

Wednesday, 29 January 2025

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2 (10.00 am)
3 **LADY HALLETT:** Ms Carey.
4 **MS CAREY:** My Lady, good morning. The first witness this
5 morning is Ms Sarah Moore.
6 **MS SARAH MOORE (affirmed)**
7 **Questions from COUNSEL TO THE INQUIRY**
8 **Q.** Ms Moore, your full name, please.
9 **A.** My name is Sarah Esther Moore.
10 **Q.** Thank you very much for the statement you provided to
11 the Inquiry which will be published later today, dated
12 21 October 2024, and you're going to help us, I hope,
13 with some issues relating to the Vaccine Damage Payment
14 Scheme, or VDPS for short.
15 Can I start with your background, though, please.
16 Ms Moore, I think, is this right, that you qualified
17 as a solicitor in 2006?
18 **A.** That's right.
19 **Q.** You are now a partner at Leigh Day, and for much of your
20 career you've been involved in group claims for people
21 who have suffered injury or other forms of loss.
22 **A.** That's correct.
23 **Q.** And I think, in terms of relevance for this Inquiry, you
24 act for approximately 50 individuals bringing a claim
25 against AstraZeneca in respect of serious injuries or

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1 result of doing what the government asked us all to do.
2 They stepped forward and they were vaccinated and some
3 of them have borne a very serious, in fact devastating,
4 consequence of that through death or serious injury.
5 The Pearson Commission recognised this and
6 proposed/recommended that a compensation scheme was put
7 in place. However, there was a change of government
8 between 1978 and 1979, so legislation was hastily put
9 together by the Callaghan outgoing government, and then
10 the Thatcher government came in and that legislation was
11 never finalised or formalised. So what we have at the
12 moment in our Vaccine Damage Payments Act, and the
13 scheme that is devised under that Act, is, essentially,
14 a stopgap piece of legislation.
15 **Q.** Right.
16 **A.** It's never been properly thought through, and to date,
17 I think I can say this on the basis of the evidence that
18 that's been given in last three weeks: there seems to
19 have been a sort of governmental or institutional
20 inertia around this particular piece of legislation. It
21 has never been carried over the line in the way that the
22 Pearson Commission intended it to be and I think that's
23 something --
24 **Q.** Let me pause you there --
25 **A.** Sure, of course.

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1 death, which they submit was caused by the AZ vaccine?
2 **A.** That's correct.
3 **Q.** And no doubt through that work with them and, indeed,
4 other work that you've conducted, you have a knowledge
5 and understanding of the Vaccine Damage Payment Scheme?
6 **A.** Yes.
7 **Q.** All right. Can I ask you about the scheme generally to
8 start. We know that it was set up, I think, in 1979.
9 Ms Moore if it helps you, I'm at paragraph 16
10 onwards in your statement, where you say there were
11 three key features of the scheme: firstly, to improve
12 public confidence in vaccination; secondly, to recognise
13 the special case that the vaccine injured constituted
14 a group who had been injured and therefore as a result
15 of being recommended for vaccinations, and I think you
16 say this: at the outset the scheme was only intended to
17 be an interim measure.
18 Can you just help with that last bit? In what way
19 was it intended to be an interim measure?
20 **A.** Yes, absolutely. So the Pearson Commission was tasked
21 with the job of looking at personal injury law in the UK
22 and compensation. One of the recommendations that they
23 came up with was to recognise the fact that vaccine
24 injured and bereaved constitute a special group. They
25 are a group of people who have been injured as a direct

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1 **Q.** -- because we may come on to look at that, but in
2 essence, is it that for the last 45 years there has been
3 no reform of that scheme although there have been
4 various changes that we may look at to the amount of
5 payment and, indeed, obviously, the inclusion of
6 Covid-19 vaccinations as falling within the ambit of the
7 scheme?
8 **A.** Yes, that's absolutely right. So it's essentially the
9 1970s safety net that was hastily put together by the
10 Pearson Commission and hasn't been changed since then.
11 **Q.** Just, briefly, it might be sensible to look at how the
12 scheme works.
13 If we could have up on screen, please, paragraphs 22
14 onwards in Ms Moore's statement.
15 We can see there you've helpfully set out the aims
16 of the Act and, indeed, the scheme as it exists is to
17 provide a single tax-free payment for those who have
18 been damaged, either through death or severe
19 disablement; it has to be proved on the balance of
20 probabilities to have been caused by vaccination, and
21 presently it amounts to an £120,000 tax-free award.
22 **A.** Correct.
23 **Q.** You set out there that in December of 2020 the
24 government announced that Covid-19 vaccines would be
25 added to the Act, and then you go on to deal with some

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1 of the detail of the scheme itself.
 2 If we look down, there are various criteria that
 3 need to be met, not just geographical, obviously the
 4 vaccine has got to be within the Act, which Covid-19 is.

5 And if one goes over the page, importantly in
 6 relation to severity of injury:

7 "... a person is, or was, immediately before his
 8 death, 'severely disabled' because of vaccination
 9 against any of the diseases to which the Act applies."

10 Now, we'll look at the disablement provision in
 11 a moment. Is this the position, though: that a payment
 12 under the scheme does not preclude the bringing of
 13 a civil claim?

14 **A.** Yes, that's correct.

15 **Q.** And I think you have seen some evidence provided by
 16 others to the Inquiry, including that by
 17 Professor Duncan Fairgrieve, King's Counsel (Honorary),
 18 who says that redress by a civil claims is challenging

19 --

20 **A.** Yes, absolutely.

21 **Q.** -- was his word. Would you agree with that assessment?

22 **A.** Absolutely. If I can just speak to that point very
 23 briefly. Yes, it's extremely challenging. Very many
 24 people will not have access to the kinds of litigation
 25 that are currently necessitated by the fact that the

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1 **A.** That's right, it's a strict sort of liability, no-fault
 2 scheme.

3 **Q.** All right. Now, I think you set out in your statement
 4 that in your experience over the last few years, and
 5 certainly over 2021 and 2022, there was a significant
 6 backlog in processing applications for Covid-19-related
 7 damages, and there was essentially a campaign of reform.
 8 Can I ask you about this: in your statement you say
 9 there was a review announced in May 2024 --

10 **A.** Yes.

11 **Q.** -- of the scheme. Is there any update that you're able
 12 to give us, Ms Moore, since then?

13 **A.** To some extent yes. So we work with a group called
 14 VIB UK, and you've already heard Kate Scott giving
 15 evidence in the course of these proceedings.

16 **Q.** Yes.

17 **A.** VIB UK were invited to a meeting with Wes Streeting, the
 18 Secretary of State for Health, in September.
 19 Mr Streeting has subsequently written to the group and
 20 said that he was -- you know, he's impressed by what
 21 they -- the evidence that they provided. He understood
 22 the need to look at this very carefully, and that the
 23 government would do so.

24 Now, we understand from an update received just
 25 before Christmas that that review process is going on

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1 Vaccine Damage Payment Scheme is not fit for purpose.
 2 These people have no other way to access redress apart
 3 from litigation, but litigation is not an option open to
 4 them. So for some people there is no option to litigate
 5 at all and for others it presents a formidable
 6 challenge, both in terms of the finances and the way in
 7 which the law is structured in this area.

8 So it is no mean feat to mount a case against
 9 a company like AstraZeneca, particularly in
 10 circumstances where we know they are indemnified by the
 11 British Government.

12 So these people who are vaccine injured and
 13 bereaved, these people who have paid the highest price
 14 for the vaccination programme, which we of course have
 15 all benefited from, are now being forced, because the
 16 Vaccine Damage Payment Scheme does not work, to take
 17 on the might of vaccine companies and the British
 18 Government.

19 **Q.** All right. I understand, therefore, that all the more
 20 reason to try to have a scheme that works for those that
 21 can't, for whatever reason, pursue a civil claim?

22 **A.** Yes.

23 **Q.** I think, is this the position though: that unlike
 24 a civil claim, there is no requirement to show
 25 negligence or any other wrongdoing under the VDPS?

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1 behind the scenes, but to date, nothing has come out
 2 of it. And I think you can understand, in the context
 3 of the way in which this legislation was formed in the
 4 first place, sort of hastily, as a stopgap measure, also
 5 as a result of the fact that a review was announced in
 6 May 2024 and nothing came of it, that there are some
 7 concerns that, whilst Mr Streeting's intentions may be
 8 very good, actually, what we need to see is action.

9 And these people cannot wait indefinitely. Many of
 10 them have waited, you know, four years already.

11 **Q.** Can we turn to the scheme itself. I think, Ms Moore,
 12 you're aware that Ms Scott, in fact, the witness who
 13 gave evidence to her Ladyship earlier, described the
 14 scheme as "too little, too late, too few"?

15 **A.** Yes.

16 **Q.** Pithy but apposite, I suspect you would agree?

17 **A.** Yes, quite.

18 **Q.** Can we look at some of those headings, though.
 19 "Too late", may I start with that, please. Are you able
 20 to give us a summary -- and if it helps you, I'm at
 21 paragraph 73 or thereabouts in your statement -- of why
 22 the application process is taking so long to force
 23 through the applications and provide the redress to
 24 those applicants?

25 **A.** Well, first of all, I mean, the fact that it is taking

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1 a very long time. If I can just speak to that in terms
 2 of the data, if that's helpful?
 3 **Q.** Yes, please do.
 4 **A.** So we know on the basis of a Freedom of Information Act
 5 response dated January 20205 that there have been
 6 17,519 applications to the scheme for those specifically
 7 injured or bereaved as a result of --
 8 **Q.** Can I pause you there, because I'm going to put up on
 9 the screen something which may help you and help
 10 everyone else follow the number and the state of
 11 applications in the scheme.
 12 Could we have up on screen, please, paragraph 76,
 13 which is at INQ000474459_20.
 14 And we're aware, Ms Moore, that there was a Freedom
 15 of Information Act request that gave us these figures,
 16 but I think if I understand you correctly they're
 17 updated figures?
 18 **A.** Yes, that's correct.
 19 **Q.** So as at 9 September they were just shy of 15,000
 20 applications, and did you say it's now --
 21 **A.** Just shy of 18,000, so 17,519.
 22 **Q.** All right. As at 9 September only 47% had been notified
 23 of an outcome. Is there an improvement or not, in that
 24 regard?
 25 **A.** Yes, so now there are 55% of decisions made. So 9,545,

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1 no doubt many.
 2 **A.** Yes.
 3 **Q.** The scheme was intended to provide prompt support. So
 4 clearly, those that have been waiting 12, 18, 24 months
 5 perhaps are not meeting that intended aim?
 6 **A.** Definitely not.
 7 **Q.** You set out in your statement that there were,
 8 pre-pandemic, four staff dealing with applications into
 9 the scheme. I think now there are something like
 10 80 members of staff. But can I ask you this: do you
 11 think that the government ought to have realised sooner
 12 that there was likely to be, given the widespread
 13 rollout of the vaccination programme, more applications
 14 being made, and therefore have more staff and resourcing
 15 in place at the outset?
 16 **A.** Yes, I think that's got to be the case, hasn't it?
 17 Logically, if you have an unprecedented vaccine rollout,
 18 then you are probably going to have an unprecedented
 19 number of adverse events. I don't think that's
 20 controversial to say.
 21 **Q.** Are you help us, Ms Moore, with some of the reasons for,
 22 perhaps, the length of time it's taking to process the
 23 applications? Clearly there's got to be an application,
 24 medical records of a sort -- what in your experience has
 25 been the reasons for some of the longer application

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1 we understand. So that's still 18,000 people without
 2 a decision.
 3 And just to speak to the point of the delays, of
 4 those 8,000 who are still -- or 8,000 approximately who
 5 are still waiting for a decision, 1,027 people have been
 6 waiting for 12 months; 438 people have been waiting for
 7 more than 18 months, and 126 people have been waiting
 8 for more than two years.
 9 Now, I know they are just figures on a page, but to
 10 animate those and to speak to the humanity of what those
 11 figures actually mean, we have people -- one gentleman
 12 within our group who has been waiting for two years. He
 13 suffered a very significant neurological injury as
 14 a result of one of the vaccines, and as a consequence of
 15 him having to wait so long to receive his £120,000 and
 16 his personal circumstances, he has been living in an
 17 elderly care home. He is in his mid-forties. And we
 18 now understand from the experts with whom we are working
 19 that that delay in accessing rehabilitation treatments
 20 has impacted his prognosis quite significantly.
 21 So it has a real world impact, this does, both --
 22 **Q.** Her Ladyship has heard some evidence, I think, indeed,
 23 from Ms Scott about the impact on her husband Jamie --
 24 **A.** Yes.
 25 **Q.** -- who can no longer work, to pick just two examples of

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1 processes that you've just told us about?
 2 **A.** I think obtaining medical records has definitely been
 3 a problem that the medical assessment panels have been
 4 experiencing. And, you know, as a personal injury
 5 lawyer, I have some sympathy with that, it can be very
 6 difficult to get hold of medical records, of course.
 7 But we are talking about a government service here, so
 8 you would think that there would be more ready access to
 9 those records.
 10 It is also important to remember that some of these
 11 people who are making these applications to the Vaccine
 12 Damage Payment Scheme are bereaved, so they are doing so
 13 where they have already been through an inquest,
 14 a coronial process, and they are making this application
 15 with the benefit of a confirmed death certificate which
 16 will say, on the face of the certificate, that the
 17 vaccine has caused the death. So, in those
 18 circumstances, it's very difficult to understand why
 19 somebody should be waiting 18 months for a medical
 20 assessment panel to make a decision about causation.
 21 And of course, very sadly, in a deceased case, you know,
 22 the extent of the disability caused is absolute.
 23 It's 100%.
 24 **Q.** There may be a distinction, then, between the way that
 25 the -- where people who have died are treated and they

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1 have a certificate that shows a link to the vaccine, and
 2 those that are injured and have a slightly different
 3 route through to receiving an award.
 4 **A.** Possibly -- sorry, but can I just say that my experience
 5 has been very specifically around something called
 6 vaccine-induced immune thrombosis with thrombocytopenia,
 7 so VITT --
 8 **Q.** VITT.
 9 **A.** -- which is accepted as caused by the AstraZeneca
 10 vaccine specifically, and most of the applications that
 11 we've assisted with have been in that context where
 12 people have submitted expert reports. So expert
 13 haematologists and neurologists reporting on causation,
 14 and it is still taking 18 months for those results to
 15 come through or those verdicts from the panel to come
 16 through.
 17 We know that the medical assessment panel have to be
 18 five years qualified but where you have coronial
 19 evidence or the best expert evidence in the country
 20 assisting them with causation, the delay does seem
 21 completely outwith what could be done here.
 22 **Q.** So there's potentially, or certainly at the beginning, a
 23 lack of resourcing in terms of people to, help the
 24 applications being made and processed. There is
 25 potentially delays in gaining access to records.

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1 **A.** Yes, so, I mean, I can try to explain the 60% but
 2 actually it's sort of beyond rational explanation,
 3 because this is a test that comes from, as I understand
 4 it, Social Security legislation -- I think it's schedule
 5 2 of the 1982 regulations -- where there is a list of
 6 percentages attributed to specific types of injury. If
 7 you look at that schedule, they're all in the context of
 8 amputations or visual impairment, deafness, I think is
 9 also listed, and you will see that 60% equals below-knee
 10 amputation. There is also a percentage for the
 11 amputation of a hand or a finger or a thumb or various
 12 other parts of the body, and that is the 60% test that
 13 is used at the moment for the Vaccine Damage Payment
 14 Scheme.
 15 Now, where we are talking about neurological
 16 injuries of the sort that Kate Scott outlined during her
 17 evidence, you can see that there is quite a big gap or
 18 quite a gymnastic calculation that needs to be done for
 19 the medical assessment panel to work out whether a brain
 20 injury the size of a credit card is equal or greater
 21 than a below-the-knee amputation.
 22 Now, quite why the scheme is still working with that
 23 calibration in place is very difficult to understand,
 24 but I think it must be very difficult for the medical
 25 assessment panel to make those calculations as well.

15

1 **A.** Yes.
 2 **Q.** Is there any other delay that you're able to point to
 3 to explain 18 months, 2 years of wait for some of these
 4 applicants?
 5 **A.** I think some of the problems also come to the point
 6 about how the disability test is made or the eligibility
 7 criteria for that, so perhaps I can speak to that.
 8 **Q.** Yes, I was going to come on to that, please. And it's
 9 really, I suppose, under the "too few" banner.
 10 **A.** Yes.
 11 **Q.** The criteria that need to be met, as I think was set out
 12 in your statement, is one of 60% disablement. Can you
 13 just help with what that looks like in the real world?
 14 What is really trying to be assessed there?
 15 **LADY HALLETT:** Just before you do answer Ms Carey's
 16 question, could I ask you to avoid naming specific
 17 companies because of litigation pending and --
 18 **THE WITNESS:** Yes, of course. My apologies.
 19 **MS CAREY:** Thank you, my Lady, and I'll try to be alert to
 20 that too, it's my fault, Ms Moore.
 21 Can we just come back to the too few --
 22 **A.** Yes.
 23 **Q.** -- and the disablement criteria and just help us with an
 24 overview of what really is being asked of the applicant
 25 in that part of the process?

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1 **Q.** At what point does 59% become 60%, or -- I follow.
 2 **A.** It's incredibly subjective and I think that also makes
 3 the scheme very opaque and it makes it very difficult
 4 for people to then trust the veracity of the results
 5 coming out and the people who are making the
 6 applications to the scheme are, of course, in extremis
 7 by definition. You don't make an application unless you
 8 feel you've suffered a significant injury.
 9 **Q.** You say in your statement, certainly on the figures as
 10 they were in the autumn of 2024, that of the nearly
 11 15,000 applications, 6,845 of those that had been
 12 notified of an outcome had claims that were rejected.
 13 And when a rejection is issued, does it tell the
 14 applicant "You've failed because you didn't meet the 60%
 15 threshold"?
 16 **A.** Yes.
 17 **Q.** Or does it tell you "You've failed because you didn't
 18 prove causation"?
 19 **A.** Both.
 20 **Q.** Both, right.
 21 **A.** It will tell you whether or not you've met the causation
 22 test, and you may meet the causation test but you may
 23 not meet the disability threshold. So you may fall
 24 below the 60%.
 25 **Q.** So may we take it that when you say in your statement of

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1 the claims that had been notified of an outcome, 97% of
2 those claims were rejected, is that because they didn't
3 meet the 60% disablement threshold?

4 **A.** That's both.

5 **Q.** Both, right.

6 **A.** So we know there's around a 2% acceptance rate, which
7 I should say is the lowest in the world, based on data
8 that's now coming out of Oxford University. We have the
9 slowest scheme in the world, based on that Oxford
10 University study, and we have the scheme with the lowest
11 acceptance rate as well.

12 But of the 9,000 -- now -- 351 rejected, around 416
13 of those people were rejected because they didn't meet
14 the 60% test. So those people receive a report from the
15 VDPS which says, "We accept that the vaccine caused this
16 injury, but you are not disabled enough to be eligible
17 for compensation of any sort or payment of any sort by
18 the government."

19 And, again, to speak to the humanity of that, that's
20 very difficult for somebody to understand why they are
21 45%, which in realistic terms may mean that their life
22 is devastated, they cannot go back to work, they cannot
23 care for their children, but that is not recognised as
24 being disabled enough for the purposes of the current
25 scheme.

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1 again, you know, your husband will never be able to go
2 back to work, you are a full-time carer and you have two
3 children, £120,000 is woefully inadequate. Nobody wants
4 to litigate. I can speak to that. I'm not going to
5 speak specifically about the litigation of course, but
6 nobody really wants to be taking on a vaccine company
7 and the British government. You know, they have other
8 things to do with their lives: pick up the pieces of
9 bereavement, care for those who have been -- you know,
10 who suffered devastating injuries.

11 **Q.** Can I just pause you there, because clearly you've
12 alluded to a number of potential problems with the
13 scheme: it's too slow, it's very difficult to
14 potentially satisfy the 60% disablement, and, on any
15 view, the 120,000 for people who have many working years
16 left and can no longer work is a drop in the ocean, if
17 I may put it colloquially.

18 **A.** Yes.

19 **Q.** Is there any appeal process for those who have had their
20 claims rejected?

21 **A.** Yes, there is, and actually the experience of people
22 with whom we've been working is that quite often they
23 are successful on appeal. But again, that's further
24 delay. And I think that also raises some doubt about
25 the validity of the initial assessments. There is a lot

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1 **Q.** Yes. Too little, please.

2 **A.** Yes.

3 **Q.** We know that the award was raised to 120,000 in 2007,
4 but there has been no -- even inflation adjustment since
5 then. I think you've assessed that if it had been
6 adjusted for inflation it would be, now, somewhere in
7 the region of £196,000?

8 **A.** That's correct.

9 **Q.** This is not compensation, I make that clear, but an
10 award to try to help the rehabilitation process, people
11 deal with whatever immediate needs they may have, but
12 clearly there are some people who may be so injured by
13 the vaccine they're unable to work again.

14 **A.** Absolutely, absolutely. And I think what we've got at
15 the moment is such a significant gap between what can be
16 achieved under the VDPS and what could be achieved
17 through civil litigation, albeit that path is very
18 difficult for people to tread, and impossible for some,
19 the fact of that gap is actually necessitating
20 litigation, because people have no choice but to
21 litigate.

22 I mean, if you're 59% injured and you cannot access
23 statutory compensation or statutory financial support,
24 then, you know, what are you supposed to do? And if you
25 are in a situation where, to take Kate Scott's example

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1 of subjectivity in this process, but yes, there is an
2 appeal, and --

3 **Q.** I think you've said if anyone wants to read more about
4 it, they can read it in your witness statement.

5 Can I ask about another couple of discrete areas
6 please. In relation to the scheme generally, do you
7 have any views or observations to make about the
8 awareness of the scheme and the profile that it received
9 or didn't, perhaps?

10 And if it helps you, I'm at paragraphs 50 and 51 in
11 your statement, Ms Moore.

12 Was there much publicity about the possibility of
13 making an application if you did in fact receive
14 a vaccine-related injury?

15 **A.** My understanding is that there wasn't. Certainly the
16 people with whom we were speaking at the beginning of
17 2021 and throughout 2021 were not aware of the fact of
18 the Vaccine Damage Payment Scheme. Quite rightly, the
19 government put a lot of money and energy into promoting
20 of the vaccines, encouraging people to come forward for
21 the vaccines, but I don't think there was any or perhaps
22 only a very small budget put into the Vaccine Damage
23 Payment Scheme, alerting people to the fact of that.

24 **Q.** Were you aware or are you aware of any publicity or
25 awareness raising that was aimed at ethnic minority

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1 communities or those that may face additional barriers
2 in accessing information? Do you know if any work was
3 done in that area to try to publicise the scheme to
4 people who may have been injured?

5 **A.** I'm not aware of any.

6 **Q.** And I think you say in your statement that initially,
7 the application was not easy to fill in, just the
8 practicalities of making --

9 **A.** Yeah, absolutely.

10 **Q.** -- an application. I think there was no way to apply
11 online?

12 **A.** No way to apply online in the context of a pandemic
13 where we were in lockdown and you couldn't leave your
14 house. You had to print out the application form, if
15 you had a printer, fill it out in ink, and then take it
16 to the post box.

17 **Q.** Clearly, some people prefer paper form, some people
18 prefer online --

19 **A.** But necessary to have the choice.

20 And also, there was no box for bereavement, so the
21 form as it was initially constituted didn't now
22 applicants to indicate that they were applying on behalf
23 of a deceased loved one, so they had to literally draw
24 in the box and tick it.

25 So that form was woefully inadequate. Little or no
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1 a serious injury or bereavement, and that was taken down
2 by Facebook because it was, we presume, flagged as
3 being, in some way, anti-vaccination, which of course it
4 was not.

5 So, no, I think people were left with nowhere to go,
6 and no clear pathway in terms of accessing financial
7 support.

8 **Q.** No. Do you know if now, in 2025, there are any services
9 provided to help an applicant fill in the form, Citizens
10 Advice, or -- that's not a lawyer?

11 **A.** Not that I'm aware of. I'm sure the great work that
12 Citizens Advice bureaus do -- perhaps there are people
13 available, but no, I'm not aware of any scheme put in
14 place.

15 I should say that the awareness of the scheme has
16 probably increased, the number of applications going
17 into the scheme has massively increased. So there is
18 probably better general awareness, but that general
19 awareness has been borne, I think, of headlines,
20 advocacy by groups affected, rather than any concerted
21 initiative by the government. As conceived of by the
22 Pearson Commission originally, the point of a Vaccine
23 Damage Payment Scheme, I think, was to shore up vaccine
24 confidence.

25 **Q.** Yes.

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1 thought, I think it's fair to say, was put into how that
2 form would work for people in the context of a mass
3 population vaccination rollout.

4 **Q.** I think the Inquiry has heard evidence, and certainly
5 you have seen in the documents provided to you, that in
6 Scotland the Scottish Social Security department
7 provided a service to help people complete the actual
8 forms. Do you know whether there was any additional --
9 sorry, any similar resources or services provided in
10 England and Wales and Northern Ireland?

11 **A.** Not that I'm aware of. And anecdotally, based on my
12 experience, I think that must be the case, because
13 people were coming to us as a law firm and asking for
14 help, and they were finding us through various routes,
15 and there were support groups, sort of grassroots groups
16 of people starting to get together and think: well, what
17 can we do here? And they formed, just like VIB UK,
18 their own support network, because there was nothing
19 institutional in place.

20 What VIB UK did try to do quite early on -- and
21 Hausfeld, the law firm I was with at the time, tried to
22 support this -- was to set up a website where people
23 could be signposted through the Vaccine Damage Payment
24 Scheme system and through the benefits system and all
25 of the mess, the necessary mess, that comes after

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1 **A.** It was seen very much as going hand in hand with, you
2 know, encouraging people to step forward for
3 vaccination. So it seems to me, if I can suggest, that
4 the government has missed a trick here. There could
5 have been concerted effort into saying: vaccines are,
6 for the most part safe, but when the worst things
7 happen, we will be there. There will be a meaningful
8 safety net.

9 And we haven't heard that narrative at all, as far
10 as I understand it, so far from the government.

11 **Q.** Can I turn, then, to a slightly wider issue. Clearly
12 there's a statutory footing for the scheme, but can I
13 ask you about, pending any statutory change which may
14 take a long time and would be very difficult to get
15 through government and Parliament, are there any
16 short-term or more immediate recommendations that you
17 would urge her Ladyship to consider to, perhaps,
18 ameliorate some of the problems with the scheme that
19 you've told us about this morning?

20 **A.** Yes, absolutely. I think we understand that any
21 statutory reform would be forward facing, and we
22 understand, based on discussions with Wes Streeting that
23 it would require a lot of Parliamentary time and that,
24 of course, would need to be done incredibly carefully
25 and that work must be done. But as a more immediate

24

1 solution here, there could be the possibility of setting
2 up a bespoke compensation scheme or support scheme
3 specifically for those who have been injured or bereaved
4 as a consequence of Covid-19 vaccinations. That would
5 be, I think, a swifter measure to put in place.

6 We know that there are, you know, a large number of
7 people who have been vaccine injured and bereaved. We
8 know that for a proportion of them, causation has
9 already been established. We know that some of them
10 haven't got any compensation at all because they've not
11 met that 60% threshold, but that is a defined group of
12 people for whom a proper financial support system could
13 be put in place now or quite rapidly, I would suggest.

14 We are very good in the UK at thinking up bespoke
15 schemes, you know, from the Thalidomide Trust back in
16 the 1980s, through to the vCJD, the mad cow, the
17 BSE bespoke scheme, right through to the infected blood
18 scheme. You know, we do have the wherewithal as
19 a consequence of academic work, legal experts, to think
20 through sensible schemes that balance the need to ensure
21 that people are given fair amounts of money to support
22 them but also are not too onerous on the public purse,
23 and recognise the fact these people, through no fault of
24 their own, have suffered these devastating consequences.

25 It could have been any of us. And I think as

25

1 **LADY HALLETT:** And what you're suggesting is that we move
2 from the award system, the grant system, to
3 a compensation system.

4 **A.** I think there is space in between. So at the moment we
5 have got, sort of, two completely juxtaposed situations
6 where we have a scheme that provides £120,000, or, as
7 I'm sure you know or your husband will definitely know,
8 for sort of significant neurological injuries you'd be
9 looking at millions of pounds of damages.

10 Now, there is probably some space in between there
11 and that gap could be closed, is my point. If we don't
12 close that gap, then litigation is going to be
13 necessitated, and I think that litigation is bad for
14 everybody. It's bad for the vaccine companies, it's
15 very bad for the people who are having to go through
16 that process, the people that I represent. But I think
17 it's also bad for public confidence and the wider, sort
18 of, public health policy point.

19 The government have indemnified the vaccine
20 companies, quite rightly, so they are paying out
21 through -- for the litigation which is ongoing, they
22 will pay out for compensation in the end if it's
23 successful. They're paying out through the VDPS and all
24 the administrative costs of that. That could all be
25 streamlined by having a sensible scheme that's put in

27

1 a society to move to do that would be, potentially, if
2 you'll excuse the pun, a shot in the arm for vaccine
3 confidence because this would be the government,
4 I think, recognising the necessity of holding up their
5 end of the social contract, the pact that is formed
6 between a government and a community when we are asked
7 to step up for vaccination.

8 **MS CAREY:** Ms Moore, thank you very much. They are all the
9 questions I have for you.

10 Are there any questions that your Ladyship would
11 like to ask?

12 Questions from THE CHAIR

13 **LADY HALLETT:** Essentially, the whole point about having --
14 for those who are not lawyers, I've got a husband who is
15 a personal injury lawyer, so I understand a bit about
16 it, I did some work myself. But for those who don't
17 understand, there's a difference between a grant or an
18 award, which is basically the Vaccine Damage Payment
19 Scheme as it is --

20 **A.** Yes.

21 **LADY HALLETT:** -- and compensation, is compensation assesses
22 the damage that has been caused and what you're going to
23 need to lead as effective a life as you can lead with
24 your disability.

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

26

1 place, that is somewhere between the civil compensation
2 standards and the current statutory amount.

3 And I think that could actually solve a lot of the
4 issues that we've seen over the last few years, and have
5 the added bonus of potentially increasing vaccine
6 confidence.

7 **LADY HALLETT:** You mentioned in your statement about how
8 funds in other countries are -- how resources are
9 provided -- (overspeaking) --

10 **A.** Mm.

11 **LADY HALLETT:** And you mentioned a levy on pharmaceutical
12 companies -- is it Sweden or Switzerland -- it's
13 Scandinavia --

14 **A.** Yes, Scandinavia, so Sweden, specifically, yes. So,
15 that's right. So in accessing the market, essentially,
16 the country with a vaccination programme, the vaccine
17 companies are asked to pay a certain krona, or whatever
18 it is in Sweden, into essentially a public pot, so that,
19 in rare event that, you know, these rare consequences
20 happen, there is a pot of money that will facilitate
21 proper compensation. I think that has the benefit of
22 also making sure that the risks are partially privatised
23 as well as the benefits being socialised.

24 I think what we do there is we recognise that
25 between the public sector and the private sector, there

28

1 are benefits and responsibilities, and the best way to
2 make sure those funds are adequate is probably to do
3 that. We've seen that with the Thalidomide Trust which
4 is partially paid into by the company involved there as
5 well. And those schemes then can be very well
6 resourced, I think, with advantages for everybody.

7 To me, if I may say, Lady chair, it is shocking that
8 we have a 1970s system that we have done nothing to
9 reform, particularly in a context like we are today,
10 post-pandemic. It was perhaps forgivable in the
11 immediate, sort of, circumstances of the pandemic, but
12 now, this many years on, I think the case for reform is
13 overwhelming and I would argue that the case for
14 a bespoke compensation scheme is significant and urgent.

15 **LADY HALLETT:** Another question. One of the advantages of
16 the scheme when established was meant to be speed.
17 I take your point about there not being the speed that
18 was intended, but the more you go into how an individual
19 is actually damaged, as you say, the longer it's going
20 to take --

21 **A.** Yes.

22 **LADY HALLETT:** -- the more complex the medical reports are
23 going to be, finding the specialist who can provide you
24 with the reports is going to take time. To what extent
25 do you lose the speed, if it were there? So let's

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1 The Equality Act has a definition for disability, as
2 I'm sure you're aware. I think it's substantial --
3 what's it -- physical or mental impairment which has
4 substantial and long-term effects on daily life.

5 I wondered about that as a possible criterion,
6 except it talks about long-term effects. And of course
7 the point is, as you say, you're trying to get money to
8 people who needed it sooner.

9 So, just supposing the scheme stayed in place. What
10 criterion would you suggest should be put in, instead of
11 the 60%?

12 **A.** So I think we would need to have some assessment of the
13 severity of the injury in the first instance and then
14 you could have multiples.

15 So there's a scheme called COVAX, which is something
16 which was set up during the course of the pandemic, and
17 actually the British Government paid into that scheme,
18 and that's for 92 lower and middle income countries
19 across the world, and they have multiples based on
20 severity from 0.25% up to 1.5%. So there is
21 a calibration by severity. I don't think you can avoid
22 that. And I think, you know, we would have to see, you
23 know, the extent of the neurological or the personal
24 injuries.

25 But then that could be -- we could also factor in

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1 just --

2 **A.** Let's presume it's there for a moment. Yes.

3 **LADY HALLETT:** Let's push that to one side for a second. To
4 what extent do you lose the speed when you go into the
5 detail of individual cases?

6 **A.** I think there has to be a balance, you're absolutely
7 right, but we do see speedy schemes that work on the
8 basis of banding. Again, the Thalidomide Trust is one
9 of those, the Infected Blood Scheme obviously is just in
10 its nascence but will enable faster decisions to be made
11 because bandings can be put in place.

12 So it's not that there's a bespoke sort of analysis
13 as for each individual case but there could be criteria
14 through which, you know, more rapid decisions could be
15 made which still took full account of the injuries and
16 the personal -- the individual's experiences.

17 At the moment it's a one-size-fits-all, and we know
18 that that just doesn't work on the basis of the evidence
19 that, you know, you've heard over the last few weeks,
20 I think.

21 **LADY HALLETT:** Going back to your point -- sorry, I'm losing
22 my voice for no reason -- about the criterion of 60%
23 disability, supposing the government said: we're going
24 to keep the Vaccine Damage Payment Scheme but we're
25 prepared to look at the criterion.

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1 a future prognosis into that. There is enough learning,
2 and wherewithal within the UK, based on, for example,
3 the judicial college guidelines, precedence, and all the
4 other data for us to be able to develop a sophisticated
5 scheme, I think, that can take account of that. And we
6 have really good examples, of these already. I don't
7 think we necessarily need to reinvent the wheel. You
8 know, we've got a pretty good map of what wheels should
9 look like from other bespoke schemes; I think we could
10 draw upon those.

11 **LADY HALLETT:** Bespokes and wheels. I think we had better
12 -- (overspeaking) -- there, hadn't we?

13 **THE WITNESS:** Quite.

14 **LADY HALLETT:** Thank you very much indeed, Ms Moore. I have
15 no other questions. I don't think there are any Core
16 Participant questions.

17 **MS CAREY:** No, there are not.

18 **LADY HALLETT:** I'm really grateful to you for your help.

19 **THE WITNESS:** Thank you.

20 **MS CAREY:** Thank you, my Lady.

21 Thank you, Ms Moore.

22 **(The witness withdrew)**

23 **MS CAREY:** My Lady, the next witness this morning is
24 Lord James Bethell, and it will just take a moment for
25 him to come in ...

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1 My Lady, may Lord Bethell please be sworn or
2 affirmed.

3 **LORD JAMES BETHELL (sworn)**

4 **Questions from COUNSEL TO THE INQUIRY**

5 **LADY HALLETT:** Lord Bethell, I hope we haven't kept you
6 waiting too long.

7 **MS CAREY:** Lord Bethell, some formalities. Your full name,
8 please.

9 **A.** James Bethell.

10 **Q.** You've made a statement to the Inquiry dated, I think,
11 6 October of last year, and I'd like to ask you about
12 number of different topics, please. Can I start with
13 a little background about you. Is this right: that on
14 9 March you were confirmed formally as the minister for
15 technology and life sciences, and you were, indeed, the
16 House of Lords minister responsible for representing all
17 health matters and legislation in the House of Lords?

18 **A.** (Witness nodded)

19 **Q.** We know from your statement that you had ministerial
20 oversight of the Antivirals Taskforce, the Therapeutics
21 Taskforce, the combined taskforce, and, as you've set
22 out, you sat on a number of engagement boards and indeed
23 other forum both for antivirals, therapeutics, and other
24 groups?

25 **A.** That is correct. I think it's worth adding that I had

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1 trials in that date.

2 Those were resolved but at an early stage they were
3 very weak.

4 **Q.** When you say early stages, are we talking March, April,
5 May 2020 --

6 **A.** Yes, we are talking -- exactly. And then, thirdly, was
7 actually liaising with the manufacturers themselves to
8 get guidance from them about what they thought would
9 work. We had great academic leadership but life
10 sciences is best done when the academics, the
11 clinicians, and the industry work together. And that
12 wasn't happening very well at the beginning.

13 **Q.** Do I take it from what you said that it improved over
14 time?

15 **A.** It did. The system kicked in in a big way and the
16 RECOVERY trial which went on to deliver huge results was
17 a good example of that.

18 **Q.** Right. May I ask, in respect of those three weaknesses
19 you've identified, did you take in your role any steps
20 to try to address or remedy those weaknesses, and if so,
21 what did you do?

22 **A.** Yes, there was a -- I mean, listen, there was a big
23 programme of trying to accelerate momentum in this.
24 There were observers from outside -- some of the
25 clinical advice I got from people like Sir John Bell was

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1 been a whip to the Health Department since the summer
2 before, so I had been involved in the proceedings of the
3 Department.

4 **Q.** Thank you.

5 May I ask about some initial observations that you
6 make in your statement, and you say early on in your
7 statement, at paragraph 7, that clearly there was
8 a recommendation to explore existing common medicines to
9 see if that might have an impact on Covid-19, and you
10 say this:

11 "Our initial efforts faltered because of the
12 weaknesses in our clinical trials system."

13 Can I ask you, please, at the outset, of an overview
14 of what, from your perspective, were those weaknesses.

15 **A.** I think there were three main areas of weakness. One
16 was about selecting the commonly used drugs that should
17 be put to trial. That really needed clear leadership.
18 We had very strong expert groups, because it is
19 difficult to get an expert group to coalesce around
20 a shortlist, and therefore we needed a better mechanism
21 for doing that. Secondly, in terms of recruitment, it
22 was extremely problematic to get people into the trials
23 and that was partly data, partly trying to get
24 clinicians to prioritise clinical trials, and partly
25 just the clunky way in which the NHS was working around

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1 that this needed to be accelerated much faster. So we
2 looked at appointing external leads, people who could
3 come in from industry to try to lead the programme, and
4 some names were looked at for that. But really what
5 made a big difference was having people like
6 Professor Landray and Professor Horby, trusted
7 clinicians, who knew how to drive clinical trials, put
8 at the centre of the organisation.

9 **Q.** I think you say that for future pandemics we need a more
10 robust emergency clinical trial system that can be stood
11 up more quickly on a bigger scale as with the decision
12 making around trial drugs.

13 Who do you think, Lord Bethell, or which department,
14 do you think should be responsible for setting up an
15 emergency clinical trial system?

16 **A.** Well, that's for sure, in terms of departments, the
17 Department of Health and Social Care. But I think that
18 the co-ordination between the NHS, the universities and
19 the industry needs to be much, much clearer.
20 Lord O'Shaughnessy has done an extremely good report on
21 this. It has crystal clear recommendations. They need
22 to be driven much harder than they are at the moment.

23 **Q.** Can I ask you this: do you consider now, looking back
24 over your time, that vaccines were prioritised over
25 therapeutics?

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1 **A.** No, I think that's a false dichotomy. They are very
2 different children. We weren't choosing one child over
3 another. With vaccines, we have a specialism in the UK
4 so that we know a lot about the science and the
5 challenge was a lot about seeing through the clinical
6 trials, and then ultimately the deployment.

7 So in that respect, although there are severe
8 obstacles, it's relatively linear, it is relatively
9 straightforward and the things you're going to be
10 worried about is there are known unknowns.

11 With therapeutics it's a completely different kettle
12 of fish. It's extremely complex. There are lots of
13 different types of therapeutics and antivirals. The
14 population itself changes as vaccination is rolled out.
15 There are lots of different types of immuno -- of
16 responses from individuals, it is highly personalised.
17 The delivery of different medicines is completely
18 different. Some might need an infusion into the arm
19 that takes hours, some might be in a pill. Some need to
20 be taken in advance, some afterwards. And also the
21 clinical trials were bouncing around an enormous amount.

22 So that's a five-sided Rubik's cube which requires
23 a completely different approach than vaccines.

24 **Q.** I understand that the dichotomy or false dichotomy, as
25 you call it, is not one you have experienced yourself

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1 **A.** Well, there were practicalities. In the very early
2 days, it was assumed that the answer to this novel virus
3 was going to be a therapeutic strategy. At the very
4 beginning, we had no medicines at all to treat it.
5 People were coming into hospital and being treated with
6 paracetamol and if they deteriorated were being
7 intubated. That is a terrible position to be in. So we
8 worked hard on therapeutics and things like remdesivir
9 came through that meant that we could treat people who
10 were poorly. And that's a phenomenal thing that Britain
11 really made a big contribution in doing.

12 Quite quickly, so we're talking April, May, June,
13 the signals from the vaccine programme became much more
14 encouraging than, I guess, at first we thought they
15 would have been. And so quite reasonably, that became
16 a focus, because we needed to stand up the delivery of
17 the vaccine. But all along, we knew that we needed
18 a fallback plan.

19 We were one phone call from disaster; we just needed
20 to know about a clinical trial that had gone badly
21 wrong, and then we would have to go to Plan B. So the
22 therapeutics were very much seen as that Plan B. And
23 certainly from my point of view, I had grave sense of
24 urgency and importance in order to make sure that we
25 delivered a fallback plan. And secondly, the vaccine

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1 but do you think there is a perception, nonetheless,
2 that vaccines were prioritised over therapeutics?

3 **A.** Listen, the success of the vaccines programme is
4 something that we can celebrate as a nation, and the
5 therapeutic programme didn't have the same profile.

6 **Q.** Why not?

7 **A.** Well, because it wasn't on TV every night. Huge amounts
8 of work by very dedicated teams who were very focused on
9 outcomes was done in the background, and they delivered
10 tremendous results which have saved many, many lives.
11 So I think it's an unsung success for the UK in many
12 ways.

13 **Q.** So it didn't get the attention it deserved?

14 **A.** No, attention is different to profile. The fact that it
15 wasn't on the front pages of newspapers doesn't mean
16 that it wasn't focused on by both the government and
17 the NHS.

18 **Q.** Right. Didn't get the profile it deserved?

19 **A.** Profile in the newspapers but you don't measure saving
20 lives in column inches.

21 **Q.** No. Understood. So from your perspective, there was
22 focus on both vaccines and the therapeutics, and from
23 your perspective, was there any ever, in your view,
24 a hesitancy or a reluctance to pursue therapeutics with
25 the force that the vaccine programme was rolled out?

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1 might not have worked for everyone, and definitely for
2 some people, therapeutics and antivirals were going to
3 be very important.

4 **Q.** I'm going to come on to look at some of those matters,
5 Lord Bethell. Can I start, though, with one of the
6 topics I'm going to ask you about is the ACCORD
7 programme. Can you just help us with those who are not
8 familiar, what was the aim of ACCORD and what was it
9 trying to achieve?

10 **A.** Well, ACCORD -- the ACCORD programme was, as you said
11 earlier, trying to look at some of the drugs that were
12 already in use so we wouldn't need to have go through
13 huge numbers of trials, which would take years to do.
14 It's a very, very common approach and in terms of its
15 mission did ultimately lead to some successes.

16 **Q.** I think it was announced towards the end of April of
17 2020, and was it really focused on trying to improve the
18 treatments for the more serious symptoms that Covid had,
19 and trying to stop people progressing to the severe
20 complications that we saw?

21 You wrote, I think, in May, on 26 May, to the
22 Secretary of State, Mr Hancock, concerned at the slow
23 progress of ACCORD.

24 Can I just look, please, on screen at INQ000486320.

25 If we see there in the middle of the page an email

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1 from you asking to update the Secretary of State with
 2 the following note relating to ACCORD:
 3 "As you will remember, this was going to be done by
 4 the private sector, but UKRI grab it at the last minute.
 5 Based on the recent oversight committee it is going very
 6 slowly. Initially problems getting the trial medicines.
 7 Now problems recruiting the trial patients. For
 8 example, drugs have been in recruitment for weeks but
 9 only have one recruit. Many have none. Alok [Sharma]
 10 is battling hard to make progress. This is a hugely
 11 important project to mobilise established drugs for
 12 Covid treatment ..."

13 Why were you so keen to let Mr Hancock know that
 14 there were problems with the ACCORD programme?
 15 **A.** The ACCORD programme was extremely well intentioned but
 16 it fell into the worst of the bureaucratic and
 17 low-energy approach to clinical trials that may work
 18 well for academic study, but were not suitable for
 19 either an emergency or the very large-scale challenge
 20 that we had. I sat in meetings on a weekly basis in
 21 order to go through progress, and had quite a detailed
 22 understanding of where we were going, and you only had
 23 to look at the arithmetic progress to realise that the
 24 epidemic was going to be over before we came up with
 25 a solution.

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1 ACCORD.

2 And towards the bottom of the page, Lord Bethell,
 3 you say:
 4 "I want to also share my thoughts on how to build on
 5 all the work in this space to date, particularly
 6 learning what works and what does not ..."
 7 You say there:
 8 "It is essential that research is driven by clinical
 9 need, with a rigorous focus on finding treatments ..."
 10 You suggest that the CMO or DCMO should lead on
 11 identifying the critical questions.
 12 "This should be delivered primarily through a new
 13 single lead National Trials Programme for Covid-19
 14 therapeutics."
 15 And then there was other suggestions on the second
 16 page of that.
 17 But it's really that final line there, Lord Bethell,
 18 the new single lead National Trials Programme for
 19 Covid-19 therapeutics.

20 Why were you so keen to advocate for such
 21 a programme?
 22 **A.** The problems with ACCORD, and actually some other trials
 23 that were going on, were very typical of the problems we
 24 have in our clinical trials system in the UK overall,
 25 and we were trying to apply ordinary, day-to-day

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1 In particular, recruitment was simply way off the
 2 scale we needed. And therefore, I was recommending
 3 a re-boot, which did in fact happen, and led to RECOVERY
 4 which moved much more quickly.

5 **Q.** RECOVERY was, I think, a little later or something
 6 running alongside this, but here we are a month into
 7 ACCORD, and it's already making slow progress. Was
 8 there any noticeable uptake, you having emailed the
 9 Secretary of State and as you say, encouraging Alok
 10 Sharma to battle hard and make progress?

11 **A.** No, I think this was an approach problem rather than a
 12 lack of scrutiny problem. Alok was doing everything he
 13 could do. But listen, the way in which an intellectual,
 14 academic-led organisation like UKRI does clinical trials
 15 is simply completely off the pace when it comes to an
 16 epidemic and we moved on to a different approach.

17 **Q.** All right, I was going to ask you about that, please,
 18 because certainly you wrote to Alok Sharma on 23 June.

19 Could we have on screen, please, INQ000478977, where
 20 you're writing to him to suggest how we might move
 21 forward with a renewed national programme for clinical
 22 trials.

23 And you set out that it's important to test
 24 repurposed drugs through large-scale trials. And you
 25 note your disappointment with recruitment in relation to

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1 practices to an emergency situation, and the system
 2 creaked badly. Actually, what we needed to have had
 3 before the epidemic hit us, was a programme for warp
 4 speed style acceleration, and central decision making.

5 The reference here to the CMO leading on identifying
 6 critical questions refers to what I said earlier about
 7 identifying the compounds that should go into the
 8 system.

9 **Q.** Yes.

10 **A.** And having a national trials programme referred, in
 11 part, to that liaison with industry and with the NHS, so
 12 that prioritisation could be given to these trials, and
 13 that should be a recommendation that I'd like to put to
 14 the Inquiry: that this should be in place for when the
 15 next epidemic comes along.

16 **Q.** And who would you envisage leading the programme or
 17 being responsible for it? DHSC again?

18 **A.** Well, I'm agnostic about institutionally where there
 19 that should be. DHSC isn't really a clinical
 20 organisation and often during the epidemic stepped in
 21 when there was a gap. So it could be UKHSA, it could be
 22 an updated JCVI. There are a number of possible homes.
 23 Certainly someone like Professor Van-Tam did provide
 24 personally the kind of leadership that we needed and I'd
 25 like to see that institutionalised rather than relying

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1 on individuals stepping up to solving problems.

2 **Q.** I think just finally on this topic, I think you chaired
3 a roundtable in relation to clinical trials reform, and
4 you made a call for a renewed national programme?

5 **A.** Yes.

6 **Q.** What happened in response to your call, Lord Bethell?

7 **A.** Well, we got a lot of very good papers. I happen to
8 remember Baroness Blackwood, my predecessor, and Lord
9 O'Shaughnessy both putting in papers that were very
10 thoughtful, and it did provide some energy and some
11 focus, Be Part of Research, the very good scheme, were
12 involved in some of the response, and there were
13 individual programs to try to accelerate clinical trials
14 of the kind that I would like to see more of.

15 I fear that since then, a lot of that energy has
16 fallen back and, in fact, clinical trials in the UK have
17 fallen back in quite a worrying way since that moment of
18 energy.

19 **Q.** A slightly different topic in relation to --

20 **LADY HALLETT:** Just before you move on, if I may.

21 **MS CAREY:** Certainly.

22 **LADY HALLETT:** You say you think you fear that the clinical
23 trials have fallen back. Apart from the national -- do
24 you believe that if there were a national trials
25 programme, that would solve the problems you've been

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1 everyone's minds.

2 Certainly issues like pregnant women, which I think
3 has come up before in the Inquiry, were things that came
4 up in our conversations and I drove as hard as I could.

5 **Q.** Were you aware of any specific efforts to try to drive
6 up diversity within ethnic minorities?

7 **A.** Not off the top of my head. I'd have to refer to my
8 papers for that.

9 **Q.** Thank you.

10 Can I turn to some questions about antivirals,
11 please. And if it helps you, Lord Bethell, I'm at
12 paragraphs 59 and 60 onwards in your statement.

13 We are moving forwards in time, I think, to 2021.
14 And you set out there that in February 2021 you received
15 plans for the proposed antivirals programme to look at
16 three effective antivirals. And there was a proposal
17 put to you, I think, that Charlotte Taylor shared with
18 you and the Secretary of State, setting out the plan.
19 Clearly, you say there, it was important, because the
20 vaccine was not 100% effective and not everyone can have
21 it, and so there was a need for the antivirals.

22 And you say this in your statement: that you were
23 excited about the antivirals programme, noting, to quote
24 you, it was a "really impressive piece of work".

25 Just help us, what was it about the programme that

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1 identifying or are there other things that would need to
2 be in place to solve the problems?

3 **A.** I'm afraid that the problem to our Covid trials is
4 a list of about 20 things. So having one programme is
5 a good way of providing leadership and structure, but
6 there is a lot more things that need to be done and
7 I could drop a note, if that would be helpful.

8 **LADY HALLETT:** That would. Thank you very much.

9 **MS CAREY:** It's not the silver bullet but it is part of the
10 way to --

11 **A.** Correct.

12 **Q.** -- solving the problem. I understand.

13 Just on a wider angle in relation to clinical
14 trials, did you take any measures, as minister, to
15 address the lack of diversity in clinical trials, and
16 help ensure that there was adequate representation of
17 ethnic minorities, particularly given that we know the
18 disproportionate impact that Covid-19 had on those
19 communities?

20 **A.** Yes, well, getting equality in clinical trials is
21 a massive priority of any clinical trial system. I
22 don't think I necessarily had to drive that hard. It is
23 a priority for anyone organising the testing of drugs,
24 and in particular, both gender, ethnic, and any other
25 kind of diversity. So I think that was uppermost in

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1 enthused you?

2 **A.** Well, I think that we were grabbing it and something was
3 being done. I think that there is a -- as you said
4 yourself, that it didn't get the profile of the
5 vaccination programme, but actually, there were some
6 very ambitious and high energy work that was being done.

7 I could see, like everyone, that there were gaps in
8 the vaccine delivery mechanism, there were going to be
9 people who didn't respond to the vaccine. There was
10 also the chance that the variant would escape the
11 vaccine, that suddenly we would be dealing with a new
12 virus that was not easily controlled by our plan A.
13 That was very much on my mind.

14 It seems an odd thing to be worried about in
15 retrospect, but right then, in February 2021, I didn't
16 want to be walking into another epidemic because the
17 virus had somehow jumped the shark and become immune to
18 the vaccine.

19 So having that in place was a really big priority
20 and I was impressed by the team's work.

21 **Q.** Do you know -- I know you left, I think, in
22 September 2021 --

23 **A.** Yes.

24 **Q.** -- but had there been a discernible improvement or
25 outcome as a result of the programme that was being

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1 suggested to you back in February of that year?
 2 **A.** Sorry, could you repeat the question.
 3 **Q.** Yes. By the time you left office, effectively, had you
 4 seen the benefit of the fruits of the antivirals
 5 programme?
 6 **A.** Well, yes. They had -- you know, Eddie had done a good
 7 job-off identifying key antivirals that could
 8 potentially be put to use, but in some ways history had
 9 moved on. The vaccination programme had delivered, for
 10 most of the population, a really good protection,
 11 certainly from severe disease and death.
 12 It didn't stop transmission, it didn't stop
 13 Long Covid, it didn't work for absolutely everyone, but,
 14 broadly speaking, it was a route to escaping the
 15 epidemic. So in some ways, this work was less important
 16 than it had been in February.
 17 **Q.** You say in your statement that, regarding antivirals,
 18 you believe that:
 19 "... we might have been more creative about the
 20 possible ways we could mobilise antivirals using modern
 21 diagnostic, digital and delivery technologies [there]."
 22 What were you trying to say in that statement,
 23 Lord Bethell?
 24 **A.** Sure. So the big problem with antivirals is you need to
 25 give them to people before they show symptoms, really.

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1 **A.** Yes, I think in terms of delivery mechanisms, I'm really
 2 thinking about the NHS. Antivirals are a very commonly
 3 used medicine, they are regularly very difficult to get
 4 to people at the right moment, so this is a longstanding
 5 complexity within our treatment system.
 6 Our treatment system relies on people falling ill,
 7 having a symptomatic, and then going to the GP. That is
 8 a very reactive way of doing medicine, and I'm making
 9 the observation that there are ways of trying to use
 10 data and home diagnostics to spot people much earlier
 11 on, and therefore get the kinds of medicines that catch
 12 disease at a very early stage to knock it out before the
 13 symptoms emerge.
 14 That is the way that medicine is going across the
 15 board, and in order for our health system to be up to
 16 date and ready for the next epidemic, it is worth us
 17 thinking today about how we put in place those kinds of
 18 mechanisms.
 19 **Q.** Now, you say candidly in your paragraph 68 that you
 20 think we could have been more creative.
 21 "We were, perhaps, put off by the initial costs of
 22 the drugs and the prospects of huge unaffordable
 23 bills ..."
 24 Can you help us, please, perhaps with that tension
 25 about the costs, the creativity, the need to protect

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1 Once your nose is running and you're coughing it's
 2 probably too late, the medicine can't get in early
 3 enough. I take antivirals for a condition I have, so
 4 I know this personally to be true.
 5 In order to get antivirals into someone before they
 6 show symptoms, you kind of need to know -- you need to
 7 get them to them very, very quickly, for instance on
 8 a motorbike, the moment that they test positive. So
 9 you'd need to test and treat. And also, you maybe give
 10 them to other people in their household or in their care
 11 home because they are most likely to catch the disease
 12 from the infected person.
 13 I felt that within the NHS we could have been more
 14 creative about test, trace and treat, and within care
 15 home communities within prophylactically giving people
 16 antivirals and having them available for moments of
 17 outbreak.
 18 **Q.** So, from your perspective, they had a dual benefit,
 19 potentially, for those who needed them once they had
 20 early symptoms, but indeed for those pre-symptoms to --
 21 **A.** Correct. It was prophylactic and -- treatment
 22 -- (overspeaking) --
 23 **Q.** I understand. All right. Now you say in that paragraph
 24 that "we could mobilise". Who is the "we" that you're
 25 referring to there?

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1 those for whom the vaccine may not work; was this people
 2 just saying it's just too expensive?
 3 **A.** So there are two separate things. So antivirals are
 4 typically very cheap. They're short molecules, pretty
 5 easy to make once you've got them. Biologics can be
 6 incredibly expensive. It's sort of like claret wine,
 7 I think Professor Van-Tam explained the manufacture
 8 of it is incredibly complicated. Also you also have to
 9 infuse people. So, often they have to go to hospital
 10 and sit in a chair for an hour or two, and then be
 11 observed afterwards. So there are practical challenges
 12 with delivering some of these medicines. Some of them
 13 have high costs, some of them have low costs.
 14 There is then the actual delivery mechanism, the use
 15 of motorcycles and also issuing large amounts of drugs
 16 to households on a pre-emptive basis.
 17 So we did do that with diagnostics, we essentially
 18 gave every household an LFD, a lateral flow device, so
 19 they could use it the moment that someone within the
 20 household was spotted with the disease.
 21 It is possible that if you had the right antiviral
 22 you could do roughly the same thing and issue them very
 23 widely. Of course that's -- we're talking, there,
 24 massive costs. So yes, money is a consideration.
 25 **Q.** Coming on to the test, trace, treat option. You say in

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1 your statement that you had early discussions about
2 trialling a test, trace and treat option whereby
3 a household or care homes would receive a delivery of
4 the antivirals by bike for the non-symptomatic. But you
5 say:

6 "... it was unfortunate that this approach was not
7 pursued more emphatically early on, as it was offered
8 strong potential for containing the spread of the
9 disease ..."

10 Why wasn't it pursued and who did not pursue it?

11 **A.** I think it's unfortunate because we might need it in the
12 next epidemic. Actually, in this epidemic the sequence
13 of it was that we didn't identify effective antivirals
14 until later by which time, frankly, the vaccine had got
15 it mostly covered. By the time of the next epidemic, we
16 should be in a place where we are studying the right
17 antivirals against the right diseases in advance, and
18 have the delivery mechanism stood up beforehand so that
19 we have this alternative platform to respond to
20 a disease. Otherwise we'll be scrambling again, as we
21 were. And we shouldn't put all of our eggs in the
22 vaccine basket because next time round, maybe the
23 vaccine won't be the one that comes through; we'll be
24 relying on therapeutics and antivirals for our primary
25 response.

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1 I shall return at 11.25.

2 (11.10 am)

3 (A short break)

4 (11.25 am)

5 **LADY HALLETT:** Ms Carey.

6 **MS CAREY:** Thank you, my Lady.

7 Lord Bethell, may we turn, please, to some of the
8 work you did in relation to the immunocompromised
9 members of society, and in particular if it helps you,
10 paragraph 69 onwards in your statement.

11 Now, I think the Inquiry has already heard that in
12 2021, the CMO and DCMO decided not to buy Evusheld --
13 subsequently known as Astronaut, and there's various
14 other ways in which it's referred to -- for use as
15 a prophylactic. Do I take it from that that it was not
16 your decision to not go ahead with that purchase? Were
17 you consulted on the CMO and DCMO's decision not to
18 purchase?

19 **A.** What was the date of their ...?

20 **Q.** February 2021.

21 **A.** So -- well, I wasn't consulted in terms of their
22 decision -- in their submission. Their submission did
23 come to me and I think I commented on it. I had,
24 though, been a champion for measures to try to meet the
25 concerns of the immunocompromised and had a huge amount

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1 **Q.** I think you explain there perhaps why it wasn't pursued,
2 but who or which department was the impediment to the
3 pursuit of this potential option?

4 **A.** Look, I wasn't aware of an obstacle, a lot of people
5 were very busy and it didn't get prioritised -- I think
6 partly because, frankly, NHS and primary care in
7 particular were flat out in their response, and
8 weren't -- didn't have the spare capacity to look at
9 this interesting but secondary mechanism.

10 **Q.** Final question on this topic, please: do you know, was
11 any thought given to trialling this option on a small
12 geographical area or in some way just seeing if it did
13 in fact work and what the logistical problems may or may
14 not be and the success or otherwise of this option? Was
15 that ever thought about?

16 **A.** It's funny you should say that because I think it was,
17 but when I went through my papers to try to find details
18 of it, I couldn't find it. So I apologise for that.
19 And I am afraid I can't give a conclusive answer.

20 **MS CAREY:** Not at all.

21 My Lady, I'm moving on to a totally different topic.

22 Would that be a convenient moment?

23 **LADY HALLETT:** Certainly. I hope you were warned that we
24 take a break, Lord Bethell, but I promise we will finish
25 your evidence shortly after we return, I'm sure.

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1 of sympathy for the situation that they were in.

2 **Q.** Right. May I add, it wasn't their decision, but it was
3 their recommendation not to purchase Evusheld and
4 I ought to correct myself before there are any
5 misunderstandings.

6 **A.** Yes, of course.

7 **Q.** Did you agree with the recommendation not to buy
8 Evusheld?

9 **A.** Yes, of course. If the CMO puts in a thoughtful,
10 substantial evidence submission, a recommendation like
11 that, then absolutely, one would go along with that.

12 **Q.** Now, I ask you that because certainly by
13 19 February 2021, you were -- emailed Matt Hancock to
14 ask about the strategy for the immunocompromised.

15 Can we have on screen, please, INQ000497981.

16 At the top of the page, can we see there an email
17 effectively between the private secretaries but from you
18 to him:

19 "Lord Bethell fed back on this ... he is inclined to
20 agree, but before, he would like to ask:

21 "what is our strategy for the immunocompromised who
22 cannot take the vaccine or who might not be protected by
23 the vaccine, and how are we going to protect them."

24 And what was the answer to the questions that you
25 were posing of the Secretary of State there?

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1 **A.** Well, in some ways the answer was a large number --
2 a large investment in therapeutics and antivirals, and
3 also a research programme led by NIHR around it, that it
4 included the OCTAVE clinical trials and research. So
5 there was activity in order to try to answer this
6 question.

7 I think the reason why I flagged this to the
8 Secretary of State is that I did want that activity to
9 be thoughtfully coordinated, and that this is one
10 group -- and there were many groups -- the autistic, the
11 homeless, the -- who were particularly hard hit by this
12 horrible virus, and given the state of where we were in
13 terms of the national response, it seemed to me
14 important that they had -- there was some kind of
15 leadership that targeted the situation they were in.

16 **Q.** And was there, certainly whilst you were involved,
17 someone put in place to provide that thoughtful
18 coordination., of not just the immunocompromised but all
19 of the other hardest hit communities?

20 **A.** Well, I think collectively, the response came from our
21 collective actions. You couldn't necessarily appoint
22 a tsar for every single group. It did occur to me,
23 though, that because the situation that the
24 immunocompromised were in was particularly complicated,
25 and where the data was particularly patchy, it was

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1 talk about that if that would --

2 **Q.** We'll follow the thread through and perhaps we'll come
3 back to that, Lord Bethell.

4 So there was a strategy devised in March of 2021,
5 and as you set out in your statement, you met -- in July
6 of 2021, there was a meeting with the immunocompromised,
7 where there was the Department of Health and Social Care
8 and, indeed, blood cancer charities in attendance.

9 And can we have a look, please, briefly at
10 INQ00497986. Thank you.

11 12 July, there's a readout of the meeting that
12 looked like it happened on 7 July. Various attendees,
13 including Baroness Brinton, and if we look towards the
14 bottom of the page, Lord Bethell, the baroness noted she
15 would like to know who is the clinical lead for the work
16 on prophylactic antibodies:

17 "Who is leading the policy on how to protect the
18 immunocompromised? Is there a responsible minister?"

19 Do you know the answers to those questions that the
20 baroness posed?

21 **A.** Yes. If I may just add, can I just point out that I was
22 up in the House of Lords, two, three, four, five times
23 a day, and peers raised the immunocompromised with me
24 almost every day, and Baroness Brinton in particular,
25 partly because her own personal expertise in the

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1 worthy of focus.

2 **Q.** I think in response to that email there was a strategy
3 that was devised in March of 2021, and I won't go
4 through all of it, but did the strategy, to your mind,
5 alleviate the concerns that you were raising on behalf
6 of the immunocompromised?

7 **A.** Well, yes, and no. Yes, that it was a strategy and it
8 was the best response we could come up with, but no
9 because I felt heartbroken that there wasn't more that
10 we could do.

11 If you have a virus that attacks the immune system,
12 and a vaccine that supports the immune system, those
13 with compromised immune systems are particularly hard
14 hit. So some of those questions don't have great
15 answers, frankly.

16 **Q.** You say not more we could do. Do I take it from the
17 answer you gave that it was inherent with the problems
18 that Covid causes --

19 **A.** Yeah.

20 **Q.** -- that we couldn't do more, or was there anything that
21 actually could be done, more, at ministerial level,
22 departmental level?

23 **A.** Well, not wishing to avoid the question, concretely,
24 what more could have been done was to have a plan for
25 the immunocompromised before we began. And I'm happy to

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1 situation, was an advocate. So this wasn't an issue
2 that wasn't flagged to me --

3 **Q.** No.

4 **A.** -- on an almost daily basis and therefore I was very
5 live to it. Was there a lead on it? There wasn't
6 a named individual, but it was very much part of the
7 system's priorities, including JVT, who had met them and
8 done an enormous amount of work on it. And was there
9 a responsible minister? Yes, that was me.

10 **Q.** Do you think a clinical lead would have lead to
11 a different outcome in terms of how to best protect or
12 try to protect the immunocompromised?

13 **A.** Well, if I may answer that in the round a little bit, if
14 you'll give me a second. I think one of the things
15 I learnt from this is that there are, with a big
16 epidemic like this, national responses that address the
17 whole population, and it's reasonable to prioritise
18 those. But there are also a large number of special
19 groups who are going to not be necessarily catered for
20 by the national response. And therefore, you need to
21 have a system that deals with edge cases and special
22 cases. We didn't have that programme, we didn't have
23 a 'What do we do with the immunocompromised' plan at the
24 very beginning, and so we were putting these things
25 together after the fact.

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1 Now, partly that's because you don't necessarily
2 know who is going to be, as it were, let down by the
3 national response. So it's difficult. But there are
4 going to be some groups you definitely know might be
5 a problem, and it did strike me that the
6 immunocompromised were one of those groups.

7 **Q.** And can I stand back from that for a moment, because I
8 think you are aware that in August 2021, in an email
9 thread -- and can we have it up on screen, please,
10 INQ000066712_2. We are -- the date has been excised but
11 it's 20 August 2021, Lord Bethell.

12 Can you see there in an email from Charlotte Taylor,
13 she has had a brief conversation with the Government
14 Chief Scientific Adviser including the Astronaut data,
15 or Evusheld data, on prophylactics:

16 "I said there is limited enthusiasm for prophylactic
17 use across the system. His reply:

18 "I think that is misguided. There is a clear place
19 for them and it just needs to be defined."

20 Two questions, please. Did you, as your time as
21 minister, sense a limited enthusiasm for prophylactic
22 use?

23 **A.** I think the response was based on evidence. I don't
24 think that there was a -- sort of a prejudice. I think,
25 as I've said before, and as the Chief Scientific Adviser

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1 remain vulnerable to the disease? And that included,
2 but not only, the immunocompromised.

3 And that's when the renewed focus was put on all of
4 the other therapies, including the antivirals, to offer
5 those who were shielding, who had led very worried lives
6 for nearly two years -- how were we going to protect
7 them? And that's really the state of things when I was
8 leaving.

9 **Q.** Okay, just a few questions, please, about Evusheld
10 itself, and please say if you're not able or in
11 a position to answer some of them, because they may
12 relate to after your tenure.

13 But from your perspective, did you get a sense of
14 how much, if at all, cost was an issue in the decision
15 not to purchase Evusheld?

16 **A.** Well, across the board, cost did not arise as issues,
17 generally speaking. We were, largely speaking, given
18 everything that we needed in order to fight the virus,
19 and recommendations from the CMO and others were based
20 on clinical evidence, not on economic evidence.

21 That said, cost isn't just a pound, shilling and
22 pence; there's an opportunity cost in terms of how do
23 you prioritise healthcare resources, which were
24 extremely limited. So I wouldn't say that resources in
25 the broad sense weren't a consideration.

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1 pointed out, it's good to challenge assumptions, and
2 maybe there could have been scope for more creativity,
3 which was the point I think I made earlier, so in that
4 respect, I was probably aligned with his thinking, but
5 no, I don't think that there was in any way a sort of
6 built-in prejudice against any particular vector of
7 treatment.

8 **Q.** Do I take it from your answer that if there had been
9 that limited enthusiasm, you would agree that it was
10 misguided?

11 **A.** Well, I pushed against it quite hard, as you saw in my
12 note to the Secretary of State. So I was in there
13 challenging and pushing, but decisions were made on the
14 basis of evidence and non-clinical ministers can only go
15 so far in terms of questioning the evidence.

16 **Q.** Right. That's August of 2021, and by September 2021 you
17 left the government. What was the state of play as at
18 the time you left the government in terms of
19 prophylactics and, indeed, protection of the
20 immunocompromised? So we are coming into about to be
21 the autumn/winter of 2021. What was the state of play
22 at that time?

23 **A.** Well, we were swinging out of lockdowns and intense
24 national programmes, and one of the things that we were
25 focusing on was: how do you deal with the people who

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1 **Q.** Do you think by not procuring Evusheld, there was
2 a missed opportunity to provide protection and, indeed,
3 short-term freedoms, perhaps, for the immunocompromised?

4 **A.** I don't think I'm qualified to answer that. I saw the
5 submissions on the pre-purchase agreements earlier in
6 the year, and there they were based on the clinical
7 evidence, the -- the compounds hadn't been through
8 clinical trials yet. The later decisions came after I'd
9 left.

10 **Q.** Let me see if you can help with this, and please say if
11 you can't. In light of the decision not to procure
12 Evusheld, how do you consider the needs of the
13 immunosuppressed were probably taken into account after
14 that decision had been made?

15 **A.** I don't know if I can answer after. I would be happy to
16 make comment on the period before.

17 **Q.** Finally this, please: the Inquiry has heard evidence
18 that the vaccines were purchased on an at-risk basis.

19 **A.** Yes.

20 **Q.** Are you able to help with why the position was not the
21 same for Evusheld?

22 **A.** Yes, well, I don't know if I can say -- well, yes, and
23 not just Evusheld, you know, across the board. The
24 Therapeutics Taskforce did not have a blank chequebook.
25 It was the big distinction between the Vaccine Taskforce

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1 and the therapeutics.

2 One of the reasons for that is the therapeutics and
3 antivirals worked in different ways in different
4 circumstances. The five-sided Rubik's cube
5 that I mentioned earlier. Putting taxpayers' money at
6 risk for that complexity of procurement really wouldn't
7 have made sense. It would also have been a big
8 distraction for the healthcare system which, by
9 implication, would have had to twist to meet the
10 delivery demands of each treatment vector, which frankly
11 was beyond the scope of the resources we had.

12 **Q.** Different topic, please, Lord Bethell, and just a few
13 questions, please, about the Moral and Ethical Advisory
14 Group, or MEAG, as it is sometimes known.

15 **A.** Mm.

16 **Q.** Clearly you set out, and we know, that they provide
17 independent advice to the government. The advice is not
18 binding. But you, in your statement, certainly say that
19 it's important to have external ethical advice. You
20 consider it to be important, particularly during the
21 pandemic.

22 Are you aware, certainly, of any advice that
23 specifically addressed the health inequalities faced by
24 ethnic minority groups and how that was integrated into
25 policy decisions or the decisions that you had to make?

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1 analysis. So their analysis on something like that was
2 highly valued.

3 But I didn't agree with the Nuffield blog that said
4 politicians needed to have handholding by ethicists in
5 order to understand the implications of their own
6 decisions. That's what we have in Parliament. I was up
7 every day being challenged on our decisions. So having
8 a broad framework against which our homework would be
9 scored, as it were, seemed to me to be a bit of
10 overreach and I would draw the line at that kind of
11 generalised ethical advice.

12 **Q.** Do you think, and I am asked to ask you this, whether
13 the publication of a framework could have benefitted
14 and, indeed, protected the vulnerable groups?

15 **A.** No, we were doing that every day.

16 **Q.** Finally, this, please Lord Bethell. I think we may have
17 touched on it throughout your evidence. But you make in
18 your statement a number of recommendations and, indeed,
19 you've already spoken powerfully about the need for
20 preparedness, something which will resonate with her
21 Ladyship's evidence in Module 1, no doubt, but is there
22 a key lesson that you would wish to put before her
23 Ladyship?

24 **A.** Yes, I think there are probably two, and they are
25 consistent with a lot of what has been said already here

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1 **A.** Well, our day-to-day conversations about the impact of
2 the vaccine always included the vulnerable and health
3 inequalities generally. They were a massive priority in
4 everything that we did. I don't think we needed an
5 ethical group to remind us of the importance of that.

6 **Q.** In relation to MEAG itself, I think you were, in May of
7 2020, asked to decide whether to publish MEAG's advice
8 on the government website and you agreed to that.

9 **A.** Mm.

10 **Q.** You were also asked to create what was called
11 a shortlist of principles on moral and ethical issues
12 for policymakers to consider when developing a new
13 policy. Let's call it a framework for short.

14 **A.** Yes.

15 **Q.** Why did you decide against the creation of such
16 a framework?

17 **A.** Well, I thought that the MEAG was an excellent
18 organisation that worked extremely hard and
19 thoughtfully, in particular when there were requests
20 from ministers on particular issues that had technical,
21 ethical considerations. So something like vaccine as
22 a condition of deployment. That has a political
23 implication, an economic implication, a clinical
24 implication, but also a highly technical ethical
25 implication that would go beyond day-to-day political

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1 before: there should have been a plan for containing the
2 disease, and then treating those both who caught the
3 disease and who -- for whom the vaccine didn't work in
4 advance. Instead, we put one together, and I admire the
5 hard work, diligence and effectiveness of those who were
6 part of that response. But it was notable that we were
7 working from a really, not from a blank sheet in as much
8 as there was previous work obviously in this field, but
9 without a clear framework.

10 And secondly, the shape of the healthcare system was
11 not suited for a fast response and delivery. So if you
12 look at the clinical trials or the delivery of
13 antivirals, or of biologics, or of the manufacture and
14 supply chain elements, no thought or consideration had
15 been put into the resilience of the system for when we
16 were going to be hit. And that's really what held us
17 back in this area the most, is the lack of warm
18 resources, resources that were in play on a day-to-day
19 basis but could be scaled on a national basis when
20 needed.

21 **Q.** Can I ask you this, then: in your statement you refer to
22 gaps in the system, perhaps the weaknesses that we
23 alluded to at the beginning of your evidence, certainly
24 falling behind in terms of commercial clinical trials.

25 Do you think now that, perhaps, rather than learning

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1 lessons and being more resilient, we are less resilient
 2 than we were when we went into the pandemic?
 3 **A.** Frustratingly, I do. I think we are in worse shape
 4 today than we were five years ago. The NHS is clearly
 5 under a huge amount of pressure in terms of capacity,
 6 the workforce are under pressure and there's been
 7 a drop-off on recruitment. International surveillance
 8 of viruses is not where it could or should be. In terms
 9 of the institutions of resilience, UKHSA, for instance,
 10 should be a national agency with heft and resources, and
 11 I'm disappointed that it has been denuded in the way it
 12 has been.

13 Local Resilience Forums remain a shadow organisation
 14 rather than something with strong local reach.

15 Your Ladyship, I could go on, but there are a dozen
 16 of these areas where we should have learnt the lessons
 17 on where we simply haven't moved forwards.

18 **Q.** Finally this please: would you support the development
 19 of a more diverse portfolio of vaccines and, indeed,
 20 antivirals as part of future pandemic preparedness
 21 plans?

22 **A.** Yes. As an illustrative point, there is an organisation
 23 called REDDI, that is trying to put together today
 24 genomic data on future viruses in order to have the
 25 resources in place to design antivirals for the future.

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1 **A.** Well, "should have" is carrying a lot of weight in that
 2 sentence. I think that the use of antivirals is
 3 fundamentally challenging, because of the problem
 4 I mentioned, which is you need to get them to people
 5 either before they've got the disease or at the very
 6 earliest stages, probably before they've got a symptom.

7 And that, not unreasonably, means that they are not
 8 put into work very often, because of the basic challenge
 9 of getting them to work.

10 I think we've reached a moment in history where the
 11 technologies around identifying risk and of distributing
 12 medicine, and of also manufacturing, extremely cheaply,
 13 antivirals means that we should be rethinking that whole
 14 mindset. It was difficult to do right in the middle of
 15 an epidemic, because it requires mechanistically putting
 16 together new processes, new arrangements, new ethical
 17 agreements and a whole different pathway for clinicians.
 18 These are not insubstantial things to do. But I would
 19 highly recommend we look at that agenda so that we are
 20 in better shape for next time.

21 **Q.** But the systems that were in place, that you'll have
 22 overseen, such as the five-day window you needed to
 23 apply for antivirals, in certain circumstances, do you
 24 think those systems were effective or are you suggesting
 25 that they weren't -- they weren't particularly

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1 That is an illustration of the kind of preparedness that
 2 I think we should be committed in to, and, you know,
 3 would be a strong recommendation that should come from
 4 this Inquiry.

5 **MS CAREY:** No doubt one of many.

6 Lord Bethell, thank you very much.

7 **LADY HALLETT:** I think there is one more question I've
 8 allowed from Mr Wagner. If you can't answer it, please
 9 say, Lord Bethell, but I've given Mr Wagner permission
 10 to ask one question.

Questions from MR WAGNER

12 **MR WAGNER:** Thank you, and I'm grateful for the permission.

13 Good morning, Lord Bethell, I ask questions on
 14 behalf of Clinically Vulnerable Families. I just wanted
 15 to ask you a question about something you said earlier
 16 which was: you felt that within the NHS, we could have
 17 been more creative about Test and Trace and Treat, and
 18 within care home communities within prophylactically --
 19 I don't know whether the draft transcript is quite
 20 right -- prophylactically giving people antivirals,
 21 having them available for moments of outbreak.

22 Is the implication of what you're saying that the
 23 urgent distribution of antivirals during the pandemic to
 24 those who needed them was not as effective as it perhaps
 25 could have been with more creative thinking?

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1 effective?

2 **A.** Well, I'm not a clinician, but my impression is that
 3 a five-day window is not a great way of running the
 4 antivirals programme, yes.

5 **MR WAGNER:** Thank you.

6 **LADY HALLETT:** Thank you, Mr Wagner.

7 Thank you very much indeed, Lord Bethell, those are
 8 all the questions we have for you. I'm very grateful to
 9 you for your insight and your candour and also for the
 10 fact that you highlighted the important work on
 11 therapeutics and antivirals, and thank you for the
 12 pressure you tried to maintain while you were in office.
 13 Thank you very much indeed.

14 **THE WITNESS:** Thank you.

(The witness withdrew).

16 **MR KEITH:** My Lady, the next witness is Eddie Gray.

MR EDDIE GRAY (affirmed)

Questions from LEAD COUNSEL TO THE INQUIRY FOR MODULE 4

19 **LADY HALLETT:** I hope you were warned you weren't the first
 20 witness on, Mr Gray.

21 **THE WITNESS:** Thank you.

22 **MR KEITH:** Good morning, Mr Gray.

23 Can you commence your evidence this morning, please,
 24 by giving us your full name.

25 **A.** Yes. My full name is Edward James Gray.

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1 Q. Thank you very much and thank you for attending today
2 and also for the provision of your witness statement
3 dated 2 October 2024.

4 Mr Gray, you have, I think, some 40 years in the
5 pharmaceutical and biotechnology sectors.

6 A. Correct.

7 Q. You were president of European Pharmaceutical Business
8 at GlaxoSmithKline, GSK, and I think you were CEO of
9 a company called Dynavax Technologies and, for some
10 time, a board member of the Association of the British
11 Pharmaceutical Industry.

12 For our purposes, the most relevant part of your
13 career is that you were chair of the Antivirals
14 Taskforce from 1 June 2021 to 1 April 2022; is that
15 right?

16 A. That is correct.

17 Q. And we'll look at the detail, of course, of what you did
18 as the chair of the Antivirals Taskforce in a moment,
19 but, very broadly, was it the Antivirals Taskforce that
20 led on the negotiations for, and secured the provision
21 of, around 5 million courses of two oral antivirals?
22 And they were: Paxlovid, nirmatrelvir/ritonavir,
23 a Pfizer product known to you as Project Tyne; and also
24 molnupiravir, known as Project Arrow, a Merck product
25 called, I think, Lagevrio?

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1 And in the case of antivirals, and you were
2 concerned with oral antivirals, is that something that
3 can be given prophylactically as well as by way of
4 treatment, or is it something that, in general terms,
5 needs to be given as you're under attack from the virus,
6 and therefore needing the beneficial impact of the
7 antivirals?

8 A. Right.

9 Q. It does what it says on the tin?

10 A. Yes. So I think you referenced differences between the
11 Antivirals Taskforce task and that of the vaccines. And
12 I think clarity around the utility of the different
13 medicines was one of the key differences. Because
14 I think, for vaccines, a very early position was adopted
15 that if you could find effective vaccines, as
16 a population intervention they were likely to be the
17 most effective response to the pandemic.

18 But there was no real question about their utility.
19 If Kate and her team could identify and find these
20 vaccines, then we were all going to get lined up and
21 jabbed with them. So that was fairly straightforward.

22 But with antivirals, there are different ways in
23 which they can be employed.

24 Q. So do you mean by way of oral ingestion or injection,
25 that sort of means?

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1 A. Yes, it was.

2 Q. This is a complex field, Mr Gray, and I'd like you to
3 start, please, just by highlighting some of the
4 differences between antivirals and more broadly,
5 therapeutics and vaccines, because we've heard a great
6 deal of evidence about various types of therapeutics
7 and, of course, vaccines. And we need to put it into
8 its proper context.

9 Therapeutics, in the form of drugs, are not
10 necessarily vaccines. That's right, isn't it? And
11 drugs or medicines, or therapeutics, may fall into
12 number of different categories.

13 A. (Witness nodded)

14 Q. You might have small molecule drugs, which are known
15 also as --

16 A. (Witness nodded)

17 Q. -- or generally are antivirals, and you may also have
18 something called neutralising monoclonal antibodies, and
19 we've heard of one in particular: Evusheld.

20 But you were concerned in the Antivirals Taskforce
21 with molnupiravir and nirmatrelvir, which are not
22 neutralising monoclonal antibodies, are they?

23 A. They are not.

24 Q. And unlike vaccines, drugs may be given prophylactically
25 as well as by way of treatment for a disease?

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1 A. No, they were oral medicines, and we were seeking oral
2 medicines because that was the easiest way to deliver
3 them when we had them.

4 But you can utilise them in a broad population
5 basis, possibly prophylactically, where the goal that
6 you're trying to achieve there is really to interrupt
7 transmission, to reduce the level of impact upon
8 individual patients of having contracted the virus, and
9 to clear them of the virus and to stop them passing it
10 on to other people.

11 Alternatively, you can not give to it a widespread
12 population but you can hold it back and recognise that
13 there are certain people in the population who are more
14 badly affected by the virus, and in this instance the
15 focus was really on people who might go on to be
16 hospitalised or indeed to -- death as a consequence, and
17 in that instance, you're really looking for a very
18 high-value response in reducing hospitalisation and
19 death, but you're restricting its use and it's really
20 then only about treatment. There is no prophylaxis
21 involved in that particular case.

22 Q. So at some stage in the process a clear strategic
23 decision needs to be taken as to whether or not you're
24 aiming to try to protect the country at a population
25 level --

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1 A. Yes.

2 Q. -- or whether you're trying to focus on, and if you have
3 only the means to try to focus on sectorial groups,
4 those special cases who are particularly vulnerable?

5 A. Yes, I think it's reflected by when I arrived as the
6 chair of the taskforce, I basically arrived with three
7 questions: why are we buying these medicines? What are
8 we trying to achieve with them? And do we know how to
9 get the best out of them? And driving through responses
10 to those questions really gets you then to the choices
11 that you make.

12 Q. You became the chair on 1 June 2021. There had already
13 been in existence for almost a year the Therapeutics
14 Taskforce, which was constituted, I think, in
15 April 2020.

16 A. Yes.

17 Q. Why was an Antivirals Taskforce needed in your view?
18 Why could not the issue of oral antivirals be addressed
19 by the Therapeutics Taskforce, oral antivirals being, of
20 course, a therapeutic?

21 A. Well, as I understand the decision-making process, and
22 it was only communicated to me, I think there was a view
23 felt that with the winter approaching, and that was
24 going to be the most fertile period of use of effective
25 antivirals, that much like the decision around the

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1 A. Well, the waves of Covid were coming to their own
2 pattern, I think is the best way of doing it, but
3 generally speaking, yes, in a winter environment,
4 respiratory infections are generally more prevalent and
5 more likely to cause widespread problems. So we did
6 expect winter to be more of an issue, yeah.

7 Q. And antivirals themselves need to be speedily given,
8 that is to say they need to be given at a relatively
9 early stage in the disease path, bluntly, in --

10 A. -- (overspeaking) -- sorry.

11 Q. -- they need to be given as quickly as you can get them
12 into people who are beginning to show signs of suffering
13 from -- (overspeaking) --

14 A. Generally in respiratory infections there's a benefit to
15 getting them in early, yes.

16 Q. You were approached, I think, first, in March 2021 to
17 become the Chair of the Antivirals Taskforce, but you
18 weren't appointed until 1 June.

19 A. Yes.

20 Q. In the context of trying to identify and make available
21 two oral antivirals by that same winter, that seems to
22 be quite a significant elapse of time?

23 A. Well, I think from my written statement I went through
24 the process of calculating it was 25% of the available
25 time which, I have to say, I felt a strange use of the

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1 Vaccine Taskforce, there was benefit to separating it
2 out and having focus upon it, and therefore it was
3 removed from the therapeutics and set up as a separate
4 taskforce.

5 Q. And were you aware of a clear political imperative or
6 drive or direction that you tried to identify, and then
7 procure and make available two antivirals in particular?
8 Not two particular types, but you were tasked to try to
9 identify two oral antivirals?

10 A. Yes. And actually, that made a great deal of sense.
11 And actually, to the point you just made there,
12 actually, you do want them to be two slightly different
13 modes of action because if you have two different modes
14 of actions in antivirals within a certain patient
15 population -- that's a long story as to why, but it's
16 beneficial in heading off the potential for resistance
17 if you have different modes of action operating in the
18 population at the same time.

19 So we did want two and we were hopeful that we would
20 get two different modes of action.

21 Q. And you were hopeful that you would get them there by
22 the winter of that year?

23 A. That was the key issue, yes.

24 Q. And was that because of the prospect of a further wave
25 of Covid or because it was winter?

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1 time. It wasn't clear to me why that was the case.
2 I think I speculate in my witness statement around why
3 the possible reasons for that, although you kindly sent
4 me some other witness statements as part of preparation
5 for this, and I did note in there, I think it was
6 Patrick Vallance's statement that the Permanent
7 Secretary at the time was advocating not to have an
8 external chair so I presume that was part of the
9 background to the delay.

10 Q. We needn't, perhaps, look at the reasons why the process
11 did become so protracted, but it must have been obvious
12 to you that by comparison, perhaps, to Dame Kate
13 Bingham, whose appointment as the external chair of the
14 Vaccine Taskforce went through within a matter of weeks,
15 and also, perhaps, by comparison to Charlotte Taylor of
16 the DHSC who chaired the Therapeutics Taskforce, the
17 process of getting you in place seemed to have been much
18 more protracted?

19 A. Yes, it was. And I think -- we're talking a year on,
20 and I think obviously, when you look at Kate's evidence
21 and Kate's experience, the concern about the pandemic at
22 that point in time led to a lot of very different
23 decisions and the set-up of the Vaccine Taskforce in
24 BEIS with the direct reporting line to the
25 Prime Minister. I think by the time antivirals were set

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1 up a year later, the world had moved on and I think we
2 were rather more -- what's the right way to phrase it?
3 There was a greater sense of a return to normal business
4 and this had a taskforce plonked on top of it, and
5 that's the situation we found ourselves in.

6 **Q.** Were you able to form an understanding as to the degree
7 of autonomy that you would be permitted -- the
8 Antivirals Taskforce was within the DHSC, was it not?

9 **A.** Yes.

10 **Q.** So not BEIS like the Vaccine Taskforce and not an
11 entirely external body. Do you happen to know whether
12 or not the DHSC, for example, welcomed the existence of
13 the Antivirals Taskforce within the DHSC, and whether or
14 not perhaps it opposed having a more external and
15 independent body?

16 **A.** Well, as I say, I've learnt from the other submissions
17 that you've provided to me that the Permanent Secretary
18 at the time was apparently arguing against Patrick's
19 support of an external chair. The fact that I was
20 appointed presumably means that others thought it was
21 important to have the external chair. And I think
22 perhaps on this subject, I've taken a point of having
23 a look through various submissions' lessons, and
24 watching some of the other people giving evidence to you
25 in this particular molecule. It has struck me that

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1 the vaccine or for whom the vaccines would have
2 comparatively a lesser degree of benefit.

3 So the government was hopping to achieve the same
4 success as the Vaccine Taskforce.

5 Over the page, we can see the objectives which were
6 identified for your taskforce: to have two effective
7 antiviral treatments deployable by the winter, identify
8 the most promising treatments, work with developers,
9 licence holders, help manufacturers to scale up, drive
10 commercial discussions, and create a pipeline -- and
11 this is obviously a nod to the future -- of additional
12 promising novel antivirals.

13 Were those core objectives the right ones, as you
14 saw it, Mr Gray?

15 **A.** Yes.

16 **Q.** And in terms of reporting, was there a proper system in
17 place for your reporting structures?

18 **A.** Well, as you can see here, I was reporting to
19 Lord Bethell, but there was an expectation that I would
20 work independently and show leadership of the taskforce
21 personnel.

22 I'd gone through quite a protracted process in
23 ensuring that I had clearance to what was called "direct
24 people" on the team and officials, and that was
25 something I insisted on, having consulted people like

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1 there has been much acknowledgement of the need for
2 different decision making, for embedding of certain
3 skills, et cetera. Nowhere in the lessons learned is
4 there a comment around the contribution or value of an
5 external chair in these things that I could find. There
6 may be one there but if there is, I couldn't find it.

7 **Q.** Actually, my Lady asked a question directly of an
8 earlier witness as to the undoubted benefits --

9 **A.** Ah, I missed that, apologies.

10 **Q.** -- of external experience, and of course we're well
11 aware of the differences between the private and the
12 public sectors in terms of running such bodies.

13 Let's have a look, please, at your letter of
14 appointment. Was it from Mr Hancock?

15 Were you appointed by Mr Hancock?

16 **A.** I was.

17 **Q.** At INQ000410503.

18 If we look at that page -- and the letter is dated
19 27 May 2021, so four or five days before your formal
20 appointment -- we can see that at the bottom of the
21 page, he refers to the great success of the vaccination
22 programme. But he is alert to -- and of course this was
23 a very obvious concern -- that there would be certain
24 groups in relation to whom presentation for vaccine was
25 lower, and also significant groups who could not take

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1 Kate and others who had worked in these environments
2 before, because I did feel that was important, you
3 couldn't be sidelined just as an adviser whose input
4 could be followed or not followed, depending on which
5 way the wind was blowing.

6 And so I think it was very clear at this point that
7 we were not going to get an organisation, a structure
8 and a reporting line similar to the vaccine question,
9 but I did feel this was a very important job that needed
10 doing, and therefore felt I should say yes to doing it,
11 but secured that as a mechanism for ensuring that
12 I could have an impact.

13 And of course, there was nothing, as we will no
14 doubt come on to discuss later, stopping me writing to
15 whoever I chose to write to where I --

16 **Q.** And you wrote I think prolifically, didn't you --

17 **A.** Yes, I did.

18 **Q.** -- to the Prime Minister repeatedly --

19 **A.** Yes.

20 **Q.** -- and to the Secretary of State on an almost weekly
21 basis.

22 **A.** Exactly.

23 **Q.** It is notable that when Dame Kate Bingham agreed to
24 become the Chair of the Vaccine Taskforce, she demanded
25 and got the condition, or at least the agreement of

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1 government that she would have a clear mandate with
2 a direct reporting line to the Prime Minister. Also
3 that the Vaccine Taskforce would be located within BEIS,
4 not, by implication, the DHSC. And also that she would
5 have the ability to establish a dedicated budget across
6 government.

7 You were not given -- perhaps you didn't seek them,
8 but you were not given that degree of largesse, were
9 you?

10 **A.** No, but as I say, I think the world had moved on. It
11 was clear that there had been conversations behind the
12 scenes both about the BEIS decisions, and I think you've
13 been investigating them here, and -- you know, one
14 person's fruitful discussion between colleagues is
15 another person's turf war. I have no idea where on that
16 spectrum all of this sat, but, again, I did feel that
17 the issue of getting these two across the line for
18 winter was the most critical issue. And at some point
19 you just have to get started.
20 **Q.** And to that end, you had a number of structures within
21 the taskforce. You had a steering committee, you had
22 a programme board, and within your organisation, you had
23 a number of subgroups, did you not, that dealt with
24 specific topics such as trial implementation,
25 deployment, planning, procurement, supply, manufacture,

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1 be challenging to meet.

2 **Q.** Ie, you would need a lot more money than provisionally
3 had been set aside?

4 **A.** Correct.

5 **Q.** The Vaccine Taskforce proceeded on the basis that it
6 would be able to enter negotiations with manufacturers
7 and ultimately procure vaccines at risk, that is to say
8 they would be able to enter into commercial
9 arrangements, even quite a long way down that path, so
10 not just by way of entering into heads of agreement, but
11 agreeing contracts, at risk. That is to say without
12 knowing whether or not the particular vaccine would
13 work, let alone be authorised.

14 Was that the same approach that was applied to the
15 purchase of the potential two oral antivirals?

16 **A.** Yes. And of course we also took every opportunity to
17 mitigate that risk. So every contract that we signed
18 was subject to completion of the clinical trials and
19 approval of the medicines by the MHRA.

20 **Q.** So you were given that same strategic opportunity as the
21 Vaccine Taskforce had been given?

22 **A.** We were.

23 **Q.** Was there, in relation to the budgeting and approval of
24 the financing for individual oral antivirals, any form
25 of ministerial panel, of which we've heard much in the

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1 policy, and so on?

2 **A.** That is correct.

3 **Q.** In general terms what did you understand to be the
4 position in terms of budget when you took on the task of
5 becoming the chair?

6 **A.** So about two or three weeks in, we indicated that
7 a budget had been set for the purchase of antivirals.
8 It became clear that that was calculated by going back
9 to a prior pandemic in the, sort of, 2008, and there had
10 been antivirals employed there which were already
11 available, were there for flu, and the price was set,
12 and -- et cetera. And so a calculation had been simply,
13 say, multiply that up by however many we think we might
14 need this time, and that was the budget.

15 But of course, in this instance, the medicines were
16 developed in a very different way. The companies
17 involved, to their credit, took on the most difficult
18 challenge by setting their phase III trial endpoints to
19 be the reduction in hospitalisation and death. And as
20 a consequence of that, they could see, and expected to
21 be, recompensed for a much higher value product. The
22 consequence of that then meant that, actually, the
23 original calculations were sort of comparing apples to
24 oranges, and I think it was always likely from that
25 point on that the budget that had been set was going to

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1 context of the Vaccine Taskforce, a body bringing
2 together ministers from the Treasury as well as DHSC and
3 perhaps other governmental spending departments, to
4 authorise payments above a certain amount?

5 **A.** There was, I believe, a sort of mechanism for approval
6 of financial decisions which was primarily set up within
7 the Therapeutics Taskforce, and I think the idea was
8 that, as antivirals, we would use that same mechanism.
9 But I think the speed at which we were moving and the
10 questions we were answering, and the fact that we were
11 buttressing up against what I think was a poorly
12 calculated initial budget meant that we moved to
13 different mechanisms of trying to get decisions made.

14 **Q.** And very soon after you became the chair, did you have
15 to address the issue of whether or not, in reality, that
16 funding would be available?

17 **A.** Yes. So if you recall what I said about the different
18 ways that you can use these, if you look at the initial
19 brief to the taskforce, basically every single possible
20 way of using them was in the brief. And the
21 consequence, of course, when you then calculate against
22 that brief, you come up with an immense number,
23 literally billions, of how much that would cost.

24 And I don't remember who it was, but somebody at the
25 time said: well, look, we have to acknowledge that the

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1 taskforce have very comprehensively answered the exam
 2 question that was set, we just don't like the answer.
 3 And I had sympathy with that, it was that the original
 4 brief hadn't been thought through properly.
 5 But the fact that that number came up and got
 6 everybody's attention I think was very useful because it
 7 stimulated, then, a much more sensible conversation
 8 around how should we use these? What is the appropriate
 9 way to use them? We had more information now on
 10 vaccines, and their rollout, and what we were starting
 11 to see, and whilst you could never take away the idea
 12 that a true vaccine escape would put greater pressure
 13 back on antiviral use, you could then start to have
 14 a sensible conversation which resulted in
 15 a recommendation that we should purchase antivirals to
 16 cover those people who were immune compromised and would
 17 struggle with getting a good vaccine response, and
 18 that's what we then started to focus all our activity
 19 on.
 20 **Q.** Of course by June 2021, the United Kingdom had gone
 21 through the entirety of the phase I of the JCVI's
 22 priority list?
 23 **A.** Yes.
 24 **Q.** 99% of those most vulnerable to morbidity or mortality
 25 had been offered vaccination, and it was becoming clear

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1 well, and there was a very open debate at this point in
 2 time about the economic impacts of the pandemic, which
 3 I think it's fair to say back in 2020 you didn't see in
 4 the public commentary at all.
 5 So we were caught up in that, undoubtedly, yes.
 6 **Q.** I should have asked you -- I neglected to do so -- in
 7 terms of the devolved administrations, Scotland, Wales
 8 and Northern Ireland, did the remit of the Antivirals
 9 Taskforce extend across the United Kingdom, so whatever
 10 oral antivirals you were able to identify, procure and
 11 make available, were you doing so for the whole of the
 12 United Kingdom?
 13 **A.** We were, and there were meetings with the devolved
 14 administrations where the plans were presented to them,
 15 and they all agreed that they would prefer to be with
 16 the taskforce's work rather than reproduce it for
 17 themselves.
 18 **Q.** They were happy for you to lead the charge --
 19 **A.** Correct.
 20 **Q.** -- and to take whatever benefit you were able to --
 21 **A.** Correct.
 22 **Q.** Let's look, then, at the chronology of how you reached
 23 the position whereby you were able to procure 5 million
 24 of those courses.
 25 In your statement you've very helpfully set out

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1 that the vaccination programme, to a very large extent,
 2 was going to succeed?
 3 **A.** Correct.
 4 **Q.** Do you think that against that political backdrop, there
 5 was less willingness on the part of the government to
 6 give you the funding that you felt you needed, or to
 7 give you the degree of largesse, my word, that the
 8 Vaccine Taskforce was itself permitted?
 9 **A.** I think I should probably say that I've never taken
 10 a business decision, I can recall, where some element of
 11 affordability -- or, in small companies, even whether
 12 you've got the cash available -- is not part of the
 13 equation. So the idea that somebody somewhere was
 14 trying to sort of balance out the public health position
 15 that we were advocating with the country's ability to
 16 afford it, in principle I had no objection to.
 17 The issue for me was really: was the process in
 18 place and the appropriate people in place to make that
 19 trade-off? And I didn't believe that was what was
 20 happening. And that's what led me to try to step out of
 21 the system to sort of do that.
 22 But yes, I think in 2021 the world had undoubtedly
 23 moved on. There was a great deal more commentary in the
 24 public environment about how the pandemic was being
 25 managed, what was deemed to be going well, or not going

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1 a chronology of the events, and we're just going to look
 2 at a few of the paragraphs.
 3 INQ000474342, page 9.
 4 Paragraph 27.4, you refer to the fact that on
 5 18 June you were informed that the Treasury had approved
 6 a funding envelope with the Antivirals Taskforce of
 7 £621.5 million for the financial year 2021-22.
 8 Obviously you were in June of 2021, so you were
 9 looking for approval for expenditure throughout the rest
 10 of that financial year.
 11 Going forward from April 2022 would be another
 12 matter.
 13 **A.** Correct.
 14 **Q.** You weren't in fact the chair after April 2022, were
 15 you?
 16 **A.** No, but obviously we were looking, as we may get on to
 17 talk to, we came to the conclusion that attempting to
 18 purchase to cover the first two winters was the
 19 appropriate strategic picture to take, given a whole
 20 host of factors, not the least of which was likely
 21 availability of supply, and so that would have incurred
 22 additional costs later in the system after I had in fact
 23 left, yes.
 24 **Q.** All right.
 25 Now, I don't want you to give me the exact amount,

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1 because some might be able to work out, from the overall
2 amount that you sought, the unit cost of the individual
3 courses --

4 **A.** Yes.

5 **Q.** -- for the two drugs. But in general terms, although
6 the Treasury had approved a funding envelope for
7 621.5 million, had a figure in the billions been
8 initially suggested and perhaps put round government
9 departments to the effect that that was the sort of
10 funding which might be required if you were going to try
11 to provide therapeutic remedy to a much larger part of
12 the population?

13 **A.** So I think that I did hear somebody earlier in their
14 evidence talk about two phases. I'd actually describe
15 it as three phases. So the first phase was -- the first
16 phase was answering the original exam question, which
17 was many, many billions, and was clearly not appropriate
18 in the circumstances.

19 The second phase was when we started to advocate
20 what we felt was necessary to cover the
21 immunocompromised. And we were doing so now having
22 found out that this was the budget set.

23 The number we recommended was not of the original
24 magnitude, but was greater than the 621, had we procured
25 the full amount that we recommended. But as I think you

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1 **Q.** By escape variant you mean the possibility of a variant
2 of coronavirus SARS-2 coming into play meaning that the
3 existing vaccines would no longer be as efficient --

4 **A.** Correct, correct.

5 **Q.** Or would be no longer as effective. All right.

6 Then in August, the middle of August, on the 18th --
7 INQ000064095 -- you wrote to the Prime Minister to say
8 that you had identified three antiviral candidates. Two
9 of them were molnupiravir and nirmatrelvir/ritonavir,
10 the Paxlovid Pfizer oral antiviral, and those two were
11 the two you went on to procure. There was a third one
12 that didn't go anywhere.

13 On page 2, having identified the two novel antiviral
14 treatments, you deal with the process of supporting
15 priority antiviral candidates to progress rapidly in
16 clinical trials.

17 Presumably whatever oral antiviral you had
18 identified would have to go through clinical trials, in
19 order to be able to secure authorisation from the MHRA?

20 **A.** Correct.

21 **Q.** And was there a system already in place for the carrying
22 out of those clinical trials?

23 **A.** So the clinical trials for antiviral candidates were the
24 responsibility of the companies that were developing
25 them. And by the time I became the chair, those trials

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1 see in the documentation, we secured less than was
2 originally --

3 **Q.** We'll come to that.

4 **A.** -- but was consistent with this number.

5 **Q.** Just on that first point, though, of the first phase:
6 the importance of this point is, though, that there are
7 some who say the government should have made billions of
8 pounds available, but you, as the professional, and the
9 external head of The Antivirals Taskforce, appreciated
10 and proceeded on the basis that you had to be much more
11 realistic in terms of what level of funding would be
12 available from the Treasury?

13 **A.** Yes. And I think that was based on this continuing
14 accumulation of evidence about the progress of the
15 pandemic and, in particular, the success that the
16 vaccine --

17 **Q.** Programme was having.

18 **A.** Was having.

19 There was always one big unknown that you simply
20 couldn't control for, and that was an escape variant.
21 And that was a completely different environment,
22 obviously, and the scale of what response you would have
23 to generate on antivirals was out there.

24 But I think the emerging view of the CMO and others
25 was that that was a manageable risk.

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1 were well advanced. Clearly, this is very much a normal
2 operational practice for these organisations. They --
3 I think I'm right in saying at the time I started that
4 two of the three candidates were already in phase III,
5 and the third one was in phase II.

6 And so they were progressing, and we did talk to
7 both organisations about the ability of having trial
8 sites in the UK, and I think one of the companies, if my
9 recollection is correct, did recruit some UK patients.
10 But we were not in any way getting formally involved in
11 the trial. That was their responsibility, and I think
12 one company had UK patients and the other didn't, if
13 memory serves me correctly.

14 **Q.** So you didn't have to deal with the difficulties that
15 other, particularly phase II clinical trials --

16 **A.** We did not.

17 **Q.** -- for therapeutics had to encounter, which was
18 difficulties of recruitment and whether the trials were
19 sufficiently diverse or underpowered, or managed.

20 **A.** We did not.

21 **Q.** You had a clear line of sight?

22 **A.** We did. And the issues of things like diversity, of
23 course, these large pharmaceutical companies are doing
24 these trials in different areas all the time. Those
25 goals of diversity, et cetera, are part of their normal

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1 standard operating procedures. So I was confident that
 2 we were going to get properly managed, high-quality
 3 studies, and that the MHRA would be able to make their
 4 decision.

5 **Q.** All right. Then at the end of August you wrote to the
 6 Secretary of State, INQ000489913, I think on 30 August,
 7 to give advice as to what he should do, and by this
 8 stage, August 2021, the Secretary of State would have
 9 been Sir Sajid Javid --

10 **A.** Yes.

11 **Q.** -- Mr Hancock having resigned, and you submitted options
 12 for purchase of antivirals over the next two years. And
 13 how many courses did you, in terms of millions,
 14 recommend be purchased?

15 **A.** So -- 25 million.

16 **Q.** And was that over that year to the winter 2021 --

17 **A.** No, that was --

18 **Q.** -- or was it over the two years?

19 **A.** No, that was over the two years.

20 **Q.** All right. And in the middle of the page we can see, I
 21 believe, reference to the amount of the funding which
 22 had been available, and if it's not on this page it'll
 23 be on the next.

24 Yes, it's the top of the page, thank you. The top
 25 line:

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1 provided a number of options, but you identified that as
 2 an absolute minimum, you had to get 1.8 million courses
 3 from Arrow, Arrow being Merck, that's the
 4 molnupiravir --

5 **A.** Yes.

6 **Q.** -- oral antiviral, isn't it? And the full 250,000 from
 7 Tyne, so that's the Paxlovid and the Pfizer:

8 "... from this autumn and winter, giving us a total
 9 of 2.05 million doses."

10 And then you wanted another 700,000 courses of
 11 molnupiravir.

12 **A.** That was our advice, yes.

13 **Q.** Around this time the Inquiry has seen evidence in the
 14 form of emails from you to Sir John Bell and the then
 15 Government's Chief Scientific Adviser Sir Patrick
 16 Vallance, saying, in essence, about the Secretary of
 17 State, Sir Sajid Javid, "He's supported our
 18 recommendations, which is good, but getting decisions
 19 across him, the Prime Minister and the Chancellor has
 20 been ridiculously hard."

21 Why were you saying that in email correspondence
 22 whilst at the same time you had given the government or
 23 the Treasury options as to how they should proceed in
 24 terms of funding?

25 **A.** Well, the memo that you've just shown was consistent,

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1 "... highlight that the ATF budget of £623 million
 2 is insufficient to allow procurement of any reasonable
 3 volume, given market dynamics ... and the international
 4 context of constraint global supply until at least
 5 2024."

6 So, in essence, were you saying, "The budget is not
 7 going to be enough to get the number of courses that we
 8 would recommend that we pursue, you're going to have to
 9 increase it"?

10 **A.** That is what I was saying, yes.

11 **Q.** Further down the page, at paragraph 8, if we scroll out,
 12 we'll see that you say this:

13 "... I do feel it is important that decisions are
 14 not 'reverse engineered' from a financial target ..."

15 What did you mean by that?

16 **A.** What I felt it was important was that we were -- that
 17 we -- in negotiating the balance between the public
 18 health goal and the affordability, that we started from
 19 the process of public health, and ensuring that we
 20 reached absolutely what we felt was, at the very least,
 21 the minimum that would achieve our goal, rather than
 22 starting from 623, and working out what you could get
 23 for that.

24 **Q.** All right. And was that why, if we look at page 3,
 25 paragraph 14, you provided -- thank you very much -- you

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1 I think, with the frustration I was starting to feel at
 2 this point in time about the decision-making process.
 3 And the only way in which I had -- I was concerned that
 4 the process on constant reiteration meant that this
 5 potential trade-off between public health goals and
 6 affordability goals ended up being -- the decision being
 7 made by junior civil servants. Because in the system
 8 that operates, there appears to be a premium for the
 9 Civil Service to agree an answer to a question, feed
 10 that answer up on both sides of the house, and then, so
 11 the same recommendation goes to ministers in two
 12 separate pots. And I didn't, in this instance, feel
 13 that that was appropriate.

14 I thought that if we were making a trade-off of this
 15 nature, I fully understand that it may have to be made,
 16 but the senior responsible people should be making that
 17 decision, and consequently, rather than allow that to
 18 sort of continue, I simply wrote to the Secretary of
 19 State saying, "Here's my advice."

20 Now, separately, we were starting to stimulate the
 21 process around thinking about the next phase, and future
 22 medicines, and John Bell was involved in helping us set
 23 that up and introduce us to people who could contribute,
 24 but as you said, John was involved in many other things
 25 in the -- Sir John was involved in many other things,

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1 and he'd picked up from somewhere that, you know, the
2 conversation over this particular decision was sort of
3 getting a bit mired and going a bit slow and not
4 necessarily going very well.

5 So I think I'm right in saying, if you follow that
6 email trail back, it started with John's letter, not
7 mine. John's email, not mine --

8 **Q.** It did.

9 **A.** -- and I was responding to that and sharing my
10 frustration that he'd already identified.

11 **Q.** So in essence, Mr Gray, what you're saying is that you
12 would have preferred your departmental officials, the
13 people within the DHSC, the people who were assisting
14 you within government and assisting the Antivirals
15 Taskforce, to be more proactive in terms of putting
16 their fiscal case to the Treasury --

17 **A.** Yes.

18 **Q.** -- and then seeing where the cards fell?

19 **A.** Yes.

20 **Q.** As opposed to, within the bureaucracy of government,
21 trying to find the lowest common denominator?

22 **A.** Yes.

23 **Q.** That is to say, a fiscal package that would itself be
24 acceptable to the Treasury; is that what you're saying?

25 **A.** I am.

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1 medicines -- so, in essence, you need to get on and buy
2 them.

3 And on page 2 -- page 3, I'm sorry, you set out
4 again the options:

5 "... order immediately from Arrow 2.5 million
6 courses ... intermediate ... order some lower than
7 2.5 million courses from Arrow ..."

8 Arrow being Merck.

9 "Not affordable option: order no further courses or
10 only those courses affordable under the current budget
11 or only sufficient courses to support the [National
12 Institute of Health Research] trial."

13 In the event, on 26 September, so about ten days
14 later, you were informed, were you not, that what had
15 been agreed at that, presumably very high, level that
16 you may proceed to buy or negotiate over the purchase of
17 480,000 molnupiravir courses, that is to say Project
18 Arrow? That was way short of what you were looking for,
19 was it not?

20 **A.** Yeah.

21 **Q.** And did there come a time where you had to go back in to
22 bat, you had to try to get the numbers up, and you
23 pursued the DHSC and HMT to agree a larger number of
24 courses?

25 **LADY HALLETT:** Just before you go on, Mr Keith, I remember

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1 **Q.** Right.

2 **A.** I think part of the concern I had with the process I was
3 observing was a clear power imbalance. And I could see
4 officials in the Department of Health and Social Care
5 essentially starting to undermine their own argument for
6 the recommendation we were making before we'd ever had
7 the proper discussion at the right level. And as I have
8 said, my conclusion was the only way to sort of spike
9 that was to step out of the system --

10 **Q.** -- (overspeaking) -- all right.

11 **A.** -- and go directly to those people I felt should be
12 making the decision.

13 **Q.** So, in fact, you emailed the Secretary of State on
14 8 September and then, not content with that, or perhaps
15 the reaction in the meantime, you emailed the
16 Prime Minister directly on 15 September.

17 If we just look, please, at the email to the
18 Prime Minister of 15 September, INQ000410527.

19 In essence, you, if I can summarise your email in
20 this way: you set out what the aims of your Antivirals
21 Taskforce were, and in particular, the procurement of
22 the two oral antivirals for that winter, and of course,
23 by now we're talking September, and you say at the
24 bottom of the page: you recognise that you were in
25 competition with other countries for a limited supply of

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1 once when I was having to negotiate with ministers
2 that I was told that only certain people necessarily
3 have their letters or emails forwarded directly to the
4 minister or Secretary of State.

5 **A.** Right.

6 **LADY HALLETT:** Were you confident that your emails and
7 letters were going to either Mr Hancock or the
8 Prime Minister?

9 **A.** Yes, because, generally speaking, I asked for a reply.
10 And so I knew if I didn't get one of those, yes. Yes.

11 **MR KEITH:** And I think it's fair to say, Mr Gray, that when
12 you emailed the Secretary of State and the
13 Prime Minister, you made sure that you'd emailed all the
14 private secretaries, permanent secretaries,
15 undersecretaries.

16 **A.** Yes.

17 **Q.** There wasn't any way that it wasn't going to get to
18 their attention in the end?

19 **A.** No. And I think it goes back a little to the point you
20 were making right at the very beginning about the
21 different set-up. I think, you know, my view was that I
22 always that the option, if that's the right phrase, of
23 throwing my toys out of the pram if necessary, and this
24 felt like an appropriate time to do.

25 **Q.** So the amount -- the number of courses agreed by the

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1 Prime Minister, you presume it was the Prime Minister,
2 but somebody at a high level, was less than you thought,
3 but you had got, then, agreement in principle to that
4 purchase.

5 However, in the middle of October, on the 21st, the
6 evidence before the Inquiry suggests that HMT, the
7 Treasury, requested of you, your taskforce, what was
8 called a deployment plan. That is to say, evidence of
9 why you needed the courses of molnupiravir, how they
10 were going to be deployed if you got them and what
11 benefit, I suppose, would be derived thereby.

12 **A.** Mm.

13 **Q.** Agreement having been made to that purchase, although it
14 was a purchase you wouldn't have agreed to yourself --
15 it was less than you wanted -- why was the Treasury
16 asking for further information in support of your
17 request for authority to purchase?

18 **A.** So I think I read it slightly differently.

19 So, first of all, I think the fact that we had an
20 operational plan to get the best from what we'd been
21 able to secure, I had, in principle, no issue with.
22 Absolutely, particularly if you have been restricted in
23 how much you want, I think one of the big benefits of
24 the PANORAMIC trial that we eventually went on to
25 utilise was that it absolutely guaranteed that the

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1 **A.** Yes, I think there were two sources of frustration for
2 me in this whole process. One was bypassing the normal
3 practice to get right people to make the decision. But
4 even when you did that, the timeliness of that decision
5 was then a separate problem.

6 And so Sajid -- or the Secretary of State had
7 requested us to go out and secure more supply. We had
8 negotiated with the companies concerned. Clearly we
9 were not the only country coming back to them at this
10 point in time, because this whole initiative was now on
11 the back of the emergence of Omicron and of course all
12 other countries had the emergence of Omicron at the same
13 time.

14 So, having responded swiftly and effectively to the
15 request, we were then in the same situation of how do we
16 get the final approval for the spend. And that turned
17 out to be as slow as previous occasions, which was
18 equally frustrating as previous occasions.

19 **Q.** All right.

20 In November and December, authorisation was granted
21 for the two oral antivirals by the MHRA, we know from
22 other evidence, and you had reached agreement with the
23 manufacturers for those further courses to be bought.

24 And then, were the two oral antivirals put through
25 what was called the PANORAMIC trial, a clinical trial

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1 courses that we'd bought would in fact go to the people
2 who really needed them, rather than to, sort of, just
3 dissipate throughout the system.

4 I think the Treasury saw it as their responsibility
5 to ensure that, having spent the money, that we were
6 getting cost effective use out of it, and it was
7 a natural fallout of a plan we were putting together
8 anyway, so it didn't strike me as a particular hindrance
9 or a burden.

10 **Q.** All right. In the event, negotiations with government
11 or at least communications with government as to the
12 procurement of a larger number of courses of stocks
13 proceeded, and Sir Sajid Javid, I think, authorised more
14 stocks to be bought, more courses to be bought, by the
15 end of November.

16 There was an email that we asked Sir Sajid to
17 comment on, it's not on the screen and won't be in the
18 system, but it was an email dated 1 December 2021 in
19 which you referred to a "dreadful sense of deja vu and
20 being mired in the treacle of interdepartmental process
21 and argument".

22 Lovely prose, but by 1 December, Mr Gray, Sir Sajid
23 had authorised the purchase of, or the pursuit of the
24 procurement of the greater number of stocks that you'd
25 looked for.

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1 process, in order to ensure that, of course, in terms of
2 effectiveness and safety, they were appropriate for use?

3 **A.** Yes. I think there were two reasons why I supported
4 PANORAMIC. One of them I've already mentioned, which
5 was to simply put the stock we had out into the national
6 health system ran the risk of people who were not in the
7 most vulnerable groups getting courses, and then we get
8 to a point in the process where people on the vulnerable
9 list needed the courses and we'd run out.

10 So this was a means of managing the process by which
11 the people who we'd bought them for were the people who
12 got them.

13 I think the second value of PANORAMIC was
14 a reflection now that we were in a world where everybody
15 had been vaccinated and, whilst the outcome of PANORAMIC
16 wasn't necessarily going to determine any of our actions
17 in that first winter, a much better understanding of the
18 impact of these antivirals in a vaccinated setting was
19 going to be useful going forward in the future. So
20 I thought they were the two primary reasons that led me
21 to support PANORAMIC as a good idea.

22 **Q.** Once the oral antivirals had been authorised and they'd
23 been trialled -- they're two separate processes, of
24 course --

25 **A.** Yeah.

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1 Q. -- and therefore proved to be effective and safe, they
 2 were allowed to be made available --
 3 A. Correct.
 4 Q. -- to those groups for whom vaccines, for a variety of
 5 reasons, may not work?
 6 A. Correct.
 7 Q. We know from the evidence before the Inquiry that the
 8 route by which, in general terms, the antivirals were
 9 made available was through a body called the Covid
 10 Medicines Delivery Unit. Was that something of which
 11 you had oversight? Was that a process with which you
 12 were involved at all, or was that down the road --
 13 further down the course of making antivirals available
 14 and for other parts of government?
 15 A. So that was within the National Health Service. And my
 16 recollection, which -- I'm happy to be contradicted if
 17 my recollection is not right, but the setting up of
 18 PANORAMIC primarily involved people's presentations of
 19 general practice, identification and confirmation of
 20 infection, and then they were given the antiviral
 21 medicine.
 22 Two things came up. The CMO, if my recollection is
 23 correct, identified that within that highly -- within
 24 that population, there was an even more vulnerable
 25 group, the most vulnerable group of all, a smaller
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1 adhering to what we've heard was the 100 Days Mission,
 2 which was the United Kingdom/G7 promoted policy.
 3 You wrote a number of letters to the Secretary of
 4 State on 10 January 2022 and then later in January 2022,
 5 about manufacturing in future pandemic preparedness.
 6 Why did you feel there was a need to write directly to
 7 the Secretary of State on these issues?
 8 A. My recollection at the time was that that was in
 9 response to a request to do so.
 10 Q. In your emails, we needn't put them up, you deal with
 11 the issues of onshore manufacturing, you call or you
 12 observe that there's a great need to develop appropriate
 13 infrastructure. You need different options for
 14 manufacturing, alternatives to manufacturing, and of
 15 course having as wide a range of therapeutics, or
 16 particularly oral antivirals, as possible.
 17 That process culminated in a letter you sent to the
 18 Secretary of State on 28 March 2022, which must have
 19 been a week or so before you stood down. And you talk
 20 in that letter of questions needing to be addressed, and
 21 challenges needed to be overcome. And you talk in terms
 22 of the interface, to use a neutral word, between Civil
 23 Service and external professional experience, and how
 24 your job, in terms of getting these two oral antivirals
 25 out of the door, was made a great deal harder by that
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1 group, for whom putting them in a trial setting was not
 2 appropriate. So they had to have the antiviral.
 3 Q. They had to be offered it outwith the --
 4 A. Any other -- outwith of the treatment thing.
 5 And there was also, I seem to remember, some
 6 question mark as well about very rural areas being able
 7 to get the antivirals to them. So CDMUs, in my
 8 recollection, were set up to sort of help address those
 9 two questions. But, as I say, I would accept if my
 10 recollection of that is not wholly accurate.
 11 So, no, I wasn't responsible for it, but I was
 12 involved in meetings and discussions about the need for
 13 them.
 14 Q. Yes. Within your functions, Mr Gray, lay an obligation
 15 to consider future pandemic preparedness, and in for the
 16 autumn of 2021 did you task a team within your taskforce
 17 to look at future pandemic preparedness, and were
 18 a number of papers -- (overspeaking) --
 19 A. We did, although the paper did not -- wasn't finalised
 20 until after I'd left, but I did kick it off, yes.
 21 Q. We've seen a paper, it's undated, but it talks about
 22 a meeting called the "Eddie/FPP", future pandemic
 23 preparedness group, regarding future pandemic
 24 preparedness, and it talks about the need, of course,
 25 for onshore manufacturing, the need for speed, for
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1 working relationship --
 2 A. Yeah.
 3 Q. -- or the lack of working relationship.
 4 Why, again, did you think it necessary to write to
 5 the Secretary of State about this aspect of the
 6 administrative structures inside government?
 7 A. Well, this was essentially my goodbye letter, and
 8 I think I knew that the decision post my leaving wasn't
 9 to have antivirals remain as a separate taskforce; it
 10 was going to be folded back into the Therapeutics
 11 Taskforce. And I also knew, with my own departure, that
 12 all the other external people were leaving as well.
 13 I just felt it would be important for the Secretary of
 14 State to have, as a resource, essentially my summation
 15 of where we were and what -- and the things that I
 16 thought he would need to have at the front of his mind
 17 as the pandemic continued to play out.
 18 So it was simply meant as a sort of helpful, you
 19 know, "Here's my leaving, here's a mind dump of the
 20 things I think I've learned. Hopefully it's of use to
 21 you."
 22 Q. In 2020 there was no vaccine. Did you therefore ask, in
 23 your letter, the Secretary of State to consider what
 24 might have happened, what might have been possible if,
 25 in the course of 2020, there had been available oral
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1 antivirals or, perhaps, neutralising monoclonal
2 antibodies, in the absence of the vaccine? What would
3 have been the likely impact, in terms of hospitalisation
4 and death in the United Kingdom?

5 **A.** Yes. I felt, thinking about 2020 was just a useful
6 analytical construct for thinking about a future
7 pandemic, because even with 100 day missions and other
8 good plans in place, I think one of the things we have
9 to recognise in this pandemic was we were very fortunate
10 that we got a vaccine quickly that worked, and as
11 I believe you've had in evidence from other people, we
12 cannot guarantee that that will happen next time.

13 So the idea of looking at this current pandemic and
14 saying, "How do we avoid 2020 next time," just seemed to
15 me a useful way to think about it, and to sort of then,
16 in thinking about preparation for another one, don't
17 have the concentration of that thinking upon getting to
18 a vaccine as the only thing you're thinking about,
19 because there may well be things that you can do in the
20 run-up to that, which mitigates some of the impacts that
21 we experienced in 2020 this time round.

22 So that was my thought process.

23 **Q.** And that's an appeal which you presumably reiterate to
24 this Tribunal?

25 **A.** Absolutely, yes.

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1 recommendations which my Lady has heard much about:
2 firstly, to develop a research and development
3 infrastructure that supports the exploration of a broad
4 spectrum of oral antivirals or therapeutics; secondly,
5 build a library of prototype antivirals that can then be
6 put properly but safely, but rapidly through
7 phase II/III clinical trials; and also increase
8 investment in diagnostic development work?

9 **A.** Yes.

10 **Q.** Are those the three, in your assessment, the three most
11 important recommendations that you've put in your
12 statement, and which in fact appear in the report that
13 was finalised after you left?

14 **A.** Yes, I would still be in support of all of those three.

15 **MR KEITH:** Thank you very much.

16 **LADY HALLETT:** Thank you very much, Mr Keith.

17 Mr Gray, thank you so much for the help you've given
18 the Inquiry. I think your evidence has highlighted the
19 need to have external chairs, if I say so -- not
20 that I needed any persuading. It must have been very
21 frustrating for you at times.

22 And may I say on behalf of the population of the
23 United Kingdom, we are extremely fortunate that people
24 like you and Kate Bingham were prepared to bring your
25 skills and expertise to chair the taskforces, and I'd

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1 **Q.** Your statement doesn't pull its punches, Mr Gray, in
2 terms of your reflections on working in government. And
3 I'm just going to summarise them, if I may.

4 You, like, in fact, Dame Kate Bingham before you,
5 note the lack of what you describe are necessary skills
6 and experience to make informed decisions in this
7 technical/business/scientific arena. And you say that
8 the Civil Service suffered from a lack of relevant
9 experience. There were too many generalists, not
10 enough, I think you would say STEM graduates, too many
11 committees, too much paperwork, writing endless
12 submissions and emails, and therefore a process which
13 was burdened by its administrative weight --

14 **A.** Yes.

15 **Q.** -- and leading to decisions which seemed to you being
16 made that were safer, and therefore wrong --

17 **A.** Yes.

18 **Q.** -- than a decision that was perhaps just riskier and
19 braver, and more likely to get us to where we needed to
20 be? Is that a fair summary?

21 **A.** Sadly, yes, it is.

22 **Q.** You mentioned earlier how you'd started in November of
23 2021 formulating some policy proposals for the future,
24 in particular in relation to future pandemic
25 preparedness, and were three of them in fact

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1 like to offer you our thanks.

2 **THE WITNESS:** Well, firstly, thank you. I did put in my
3 final letter to the Secretary of State that I think it
4 was -- I know everybody outside of government to have
5 contributed felt very positive about the opportunity to
6 do so. And I should actually say, despite my criticisms
7 of the Civil Service, that the team that we formed,
8 combining external and Civil Service people in the
9 taskforce, I think did an outstanding job, including
10 a very smart and impressive cohort of young civil
11 servants, and I remain very proud of what they achieved,
12 and I should thank them.

13 **MR KEITH:** My Lady, would you allow me simply also to
14 observe, through Mr Gray, that the head of your
15 programme board was, I think, Charlotte Taylor.

16 **A.** She was.

17 **MR KEITH:** And she was also the official who was in charge
18 of the Therapeutics Taskforce?

19 **A.** Correct.

20 **MR KEITH:** And she obviously did an amazing job.

21 My Lady, for a variety of reasons, it hasn't been
22 possible to call her to give evidence before you, but
23 she is possibly the last person in the trilogy of chairs
24 to whom great tribute must be paid.

25 **LADY HALLETT:** And thank you for what you said too about the

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1 officials with whom you worked closely, obviously,
 2 Mr Gray. I'm not suggesting the entire Civil Service is
 3 full of people who impose bureaucracy, but I think one
 4 of the messages that I'm getting from you and from
 5 Dame Kate is that processes may be important in
 6 peacetime, but when it comes to an emergency, you need
 7 to be able to push aside some of the --

8 **THE WITNESS:** I would 100% agree with that, yes.

9 (The witness withdrew)

10 **LADY HALLETT:** Thank you very much. I shall return at

11 1.55 pm.

12 **(12.53 pm)**

13 **(The Short Adjournment)**

14 **(1.55 pm)**

15 **LADY HALLETT:** Mr Keith.

16 **MR KEITH:** My Lady, the next witness is Sir Munir

17 Pirmohamed, if he could be sworn, please.

18 **SIR MUNIR PIRMOHAMED (affirmed)**

19 **Questions from LEAD COUNSEL TO THE INQUIRY FOR MODULE 4**

20 **LADY HALLETT:** I hope you were told you wouldn't be on until

21 this afternoon.

22 **THE WITNESS:** Yes.

23 **MR KEITH:** Sir Munir, could you commence your evidence,

24 please, by giving us your full name.

25 **A.** Munir Pirmohamed.

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1 **A.** That's right.

2 **Q.** Having joined, as you say, the Pharmacovigilance Expert
 3 Working Group in 1996, did you become a member of the
 4 Commission on Human Medicines in January 2020?

5 **A.** That is correct.

6 **Q.** And were you appointed the chair of that body on
 7 12 February 2021 for a four-year term?

8 **A.** That's correct.

9 **Q.** So you're still in harness.

10 **A. (Witness nodded)**

11 **Q.** We've heard a considerable amount of evidence about the
 12 expert working groups which form part of the Commission
 13 on Human Medicines. During Covid, were you member of
 14 three of those expert working groups, the vaccine safety
 15 surveillance methodologies expert working group, the
 16 vaccine benefit risk expert working group, and the
 17 therapeutics expert working group?

18 **A.** That is correct, I chaired the vaccine benefit risk
 19 expert working group.

20 **Q.** The Commission on Human Medicines is obviously
 21 a statutory body because it was established by the Human
 22 Medicines Regulations 2012. But how long had its
 23 predecessor statutory body been around for, and before
 24 then, how long had the *ad hoc* committee dealing with
 25 giving advice on the safety of medicines been around

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1 **Q.** Thank you for attending today and also for your
 2 provision of your witness statement, which is dated
 3 5 September 2024, including a large number of exhibits,
 4 all of which, of course, has been very carefully looked
 5 at by the Inquiry and will continue to be so.

6 By way of background, please, and your
 7 qualifications and experience, Sir Munir, you qualified
 8 in medicine, did you not, from the University of
 9 Liverpool in July 1985, you've undertaken clinical work
 10 in the NHS for many years, you're a consultant
 11 physician, but you first joined the Commission on Human
 12 Medicines in 1996; is that right?

13 **A.** I joined the -- one of the expert working groups, which
 14 was the Pharmacovigilance Expert Advisory Group, in
 15 1996.

16 **Q.** When you give your answers, could you try to go as slow
 17 as you can, it simply makes the task a bit easier for
 18 our hardworking stenographer. Thank you.

19 You have carried out a vast amount of research in
 20 the field of the safety of medicines, I think you've
 21 published over 660 academic papers in that area.

22 You are a clinical academic researcher and you hold
 23 the David Weatherall Chair of Medicine at the University
 24 of Liverpool and a number of other chairs; is that
 25 right? In particular in the field of pharmacogenetics.

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1 for?

2 **A.** So the first committee was set up after the thalidomide
 3 disaster, which was in 1964. It was the Committee on
 4 Safety of Drugs, which was called the Dunlop Committee.
 5 This was then succeeded by the Committee on Safety of
 6 Medicines, and then in 2005, this was then changed to
 7 the Commission on Human Medicines.

8 **Q.** Was the Yellow Card Scheme first introduced at the time
 9 of the Dunlop Committee?

10 **A.** It was.

11 **Q.** So it's been around for a very long time?

12 **A.** A long time, yeah. 70 years last year.

13 **Q.** In very general terms, do the functions of the
 14 Commission on Human Medicines extend to looking at
 15 safety with a high degree of exactitude in the context
 16 of the clinical trial process, the authorisation process
 17 the process by which the MHRA authorises therapeutics
 18 and vaccines, medicines, but also post-authorisation.
 19 So from the very beginning of the process by which any
 20 medicine is developed, right to the end of the process
 21 years after it may have been authorised?

22 **A.** That is correct.

23 **Q.** Is it operationally independent of the MHRA, the JCVI,
 24 the DHSC, and all the other myriad bodies about which we
 25 have heard?

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- 1 **A.** Yes, it is an independent body and it is important it
2 remains an independent body.
- 3 **Q.** I think your secretariat is provided by the MHRA, but is
4 the CHM, I am going to use the acronym from now on,
5 operationally and functionally completely independent
6 from the MHRA? You don't adopt its advice, you won't
7 necessarily take the same position as it will and it has
8 no influence on any of your thinking?
- 9 **A.** Yes, it is independent. We get the secretariat from the
10 MHRA but it is independent and provides advice as an
11 independent body to the MHRA and the Secretary of State.
- 12 **Q.** Formerly, you give advice, do you not, to the MHRA and
13 where there is a Licensing Minister in place as the
14 licensing authority, which is what the MHRA is
15 ordinarily, to the Licensing Minister as well.
- 16 **A.** That's correct.
- 17 **Q.** During the course of the pandemic did the MHRA and/or
18 the Licensing Minister -- and there were a number of
19 licensing ministers during the course of the pandemic --
20 following the advice given by the CHM?
- 21 **A.** Yes, they followed all the advice that was given by CHM.
22 I do not know of any incident where CHM advice was not
23 followed.
- 24 **Q.** You're subject, I think, to a very strict Code of
25 Practice; is that right?

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- 1 Health Wales and the Health and Social Care Committee in
2 Northern Ireland?
- 3 **A.** That's correct, as well as JCVI.
- 4 **Q.** And JCVI. All right. Give us, please, some scale of
5 the degree of work and attention paid to the issue of
6 vaccine safety. Roughly, how many times did the vaccine
7 benefit risk expert working group meet between 2020 and
8 2023?
- 9 **A.** There were 93 formal meetings but there were other
10 meetings in between as well, so I would expect that we
11 probably met more than 100 times.
- 12 **Q.** We needn't, I think, spend any time looking at the role
13 of the CHM in the course of the clinical trial process.
14 We've looked at the clinical trial procedures from
15 a number of different angles already, so we can focus on
16 the introduction of the CHM's input from the moment of
17 authorisation onwards.
- 18 But presumably, prior to authorisation being granted
19 in the case of each of the three Covid-19 UK vaccines,
20 the CHM was very well aware of the nature of the
21 vaccines in each case: the clinical position,
22 safety-related issues, really everything to do with
23 their development, and production, because you were
24 involved from the very start?
- 25 **A.** That's right. So obviously the rolling review that

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- 1 **A.** That's correct.
- 2 **Q.** And do we see, and we'll see perhaps in a moment, that
3 in the course of every CHM meeting, there are long pages
4 devoted every single individual member of the committee
5 declaring relevant connections and links and also at the
6 end of the meeting minutes, again, a long list of
7 declarations of links, personal, non-personal, specific,
8 non-specific, and so on?
- 9 **A.** That is correct.
- 10 **Q.** In terms of the devolved administrations, is the CHM
11 UK-wide?
- 12 **A.** It is UK-wide.
- 13 **Q.** So it gives advice to the MHRA which is itself
14 a statutory body --
- 15 **A.** Yeah.
- 16 **Q.** -- which has UK remit, and did you happen to have
17 a close working relationship with representatives of the
18 devolved administrations?
- 19 **A.** So we advise the MHRA. We did have representatives from
20 the devolved nations attending some of our meetings as
21 observers.
- 22 **Q.** So not as members but as observers?
- 23 **A.** As observers.
- 24 **Q.** And were those observers from in England the NHSE, and
25 PHE, UKHSA, Scotland, Public Health Scotland, Public

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- 1 happened was very important, you know, in order for us
2 to be able to look at the data that was coming in with
3 regard to efficacy, but we spent a lot of time on the
4 quality particularly at the beginning, because if you
5 don't have a product which is of good enough quality
6 then it won't go through the authorisation process. But
7 then, when the safety issues also started coming
8 through, we were able to look at that as part of the
9 rolling review.
- 10 **Q.** Coming forward to 8 December, the Pfizer vaccine had
11 been authorised on the 2nd, and the first vaccination
12 was given to Mrs Keenan --
- 13 **A.** Yes.
- 14 **Q.** -- on the 8th. When the Pfizer vaccine was rolled out
15 on that first day, was there, at the moment the
16 programme started, a 15-minute observation period?
- 17 **A.** There wasn't when the first vaccine was given.
- 18 **Q.** What happened on that night, the first day of the
19 programme?
- 20 **A.** So there were two reports of anaphylaxis on the first
21 day, and I got a phone call at quarter to midnight
22 saying that we need to meet now to be able to discuss
23 what happened and what are we going to do to be able to
24 make sure that the vaccination programme can continue
25 but ensure that we monitor the safety of the vaccines

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1 and ensure there is mitigation in case of further cases
 2 occur.

3 **Q.** Were you able, that night to, to establish whether there
 4 was any link, other than temporal, between the
 5 occurrence, the incidence of anaphylaxis and the receipt
 6 of the Pfizer vaccine?

7 **A.** Obviously anaphylaxis, by definition, is an adverse
 8 event which occurs very soon after the administration of
 9 a medicine such as a vaccine. So from that we were able
 10 to assess that temporal relationship and it was clear
 11 that these individuals who had developed the reaction
 12 had a complex history but nevertheless we felt that the
 13 vaccine was probably responsible and therefore we then
 14 instituted changes to the drug label, to the product
 15 information, patient information leaflet, as well as
 16 introduce the 15-minute waiting time after vaccination.

17 **Q.** Overnight?

18 **A.** Overnight.

19 **Q.** So that when vaccination continued in the morning, the
 20 up-to-date position was being given to the public as
 21 well as the clinicians or the vaccinators?

22 **A.** Yeah. I should also say that on the next day, we got
 23 together with experts in immunology, allergy, and
 24 brought them together to get further advice in terms of
 25 making sure that we were looking after the risks

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1 **Q.** But regardless of those concerns, you thought, and you
 2 advised accordingly, that the right thing to do was to
 3 introduce this observation period nevertheless?

4 **A.** Absolutely. We felt it was important for the safety of
 5 the people who were being vaccinated. As we got more
 6 data, and you may want to go through that later, we were
 7 able to relax that 15 minutes.

8 **Q.** So during the booster campaign, 2022, the 15-minute
 9 observation period was removed, was it not?

10 **A.** Yes, we said we would remove it first of all for anybody
 11 who had had two doses of the mRNA vaccine and therefore
 12 for them to get anaphylaxis on the third dose would be
 13 extremely unlikely, so we removed the 15-minute period
 14 for them first, and then we got further data later on
 15 and we removed it for other people getting vaccines for
 16 the first time, but at the same time, we asked the
 17 UKHSA, as well as NHS England, to provide us with data
 18 to make sure there were no adverse incidents occurring
 19 and that patient safety was paramount at all times.

20 **Q.** Having said we wouldn't look at the clinical trials,
 21 there is one area that I wanted to ask you about.
 22 I apologise. It's a matter of particular concern to
 23 many people, but in particular, some of the Core
 24 Participant groups in this process, as to whether there
 25 was sufficient diversity in the clinical trial process

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1 associated with the vaccine in terms of anaphylaxis.

2 **Q.** It was no small matter to introduce a 15-minute
 3 observation time?

4 **A.** No.

5 **Q.** Because presumably there was a huge impact in terms of
 6 the arrangements that were being made in every single
 7 vaccination site?

8 **A.** Absolutely. Because all the processes which had been
 9 developed in the weeks before the first vaccine was
 10 authorised was all based on getting large numbers
 11 through. But then when you have a 15-minute waiting
 12 time you need more space in the waiting room, and your
 13 throughput actually goes down.

14 **Q.** So you were concerned about slowing down the rollout by
 15 doing this?

16 **A.** Right.

17 **Q.** Were there also concerns about whether or not by
 18 requiring everyone to wait for 15 minutes, you would
 19 inadvertently add to the risk of transmission in
 20 vaccination sites?

21 **A.** Absolutely, and we discussed all the risks associated
 22 with that 15-minute period, particularly with people in
 23 close contact with each other in a small waiting room,
 24 and the increased risk of transmission, but also the
 25 reduction in throughput.

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1 for the Covid-19 UK vaccines. The Commission on Human
 2 Medicines is not directly responsible for the setting up
 3 of trials. It appears to be a process which has many
 4 parents, in terms of the manufacturers, the funders,
 5 government bodies, and the MHRA.

6 So to what extent did the Commission on Human
 7 Medicines express views on the diversity of the clinical
 8 trials as they were ongoing?

9 **A.** So when we looked at the data through the rolling review
 10 we were able to look at the diversity aspects of the
 11 trials which had been undertaken, and by diversity, not
 12 only ethnicity but also sex, but also age as well, and
 13 importantly, to make sure that elderly who were the most
 14 vulnerable, were included in the trials.

15 **Q.** Why, in general terms, is it important for the CHM to
 16 express views on the diversity of particular sectoral
 17 groups, whether it be defined by age or sex or
 18 ethnicity?

19 **A.** It's important because we want to make sure that the
 20 vaccine is going to be effective, equally, in the whole
 21 of the population that is present in the United Kingdom.
 22 If there was a particular group that was not included,
 23 then it is possible that we may, at the time of
 24 licensing advise the MHRA that that particular group
 25 should be excluded from receiving the vaccines. So, for

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1 example, for the Valneva vaccine which came later on,
2 there wasn't enough evidence for over 65s, so we
3 actually just licensed it for under 65s.

4 **Q.** So issues of width of diversity are directly linked to,
5 firstly, whether or not authorisation will be given, for
6 a particular sector or age, and secondly, any conditions
7 that might be imposed on the grant of authorisation
8 subsequently.

9 **A.** That's right. We will always give advice on
10 a particular medicine, a vaccine, based on the clinical
11 trial population that was included in the pivotal trial.

12 **Q.** And did you have access to data on diversity for those
13 trials that were physically taking place in the
14 United Kingdom -- and AstraZeneca had at least two
15 trials, CoV-1 and 2 in the United Kingdom --

16 **A.** Yes.

17 **Q.** -- or trials globally?

18 **A.** Yes, we were -- we had data on age, sex, and the ethnic
19 characteristics, as well, of the participants.

20 **Q.** From everywhere in the world where the trials were being
21 conducted, or just the United Kingdom?

22 **A.** So, because most of the trials which were undertaken
23 were international, we did ask for all the data from all
24 the different trials.

25 **Q.** And did you get it?

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1 safety.

2 Could we look, please, at INQ000274036.

3 This is a report dated 5 February 2021 or at least
4 published on 5 February 2021. It's a document that
5 comes from the -- one of the expert working groups, the
6 vaccine safety surveillance working group, of the
7 Commission on Human Medicines, and therefore is
8 concerned with safety surveillance. If we look at it --
9 and perhaps we'll just go to page 2 or 3, thank you very
10 much -- the document refers to the background, obviously
11 the emergence of the vaccines and their authorisation,
12 and then, at the bottom of that page, the need for
13 post-authorisation vigilance.

14 It sets out, in very large part, the MHRA's own
15 working practices relating to pharmacovigilance, in
16 particular, what we now know to be the four pillars of
17 the MHRA's pharmacovigilance system.

18 Why was it necessary for the CHM expert group to be
19 opining upon the nature of the MHRA's pharmacovigilance
20 system? I mean, you could not be unaware of it, you
21 must know this issue like the back of your hand. Why
22 was the working group concerning itself with reporting
23 on this?

24 **A.** So very early on in the pandemic, if a vaccine was going
25 to become available, we knew that we would have to

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1 **A.** Yes. And I should say, sorry, it was published as well
2 when -- the papers were published in the New England
3 Journal of Medicine or The Lancet, very respectable
4 journals, which data on the groups which were included
5 in the trials was published in those papers.

6 **Q.** Yes, we've seen The Lancet article, including the
7 AstraZeneca data, published, I think, in December 2020.
8 Presumably the data which you sought and you were
9 provided with included not just data on diversity, but
10 the data in relation to those cohorts of people who were
11 excluded necessarily from trials on account of the risk
12 or because it was obvious that they wouldn't benefit
13 from trials and therefore wouldn't benefit from
14 vaccines.

15 **A.** Absolutely. And this is where the risk management plan
16 comes in, where there's data not available in
17 a particular group, for example, the immunosuppressed or
18 immunocompromised individuals, for example people with
19 HIV, and so on. So it was important for us to be able
20 to identify where there was missing information, and
21 that becomes part of the risk management plan to ensure
22 there's post-authorisation commitments to get that data
23 for the future.

24 **Q.** Turning now to the procedures and the processes which
25 were in place for the CHM to be able to advise on

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1 vaccinate millions of people, so it was important to
2 have a very robust plan in place to ensure that we could
3 monitor the safety of the vaccine.

4 So the MHRA -- this expert working group was set up,
5 really, with experts in all sorts of fields to advise
6 the MHRA on what those four pillars should be and the
7 necessary requirements for those four pillars.

8 **Q.** Ah, so the MHRA changed its working practices in the
9 course of the pandemic, or at least at the beginning of
10 the pandemic, on advice, in part, from the Commission on
11 Human Medicines, in order to tighten up and improve,
12 insofar as it could be improved, the pharmacovigilance
13 system?

14 **A.** Yes. So, for the other vaccines which had been
15 authorised before the pandemic, some of these processes
16 were already in place, but in this particular area, the
17 four processes were brought together so that we could
18 have the most robust proactive pharmacovigilance system.

19 **Q.** Part of one of the four pillars is the Yellow Card
20 Scheme, is it not?

21 **A.** Yes.

22 **Q.** You told us that had long been established, it had been
23 first commenced in 1964. Is it a scheme that's run by
24 the MHRA or CHM or both?

25 **A.** It's both. It's part of -- when it was set up, it was

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1 under the aegis of the regulatory agency at that time,
 2 which wasn't called the MHRA, and the CSM.

3 **Q.** We've heard evidence that in May 2020 a dedicated portal
 4 was set up to report Covid-related adverse events.

5 **A.** Yes.

6 **Q.** Was that in part because of the report from the CHM's
 7 working group or was that something that was already
 8 envisaged and brought into play?

9 **A.** So the portal was set up, as far as I can remember,
 10 largely to help people to be able to report. It was
 11 very important to make sure that people were aware of it
 12 and report through a particular portal to recognise when
 13 they had their Covid vaccines or Covid therapeutics.

14 There was the other portal, which is for the other
 15 medicines, which were continued at the same time.

16 In the end, they all went to the same database and,
 17 using statistical techniques, you can identify which are
 18 the Covid-related reports compared to the
 19 non-Covid-related reports.

20 **Q.** Can you please tell us what the broad benefits are or
 21 the broad purposes are of the Yellow Card Scheme?
 22 Firstly, it's obvious that when a reporter submits
 23 a report through the Yellow Card Scheme, online or on
 24 paper, that person brings to the attention of the MHRA
 25 and the CHM the actuality of a possible adverse event.

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1 request additional information, either from the reporter
 2 or from the GP (primary care) or the hospital (secondary
 3 care)?

4 **A.** Yes, absolutely. So that is very important because the
 5 amount of information received in different Yellow Cards
 6 from different people varies, and the quality varies.
 7 So it is important to ensure that we can get as much
 8 information as possible, particularly when you are
 9 reporting serious adverse reactions.

10 **Q.** And presumably the database and the software to which
 11 you've already referred crunches all the events, the
 12 reports, all the associated information -- and I'll come
 13 back to what additional information you can get --
 14 crunches it, and tells you whether or not there is
 15 a significant identifiable trend in terms of
 16 a particular adverse event?

17 **A.** That's right. So there are various statistical
 18 techniques, and they've been covered by other expert
 19 reports, in terms of how you can actually identify
 20 signals that are occurring for the large numbers of
 21 reports that are received.

22 **Q.** Do you, on the back of the Yellow Card report, go
 23 directly to the manufacturer and say, "What's this
 24 about? What's happened?"

25 **A.** So the Yellow Card Scheme is a signal-generating system.

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1 They're telling you about something that's happened.

2 How important is it, though, also, for the CHM and
 3 the MHRA to understand the perspective from the patient
 4 as to what they believe has occurred to them.

5 **A.** So, if you look at the Yellow Card Scheme from the time
 6 it was set up in 1964, it has evolved quite a lot.
 7 Initially it was set up for doctors, dentists and
 8 coroners, and then work was undertaken, by one of my
 9 predecessors as chair of the commission of medicines,
 10 looking at pharmacists reporting and that -- then
 11 introduced pharmacists to be able to report the Yellow
 12 Card Scheme.

13 I then undertook a study in nurses and then produced
 14 the evidence that enabled the nurses to start reporting.
 15 And then there was another report, and work done on
 16 patients.

17 And all those different groups can provide valuable
 18 data to the overall scheme, but they come from different
 19 perspectives. And that's part of the richness of the
 20 data that we receive in the Yellow Card Scheme, which
 21 allows us to be able to assess potential signals of
 22 adverse reactions.

23 **Q.** And if a reporter makes a report and tells you about
 24 a possible or suspected adverse event, is the scheme
 25 designed so that you can, or somebody in the MHRA can,

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1 There's a potential signal arising. Further work then
 2 has to be undertaken to determine whether the signal is
 3 a true signal or a false signal, in which case the
 4 advice from the CHM to the MHRA might be that you do
 5 need to go to the manufacturer for them to be able to
 6 undertake further evaluation. And a manufacturer may
 7 have reports from all over the world, which the MHRA may
 8 not have, so to be able to provide us with the overall
 9 totality of data of in the global population, for
 10 example.

11 **Q.** And what proportion during Covid of the Yellow Card
 12 reports related to reactogenic injury, that is to say
 13 injection site reactions?

14 **A.** The majority of the reports that we received were
 15 reactogenic events.

16 **Q.** Was there a proportion of the Yellow Card reports that
 17 were, to use the expression in your statement, placebo
 18 related?

19 **A.** So obviously the Yellow Card Scheme is designed to
 20 report suspected -- so there's no determination of
 21 causality from individual reports, but studies have been
 22 undertaken since then, and systematic reviews and
 23 meta-analysis, which have highlighted that, of all the
 24 reactogenicity events which have been reported, at least
 25 two-thirds are probably nocebo effects while one-third

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1 are truly related to the vaccine.

2 **Q.** What does that mean, placebo effects?

3 **A.** So, a nocebo effect is a negative expectation --

4 **Q.** Oh, sorry, nocebo, not placebo --

5 **A.** Nocebo effect. A placebo is a positive expectation of
6 something's going work, a nocebo effect is a negative
7 expectation that something is going to cause harm to
8 you.

9 **Q.** How easy is it for the CHM and the MHRA to follow up an
10 individual Yellow Card report in terms of getting access
11 to primary care data, GPs notes, GP observations,
12 treatment, and, perhaps more relevantly, hospital notes,
13 so that's notes from treating clinicians, and also
14 X-rays or radiographical information?

15 **A.** Sure, on an individual basis, if we get an individual
16 Yellow Card report, to get more information one has to
17 contact the reporter. So it becomes hugely
18 resource-intensive, reporters may be moved, the doctors
19 may have moved, nurses may have moved. They often don't
20 respond to the MHRA, which means that the process of
21 actually getting more information on individual Yellow
22 Cards is quite difficult and takes a long time. And the
23 team at the MHRA worked very hard to be able to get as
24 much information as possible from the individual Yellow
25 Card reports, which was hugely important, because some

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1 and CHM and the coronial system.

2 Are coroners able to report the outcome of inquests
3 directly to the MHRA or CHM, or do they have to go
4 through the Yellow Card Scheme themselves?

5 **A.** So when the Yellow Card system was set up, it was set up
6 for doctors, dentists and coroners so they could report
7 via the Yellow Card system. However, they can also
8 write directly to the MHRA if there are particular
9 concerns. And sometimes, sorry, the coroner's report
10 comes to some of the expert advisory groups, such as the
11 Pharmacovigilance Expert Advisory Group on particular
12 issues.

13 **Q.** All right. In terms of -- and you have many, many years
14 of experience nationally, internationally, of dealing
15 with systems for the reporting of safety signals and
16 adverse events, how does the Yellow Card Scheme in the
17 United Kingdom compare to its international analogues?

18 **A.** Maybe I'm biased but I would say it is one of the better
19 ones across the world. You know, there are many systems
20 out there and many countries have copied the Yellow Card
21 system once it was set up, but it is perhaps one of the
22 most robust ones. That doesn't mean there is no room
23 for improvement. Any system can be improved.

24 **Q.** There appears to be considerable material before the
25 Inquiry suggesting that, perhaps surprisingly, a lot of

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1 of the data which was being received was -- did not have
2 enough information. So it was really important that we
3 got as much information as possible, so that we could
4 make the right decisions.

5 **Q.** And if a reporter did respond, and gave you access to
6 their medical records, how difficult was it to get into
7 GP databases and hospital databases to get the clinical
8 information?

9 **A.** So when the reporter does respond, they respond in terms
10 of questions which are asked. They don't give us access
11 to the medical notes. So we don't get access to
12 individual medical case -- (overspeaking) --

13 **Q.** Ever?

14 **A.** No.

15 **Q.** All right. Sadly, there were a number of Yellow Card
16 reports involving death, fatality, where somebody,
17 a member of a family had reported the death of a loved
18 one through the Yellow Card system. Were all Yellow
19 Card fatality reports followed up by the MHRA or the CHM
20 by way of going back to the reporter and following it
21 up?

22 **A.** That's correct. Every phase -- every report which --
23 or, as I say, fatality is followed up by the MHRA.

24 **Q.** Concerns have been expressed in some of the Core
25 Participant material as to the liaison between the MHRA

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1 people are simply not aware of the Yellow Card Scheme,
2 or if they are aware of it, don't know how to use it to
3 their best benefit. Putting aside the mechanics, I'm
4 not going to ask you about the mechanics of the scheme,
5 is there anything that could be done, do you think, to
6 raise awareness of the scheme in the public sphere, or
7 to encourage reporting of adverse events or possible
8 adverse events by clinicians?

9 **A.** Sure. So there are many things which have been done in
10 the past to be able to improve reporting. For example,
11 when I was a junior doctor, because this was my area of
12 interest, which is drug safety, I developed a poster
13 which I posted all around the Royal Liverpool Hospital
14 which says, "Don't delay, report today", and simple
15 things like that can help in terms of improving of
16 reporting from hospitals, for example. But the
17 important thing to do, always, is to continue with
18 continual reminders to people. You can do an
19 advertising --

20 **Q.** You mean in the public sphere?

21 **A.** Yes, that's right. You can do an advertising campaign
22 which leads to a spike of reports, but then within a few
23 weeks it's gone down back to baseline. So it's the
24 continual reminders which become really important.

25 **Q.** I don't think His Majesty's Treasury will thank me for

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1 asking you this question, but have there in the past
 2 been processes, I think in France, where people were
 3 paid if they made a Yellow Card report?
 4 **A.** -- (overspeaking) --
 5 **Q.** That had the effect of increasing the use of the system,
 6 albeit when the process of paying people ended, the
 7 figures went back down.
 8 **A.** So it was in fact done in Ireland by Professor John
 9 Feeley. He did a very nice study which he paid people
 10 to report, and that led to a spike in the reports but as
 11 soon as the payments were withdrawn, the numbers of the
 12 report went down again.
 13 **Q.** All right. I think, Professor, the Inquiry's own
 14 expert, Professor Stephen Evans, suggested that there be
 15 prizes awarded to clinicians who first reported on
 16 a novel adverse event.
 17 **A.** Yes.
 18 **LADY HALLETT:** How do you ensure they're reliable reports,
 19 if you've given someone a financial incentive?
 20 **A.** So, obviously, a robust evaluation was done of those
 21 reports, and they were of good quality.
 22 **MR KEITH:** We'll come back to the issue of whether or not
 23 the data systems in primary and secondary healthcare
 24 worked well enough in terms of being able to link them,
 25 and also in terms of accessibility to the MHRA and CHM

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1 Thrombocytopenia is the low platelet syndrome, isn't it?
 2 And those reports were associated with the
 3 AstraZeneca vaccine, were they not?
 4 **A.** That's right.
 5 **Q.** The expert working group, on 25 February, in the CHM,
 6 presented a paper on something called immune
 7 thrombocytopenic purpura; is that correct?
 8 **A.** That's correct.
 9 **Q.** And was that in response to the receipt of Yellow Card
 10 reports?
 11 **A.** It was related to the Yellow Card reports on that
 12 particular population, it was -- we were focusing on
 13 immune thrombocytopenic purpura, but then there were, I
 14 think, three reports at the time of the occurrence of
 15 thrombosis with thrombocytopenia which was very unusual
 16 and we highlighted that these need to be followed up in
 17 more detail and further monitored.
 18 **Q.** Concurrently in Europe, from 11 March onwards, a number
 19 of not regulators but health authorities, suspended the
 20 deployment of AstraZeneca following the emergence of
 21 these reports. In particular, I think there was a lady
 22 in Denmark who had presented a very unusual clinical
 23 picture as a result of taking the AstraZeneca, or
 24 following the receipt of AstraZeneca. And so on
 25 17 March, did you convene, or was there convened, your

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1 at the end.
 2 Can we then turn to the question of thrombotic
 3 thrombocytopenia syndrome, TTS. Blood clots.
 4 Thrombotic events were not identified, were they, as
 5 adverse reactions, in the course of the clinical trials
 6 themselves?
 7 **A.** They were not.
 8 **Q.** But was thrombosis known to be a potential side effect
 9 of vaccines historically?
 10 **A.** So from other vaccines, it wasn't one of the adverse
 11 events of special interest. Thrombocytopenia, which is
 12 a lowering of platelets, was one of the adverse events
 13 of special interest, but thrombosis per se was not.
 14 **Q.** All right. And the system of adverse events of special
 15 interest, is that the system by which, during the
 16 clinical trial process, manufacturers and regulators
 17 require the identification of particular safety events
 18 or adverse events, which may be likely to give rise to
 19 problems in the future, because historically, they've
 20 appeared?
 21 **A.** Yeah, not only during the clinical trials but
 22 post-authorisation as well.
 23 **Q.** All right. Then in February 2021, the MHRA first
 24 started to receive Yellow Card reports of suspected
 25 thrombosis and associated thrombocytopenia.

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1 vaccine benefit risk expert working group to look at
 2 what should be done about how properly to respond to
 3 these emerging reports?
 4 **A. (Witness nodded)**
 5 **Q.** We'll look at it, INQ000409517. We can see a very
 6 significant attendance list. There are a lot of people
 7 there, aren't there, Sir Munir?
 8 **A.** [No audible response]
 9 **Q.** "Participants present" on the left-hand side.
 10 If we go over to page 2, some personal data is
 11 redacted, but I think if we then go over further one
 12 page, we can start seeing the introduction and
 13 announcement.
 14 There is a reference there, isn't there, to the
 15 conflict of interest policy? At the beginning of every
 16 single meeting does the chair remind everybody present,
 17 members and participants, of their obligation to declare
 18 any financial interests, personal or non-personal,
 19 specific or not-specific, which they have or which an
 20 immediate family member has, in any of the agenda items?
 21 **A.** That's right.
 22 **Q.** All right. And did some people declare interests,
 23 however than tangential, in that annex?
 24 **A.** Yes.
 25 **Q.** If we then go, please, to paragraph 2.5 on page 6, we'll

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1 see that the group, having looked at the data and the
2 evidence relating to these reports of thrombosis with
3 thrombocytopenia:

4 "... agreed that there was no evidence of an
5 increased risk of peripheral venous thromboembolism.
6 The group also agreed the evidence did not support an
7 increased risk of thrombocytopenia alone."

8 Could you just explain that paragraph to us --

9 **A.** Sure.

10 **Q.** -- but in particular, was the group reaching a view on
11 these particular conditions or was it reaching a view
12 generally on the risk of thrombotic thrombocytopenia
13 syndrome?

14 **A.** So you can have different clinical presentations. There
15 were people who were reporting the occurrence of
16 thrombosis in their legs, a deep venous thrombosis, for
17 example, but there were other people who just had low
18 platelets without thrombosis, and then there were people
19 who had thrombosis together with the low platelets. And
20 so we had to consider the three groups separately to
21 understand whether there was an increased risk and at
22 that time, in terms of the evidence we had, we concluded
23 there was no evidence of increased risk of peripheral
24 venous thromboembolism and no increased risk of
25 thrombocytopenia alone. However, we highlighted the

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1 available in this country to be able to define what that
2 background incidence was of thrombosis with
3 thrombocytopenia. So that was the first issue.

4 The second issue is that Covid itself can cause
5 thrombosis. Covid itself can cause thrombocytopenia.
6 And it was likely that Covid itself could cause
7 thrombosis and thrombocytopenia together. Again, we do
8 not have much data on that. And so it was important to
9 be able to understand what was going on to determine
10 whether it was truly vaccine-related or related to the
11 underlying disease.

12 **Q.** You're the specialist adviser on these, of course very
13 complex but extraordinarily serious issues. Why was
14 there not available a case definition or at least data
15 as to what the pre-existing position in the community
16 was in relation to this condition? I mean, isn't that
17 the sort of data which should be always available to you
18 so that you can make a careful and rational conclusion
19 as to whether or not these new reports are out of the
20 ordinary?

21 **A.** So there was no case definition available when these
22 reports started appearing, largely because this
23 condition is relatively rare. As I said, in 30 years of
24 clinical practice, I've only seen one case of this in my
25 career. So what we did, very quickly, was to get expert

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1 unusual cases of thrombosis with thrombocytopenia and
2 the need for further follow-up of those cases.

3 **Q.** So in relation to that particular type of condition,
4 thrombosis with thrombocytopenia, so blood clots and low
5 platelets, there was something to suggest a problem, an
6 issue, which was why you said further information needs
7 to be rapidly gathered?

8 **A.** That's right. Maybe I can add that in my career without
9 the vaccines, I think I'd seen one case like that in the
10 past. So this is an extremely rare condition that
11 occurs. And so we were just wanting to know how often
12 it was occurring and why. Was this just because of
13 heightened awareness that these cases were being
14 reported?

15 **Q.** Can you just, please, explain the importance of that
16 observation about the extreme rarity of this condition
17 in background, that is to say in normal day-to-day life?
18 So, by comparison, if you are starting to get a number
19 of reports temporarily following vaccination, that's got
20 to be compared against the extreme rarity of it
21 occurring in day-to-day life?

22 **A.** Yes. So any condition that -- unfortunately, any
23 diseases that occurs in the human population has
24 a background incidence. And one of the limitations that
25 we had was that we didn't have the data resources

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1 haematologists together and work with them to develop
2 that case definition, and I want to thank them for the
3 enormous amount of help they gave the Commission of
4 Human Medicines and the MHRA in developing that case
5 definition very quickly.

6 **Q.** Sir Munir, this meeting was on 17 March. The first
7 reports of suspected thrombosis and associated
8 thrombocytopenia had first started emerging in Europe,
9 I think in the second week in February. Why could that
10 passage of time between February and March not have been
11 used to try to bottom out the case definition, or to see
12 what data there was about background incidence?

13 **A.** So as I said, the data was trickling in, and it was
14 incomplete, and we had to keep on going back to the
15 individual reporters, to the haematology community who
16 were gathering more data for us, and so a case
17 definition really needs to be robust to be able to get
18 as much data as possible so that you can have a
19 definition which other people can follow. If you have
20 a case definition which is incomplete, then it will lead
21 to a lot of noise in the system.

22 **Q.** The meeting was on 17 March. By that stage, I think
23 a number of European member states -- I emphasise not
24 their regulators, so the regulators weren't withdrawing
25 authorisation, but their health authorities, and that's

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1 Austria, Norway, Iceland, Italy, Estonia, Latvia,
 2 Luxembourg, and Lithuania, had suspended the practical
 3 deployment of AstraZeneca. If was good enough -- if the
 4 concerns in the emergence of this extremely rare
 5 condition was good enough for them to put in place
 6 a suspension of deployment, why wasn't it good enough
 7 for the United Kingdom?

8 **A.** So the vaccination practices were different in those
 9 countries, compared to the UK. They were --

10 **Q.** -- (overspeaking) -- why was it different?

11 **A.** So they were vaccinating different age groups. We were
 12 following the nine priority groups determined by the
 13 JCVI, particularly the vulnerable group and so on,
 14 whereas AstraZeneca vaccine was being more used in the
 15 younger population in some of the European countries.

16 **Q.** And so, just to make that point as clear as you can,
 17 Sir Munir, the CHM deduced that because the AstraZeneca
 18 vaccine in the United Kingdom was not being used on
 19 younger people, because we were still in the priority
 20 list of elderly people, there was less risk, because
 21 this syndrome, TTS, appeared to be more prevalent in
 22 younger people from the reports that were emerging from
 23 Europe?

24 **A.** So at that time we had some suggestion it was more
 25 prevalent in the younger population, but not good enough

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1 "The Commission concluded that while there was
 2 a temporal association between vaccination and the
 3 reported events, the mechanism had not been confirmed
 4 and thus a causal association with the AstraZeneca
 5 vaccine could not established."

6 Sir Munir, by now, 27 March, almost a month and
 7 three-quarters had elapsed from the time of the first
 8 reports being received from Europe. Why was it not
 9 possible to confirm the mechanism? We presume, from
 10 that, it means the data hadn't been made available that
 11 would have established one way or the other whether
 12 a causal connection was there.

13 **A. (Witness nodded)**

14 **Q.** I mean, more weeks had passed. Why was that data not
 15 available?

16 **A.** So the data was trickling in, as I said. It was very
 17 difficult to get that data. Also, the data linkages
 18 that were required to get that data as quickly as
 19 possible were just not available.

20 **Q.** What were they? What were those data linkages?

21 **A.** So if you consider -- some people have talked in this
 22 module about triangulation of data. Obviously if you
 23 have a vaccine in a vaccine centre, that data then is
 24 linked to the primary care record, but then if you
 25 develop a serious adverse event, that usually ends up in

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1 data. But that was one of the reasons, then, as we were
 2 working through the nine priority groups, it was more
 3 being used in the older age groups at that time.

4 And also, I should say that the vaccine availability
 5 was different. So obviously in some of the EU countries
 6 which were able to stop the AstraZeneca vaccine, they
 7 will have looked at what other vaccines were available
 8 to continue the vaccination of the population.

9 **Q.** At that date, on 17 March, had the JCVI issued its
 10 phase II list, that is to say the list of people who
 11 should be offered vaccination, after phase I, the
 12 priority list, was complete?

13 **A.** I would have to check on that. I can't remember the
 14 exact date when they actually produced that.

15 **Q.** All right. There were then a number of further
 16 meetings. The expert working group met again on
 17 23 March, the vaccine benefit risk expert working group
 18 met on 24 March. I think you convened an independent
 19 panel on 26 March. Was that of haematologists?

20 **A.** That's right.

21 **Q.** Then, on 27 March, the full CHM convened. That's
 22 INQ000409498. The minutes, again we're can see the
 23 attendees on the left-hand side the page. If we go to
 24 page 6, please, this is a Saturday -- Saturday,
 25 27 March -- paragraph 2.11:

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1 hospital admission. So you need that triangulation to
 2 the hospital data.

3 But even within hospitals, some of the linkages just
 4 do not exist. So, for example, admission to the A&E
 5 department may be difficult to link to the laboratory
 6 data, to the imaging data. And so it was very difficult
 7 to link all that data together. And I think that
 8 linkages -- the deep linkages are going to be critical
 9 in the future for us to be able to get the best
 10 information as quickly as possible for these kind of
 11 serious, complex events.

12 **Q.** At its heart, are you concerned there with data in
 13 hospitals and in the health service?

14 **A.** That's correct. So I think the data in hospitals
 15 particularly needs to be looked at and how it can be
 16 coded appropriately, and linked to the primary care
 17 records, so that we get a whole picture of what's going
 18 on with the complex pictures -- with complex syndromes
 19 such as this.

20 **Q.** Are you aware of the review on health data done by
 21 Professor Cathie Sudlow --

22 **A.** I am. Very much, yeah.

23 **Q.** -- of November last year. Was that the field in which
 24 she was reporting, so she was focusing on data links in
 25 hospitals and at primary and secondary healthcare

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1 levels?

2 **A.** Yeah. Data linkage is a critical, and linkages to the
3 laboratory systems are critical, which is just not
4 present at the moment.

5 **Q.** Paragraph 2.17 on page 7 of this document.
6 "The Commission discussed whether risk mitigation
7 was needed due to the presence of an alternative vaccine
8 where these events are not seen at the same level
9 [bluntly, Pfizer or Moderna], [but] it was agreed that
10 risk benefit evaluations should be made without
11 consideration of other vaccines."
12 What does that mean?

13 **A.** So when we look at vaccines, we have to look at
14 individual vaccines and the data associated with
15 individual vaccines, rather than do comparative
16 effectiveness secondarily. That's not within the remit
17 of the CHM to do comparative effectiveness secondarily.

18 **Q.** In the context of looking at benefit risk, one can
19 readily see why you need to focus on the vaccine, which
20 is giving rise to the problem. But wasn't the
21 possibility or the existence of an alternative vaccine
22 highly relevant to whether you could say to the public,
23 "All right, there's a worry about AstraZeneca, let's use
24 Pfizer or Moderna"?

25 **A.** So the benefit-risk evaluation of each individual
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1 the potential adverse effects which may be occurring so
2 that they can make an informed choice as to whether to
3 receive the vaccine. It is important for openness and
4 transparency so that the public are made aware of, you
5 know, potential adverse effects. And I think on
6 18 March Dame June Raine gave a, sort of, press
7 conference with the Prime Minister, where she
8 highlighted that we were -- MHRA was still investigating
9 these rare cases of thrombosis and thrombocytopenia.
10 So at every -- whenever it was possible that -- we
11 wanted to make sure the public was aware that these
12 events were being investigated.

13 **Q.** As that date, 1 April and the CHM meeting, was
14 consideration given to at least, if not -- not changing
15 the conditions of authorisation, but at least given to
16 making a recommendation that AstraZeneca could not be
17 used under a certain age group?

18 **A.** So we did discuss that, particularly I think on 4 April,
19 looking at the age cut-off and whether there were
20 particular age groups which were more likely to get this
21 serious adverse event. And although there does seem to
22 be some age stratification, we, sort of, were getting,
23 as I said, trickling -- more data was trickling in. And
24 then we had -- a few days later we had data globally
25 from AstraZeneca and the presentation of AstraZeneca,
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1 vaccine showed that the benefit far exceeded the risk
2 for each vaccine at a population level.

3 **Q.** For each of them separately?

4 **A.** Yeah, for each of the -- and, there -- you know, if you
5 looked, there was no direct comparative trials between
6 the Pfizer and the AstraZeneca. So it's very difficult,
7 secondarily, to start comparing whether one is more
8 beneficial than the other, because the different
9 populations were studied in those two different vaccine
10 trials.

11 **Q.** All right. By 1 April, and the next CHM meeting, the
12 commission agreed or concluded that causality was still
13 not established. You still couldn't show that there was
14 a significant link. And the number of cases, whilst
15 rising, was still at a level which showed that it was
16 extremely rare. I think the incidence was about four in
17 a million?

18 **A.** That's right.

19 **Q.** So four cases of TTS in a million doses.
20 But the commission recommended that information on
21 the risk nevertheless be communicated to healthcare
22 professionals and the public. Why should that risk be
23 communicated where you've concluded you cannot agree
24 a causative connection?

25 **A.** So it is important to make sure that people are aware of
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1 which made -- it showed more holistic data, and it was
2 difficult for us to say there was a truly an age cut-off
3 that we could actually use based on the occurrence of
4 the TTS.

5 **Q.** But that Sunday, 4 April, I think Easter Sunday, when
6 the CHM had convened on Easter Sunday to look at this
7 issue, the committee, the commission, recommended that
8 the authorisation under, as it happens, Regulation 174,
9 be amended to reflect the fact that that risk-benefit
10 balance was less favourable to the individual patient if
11 they were under 40.
12 That decision was taken on Sunday, the 4th, before
13 AstraZeneca provided, I think, quite a considerable
14 amount of data, which it did on 6 and 7 April.
15 Why wasn't that recommendation on age cut-off in
16 effect made earlier, on 1 April, at that earlier CHM
17 meeting, when you had instead decided to tell healthcare
18 professionals about the risk and to better inform the
19 public? Why wasn't that position reached earlier?

20 **A.** So as you can see, we were taking this particular
21 condition very seriously and we were ramping up meetings
22 and meeting at short notice, not only the vaccine
23 benefit risk expert working group, but the CHM were
24 meeting on Saturday, meeting on Sunday, as data was
25 trickling through. And the data was coming through and,
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1 you know, we were asking the MHRA to get more
2 information on individual reports, to strengthen the
3 amount of data that we had.

4 And so it was very, very sort of, you know, fluid
5 situation, if you like, whereby we had to make decisions
6 on days' notice based on amount of data that we were
7 receiving.

8 **Q.** And so is that why, on 6 April, the CHM meeting, the
9 commission said, "We haven't quite got there yet. We
10 can't justify recommending or authorising --
11 I apologise -- recommending a change in the
12 authorisation conditions for AstraZeneca to have
13 vaccination only above a certain age because the data is
14 just not there to justify that step."

15 Is that the nub of it?

16 **A.** Yes, so we said, I think on 6 April, that the public
17 should be made aware of this particular event.

18 **Q.** And then just finally on this point, on this subject,
19 did you give a press conference on 7 April along with
20 Professor Sir Jonathan Van-Tam, Dame June Raine, and
21 Professor Lim?

22 **A.** We did.

23 **Q.** We'll just briefly look at that.

24 INQ000408460, please.

25 At pages 2 and 3, we can see -- it's quite hard to
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1 And then you give the advice for pregnant women,
2 those persons with a history of blood disorders, and
3 those who experience cerebral or other major blood clots
4 after the first dose.

5 **A.** Correct.

6 **Q.** And that's where matters were left until, I think, May,
7 when a positive recommendation was made that alternative
8 vaccines should be used for 30 to 39-year olds in
9 outline?

10 **A.** Yes, 7 April, I think the JCVI made an announcement of
11 30-year age cut-off and then on 7 May it was a 40-year
12 age cut-off.

13 **Q.** 30 to 39 -- (overspeaking) --

14 **A.** Yeah, and that was based on benefit-risk rather than the
15 risk itself because the benefit in the under
16 30-year-olds was more marginal.

17 **Q.** And is it essential, and is this what you did, to look
18 at and to weigh up the potential benefits and harms for
19 each age cohort?

20 So if we have INQ000497993, is this a diagram from
21 somebody called the Winton Centre, which sets out in
22 a bar chart the benefit-risk analysis for each group.

23 And just very simply, Sir Munir, I don't suppose I'm
24 doing the issue sufficient credit at all, but we can see
25 that the potential benefit for a 20-year-old of

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1 spot, but on page 2 we can see references to your name.

2 It might be further down the page. Yes:

3 "So Professor Sir Munir, over to you.

4 "... Thank you very much."

5 And you say:

6 "... I've worked with the Commission on Human
7 Medicines and the Expert Working Group separately to
8 thoroughly review all the cases coming in on the
9 Oxford-AstraZeneca vaccine in the UK. We've taken into
10 account a wide range of data sources. We've looked at
11 information about ... usage ... updated incidents rates,
12 and benefit-risk comparisons for different populations
13 by age and gender."

14 You say both the committees -- that's presumably the
15 CHM and the expert working group?

16 **A.** That's right.

17 **Q.** -- have spent almost 24 hours in committee reviewing
18 these reports. You've scrutinised them and you've had
19 independent adjudication by an expert haematologist. Is
20 that the independent committee to which you have
21 referred?

22 **A.** (No audible response).

23 **Q.** And:

24 "... we've worked with another group of
25 haematologists to develop a case definition".
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1 AstraZeneca vaccination is put at 0.8. The benefit for
2 an over 60-year-old is put at 14.1, so massively greater
3 benefit.

4 In relation to the potential harm, for
5 a 60-year-old, the risk of TTS from AstraZeneca is put
6 at 0.2, and therefore that's weighed against the massive
7 benefit. But in relation to 20 to 29-year-olds, the
8 potential harm is put at 1.1, which slightly exceeds the
9 0.8 benefit, and that's the exercise that you did?

10 **A.** That's right. And this also depended on how much the
11 virus was circulating in the community at the moment.
12 So the first graph shows you with low exposure risk but
13 then if you go down the graphs and so on, there's medium
14 exposure risk and then high exposure risk as well.

15 **Q.** So you've got to take into account incidence and
16 transmission and risk of getting infected.

17 **A.** Absolutely.

18 **MR KEITH:** All right.

19 My Lady, is that a convenient moment?

20 **LADY HALLETT:** Certainly.

21 You were warned that we take breaks, Professor, I
22 hope. I shall return at 3.15.

23 (2.58 pm)

(A short break)

24
25 (3.15 pm)

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1 **LADY HALLETT:** Mr Keith.
 2 **MR KEITH:** As a result of the commission's examination of
 3 the issue of TTS, did you, have you reached some views
 4 as to what lessons can be learnt in terms of making the
 5 job of the CHM easier in the future, and more efficient,
 6 in relation to, firstly, getting more information from
 7 the Yellow Card Scheme that better enables the CHM from
 8 being able to get into the reporter's medical records to
 9 find out more about the event they are reporting; and
 10 secondly, as you've described, the linkage between
 11 primary and secondary healthcare data?
 12 **A.** That is correct, and the first point about getting
 13 access to the medical records and getting the detail
 14 that's required, particularly when you have a complex
 15 event. The third aspect, which I haven't mentioned, is
 16 that there should be accompanying research which allows
 17 one to be able to understand a mechanism behind that
 18 which helps in terms of determining causality. And
 19 I, as a clinician scientist, was able to develop
 20 a consortium which allowed us to be able to start
 21 looking at the underlying mechanisms of why this was
 22 happening.
 23 **Q.** Now, turning to the concerns raised in the public sphere
 24 about the incidence of myocarditis and pericarditis.
 25 The Vaccine Benefit Risk Expert Working Group first

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1 Following the pandemic, was there an article
 2 published concerning data from Denmark, Finland, Norway,
 3 and Sweden, in relation to myocarditis in the community?
 4 **A.** That's right.
 5 **Q.** And what did that article show?
 6 **A.** That the data particularly from Israel was very helpful
 7 in terms of highlighting that the risk of myocarditis
 8 was higher after the second dose, and it was greater in
 9 younger men.
 10 **Q.** Did the article also say something about the outcome
 11 from suffering from myocarditis, and comparing the
 12 outcome if you get myocarditis from Covid as opposed to
 13 myocarditis from vaccines?
 14 **A.** Yes, most cases of myocarditis, and pericarditis, were
 15 relatively mild after the vaccine, usually resulting in
 16 hospital admission of less than two days, whereas the
 17 myocarditis that was occurring from Covid was more
 18 severe and sometimes did, unfortunately, lead to a --
 19 fatalities.
 20 **Q.** So if you happen to have Covid and then you unknowingly
 21 present for vaccination, and you get a vaccine, and you
 22 then develop myocarditis or pericarditis, from that
 23 temporal link alone, you won't know whether or not it's
 24 from the vaccine or from pre-existing Covid?
 25 **A.** Absolutely. We wouldn't know because there's no clear

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1 discussed that issue on 4 February 2021, Sir Munir.
 2 Is it difficult, in general terms, to diagnose
 3 myocarditis and pericarditis?
 4 **A.** Extremely difficult. It can be very heterogeneous in
 5 terms of the symptoms it presents with, and you do need
 6 laboratory tests as well as imaging, as well, of the
 7 heart, to be able to make a proper diagnosis of
 8 myocarditis.
 9 **Q.** Can it be caused, can either condition be caused by
 10 viral infection, and of course, most particularly,
 11 Covid?
 12 **A.** Absolutely. The most common cause is viral infections,
 13 and we often do not know which virus has caused it. But
 14 we also had evidence during the pandemic that people
 15 with Covid infection were getting myocarditis.
 16 **Q.** To get some idea of the scale of myocarditis in the
 17 community, what sort of figures were there concerning
 18 admissions in England for myocarditis between 1988 and
 19 2017?
 20 **A.** So I don't have that data in front of me, but you may
 21 already have that data.
 22 **Q.** Sir Munir, you are right, I do. The figure which you've
 23 provided is around about 13,000, so 13,000 admissions
 24 for myocarditis itself in England, pre-pandemic, in that
 25 period.

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1 single test which can tell us whether it's related to
 2 the virus or due to the vaccine.
 3 **Q.** The expert working groups in the commission and the
 4 commission itself looked at this issue between
 5 4 February 2021, and 23 June 2021, and although there
 6 was no evidence to suggest any fatalities in relation to
 7 myocarditis or pericarditis linked to vaccination, you
 8 recommended that the product information be updated to
 9 include a warning to the effect that such cases have
 10 been reported with the vaccines, and also to highlight
 11 clinicians to the possible risk?
 12 **A.** That is correct, and also to give the relevant advice to
 13 people who may have developed myocarditis in terms of
 14 exercise, but also what to do with regard to future
 15 vaccination as well.
 16 **Q.** Have you seen the expert report from
 17 Professor Prieto-Alhambra?
 18 **A.** Yes, I have, yes.
 19 **Q.** You may also have seen his evidence, I don't know.
 20 **A.** Yes.
 21 **Q.** In his report, he quantifies, he highlights, the amount
 22 of evidence, scientific and medical evidence in the
 23 public domain, and examines it for the quality, its
 24 quality, and, in particular, whether or not that
 25 evidence bears to show an association between any of the

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1 Covid-19 vaccines and a very long list of conditions
2 identified in the material before the Inquiry.

3 We've looked at TTS and myo- and pericarditis, in
4 relation to which he concludes that there is good
5 evidence, good quality evidence, to show at least an
6 association, without diving into the more complex
7 question of whether there is a direct causative link,
8 but at least an association?

9 **A.** Yeah, that's correct.

10 **Q.** And your evidence is to similar effect.

11 **A.** Yes.

12 **Q.** Do you also agree with what he says about the quality of
13 the evidence establishing an association, or lack of
14 association, in relation to Bell's palsy, Guillain-Barré
15 syndrome, transverse myelitis, and acute disseminated
16 encephalomyelitis?

17 **A.** So we looked at each of those conditions as the reports
18 were coming through and we did advise the MHRA to
19 include them in the drug label with -- the
20 Guillain-Barré syndrome, the transverse myelitis, and
21 ADEM, acute disseminated encephalomyelitis, in the
22 AstraZeneca vaccine.

23 With regard to Bell's palsy, in fact the clinical
24 trial with the Moderna vaccine had shown there was an
25 imbalance between the active and the placebo arm and so

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1 **A.** So when the -- a vaccine is first authorised, one of the
2 things that the CHM does in terms of its advice to the
3 MHRA is to look at the summary product characteristics,
4 as well as the patient information leaflet and identify
5 whether there needs to be more information included in
6 there, whether it's in appropriate language to be
7 understandable. So we look at that in detail.

8 Obviously, as more evidence came through in terms of
9 further adverse effects, we made suggestions or
10 recommendations to the MHRA that the patient information
11 leaflet should be changed to include new adverse events
12 which were appearing.

13 So over time, the patient information leaflet for
14 each individual vaccine did evolve as more information
15 came through. So I think that was appropriate and
16 timely in all cases.

17 **Q.** That's, of course, from the standpoint of the CHM in
18 terms of putting the information into the public domain,
19 period.

20 **A.** Yeah.

21 **Q.** But there is obviously the issue as to the extent to
22 which information you put into the public domain is
23 acknowledged or read or picked up. Were you concerned,
24 during the pandemic, that the objective picture which
25 you were putting into the public domain was being

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1 we did actually include it from the beginning in the
2 Moderna vaccine.

3 **Q.** All right. So is it your position, and you were looking
4 at all these conditions at the time of the pandemic,
5 that there is good evidence to suggest at least an
6 association, so that obviously brings some degree of
7 support and succour to those who believe that they've
8 suffered conditions as a result of vaccination, but you
9 can't say whether or not they are directly causatively
10 linked?

11 **A.** That is correct.

12 **Q.** The issue of public information -- patient information
13 leaflets, and to a lesser extent, summary of product
14 characteristics, has been before the Inquiry. A number
15 of Core Participant groups have expressed concern that
16 the patient information leaflets may not have been given
17 to patients at the point of vaccination, or did not
18 contain a requisite amount of detail so as to put them
19 on guard in relation to any possible adverse event or
20 risk associated with any vaccines.

21 Have you formed a view about the level of
22 information about risks that was provided to the public
23 in the course of the pandemic? Do you think enough
24 information about possible side effects was put into the
25 public domain?

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1 crowded out by other forms of information, by social
2 media -- well, by, just in the nature of these things,
3 the messaging -- (overspeaking) -- taken on board --

4 **A.** Absolutely, and we did -- we did discuss this many times
5 with CHM, that, you know, it was really important that
6 people who were being vaccinated did get the right
7 information at the time, but obviously the
8 misinformation and disinformation on social media was
9 sometimes drowning out the correct information that
10 should have been received by people.

11 **Q.** In reality, was there anything you could do about that?

12 **A.** Not really, not from the CHM's remit at least.

13 **Q.** Now turning to therapeutics. I haven't asked you, but
14 it's obvious, isn't it, that the CHM's remit went beyond
15 vaccines to -- and included therapeutics, in the same
16 way that the MHRA's does.

17 The picture concerning the authorisation and the
18 putting into the public domain of relevant
19 safety-related information is rather more complex in
20 relation to drugs, isn't it, because you've got new
21 drugs, you've got repurposed drugs, you've got small
22 molecule drugs, you've got neutralising monoclonal
23 antibodies. It's a more crowded field.

24 But was there any significant difference in terms of
25 the rigour or the level of scrutiny that the CHM applied

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1 to safety in the course of therapeutic examination as
 2 opposed to vaccine related?
 3 **A.** Absolutely not. We looked at every new medicinal
 4 product, which includes vaccines and therapeutics, with
 5 the same rigour in terms of quality, safety and
 6 effectiveness.
 7 **Q.** Was your role -- was your job made harder in the case of
 8 therapeutics because of a more fragmented, perhaps
 9 a less good picture, from the clinical trial processes,
 10 in terms of the degree of the quality of the science,
 11 the nature of the clinical trials, whether they were
 12 underpowered or under-resourced, or under-participated
 13 in, and also public and media reaction to the possible
 14 benefit of particular drugs?
 15 **A.** Yes. So at the beginning of the pandemic there were
 16 trials which were appearing, often in pre-print servers,
 17 before they were peer-reviewed, and picked up by the
 18 press, which were of low quality, which led to a lot of
 19 information relating to the effectiveness of a drug
 20 where probably the effectiveness did not really exist.
 21 And so it was really important to do some robust trials,
 22 and obviously that mantle was taken on by RECOVERY, in
 23 terms of the hospitalised patients, and then, later, on
 24 in terms of primary care, by PRINCIPLE and PANORAMIC
 25 trials, in order to develop that robust evidence base,

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1 and -- who was one of the co-leads of the RECOVERY
 2 trial, along with Professor Sir Peter Horby, wrote
 3 a paper making a number of recommendations about how
 4 this process of clinical trial for therapeutics might be
 5 made a little more orderly, and he referred to things
 6 like having a clearer list of national priorities in
 7 terms of what sorts of trials should be allowed to
 8 proceed, having earlier phase II assessments so that you
 9 know earlier on whether or not a particular therapeutic
 10 is worth pursuing it, having a greater use of randomised
 11 controlled trials, and having wider diversity, in fact.

12 Are those all suggestions or calls with which you
 13 would agree?

14 **A.** Absolutely. I think it is important that we have
 15 a proper system to develop trials from the very
 16 beginning, phase I and phase II, right through to the
 17 phase IV trials, like RECOVERY, robustly undertaken with
 18 appropriate governance framework, monitoring safety, at
 19 all stages.

20 The critical issue, particularly for the early phase
 21 trials, is to try to determine what dose is important,
 22 and maybe that wasn't done as well as we could have done
 23 it until later on, when new platforms were set up, such
 24 as the AGILE platform from Liverpool.

25 **Q.** Obviously in relation to therapeutics, where you're

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1 which was trial-based, which allowed us to be able to
 2 determine where there was true benefit.

3 **Q.** Was the CHM asked to give its advice as to how this
 4 process of clinical trial for therapeutics be better
 5 managed, better organised and, perhaps, better delivered
 6 in terms of the provision of data and information to you
 7 and the MHRA?

8 **A.** So the CHM has got Clinical Trial Authorisation as part
 9 of its remit. The MHRA can come to us in terms of
 10 advice, and in fact many of my colleagues, particularly
 11 on the infection expert advisory group and the clinical
 12 trials expert advisory group, have spent hours looking
 13 at clinical trial protocols, at short notice, and turned
 14 them round quickly so that all these clinical trials
 15 could be authorised within two days. And I want to
 16 thank them for that and acknowledge the enormous amount
 17 of work that they undertook.

18 But also in terms of trials which were being
 19 undertaken, it was important that we were able to
 20 monitor what was going on if there were particular
 21 issues which were arising, it was possible for the
 22 Clinical Trials Unit at the MHRA to be able to bring
 23 them back to the MHRA for -- to the CHM, sorry, for any
 24 advice.

25 **Q.** The Inquiry is aware that Professor Sir Martin Landray

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1 dealing with already-authorized therapeutics which may
 2 be open to re-purposing, you don't need to go back and
 3 re-examine, do you, the issue of safety?

4 **A.** No, there should be a good safety database for
 5 repurposed medicines. However, what you can't exclude
 6 is the possibility that that repurposed medicine may
 7 interact with the disease, which is a new disease, and
 8 somehow cause other problems so it is important to
 9 continually monitor the safety.

10 **Q.** And of course, as the pandemic rolled on and as
 11 different variants of the SARS-CoV virus emerged, that
 12 made the issue of identifying suitable therapeutics
 13 harder, because they may be less susceptible to
 14 protection against the virus, and also some of the
 15 trials were taking place before the variants had emerged
 16 so you couldn't tell whether or not the benefit would
 17 have been maintained?

18 **A.** That's particularly the case for the monoclonal
 19 antibodies.

20 **Q.** All right. We needn't run through all the therapeutics
 21 which were ultimately authorised on the advice of the
 22 CHM, but just, perhaps, to pick up one or two points.

23 Obviously, you gave advice on, and you reviewed and
 24 ultimately the use of molnupiravir, and nirmatrelvir and
 25 ritonavir, Paxlovid, that those were authorised by the

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1 MHRA and they were the two oral antivirals --
 2 **A.** That's right.
 3 **Q.** -- of which we heard from Mr Gray.
 4 You reviewed and ultimately this was authorised,
 5 dexamethasone? That was the highlight, perhaps, of the
 6 RECOVERY trial process of which you've spoken.
 7 In relation to that, did the CHM become engaged in
 8 a debate with the leaders of the RECOVERY trial as to
 9 whether or not there was sufficient evidence of benefit
 10 prior to you giving advice on its authorisation?
 11 **A.** So the CHM and the Covid Therapeutics Advisory Group did
 12 evaluate the role of dexamethasone, looking at data in
 13 terms of how steroids had been used previously for
 14 influenza, and the data for influenza in terms of
 15 effectiveness was not very strong in terms of whether it
 16 was helping, and what the CHM wanted to know was what
 17 evidence was the dose based on, for example, in
 18 RECOVERY? And as we've seen in terms of RECOVERY doing
 19 further studies on higher doses, you don't get the same
 20 benefit with a higher dose of dexamethasone or other
 21 steroids as you do with the 6 milligrams of
 22 dexamethasone. And so the CHM asked questions in terms
 23 of what the rationale was, not only for using
 24 dexamethasone but also for the dose that was used in
 25 the trial.

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1 we looked at all the data. The data was not very
 2 robust, and we felt that there was no good evidence of
 3 effectiveness and it should not be used outside of a
 4 clinical trial setting.
 5 **Q.** And then finally, were there two other results from the
 6 RECOVERY trial: Ronapreve, casirivimab, imdevimab; and
 7 tocilizumab, RoActemra, which you reviewed and then
 8 authorised?
 9 **A.** Absolutely, and changed the label as a result of the
 10 results from the RECOVERY trial.
 11 **Q.** There was another drug or therapy, hydroxychloroquine
 12 which became, similarly to Ivermectin, highly polarised
 13 was the benefit of hydroxychloroquine and chloroquine
 14 looked at by the CHM?
 15 **A.** It was, on several occasions.
 16 **Q.** Was it looked at for the purposes of treatment as well
 17 as for possible prophylactic use?
 18 **A.** So, yes, looked for both treatment and prophylactic use.
 19 There were trials going on both for treatment in
 20 different patient groups but also the prophylaxis as
 21 well.
 22 **Q.** The Inquiry's expert, Professor White, has drawn the
 23 Inquiry's attention to the fact that there was a study
 24 published in The Lancet which apparently showed not just
 25 a lack of benefit but the possibility of harm in

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1 **Q.** And happily, RECOVERY trial proceeded, the rest is
 2 history. They produced clear evidence of benefit
 3 leading to its authorisation, and the saving of --
 4 **A.** Yes, and the RECOVERY trial, as far as I recall, replied
 5 to the Covid Therapeutics Advisory Group and, you know,
 6 we were happy for the trial to continue.
 7 **Q.** Evusheld was reviewed by you, and authorised, and we've
 8 heard a great deal of evidence about the process by
 9 which it wasn't ultimately made available. Could you
 10 just tell us, please, though, whether or not other
 11 regulators, other than the MHRA, did ultimately withdraw
 12 authorisation for Evusheld on the grounds of lack of
 13 apparent benefit?
 14 **A.** Yes, so the FDA, Federal Drug Administration in the
 15 United States, did give it emergency use authorisation
 16 but as the variants changed and became more resistant it
 17 withdrew that emergency use authorisation.
 18 **Q.** Ivermectin was the subject of a considerable amount of
 19 debate in the public sphere. The debate about the
 20 benefits of Ivermectin became, I think, politically
 21 highly polarised. Was it reviewed by the CHM in March
 22 and October 2021, and did you give advice that there was
 23 insufficient evidence as to benefit?
 24 **A.** Yes, we reviewed it several times, I think about three
 25 times, in the different groups, including the CHM, and

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1 relation to hydroxychloroquine and chloroquine.
 2 As a result of that publication, did the CHM go back
 3 and specifically review clinical trial data in relation
 4 to hydroxychloroquine?
 5 **A.** So that particular publication you're referring to,
 6 Mehra et al, I think, was eventually withdrawn, but that
 7 was one of the pieces of evidence we looked at
 8 initially, but also there were other trials which were
 9 smaller. The Mehra et al study which was withdrawn, was
 10 an observational study but there were other trials which
 11 had been undertaken with different doses. We looked at
 12 overall evidence in terms of benefits and safety.
 13 **Q.** And was there a particular commission meeting on 21 May
 14 2020 -- perhaps we'll look briefly at it --
 15 INQ000409486 -- in which you looked at that article and
 16 the study which gave rise to the article in The Lancet,
 17 and you looked at other data about the risk-balance and
 18 whether or not there was a benefit, and recommended,
 19 I think, reassessment overall as to what the
 20 benefit-risk level was.
 21 **A.** Yeah. So it was particularly important --
 22 **Q.** Thank you.
 23 **A.** -- for hydroxychloroquine to understand what the safety
 24 aspects would be in this particular group, given that
 25 patients who were particularly vulnerable to severe

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1 effects from Covid were the elderly, vulnerable, and
 2 they maybe on other drugs. Hydroxychloroquine is known
 3 to cause effects on the heart, and other drugs which can
 4 be -- also interact with it to accentuate those effects
 5 on the heart. So it was important for the CHM to give
 6 advice to the MHRA to understand the safety aspects, how
 7 they were being monitored within the trials, and for the
 8 investigators to come back to the MHRA to reassure that
 9 the safety was being monitored appropriately. Patient
 10 safety was obviously paramount to CHM in terms of making
 11 sure that these drugs were not causing any unintended
 12 harms.

13 **Q.** And if we look at this document, I think on the
 14 following page, please, 16, we can see you looked at
 15 a number of studies, you looked at the article in
 16 The Lancet and the study which underpinned it. You
 17 looked at the issue of risk-benefit.

18 And then, over to page 17, you discussed what advice
 19 should be given. And you also, particularly, looked at
 20 the issue of whether or not you should speak to the
 21 investigators in the trials, or at least whether the
 22 MHRA should, to see whether or not the trial should be
 23 suspended whilst you looked further at the issue of
 24 safety?

25 **A.** Yes. So that was one of the things about pausing the

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1 **Q.** One of the trials was permitted to restart. Was that
 2 the COPCOV trial?

3 **A.** It was.

4 **Q.** And was that the one with which the Inquiry's expert,
 5 Professor White, is concerned?

6 **A.** That's right. I think he's a principal investigator for
 7 that. That is a prophylaxis trial to give the drug at
 8 a lower dose to people who are -- for prophylaxis who
 9 don't have Covid, to prevent occurrence of Covid.

10 **Q.** But by the time that trial had reported, things had
 11 moved on even further insofar as obviously the --

12 **A.** That's right.

13 **Q.** -- vaccine programme had reached fruition, and there
 14 were further variants out there in the public domain
 15 and, therefore, there were then further issues about
 16 benefit-risk?

17 **A.** Yes.

18 **Q.** All right.

19 **A.** So Professor White and his team did reply back to us and
 20 put some additional measures in to ensure the safety of
 21 the participants in the trial.

22 **Q.** From all that, Sir Munir, you've taken care to put into
 23 your statement a number of recommendations. I just want
 24 to highlight some of the most important ones. Obviously
 25 my Lady will be going through your statement with great

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1 trials, and the RECOVERY came back to us with the robust
 2 justification.

3 We also met with the chair of the Data Safety
 4 Monitoring Committee, who came to give evidence to CHM
 5 in terms of how they were monitoring the safety, and we
 6 were happy for the RECOVERY trial to continue.

7 We were waiting for the responses from the other
 8 hydroxychloroquine trials but the RECOVERY trial then
 9 reported that there was no benefit, and I guess that the
 10 other investigators decided to not come back to the MHRA
 11 to restart their trials.

12 **Q.** So the position that was ultimately reached was that,
 13 I think, whilst you were actually in session, on 5 June,
 14 you received information that the clinical trials had
 15 stopped themselves, the trialists had suspended their
 16 own trials?

17 **A.** Yes.

18 **Q.** And therefore there was nothing further for you to do.

19 And so even though the press article which had made
 20 claims against hydroxychloroquine had been withdrawn, it
 21 didn't matter in the event, because the trialists
 22 stopped their own trials anyway?

23 **A.** Yes.

24 **Q.** And told you accordingly.

25 **A.** Yeah.

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1 care.

2 In no particular order, do you feel that in the
 3 course of your commission's functions, a closer working
 4 relationship and collaboration with the European
 5 Medicines Agency would have been more helpful, given
 6 that we have, of course, as a result of Brexit,
 7 withdrawn from that system? And in particular it's the
 8 European community -- not Union -- system of
 9 EudraVigilance?

10 **A.** That is correct, irrespective to whether you're in
 11 a pandemic or outside a pandemic, it is important to get
 12 up-to-date information from regulators not only within
 13 the European Union but also outside the European Union
 14 as well, so you get the overall picture of what's going
 15 on with a particular medicine.

16 **Q.** That said, was there any shortage of communication from
 17 your international colleagues, regulators and advisers
 18 on the issue of safety? I mean it looks as if you're in
 19 touch a lot.

20 **A.** Yes, yes -- yes, we were.

21 **Q.** All right.

22 Better access to linked-up health data you've
 23 addressed us on. Improvements to the Yellow Card Scheme
 24 you have said something about. And finally, this issue
 25 of dis- and misinformation.

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1 From the viewpoint of the Commission, it must be of
2 some frustration to see your carefully honed,
3 scientifically-based, objective information being put
4 into the public domain and being swamped by other
5 sources of information?

6 **A.** Very much so.

7 **Q.** In reality, is there really anything that can be done
8 about that or do we just -- do you just have to keep on
9 pronouncing the message?

10 **A.** I think providing the message to the public is very
11 important, and continual reminders of the true facts of
12 the benefits and risks of the vaccine.

13 **MR KEITH:** Thank you very much.

14 **LADY HALLETT:** Just a few more questions for you, Professor.

15 Ms Douglas, who is that away, has a couple of
16 questions for you.

17 Questions from MS DOUGLAS

18 **MS DOUGLAS:** Thank you, my Lady.

19 Good afternoon, Sir Munir. I act on behalf of
20 Clinically Vulnerable Families who represent the
21 clinically vulnerable, the clinically extremely
22 vulnerable and the immunosuppressed. The vulnerable
23 person that CVF represents are at a higher risk of
24 severe outcomes from Covid-19.

25 We've heard a little bit this afternoon about the
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1 vaccine does provide some efficacy but it is not as much
2 efficacy as in the non-immunosuppressed, and so on. But
3 booster doses help in terms of improving that vaccine
4 efficacy. So it is important to ensure that we have the
5 relevant, diverse group of people involved in the
6 therapeutic trials and the vaccine trials to make sure
7 that we have adequate information that covers the whole
8 population.

9 **Q.** Thank you.

10 If I may, my Lady, just because it went to the
11 question about the formats of the vaccine, the point
12 I was getting to more was that there are obviously, as
13 we've heard, the mRNA formats, protein-based formats,
14 and it's whether you would support a diversity of that,
15 of having a range of formats of vaccines and antivirals?

16 **A.** Absolutely. So, it's very, very important not just to
17 rely on one particular platform, but to have the
18 protein-based platforms, the adenoviral platform, the
19 mRNA platform, plus other types of platforms that may be
20 coming through. But also different -- as we move
21 forward, also different ways of being able to administer
22 vaccines. For example, the ones we have been using have
23 been intramuscular but nasal vaccines are being
24 developed, which is going to be important. So having
25 a portfolio of vaccines with different routes of
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1 various vaccines and therapeutics that were authorised
2 on the advice of the CHM. And my question is this:
3 would you support the development of a more diverse
4 portfolio of vaccine formats and antivirals, both as
5 part of future pandemic preparedness plans, and during
6 what others have described as peacetime, to ensure that
7 clinically vulnerable groups are adequately protected?

8 **A.** Absolutely. I think it's really important to make sure
9 that we have good therapeutics and vaccines for the
10 whole population, those who are clinically vulnerable as
11 well as in different groups as well. So it is important
12 elderly participate in these particular trials to make
13 sure particular vaccines are, and therapeutics, are
14 relevant for that group, particularly in Covid, that
15 they were the most vulnerable. But if you look at other
16 infections, such as influenza, maybe children are more
17 vulnerable, to make sure that the relevant groups take
18 part in trials so we develop those therapeutics and
19 vaccines for the relevant groups.

20 **Q.** Thank you. And if I may just expand on that, why is it
21 important to have that breadth of formats?

22 **A.** Well, if you take the vulnerable in terms of the
23 immunosuppressed, giving -- not many were involved in
24 the initial trials, so we did not know whether the
25 vaccine would be effective. So we now know that the
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1 administration is going to be very important in terms of
2 preparing for the next pandemic.

3 **MS DOUGLAS:** Thank you.

4 Thank you, my Lady.

5 **LADY HALLETT:** Thank you, Ms Douglas.

6 M Morris.

7 Ms Morris is over that way. Please make sure your
8 answers go into the microphone.

9 **THE WITNESS:** Okay.

10 **LADY HALLETT:** Ms Morris will understand if you don't look
11 at her all the time.

12 **MS MORRIS:** Thank you. Thank you, my Lady.

13 Questions from MS MORRIS KC

14 **Q.** Sir Munir, I ask questions on behalf of the Covid
15 Adverse Reaction and Bereaved groups. These are groups
16 who represent those who were injured by the vaccine or
17 lost loved ones following their acceptance of the
18 vaccine.

19 In your evidence you have stressed the importance of
20 having more healthcare data in relation to those who
21 have suffered a suspected adverse reaction. Do you
22 accept that having patient medical records as one of the
23 sources of that post-authorisation safety monitoring
24 depends largely on what is recorded in that record by
25 the healthcare provider, as to whether the symptoms may
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1 or may not be connected to the vaccine, for example,
 2 before you even get to the triangulation point that you
 3 made in your evidence?
 4 **A.** So -- sorry, I'll just speak into the microphone. So it
 5 is really important that adequate data is entered into
 6 the medical record. So if you look at primary care
 7 data, it may be coded or it may not be coded and so one
 8 can track it easily. But as we develop new tools such
 9 as artificial-based tools, natural language processing,
 10 it may be possible to actually look at the textured
 11 data, which is unstructured data, to be able to get that
 12 adequate information.
 13 If you look at hospital data, clearly, if a vaccine
 14 has resulted in an adverse effect which is severe enough
 15 to lead to hospital admission, then that should be
 16 recorded and coded so that we can make that linkage
 17 between the vaccine and the admission to hospital.
 18 **Q.** Again, depending on what's put in, what is coded by the
 19 practitioner into the records in the first place?
 20 **A.** Absolutely. And coding is getting better but it's not
 21 perfect. And I think we needed to think about how we
 22 can improve coding at -- in real time. So that we get
 23 that information quickly coming through to the
 24 regulators, to the health authorities, so that we
 25 understand whether -- the harms and benefits occurring

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1 with new medicines as well as established medicines.
 2 **MS MORRIS:** Thank you, that's helpful.
 3 Thank you, my Lady.
 4 **LADY HALLETT:** Thank you, Ms Morris.
 5 Thank you very much indeed, Professor,
 6 extraordinarily grateful to you. You and your
 7 colleagues obviously worked extraordinarily hard to try
 8 to ensure the safety -- or monitoring of the safety of
 9 vaccines for the protection of the public. And I know
 10 we are all indebted to you.
 11 And thank you for the help you have given to the
 12 Inquiry and for giving evidence today.
 13 (The witness withdrew)
 14 **MR KEITH:** My Lady, that concludes the evidence for today.
 15 **LADY HALLETT:** Thank you. 10.00 tomorrow, please.
 16 (3.52 pm)
 17 (The hearing adjourned until 10.00 am the following day)
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