29/17 35/10 36/19 49/25 56/20 80/3 129/25 131/23 137/16 162/18</p> <p>given [21] 5/25 32/11 40/24 57/6 69/21 72/11 83/6 96/23 98/22 100/23 102/1 112/7 112/11 112/14 117/11 134/22 152/9 157/18 169/3 174/23 189/20</p> <p>gives [1] 172/8</p> <p>giving [4] 31/21 33/25 86/19 188/23</p> <p>Glasgow [4] 84/15 91/5 95/22 123/20</p> <p>Glasgow's [1] 94/7</p> <p>gleaned [1] 141/23</p> <p>Gloria [1] 185/14</p> <p>Gloria Hooper [1] 185/14</p> <p>go [110] 4/11 4/19 5/10 5/11 5/18 8/3 8/5 8/15 8/19 9/2 9/9 12/8 12/23 14/16 15/16 15/22 17/6 20/4 20/11 21/18 21/19 22/1 22/24 23/14 24/14 25/1 25/9 25/21 26/9 27/13 27/21 29/20 30/25 32/16 33/20 40/21 41/2 44/15 44/18 45/15 48/9 48/9 48/21 62/5 63/11 65/16 66/19 68/3 69/1</p>	<p>73/1 76/1 77/5 82/18 82/24 84/25 85/2 85/10 88/10 89/8 89/13 90/23 91/4 92/17 93/16 93/19 93/20 94/1 96/20 99/7 100/7 104/13 106/17 107/3 108/15 109/13 110/4 110/9 111/1 111/18 113/13 115/1 116/1 118/24 119/11 121/14 124/9 131/13 133/4 134/21 135/13 135/18 137/5 139/4 140/18 142/3 143/22 149/21 150/2 150/24 151/1 151/22 153/10 153/10 153/16 155/1 158/23 159/7 172/19 173/19 190/11</p> <p>go-between [1] 124/9</p> <p>goal [1] 99/15</p> <p>god [1] 60/2</p> <p>goes [3] 9/6 14/13 138/19</p> <p>going [38] 4/4 4/9 4/9 15/16 20/9 59/17 60/22 63/3 65/5 65/19 76/17 77/9 85/7 87/11 98/21 99/4 99/7 110/9 118/8 124/16 129/1 143/24 144/18 144/18 144/19 145/19 146/7 149/10 151/4 152/21 154/9 162/7 162/15 163/21 171/13 171/20 173/1 190/9</p> <p>gone [2] 59/13 60/13</p> <p>good [16] 36/22 41/19 41/20 47/5 52/7 71/10 99/22 109/20 120/13 126/3 128/3 132/15 138/19 138/20 147/9 175/13</p> <p>got [23] 1/18 4/22 9/13 12/23 21/9 23/15 23/18 37/25 54/15 57/19 85/8 96/22 97/15 128/13 128/18 133/10 135/22 135/23 136/16 150/12 153/14 155/13 182/20</p> <p>government [8] 132/21 146/1 150/5 183/24 186/15 188/17 190/3 190/6</p> <p>governments [3] 186/16 187/2 188/18</p> <p>GP [1] 176/14</p> <p>granted [1] 1/13</p> <p>grave [1] 41/25</p> <p>great [1] 144/6</p>	<p>greater [5] 102/3 102/9 102/17 102/23 109/4</p> <p>Groningen [6] 71/6 71/7 71/24 75/5 75/6 75/8</p> <p>group [15] 56/7 63/5 68/6 68/8 68/23 70/18 84/10 86/23 96/12 99/20 100/4 100/9 101/17 102/12 107/8</p> <p>groups [10] 36/3 67/21 67/25 95/20 95/21 95/22 97/14 114/24 121/23 177/14</p> <p>growing [1] 42/3</p> <p>grown [1] 173/6</p> <p>guess [2] 120/1 120/8 48/18 50/22 50/23 114/20 151/24</p> <p>guided [1] 152/16</p> <p>guideline [1] 124/3</p> <p>guidelines [1] 107/18</p> <p>Gunson [1] 134/8</p> <p>Gunson's [1] 150/4</p> <p>Gutowski [1] 184/19</p>	<p>125/18 127/3 127/10 127/12 128/2 128/7 128/16 129/18 129/22 130/13 131/11 133/16 139/21 141/20 143/5 148/17 148/21 149/20 150/12 150/17 150/23 154/23 156/1 156/11 156/12 157/20 160/25 161/20 164/5 164/9 164/14 164/18 166/20 166/23 167/22 168/22 171/8 171/15 171/18 171/18 171/21 171/23 171/23 174/17 176/1 176/14 176/25 177/12 177/18 177/25 178/4 179/4 179/5 179/10 179/13 180/9 181/15 181/20 190/4</p> <p>hadn't [6] 15/15 74/5 77/15 103/5 132/13 174/17</p> <p>haematologists [2] 34/25 35/14</p> <p>haematology [3] 79/7 80/23 155/2</p> <p>haemolysis [1] 7/22</p> <p>haemophilia [74] 11/18 32/24 33/5 34/2 34/7 34/18 34/23 35/14 36/5 36/6 37/24 38/1 38/15 38/21 47/17 47/22 53/23 54/13 56/4 56/9 56/15 56/18 57/9 57/16 58/14 59/7 61/7 63/1 63/24 64/9 66/17 67/7 69/10 70/2 79/7 79/8 80/23 81/4 81/9 81/10 82/11 84/4 84/15 95/6 96/5 97/13 97/21 98/8 100/21 103/12 103/24 114/13 115/21 117/11 121/8 121/17 122/1 122/5 122/13 123/12 124/11 125/1 125/10 125/16 126/6 126/21 127/19 128/5 157/6 165/16 179/5 179/8 181/19 184/18</p> <p>haemophilic [7] 73/11 110/16 115/5 116/5 119/9 120/25 121/1</p> <p>haemophiliacs [13] 82/17 85/14 91/8 91/10 91/22 108/24 110/7 112/11 112/15 117/1 123/8 125/8 156/24</p> <p>haemophilic [5] 3/17</p>	<p>20/25 21/24 23/1 113/1</p> <p>half [9] 4/20 20/12 27/25 63/12 65/17 69/2 93/20 162/23 165/1</p> <p>halfway [1] 29/22</p> <p>hand [14] 13/10 16/6 20/12 22/25 23/15 25/2 25/19 25/23 26/10 27/13 27/24 77/12 89/12 136/7</p> <p>handful [4] 73/1 88/1 99/8 144/23</p> <p>handle [1] 171/2</p> <p>handwritten [2] 113/16 120/22</p> <p>Hann [1] 67/6</p> <p>happen [2] 50/3 127/9</p> <p>happened [11] 51/7 72/4 78/18 79/23 80/2 121/14 122/16 122/17 171/10 180/24 190/5</p> <p>happening [1] 106/12</p> <p>happy [1] 118/17</p> <p>harassing [1] 168/10</p> <p>hard [1] 121/20</p> <p>Harris [3] 135/4 135/22 141/1</p> <p>Harrison [1] 89/10</p> <p>has [42] 1/17 3/19 5/23 6/1 11/8 13/15 13/17 13/25 14/6 17/12 17/15 18/9 22/1 24/10 24/12 24/14 25/10 31/10 39/17 47/20 48/1 51/24 52/9 71/9 71/9 71/10 74/19 85/24 89/18 89/19 91/23 93/9 99/6 101/15 111/4 121/22 137/8 148/11 158/21 158/25 167/14 185/9</p> <p>hasn't [2] 9/13 21/25</p> <p>have [314] haven't [4] 9/20 12/15 12/18 90/17</p> <p>having [22] 42/13 49/20 55/7 58/16 66/5 71/15 72/23 73/11 74/12 88/20 91/1 100/8 101/22 102/9 119/19 120/17 120/20 147/22 163/14 165/5 181/16 188/17</p> <p>Hazel [1] 186/23</p> <p>Hazel Blears [1] 186/23</p> <p>hazmat [1] 178/3</p> <p>HB [1] 5/24</p> <p>HCV [3] 138/25 151/10 151/18</p>
---	--	---	--	---	---

H	138/1 healthy [1] 26/1 hear [5] 43/5 43/6 183/25 189/2 189/15 heard [12] 71/1 71/23 84/11 158/16 163/4 168/25 189/14 189/16 189/21 189/22 190/1 190/3 hearing [10] 182/21 183/2 183/18 184/25 185/8 185/13 188/24 189/8 189/13 190/5 hearings [2] 190/10 191/6 heat [45] 1/23 2/18 2/24 9/15 10/5 10/16 10/20 10/25 11/8 12/17 13/8 13/25 14/5 14/18 14/20 14/25 16/20 17/6 17/15 18/23 48/6 61/22 81/17 82/3 82/7 82/20 82/21 85/11 94/11 99/5 101/5 101/12 101/20 101/24 101/25 103/8 103/15 103/21 110/18 157/3 173/10 173/12 174/22 174/23 175/1 heat-treated [17] 2/18 10/16 10/20 10/25 13/8 14/18 14/25 17/6 18/23 48/6 81/17 82/7 94/11 101/12 110/18 174/22 175/1 heated [4] 15/13 18/16 80/3 80/8 heating [2] 78/19 78/19 heavily [1] 177/5 held [15] 33/17 68/15 72/16 79/5 79/7 80/25 81/1 108/11 114/6 153/6 167/4 169/12 174/17 174/18 181/17 help [6] 55/3 64/13 65/5 88/13 104/3 159/19 helpful [1] 158/5 helpfully [1] 15/18 heparin [2] 26/19 28/3 hepatitis [95] 3/4 5/7 7/14 7/22 8/12 8/25 9/6 9/23 10/3 11/4 11/12 11/13 11/13 11/22 12/6 13/7 13/16 14/5 14/5 14/8 17/2 17/19 17/22 18/12 18/15 18/20 19/9 19/17 19/17 21/10 23/4 23/12 24/1 24/12	25/7 26/24 27/18 28/22 28/25 29/1 34/2 34/10 34/17 34/19 34/24 35/3 35/6 35/11 35/13 35/16 35/21 36/11 37/5 37/11 37/14 37/18 38/11 39/1 39/14 39/15 45/21 96/23 100/24 102/1 102/13 102/19 102/25 105/20 106/8 107/24 108/4 109/22 109/25 110/3 110/20 115/11 122/20 132/6 138/24 144/25 145/15 145/19 146/19 147/3 148/2 150/17 164/7 164/8 166/14 167/20 169/18 170/18 176/6 176/8 180/12 hepatitis B [15] 11/4 11/13 14/5 19/17 23/4 23/12 27/18 34/19 107/24 164/7 169/18 170/18 176/6 176/8 180/12 hepatitis C [9] 132/6 138/24 144/25 145/15 145/19 146/19 147/3 148/2 150/17 hepatologists [1] 35/1 her [1] 188/8 here [32] 12/9 20/13 21/9 23/2 23/18 24/13 26/11 28/6 33/25 48/19 49/5 49/8 55/17 55/19 57/7 66/12 67/18 79/14 79/16 90/24 93/10 94/3 119/18 121/6 127/18 135/22 149/8 149/11 156/15 165/1 182/6 191/14 here's [1] 119/12 hesitate [1] 165/20 hesitating [1] 138/6 hide [1] 39/25 Higgins [1] 179/15 high [7] 37/5 65/6 86/9 98/7 101/13 129/17 155/12 high-risk [1] 86/9 highlight [2] 88/21 190/11 highly [6] 29/10 41/18 41/22 41/23 54/2 143/13 Hilary [1] 183/3 him [16] 46/19 47/8 51/21 51/23 55/9 63/3 74/25 85/25 103/13	119/15 120/20 127/13 158/22 159/3 174/8 174/9 hindsight [11] 106/9 106/13 114/4 121/13 122/9 122/21 125/15 130/21 138/9 152/9 180/25 hip [1] 155/11 his [18] 7/9 39/23 41/11 46/25 63/10 67/12 110/20 127/6 127/15 128/5 147/17 156/14 156/18 157/19 159/3 168/9 185/10 186/5 history [3] 23/9 26/4 85/5 HIV [62] 11/24 15/6 15/15 19/4 19/18 27/19 28/21 39/22 40/25 41/21 42/18 44/25 48/6 61/7 61/8 61/20 61/21 62/12 70/23 85/13 87/8 87/18 90/22 93/24 94/5 94/9 94/21 102/19 102/22 103/6 104/2 105/17 122/20 132/18 146/19 156/23 157/2 157/21 162/11 167/20 168/16 168/17 168/23 168/24 169/5 169/16 170/7 170/10 170/12 170/13 170/15 170/16 174/8 174/12 179/3 179/8 179/18 179/19 180/14 180/14 180/24 184/18 HLA [1] 89/22 HLB3185 [1] 89/22 hoc [3] 2/8 2/12 131/18 hold [2] 82/2 180/5 holders [2] 51/11 131/12 home [12] 33/7 46/5 74/12 79/9 165/3 165/4 165/10 165/13 165/24 165/25 166/5 187/7 homes [3] 80/25 81/2 82/5 honest [1] 38/2 honesty [1] 169/6 Hooper [2] 185/14 185/14 hope [10] 15/22 24/18 43/5 72/19 79/16 86/2 181/22 188/22 189/7 189/16 hoped [1] 117/7	hospital [6] 69/15 89/19 94/7 94/14 146/22 146/23 hospitals [3] 30/6 147/1 155/2 hour [2] 15/12 162/23 hours [7] 5/5 11/9 14/1 76/8 82/23 110/2 112/6 house [3] 100/13 131/10 172/23 how [41] 1/10 4/1 26/7 29/4 29/18 31/20 42/25 44/10 51/7 55/16 59/8 60/4 70/21 72/4 72/22 77/15 83/7 93/6 95/12 96/11 96/13 99/16 102/12 102/16 105/1 113/2 123/13 128/8 129/21 155/5 155/10 162/20 167/25 171/10 171/20 173/25 175/4 176/18 189/14 189/22 190/1 however [10] 45/16 48/1 48/12 63/18 67/7 100/15 113/23 134/1 144/5 186/19 HTLV [30] 12/1 13/25 14/4 17/19 18/22 19/2 27/3 28/21 40/10 43/13 52/5 52/10 57/24 70/18 71/16 72/17 73/12 74/3 76/23 77/25 82/16 89/2 89/21 91/7 92/19 96/23 103/7 104/20 107/24 168/24 HTLV-III [25] 12/1 13/25 14/4 17/19 18/22 19/2 27/3 28/21 40/10 43/13 52/5 52/10 57/24 70/18 71/16 72/17 73/12 74/3 76/23 77/25 89/2 89/21 96/23 103/7 107/24 HTLV-III/AIDS [1] 168/24 HTLV3 [1] 88/17 HTLVIII [2] 76/6 91/17 human [10] 3/17 17/1 18/11 20/8 23/1 23/6 23/25 25/6 25/25 27/15 hypothetical [3] 100/23 101/3 101/9	I am [5] 48/12 74/19 106/20 107/19 159/17 I appreciate [4] 2/4 73/20 94/9 127/8 I ask [4] 14/9 38/6 104/3 156/6 I asked [1] 168/15 I assume [2] 67/10 114/15 I believe [3] 2/2 9/15 151/7 I can [22] 6/17 26/14 57/13 59/4 64/21 65/5 67/17 85/19 90/18 91/11 109/20 117/18 121/14 139/5 142/9 148/14 149/5 150/24 154/2 160/1 168/6 170/23 I can't [20] 1/20 16/12 22/11 50/24 51/6 51/16 51/16 79/1 87/2 94/21 107/12 131/23 135/14 136/21 146/18 148/13 157/16 173/8 175/3 179/7 I cannot [1] 47/12 I certainly [3] 53/24 153/8 160/1 I clearly [1] 84/1 I considered [1] 138/7 I could [2] 127/22 146/18 I couldn't [1] 143/22 I described [1] 70/11 I did [4] 29/6 45/16 124/6 141/22 I didn't [6] 84/19 85/21 105/3 121/2 121/15 127/25 I disagree [1] 159/9 I discussed [1] 47/13 I do [5] 19/22 39/17 77/18 94/17 159/10 I don't [58] 6/11 6/22 7/7 15/25 22/5 23/13 25/2 25/16 27/5 32/14 32/19 35/11 38/13 39/6 40/12 42/10 42/13 46/19 57/13 57/21 62/14 62/15 62/18 67/17 74/3 78/1 83/24 85/17 87/20 89/5 90/20 93/12 93/19 94/17 96/19 97/3 99/22 102/16 105/23 112/8 124/6 126/3 137/12 140/14 159/2 160/1 161/16 162/22 163/4 165/19 166/2 169/11 169/15 170/1 170/23 175/3
----------	--	--	--	---	---

<p>I</p> <p>I don't... [2] 180/22 181/3</p> <p>I felt [2] 114/4 160/25</p> <p>I found [1] 144/1</p> <p>I framed [1] 121/9</p> <p>I gained [1] 130/19</p> <p>I gleaned [1] 141/23</p> <p>I guess [2] 120/1 120/8</p> <p>I had [7] 4/12 59/21 85/22 98/5 117/7 129/18 160/25</p> <p>I have [18] 29/9 46/16 51/23 52/13 58/25 60/13 76/4 76/18 93/8 98/18 117/17 118/17 132/15 138/11 166/18 166/19 169/7 174/16</p> <p>I haven't [4] 9/20 12/15 12/18 90/17</p> <p>I heard [2] 71/1 71/23</p> <p>I held [1] 72/16</p> <p>I hope [5] 15/22 43/5 79/16 189/7 189/16</p> <p>I imagine [1] 12/15</p> <p>I just [18] 12/9 32/16 33/20 40/23 41/4 46/24 48/20 52/6 61/3 82/24 84/22 129/2 132/8 144/22 153/22 156/15 172/1 182/19</p> <p>I knew [3] 142/22 142/25 143/21</p> <p>I know [6] 29/12 42/2 133/7 147/20 189/11 190/12</p> <p>I learnt [1] 71/5</p> <p>I left [1] 87/19</p> <p>I make [1] 191/2</p> <p>I may [4] 19/21 64/4 88/2 181/9</p> <p>I mentioned [1] 10/18</p> <p>I might [1] 157/22</p> <p>I need [2] 23/13 181/11</p> <p>I never [1] 139/25</p> <p>I only [2] 90/15 90/15</p> <p>I read [1] 33/21</p> <p>I recall [3] 30/8 80/20 140/7</p> <p>I remember [1] 140/24</p> <p>I returned [1] 71/23</p> <p>I say [11] 30/13 44/11 103/3 105/10 126/1 126/3 133/1 152/21 172/15 176/23 181/11</p> <p>I see [1] 31/20</p> <p>I set [1] 120/1</p> <p>I shall [1] 191/1</p>	<p>I share [1] 156/17</p> <p>I should [2] 33/15 137/14</p> <p>I sincerely [1] 181/22</p> <p>I still [1] 155/23</p> <p>I suggest [1] 143/7</p> <p>I supplied [1] 137/2</p> <p>I suspect [2] 77/11 118/13</p> <p>I take [3] 40/16 66/22 177/23</p> <p>I thank [1] 182/5</p> <p>I then [7] 32/10 44/14 62/20 70/17 100/6 105/13 145/16</p> <p>I think [304]</p> <p>I thought [4] 70/3 138/8 138/25 160/8</p> <p>I took [2] 150/14 160/2</p> <p>I tried [1] 117/2</p> <p>I understand [14] 5/12 10/4 21/17 31/13 33/24 36/14 39/10 52/11 55/18 64/6 79/24 80/5 112/1 155/9</p> <p>I want [7] 1/8 106/11 110/4 132/3 138/3 140/19 190/10</p> <p>I wanted [6] 21/18 64/13 85/9 89/4 95/2 157/8</p> <p>I was [23] 42/9 65/5 70/1 70/6 75/6 75/7 85/21 120/7 121/24 125/24 130/17 130/18 138/6 143/17 143/18 143/18 148/23 157/15 160/16 160/18 160/24 162/24 171/17</p> <p>I wasn't [1] 84/14</p> <p>I went [1] 134/10</p> <p>I will [9] 12/3 12/19 40/3 48/9 61/23 62/3 106/2 107/24 158/22</p> <p>I won't [3] 26/15 84/20 159/6</p> <p>I wondered [1] 65/10</p> <p>I would [25] 28/13 41/14 51/18 53/2 75/8 84/2 84/6 84/6 84/7 84/7 85/23 85/24 94/17 96/12 105/4 121/18 125/14 128/4 129/19 138/16 165/19 168/8 181/8 181/12 191/14</p> <p>I wouldn't [4] 2/12 101/8 127/23 127/25</p> <p>I write [1] 115/16</p> <p>I wrote [3] 138/7</p>	<p>178/17 179/22</p> <p>I'd [2] 43/25 122/4</p> <p>I'd think [1] 43/25</p> <p>I'll [3] 74/20 136/17 163/5</p> <p>I'm [90] 2/5 3/13 4/4 4/7 4/9 7/8 10/17 12/13 15/16 16/3 16/5 20/9 36/6 40/7 42/1 49/10 53/18 55/19 55/24 55/24 58/9 59/13 59/21 60/2 60/13 60/22 64/17 64/24 65/5 65/11 65/19 70/15 77/17 79/13 79/18 79/21 80/2 83/15 84/25 85/7 87/2 90/15 93/14 94/19 96/11 98/11 98/18 98/21 99/4 99/7 103/23 107/15 109/16 110/1 110/9 111/7 113/16 114/4 121/5 125/24 126/14 127/3 129/1 129/6 132/15 133/7 133/11 139/10 144/18 144/18 144/19 149/10 149/12 151/4 152/21 155/19 157/15 162/16 163/21 164/25 165/7 165/20 170/2 174/3 175/16 176/18 178/2 179/6 190/5 190/16</p> <p>I've [13] 57/25 59/5 79/16 81/21 81/21 88/12 97/6 99/8 102/20 107/15 122/9 153/13 181/10</p> <p>idea [5] 70/5 70/13 72/12 74/6 124/21</p> <p>ideal [1] 125/15</p> <p>ideas [1] 66/11</p> <p>identical [2] 9/21 159/16</p> <p>identification [1] 92/15</p> <p>identified [6] 90/21 98/4 98/7 101/16 103/6 126/21</p> <p>identifies [1] 77/10</p> <p>identify [5] 75/20 87/13 106/20 165/23 177/2</p> <p>identifying [5] 66/4 92/25 97/13 123/1 174/8</p> <p>ie [5] 32/24 48/18 70/2 96/8 113/10</p> <p>if [195]</p> <p>ii [2] 66/25 151/15</p> <p>iii [32] 12/1 13/25 14/4</p>	<p>17/19 18/22 19/2 27/3 28/21 40/10 43/13 52/5 52/10 57/24 70/18 71/16 72/17 73/12 74/3 76/23 77/25 82/16 89/2 89/21 91/7 92/19 96/23 103/7 104/20 107/24 113/21 151/17 168/24</p> <p>illegal [1] 165/20</p> <p>illness [1] 89/21</p> <p>illuminate [1] 129/9</p> <p>imagine [2] 12/15 168/8</p> <p>immediate [5] 104/18 113/23 117/17 167/8 191/13</p> <p>immediately [3] 74/24 119/7 178/21</p> <p>imminent [1] 115/21</p> <p>imminently [1] 182/16</p> <p>immune [2] 14/3 19/2</p> <p>immunity [1] 130/10</p> <p>immunoglobulin [2] 173/15 176/16</p> <p>impact [2] 72/5 181/13</p> <p>impacts [1] 141/21</p> <p>impending [1] 83/14</p> <p>impetus [1] 105/8</p> <p>implement [1] 148/25</p> <p>implementation [5] 61/25 132/18 146/21 150/16 151/9</p> <p>implemented [5] 82/21 95/14 96/16 148/18 153/5</p> <p>implementing [3] 139/2 147/15 175/12</p> <p>implicated [11] 61/6 74/7 75/22 77/7 87/11 89/22 90/11 92/8 93/7 173/22 173/25</p> <p>implications [2] 35/17 82/15</p> <p>imply [2] 11/20 90/12</p> <p>implying [1] 6/22</p> <p>import [1] 61/12</p> <p>importance [6] 55/22 58/20 157/20 161/7 167/9 168/22</p> <p>important [12] 59/9 63/10 68/17 97/7 134/1 137/24 142/23 153/6 154/21 155/24 174/12 181/2</p> <p>imported [1] 52/3</p> <p>impression [1] 140/13</p> <p>improper [1] 41/18</p> <p>inactions [1] 59/25</p> <p>inactivate [5] 14/2</p>	<p>105/17 106/8 110/3 173/17</p> <p>inactivated [3] 28/12 61/22 105/20</p> <p>inactivates [1] 96/22</p> <p>inactivating [2] 61/20 122/20</p> <p>inactivation [10] 61/2 99/5 99/15 100/4 100/14 100/18 105/9 172/7 172/14 172/24</p> <p>inappropriate [2] 57/1 154/17</p> <p>inception [1] 132/11</p> <p>incidence [2] 162/11 162/11</p> <p>incident [3] 88/21 89/14 119/24</p> <p>incidents [3] 35/6 91/12 176/13</p> <p>include [14] 5/1 11/23 40/24 47/15 48/5 48/23 52/8 53/7 58/6 58/9 59/17 62/12 100/17 165/17</p> <p>included [14] 9/16 33/3 33/10 33/18 35/19 54/2 61/9 62/8 83/3 98/13 135/24 151/11 172/23 180/16</p> <p>includes [2] 24/9 31/7</p> <p>including [8] 35/8 44/24 45/6 100/15 148/18 152/13 154/24 157/6</p> <p>inclusion [3] 23/19 45/4 47/23</p> <p>inconsistency [1] 159/22</p> <p>inconvenience [1] 22/20</p> <p>increase [3] 67/22 67/24 171/15</p> <p>increased [4] 6/21 169/10 171/12 171/17</p> <p>increasing [2] 37/16 154/14</p> <p>increasingly [3] 35/15 46/4 180/12</p> <p>indeed [14] 42/15 46/20 98/8 101/9 103/16 120/16 127/22 133/14 157/1 158/5 161/22 162/5 162/6 162/14</p> <p>INDEX [1] 191/19</p> <p>indicated [3] 74/15 108/22 189/5</p> <p>indicates [1] 106/25</p> <p>indicating [2] 57/7 110/19</p> <p>indications [4] 4/23</p>	<p>5/1 8/8 109/3</p> <p>indicative [1] 189/4</p> <p>indicator [1] 172/10</p> <p>individual [20] 13/23 14/19 15/5 34/6 34/7 46/3 48/13 50/21 55/1 65/18 68/14 76/19 77/10 81/11 97/15 122/12 124/19 146/12 169/14 180/10</p> <p>individuals [1] 139/8</p> <p>industry [2] 38/14 50/22</p> <p>inescapable [1] 167/2</p> <p>inevitability [2] 19/8 168/19</p> <p>infected [10] 77/16 98/17 98/18 102/22 104/2 162/8 186/5 188/22 188/25 189/20</p> <p>infection [13] 19/8 28/7 39/14 61/8 62/12 85/14 85/16 89/21 108/22 125/13 156/23 167/6 168/20</p> <p>infections [1] 60/7</p> <p>infectious [3] 166/23 167/17 176/2</p> <p>infective [11] 11/10 11/19 14/7 17/16 17/21 98/12 119/8 125/19 177/1 177/2 177/4</p> <p>infectivity [7] 11/16 32/25 37/5 116/20 118/21 172/11 180/2</p> <p>Infirmary [1] 84/11</p> <p>influence [4] 55/23 125/25 144/8 160/20</p> <p>inform [4] 19/6 35/5 143/20 144/8</p> <p>informal [2] 51/25 52/1</p> <p>informally [1] 127/14</p> <p>information [66] 4/5 5/8 8/2 10/15 10/17 19/19 26/19 32/7 33/7 33/9 33/14 35/2 35/4 35/20 36/19 37/19 37/25 38/3 38/5 38/12 40/24 41/9 41/21 41/24 48/16 52/14 53/13 53/15 54/7 54/23 56/4 56/20 58/18 58/24 59/17 60/10 66/10 71/8 71/11 73/18 74/4 77/12 77/23 92/22 93/3 93/13 104/17 129/14 130/19 141/23 143/13 164/7 164/23 165/10 165/12 165/14</p>
---	---	---	--	--	--

I	instances [1] 167/19 instead [1] 152/15 instinctive [1] 56/14 instructed [2] 79/3 184/17 instruction [2] 79/5 80/20 instructions [3] 16/24 17/12 18/9 insufficient [2] 73/19 136/25 integral [1] 140/6 intend [1] 186/14 intended [4] 11/20 11/23 81/3 112/2 intensive [1] 190/9 intention [2] 81/15 115/12 interest [7] 129/21 130/1 130/8 130/18 130/22 141/16 161/1 interested [7] 6/10 149/13 155/18 159/14 159/15 159/17 160/18 interesting [1] 28/24 interface [2] 59/9 86/24 interim [3] 91/19 107/21 108/6 intermediate [7] 63/25 64/14 64/15 64/24 65/1 65/14 65/24 internal [1] 104/10 international [3] 86/11 87/5 107/18 internationally [1] 100/16 interpret [1] 67/18 interpretation [1] 7/9 interpreted [2] 105/3 122/7 intervening [1] 114/9 intervention [1] 176/20 intimating [1] 41/25 into [19] 31/10 31/17 59/13 60/14 72/21 75/16 80/19 84/8 85/22 90/9 95/20 102/3 105/13 116/19 118/7 120/12 164/24 168/25 189/23 intravascular [4] 7/22 8/14 9/7 14/14 introduce [8] 103/21 111/6 115/12 146/6 146/7 152/2 152/10 175/10 introduced [19] 2/18 14/24 14/25 15/12 15/13 15/13 15/15	31/13 62/2 66/6 95/10 95/13 96/21 98/9 98/12 103/18 106/7 148/2 157/5 introducing [3] 10/19 66/21 171/24 introduction [15] 1/23 9/15 45/18 48/14 63/13 64/2 65/3 85/11 115/15 115/22 132/6 151/18 151/25 152/12 157/2 Inverness [2] 63/24 95/23 investigation [2] 90/9 93/5 invite [1] 62/22 invited [1] 175/22 inviting [1] 64/7 invoking [1] 101/6 involve [1] 122/25 involved [14] 30/8 46/21 49/21 85/22 86/24 88/5 95/18 117/12 126/17 132/20 133/25 152/23 155/25 156/5 involvement [4] 97/17 153/23 174/3 185/11 involves [1] 112/14 involving [2] 56/7 110/5 ions [4] 21/1 21/1 23/20 23/21 Ireland [13] 74/23 81/17 115/16 117/2 123/3 125/21 136/15 136/16 136/19 158/12 186/17 186/22 187/2 Irish [2] 117/25 140/10 Ironsides [1] 183/14 irritation [1] 7/23 is: [1] 170/13 is: did [1] 170/13 isn't [6] 20/16 21/10 52/10 58/25 77/14 105/21 isolated [1] 103/6 issue [29] 10/23 40/17 41/8 47/1 50/4 50/20 56/23 59/7 62/22 79/4 80/3 80/12 81/25 82/2 97/7 110/24 119/20 122/3 122/13 124/5 128/11 131/20 139/15 145/14 154/7 157/12 157/14 166/4 173/20 issued [11] 12/24 24/21 25/14 48/7 51/1 51/14 63/24 83/10	92/14 93/2 116/7 issues [28] 42/15 51/21 57/17 63/9 84/4 86/5 86/25 87/3 99/11 100/3 128/7 130/2 131/3 131/14 131/18 132/6 134/1 134/8 137/18 139/25 142/22 144/17 148/25 152/6 153/2 162/19 177/17 187/14 issuing [3] 52/17 64/11 78/21 it's [41] 9/13 9/14 16/20 16/20 16/21 17/8 17/11 18/25 20/6 32/15 32/15 35/24 36/22 53/1 53/1 54/18 58/10 73/15 75/9 88/5 89/24 90/13 94/2 94/10 97/7 99/9 102/14 104/6 104/10 104/12 110/14 111/8 122/21 127/16 129/8 132/25 133/7 142/20 181/9 182/7 189/1 italics [1] 106/19 its [29] 16/16 34/23 35/16 35/16 35/19 38/11 39/12 42/18 50/1 50/13 50/13 53/13 56/2 58/12 68/11 72/7 84/2 98/1 100/11 102/13 103/7 132/5 132/11 133/1 133/24 152/9 154/3 164/8 169/19 itself [8] 6/18 15/10 20/20 24/17 35/22 55/11 160/8 169/25 iv [1] 151/23 IX [13] 8/4 8/17 9/3 9/8 12/25 13/9 13/13 14/24 18/8 18/16 18/23 19/1 20/3	Jim Smith's [1] 120/9 JK [1] 107/1 job [4] 54/22 57/15 121/24 131/12 John [4] 183/11 184/2 185/1 186/20 Jones [3] 63/17 63/17 64/5 journalistic [1] 188/8 journey [1] 120/2 judge [1] 56/16 judgment [2] 147/23 148/4 July [35] 89/11 91/5 110/5 111/2 111/20 112/13 112/19 113/12 113/24 115/2 115/25 116/3 118/16 118/22 118/25 119/1 120/23 145/4 145/8 152/2 152/4 158/11 158/15 182/22 185/16 185/18 185/22 185/23 186/2 186/3 186/7 186/11 186/14 186/25 187/9 July 1990 [1] 152/2 July 2000 [1] 158/11 July-September '86 [1] 113/24 June [16] 40/20 110/5 110/13 182/22 184/8 184/8 184/13 184/16 184/19 184/23 184/25 185/4 185/8 185/13 185/15 190/23 just [136] 4/20 6/14 11/5 12/9 13/9 14/9 14/16 15/16 16/12 17/6 17/24 19/22 20/16 22/5 22/18 27/13 27/23 29/20 30/23 32/10 32/16 33/20 33/23 34/11 37/6 38/4 38/19 40/11 40/12 40/23 41/4 41/10 41/15 44/14 45/22 46/21 46/24 48/9 48/9 48/20 48/21 52/6 53/24 55/4 57/22 59/12 60/16 61/3 62/20 64/4 65/20 66/22 68/2 68/7 69/2 69/12 73/1 73/1 73/7 73/16 75/9 76/17 77/5 81/20 82/9 82/24 84/22 85/9 85/25 87/11 88/1 88/3 89/6 89/13 90/10 90/13 95/2 98/5 98/13 100/2 100/3 106/11 106/14 106/17 107/10 108/9 109/13 110/4 113/6	114/5 118/11 118/23 119/1 125/1 126/23 127/3 129/2 129/8 132/8 132/9 134/20 135/13 137/14 137/15 138/16 138/25 144/20 144/22 144/22 145/16 146/10 149/5 150/24 151/4 153/13 153/22 153/24 156/15 158/16 161/4 165/3 166/15 172/1 172/5 172/20 173/2 175/21 176/24 177/10 179/4 181/8 181/9 181/10 182/19 190/3 190/19 Justice [1] 147/23 justification [1] 139/1 justified [2] 55/12 60/11 Justin [1] 184/16 Justin Fenwick QC [1] 184/16
				K	
				Keel [1] 187/5 keen [2] 159/22 160/12 keep [3] 51/2 129/19 141/7 kept [1] 71/10 Kernoff [3] 37/2 37/22 161/18 key [8] 37/21 50/7 61/9 61/10 61/24 62/8 155/10 183/23 kind [1] 47/9 Kingdom [2] 43/11 148/3 knee [1] 155/11 knew [14] 15/4 35/25 103/5 120/19 123/13 142/22 142/25 143/21 173/11 174/11 180/8 180/9 180/14 180/21 know [61] 6/4 6/15 10/14 16/16 22/5 25/12 25/16 28/9 28/15 29/3 29/12 34/8 34/22 42/2 42/10 45/5 45/22 50/18 60/5 60/6 63/6 75/1 75/2 77/18 78/17 81/2 84/10 85/17 87/7 87/23 89/5 90/8 92/25 93/4 97/4 99/20 102/16 103/7 103/8 109/20 127/17 133/7 143/16 144/11 147/20 148/1 156/3 160/1 162/22 163/4 167/25 170/2 171/10 174/1 177/1 181/4	

<p>K</p> <p>know... [5] 181/20 182/21 188/20 189/11 190/12</p> <p>knowing [1] 37/9</p> <p>knowledge [29] 19/16 29/3 30/19 34/3 34/24 35/16 35/22 36/16 36/22 36/25 37/15 37/16 37/20 41/18 48/17 51/15 81/11 81/18 88/24 89/2 94/15 94/18 101/4 106/2 123/13 125/17 130/19 164/25 167/18</p> <p>knowledgeable [1] 34/8</p> <p>known [16] 54/25 61/5 71/3 71/12 74/1 77/7 80/11 80/12 92/19 100/24 105/22 106/11 125/4 136/3 167/22 179/16</p> <p>knows [1] 53/10</p>	<p>101/13 131/9 135/16 167/3 171/11</p> <p>largely [4] 9/22 85/16 99/6 152/3</p> <p>last [18] 4/12 17/13 18/7 31/2 57/6 59/12 64/12 64/12 64/19 112/21 113/8 117/2 117/8 169/1 174/21 181/22 182/11 189/22</p> <p>late [17] 47/21 52/10 57/24 66/9 68/10 78/22 81/13 97/2 97/3 102/8 102/15 103/23 107/13 151/9 151/17 168/7 171/22</p> <p>later [6] 68/4 70/17 74/11 142/2 171/4 191/6</p> <p>latterly [3] 19/18 31/14 101/9</p> <p>LAV [2] 14/4 19/2</p> <p>Law [1] 69/15</p> <p>lawyer's [1] 191/9</p> <p>lay [2] 88/22 98/6</p> <p>lead [10] 45/16 64/1 65/2 65/8 97/24 100/18 100/25 125/11 146/4 146/5</p> <p>leadership [1] 97/10</p> <p>leading [8] 56/11 63/16 73/4 100/19 103/2 151/9 167/6 180/4</p> <p>leads [2] 40/9 53/21</p> <p>leaflet [29] 1/10 1/24 4/3 5/14 7/11 8/17 9/11 9/14 9/16 10/5 10/8 10/13 10/18 10/25 12/24 13/3 14/15 14/16 15/9 15/11 17/18 20/18 26/21 31/15 42/21 49/23 50/13 63/14 68/25</p> <p>leaflets [22] 1/15 2/21 4/4 13/21 19/14 32/8 33/14 33/17 35/19 40/14 40/14 41/22 43/22 44/3 45/13 45/20 46/8 46/22 164/4 164/8 164/23 165/9</p> <p>leap [1] 163/23</p> <p>learn [2] 158/25 171/8</p> <p>learnt [4] 70/22 71/5 72/22 148/16</p> <p>least [18] 6/2 13/18 21/17 27/2 37/15 52/17 62/15 86/2 87/6 92/13 93/1 93/11 135/16 146/25 152/5</p>	<p>160/6 179/2 179/9</p> <p>leave [5] 48/25 79/22 105/21 125/2 133/5</p> <p>Leaving [2] 124/19 150/9</p> <p>lecture [1] 157/18</p> <p>lectures [1] 35/10</p> <p>led [3] 48/13 161/12 171/16</p> <p>left [7] 13/10 25/2 27/13 27/24 78/12 87/19 136/7</p> <p>left-hand [5] 13/10 25/2 27/13 27/24 136/7</p> <p>legal [4] 146/18 163/23 190/17 190/22</p> <p>legally [1] 146/16</p> <p>legitimate [5] 38/16 53/4 72/15 121/25 160/25</p> <p>lengthy [1] 103/17</p> <p>less [7] 67/7 98/17 120/5 140/9 142/20 150/8 161/15</p> <p>lest [1] 157/11</p> <p>let [4] 74/25 163/3 189/11 190/18</p> <p>let's [2] 98/24 153/16</p> <p>letter [26] 66/8 76/2 76/14 89/9 89/16 90/16 90/25 91/4 91/16 93/14 111/3 112/17 113/2 113/6 113/14 115/3 116/22 116/25 117/22 118/11 118/25 120/1 156/9 156/10 156/13 158/4</p> <p>letters [2] 118/12 118/15</p> <p>levels [3] 7/5 62/18 101/13</p> <p>liaise [1] 124/12</p> <p>liaising [1] 45/12</p> <p>licence [22] 1/11 1/12 1/16 1/18 1/19 4/15 5/13 8/7 13/4 49/19 50/5 51/10 130/15 130/20 131/6 131/6 131/12 131/18 131/19 131/25 150/18 170/3</p> <p>licensed [1] 121/16</p> <p>licensing [23] 1/12 2/3 3/1 4/5 9/21 10/1 39/11 44/13 48/22 49/5 49/17 49/22 49/24 49/25 50/4 50/11 50/16 50/19 51/10 51/13 51/14 51/19 164/11</p> <p>licentiateship [1] 150/18</p>	<p>life [3] 57/4 58/23 140/25</p> <p>life-saving [1] 57/4</p> <p>light [2] 93/9 115/21</p> <p>like [27] 6/23 10/11 12/24 16/2 16/4 16/9 17/10 36/17 43/20 89/6 105/3 117/9 117/19 123/10 124/7 124/8 128/4 161/18 165/15 168/10 172/13 173/14 175/10 181/8 181/12 190/7 191/14</p> <p>likeliest [1] 127/18</p> <p>likelihood [1] 39/14</p> <p>likely [15] 2/6 12/16 19/3 37/13 43/12 76/22 107/25 108/3 109/6 123/14 123/19 125/6 125/18 128/1 128/11</p> <p>Limitation [1] 65/18</p> <p>limited [3] 36/18 52/14 123/16</p> <p>Lindsay [2] 72/12 158/12</p> <p>line [11] 40/22 139/5 139/13 140/20 142/12 147/15 149/15 149/21 150/7 156/16 172/22</p> <p>line 10 [2] 139/5 149/15</p> <p>line 17 [1] 149/21</p> <p>line 18 [1] 139/13</p> <p>line 21 [1] 142/12</p> <p>line 4 [1] 40/22</p> <p>line 5 [1] 150/7</p> <p>line 6 [1] 140/20</p> <p>Liquid [1] 172/6</p> <p>list [2] 93/21 109/14</p> <p>listed [2] 135/24 136/14</p> <p>listening [3] 4/8 182/21 191/15</p> <p>Lister [1] 184/13</p> <p>lists [1] 148/4</p> <p>Litigation [1] 184/18</p> <p>little [21] 4/9 4/21 13/9 28/23 44/9 61/23 62/3 62/4 72/6 81/23 106/17 116/11 126/23 129/9 134/13 144/15 157/16 158/23 163/24 176/9 182/10</p> <p>liver [1] 110/19</p> <p>local [1] 104/12</p> <p>locally [1] 119/3</p> <p>location [1] 86/11</p> <p>London [2] 89/19 141/4</p> <p>long [3] 60/6 162/20 175/6</p>	<p>long-term [2] 60/6 175/6</p> <p>longer [2] 63/23 64/11</p> <p>look [39] 1/18 3/6 4/4 4/6 4/19 13/5 13/9 13/11 14/10 15/24 18/7 20/1 20/7 20/11 22/5 23/14 25/23 32/10 40/11 48/3 60/22 65/16 65/20 69/12 74/15 81/20 82/9 84/22 106/11 108/9 111/3 113/6 132/8 140/14 155/19 156/6 158/9 158/13 172/1</p> <p>looked [15] 2/11 12/3 15/17 18/14 32/18 40/14 45/24 46/18 66/23 72/11 90/5 118/11 156/13 172/5 172/21</p> <p>looking [17] 17/7 19/5 36/25 37/9 38/6 38/9 71/18 77/1 131/17 136/24 138/15 161/6 172/20 173/9 183/7 190/5 191/13</p> <p>looks [9] 10/10 12/24 16/2 16/4 16/8 16/9 17/8 17/10 29/25</p> <p>loosened [1] 144/15</p> <p>Lord [4] 184/3 185/19 186/20 187/17</p> <p>Lord Crisp [1] 187/17</p> <p>Lord Waldegrave [1] 185/19</p> <p>lose [1] 189/13</p> <p>lost [3] 79/16 98/19 123/10</p> <p>lot [2] 18/1 56/22</p> <p>LOTH0000005 [1] 76/1</p> <p>LOTH0000045 [2] 156/8 156/8</p> <p>loud [1] 59/4</p> <p>low [1] 173/17</p> <p>low pH [1] 173/17</p> <p>lower [3] 7/5 162/1 162/2</p> <p>Ludlam [25] 39/20 39/23 40/6 41/12 67/4 71/18 73/9 74/12 75/9 76/5 76/9 76/16 84/12 103/14 110/13 112/21 113/4 124/4 124/9 124/16 127/12 128/2 156/12 157/18 157/20</p> <p>Ludlam's [2] 70/18 128/15</p> <p>Luncheon [1] 99/2</p>	<p>M</p> <p>MACK0001870 [1] 91/4</p> <p>MACK0002301 [1] 93/17</p> <p>Mackintosh [1] 147/14</p> <p>made [24] 2/10 3/16 3/19 8/3 34/5 38/7 38/9 50/18 52/25 55/4 67/23 79/15 83/13 110/6 117/21 123/5 123/25 131/1 144/23 149/6 167/1 169/25 179/23 181/25</p> <p>Madhok [2] 91/5 93/13</p> <p>Mail [1] 188/7</p> <p>main [4] 103/19 110/14 132/3 153/3</p> <p>mainly [1] 86/3</p> <p>maintain [2] 52/7 61/14</p> <p>maintaining [2] 51/9 100/5</p> <p>major [9] 70/24 72/4 102/11 122/13 154/24 158/18 159/20 160/2 185/1</p> <p>majority [2] 131/5 179/9</p> <p>make [18] 22/17 28/13 29/18 30/16 44/4 46/24 51/17 53/16 53/18 95/17 150/5 159/11 162/13 167/11 176/19 181/8 181/11 191/2</p> <p>makes [2] 81/23 108/1</p> <p>making [23] 39/24 44/1 46/11 47/19 65/6 84/1 97/15 130/16 132/20 144/9 144/25 145/17 152/20 152/24 154/5 158/4 185/24 186/15 187/1 188/18 189/3 189/4 190/24</p> <p>managed [4] 22/12 129/22 148/21 168/1</p> <p>management [2] 104/12 151/8</p> <p>management's [1] 177/16</p> <p>manager [2] 147/14 153/9</p> <p>managers [2] 104/10 151/16</p> <p>managing [3] 59/8 130/3 144/1</p> <p>mandatory [1] 170/3</p>
---	--	--	---	--	--

M	may [75] 4/7 5/6 6/20 7/4 7/23 8/11 12/9 12/16 14/23 19/12 19/21 37/2 38/7 38/23 41/20 42/9 42/21 43/5 44/11 47/5 49/11 49/13 53/20 53/25 54/12 55/5 64/4 69/10 70/22 71/2 71/7 71/13 71/15 71/16 78/3 78/5 79/6 88/2 103/25 112/15 115/19 122/24 131/10 131/24 135/10 135/10 135/19 136/24 145/3 145/11 153/1 161/12 163/4 163/9 163/10 165/14 165/15 165/23 179/21 181/9 182/13 182/14 182/21 182/23 182/24 183/2 183/8 183/11 183/13 183/18 183/24 184/2 189/14 191/4 191/18 maybe [7] 68/16 72/19 96/13 121/14 125/9 133/7 156/4 McClelland [19] 68/21 73/3 73/9 73/16 74/12 74/14 74/21 75/10 75/11 76/2 76/17 84/14 86/5 86/6 88/8 88/15 112/22 112/23 156/4 McGovern [2] 94/2 94/22 McIntyre [1] 136/18 me [25] 17/8 36/7 47/20 55/3 67/19 107/16 116/12 122/1 122/14 122/21 127/4 128/10 138/18 138/22 142/21 143/2 143/23 160/23 163/3 163/4 171/24 179/15 189/11 190/14 190/24 mean [4] 39/6 51/25 120/5 157/13 meaning [2] 7/9 114/15 meaningful [1] 131/23 means [4] 3/19 49/25 143/10 144/4 meant [3] 7/8 64/22 67/18 meantime [1] 112/10 measure [5] 56/25 82/21 167/9 169/4 180/25 measurements [1] 169/24 measures [4] 157/3 157/4 166/12 167/7	mechanism [3] 50/15 128/11 133/8 Med [1] 183/4 media [1] 159/13 medical [20] 23/7 23/9 26/4 34/12 38/20 45/7 56/2 59/21 76/10 133/5 133/13 135/2 136/11 139/21 141/2 182/25 183/3 185/25 187/5 187/6 medicines [15] 19/14 42/11 46/17 49/6 49/9 49/14 49/15 129/5 129/15 129/16 130/12 130/24 136/11 136/13 184/11 meet [4] 107/17 117/16 118/7 138/21 meeting [67] 47/22 63/2 63/3 63/5 63/7 66/13 67/13 68/5 68/9 68/15 71/6 75/7 76/12 76/16 82/9 82/11 82/14 83/17 84/1 84/10 84/10 84/13 84/13 88/4 88/5 95/7 97/21 104/6 104/9 104/10 104/12 104/16 105/4 108/9 108/11 108/16 109/11 109/12 109/17 109/18 120/13 129/19 131/9 132/11 135/19 140/2 140/24 141/10 141/12 141/18 141/23 145/2 145/3 145/4 145/5 145/6 145/7 145/8 145/9 145/10 145/11 149/12 150/9 156/13 172/2 178/25 179/1 meetings [26] 47/4 51/19 51/21 66/16 86/23 129/7 129/10 129/14 129/24 131/4 131/17 134/10 134/16 134/25 135/5 139/7 139/7 144/19 144/21 145/1 145/13 145/14 148/15 153/6 166/4 180/1 Mellor [1] 183/25 member [6] 37/22 42/12 142/17 143/10 152/23 184/11 members [9] 67/2 83/8 129/13 135/23 139/23 141/6 143/11 144/5 180/6 membership [3] 46/25 135/21 137/1 memo [2] 73/3 179/21	memorandum [2] 178/18 178/20 memory [6] 67/17 71/10 71/22 76/18 93/10 179/14 memos [1] 166/19 mention [1] 127/17 mentioned [4] 10/18 41/10 174/25 183/6 mentioning [2] 30/7 191/3 message [3] 57/7 57/9 141/9 met [6] 29/8 117/11 120/12 128/6 131/15 169/9 methods [7] 7/14 27/20 100/11 100/13 167/11 172/23 178/18 Metters [4] 135/1 135/22 149/17 150/11 Michael [1] 184/9 mid [3] 56/11 178/22 179/22 mid-80s [1] 56/11 mid-November 1984 [2] 178/22 179/22 middle [5] 4/14 15/7 15/8 169/2 179/16 might [64] 12/4 16/9 28/9 30/6 31/23 39/3 41/3 42/16 44/9 47/25 55/8 55/11 55/12 55/13 57/3 58/13 58/19 59/1 59/15 71/12 74/7 75/21 83/21 95/21 101/5 101/6 101/21 102/4 104/24 107/13 113/4 117/25 118/15 124/20 125/8 126/6 126/7 127/9 127/20 131/14 136/15 137/23 140/5 143/8 143/13 143/16 144/6 146/11 150/1 157/22 159/23 159/24 161/1 161/2 162/21 165/3 166/5 174/14 176/5 176/20 177/2 178/9 178/11 180/6 Mike [3] 94/2 94/4 94/22 mind [6] 25/12 37/3 49/8 126/4 132/1 161/22 minded [1] 137/22 minds [1] 161/23 mine [2] 36/9 158/3 minimal [2] 67/8 110/16 minimally [5] 110/7 114/16 114/22 120/25	125/7 minimise [1] 96/15 minimised [1] 157/20 minimising [1] 161/7 minimum [8] 3/11 3/11 29/11 29/12 30/11 31/3 32/3 49/2 Minister [5] 183/25 185/3 185/5 186/12 188/13 ministers [9] 83/9 132/24 133/6 133/9 133/23 135/10 135/15 152/13 190/6 minor [2] 22/17 136/2 minute [3] 89/2 104/14 105/4 minutes [21] 10/18 55/6 57/6 60/13 68/19 88/25 97/21 104/9 104/14 105/5 135/18 137/9 140/15 140/16 140/21 140/23 141/25 144/3 148/7 149/10 153/14 misaid [1] 107/16 misled [1] 81/21 mismatched [1] 154/9 missing [1] 150/1 Mitchell [1] 136/1 MMWR [2] 12/12 12/16 model [4] 172/12 172/14 172/17 173/2 models [1] 173/7 modest [1] 115/18 modification [1] 100/16 modifications [2] 2/1 2/2 modifying [1] 47/15 molecule [1] 101/5 moment [5] 3/6 6/14 63/18 106/3 182/9 moments [1] 140/25 momentum [1] 105/9 Monday [2] 186/2 187/16 monograph [1] 25/20 monographs [4] 21/15 22/18 28/14 30/9 month [5] 63/4 87/6 105/11 110/18 131/8 months [5] 68/16 108/23 128/22 189/22 190/2 more [59] 2/6 6/1 6/6 6/11 6/16 6/18 6/18 7/2 7/2 7/3 11/6 11/19 13/9 13/18 26/1 30/9 32/6 34/8 34/18 35/24	38/24 39/21 50/19 54/14 59/24 62/3 68/16 72/19 80/16 81/23 85/19 94/17 96/13 98/16 101/21 109/7 116/17 119/18 125/25 128/1 128/11 132/2 137/24 140/12 142/19 142/25 143/20 149/13 152/19 156/22 164/24 168/1 168/22 175/12 178/16 178/16 181/10 181/16 191/13 morning [4] 1/8 76/8 161/18 188/6 Mortimer [1] 136/1 most [10] 10/22 46/3 57/25 76/22 93/20 112/1 131/7 154/14 155/17 182/8 move [8] 66/13 70/17 95/2 98/21 99/4 105/13 129/1 188/21 moved [1] 11/21 Mr [21] 4/16 6/7 7/8 42/11 45/4 45/5 46/16 46/24 47/3 51/18 115/3 115/25 116/12 116/24 118/3 118/25 124/17 129/22 136/5 147/14 147/23 Mr Canavan [1] 136/5 Mr Justice Burton [1] 147/23 Mr Mackintosh [1] 147/14 Mr Pettet [6] 115/3 115/25 116/12 116/24 118/3 124/17 Mr Pettet's [1] 118/25 Mr Watt [11] 4/16 6/7 7/8 42/11 45/4 45/5 46/16 46/24 47/3 51/18 129/22 MRC [1] 183/12 MS [5] 1/4 163/20 182/13 189/10 192/3 MS RICHARDS [5] 1/4 163/20 182/13 189/10 192/3 much [33] 4/1 7/5 15/14 18/2 19/16 34/8 39/21 54/23 59/24 80/7 84/3 99/16 102/16 113/3 113/4 140/6 142/19 143/20 146/5 150/22 155/10 155/20 156/24 164/23 164/23 167/8 168/1 168/22 168/22 175/3 175/12 181/3 189/10 multi [2] 45/19 46/6
----------	---	--	--	---	--

<p>M</p> <p>multi-vial [1] 45/19</p> <p>multiple [4] 62/2 132/20 163/25 185/10</p> <p>mumps [2] 172/15 173/4</p> <p>must [8] 26/2 76/7 89/1 92/14 93/2 125/6 163/11 191/8</p> <p>mustn't [1] 190/11</p> <p>my [85] 2/25 6/7 7/1 7/6 7/9 11/16 28/18 34/11 35/7 36/7 39/22 41/14 42/15 44/10 44/19 47/13 50/18 60/12 62/14 67/17 69/18 70/25 71/4 71/5 71/22 73/25 75/6 81/11 81/18 83/24 87/19 93/10 93/13 97/8 98/2 98/6 98/19 103/20 107/15 109/7 114/20 114/25 121/6 121/6 121/20 122/9 123/15 126/4 126/18 127/7 127/16 128/1 130/23 131/10 131/24 132/14 135/12 137/4 137/8 138/7 140/13 143/20 146/9 148/23 148/24 149/3 150/14 151/17 152/25 153/2 153/14 155/20 160/17 161/22 167/18 171/20 173/1 174/2 174/3 178/18 179/14 181/12 181/17 181/22 189/11</p> <p>myself [11] 2/13 35/9 58/1 72/16 76/17 98/9 124/9 125/24 127/4 127/25 130/6</p>	<p>necessary [7] 2/15 82/5 95/17 97/18 100/1 100/1 117/19</p> <p>need [34] 23/13 25/2 31/24 32/19 36/10 38/2 40/12 53/7 56/25 59/8 61/12 67/20 67/24 69/3 70/8 70/10 75/17 93/19 96/19 112/8 117/25 119/18 120/13 122/7 136/17 138/21 140/14 142/3 143/16 158/17 162/17 162/21 181/11 187/3</p> <p>needed [4] 46/19 130/13 178/15 191/1</p> <p>needle [3] 31/16 31/18 31/22</p> <p>needless [1] 83/5</p> <p>needlestick [4] 176/11 176/17 176/17 180/23</p> <p>needs [2] 53/16 138/1</p> <p>negative [1] 27/20</p> <p>neither [3] 38/17 51/12 92/7</p> <p>network [1] 126/20</p> <p>neuropathology [1] 183/15</p> <p>never [18] 39/11 70/13 77/14 87/17 97/20 128/13 128/18 130/18 139/25 141/24 141/25 142/7 142/15 142/16 165/15 165/25 167/19 168/12</p> <p>Nevertheless [1] 7/12</p> <p>new [8] 12/12 24/20 24/22 45/18 51/2 67/5 81/25 112/3</p> <p>newly [1] 127/19</p> <p>news [3] 70/22 72/3 105/11</p> <p>next [49] 5/10 5/18 8/5 8/15 8/19 9/9 10/4 12/8 12/23 13/8 15/16 17/6 20/4 20/11 22/1 24/14 25/9 27/10 27/11 31/1 44/19 45/15 48/3 52/20 53/21 56/23 63/22 65/25 69/1 69/12 89/7 95/2 110/4 112/17 117/5 117/14 132/3 138/4 144/18 150/3 150/4 151/22 153/22 167/23 170/13 171/20 173/1 189/15 190/2</p> <p>NHBT000041 [1] 145/3</p> <p>NHBT000072 [2] 145/5 145/8</p>	<p>NHBT000073 [1] 145/10</p> <p>NHBT000042 [1] 145/12</p> <p>NHBT0005019 [2] 135/20 145/4</p> <p>NHBT0005043 [1] 145/6</p> <p>NHS [7] 19/9 37/6 37/17 126/13 183/11 189/21 189/24</p> <p>NHS products [1] 37/17</p> <p>NIBSC [10] 136/2 136/4 169/16 169/25 170/4 170/8 170/20 170/24 171/1 173/23</p> <p>Nicky [1] 183/19</p> <p>Nigel [1] 187/17</p> <p>Nigel Crisp [1] 187/17</p> <p>nine [1] 144/5</p> <p>ninth [1] 145/10</p> <p>no [123] 4/12 5/1 6/5 6/25 11/15 11/15 11/25 12/2 12/12 18/14 18/19 18/21 18/22 19/11 25/5 25/21 26/15 27/5 27/5 27/8 27/8 28/6 28/8 28/8 28/24 29/13 32/9 35/4 36/9 36/9 38/13 39/2 39/16 40/8 40/12 41/2 41/10 42/2 42/7 42/19 42/24 43/23 45/23 47/7 47/10 47/10 48/5 48/22 50/18 51/23 52/4 52/18 52/21 53/1 53/22 53/25 54/18 55/10 59/2 59/21 63/23 64/10 72/25 74/6 75/18 78/6 78/8 79/18 80/2 80/13 84/14 84/19 87/9 89/2 90/10 91/14 92/10 92/22 93/8 97/16 99/22 104/1 107/12 108/22 110/2 113/19 121/2 121/22 131/22 137/8 139/21 144/10 146/11 147/5 147/9 147/18 149/2 155/9 155/21 156/2 156/4 156/19 158/18 160/10 160/14 164/9 166/7 167/8 167/15 167/16 169/15 170/15 170/17 175/6 177/12 177/14 180/8 180/8 180/16 180/16 181/5 181/10 191/2</p> <p>nobody [3] 103/5</p>	<p>171/18 171/21</p> <p>non [89] 11/10 11/19 14/5 14/6 14/7 16/20 17/16 17/21 18/15 18/15 19/9 19/9 19/17 19/17 28/22 28/22 28/23 28/23 29/1 29/1 34/1 34/2 34/9 34/9 34/24 34/24 35/2 35/2 35/13 35/13 35/21 35/21 36/11 36/11 37/5 37/5 37/18 37/18 38/11 38/11 38/25 38/25 39/13 39/13 39/15 39/15 96/23 96/23 102/1 102/1 102/10 102/10 102/13 102/13 102/19 102/19 102/25 102/25 105/20 105/20 105/24 105/24 106/8 106/8 108/4 108/4 109/22 109/22 109/25 109/25 110/3 110/3 110/19 110/19 119/8 122/20 122/20 125/19 125/19 125/19 161/24 161/24 164/8 164/8 168/18 168/18 172/11 180/13 180/13</p> <p>non A, non B</p> <p>hepatitis [1] 108/4</p> <p>non-A [39] 14/5 18/15 19/9 19/17 28/22 28/23 29/1 34/1 34/9 34/24 35/2 35/13 35/21 36/11 37/5 37/18 38/11 38/25 39/13 39/15 96/23 102/1 102/10 102/13 102/19 102/25 105/20 105/24 106/8 109/22 109/25 110/3 110/19 122/20 125/19 161/24 164/8 168/18 180/13</p> <p>non-B [39] 14/6 18/15 19/9 19/17 28/22 28/23 29/1 34/2 34/9 34/24 35/2 35/13 35/21 36/11 37/5 37/18 38/11 38/25 39/13 39/15 96/23 102/1 102/10 102/13 102/19 102/25 105/20 105/24 106/8 109/22 109/25 110/3 110/19 122/20 125/19 161/24 164/8 168/18 180/13</p> <p>non-heat-treated [1] 16/20</p> <p>non-infective [7] 11/10 11/19 14/7 17/16 17/21 119/8</p>	<p>125/19</p> <p>non-infectivity [1] 172/11</p> <p>none [5] 7/12 8/23 19/19 87/22 92/18</p> <p>nonetheless [1] 167/2</p> <p>nor [3] 51/14 159/5 166/1</p> <p>normal [2] 20/25 65/7</p> <p>normally [4] 59/14 60/14 64/1 65/2</p> <p>Northeast [1] 89/10</p> <p>Northern [14] 74/23 81/17 115/16 117/1 117/24 123/3 125/21 136/15 136/16 136/19 140/10 186/17 186/22 187/2</p> <p>Northern Ireland [3] 81/17 136/16 186/22</p> <p>not [183] 3/13 5/3 5/5 7/8 10/17 11/12 14/24 14/25 15/16 16/3 17/18 17/19 18/21 18/25 19/11 19/11 20/9 22/11 28/18 28/21 30/16 30/21 31/2 31/3 31/9 33/8 34/1 34/11 34/15 36/10 37/6 37/9 38/10 38/19 39/3 39/4 39/25 40/6 40/7 42/2 42/3 42/9 43/18 43/21 44/4 45/3 46/3 47/12 49/10 52/8 53/18 54/21 54/25 55/10 55/11 55/22 55/23 55/24 58/9 58/18 59/17 59/21 60/2 62/12 64/17 64/24 65/5 65/11 65/19 68/12 70/15 71/3 72/3 72/10 76/19 77/7 77/9 77/17 79/16 79/25 80/9 83/10 83/15 83/19 84/8 84/18 84/25 85/7 85/22 88/4 90/22 93/14 93/25 94/4 94/10 96/11 96/23 97/9 97/23 98/11 98/18 99/7 100/1 102/19 105/20 107/21 108/3 109/9 109/16 109/21 110/1 111/7 114/4 115/22 115/23 117/15 120/2 121/5 121/5 121/16 122/3 122/9 122/13 122/20 122/23 125/24 126/11 126/14 127/3 127/7 127/16 129/6 129/13 132/14 132/15 133/7</p>	<p>133/12 133/25 134/12 135/10 138/11 138/13 138/17 143/12 144/5 144/7 144/18 146/25 148/21 148/23 149/4 149/10 149/18 152/21 157/5 157/15 158/5 159/10 159/10 159/15 160/18 161/22 162/15 162/24 163/9 164/20 165/20 166/3 169/9 169/22 170/2 176/18 177/15 178/2 178/8 179/1 180/11 184/7 184/22 188/20 189/16 190/13 190/19</p> <p>note [9] 108/11 108/16 112/12 113/16 113/16 120/22 137/2 139/20 172/2</p> <p>noted [5] 63/23 69/9 84/6 85/13 164/22</p> <p>notes [3] 62/24 62/25 181/11</p> <p>nothing [7] 6/23 19/6 21/22 32/4 132/1 143/4 155/7</p> <p>notice [3] 68/1 89/15 178/20</p> <p>noticed [3] 171/19 171/21 171/22</p> <p>notifications [2] 2/24 51/6</p> <p>notified [1] 2/3</p> <p>notify [2] 74/23 120/23</p> <p>notifying [1] 75/11</p> <p>noting [1] 153/13</p> <p>notion [1] 147/5</p> <p>Notwithstanding [1] 33/6</p> <p>novel [1] 117/8</p> <p>November [25] 71/7 73/4 74/10 74/20 74/21 76/2 76/15 76/16 82/12 88/7 88/7 88/16 104/4 104/7 134/22 145/5 145/9 148/5 149/12 156/9 156/11 178/22 179/22 189/2 189/6</p> <p>November 1984 [2] 88/7 104/4</p> <p>November 2011 [1] 134/22</p> <p>November 3 [1] 74/21</p> <p>now [75] 10/5 13/9 14/15 20/16 24/17 36/25 38/6 38/9 38/24 44/9 44/17 48/25 52/6 58/9 60/15 60/17 60/23 62/7 62/24 64/4</p>
--	--	--	---	--	---

<p>N</p> <p>now... [55] 67/3 68/4 73/20 76/10 77/9 78/17 80/3 83/15 85/23 88/4 89/7 90/2 91/11 95/8 98/22 99/5 101/21 104/24 108/1 110/18 112/1 115/19 117/16 117/20 118/10 118/17 118/25 119/19 120/16 126/18 129/1 132/3 135/18 136/22 140/14 142/21 144/18 145/13 147/20 147/21 148/1 149/8 152/18 152/22 157/23 161/4 162/17 163/15 163/22 166/2 172/1 178/25 181/20 191/3 191/11 NSBT [1] 134/11 nuanced [1] 54/20 nucleic [1] 6/23 number [32] 2/5 12/12 18/1 20/23 21/4 21/12 23/19 24/10 25/5 26/18 28/2 46/18 57/23 66/2 68/21 97/18 101/13 102/24 103/4 103/12 127/8 135/23 135/24 140/15 145/16 148/1 149/9 151/7 154/23 162/8 180/23 188/2 numbered [1] 77/6 nurse [1] 155/1 nurses [1] 154/25 NY [7] 105/18 105/20 106/5 109/24 125/6 173/22 175/1</p>	<p>19/25 38/8 45/8 49/21 49/24 64/5 70/25 73/20 77/9 106/7 107/13 109/5 120/18 145/13 185/2 185/9 188/8 occasion [2] 80/18 121/24 occasionally [2] 7/23 115/5 occasions [4] 46/18 167/2 173/5 176/12 occupied [1] 186/21 occur [1] 131/23 occurred [4] 2/14 62/19 108/23 157/17 Octapharma [1] 101/11 October [15] 8/4 15/7 15/8 52/4 73/10 74/8 74/18 86/17 107/22 108/5 172/3 178/25 188/23 191/3 191/6 October '78 [1] 8/4 October 1985 [2] 15/7 15/8 October 1986 [2] 107/22 108/5 October 3rd [1] 74/18 off [1] 57/12 officer [9] 74/25 133/5 133/13 135/2 141/2 182/25 183/3 187/5 187/6 officers [3] 139/21 177/19 185/25 offices [1] 128/3 official [2] 124/3 133/14 often [2] 29/9 128/19 oh [6] 27/8 32/15 79/19 94/24 137/8 157/15 okay [6] 1/9 27/8 94/24 95/1 118/14 164/1 once [7] 1/12 12/3 80/18 96/16 119/20 178/8 190/19 one [50] 3/2 6/14 12/12 21/24 24/21 30/23 36/22 42/4 49/24 56/5 57/17 61/1 64/11 76/25 77/6 77/15 82/9 84/22 85/9 86/5 87/6 95/22 98/13 100/6 103/14 104/3 106/15 115/8 119/24 119/25 133/3 144/21 146/22 147/20 148/15 148/15 150/17 154/14 154/24 155/10 161/4</p>	<p>174/16 175/7 175/21 176/19 177/21 178/18 187/4 190/16 191/5 one's [1] 140/25 ongoing [2] 67/20 116/20 online [1] 163/9 only [42] 11/22 19/1 19/13 19/23 20/19 30/16 31/6 34/5 45/21 50/3 53/10 53/15 59/5 59/21 62/9 64/21 67/18 72/13 75/16 78/8 78/14 80/3 87/9 90/15 90/15 90/18 96/21 97/15 98/5 106/9 122/10 122/20 123/11 127/2 128/20 128/21 149/1 153/14 155/7 156/19 168/12 178/12 onto [2] 19/12 46/5 onwards [1] 139/5 open [2] 51/9 167/3 opening [1] 97/4 openness [1] 187/14 operated [2] 54/12 164/17 operates [1] 53/15 operating [4] 160/24 171/9 175/8 177/25 operation [3] 68/14 97/11 125/20 operational [9] 56/8 97/14 123/4 133/25 134/6 150/20 151/16 152/7 152/10 operative [3] 16/10 177/18 180/21 opinion [2] 99/25 144/7 opinions [1] 159/2 opportune [1] 66/1 opportunities [2] 51/25 52/1 opportunity [12] 2/20 15/10 15/11 51/20 90/17 98/19 123/11 125/20 126/22 153/19 162/18 191/7 opposed [2] 100/24 161/14 optimism [1] 105/25 optimistic [2] 109/7 109/9 option [3] 70/9 100/12 152/15 or [254] oral [2] 149/6 189/4 order [3] 53/7 80/2 117/3 organisation [5]</p>	<p>29/13 122/22 123/12 125/17 126/20 organisations [6] 30/19 101/10 130/15 132/20 134/3 169/23 origin [6] 17/1 18/11 23/25 25/7 30/2 30/2 original [1] 120/1 originals [2] 25/18 32/18 originated [1] 115/20 other [54] 2/1 11/21 17/22 21/1 23/21 28/3 30/3 30/13 30/14 30/17 33/17 35/5 36/18 41/10 49/19 50/5 57/21 64/2 65/4 67/25 72/7 77/3 77/8 78/6 79/1 80/12 80/14 90/13 92/25 93/6 99/16 117/18 120/23 123/18 128/16 128/20 130/15 131/18 133/15 136/14 143/11 148/1 148/8 148/20 151/13 157/3 159/14 161/22 172/16 173/13 176/9 179/23 182/18 188/8 others [15] 2/14 19/7 35/9 45/6 47/13 56/3 77/22 78/18 139/11 143/12 143/14 153/1 159/25 164/10 173/7 otherwise [1] 177/1 our [43] 1/18 10/19 15/1 31/13 37/20 38/20 39/22 42/19 43/21 43/21 47/15 52/12 54/17 54/22 55/21 57/15 57/15 58/15 76/11 77/21 91/9 91/11 102/24 111/10 111/10 115/10 115/20 115/21 117/9 130/23 147/15 156/20 156/21 157/1 157/12 157/13 158/19 159/17 169/8 170/24 172/16 182/16 184/10 ours [1] 159/5 ourselves [2] 25/18 148/21 out [43] 22/21 25/18 27/16 27/19 29/23 31/22 32/6 32/17 36/11 36/13 46/10 48/19 51/2 51/5 52/12 56/16 58/20 60/10 61/10 67/9 73/4 85/8 100/22 114/11 120/1 120/18 122/11 135/15 152/18 155/1 159/6</p>	<p>162/10 162/12 162/19 164/2 166/19 169/19 170/20 175/8 175/21 178/19 181/4 186/18 outcome [9] 58/10 58/25 60/5 77/17 98/16 125/15 130/22 160/10 169/10 outcomes [4] 109/10 138/20 138/21 160/20 outer [2] 31/15 46/13 outlined [1] 108/19 outnumbered [1] 137/21 output [1] 169/9 outset [1] 146/19 outside [2] 50/20 144/16 over [45] 2/23 4/11 5/10 7/18 8/3 9/2 10/21 12/11 21/19 23/14 25/1 25/21 26/14 27/21 37/19 38/17 44/18 48/9 57/6 60/13 65/16 66/19 69/1 74/8 75/9 76/17 77/5 78/18 82/18 83/18 85/4 88/10 92/1 92/17 106/4 107/3 107/24 132/17 135/4 135/23 144/14 147/9 147/9 163/23 191/15 over-exaggerate [1] 38/17 over-stick [1] 10/21 over-stuck [1] 2/23 overall [5] 73/21 75/16 118/21 134/14 151/8 overestimate [1] 109/9 overlap [1] 134/9 overly [1] 121/20 oversaw [1] 190/4 overspeaking [1] 137/10 overwhelming [1] 115/23 own [11] 29/3 95/8 103/20 110/20 112/3 115/13 115/20 146/12 153/15 157/1 189/11</p>	<p>50/14 page [111] 4/12 4/13 4/19 4/20 5/10 5/18 7/18 7/19 8/3 8/5 8/6 8/15 8/19 9/2 9/9 10/4 12/8 12/23 13/8 15/16 20/4 20/6 20/7 20/11 20/12 21/19 21/25 22/1 22/25 23/14 23/15 24/14 24/24 25/1 25/2 25/9 25/21 25/22 26/9 26/10 27/11 27/21 27/25 29/21 31/1 32/16 40/21 44/19 44/19 45/15 48/9 60/25 61/3 61/4 63/11 63/12 65/17 65/20 65/25 66/19 68/18 68/19 69/1 69/2 69/3 77/5 82/18 82/24 85/2 85/4 85/10 88/10 89/8 89/13 92/17 93/21 94/1 100/8 104/13 104/14 106/17 107/3 108/15 108/17 109/14 112/1 112/9 134/21 134/23 134/23 137/14 137/15 138/4 139/4 140/18 142/4 142/9 142/11 142/12 149/7 150/3 150/4 151/1 151/4 151/22 158/13 159/7 172/4 172/20 173/19 173/21 page 10 [2] 4/13 85/10 page 116 [2] 134/21 134/23 page 133 [1] 173/19 Page 137 [1] 137/14 page 14 [1] 139/4 page 141 [2] 142/4 142/11 page 146 [1] 151/1 page 16 [1] 140/18 page 3 [1] 60/25 page 37 [2] 100/8 172/20 page 4 [2] 63/11 68/18 page 5 [1] 4/12 page 50 [1] 149/7 page 98 [1] 40/21 pages [4] 4/13 5/11 22/4 65/16 Pages 11-12 [1] 22/4 paid [1] 137/23 painted [1] 159/23 palliative [1] 190/1 panels [2] 188/22 188/25</p>
<p>O</p>					
<p>o'clock [4] 60/18 60/18 98/23 98/24 objective [1] 153/25 observation [4] 28/13 149/5 149/14 154/14 observations [4] 144/23 152/19 152/25 153/1 observed [1] 116/8 observers [5] 133/17 136/7 136/8 136/14 140/12 obstacle [1] 146/11 obtain [5] 24/18 110/6 112/24 113/9 119/22 obtained [6] 21/5 23/6 26/1 58/3 114/1 114/3 obtaining [1] 128/3 obvious [1] 83/21 obviously [18] 2/5</p>	<p>oh [6] 27/8 32/15 79/19 94/24 137/8 157/15 okay [6] 1/9 27/8 94/24 95/1 118/14 164/1 once [7] 1/12 12/3 80/18 96/16 119/20 178/8 190/19 one [50] 3/2 6/14 12/12 21/24 24/21 30/23 36/22 42/4 49/24 56/5 57/17 61/1 64/11 76/25 77/6 77/15 82/9 84/22 85/9 86/5 87/6 95/22 98/13 100/6 103/14 104/3 106/15 115/8 119/24 119/25 133/3 144/21 146/22 147/20 148/15 148/15 150/17 154/14 154/24 155/10 161/4</p>	<p>opinion [2] 99/25 144/7 opinions [1] 159/2 opportune [1] 66/1 opportunities [2] 51/25 52/1 opportunity [12] 2/20 15/10 15/11 51/20 90/17 98/19 123/11 125/20 126/22 153/19 162/18 191/7 opposed [2] 100/24 161/14 optimism [1] 105/25 optimistic [2] 109/7 109/9 option [3] 70/9 100/12 152/15 or [254] oral [2] 149/6 189/4 order [3] 53/7 80/2 117/3 organisation [5]</p>	<p>out [43] 22/21 25/18 27/16 27/19 29/23 31/22 32/6 32/17 36/11 36/13 46/10 48/19 51/2 51/5 52/12 56/16 58/20 60/10 61/10 67/9 73/4 85/8 100/22 114/11 120/1 120/18 122/11 135/15 152/18 155/1 159/6</p>	<p>over [45] 2/23 4/11 5/10 7/18 8/3 9/2 10/21 12/11 21/19 23/14 25/1 25/21 26/14 27/21 37/19 38/17 44/18 48/9 57/6 60/13 65/16 66/19 69/1 74/8 75/9 76/17 77/5 78/18 82/18 83/18 85/4 88/10 92/1 92/17 106/4 107/3 107/24 132/17 135/4 135/23 144/14 147/9 147/9 163/23 191/15 over-exaggerate [1] 38/17 over-stick [1] 10/21 over-stuck [1] 2/23 overall [5] 73/21 75/16 118/21 134/14 151/8 overestimate [1] 109/9 overlap [1] 134/9 overly [1] 121/20 oversaw [1] 190/4 overspeaking [1] 137/10 overwhelming [1] 115/23 own [11] 29/3 95/8 103/20 110/20 112/3 115/13 115/20 146/12 153/15 157/1 189/11</p>	<p>package [12] 5/14 8/16 20/18 26/13 26/17 26/22 31/15 32/7 41/22 44/25 49/23 57/24 packaging [8] 2/23 45/16 45/19 45/20 46/12 46/13 46/23</p>
<p>P</p>					
<p>package [12] 5/14 8/16 20/18 26/13 26/17 26/22 31/15 32/7 41/22 44/25 49/23 57/24 packaging [8] 2/23 45/16 45/19 45/20 46/12 46/13 46/23</p>	<p>page [111] 4/12 4/13 4/19 4/20 5/10 5/18 7/18 7/19 8/3 8/5 8/6 8/15 8/19 9/2 9/9 10/4 12/8 12/23 13/8 15/16 20/4 20/6 20/7 20/11 20/12 21/19 21/25 22/1 22/25 23/14 23/15 24/14 24/24 25/1 25/2 25/9 25/21 25/22 26/9 26/10 27/11 27/21 27/25 29/21 31/1 32/16 40/21 44/19 44/19 45/15 48/9 60/25 61/3 61/4 63/11 63/12 65/17 65/20 65/25 66/19 68/18 68/19 69/1 69/2 69/3 77/5 82/18 82/24 85/2 85/4 85/10 88/10 89/8 89/13 92/17 93/21 94/1 100/8 104/13 104/14 106/17 107/3 108/15 108/17 109/14 112/1 112/9 134/21 134/23 134/23 137/14 137/15 138/4 139/4 140/18 142/4 142/9 142/11 142/12 149/7 150/3 150/4 151/1 151/4 151/22 158/13 159/7 172/4 172/20 173/19 173/21 page 10 [2] 4/13 85/10 page 116 [2] 134/21 134/23 page 133 [1] 173/19 Page 137 [1] 137/14 page 14 [1] 139/4 page 141 [2] 142/4 142/11 page 146 [1] 151/1 page 16 [1] 140/18 page 3 [1] 60/25 page 37 [2] 100/8 172/20 page 4 [2] 63/11 68/18 page 5 [1] 4/12 page 50 [1] 149/7 page 98 [1] 40/21 pages [4] 4/13 5/11 22/4 65/16 Pages 11-12 [1] 22/4 paid [1] 137/23 painted [1] 159/23 palliative [1] 190/1 panels [2] 188/22 188/25</p>	<p>package [12] 5/14 8/16 20/18 26/13 26/17 26/22 31/15 32/7 41/22 44/25 49/23 57/24 packaging [8] 2/23 45/16 45/19 45/20 46/12 46/13 46/23</p>	<p>package [12] 5/14 8/16 20/18 26/13 26/17 26/22 31/15 32/7 41/22 44/25 49/23 57/24 packaging [8] 2/23 45/16 45/19 45/20 46/12 46/13 46/23</p>	<p>package [12] 5/14 8/16 20/18 26/13 26/17 26/22 31/15 32/7 41/22 44/25 49/23 57/24 packaging [8] 2/23 45/16 45/19 45/20 46/12 46/13 46/23</p>	<p>package [12] 5/14 8/16 20/18 26/13 26/17 26/22 31/15 32/7 41/22 44/25 49/23 57/24 packaging [8] 2/23 45/16 45/19 45/20 46/12 46/13 46/23</p>

<p>P</p> <p>paper [5] 66/20 66/21 85/18 85/21 106/23</p> <p>paragraph [44] 5/19 8/20 9/19 11/2 13/2 13/11 21/24 26/20 27/13 27/23 29/22 33/16 33/21 62/5 63/22 64/5 64/13 64/18 64/19 73/9 74/18 76/3 76/24 77/6 82/13 82/19 82/25 88/10 91/19 91/21 100/8 107/5 108/17 110/14 110/15 113/8 113/17 113/18 115/3 115/14 117/5 117/14 151/4 172/20</p> <p>paragraph 1 [1] 73/9</p> <p>paragraph 106 [2] 100/8 172/20</p> <p>paragraph 2 [1] 82/13</p> <p>paragraph 458 [1] 151/4</p> <p>paragraph 5 [2] 74/18 108/17</p> <p>paragraph 6 [1] 82/19</p> <p>paragraph 8 [1] 82/25</p> <p>paragraphs [2] 33/21 111/5</p> <p>Parliamentary [4] 184/3 185/16 186/23 188/12</p> <p>part [26] 5/19 7/17 22/25 23/15 39/8 45/13 46/9 47/2 51/17 61/1 64/12 90/4 101/16 109/18 112/13 126/20 130/16 139/16 139/22 140/7 143/18 150/11 152/6 167/24 168/8 173/12</p> <p>Participant [1] 175/22</p> <p>participants [9] 99/10 99/11 140/12 153/19 162/18 163/6 163/22 175/17 191/4</p> <p>participate [1] 117/9</p> <p>participated [1] 139/20</p> <p>participating [1] 119/5</p> <p>particular [64] 10/13 11/15 16/1 16/2 18/19 19/4 21/22 27/18 29/20 50/24 50/25 51/2 56/17 57/19 75/12 84/8 85/6 85/18 86/7 86/18 86/19 87/17 88/12 90/25 93/4 94/21 95/13 97/6</p>	<p>104/3 105/14 110/24 111/4 121/7 122/8 123/16 123/16 129/6 132/9 132/10 134/7 137/25 139/15 143/21 143/22 144/16 146/22 150/9 153/5 154/19 155/21 161/5 162/10 166/3 168/4 170/6 173/22 174/4 174/13 177/3 182/5 183/4 183/10 185/12 187/1</p> <p>particularly [12] 11/23 32/7 46/4 46/13 55/4 96/6 99/22 102/20 141/14 169/22 184/10 190/17</p> <p>particulate [1] 31/23</p> <p>parties [1] 159/14</p> <p>pass [2] 47/3 177/8</p> <p>passage [9] 3/13 21/23 47/11 85/9 94/19 100/6 106/18 133/7 172/5</p> <p>passaged [1] 133/11</p> <p>passed [3] 58/18 144/15 178/15</p> <p>passing [1] 110/13</p> <p>passionately [1] 153/9</p> <p>past [2] 16/16 91/2</p> <p>pasteurisation [2] 100/11 172/6</p> <p>pasteurised [1] 101/24</p> <p>paternalistic [2] 59/16 59/24</p> <p>patient [33] 33/13 66/3 75/25 76/19 76/20 77/6 77/10 77/15 78/2 78/2 81/16 89/19 95/20 95/21 95/22 95/24 96/12 96/15 97/13 98/14 103/2 110/21 115/8 116/18 117/25 120/11 123/19 125/13 128/15 154/3 154/6 154/10 164/22</p> <p>patient's [1] 90/14</p> <p>patients [127] 7/23 33/4 33/6 33/6 35/3 35/6 35/17 35/21 36/3 36/13 36/17 36/20 38/1 43/3 46/4 47/25 54/22 55/1 55/13 56/20 57/3 57/4 57/10 57/11 57/11 58/15 58/19 58/23 59/9 59/22 61/8 62/1 62/11 65/18 67/8 67/21 67/25 70/19 70/25</p>	<p>71/14 71/16 71/18 73/11 74/2 74/16 75/20 75/23 76/25 77/3 77/19 78/21 78/25 79/14 80/25 81/2 81/11 83/4 83/13 83/15 83/19 84/5 86/18 87/10 91/2 91/23 92/2 92/7 95/18 95/19 96/4 96/8 96/11 97/15 98/17 98/17 100/19 101/7 101/14 102/21 104/1 107/8 110/7 114/16 114/18 114/22 114/23 114/25 115/19 117/10 117/15 118/6 118/8 118/20 121/23 123/1 123/6 123/14 126/2 126/8 127/6 128/8 128/14 128/18 147/1 158/6 161/21 164/6 164/19 164/20 164/21 165/2 165/10 165/13 165/15 165/18 165/22 165/24 166/1 166/6 166/11 175/4 179/8 179/10 181/15 181/19 181/21 182/1</p> <p>patients' [3] 79/9 82/5 83/4</p> <p>Patten [2] 184/3 184/3</p> <p>pattern [1] 189/17</p> <p>pausing [4] 20/16 45/22 53/24 107/10</p> <p>pedantic [1] 42/25</p> <p>peer [1] 155/16</p> <p>Pending [1] 115/15</p> <p>Penrose [26] 3/3 32/11 40/17 41/7 41/13 44/15 44/18 44/21 60/24 84/23 106/16 121/4 122/10 129/12 134/15 134/20 136/22 136/23 137/17 140/20 142/2 144/23 147/21 149/9 152/18 174/11</p> <p>Penrose Inquiry [1] 40/17</p> <p>penultimate [1] 8/22</p> <p>people [20] 36/23 53/11 53/16 56/7 79/12 86/24 127/9 127/18 127/19 130/13 130/14 138/11 155/17 161/18 163/10 166/24 178/15 180/8 188/22 188/25</p> <p>people's [1] 161/23</p> <p>per [6] 37/18 66/2 66/3 149/1 154/18</p>	<p>154/20</p> <p>perceived [1] 159/13</p> <p>perception [2] 57/14 57/15</p> <p>perfect [1] 138/20</p> <p>perfectly [2] 72/15 81/12</p> <p>perhaps [42] 6/6 7/2 28/23 34/19 39/19 40/11 51/1 58/6 59/7 60/15 83/5 85/19 85/23 86/8 97/4 97/8 98/22 102/8 106/14 113/9 114/4 117/8 123/24 125/25 126/11 126/13 126/25 127/11 127/14 127/19 131/8 136/20 137/14 138/9 138/12 140/4 142/20 149/4 153/18 156/22 168/11 169/18</p> <p>period [16] 28/15 29/6 37/19 45/8 45/18 54/11 59/3 103/1 114/9 125/3 137/24 153/4 162/10 162/21 171/1 185/6</p> <p>periodically [6] 22/8 35/8 139/14 141/11 142/21 176/15</p> <p>permanent [1] 187/17</p> <p>permission [1] 146/16</p> <p>permits [1] 182/5</p> <p>permitted [1] 44/4</p> <p>PERRY [40] 1/3 1/6 4/10 9/12 18/14 19/21 22/6 25/12 29/3 32/2 33/21 33/25 47/19 58/13 59/11 60/22 64/20 69/20 76/9 83/16 85/18 88/5 88/14 99/4 100/22 102/21 104/6 104/16 110/9 112/2 129/1 153/15 157/9 161/4 162/17 163/3 163/21 181/6 182/3 192/2</p> <p>Perry's [1] 162/19</p> <p>persistent [1] 59/4</p> <p>person [1] 127/10</p> <p>personal [2] 152/25 160/4</p> <p>personality [1] 168/3</p> <p>personally [1] 42/13</p> <p>perspective [7] 62/14 62/22 75/13 136/25 138/13 150/14 153/2</p> <p>persuading [1] 55/9</p> <p>pestering [1] 112/20</p> <p>Peter [5] 37/22 63/17 99/7 161/18 174/7</p> <p>Peter Kernoff [2]</p>	<p>37/22 161/18</p> <p>Peter's [2] 156/17 158/3</p> <p>Pettet [6] 115/3 115/25 116/12 116/24 118/3 124/17</p> <p>Pettet's [1] 118/25</p> <p>PFC [118] 1/14 6/9 16/22 17/17 24/3 30/2 32/5 33/19 34/5 34/22 35/18 36/9 36/10 36/12 37/10 38/3 38/9 38/13 38/19 39/11 40/24 41/8 44/24 45/4 45/17 47/14 48/17 50/18 51/13 51/14 52/8 53/22 54/2 56/1 56/8 57/8 58/18 60/9 70/9 70/12 70/22 71/12 72/1 72/7 73/13 73/19 73/23 74/4 74/25 75/14 76/6 76/7 78/20 82/19 83/16 84/2 86/18 86/20 87/23 89/3 89/16 89/23 89/25 90/3 90/9 90/18 92/22 93/2 97/16 99/16 99/17 100/2 100/10 102/7 104/10 104/19 105/7 106/7 106/21 108/11 111/5 111/14 113/19 114/1 114/3 114/7 114/10 115/17 117/17 117/20 118/18 122/25 123/7 124/13 126/4 128/4 128/23 131/10 161/13 164/5 164/9 164/13 164/18 164/25 165/14 166/8 166/13 167/6 167/16 167/21 170/8 170/19 171/7 171/10 172/18 173/2 174/6 176/7</p> <p>PFC 795 [1] 89/25</p> <p>PFC batches [1] 170/8</p> <p>PFC's [12] 2/9 4/16 5/14 32/12 57/14 57/15 96/1 97/17 105/18 112/3 115/12 157/24</p> <p>PFC/SNBTS [1] 48/17</p> <p>PFL [3] 101/22 106/21 116/2</p> <p>pH [1] 173/17</p> <p>phage [1] 173/5</p> <p>pharmaceutical [10] 22/13 32/6 41/19 42/5 43/10 43/23 44/2 50/7 93/21 136/12</p> <p>pharmaceuticals [3]</p>	<p>3/18 30/17 30/22</p> <p>pharmacies [1] 30/5</p> <p>pharmacology [1] 184/10</p> <p>pharmacopoeia [26] 3/6 3/8 3/9 3/15 3/20 3/23 17/5 19/23 20/1 20/6 20/22 21/9 21/21 22/3 22/8 22/14 24/9 24/16 24/20 25/11 27/3 28/14 29/4 29/7 30/14 48/25</p> <p>pharmacopoeial [1] 32/22</p> <p>pharmacopoeias [1] 24/19</p> <p>phase [7] 112/5 112/6 113/21 139/2 148/17 148/17 162/1</p> <p>Phase I [2] 139/2 148/17</p> <p>phoning [1] 73/9</p> <p>phrase [1] 191/10</p> <p>physical [3] 78/14 101/18 103/8</p> <p>pick [17] 1/8 32/16 44/11 46/24 61/3 68/18 73/1 82/25 98/22 106/14 107/5 134/20 137/14 139/5 140/19 149/5 151/3</p> <p>picked [4] 7/4 56/23 112/17 138/24</p> <p>picking [2] 7/5 77/5</p> <p>Pickles [4] 136/8 136/10 139/10 183/3</p> <p>picks [2] 143/24 156/10</p> <p>picture [3] 19/22 159/23 168/6</p> <p>pipeline [1] 190/13</p> <p>pitched [1] 178/13</p> <p>place [22] 35/23 39/11 42/4 47/16 63/4 72/23 80/24 81/22 84/10 86/22 115/23 125/23 128/21 128/22 131/22 132/17 144/21 147/10 147/11 147/13 154/22 177/13</p> <p>plainly [3] 29/19 127/12 179/17</p> <p>plan [4] 111/10 112/14 120/19 151/23</p> <p>planning [2] 142/23 158/20</p> <p>plans [1] 189/8</p> <p>plant [1] 167/7</p> <p>plants [1] 166/14</p> <p>plasma [22] 5/21 13/13 13/23 13/24 14/19 14/19 15/6</p>
--	---	---	---	---	---

<p>P</p> <p>plasma... [15] 20/25 26/1 27/15 30/16 52/5 58/7 69/6 155/8 162/9 162/11 166/23 167/4 171/12 179/12 180/10</p> <p>please [47] 4/21 5/10 5/18 8/5 9/9 13/10 20/4 27/14 27/21 27/24 31/1 40/19 40/21 44/16 48/3 60/25 62/5 66/15 68/3 69/2 73/2 76/1 84/24 89/7 89/8 89/13 90/23 93/17 100/8 106/18 108/15 111/1 111/18 111/25 113/6 115/1 134/21 134/23 135/20 139/4 140/18 142/11 143/23 151/2 151/22 157/9 190/22</p> <p>plus [1] 38/22</p> <p>pm [8] 60/21 99/1 99/3 162/25 163/15 163/17 163/19 191/17</p> <p>point [32] 21/2 21/3 25/5 29/19 30/24 46/24 47/5 51/17 52/2 52/20 52/25 52/25 53/21 56/24 59/12 65/6 66/19 67/23 72/6 73/16 78/6 88/12 92/6 102/6 106/6 107/21 108/2 131/10 141/3 148/15 149/24 169/4</p> <p>Point 1 [1] 92/6</p> <p>point 5 [2] 21/2 66/19</p> <p>point 9 [1] 21/3</p> <p>pointed [1] 67/9</p> <p>points [2] 48/20 141/22</p> <p>poised [1] 111/6</p> <p>policy [17] 66/6 67/6 69/6 114/21 122/24 132/20 133/24 134/12 134/12 135/15 149/18 150/5 151/24 184/14 184/20 187/21 187/24</p> <p>policy-making [1] 132/20</p> <p>political [1] 188/6</p> <p>pool [10] 21/4 21/13 69/8 69/9 162/9 168/15 168/16 169/3 169/7 169/12</p> <p>pools [5] 13/23 14/19 15/6 167/4 169/14</p> <p>populate [2] 182/17 182/18</p> <p>population [1] 86/12</p> <p>position [21] 46/15</p>	<p>57/13 67/16 79/25 125/25 127/11 127/15 127/16 128/1 140/5 143/5 144/8 148/8 150/5 150/6 157/1 160/6 165/2 165/21 168/18 186/9</p> <p>positions [2] 159/17 186/21</p> <p>positive [4] 74/2 90/22 92/20 138/25</p> <p>positively [2] 120/8 166/9</p> <p>possibility [6] 7/13 8/24 44/24 45/6 47/14 66/5</p> <p>possible [17] 22/18 22/19 41/11 47/16 56/4 72/23 87/13 112/24 113/9 115/17 117/4 123/9 159/1 167/1 172/10 179/23 181/23</p> <p>possibly [3] 30/7 138/14 178/6</p> <p>post [1] 180/24</p> <p>post-HIV [1] 180/24</p> <p>postdated [2] 101/15 174/2</p> <p>posts [1] 73/7</p> <p>potency [6] 169/17 169/18 169/20 169/23 170/5 170/6</p> <p>potential [8] 9/8 59/17 87/4 121/10 129/25 130/8 167/5 174/23</p> <p>potentially [6] 17/4 77/10 78/3 93/1 100/19 129/21</p> <p>potentiating [1] 101/7</p> <p>PPE [2] 177/25 178/4</p> <p>practical [1] 80/9</p> <p>practice [9] 28/17 31/12 38/13 52/19 58/19 63/6 63/10 154/11 168/11</p> <p>practices [4] 64/2 65/3 167/10 177/24</p> <p>practicing [1] 155/14</p> <p>practitioner [1] 23/7</p> <p>practitioners [1] 155/1</p> <p>pre [1] 107/13</p> <p>pre-dated [1] 107/13</p> <p>Precautions [2] 4/24 8/8</p> <p>preceded [1] 130/25</p> <p>precise [3] 71/25 107/16 133/8</p> <p>precisely [3] 20/21 106/20 133/1</p> <p>predecessor [2] 6/7</p>	<p>68/11</p> <p>predicated [1] 95/16</p> <p>prefer [1] 116/16</p> <p>preferable [2] 113/25 114/2</p> <p>preference [2] 54/16 124/11</p> <p>preferred [2] 67/4 100/12</p> <p>preferring [1] 152/15</p> <p>premature [1] 104/1</p> <p>preparation [14] 5/5 5/21 6/1 13/13 13/17 17/1 18/11 21/5 23/25 25/6 26/19 26/24 27/15 173/15</p> <p>prepare [2] 63/6 63/8</p> <p>prepared [6] 25/25 26/7 62/24 63/2 66/14 66/21</p> <p>preparing [1] 23/5</p> <p>prerequisite [1] 54/7</p> <p>prescribe [1] 54/24</p> <p>prescribed [11] 3/5 3/10 3/22 29/10 31/3 53/12 55/21 114/21 143/3 164/16 168/12</p> <p>prescribers [1] 32/23</p> <p>prescribing [4] 19/15 20/17 34/16 54/23</p> <p>prescription [2] 19/13 154/5</p> <p>prescription-only [1] 19/13</p> <p>presence [3] 5/23 13/15 13/24</p> <p>present [15] 19/24 41/21 47/24 66/18 67/5 76/7 82/13 83/11 83/17 84/13 108/14 109/17 125/2 125/8 131/13</p> <p>presentation [4] 46/2 158/8 183/22 185/24</p> <p>presentational [1] 156/18</p> <p>presentations [5] 35/10 188/3 188/9 188/14 188/19</p> <p>presented [6] 3/17 15/10 113/1 135/15 138/23 159/24</p> <p>presenting [3] 87/10 115/8 180/17</p> <p>presents [3] 115/6 116/5 119/9</p> <p>press [2] 83/10 104/18</p> <p>presumably [6] 1/13 16/2 90/2 96/25 112/22 180/4</p> <p>pretty [1] 43/17</p>	<p>prevailing [1] 34/4</p> <p>prevent [1] 32/4</p> <p>previous [7] 12/11 25/4 29/21 96/25 111/22 115/5 137/15</p> <p>previously [14] 110/16 112/25 114/16 114/22 116/18 120/11 123/2 123/19 126/8 128/8 128/14 128/18 187/11 189/5</p> <p>primarily [4] 19/15 97/11 151/19 179/9</p> <p>Prime [1] 185/3</p> <p>principal [2] 22/7 183/3</p> <p>principle [5] 73/8 151/17 152/1 162/7 176/23</p> <p>principles [1] 166/21</p> <p>Prior [2] 183/12 183/12</p> <p>prior [11] 9/14 9/14 31/18 45/8 48/16 52/3 52/21 86/16 130/11 170/21 187/6</p> <p>priorities [1] 98/6</p> <p>priority [3] 98/7 99/17 99/18</p> <p>pro [1] 171/9</p> <p>proactive [1] 49/3</p> <p>proactively [1] 50/20</p> <p>probably [26] 11/17 43/17 67/18 72/16 77/11 77/23 83/25 85/22 87/23 94/17 96/19 99/9 102/14 103/16 107/17 113/24 116/22 125/14 130/21 140/9 153/13 156/4 162/22 167/21 170/25 179/24</p> <p>problem [6] 3/25 83/21 130/4 141/19 143/25 147/7</p> <p>problems [8] 83/3 128/7 143/7 146/25 148/19 153/3 160/2 174/24</p> <p>procedure [2] 154/19 155/12</p> <p>procedures [1] 177/25</p> <p>proceedings [2] 47/2 140/17</p> <p>process [39] 2/7 2/8 46/9 46/16 48/13 49/19 50/6 76/12 78/19 78/24 79/1 80/6 80/17 81/1 81/12 97/10 101/20 129/9 130/16 132/19 139/25</p>	<p>140/7 141/25 143/3 144/14 144/25 145/17 146/9 147/8 149/11 149/23 151/8 152/20 154/22 159/12 166/15 171/15 173/13 175/14</p> <p>processes [8] 61/20 100/14 100/17 132/17 151/15 172/17 172/24 173/14</p> <p>processing [2] 69/6 166/13</p> <p>produce [5] 30/20 67/10 70/10 101/12 128/17</p> <p>produced [12] 10/9 14/22 22/8 22/10 28/14 29/13 46/5 68/1 74/2 114/20 130/2 165/24</p> <p>producers [1] 129/23</p> <p>producing [2] 32/4 70/5</p> <p>product [138] 1/7 1/12 1/16 1/18 1/21 2/15 2/19 2/24 3/16 4/1 4/2 4/16 5/6 7/4 7/14 8/11 9/17 10/16 10/20 10/23 11/8 11/10 13/23 13/25 14/7 14/24 15/13 16/21 17/15 19/3 23/23 31/14 31/17 32/24 36/10 37/10 37/13 38/11 38/18 38/25 41/19 41/20 42/5 42/21 45/19 45/19 45/23 46/3 46/8 48/16 51/4 52/9 54/8 55/24 56/17 58/4 58/21 60/7 66/10 69/20 70/10 70/16 70/22 76/8 79/5 79/6 79/11 79/12 80/4 80/7 80/8 80/10 80/16 80/24 81/13 82/3 88/20 89/3 89/15 89/16 92/3 94/8 94/10 95/17 96/3 96/4 96/8 96/22 98/3 101/12 105/17 105/18 110/18 110/22 111/7 111/14 111/15 112/3 112/5 113/19 113/21 115/10 115/13 115/15 115/22 116/14 116/21 117/20 120/10 121/12 121/16 121/18 122/6 122/8 122/8 122/19 123/7 125/18 126/2 128/3 128/12 128/13 128/23 130/15 131/12 148/17</p>	<p>157/24 161/14 161/15 164/3 169/11 171/14 171/17 171/25 174/5 174/15 175/5 177/23</p> <p>production [2] 67/3 70/12</p> <p>products [79] 2/10 19/10 19/18 28/10 28/20 29/1 29/18 30/11 30/16 30/17 30/20 31/14 33/1 33/19 33/19 34/5 34/6 34/14 34/23 35/10 36/1 36/24 37/17 37/17 39/22 40/25 42/19 45/17 46/7 48/15 48/23 52/3 52/4 52/8 52/13 52/15 52/23 53/12 53/17 55/21 58/2 58/5 58/12 58/16 60/10 61/13 73/13 73/19 82/7 87/25 90/3 91/3 94/20 105/16 108/20 112/25 121/22 122/4 127/6 128/16 129/24 130/2 155/8 161/9 161/19 161/23 162/5 162/6 162/14 162/14 165/4 165/5 170/25 176/1 178/7 178/9 189/20 189/23 189/24</p> <p>professional [1] 134/2</p> <p>professionals [1] 147/5</p> <p>professor [38] 11/17 35/9 38/21 39/20 39/23 40/4 41/11 41/12 46/20 47/21 54/17 55/5 55/7 55/21 56/3 64/22 67/23 71/18 103/11 103/14 124/9 126/10 126/25 127/5 135/25 137/3 137/17 156/10 156/11 157/18 167/25 183/11 183/14 183/14 184/9 184/9 185/9 187/5</p> <p>Professor Aileen Keel [1] 187/5</p> <p>Professor Cash [20] 11/17 35/9 38/21 39/20 40/4 41/11 46/20 47/21 55/5 55/7 55/21 56/3 64/22 67/23 103/11 126/10 137/3 156/10 156/11 167/25</p> <p>Professor Cash's [1] 54/17</p> <p>Professor Forbes [2]</p>
---	--	--	--	--	--

P	<p>protocol [2] 116/8 116/10</p> <p>proved [1] 157/5</p> <p>proven [3] 39/3 39/4 43/18</p> <p>provide [18] 30/10 30/18 30/21 32/22 44/3 50/8 54/19 54/23 56/3 57/2 96/2 97/18 117/12 156/19 164/6 164/14 165/14 181/23</p> <p>provided [23] 10/15 10/17 19/25 25/13 30/11 32/14 33/8 35/21 37/25 38/5 39/18 41/22 52/14 83/6 117/10 158/21 159/1 165/13 165/16 165/18 166/10 167/13 190/15</p> <p>providing [7] 34/13 35/2 36/23 58/23 120/10 165/10 165/21</p> <p>proving [1] 122/19</p> <p>provision [1] 177/17</p> <p>PRSE0000040 [2] 172/1 172/4</p> <p>PRSE00001773 [1] 90/23</p> <p>PRSE0000828 [1] 73/2</p> <p>PRSE0000976 [1] 145/9</p> <p>PRSE0001258 [2] 60/25 106/14</p> <p>PRSE0001324 [1] 44/16</p> <p>PRSE0001397 [1] 116/1</p> <p>PRSE0001477 [1] 145/7</p> <p>PRSE0001556 [1] 66/15</p> <p>PRSE0001784 [1] 111/18</p> <p>PRSE0001885 [1] 40/11</p> <p>PRSE0002066 [1] 82/10</p> <p>PRSE0002280 [1] 145/11</p> <p>PRSE0002616 [1] 119/11</p> <p>PRSE0002620 [1] 32/13</p> <p>PRSE0002643 [1] 119/14</p> <p>PRSE0002726 [1] 4/11</p> <p>PRSE0002783 [1] 111/24</p> <p>PRSE0002801 [1]</p>	<p>84/24</p> <p>PRSE0003030 [1] 111/1</p> <p>PRSE0003143 [1] 118/10</p> <p>PRSE0003506 [1] 91/16</p> <p>PRSE0003693 [1] 116/24</p> <p>PRSE0003764 [1] 108/10</p> <p>PRSE0003814 [1] 113/13</p> <p>PRSE0003845 [1] 110/8</p> <p>PRSE0004097 [1] 112/18</p> <p>PRSE0004146 [1] 118/24</p> <p>PRSE0004148 [1] 104/5</p> <p>PRSE0004383 [1] 115/1</p> <p>PRSE0004741 [1] 62/23</p> <p>PRSE0006038 [1] 40/19</p> <p>PRSE0006068 [4] 134/21 137/6 137/8 149/6</p> <p>public [17] 134/2 136/25 138/1 138/13 138/21 141/15 151/20 152/13 156/23 156/24 157/10 158/20 159/12 160/13 179/17 188/12 188/13</p> <p>publication [4] 37/2 37/3 37/4 37/21</p> <p>publications [4] 36/2 37/25 53/17 161/18</p> <p>publicised [1] 104/17</p> <p>publicity [4] 83/5 83/14 105/1 105/10</p> <p>publicly [1] 144/3</p> <p>published [7] 24/22 63/16 93/24 93/25 108/5 186/9 187/11</p> <p>publishing [1] 182/15</p> <p>purchase [1] 169/11</p> <p>purity [1] 64/15</p> <p>purpose [5] 19/13 82/13 132/24 156/19 171/24</p> <p>purposes [8] 19/24 117/13 125/3 160/7 166/22 172/21 175/25 184/10</p> <p>Purves [3] 136/8 136/12 139/12</p> <p>put [30] 3/19 4/2 22/21 31/3 31/25</p>	<p>35/18 42/20 51/5 54/14 56/16 57/12 60/10 82/1 102/21 106/23 109/20 117/17 118/3 125/22 126/23 127/12 134/17 136/22 139/19 140/19 154/22 163/7 163/12 178/19 178/20</p> <p>putting [2] 31/10 54/7</p> <p>pyrogen [1] 5/2</p>	<p>Q</p> <p>QC [1] 184/16</p> <p>quality [2] 45/11 131/14</p> <p>quantities [2] 92/23 126/17</p> <p>quantity [1] 115/18</p> <p>question [32] 1/17 31/9 36/7 38/6 40/9 40/22 44/22 50/19 52/11 53/19 55/18 55/25 59/12 83/18 99/4 99/13 100/22 102/20 105/21 106/18 124/19 146/6 148/10 150/10 161/4 164/2 164/3 167/23 170/13 171/20 173/1 174/21</p> <p>Questioned [2] 1/4 192/3</p> <p>questioning [1] 60/12</p> <p>questions [19] 59/10 88/1 99/9 110/10 153/15 153/20 162/16 163/8 163/9 163/12 163/21 175/16 175/19 175/20 175/22 180/3 181/4 186/5 192/4</p> <p>quick [1] 10/22</p> <p>quicker [1] 75/15</p> <p>quickly [3] 2/20 75/14 175/10</p> <p>quite [24] 16/3 16/12 36/18 60/1 60/16 70/11 97/6 97/20 103/16 103/17 107/17 118/6 120/7 120/9 126/2 139/21 141/20 146/25 153/7 155/18 157/19 166/7 171/13 179/22</p>	<p>random [1] 189/16</p> <p>range [5] 32/17 57/17 108/12 108/13 109/15</p> <p>rapid [1] 61/19</p> <p>rare [2] 7/21 9/4</p> <p>rata [1] 171/9</p> <p>rate [1] 149/1</p> <p>rather [20] 20/3 34/25 37/10 37/12 49/3 52/10 63/19 101/4 124/12 125/12 137/23 138/20 139/2 151/20 152/7 153/4 165/4 168/2 171/22 190/20</p> <p>rationale [1] 76/21</p> <p>rationales [1] 181/24</p> <p>Rawlins [1] 184/9</p> <p>re [2] 2/7 70/11</p> <p>re-configuring [1] 70/11</p> <p>re-examining [1] 2/7</p> <p>reached [1] 93/6</p> <p>reaction [4] 72/1 72/1 128/16 128/17</p> <p>reactions [1] 154/8</p> <p>read [18] 8/19 15/17 15/20 15/23 20/9 23/13 25/3 33/15 33/21 41/15 65/19 104/24 144/20 146/10 147/23 151/4 159/6 190/16</p> <p>reader [1] 19/6</p> <p>readiness [2] 152/8 152/9</p> <p>reading [1] 130/20</p> <p>reads [4] 13/12 105/1 110/14 117/22</p> <p>ready [2] 153/10 190/18</p> <p>real [11] 53/9 53/11 58/23 100/24 101/14 102/7 103/10 130/4 131/1 146/11 190/14</p> <p>realised [1] 127/10</p> <p>really [31] 2/19 48/20 49/7 50/19 72/12 76/17 97/2 102/1 103/16 127/3 127/7 127/16 129/8 131/23 132/14 140/1 141/2 141/20 142/7 142/15 142/16 146/24 149/13 155/7 160/1 160/18 165/1 171/20 175/21 176/24 181/10</p> <p>reason [13] 30/20 41/20 52/7 52/8 80/13 99/22 105/25 110/2 121/5 126/3 138/6 147/9 149/2</p> <p>reasonable [5] 33/1</p>	<p>34/1 116/15 139/1 150/14</p> <p>reasoning [1] 41/15</p> <p>reasons [6] 99/20 102/24 128/24 142/6 142/15 169/6</p> <p>reassessed [1] 69/11</p> <p>recall [41] 30/8 41/7 45/2 46/19 47/12 62/14 62/15 69/23 73/5 73/8 73/19 76/12 78/24 79/2 79/5 79/6 79/10 79/11 79/17 80/1 80/10 80/18 80/20 81/21 81/25 82/8 86/18 87/2 89/15 91/9 94/22 107/10 107/12 129/21 131/16 135/14 139/10 140/7 148/9 169/11 169/13</p> <p>recalled [3] 74/24 75/12 80/13</p> <p>recalls [3] 39/19 47/21 80/11</p> <p>receive [3] 43/6 53/23 77/7</p> <p>received [24] 53/22 74/13 74/16 75/20 76/25 77/2 77/2 77/3 77/15 89/25 90/14 90/18 92/3 92/7 92/18 92/23 93/14 96/4 105/11 110/17 110/22 118/11 120/17 123/15</p> <p>receiving [5] 55/14 78/24 91/3 91/23 146/23</p> <p>recent [1] 82/16</p> <p>recently [4] 58/1 58/1 90/16 115/9</p> <p>recipient [1] 100/19</p> <p>recipients [2] 37/19 76/5</p> <p>recognised [4] 32/25 122/23 130/9 189/17</p> <p>recognising [1] 17/22</p> <p>recognition [1] 181/13</p> <p>recollection [21] 2/25 11/16 35/8 47/8 67/12 67/14 67/17 70/21 71/1 71/4 73/24 73/25 75/7 76/18 83/1 83/23 83/24 93/8 94/18 139/17 149/16</p> <p>recommend [1] 48/14</p> <p>recommendation [4] 3/12 21/11 24/9 151/17</p> <p>recommendations [4] 49/2 189/3 190/23 191/1</p>
----------	---	--	--	---	--	---

R	12/10 144/20	reinforce [2] 58/19 167/9	58/1 141/13	requirements [5] 38/22 50/5 81/8 116/25 166/5	28/16 29/10
recommended [1] 23/18	referencing [3] 11/22 17/18 17/19	reinforced [3] 134/10 141/12 162/13	remits [1] 133/21	requiring [1] 112/11	return [2] 71/5 183/24
recommending [1] 68/23	referred [6] 37/1 88/15 91/15 100/9 113/17 173/3	reintroduced [1] 171/4	removal [1] 130/10	research [7] 71/20 74/3 88/6 99/15 100/10 171/14 183/16	returned [2] 71/23 174/9
reconstituted [1] 31/17	referring [8] 64/5 69/13 91/1 94/2 116/3 140/21 157/15 172/10	reiterating [1] 66/12	render [1] 104/19	reserves [1] 65/23	returns [1] 81/13
reconstituting [1] 31/10	refers [20] 5/20 11/3 23/2 23/11 23/12 24/24 63/13 68/24 73/9 73/16 77/6 91/19 93/23 94/8 111/20 112/5 112/6 115/4 117/5 173/21	reject [1] 57/4	renewal [4] 1/19 50/3 131/6 131/19	resign [1] 130/7	revealed [1] 91/23
reconstitution [6] 5/2 16/25 17/13 21/2 23/23 46/8	reflect [3] 99/9 121/10 124/10	rejected [2] 47/24 135/16	repeat [2] 59/5 152/21	researching [1] 90/17	reversal [1] 70/7
record [6] 48/2 51/23 104/15 111/22 140/16 181/12	reflected [6] 38/13 48/17 57/7 68/12 122/9 154/13	related [3] 20/2 25/14 91/18	repeated [1] 31/4	resistant [1] 173/12	reversion [2] 62/12 62/16
recorded [2] 22/23 73/22	reflecting [5] 28/10 28/17 38/4 46/15 72/12	relates [1] 167/23	replace [1] 80/7	resolve [2] 148/21 148/24	review [9] 2/15 45/16 45/25 46/1 46/10 66/20 107/21 155/16 168/11
recording [2] 8/22 89/1	reflection [1] 83/22	relating [7] 21/23 23/23 36/11 96/19 130/2 132/6 186/15	replaced [1] 123/7	resolved [1] 149/20	reviewed [1] 1/25
recordkeeping [2] 187/15 188/4	reflects [1] 111/20	relation [20] 3/4 8/9 9/23 10/5 12/24 17/13 18/9 23/3 40/17 43/7 44/12 79/23 84/20 93/23 101/21 112/8 168/15 168/18 174/21 185/11	replacement [3] 113/1 155/11 155/12	resources [5] 69/21 69/25 100/2 100/2 126/15	reviewing [2] 1/15 76/9
records [7] 14/10 74/14 74/21 75/25 76/20 87/13 172/7	refreshing [1] 191/15	relationships [4] 52/22 53/4 156/21 177/18	report [14] 68/20 76/10 85/1 85/8 91/11 91/15 91/19 95/3 139/15 143/12 158/19 174/4 176/13 178/22	respect [7] 30/24 34/9 55/8 88/11 125/19 161/24 180/1	revised [1] 140/4
recover [1] 80/22	regard [5] 14/8 101/22 119/19 157/2 164/10	relatively [6] 68/1 102/8 107/7 122/11 126/17 151/9	reported [7] 8/1 93/10 93/22 107/8 107/11 107/22 160/23	respected [1] 136/3	revision [1] 50/8
red [4] 101/10 167/23 168/2 168/13	regarded [3] 84/3 103/25 108/3	relatives [2] 83/4 83/19	reporting [3] 73/10 73/16 89/6	respective [2] 133/21 159/17	revisions [1] 68/25
reduce [3] 62/1 154/16 169/5	regarded that 8Y [1] 108/3	release [2] 58/21 112/3	reports [3] 71/14 94/20 109/7	respectively [1] 91/25	reward [1] 154/21
reduced [3] 67/3 169/8 169/8	regarding [2] 91/9 132/2	relationship [4] 52/22 53/4 156/21 177/18	represent [1] 152/22	respects [2] 80/9 97/25	RIAs [1] 6/17
reducing [6] 66/2 154/15 154/20 169/3 169/7 169/12	region [3] 91/10 96/13 146/23	reluctance [2] 150/11 152/15	representation [2] 68/24 133/16	respond [3] 59/8 83/7 166/24	RIAs [1] 6/17
refer [10] 33/11 35/11 100/12 106/23 107/3 113/21 115/8 115/12 139/12 147/21	regional [13] 56/7 66/8 75/11 79/3 79/5 80/21 89/10 89/24 95/20 97/12 119/16 142/24 146/15	relatively [6] 68/1 102/8 107/7 122/11 126/17 151/9	representative [5] 136/18 136/20 143/17 163/7 191/5	responded [4] 50/11 111/2 120/8 166/9	Richard [2] 184/19 185/9
reference [66] 6/4 6/5 7/25 8/13 9/5 9/13 10/1 10/12 11/6 11/12 11/15 12/1 12/5 12/11 13/5 14/18 14/20 17/23 17/24 18/3 18/5 18/15 18/22 18/25 19/1 21/10 25/5 26/7 26/23 27/3 27/5 27/8 27/14 28/6 28/25 30/7 30/15 30/15 34/1 34/20 40/4 44/24 46/25 47/18 48/6 48/12 55/4 56/21 57/24 58/16 64/10 64/14 66/20 66/22 68/20 69/5 74/11 88/19 89/15 90/2 107/16 111/23 116/22 148/7 152/19 158/2	regions [3] 64/3 65/4 120/24	relatives [2] 83/4 83/19	representatives [6] 108/13 108/14 140/11 163/23 190/17 190/22	responding [4] 113/15 118/25 121/7 121/25	Richard Gutowski [1] 184/19
referenced [2] 40/5 166/18	registered [1] 23/7	release [2] 58/21 112/3	representing [2] 160/5 160/24	response [13] 46/1 84/2 114/13 121/6 122/12 123/15 123/16 157/6 157/21 159/8 186/16 187/1 188/18	RICHARDS [5] 1/4 163/20 182/13 189/10 192/3
references [3] 12/9	regular [3] 22/21 179/25 179/25	released [1] 141/25	republishing [1] 22/17	responsibility [14] 33/4 34/15 34/16 83/16 97/10 124/20 126/5 164/6 164/9 164/10 164/14 164/18 177/16 190/4	right [76] 2/4 4/17 5/15 10/6 10/10 11/11 12/18 16/6 18/18 20/12 20/17 21/16 22/7 22/25 23/15 24/3 25/19 25/23 26/10 32/9 32/9 35/18 39/16 39/16 42/6 43/9 49/13 51/12 53/25 54/5 57/5 58/10 60/16 62/7 62/10 69/13 70/13 72/9 73/25 74/20 77/14 79/23 87/12 89/12 90/7 94/25 104/11 105/15 108/5 109/1 112/4 112/12 114/8 122/14 124/18 129/16 131/4 132/25 134/18 135/6 137/1 142/8 142/16 144/13 144/13 150/12 154/3 154/3 154/4 154/6 154/6 163/6 179/7 179/15 179/20 182/4

R	38/21	79/2 90/18 98/4 99/10	147/7 147/8 147/10	76/24 82/13 85/3 88/8	152/5 187/10 187/13
rise [1] 129/25	RTCs [1] 124/12	100/10 100/14 102/15	147/17 151/10 152/12	88/13 89/11 89/14	187/16 187/23 188/2
rises [1] 110/19	run [2] 74/3 174/11	103/3 105/10 105/15	153/7 153/10 154/1	91/13 91/17 93/21	188/2 188/5 188/11
risk [42] 5/6 7/15 8/11	run-up [1] 174/11	106/19 106/24 107/6	156/3 160/16 161/8	106/15 108/12 108/16	188/16 188/21 190/15
8/14 8/25 11/16 11/20	running [1] 156/1	111/5 111/6 113/17	178/14 182/7 186/16	108/18 110/12 111/19	September '86 [1]
15/3 19/4 34/14 37/5	ruthful [1] 110/20	113/22 116/6 119/17	186/22 187/2 187/6	112/7 112/17 113/14	113/20
37/12 39/22 41/21	S	119/19 126/1 126/3	Scottish [10] 62/25	115/2 117/7 118/10	September 1985 [1]
44/25 45/21 50/14	safe [6] 154/12	127/4 133/1 134/24	68/24 74/22 82/16	119/11 119/14 120/16	48/7
50/24 53/9 53/11 57/1	161/14 162/15 162/22	135/9 138/4 138/11	85/14 117/24 136/18	135/21 137/15 140/15	September 1991 [2]
59/18 77/8 86/7 86/9	167/1 177/24	142/2 142/13 143/22	140/10 152/13 187/7	158/14 158/23	150/22 152/5
87/4 100/24 101/8	safer [4] 161/24 162/7	146/19 149/15 149/21	screen [6] 73/15	Seedat [1] 187/20	sequelae [1] 60/6
101/9 101/14 101/16	162/15 167/11	151/5 151/6 152/21	120/17 137/7 137/8	seeing [1] 159/17	serial [1] 118/20
102/13 103/10 103/14	safety [22] 42/11	155/19 156/15 156/16	137/11 137/12	seem [4] 115/23	series [1] 48/19
154/15 154/20 164/7	46/17 49/15 129/4	158/20 159/8 159/19	screened [2] 5/23	153/3 156/19 169/24	serious [3] 101/8
169/5 177/8 177/22	129/15 129/16 130/11	163/4 163/5 165/20	13/15	seemed [4] 67/6	146/25 147/13
178/11 178/15	130/24 131/14 132/5	172/15 176/23 181/11	screening [11] 11/4	128/10 138/18 154/21	seriousness [1] 18/20
risks [31] 14/13 17/22	166/20 166/22 176/1	181/11 190/6 190/8	23/3 69/5 132/7 138/2	seems [8] 9/22 9/24	seroconversion [2]
19/12 19/17 24/12	177/8 177/13 177/14	saying [14] 37/10	144/25 145/15 145/19	16/11 63/18 67/19	70/18 86/17
32/25 33/3 33/3 34/8	177/17 177/19 180/1	37/13 38/24 47/8	146/6 146/7 148/2	89/5 94/4 122/21	seroconversions [13]
35/5 36/1 36/11 36/13	180/1 181/1 184/11	51/23 55/17 55/19	scrupulous [1] 71/10	seen [9] 4/8 10/22	88/2 91/2 91/7 91/10
36/16 38/11 38/18	said [35] 1/15 3/2 8/9	58/10 65/11 117/22	scrutiny [1] 156/25	22/14 49/22 53/25	91/13 91/18 91/20
40/25 41/9 42/18 44/7	9/23 39/2 43/12 52/13	118/3 158/24 161/1	searching [7] 6/2 6/11	57/25 122/3 161/9	92/9 92/11 92/13
55/11 164/24 165/23	58/8 58/13 59/5 59/15	161/2	6/16 6/18 6/19 13/18	166/18	92/16 94/11 94/16
167/5 167/5 167/17	67/4 69/20 94/14	says [27] 16/25 17/14	138/20	selected [2] 173/9	seroconverted [2]
176/4 176/10 180/5	101/21 104/24 116/12	18/10 23/4 25/24	SEB [1] 183/4	173/14	91/24 93/3
180/11 180/17	127/15 129/25 136/22	26/20 27/15 63/14	SEBTS [1] 86/20	selecting [1] 121/22	seroconverters [3]
risky [2] 161/9 161/15	138/23 140/22 140/24	65/21 69/19 73/17	second [29] 4/19 5/19	selection [3] 23/3	92/4 92/19 92/24
Rizza [2] 107/8 107/11	142/4 143/4 146/11	74/18 76/3 85/11	8/20 9/18 11/2 12/7	87/1 127/6	serum [3] 5/7 8/12
Rizza's [1] 125/3	147/18 156/12 168/12	88/11 89/16 91/21	13/2 13/6 13/11 26/20	self [4] 64/6 100/5	11/12
ROBERT [4] 1/3 186/4	168/17 171/1 171/7	92/2 92/17 94/2 112/9	32/16 51/17 52/2	161/6 167/25	servant [1] 187/21
190/7 192/2	174/16 175/24 191/10	113/3 113/8 116/24	61/18 64/12 68/24	self-evident [1] 64/6	servants [1] 190/6
robust [1] 153/7	same [16] 9/23 44/1	117/14 137/19 172/22	89/8 91/20 104/13	self-sufficiency [3]	served [3] 88/21
robustly [1] 152/11	81/25 91/6 102/6	says: [1] 59/16	107/5 110/15 111/5	100/5 161/6 167/25	156/20 182/1
role [12] 45/13 68/11	113/14 116/23 117/19	says: we [1] 59/16	115/14 135/18 143/25	send [3] 118/4 119/6	serves [1] 179/15
68/13 96/1 97/17	118/4 118/12 121/19	SBTS0000615 [1]	145/3 156/16 190/21	119/7	service [5] 63/1 63/1
97/17 129/3 132/4	130/7 133/18 142/3	68/3	191/2	sending [2] 90/3	70/2 138/2 168/8
133/1 134/11 139/17	173/19 181/20	SBTS0002189 [1]	secrecy [1] 151/12	119/12	services [9] 134/2
185/24	same-day [1] 118/4	19/24	secret [1] 141/8	senior [4] 133/13	134/2 134/6 141/21
roles [3] 133/21	sample [1] 16/13	scale [1] 181/13	secretariat [6] 51/22	139/21 141/24 182/24	142/24 146/12 150/21
133/21 188/8	samples [4] 118/20	scanning [1] 53/14	130/14 134/18 136/5	sense [19] 19/16	152/7 176/14
rolled [1] 114/10	170/4 171/3 174/15	scant [1] 101/4	139/6 139/18	37/24 72/9 72/14	session [1] 182/11
rollout [2] 174/21	sat [1] 134/8	scene [1] 168/6	secretary [11] 145/21	81/23 86/1 102/3	set [20] 31/21 32/17
175/2	satisfactory [2]	scenes' [1] 151/14	147/16 184/1 185/1	102/7 102/9 102/17	48/19 61/10 81/15
room [1] 174/18	141/24 150/20	science [1] 138/9	185/6 185/19 185/20	102/23 104/24 132/12	85/8 99/21 99/23
Rotblat [2] 136/8	satisfied [2] 150/17	scientific [3] 41/17	186/13 186/20 186/22	160/5 160/23 161/12	99/24 102/12 117/12
136/11	150/23	151/20 157/4	187/18	162/20 175/7 177/21	120/1 132/13 133/23
roughly [2] 14/21	satisfying [1] 38/22	scientifically [1] 39/5	section [4] 11/11	sensible [2] 63/18	134/5 152/18 155/22
170/7	Saturday [1] 73/17	scientists [1] 53/4	73/14 104/9 183/20	180/20	155/25 156/2 170/1
round [2] 111/24	saving [1] 57/4	Scotland [61] 6/6 15/1	security [2] 157/12	sensitive [4] 6/7 7/2	sets [1] 149/10
136/17	saw [7] 25/4 66/7	57/9 57/22 62/11	184/4	11/6 27/19	setting [4] 32/6 58/20
route [1] 124/15	90/15 95/3 120/22	69/16 77/19 81/16	see [70] 1/10 4/25	sensitivity [5] 6/21	73/4 97/14
routes [1] 117/23	178/17 180/6	82/4 84/14 88/16 91/7	5/12 5/19 7/22 8/6 8/6	7/13 8/24 54/10 56/22	seventh [1] 145/8
routine [3] 7/6 14/25	say [81] 30/13 32/20	91/22 92/4 92/7 92/8	8/15 9/18 9/20 10/2	sent [8] 81/14 117/20	several [2] 76/4 76/8
53/14	34/17 35/13 38/24	92/10 92/24 93/25	11/2 12/6 14/10 15/20	119/16 120/18 166/19	severe [1] 123/8
routinely [3] 6/12	39/2 39/3 41/5 41/6	95/19 102/22 109/13	16/24 17/4 18/8 18/13	174/5 174/8 174/8	severely [1] 63/19
37/23 123/7	41/16 43/20 43/23	115/6 115/16 117/1	20/2 20/13 20/22	sentence [8] 8/22	severity [1] 161/25
Royal [3] 84/11 94/7	43/24 44/11 45/15	117/8 117/23 120/5	21/19 22/23 23/1	12/7 13/6 17/13 48/3	shall [2] 153/16 191/1
94/14	45/23 47/11 48/11	121/10 121/12 121/17	24/13 24/24 25/19	69/12 85/20 157/8	shape [1] 144/8
RPH [1] 6/18	51/18 53/3 53/21 54/1	122/6 123/3 123/6	27/12 28/1 31/20	separate [1] 156/6	share [3] 129/13
RTC [2] 34/12 38/21	56/24 57/13 58/12	123/18 123/20 124/25	43/25 57/7 62/25	September [19] 48/7	143/12 156/17
RTC colleagues [1]	61/3 62/7 65/5 77/9	125/21 126/6 128/6	65/17 66/16 66/18	90/1 111/12 113/20	shared [1] 144/4
		136/15 142/25 146/14	66/25 73/7 74/10	113/24 115/20 150/22	sharp [1] 137/20

<p>S</p> <p>SHHD [5] 147/18 151/25 152/13 152/14 153/10</p> <p>SHHD/Scottish [1] 152/13</p> <p>shock [1] 72/3</p> <p>shocked [1] 171/8</p> <p>shocking [1] 72/3</p> <p>short [12] 60/20 68/1 109/5 120/2 120/4 126/12 127/2 141/20 160/10 163/18 171/1 175/6</p> <p>short-term [2] 141/20 175/6</p> <p>shortcomings [1] 151/8</p> <p>shortly [1] 1/10</p> <p>should [62] 5/3 5/4 20/17 20/19 28/20 31/6 33/15 38/17 39/12 39/21 43/2 54/14 58/12 58/17 60/3 60/17 74/19 74/24 75/12 79/14 80/22 81/13 81/17 83/4 83/6 83/7 83/12 83/19 83/22 85/13 97/23 98/20 110/22 111/11 115/23 118/9 119/4 121/3 121/13 122/6 122/16 123/24 124/20 124/24 125/10 125/11 127/1 127/5 127/13 137/14 141/18 147/6 147/15 149/18 153/8 153/10 157/11 159/2 159/4 159/5 165/8 166/24</p> <p>shouldn't [4] 44/6 55/10 126/15 149/2</p> <p>show [1] 62/20</p> <p>shows [2] 95/8 110/18</p> <p>Sick [2] 94/7 94/14</p> <p>side [11] 7/18 9/2 9/8 9/24 12/5 13/5 13/10 14/10 27/13 27/24 136/7</p> <p>sight [1] 189/14</p> <p>sign [1] 129/18</p> <p>signaling [4] 64/23 67/22 70/1 70/6</p> <p>significance [3] 21/22 108/25 168/22</p> <p>significant [8] 1/21 2/14 28/15 62/15 65/23 72/21 93/15 101/2</p> <p>significantly [1] 148/2</p> <p>signs [3] 87/10</p>	<p>110/19 125/4</p> <p>similar [18] 8/7 8/9 8/21 9/25 13/3 13/20 24/2 60/4 64/2 65/3 72/23 80/17 103/22 115/19 118/6 121/18 123/25 130/2</p> <p>similarly [1] 8/15</p> <p>Simmonds [2] 174/7 174/15</p> <p>simple [4] 23/8 31/22 119/21 130/5</p> <p>simply [17] 2/23 6/22 10/20 22/18 31/9 70/1 70/6 87/7 88/24 95/25 97/18 105/10 125/22 139/19 144/11 157/22 181/12</p> <p>simultaneously [1] 81/24</p> <p>since [2] 85/15 182/10</p> <p>sincerely [1] 181/22</p> <p>single [3] 68/23 146/20 147/6</p> <p>SIO [1] 83/9</p> <p>sir [20] 12/19 24/18 25/17 55/25 60/12 98/21 98/25 108/11 153/13 162/16 163/2 175/16 175/20 181/5 182/14 184/9 185/1 186/4 190/7 192/4</p> <p>Sir John Major [1] 185/1</p> <p>Sir Robert Francis [1] 186/4</p> <p>sit [1] 29/6</p> <p>site [1] 7/24</p> <p>sits [1] 184/24</p> <p>sitting [5] 76/19 129/24 182/12 184/7 184/22</p> <p>situation [6] 2/23 11/22 83/13 98/2 116/17 146/22</p> <p>situations [2] 154/17 167/3</p> <p>six [4] 48/19 73/10 95/22 189/22</p> <p>sixteenth [1] 78/2</p> <p>sixth [1] 145/7</p> <p>size [7] 63/25 64/13 65/1 168/16 169/7 169/8 169/12</p> <p>sizes [2] 168/15 169/3</p> <p>skip [3] 26/14 92/1 107/24</p> <p>slavishly [1] 3/14</p> <p>SLC [1] 16/8</p> <p>slight [3] 7/23 8/13 102/18</p>	<p>slightly [13] 15/23 30/23 36/7 53/1 53/5 73/15 81/21 116/16 124/15 126/16 140/23 150/8 159/9</p> <p>slogan [1] 154/3</p> <p>small [9] 4/1 46/7 69/8 69/9 107/8 117/23 120/24 122/12 126/17</p> <p>Smith [9] 101/23 107/1 108/19 116/2 116/14 117/7 119/3 119/12 124/17</p> <p>Smith's [2] 109/8 120/9</p> <p>smoothly [1] 122/14</p> <p>Snape [10] 89/9 89/18 130/6 130/25 130/25 158/16 159/24 160/3 160/22 161/1</p> <p>SNBTS [58] 19/25 25/13 33/17 35/12 47/21 47/22 48/1 48/17 55/9 55/20 55/23 56/2 56/5 56/15 57/8 57/22 58/17 61/7 63/20 64/2 64/7 65/3 65/23 66/17 66/20 68/14 68/17 70/16 70/25 73/21 82/12 87/20 91/18 91/23 92/12 94/10 95/6 100/2 106/21 108/14 125/1 143/19 143/19 152/11 153/6 155/22 158/5 159/25 160/5 160/13 161/13 162/5 162/14 166/8 174/2 174/6 174/13 181/17</p> <p>SNBTS/PFC [1] 106/21</p> <p>so [264]</p> <p>so essentially [1] 74/11</p> <p>so-called [1] 96/2</p> <p>Social [1] 184/4</p> <p>sodium [2] 21/1 23/20</p> <p>sold [1] 30/4</p> <p>solidified [1] 143/5</p> <p>solution [5] 5/4 5/6 125/12 130/4 132/22</p> <p>some [62] 1/25 2/15 3/18 4/4 4/6 7/22 21/18 29/17 30/9 32/10 33/6 40/16 49/16 56/25 58/5 58/16 67/21 71/2 72/11 73/7 76/5 83/18 97/25 99/10 99/11 110/6 110/10 110/13 112/24 117/15 117/17</p>	<p>118/4 123/7 126/19 126/20 128/16 132/9 132/16 141/20 141/22 142/22 148/3 148/7 150/1 152/19 153/2 156/12 166/17 167/12 173/5 174/7 174/9 174/19 177/22 179/17 180/4 182/10 182/17 187/10 189/12 189/17 190/12</p> <p>somebody [6] 120/11 124/24 125/9 125/11 126/19 179/4</p> <p>someone [7] 22/1 24/14 25/10 32/4 74/19 119/6 152/22</p> <p>someone's [1] 21/19</p> <p>something [12] 39/4 43/20 49/14 59/15 63/7 86/15 96/25 127/5 127/9 127/10 127/20 138/7</p> <p>somewhere [3] 31/11 39/18 40/5</p> <p>soon [4] 117/3 158/19 176/6 186/8</p> <p>sooner [3] 15/14 98/20 99/23</p> <p>sophisticated [2] 7/3 31/21</p> <p>sorry [25] 4/20 11/2 16/5 24/8 25/22 36/8 44/19 51/18 64/20 73/14 77/2 79/14 79/18 79/21 81/21 109/17 110/14 112/20 119/6 142/9 165/7 169/15 170/9 170/17 185/16</p> <p>sort [8] 41/21 54/20 97/24 126/18 132/3 155/16 157/23 168/6</p> <p>sorts [1] 120/6</p> <p>sought [2] 121/19 131/18</p> <p>sound [2] 44/9 108/1</p> <p>sounds [1] 42/25</p> <p>source [1] 157/17</p> <p>sources [1] 163/25</p> <p>South [3] 84/14 92/3 92/8</p> <p>South-East [2] 92/3 92/8</p> <p>speak [1] 81/10</p> <p>speaking [1] 168/9</p> <p>special [5] 68/5 113/25 114/12 114/15 165/10</p> <p>specialist [1] 154/25</p> <p>specific [12] 33/13 48/6 68/13 87/2</p>	<p>114/13 121/8 121/8 121/23 131/25 148/14 158/7 167/15</p> <p>specifically [1] 139/15</p> <p>specification [4] 1/22 30/11 30/15 51/4</p> <p>specifications [1] 3/20</p> <p>specificity [1] 149/1</p> <p>speculation [2] 39/8 42/15</p> <p>spell [1] 36/11</p> <p>spelling [1] 36/12</p> <p>spent [2] 76/8 163/14</p> <p>spinning [2] 159/15 160/19</p> <p>spoke [1] 12/16</p> <p>spoken [3] 117/7 119/3 127/14</p> <p>spontaneously [1] 50/9</p> <p>stability [1] 173/10</p> <p>staff [22] 44/23 80/21 110/21 166/19 167/10 167/13 167/16 167/21 175/24 176/4 176/7 176/12 176/15 176/20 176/21 178/18 178/19 178/20 179/23 180/7 180/17 180/18</p> <p>stage [23] 12/2 27/6 41/1 41/17 42/19 42/20 42/23 58/5 70/3 71/17 73/24 74/1 74/4 75/3 87/3 98/5 99/17 102/8 104/2 108/21 109/6 179/6 179/12</p> <p>stages [1] 152/20</p> <p>staging [1] 73/7</p> <p>standard [4] 42/4 114/24 155/12 177/25</p> <p>standards [4] 29/11 32/22 59/23 175/11</p> <p>standing [1] 138/12</p> <p>start [8] 4/11 25/20 29/20 32/13 88/3 110/8 152/4 182/23</p> <p>started [6] 1/6 101/25 122/4 122/11 169/19 189/19</p> <p>starting [2] 147/1 148/5</p> <p>starts [1] 189/18</p> <p>state [25] 11/9 14/2 20/23 21/12 26/13 26/17 30/12 30/21 37/14 39/4 41/17 145/21 147/16 172/6 184/1 185/5 185/6 185/17 185/20 186/12 186/13 186/20 186/22</p>	<p>186/24 188/13</p> <p>stated [1] 133/24</p> <p>statement [18] 32/14 39/13 39/25 44/1 44/17 53/2 83/10 89/5 98/19 100/7 138/8 144/24 150/25 158/21 159/4 160/17 172/19 191/12</p> <p>statements [15] 3/2 32/21 33/18 33/22 53/16 61/1 106/16 156/23 158/5 159/12 159/15 160/9 160/19 190/12 190/15</p> <p>states [4] 20/15 26/22 72/18 148/10</p> <p>stating [2] 28/7 38/10</p> <p>stay [1] 25/22</p> <p>stealing [1] 126/15</p> <p>steeply [1] 171/13</p> <p>step [2] 82/2 175/14</p> <p>steps [3] 100/17 158/18 168/4</p> <p>stick [1] 10/21</p> <p>still [22] 14/6 29/1 41/14 41/14 42/17 46/14 68/2 72/17 78/1 98/15 101/15 101/15 102/25 122/22 135/22 137/8 148/25 155/23 155/23 161/20 161/25 179/12</p> <p>stipulated [1] 28/1</p> <p>stipulations [1] 49/2</p> <p>stock [10] 65/12 78/20 80/14 80/24 81/25 114/7 119/8 120/24 171/17 171/24</p> <p>stocked [1] 80/24</p> <p>Stockholm [1] 169/2</p> <p>stockpile [2] 90/4 171/6</p> <p>stocks [19] 64/1 64/14 64/23 64/25 65/1 65/6 65/13 65/14 66/10 79/9 79/13 80/23 80/25 81/1 82/7 82/22 95/17 96/6 98/3</p> <p>storage [5] 5/2 21/7 24/5 28/4 174/17</p> <p>straightforward [3] 119/22 130/5 132/19</p> <p>strange [1] 16/11</p> <p>strategy [6] 61/8 62/8 62/11 135/15 151/24 167/24</p> <p>strictly [2] 117/15 129/20</p> <p>striking [1] 57/25</p> <p>stroke [1] 154/20</p> <p>strong [1] 137/22</p>
--	--	---	---	--	---

<p>S</p> <p>strong-minded [1] 137/22</p> <p>stuck [1] 2/23</p> <p>studied [1] 36/3</p> <p>studies [3] 15/2 69/6 107/18</p> <p>study [12] 26/4 99/19 100/4 100/9 101/17 107/17 107/22 116/20 118/21 120/15 175/12 186/6</p> <p>subcommittee [9] 47/1 47/3 49/16 51/20 51/22 129/4 129/11 130/12 131/17</p> <p>subgroup [1] 29/8</p> <p>subject [2] 90/19 104/18</p> <p>subjected [2] 83/5 101/19</p> <p>subjects [1] 23/6</p> <p>submission [2] 38/7 102/5</p> <p>submissions [3] 189/5 191/9 191/12</p> <p>submit [2] 49/23 170/4</p> <p>submitted [13] 1/11 4/5 4/15 9/21 10/1 13/4 84/23 131/12 170/19 171/3 173/23 175/17 190/13</p> <p>submitting [1] 49/19</p> <p>subsequent [3] 21/15 77/18 128/10</p> <p>subsequently [5] 21/14 80/15 115/11 122/10 141/10</p> <p>substance [1] 163/12</p> <p>substances [3] 21/2 23/21 28/3</p> <p>substantially [3] 2/21 102/17 143/20</p> <p>succeeded [1] 128/2</p> <p>success [1] 121/12</p> <p>successful [2] 109/21 120/3</p> <p>successfully [1] 28/11</p> <p>such [32] 33/3 35/11 39/24 47/16 47/25 48/23 50/18 51/16 53/23 54/19 69/20 79/13 95/17 97/10 115/8 124/2 152/15 153/12 156/22 157/3 158/4 164/11 166/8 167/22 171/11 171/18 174/24 175/12 178/2 178/19 179/19 181/20</p>	<p>sufficiency [3] 100/5 161/6 167/25</p> <p>sufficiency' [1] 61/14</p> <p>sufficient [6] 7/12 8/23 36/15 44/7 52/7 163/1</p> <p>sufficiently [1] 38/10</p> <p>suggest [9] 24/20 33/18 39/21 143/7 143/25 153/19 162/18 162/24 170/5</p> <p>suggested [8] 37/4 47/22 59/1 65/22 83/17 103/20 113/4 137/19</p> <p>suggesting [7] 42/2 46/19 55/8 62/9 83/15 121/5 190/23</p> <p>suggestion [5] 47/24 67/2 114/9 133/3 169/13</p> <p>suggestions [1] 167/11</p> <p>suggests [1] 9/3</p> <p>suitable [2] 118/19 150/21</p> <p>suitably [1] 27/19</p> <p>suits [2] 178/3 178/4</p> <p>Sully [30] 4/12 5/10 8/5 13/11 14/16 20/4 23/17 25/22 26/9 27/24 31/1 33/23 40/21 44/20 48/4 60/25 62/6 70/20 73/2 73/14 100/8 106/18 108/15 113/7 119/2 134/23 142/11 151/2 153/21 161/3</p> <p>summarised [1] 92/4</p> <p>summarising [1] 40/13</p> <p>summary [1] 151/7</p> <p>summer [1] 187/8</p> <p>Sunday [1] 188/7</p> <p>supplementing [1] 120/14</p> <p>supplied [5] 48/16 58/2 114/1 114/3 137/2</p> <p>supplier [1] 54/19</p> <p>suppliers [1] 58/4</p> <p>supplies [6] 58/4 113/24 114/11 117/3 119/4 121/19</p> <p>supply [16] 56/6 60/3 72/21 80/19 115/17 115/24 116/4 117/23 118/17 119/22 120/4 120/24 171/12 171/25 180/15 191/8</p> <p>supplying [1] 58/7</p> <p>support [4] 54/4 54/6</p>	<p>56/19 103/24</p> <p>sure [39] 7/8 10/17 16/3 40/7 43/16 45/10 49/10 53/18 55/24 60/2 60/4 64/24 65/5 65/11 74/19 84/1 93/14 96/11 97/15 98/18 107/19 109/16 110/1 111/7 114/4 120/21 126/14 132/15 133/7 133/12 136/21 154/5 157/15 165/20 170/2 176/18 178/2 179/7 181/11</p> <p>surety [1] 157/14</p> <p>surface [7] 5/24 11/4 11/13 13/16 27/18 169/18 170/18</p> <p>surgical [1] 155/18</p> <p>surnames [1] 96/1</p> <p>surplus [2] 90/4 171/11</p> <p>surprise [2] 19/19 72/4</p> <p>surprised [2] 120/7 171/17</p> <p>surrounding [1] 85/1</p> <p>Surveillance [1] 183/16</p> <p>Susan [1] 188/6</p> <p>suspect [4] 77/11 77/25 80/13 118/13</p> <p>suspected [1] 176/17</p> <p>suspended [1] 171/2</p> <p>sustain [1] 97/19</p> <p>syndrome [2] 14/4 19/2</p> <p>syphilis [1] 23/11</p> <p>syringe [2] 31/10 31/17</p> <p>system [35] 1/14 1/20 22/20 29/14 44/10 51/8 56/5 59/16 59/25 61/25 66/5 66/11 81/15 87/24 95/9 95/13 95/16 95/18 96/2 96/14 96/21 97/19 98/14 114/6 130/3 131/8 148/17 148/25 150/18 155/16 170/1 171/9 171/25 171/25 175/9</p> <p>systematic [1] 2/7</p> <p>systems [6] 45/17 87/21 97/14 147/10 166/25 167/3</p>	<p>75/24 78/9 81/22 97/24 102/21 131/22 133/6 139/19 142/9 144/19 144/22 153/20 158/18 161/3 163/15 174/20 177/23</p> <p>taken [17] 41/25 48/5 70/14 72/23 75/1 85/4 86/22 118/20 125/10 140/3 146/10 149/8 149/18 150/13 160/10 166/12 176/9</p> <p>takes [2] 135/23 163/13</p> <p>taking [8] 35/18 35/23 45/8 128/21 146/12 150/7 165/3 191/7</p> <p>talk [8] 9/6 14/13 103/1 149/15 156/18 180/12 180/13 186/4</p> <p>talked [2] 36/1 98/13</p> <p>talking [16] 1/6 36/4 36/6 49/5 49/13 53/11 55/6 64/25 79/16 79/19 80/2 94/10 94/10 126/24 127/17 165/1</p> <p>talks [3] 29/11 35/10 150/2</p> <p>target [2] 33/8 102/19</p> <p>targeted [2] 19/15 29/15</p> <p>targets [1] 155/10</p> <p>TDs [1] 67/9</p> <p>tea [2] 163/14 163/15</p> <p>team [2] 104/12 187/21</p> <p>technical [1] 33/9</p> <p>technique [1] 6/10</p> <p>techniques [5] 6/2 6/21 7/3 11/6 13/18</p> <p>technology [1] 6/24</p> <p>Tedder [4] 74/3 74/13 135/25 185/9</p> <p>telephone [3] 71/13 111/21 117/2</p> <p>telephoning [1] 74/12</p> <p>tell [5] 14/21 109/16 153/24 176/4 177/11</p> <p>temperature [1] 174/18</p> <p>temporary [1] 169/4</p> <p>ten [4] 26/1 46/7 46/7 153/14</p> <p>tend [1] 24/19</p> <p>tended [4] 28/14 49/1 105/5 140/11</p> <p>tendency [2] 30/10 56/14</p> <p>tension [1] 134/13</p> <p>tenth [1] 145/11</p> <p>tenure [1] 131/24</p>	<p>term [5] 17/17 60/6 141/20 175/6 175/6</p> <p>terminology [2] 17/21 25/6</p> <p>terms [31] 1/10 10/15 24/13 52/11 53/13 59/22 72/3 79/14 81/1 82/20 82/21 84/5 86/8 86/12 99/19 105/15 109/21 109/24 127/6 128/8 131/3 137/1 144/15 153/25 161/9 162/8 162/10 166/12 171/6 181/1 185/10</p> <p>terrible [1] 56/12</p> <p>territorial [1] 133/15</p> <p>Terry [5] 158/16 158/20 158/25 159/3 179/15</p> <p>Terry Snape [1] 158/16</p> <p>test [11] 5/25 6/15 11/5 52/18 138/24 139/2 148/25 149/20 150/18 150/21 172/13</p> <p>tested [5] 13/24 14/20 170/8 170/11 170/16</p> <p>testing [34] 11/14 15/4 15/5 15/15 23/11 23/12 100/13 132/18 146/19 146/20 146/21 146/23 147/3 148/17 150/2 151/10 151/19 151/25 152/2 152/10 152/12 169/16 169/17 169/19 170/7 170/10 170/12 170/14 170/15 170/24 171/4 172/24 173/24 175/1</p> <p>tests [8] 7/12 8/23 26/3 27/16 27/18 29/23 150/19 170/20</p> <p>text [4] 22/5 40/24 111/3 119/2</p> <p>Thames [1] 89/10</p> <p>than [44] 6/16 6/18 6/19 15/14 17/22 19/18 20/3 26/1 30/9 34/25 35/24 37/10 41/10 49/3 49/19 50/5 63/20 72/7 72/19 79/1 80/12 92/25 97/1 99/21 109/8 124/13 125/12 131/18 132/13 138/20 139/2 140/12 142/20 143/1 148/3 150/22 151/20 152/7 161/15 165/4 168/2 171/22 181/10 190/20</p> <p>thank [31] 4/14 5/11 7/10 13/11 18/6 23/17 27/25 29/21 33/23</p>	<p>70/20 73/15 89/4 95/1 98/25 119/2 137/13 153/18 153/20 161/3 163/1 163/16 174/20 175/18 181/3 182/2 182/3 182/5 182/7 182/8 189/10 191/16</p> <p>thanks [1] 69/3</p> <p>that [974]</p> <p>that's [70] 1/7 6/4 7/9 7/17 13/20 18/18 21/6 21/17 22/11 24/2 31/20 32/9 32/9 34/11 34/11 34/20 39/4 39/7 39/18 41/4 41/21 44/10 45/8 53/12 54/5 54/22 58/10 64/16 65/10 69/13 69/18 70/1 73/25 73/25 74/20 75/6 89/4 94/25 95/11 102/5 105/1 106/3 110/23 112/22 113/12 114/15 114/25 115/25 116/22 121/5 121/23 124/18 124/25 126/8 126/18 129/16 135/6 137/7 138/25 140/13 142/5 144/13 146/9 150/14 161/11 162/9 179/20 179/20 180/3 191/3</p> <p>their [49] 23/9 26/3 26/4 34/24 35/3 35/6 36/13 36/15 43/7 54/3 54/15 56/20 57/13 58/3 58/23 59/6 59/6 59/9 59/22 66/10 80/25 81/2 81/10 83/19 84/5 84/7 89/25 95/25 96/4 107/1 118/21 120/15 126/9 134/11 145/1 146/12 146/15 147/2 160/4 163/7 163/22 165/5 166/11 166/11 168/11 173/10 177/24 181/21 191/5</p> <p>them [35] 21/18 25/3 29/17 35/1 38/4 49/20 50/8 57/18 74/23 83/14 95/24 103/14 105/5 109/16 114/2 122/24 128/9 132/22 138/12 143/13 143/22 153/16 157/22 163/11 163/12 163/13 165/4 165/5 168/10 176/2 177/11 189/21 190/16 190/18 191/9</p> <p>theme [3] 44/15 150/10 161/5</p> <p>themselves [2] 34/3</p>
---	---	--	---	--	---

<p>T</p> <p>themselves... [1] 40/15</p> <p>then [245]</p> <p>theory [1] 100/24</p> <p>therapy [10] 46/5 69/10 110/17 112/11 113/1 165/11 165/13 165/24 165/25 166/6</p> <p>there [265]</p> <p>there's [32] 4/20 16/1 18/14 18/21 18/22 19/1 19/6 19/11 19/11 20/9 20/12 21/22 25/4 27/2 28/6 66/20 74/11 77/1 85/5 85/9 87/20 88/19 90/12 91/3 93/21 99/22 116/11 117/24 133/3 148/7 149/2 191/11</p> <p>therefore [5] 14/6 20/17 42/20 107/7 125/9</p> <p>thermal [1] 173/10</p> <p>these [54] 4/7 7/12 8/23 15/20 18/3 19/13 19/13 19/24 20/2 21/17 22/14 27/2 29/18 30/11 30/24 32/2 33/1 33/2 33/3 36/1 37/22 41/22 42/15 46/18 51/21 56/10 56/12 62/24 74/15 74/16 80/14 83/3 86/25 87/25 91/12 96/2 107/18 109/7 114/1 118/12 120/20 126/1 134/1 134/25 148/22 148/25 151/10 155/18 157/4 157/10 180/3 181/15 183/9 187/10</p> <p>they [136] 6/11 12/10 19/16 22/12 22/21 24/12 28/15 28/16 30/16 35/2 35/5 35/15 35/25 36/1 36/2 36/2 36/4 36/17 38/5 39/2 43/1 43/25 44/3 44/3 44/6 50/9 50/10 50/11 51/5 53/17 54/9 56/15 56/20 58/3 59/3 59/4 59/8 59/10 60/7 62/25 71/20 79/3 79/13 80/21 80/22 81/7 83/21 86/23 95/24 96/4 96/7 97/16 103/13 103/25 104/1 116/14 116/15 116/16 116/18 118/7 120/8 120/14 120/25 123/3</p>	<p>123/13 123/13 125/18 126/6 126/7 128/6 128/6 128/7 130/12 131/22 131/22 131/24 133/15 134/14 137/21 138/19 139/7 139/14 139/18 139/20 139/21 139/23 140/6 140/11 144/7 144/9 144/11 146/13 146/15 147/1 147/2 148/24 150/18 153/2 153/7 155/19 157/5 160/5 160/22 161/21 163/23 165/17 165/18 166/16 169/25 170/5 170/20 171/2 173/8 173/8 175/4 176/10 176/12 176/25 177/5 177/21 177/25 178/2 178/4 178/4 180/9 180/9 180/9 180/20 180/20 180/20 180/21 180/21 180/22 182/1 190/18 191/5</p> <p>they'd [1] 122/23</p> <p>they'll [1] 182/21</p> <p>they're [6] 22/15 34/25 127/18 136/6 144/21 178/3</p> <p>thing [3] 62/9 126/11 157/23</p> <p>things [10] 2/9 22/14 46/18 71/10 81/24 132/21 168/5 178/2 178/19 190/11</p> <p>think [370]</p> <p>thinking [4] 79/13 97/25 157/23 163/10</p> <p>thinks [1] 113/3</p> <p>third [7] 33/15 61/24 76/24 88/10 108/15 111/5 145/4</p> <p>this [308]</p> <p>those [59] 2/2 4/8 6/8 19/12 33/20 36/13 47/4 47/24 48/21 49/1 51/21 54/20 55/21 59/10 60/1 62/8 71/17 75/23 78/1 93/3 94/16 96/20 103/19 114/17 114/24 120/6 131/13 134/6 139/8 140/2 142/23 144/4 145/14 150/22 152/21 152/25 153/2 162/16 163/5 163/9 163/11 164/15 166/13 168/5 171/16 173/12 175/16 175/17 176/12 176/13 180/17 181/25 182/20 183/5 186/9 187/11 189/20 190/14 191/1</p>	<p>though [11] 12/15 16/9 17/8 71/3 98/11 104/24 108/2 117/22 163/10 169/22 179/6</p> <p>thought [25] 6/17 42/17 55/5 60/10 63/9 70/3 71/15 73/12 83/21 86/19 97/1 97/6 116/15 125/11 127/16 128/4 138/8 138/25 149/22 155/22 155/23 160/8 175/14 178/12 181/22</p> <p>thread [1] 79/16</p> <p>threatening [1] 141/3</p> <p>three [20] 5/5 61/10 62/20 68/15 71/14 71/15 71/17 73/12 74/1 77/23 78/1 91/2 92/13 93/1 93/12 95/21 128/22 135/5 150/15 190/2</p> <p>three hours [1] 5/5</p> <p>three months [1] 128/22</p> <p>thrombosis [4] 8/14 9/7 14/14 15/3</p> <p>through [38] 4/10 20/10 21/18 21/25 25/3 30/5 30/5 38/14 43/13 48/10 48/21 49/19 56/2 61/13 65/19 71/9 84/25 87/9 93/19 99/7 104/17 110/4 110/9 114/1 114/3 128/3 131/13 133/3 133/11 144/19 149/9 150/10 163/7 168/25 177/24 184/12 185/6 191/4</p> <p>throughout [5] 57/23 59/3 72/5 82/4 151/10</p> <p>Thursday [1] 117/3</p> <p>tightly [1] 175/8</p> <p>time [87] 3/13 4/9 4/12 6/18 11/24 15/4 27/9 28/15 28/19 29/2 33/19 37/19 42/12 43/8 46/11 50/4 53/6 54/11 59/13 59/25 66/1 71/1 71/5 71/22 72/13 72/14 75/5 75/6 75/19 78/6 82/1 82/10 83/25 84/17 85/15 85/25 86/4 87/8 87/22 92/22 94/18 94/19 96/21 98/6 98/22 106/6 106/12 108/2 109/12 109/24 111/8 111/10 114/21 121/20 123/22 123/23 124/3 128/10 128/21 129/24</p>	<p>130/7 130/23 133/7 133/18 135/11 135/12 135/17 141/2 148/8 148/8 148/15 153/13 154/4 156/23 160/25 163/13 163/13 164/4 164/19 169/4 171/13 174/5 177/20 178/13 179/9 181/20 190/25</p> <p>times [1] 62/18</p> <p>timescale [3] 75/17 112/7 151/24</p> <p>timescales [1] 152/16</p> <p>timetable [2] 182/16 190/9</p> <p>timing [3] 12/18 12/22 90/6</p> <p>title [1] 68/9</p> <p>to [1167]</p> <p>to AIDS [1] 40/18</p> <p>today [4] 41/14 60/1 155/23 164/3</p> <p>today's [2] 59/23 175/11</p> <p>together [7] 106/23 134/14 134/17 139/19 159/16 160/19 189/15</p> <p>told [11] 16/18 20/5 67/12 72/10 83/19 83/22 119/15 124/10 134/15 177/7 178/12</p> <p>too [11] 52/10 82/1 97/2 97/3 109/9 113/4 118/8 127/13 171/2 175/3 189/12</p> <p>took [19] 3/16 6/8 10/19 31/22 39/11 47/16 84/10 126/10 126/14 132/22 135/4 139/16 150/14 157/21 160/2 165/13 167/7 167/9 168/4</p> <p>top [22] 15/24 20/5 20/12 21/20 22/1 24/15 25/1 25/10 27/24 61/3 65/25 69/1 69/2 99/18 104/13 138/4 149/4 150/3 150/4 151/22 159/7 173/21</p> <p>topic [32] 1/7 32/11 51/24 60/13 61/2 68/2 93/16 95/2 97/5 97/7 98/7 98/21 110/25 121/4 122/11 129/2 132/3 134/16 141/14 141/15 143/21 143/22 150/24 155/21 163/24 163/24 174/11 174/12 179/1 179/24 179/25 181/2</p> <p>topics [4] 37/23 68/17</p>	<p>162/16 189/16</p> <p>total [1] 77/19</p> <p>touched [1] 95/3</p> <p>towards [8] 7/19 18/23 66/2 68/19 104/13 112/3 151/3 167/24</p> <p>tower [1] 141/4</p> <p>traceability [1] 87/24</p> <p>trade [1] 35/14</p> <p>tragedy [1] 157/2</p> <p>tragic [3] 98/15 181/16 181/20</p> <p>trails [1] 103/17</p> <p>trained [2] 36/15 176/22</p> <p>training [5] 154/24 154/25 155/1 176/23 177/16</p> <p>transaction [1] 157/16</p> <p>transcript [4] 137/12 139/4 142/3 144/22</p> <p>transferred [1] 46/5</p> <p>transformational [1] 181/18</p> <p>transfused [2] 154/6 189/23</p> <p>transfusion [41] 23/10 26/5 56/8 63/1 66/8 67/10 69/6 74/22 74/23 75/11 79/3 79/6 80/21 81/4 81/7 88/7 89/11 89/14 89/24 97/12 97/22 98/8 119/16 133/19 134/4 141/21 142/24 142/25 146/12 147/2 150/21 153/23 154/1 154/2 154/5 154/8 154/12 154/16 154/23 155/6 168/8</p> <p>transfusionists [1] 137/21</p> <p>transitory [1] 7/25</p> <p>transmissible [3] 23/9 26/5 43/13</p> <p>transmission [13] 7/15 8/25 14/12 19/9 35/16 44/25 61/6 77/25 105/12 161/10 167/20 169/5 174/12</p> <p>transmissions [4] 35/7 93/22 93/24 94/6</p> <p>transmit [10] 28/21 37/13 37/17 38/25 42/21 94/21 108/3 109/25 178/9 179/13</p> <p>transmitted [7] 52/5 52/9 70/23 76/23 87/18 133/20 134/4</p> <p>transmitting [9] 5/6</p>	<p>7/13 8/11 8/24 29/1 42/20 94/8 109/22 161/21</p> <p>transparency [1] 188/4</p> <p>transparent [1] 142/20</p> <p>travel [1] 86/11</p> <p>Treasury [3] 184/2 185/2 185/21</p> <p>treat [3] 63/18 75/23 128/9</p> <p>treated [35] 2/18 2/24 10/6 10/16 10/20 10/25 11/8 13/8 14/1 14/18 14/25 16/20 17/6 17/15 18/23 48/6 81/17 82/3 82/7 89/19 94/11 95/19 101/12 110/7 110/18 114/22 115/10 121/1 123/8 125/8 164/21 174/22 174/23 175/1 179/10</p> <p>treating [5] 19/20 54/6 54/22 121/23 164/11</p> <p>treatment [42] 1/23 9/15 12/17 14/2 14/5 14/20 33/7 36/1 36/16 52/22 57/4 59/23 61/22 67/5 67/21 70/9 82/20 82/22 85/11 96/5 99/5 100/20 101/20 101/24 103/9 103/15 103/21 112/15 114/24 115/7 115/18 116/6 119/10 121/18 123/6 125/9 126/8 157/3 165/3 173/10 173/12 181/19</p> <p>trial [13] 107/4 108/19 116/8 116/9 116/19 116/19 117/9 117/13 117/16 118/1 118/7 119/5 120/12</p> <p>trials [2] 128/25 175/1</p> <p>Tribunal [8] 72/12 158/17 159/11 159/12 159/20 159/25 160/5 160/7</p> <p>tried [3] 101/17 117/2 173/11</p> <p>triggered [2] 119/24 125/12</p> <p>trouble [2] 32/19 112/8</p> <p>true [2] 44/6 102/14</p> <p>trust [2] 159/10 179/15</p> <p>try [10] 4/13 15/17 44/11 64/4 64/21 75/19 80/6 169/4 172/16 182/4</p>
--	--	---	---	--	---

T	68/10 85/10 88/10 96/24 104/14 128/15 156/24 under-exaggerate [1] 38/17 underline [2] 138/16 141/2 underlined [1] 141/11 underlining [1] 166/16 underlying [3] 45/24 166/21 176/23 undermine [2] 156/20 157/11 undermining [1] 157/13 underscored [1] 158/4 Undersecretary [4] 184/3 185/17 186/24 188/12 understand [30] 2/4 5/12 6/17 9/11 10/4 21/17 31/13 33/2 33/24 36/14 39/10 42/6 52/11 55/18 57/5 62/10 64/6 69/13 70/13 72/9 79/24 80/5 88/13 112/1 112/12 114/8 131/4 132/25 155/5 155/9 understandable [1] 54/9 understanding [25] 3/9 7/1 7/7 34/14 39/23 44/10 69/18 69/24 87/19 99/14 107/15 114/20 114/25 118/18 121/6 132/12 132/14 132/16 133/20 135/11 135/12 145/24 146/9 155/10 181/24 understate [1] 140/23 understated [1] 37/12 understood [7] 18/6 32/25 84/6 84/7 140/1 145/18 180/14 undertaken [5] 76/13 80/6 102/4 104/22 169/16 undertaking [1] 170/24 undue [3] 58/15 142/5 142/14 unduly [1] 138/9 unexpected [4] 72/10 85/14 85/20 86/1 unexplained [1] 152/3 Unfortunately [1] 9/13 unheated [5] 12/25 15/25 18/8 78/25 80/7 union [4] 177/7	177/11 177/12 177/12 unionised [1] 177/5 unique [1] 156/20 unit [2] 56/9 183/16 United [3] 43/11 72/18 148/3 units [5] 20/24 23/19 26/18 28/2 113/10 universal [1] 102/13 unless [1] 57/19 unlicensed [3] 116/14 122/4 122/8 unlikely [2] 54/2 119/9 unnecessary [3] 47/25 55/12 151/12 unnoticed [1] 190/11 unpick [1] 64/4 unreasonable [1] 115/23 unrelated [1] 156/6 untested [1] 146/24 until [15] 15/1 16/22 18/16 18/22 48/6 52/9 60/17 81/22 85/15 107/21 113/20 143/4 149/18 155/13 191/18 untreated [11] 112/25 114/16 114/22 116/18 120/11 123/2 123/19 126/8 128/8 128/14 128/18 up [73] 1/8 1/19 4/20 7/4 7/5 16/22 32/17 44/12 45/9 46/24 56/11 56/23 61/3 64/16 68/18 73/1 73/4 77/5 78/11 78/21 79/24 81/15 82/6 82/25 89/13 90/8 90/20 91/4 91/22 93/4 96/8 97/14 98/22 99/21 99/23 99/24 102/12 103/2 106/14 107/5 111/4 111/13 112/17 122/24 124/21 128/19 132/13 133/23 134/5 134/20 137/14 138/24 139/5 140/19 143/23 143/24 144/15 149/5 150/16 151/3 155/22 155/25 156/2 156/10 158/23 170/1 171/13 174/11 175/5 178/13 185/10 187/14 188/4 update [4] 15/10 50/8 82/18 189/7 updated [1] 66/9 updates [1] 22/21 upon [4] 96/6 100/1 139/14 149/12	upset [1] 180/6 urgency [8] 102/2 102/3 102/8 102/9 102/17 102/23 104/25 175/14 urgent [1] 151/20 urging [1] 150/5 URNs [1] 145/1 us [27] 10/9 14/21 15/18 15/19 34/21 35/5 36/2 38/5 41/25 58/5 67/12 68/7 69/24 72/10 86/3 88/13 95/12 99/25 105/2 124/10 147/9 150/19 153/24 159/4 162/13 178/12 179/11 USA [4] 52/3 85/16 94/9 148/18 usage [1] 18/9 use [28] 7/20 9/3 14/25 16/16 17/18 21/7 24/6 30/14 33/1 55/24 62/16 65/8 67/7 82/2 85/23 86/12 87/5 110/6 112/25 114/23 128/12 154/16 154/18 161/7 167/23 168/2 173/12 173/17 used [43] 2/22 3/3 3/5 3/7 3/15 5/5 5/21 6/15 9/14 13/13 16/22 23/5 24/3 29/15 38/14 38/19 46/13 48/23 71/20 75/23 78/11 79/24 80/17 96/8 118/19 123/5 128/13 128/15 128/18 139/24 154/19 155/6 155/11 155/17 169/21 172/12 172/13 172/15 173/2 173/4 173/4 173/5 176/14 useful [8] 30/19 118/9 156/19 158/25 160/8 173/7 174/19 189/7 usefully [1] 163/14 user [1] 58/12 users [2] 33/2 119/4 using [15] 7/2 11/5 13/16 16/15 17/21 34/23 53/17 87/21 124/1 126/7 155/12 155/20 165/4 172/17 172/24 usual [1] 120/9 usually [2] 16/12 80/11 utilised [1] 173/6	vaccination [1] 176/6 vaccine [1] 167/15 vaccinia [4] 172/9 172/12 172/15 173/4 vaccinia data [1] 172/9 Vaccinia is [1] 172/12 valid [3] 42/17 102/25 122/22 validated [1] 71/21 value [2] 157/4 157/10 various [7] 62/17 62/18 96/18 148/4 149/19 152/20 172/16 vCJD [3] 183/10 183/18 183/23 version [4] 9/11 18/4 22/7 24/23 versions [1] 6/20 very [71] 9/25 29/8 30/25 31/2 40/1 40/1 42/25 43/1 43/2 47/5 52/14 56/6 59/4 59/4 63/18 65/20 71/8 71/14 72/2 72/6 80/17 83/2 83/20 84/3 94/1 96/16 96/17 101/2 101/8 101/13 101/14 102/25 103/10 103/13 109/8 115/5 115/8 115/17 122/14 123/23 128/19 129/3 130/4 131/1 131/9 134/14 138/10 140/6 141/9 141/15 142/23 146/5 147/13 149/17 153/9 153/9 155/14 155/24 156/24 160/21 160/22 162/4 163/14 167/17 173/6 175/8 175/10 176/22 177/18 181/3 189/10 vi [1] 152/9 via [2] 124/8 128/4 vial [9] 15/20 16/1 45/19 46/6 46/14 169/20 173/21 173/25 174/4 vials [17] 4/1 46/7 46/7 78/12 80/1 89/25 113/10 115/18 116/4 118/18 119/7 119/12 119/16 120/5 120/5 120/17 174/9 view [47] 3/16 7/7 34/4 35/12 39/12 47/6 54/17 54/18 55/2 64/21 65/22 72/15 72/16 72/17 78/21 87/7 103/20 106/3 109/7 121/20 121/21	122/9 122/22 126/10 126/14 126/16 126/18 126/19 138/15 146/20 148/23 148/24 149/3 150/8 150/14 150/15 151/18 152/22 157/19 157/19 158/3 159/5 160/3 161/22 162/5 162/14 179/12 views [12] 41/12 41/14 50/1 53/5 59/6 64/7 66/10 67/15 83/2 131/13 135/7 143/20 vigilant [1] 181/1 vigorously [1] 141/12 VIII [59] 2/19 4/16 5/21 7/20 8/9 9/18 10/5 10/25 14/18 15/12 15/25 16/19 16/21 17/7 18/1 20/2 24/25 25/15 25/20 25/25 28/11 29/13 30/1 31/5 32/5 34/6 65/7 65/12 65/13 65/24 69/8 73/5 76/6 78/20 81/18 88/16 91/18 91/24 94/12 95/20 99/19 100/4 100/9 100/11 100/16 101/5 101/17 101/19 104/19 105/16 108/20 110/17 111/7 115/6 117/9 120/4 126/13 169/21 179/11 VIIII [1] 110/22 viral [7] 61/2 93/22 99/5 99/14 161/10 167/5 172/7 virgin [9] 108/24 110/7 112/15 115/19 116/5 118/19 119/9 120/25 125/8 Virginia [1] 185/4 Virginia Bottomley [1] 185/4 Virological [1] 132/5 virologist [3] 136/3 148/24 174/6 virologists [3] 34/25 138/10 138/17 virology [2] 138/1 185/11 virucidally [1] 113/19 virus [22] 14/11 17/2 18/12 24/1 25/8 26/25 28/25 37/14 59/18 60/2 100/3 100/17 103/7 103/7 104/20 108/22 161/21 162/8 172/12 172/14 172/15 176/21 virus-infected [1]
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V	164/15 was [678] wasn't [23] 2/7 15/13 30/12 31/21 37/15 40/13 67/21 84/14 97/2 100/3 101/2 105/10 121/20 124/6 132/19 137/3 139/24 141/11 141/11 157/21 160/2 167/8 169/6 watching [1] 163/8 water [3] 5/3 28/4 46/8 Watt [11] 4/16 6/7 7/8 42/11 45/4 45/5 46/16 46/24 47/3 51/18 129/22 way [27] 10/22 14/17 16/11 22/12 35/18 44/1 47/5 53/10 65/15 72/21 73/8 103/22 109/21 118/1 120/9 120/9 120/13 121/19 126/23 131/8 135/13 136/16 140/19 146/8 153/11 154/13 167/16 ways [5] 101/18 141/22 144/1 154/15 182/7 we [497] we'd [1] 82/6 we'll [5] 17/4 19/25 79/22 182/18 188/11 we're [6] 16/18 20/5 77/9 127/17 182/17 190/3 we've [10] 12/23 18/14 21/9 53/24 66/22 127/3 161/17 182/20 189/22 191/9 website [4] 182/15 186/10 187/12 191/12 week [25] 74/11 75/9 112/21 169/1 183/8 183/13 184/8 184/24 184/24 184/25 185/18 186/2 186/3 186/7 186/14 186/18 186/20 186/25 187/9 187/10 187/13 188/16 188/20 188/21 188/23 weekend [1] 74/8 weeks [10] 78/19 182/18 182/19 184/6 184/21 184/23 187/11 189/1 189/4 189/5 weight [3] 99/14 100/23 101/2 welcome [1] 63/20 well [63] 1/17 10/9 11/18 11/21 11/24 15/5 16/3 16/13 16/15	22/18 25/17 26/14 29/6 29/12 29/16 29/17 30/9 30/17 35/24 38/23 39/1 41/6 44/6 46/1 49/13 53/10 53/20 54/10 54/12 58/25 59/21 70/24 73/24 75/6 78/10 79/9 80/9 81/6 81/12 86/21 96/16 96/17 97/3 97/9 100/5 123/15 123/23 125/14 126/2 127/2 131/24 133/23 134/14 136/3 138/16 148/24 155/19 160/14 165/14 165/23 177/8 180/3 181/8 Welsh [1] 140/10 went [6] 34/5 43/10 52/12 122/14 124/17 134/10 were [236] weren't [7] 28/16 62/9 71/20 118/8 139/18 139/23 167/15 west [8] 69/16 91/7 91/22 92/4 92/7 92/10 92/23 123/20 what [135] 1/15 2/22 3/10 6/4 7/8 10/14 10/17 12/24 13/20 17/4 19/6 20/17 20/19 20/22 25/3 31/5 34/20 34/24 35/1 35/19 40/13 41/15 42/16 43/2 43/7 44/23 45/24 49/7 54/24 54/25 55/5 55/16 55/18 57/6 58/11 59/5 60/5 60/6 60/14 61/3 61/15 64/21 64/22 64/24 65/10 67/14 67/15 67/18 67/19 68/7 69/24 70/1 71/15 75/20 76/12 76/14 77/17 78/18 78/24 79/23 80/2 80/6 84/1 87/3 89/4 90/8 90/8 90/14 98/11 99/13 100/23 101/5 103/5 106/11 106/11 106/12 110/4 110/9 111/13 116/9 116/16 120/19 121/13 121/24 122/16 122/16 124/10 128/1 133/20 140/1 140/23 141/7 143/14 143/24 144/18 146/18 150/7 151/4 153/7 153/24 153/25 155/22 155/23 156/12 156/15 157/13 158/20 158/25 161/1	161/1 165/8 166/5 166/12 168/17 168/19 170/7 170/10 170/19 172/9 173/1 173/8 174/25 178/13 178/13 181/11 188/20 189/13 189/14 189/15 189/17 189/21 190/4 190/5 190/7 190/25 what's [10] 8/9 9/23 20/13 23/18 28/1 70/21 82/19 113/16 114/12 144/11 whatever [6] 30/20 71/25 148/19 165/12 170/20 178/10 when [64] 1/18 1/21 2/9 2/14 2/17 10/10 14/21 16/16 17/25 32/11 33/13 58/21 61/5 70/21 71/23 72/22 79/2 82/6 85/6 86/6 87/19 90/3 90/18 95/14 96/4 96/7 99/24 102/11 105/22 107/10 108/4 120/8 130/1 130/9 131/15 133/1 134/15 138/22 146/7 147/7 153/4 155/25 156/3 156/14 156/23 161/5 164/3 164/22 167/5 168/7 168/16 168/23 168/24 170/23 171/1 172/14 173/9 174/10 180/14 180/14 184/6 184/21 184/23 190/18 where [38] 2/19 11/22 16/5 39/21 44/7 53/12 56/24 57/23 58/2 62/21 80/24 82/5 90/10 97/9 116/12 116/17 116/24 123/18 135/14 137/3 146/22 147/1 148/16 149/24 157/18 162/3 162/4 167/3 167/3 171/3 172/21 173/15 176/12 180/3 182/20 183/25 188/21 188/24 whereby [3] 49/25 79/12 95/16 whether [53] 3/14 22/6 22/11 25/13 30/1 32/5 39/12 40/5 40/7 40/23 45/2 47/12 52/6 53/10 53/18 54/13 54/14 56/16 56/18 56/19 64/24 75/15 81/2 82/25 83/3 83/5 83/18 85/17 86/7 88/13 93/4 93/5 93/14	93/15 98/11 98/16 101/18 101/24 103/8 109/16 111/7 123/2 124/25 127/20 133/9 133/10 146/6 147/2 149/13 165/17 170/2 172/7 178/3 which [147] 3/18 3/19 6/10 6/16 6/21 7/4 9/16 10/10 11/19 15/7 15/8 15/12 15/19 15/24 16/2 16/12 16/14 18/4 18/7 19/6 21/4 22/22 23/2 24/2 27/10 31/2 31/5 33/9 37/4 41/10 42/11 43/3 45/18 48/13 49/20 51/24 52/18 53/14 53/21 54/11 54/20 55/7 55/20 57/2 57/3 57/16 58/19 59/16 65/7 66/13 66/21 67/1 68/9 69/17 71/2 71/15 74/6 75/20 75/21 76/7 76/22 77/10 80/17 82/10 83/3 87/14 87/17 88/4 88/17 88/22 90/4 91/12 93/6 93/9 96/21 96/22 99/9 99/11 100/25 101/12 101/25 102/3 103/10 103/23 105/17 106/20 106/24 108/2 108/18 111/8 112/8 114/23 116/19 118/8 120/10 121/20 122/24 125/14 125/18 126/16 131/17 131/17 132/23 133/19 135/19 137/16 138/3 140/19 141/16 142/6 142/25 143/9 143/13 143/25 145/14 147/20 152/25 158/19 159/13 160/24 161/19 164/23 165/22 166/4 169/23 171/12 172/20 173/5 173/6 173/16 175/14 175/22 176/19 177/2 177/3 178/1 178/18 180/5 181/17 181/19 189/24 190/3 190/11 190/12 191/6 191/7 191/9 which particular [1] 177/3 while [6] 61/23 62/4 83/10 108/20 113/19 126/24 whilst [1] 171/9 who [55] 4/8 23/6 26/2 29/5 55/9 55/13 58/7 71/16 77/6 77/15	87/13 91/24 94/22 95/19 97/9 97/23 103/13 110/16 112/15 115/19 117/15 117/25 124/16 124/20 127/9 127/10 128/2 128/16 130/6 130/13 130/25 134/8 135/4 135/4 136/2 138/10 140/11 141/1 144/4 144/6 152/22 163/5 165/3 174/14 176/14 179/5 181/25 182/21 184/17 185/16 187/4 187/17 187/24 188/6 188/22 whoever [1] 16/15 whole [11] 14/16 24/20 26/9 57/17 62/5 73/14 96/3 96/10 109/17 113/6 168/3 whom [2] 73/12 136/7 whose [3] 124/19 132/24 185/9 why [21] 12/4 21/17 28/9 31/24 34/17 41/3 54/6 96/20 99/20 99/23 102/21 114/2 121/14 125/15 126/14 132/12 142/17 144/12 148/12 149/2 159/22 wide [5] 121/10 122/17 141/15 147/18 160/6 widely [1] 29/15 wider [7] 38/13 56/1 100/2 125/20 128/12 141/25 166/8 widespread [1] 168/2 will [88] 1/10 1/18 3/6 12/3 12/19 15/22 20/23 21/12 24/17 25/17 27/12 38/8 38/25 40/3 40/6 43/5 44/11 48/9 60/17 61/23 62/3 65/17 68/22 85/3 88/8 91/9 91/13 106/2 107/24 111/14 113/19 116/7 148/1 157/5 158/19 158/22 158/25 159/2 163/1 163/8 163/14 163/23 173/13 181/23 182/3 182/15 182/23 183/2 183/10 183/13 183/21 183/25 184/6 184/7 184/13 184/16 184/21 184/22 184/23 184/25 185/8 185/13 185/18 185/21 186/3 186/9 186/11 186/19 186/23 186/25 187/3 187/4 187/4 187/8
----------	--	--	---	---	---

<p>W</p> <p>will... [14] 187/9 187/13 187/16 187/20 187/23 188/1 188/5 188/9 188/14 188/20 188/24 189/2 189/19 190/7</p> <p>William [2] 185/19 187/24</p> <p>William Connon [1] 187/24</p> <p>William Waldegrave [1] 185/19</p> <p>win [2] 116/17 116/17</p> <p>win-win [1] 116/17</p> <p>wish [4] 126/7 127/13 181/7 191/14</p> <p>wished [2] 30/16 30/20</p> <p>with [210]</p> <p>withdrawn [3] 78/7 88/20 94/5</p> <p>within [13] 1/14 5/5 40/24 41/8 62/11 68/14 72/1 109/13 133/14 134/5 134/6 159/25 161/13</p> <p>without [7] 35/22 41/19 41/20 42/1 44/5 54/3 115/5</p> <p>WITN3431004 [1] 158/9</p> <p>WITN69200001 [1] 100/7</p> <p>WITN6920001 [2] 151/1 172/19</p> <p>witness [7] 98/19 100/6 150/25 158/17 158/21 159/11 172/19</p> <p>witnesses [6] 182/18 183/9 186/7 187/4 188/19 189/15</p> <p>won't [4] 8/19 26/15 84/20 159/6</p> <p>wondered [1] 65/10</p> <p>word [3] 9/20 9/20 85/23</p> <p>wording [13] 1/13 2/21 3/3 3/4 3/7 3/7 3/15 3/22 4/1 38/18 38/19 40/1 46/12</p> <p>wordings [1] 2/22</p> <p>words [5] 3/5 31/2 99/16 150/1 189/11</p> <p>work [20] 43/1 72/7 74/7 95/18 99/5 100/9 101/22 101/24 102/4 102/6 102/25 104/21 131/1 131/25 141/21 142/23 150/16 174/7 180/21 181/17</p>	<p>worked [8] 44/10 81/12 95/13 96/16 96/16 131/8 134/14 135/15</p> <p>workers [1] 167/7</p> <p>working [10] 19/16 36/23 68/23 166/13 167/12 167/16 167/21 168/9 177/24 180/9</p> <p>world [3] 57/23 122/19 142/19</p> <p>worry [1] 83/5</p> <p>would [205]</p> <p>wouldn't [12] 2/12 4/8 22/18 47/3 60/3 65/12 77/11 101/8 118/10 118/13 127/23 127/25</p> <p>write [4] 68/23 76/9 105/4 115/16</p> <p>writing [3] 118/16 119/1 174/4</p> <p>written [13] 4/25 20/13 21/20 22/1 24/14 25/10 44/17 74/19 105/6 118/12 156/11 158/21 191/8</p> <p>wrong [5] 38/10 71/2 136/16 154/9 154/10</p> <p>wrote [14] 66/7 66/8 73/3 91/5 111/19 112/21 115/2 116/2 116/12 119/15 138/7 174/16 178/17 179/22</p> <p>Y</p> <p>year [11] 22/9 66/3 87/6 91/2 91/6 96/25 139/3 171/4 178/24 182/17 189/9</p> <p>years [5] 2/6 29/7 132/22 138/12 144/14</p> <p>yes [168] 1/5 1/24 4/18 4/18 5/11 5/17 10/7 10/12 11/1 12/3 12/14 13/1 13/22 13/22 14/23 15/8 15/21 15/23 16/11 16/23 17/3 17/9 17/11 17/11 17/20 18/18 18/18 18/25 19/4 19/21 20/21 21/14 21/16 21/16 22/16 22/23 24/4 24/13 31/8 31/12 32/1 32/1 32/15 34/4 36/6 37/8 40/3 43/19 49/4 49/9 49/9 49/10 49/18 50/2 51/5 52/1 55/15 58/25 60/16 61/17 63/5 63/8 63/10 64/10 64/20 66/7 66/11 66/24 69/16 69/22 73/6 75/6</p>	<p>75/24 77/2 77/4 77/20 78/5 78/13 79/20 80/5 86/10 86/14 87/16 87/23 88/1 88/9 94/13 95/5 95/15 98/24 104/8 104/12 104/23 105/19 106/2 106/6 106/6 108/8 109/6 109/23 110/25 111/17 112/5 112/7 112/16 112/23 113/11 114/14 114/17 114/18 118/2 118/6 124/14 124/14 124/18 124/18 124/22 127/2 127/22 131/8 131/21 134/19 135/6 135/12 136/3 136/18 138/16 139/9 139/14 140/13 140/23 143/1 143/15 144/2 144/13 145/25 146/5 146/9 147/25 152/25 154/2 158/1 158/2 160/12 160/14 160/16 161/11 163/20 164/18 165/12 168/21 168/21 170/19 170/22 171/23 172/4 173/4 174/16 176/3 176/6 177/6 177/9 178/17 179/4 179/6 179/20 179/20 181/3</p> <p>yesterday [9] 1/6 33/12 37/2 66/8 70/11 90/5 124/11 161/5 168/15</p> <p>yet [7] 72/20 163/9 179/13 186/8 186/17 188/20 190/13</p> <p>yield [1] 171/15</p> <p>you [440]</p> <p>you'd [4] 116/3 120/19 178/24 190/24</p> <p>you'll [3] 21/19 93/21 114/11</p> <p>you're [11] 33/25 36/4 55/16 79/19 79/22 111/13 113/15 119/1 122/14 147/20 150/3</p> <p>you've [18] 22/14 32/17 50/15 52/25 55/4 57/6 96/22 119/2 119/3 119/5 119/16 119/25 152/18 168/17 178/12 182/6 182/6 190/3</p> <p>young [2] 63/18 110/16</p> <p>your [76] 3/2 3/9 29/3 36/21 39/8 40/16 40/20 41/2 41/6 43/9 45/2 45/13 49/23 51/15 51/17 55/25</p>	<p>58/21 61/1 62/22 64/13 70/21 71/25 73/24 75/13 78/17 88/24 91/10 95/8 99/13 100/6 106/15 108/16 109/12 109/19 115/24 116/25 116/25 120/22 126/19 126/24 129/3 129/12 132/4 133/20 134/20 135/11 136/22 136/23 137/5 138/3 138/5 138/15 139/8 139/17 140/20 140/20 142/2 143/7 144/24 145/23 147/21 147/22 149/6 149/9 149/15 150/24 152/18 152/22 153/22 159/8 161/5 164/2 164/25 171/2 171/7 172/2</p> <p>yours [2] 28/19 116/23</p> <p>yourself [3] 19/7 124/5 135/24</p> <p>Z</p> <p>Z8 [4] 106/7 106/7 112/3 112/6</p> <p>zoom [5] 9/10 27/23 69/2 69/3 119/2</p> <p>Zubeda [1] 187/20</p> <p>Zuckerman [1] 135/25</p>		
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