

Thursday, 23 January 2025

1
2 (10.00 am)
3 **LADY HALLETT:** Would you like Sir Sajid to be sworn?
4 **MR KEITH:** Yes, please.
5 **SIR SAJID JAVID (affirmed)**
6 **Questions from LEAD COUNSEL TO THE INQUIRY for MODULE 4**
7 **LADY HALLETT:** Welcome back, Sir Sajid, thank you very much
8 for coming back to help us.
9 **THE WITNESS:** Thank you. It's good to see you in person.
10 **MR KEITH:** Could you commence your evidence, please, by
11 giving us your full name.
12 **A.** Yes, it's Sajid Javid.
13 **Q.** Thank you very much for attending today and for your
14 provision of a witness statement, a further witness
15 statement for this module, dated 2 October 2024, running
16 to some 80 pages as to which you have appended the usual
17 declarations to the truth of its contents.
18 Sir Sajid, you were Economic Secretary to the
19 Treasury from September 2012; Financial Secretary to the
20 Treasury from October 2013; Secretary of State for
21 Culture, Media and Sport, and also Minister for
22 Equalities, subsequently; and then Secretary of State
23 for Business, Innovation and Skills; latterly, Secretary
24 of State for Communities and Local Government and, for
25 our purposes, most fundamentally, you were Secretary of

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1 **A.** Yes, you may. And if I may, just on the -- you just
2 on -- more generally, if I may, my Lady, just say that
3 I think the vaccine programme overall and related
4 therapeutics was a huge success for the country. It
5 saved many lives, saved many people from being ill.
6 Obviously I recognised that wasn't the case for every
7 single person; there were some people that were sadly
8 injured, and may we get on to that as well. But I just
9 want to place on record my thanks to all those people
10 who were involved, all -- from the civil servants, the
11 officials, the scientists, all the clinicians, NHS --
12 the clinicians and others, all the volunteers in the
13 vaccine deployment centres but also the many, almost
14 a million, people that came forward for trials. Without
15 what they did, we wouldn't have had that success. And
16 I think that's very important to recognise.
17 **Q.** The first issue in this context that I want to ask you
18 about is the -- concerns the vaccination of young
19 people.
20 **A.** Yes.
21 **Q.** And as I told you, we're simply going to deal with
22 a handful of discrete issues which are of particular
23 importance in the context of this module, but which
24 arose in the course of the vaccine and therapeutic
25 programmes.

3

1 State for Health and Social Care, from 26 June 2021.
2 You were also Chancellor of the Exchequer and
3 Home Secretary prior to that but, most importantly, you
4 were Mr Hancock's successor as Secretary of State?
5 **A.** Yes.
6 **Q.** The role of Secretary of State, indeed the role of the
7 DHSC was a very wide one in the context of vaccination
8 and therapeutics, was it not?
9 **A.** Yes, it was.
10 **Q.** You have set out in your statement something of the
11 nature of the role; you were concerned with funding for
12 new research, the oversight, although the MHRA reported
13 to the Secretary of State on the question of authority
14 but the oversight of the approval of vaccines, and also
15 therapeutics, the liaison with and the taking advice
16 from the MHRA, the JCVI, and other expert bodies; you
17 had to make decisions about the vaccination programme.
18 Also about deployment, the effectiveness of the
19 deployment, and the huge subject of delivery.
20 And may we take it, it's obvious, that throughout
21 your time as Health Secretary, there were meetings on
22 all these subjects, all these matters, every day? There
23 were goal meetings, there was hourly meetings, there
24 were emails, texts, i-messages, probably every -- well,
25 day and night.

2

1 **A.** Yes.
2 **Q.** The position with the vaccination of young people was
3 that technically, formally, the Pfizer and the Moderna
4 vaccines were authorised for use by the MHRA, in the
5 case of Pfizer for 12 to 15-year-olds in June 2021, and,
6 for Moderna, 12 to 17-year-olds in August of 2021.
7 And what -- was the way in which it worked was that
8 you or somebody else would invite the JCVI to give
9 advice on whether or not formal authority having been
10 given for use in supply to the population, it should
11 actually be offered to the population and in what way?
12 So you had to await for advice from the JCVI?
13 **A.** That's right. So we would -- before any decision could
14 be made to offer any vaccine to any group of people, and
15 of course you're asking me about children in this case,
16 the same sort of general safeguards and rules applied.
17 The vaccine first had to be approved by the MHRA, as
18 safe and effective, and then the JCVI, the sort of --
19 the group of independent experts that would look at it
20 in much more detail and then look at both our trials and
21 evidence from abroad and take into account a number of
22 factors, they would consider it and then provide advice
23 to me as the Secretary of State.
24 **Q.** And your predecessor, Mr Hancock, had formally asked for
25 advice from the JCVI?

4

1 A. Yeah.

2 Q. You took up that post on 26 June.

3 A. Yes.

4 Q. Very shortly after your arrival in the department the
5 JCVI provided interim advice, as it happens, dated
6 5 July. But on 6 July there was a meeting conducted by
7 you.

8 We'll have INQ000480653, please.

9 A. Yes.

10 Q. We can see from the top third of the page the date, and
11 the attendees, including yourself, permanent secretary
12 Clara Swinson, from whom we've heard, and a number of
13 officials, including from the Office of the Chief
14 Medical Officer, the CMO --

15 A. Yes.

16 Q. -- JVT -- Jonathan Van-Tam that is -- and also officials
17 from -- or members of the Vaccine Taskforce, and your
18 own department of officials.

19 There is a reference halfway down the page to ...
20 yes, thank you very much -- to the CMO,
21 Professor Sir Chris Whitty, saying:
22 "... JCVI are 'sitting on the fence'. They have
23 failed to land on a conclusive view one way or the
24 other."

25 But they:

5

1 So I think it took its, sort of, time, but, I would
2 say, in a good way.

3 Q. The JCVI had, of course, in December 2020 produced the
4 prioritisation list?

5 A. Yes.

6 Q. And phase I had had its nine cohorts. By this time, is
7 this right, the targets for the offering of vaccines to
8 everybody in that priority -- phase I priority list, had
9 been met? So we were dealing here or you were dealing
10 here, weren't you, with the decisions about whether to
11 offer vaccines to people against the background that the
12 prioritised people had already been offered, all of
13 them, a vaccine, because that original priority list was
14 for 18-year-olds and above --

15 A. That --

16 Q. -- unless they had particular health issues?

17 A. Yeah, that's right. But they -- but in considering
18 whether the vaccines should be offered to children,
19 there were other factors that you might not have
20 considered for adults that had to be taken into account.

21 Q. So it was in fact it was a more difficult -- there was
22 a more difficult debate to be had --

23 A. I wouldn't say it was necessarily more difficult; it's
24 just there are different elements to the debate, and you
25 wanted to -- I would want to be reassured that the JCVI

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1 "... will have to advise conclusively on whether
2 they deem the benefits of the vaccine to outweigh the
3 harmful impacts of children catching COVID ..."

4 And Professor Whitty said that:
5 "... on clinical grounds, he would write to the JCVI
6 ... to ask that the Committee answer that question."

7 Did you think that there had been any degree of
8 untoward delay in the JCVI responding to your
9 predecessor's request formerly for advice as to whether
10 or not 12 to 17-year olds vaccination should be offered?

11 A. No, I didn't feel that there had been any kind of
12 unnecessary delay. I think that clearly the work of the
13 JCVI, for all groups, including of course children, is
14 vital, and that it's given the time to consider. And
15 I also, I think I would have thought at the time, the --
16 in terms of priority, in terms of the population,
17 clearly adults and older groups were, you know, starting
18 with the eldest, were -- for lots of reasons, were the
19 most important, that's where the JCVI started, and it
20 eventually, once it's given its views on older groups,
21 eventually it has got to be thinking about children.
22 I believe, at this time, even though there were other
23 countries using vaccines for children, they'd authorised
24 it for earlier use than the UK had, so I think the JCVI
25 wanted to also look at that evidence.

6

1 and my own clinical advisers such as the CMO, DCMO, had
2 considered that before I'd make a decision as
3 the Secretary of State.

4 Q. On the individual level there was the perennial debate
5 about whether or not the benefits outweighed the
6 risks --

7 A. Yeah.

8 Q. -- significantly, such as to merit authority --

9 A. Yes.

10 Q. -- authorisation, and then offer?

11 A. Yes.

12 Q. And then with children, were there the additional
13 considerations as to whether or not the vaccination of
14 children would promote good educational practice, would
15 lessen the disruption to their education, and also have
16 a wider beneficial impact in terms of getting children
17 back to school and have their life prospects bettered?
18 So it was a less straightforward issue than, perhaps,
19 the issues concerning those persons who'd been in the
20 original priority list?

21 A. I think that's the case, but especially, I think, when
22 it came to the 12 to 15 cohort, when the decision was
23 made in September, so it was starting with older groups
24 so 12 to -- so I think 15 to 17 first, I believe, that
25 was in August --

8

1 Q. That's right.

2 A. -- in terms of the universal offer. Of course there
3 were offers to children that either -- (overspeaking) --
4 living with vulnerable people, or in vulnerable --
5 households with vulnerable people, or they had other,
6 you know, exceptional reasons to take the vaccine
7 earlier, but in terms of a general offer for the real --
8 the, sort of, I remember a lot of discussion around
9 wider issues about potential benefits of offering
10 vaccines to children particularly in September, and that
11 was around the 12-15 cohort.

12 The other thing I would add, my Lady, if I may,
13 I also remember around that time, sort of, through that
14 summer, really, sort of, July/August, and then leading
15 on to when the decision on 12 to 15-year-olds was made
16 in September, the Prime Minister was incredibly keen to
17 start offering vaccines as soon as possible to children.
18 So there was an immense amount of pressure from the
19 Prime Minister directly, and from, therefore, from his
20 team at Number 10 to try to speed up the process, to
21 make a decision quicker, the Prime Minister would often
22 say to me, "Why are other countries" -- he would often
23 mention Portugal, Spain, other countries in Europe --
24 Israel, he mentioned a lot, saying they're doing a much
25 better job than us, the way he would phrase it, in terms

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1 aren't you getting them jabbed?", and all that kind of
2 pressure. And my view was simply, really, pretty much,
3 just to ignore that pressure because it wasn't my job to
4 have the Prime Minister decide that children should get
5 vaccinated, I had to listen to the evidence and the
6 scientific advice and that's exactly what I did.

7 Had someone been in my job that was perhaps less
8 experienced in government, I mean, you mentioned --
9 sorry, you mentioned at the start that I'd had various
10 different roles in government before I ended up in that
11 position. I think, by then, I'd just sort of learnt
12 that -- how to do a Cabinet-level job, I guess, more
13 effectively, and to ignore certain pressures and just
14 do -- what you want to focus on as the right thing to do
15 and not be led by necessarily always what the
16 Prime Minister of the day wants you to do.

17 Q. All right.

18 If we look at INQ000089048, this is in fact the
19 minutes of a cabinet meeting on 20 July 2021, so in the
20 middle of the first debate about 16 and 17-year-olds.

21 And page 12, thank you very much.

22 You can see there that somebody was saying, probably
23 the Prime Minister, that:

24 "The UK had been a world leader in its vaccination
25 programme but was being overtaken by countries like

11

1 of vaccinating children a lot more quickly, why are we
2 taking so long? And my answer, generally to him, was
3 always that we've got a process to follow for a reason
4 to make sure it meets our standards and just because
5 other countries are doing it, doesn't mean to say we
6 should be doing it. We might get there eventually, but
7 we have a process, MHRA, JCVI, our own advisers, and we
8 must follow that process.

9 Q. I think it's fair to say that there are number of people
10 in government in the Office of the Chief Medical
11 Officer, within the Cabinet Office, as well as the
12 Prime Minister himself, who expressed concern about an
13 apparent delay in the summer of 2021 in getting the JCVI
14 decision advice out of the door.

15 A. Mm.

16 Q. There had been plenty of reference to concern about
17 apparent delay in the paperwork. Do you agree?

18 A. There was, and as I say, for the Prime Minister himself
19 and the team around him, there'd be that constant
20 pressure and sometimes I'd be told -- not directly by
21 the Prime Minister, but some of the people around him,
22 "Oh, the Prime Minister is not very happy with you, he
23 doesn't think you're doing a good enough job, you're not
24 taking this seriously enough, why aren't you getting
25 those children vaccinated a lot more quickly? Why

10

1 France, Italy, Canada and the US who had all taken the
2 decision to vaccinate those over twelve ... It was
3 unclear why the ... (JCVI) were taking so long to come
4 to a decision ..."

5 So that's a clear reference, I think, to that which
6 you've described exactly, which is that the
7 Prime Minister was vexed at the speed at which the
8 process was taking.

9 A. Yes.

10 Q. As it happened, that was 20 July. On 3 August you
11 receive advice from the JCVI on vaccinating children
12 aged between 12 and 15 who had underlying health
13 conditions, so it wasn't a universal offer at that
14 stage.

15 A. Yeah.

16 Q. You were focusing on those with health conditions. And
17 you agreed almost straight away.

18 On 4 August, the issue then arose as to whether or
19 not 16 and 17-year-olds should be offered a universal
20 vaccine, whether they should be offered universally
21 a vaccine, in addition to those who were aged 16 and 17
22 who were at risk, who were in risk groups, and there was
23 a meeting on 2 September by the JCVI in which they
24 considered 12 to 15-year-olds who were not in a clinical
25 risk group.

12

1 The JCVI decided that whilst the direct benefits of
2 vaccinating children and young people marginally
3 outweighed the risks, there were wider educational and
4 societal issues which required examination, and they
5 wrote -- or they wrote to you and your department wrote
6 to all the UK CMOs asking for their view.

7 The UK CMOs published their advice on 13 September.
8 But the result of bringing the CMOs into that process
9 and seeking their formal advice and then waiting for the
10 advice, delayed the process. It took more time.

11 Were you concerned, as the Secretary of State, that
12 the process to address universal vaccination of 12 to
13 15-year-olds had become further slowed down? Was that
14 something of concern to you?

15 **A.** I don't recollect that I was particularly that
16 concerned. Just on the basis that, again, there'd -- in
17 my mind there's a clear process to be followed: of
18 getting expert advice and then basing my decisions on
19 that. And once I'd received the JCVI advice, which was,
20 as you said, that it was -- that said marginal, but it
21 said there may be wider factors to consider which really
22 wasn't in their purview, that's why I asked the CMOs for
23 their views. And clearly for them to come to a view
24 they had to have the full JCVI advice, and I think
25 I remember at the time thinking, certainly with the

13

1 We can see there the date, 13 September 2021,
2 "Private Office Submissions". It's to the Secretary of
3 State, yourself. And it sets out the issue, which is
4 that:

5 "The JCVI concluded in ... 19th July that children
6 aged 12-15 who are 'at risk' ... should be offered
7 vaccination."

8 **But:**

9 "... they did not consider [that] the benefits
10 outweighed the risks for healthy 12-15-year-olds."

11 And so, having considered that there was a marginal
12 benefit for healthy 12 to 15-year-olds of benefit
13 against risk of vaccination, they'd wanted the CMOs
14 consulted.

15 Did you have any difficulty with agreeing to that
16 position? Ultimately, of course, it was a matter
17 entirely for the Secretary of State, was it not?

18 **A.** It was. And I didn't have difficulty, because of
19 both -- I took both pieces of advice together, and
20 considered them in that way. The JCVI advice, but also
21 what was very important to me was the advice of the
22 CMOs. And by CMOs, I mean all four CMOs of all parts of
23 the UK, and they were, all four were -- they were all
24 agreed on the position and the way forward. And then
25 I felt that as Secretary of State, that the groups of

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1 England CMO, Professor Chris Whitty, I think he said he
2 also wanted to talk to Royal colleges and other
3 consultants and paediatricians and just get wider input,
4 and also speak to people in education, I believe, as
5 well, and I think that was the right thing to do.

6 And despite, I think, the CMOs having to speak to
7 a group, I think my recollection is they did it fairly
8 quickly and in a speedy manner. They treated
9 it urgently. And so there wasn't -- it wasn't a process
10 that really sort of -- that lasted days. And eventually
11 when they gave their advice, and which they published in
12 a letter to all MPs and public consumption, I thought it
13 was quite detailed, actually, and very clear. And they
14 set out the case very clearly, which I accepted, and
15 that's why I decided to make an offer of the vaccine.
16 But I think we sort of called it a non-urgent offer, it
17 was a general offer, but -- and based on the reasoning
18 that we had set out in the CMO letter and the
19 JCVI advice.

20 **Q.** And the submission went to you after the UK CMOs had
21 advised?

22 **A.** Yes.

23 **Q.** It's dated 13 September.

24 INQ000401383, if we can just have page 2 up first.
25 Thank you very much.

14

1 people, the JCVI, the CMOs had considered this very
2 carefully, I felt that their reasoning and their
3 arguments they set out were well balanced, well thought
4 through, and I accepted the advice on that basis.

5 **Q.** Arguably, it then got harder, or even harder, because
6 the JCVI were written to by your department in
7 November 2021 asking for their formal advice as to
8 whether or not there should be a universal offer to 5 to
9 11-year-olds, so the younger cohort. The formal
10 authorisations for the use, in fact, of smaller doses of
11 vaccines for 5 to 11-year-olds and then subsequently six
12 months to four-year-olds had been granted in
13 December 2021 and then, respectively, December 2022. So
14 after the -- around about the time of the first
15 authority, that's to say for use for 5 to 11-year-olds,
16 you'd started the process rolling by which the JCVI
17 would give advice on whether or not they should be
18 offered vaccines.

19 You asked the DHSC to draw up a business case
20 dealing with issues such as the impact on reduced
21 paediatric intensive care admission, educational
22 disruption, and the potential benefit of reducing
23 anxiety in children and loved ones by having them
24 vaccinated, or by contrast, what level of anxiety might
25 be engendered by offering them a vaccination.

16

1 Why did you take that additional step of seeking
2 extra advice on those wider ancillary issues?
3 **A.** Because I felt that -- so first, as we've just gone
4 through, the decision, I felt that when it came to
5 children the key cohort, in my mind, were the 12 to
6 15-year-olds or 12 to, say, 17 in total. And to go
7 below the age of 12, so 5 to 11, in this case, would
8 require an even stronger argument because, for example,
9 with educational disruptions, and I remember some
10 discussion at the time with the CMO and others, that
11 there was an argument that educational disruption was
12 sort of -- it was more disruptive to a, sort of, 12- to
13 15-year-old cohort than it would be to younger cohorts.
14 So I thought maybe that argument in itself wasn't strong
15 enough.

16 And so I can't remember the exact discussions that
17 took place but we had a number of discussions as group
18 with the CMO, and all the others in the room, about what
19 would be the case if we were going to go lower than
20 12 years, and at the same time, by the way, there was
21 still a huge amount of pressure coming from the
22 Prime Minister at Number 10. The Prime Minister just
23 wanted to go as low as he could go, and kept pressuring
24 that we make these decisions much more quickly. Again,
25 I didn't want to succumb to that pressure, and I didn't,

17

1 "Vaccinating this cohort is unlikely to provide any
2 significant benefits against the current Omicron wave."

3 And then over the page at paragraphs 15 to 17, the
4 point is made:

5 "For this policy to be cost effective, a future wave
6 of infections would need to come about while vaccine
7 effectiveness in children is still high ..."

8 Then at 16:

9 "An alternative policy ... would be to postpone
10 a decision to deploy these vaccines until a heightened
11 threat is identified ..."

12 So it was altogether a more difficult decision, but
13 the balance was more finely weighed, or was required to
14 be more finely weighed, by comparison to the earlier
15 decision for over-12-year-olds; is that fair?

16 **A.** That's fair, yes.

17 **Q.** In your statement you say that in relation to the
18 vaccination of 5 to 11-year-olds, you personally were
19 somewhat reluctant, and "reluctant" is the word you use
20 in your statement, because you believed it was a measure
21 that, perhaps arguably, had not yet proven to be
22 necessary, and you were concerned about it.

23 Given your personal view, and you were concerned, as
24 I say, or you had a degree of reluctance about this, why
25 did you agree to accept the advice from the JCVI in

19

1 and I wanted a proper, thoughtful consideration.

2 I think that's how -- together with my team, how we came
3 up with the factors that must be looked at.

4 **Q.** A submission went to you dated 10 February 2022 -- this
5 is, again, in relation to 5 to 11-year-olds?

6 **A.** Yes.

7 **Q.** INQ000112227. We can see SO -- Secretary of State, at
8 the top left, private secretary. And it comes from an
9 unredacted name but in fact it was a submission from
10 your department --

11 **A.** Yeah.

12 **Q.** -- based upon the advice which had then -- by then been
13 received from the JCVI. And it was, as we can see, to
14 do with vaccination, the offer of vaccination to 5 to
15 11-year-olds. And we should make plain, shouldn't we,
16 Sir Javid, that authority, authorisation for the formal
17 use of vaccines for 5 to 11-year-olds had been granted
18 by the MHRA, so the Prime Minister was entitled to say,
19 "Authorisation has been granted, let's get on with it."

20 And we can see the recommendation to accept the JCVI
21 advice, agree the statutory products, agree the proposed
22 timing of publication.

23 And at pages 4 to 5, starting with paragraph 14, we
24 can see there under the heading of "Benefits and cost
25 effectiveness":

18

1 relation to the offer of vaccination to this cohort?

2 **A.** It was -- so it was the one piece of advice from JCVI
3 where they made a recommendation that I was very
4 reluctant. And I was reluctant because, as you've seen
5 in some of the evidence that has just been shared, and
6 from what I remember at the time, that I thought the
7 decision of the JCVI was very finely balanced, because
8 as -- it references we were at the Omicron wave or --
9 I think almost all infections by that time were Omicron.
10 Omicron, we knew, in a general sense, was a lot more
11 severe, a lot more people had been infected because of
12 its rate of infection, so many children would probably
13 already have been infected. And -- but then the
14 argument of JCVI and others that supported the offer was
15 that: well, this is where we are with Omicron, but you
16 don't know what's going to be around the corner, the
17 advice could change again, it could mutate and by then
18 it might be too late to vaccinate this group. So I felt
19 it was very finely balanced.

20 I was also, again, getting a huge amount of pressure
21 from the Prime Minister on this cohort as well. He --
22 his view was, again, it couldn't happen quickly enough.
23 He was aware of this advice, so it would go to his --
24 his office would be told that I'd received advice and
25 the broad conclusion of that advice. And then I felt,

20

1 when I put that together, it would have been very hard
 2 for me to take a decision to ignore the advice of the
 3 JCVI and say, "Look, I" -- and say, "Look, I know what
 4 they're saying, but I'm not going to make that
 5 decision", because my -- I felt my job clearly is not to
 6 do what I personally think is right or wrong for me or
 7 my family, it's to do what is right for the country and
 8 the population, and I had to base that decision on the
 9 expert advice that I had been given.

10 **Q.** And the JCVI is, of course, the independent --

11 **A.** Yeah --

12 **Q.** -- expert, in fact statutory body --

13 **A.** Yeah.

14 **Q.** -- tasked with the obligation of giving advice to
 15 ministers as to the correct way forward?

16 **A.** That's right. And also, I did some -- when I looked at
 17 the way the JCVI had phrased their -- even their
 18 recommendation, I think they called it a non-urgent
 19 offer, and so it wasn't -- to make the vaccine available
 20 to children, obviously for their parents to decide, but
 21 as a non-urgent offer it wasn't something that either
 22 myself, as the Secretary of State, or the department
 23 more generally, were going to, sort of, push, I guess,
 24 or advertise in the same way as the more important
 25 vaccinations early on in the pandemic for adults.

21

1 **Q.** All right. VCOD. Vaccine as a condition of deployment.

2 **A.** Yes.

3 **Q.** I'm aware you gave evidence in Module 3, and I repeat my
 4 apology that you've had to come back and give evidence
 5 again.

6 When you gave evidence in Module 3, the focus of
 7 much of the questioning was about the impact on the care
 8 and health sector of the introduction of the initial
 9 policy, which was to mandate vaccination as a condition
 10 of deployment for care workers in registered care
 11 homes --

12 **A.** Yeah.

13 **Q.** -- and what was the impact on the sector.

14 **A.** Yeah.

15 **Q.** But there was a later policy, at least a consultation
 16 for a policy, as to whether or not this mandated
 17 vaccination policy should be rolled out to the wider
 18 care and healthcare sector, health sector.

19 And particularly with an eye on the impact of -- on
 20 vaccine confidence or, alternatively, hesitancy, I want
 21 to ask you some questions about the rationale for that
 22 second policy.

23 **A.** Yeah.

24 **Q.** Which ultimately wasn't, in fact, introduced. It was
 25 pulled on 1 March 2022.

23

1 **Q.** And it's right to say that when the statement was made
 2 on 16 February that an offer would be made to
 3 5 to 11-year-olds, it was very much couched in terms of
 4 this being a non-urgent offer?

5 **A.** Yes.

6 **Q.** And that was how the JCVI put it.

7 **A.** Yeah.

8 **Q.** Was the DHSC directly concerned with the rollout of the
 9 offer and the operational side of offering vaccines to
 10 5 to 11-year olds, that there was, as it happens,
 11 a policy by which there was, I think, a 12-week wait
 12 following Covid infection before -- well, which had to
 13 be allowed to elapse before 5 to 11-year-olds could be
 14 offered the vaccine or take the vaccine.

15 Was that a policy that found its genesis in the
 16 DHSC, do you know, or was that an NHSE/Public Health
 17 England issue?

18 **A.** I think in general the recommendations and sort of
 19 clinical decisions around the 12-week period and/or
 20 other issues around the gaps between, sort of, one
 21 vaccine and your next vaccine, those were your rightly
 22 clinical decisions, but I believe in general they would
 23 either have come from the JCVI itself, or from the
 24 UKHSA, the UK Health Security Agency, and what was,
 25 before, Public Health England.

22

1 So if you could look at a briefing paper, please.
 2 INQ000497213.

3 This is the document, in fact, which provides the
 4 most recent public health evidence from the UK Health
 5 Security Agency on vaccine effectiveness, because it
 6 provided the foundation or rather government needed the
 7 up-to-date position in terms of public health evidence
 8 in order to be able to make a final decision as to
 9 whether or not that wider policy should be implemented.

10 If we look at page 2 -- and this was a document that
 11 went -- a briefing paper that went to you -- at
 12 paragraphs 9 and 10, we can see that this -- that the
 13 preliminary data showed that there was some protection
 14 being given against infection through vaccination.
 15 Compared to unvaccinated healthcare workers who'd not
 16 also had a prior infection, those with two doses were
 17 32% less likely to be infected with coronavirus, but the
 18 estimate was uncertain because the range of possible
 19 effectiveness was large, and includes evidence of no
 20 effect.

21 And then, at 10:

22 "Preliminary evidence from UKHSA [also showed] that
 23 the effectiveness of all vaccines against symptomatic
 24 infection is lower in all periods against Omicron
 25 compared to the Delta variant ..."

24

1 So was this the position, by January, February 2022,
2 as you've rightly said, Omicron was rife and the
3 emergence and the application -- or the presence of the
4 Omicron variant had a significant effect on the data as
5 to the effectiveness of the vaccines, and therefore
6 a further subsequent effect or ancillary effect on the
7 efficacy, the effectiveness, of a VCOD policy. Was it
8 worth it, bluntly. Was that the position that was
9 reached at the beginning of 2022?

10 **A.** Yes. And the way I would perhaps explain it is that
11 when the original decision was made on, you know,
12 V-C-O-D, VCOD as we referred to it in the department, in
13 2021, the end of 2021, that was at a time when there was
14 no such thing as Omicron, the Omicron variant did not
15 exist, so it was based on the virus at the time, the
16 dominant variant, I believe was Delta, and there was
17 some Alpha, and those were the facts taken into account.
18 By January 2021, and certainly by February 2022, in
19 February 2022, the -- almost all infections, I think, by
20 that time, were Omicron. In fact, I believe something
21 like, by the end of January, almost a third of all
22 infections that had ever taken place during the pandemic
23 were Omicron, and that meant that the policy had to be
24 reassessed in light of that evidence, and the facts
25 changed. And if the facts changed, we changed the

25

1 vaccination uptake and protect the workforce, but also,
2 whether or not members of the sector, the workforce,
3 would leave their posts rather than agree to be
4 vaccinated?

5 **A.** That wasn't a decisive factor, no.

6 **Q.** If we then look at paragraphs 20 and 21, I think on
7 page 3, the submission says:

8 "The evidence set out above means that the
9 cost/benefit case for the current VCOD policy is more
10 finely balanced than before. It is very likely that the
11 effect of VCOD as a means of protecting patients and
12 people with care needs is less than it was ... While
13 protection against severe disease and hospitalisation is
14 much higher and takes longer to wane, this is not the
15 purpose of VCOD."

16 So it was a much more finely balanced policy
17 decision than the earlier emanation had been and,
18 ultimately, the government didn't pursue it; is that
19 right?

20 **A.** That's correct.

21 **Q.** Were you concerned also about the impact on members of
22 ethnic minority communities and as well as, of course,
23 the care and health sector workforce itself in terms of
24 a longer-term impact on vaccine confidence? By imposing
25 a mandatory programme on healthcare workers, was there

27

1 policy.

2 **Q.** Page 5, paragraph 33, please, on this document.

3 In addition, is this correct, there was obviously
4 also significant concern about the impact on the
5 workforce, and this is something that you addressed in
6 Module 3, but we can see there the figures about,
7 firstly, the number of persons in the NHS who weren't
8 already vaccinated, and also further down, and if you
9 can scroll back out, you can see 34, 35, 36, what the
10 possible impact might be of mandatory vaccination in
11 terms of staff leaving the sector.

12 So it wasn't just a question about effectiveness of
13 the vaccines in the face of Omicron; the government
14 obviously had to be aware also of, firstly, whether or
15 not vaccination was required to be imposed mandatorily,
16 given the current uptake, and secondly, what the
17 possible impact would be on the sector if the policy
18 were to be pursued.

19 Is that right?

20 **A.** So can you ask me the question again? What's the
21 question?

22 **Q.** Was the government also concerned, not just with putting
23 Omicron into the general picture in seeing whether or
24 not vaccination was required, or at least whether or not
25 mandatory vaccination would lift the uptake of

26

1 a risk that there would be a wider disbenefit in terms
2 of decreasing confidence in vaccination generally?

3 **A.** There was clearly --

4 **Q.** A backlash.

5 **A.** Yeah, it was clearly one of the risks that we had to
6 consider, and we did, and as has been referred to and
7 I think is evident from the evidence paper, it was
8 a balanced decision. It was a balanced decision to
9 implement the policy in the first place and it was also
10 a balanced decision to change it when the facts had
11 changed.

12 But in terms of -- you referred to ethnic minority
13 workers, and relative to the population, there's
14 a disproportionate number of people actually that work
15 in the NHS that are from ethnic minority backgrounds and
16 we're incredibly proud of them, I think we're proud of
17 everyone that works in the NHS, whatever their
18 background, but my view was very firmly that everyone,
19 regardless of their ethnicity, they should be treated
20 equally, and the whole purpose of this policy was to
21 reduce the rate or the risk of infection for vulnerable
22 people, patients of the NHS, those in hospital, and
23 that's the purpose, and the virus didn't discriminate
24 about whether it was infecting a black, brown or white
25 person, and that was why we clearly had to follow the

28

1 same policy for everyone, regardless of their ethnicity
 2 and that was the correct way to do it.

3 **Q.** Widening out the debate, to what extent was the DHSC
 4 focused on reducing barriers to uptake and increasing
 5 confidence in the vaccines generally? Was that part of
 6 your core functions?

7 **A.** Just to check, do you mean with respect to VCOD or do
 8 you mean --

9 **Q.** No, no, generally, more -- widening it out --
 10 (overspeaking) -- debate?

11 **A.** Oh yes, I felt it was a very important part of my core
 12 responsibilities, but also more widely in the
 13 department, including with my junior ministers, and
 14 particularly the vaccine minister.

15 **Q.** It's obvious that there were a number of parts in the
 16 government machine concerned with the issue of reducing
 17 barriers to uptake --

18 **A.** Yes.

19 **Q.** -- and increasing vaccine confidence?

20 **A.** Yes.

21 **Q.** From the more operational end of things, NHS England,
 22 the voluntary, charitable and -- the voluntary and
 23 charitable sector, and the military and the volunteers
 24 at the operational end, as well as at the heart of
 25 government, Cabinet Office, DHSC, OCMO was obviously

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1 and Pensions, in the Home Office, you know, for example,
 2 with migrants and others, and so I think the Cabinet
 3 Office was the right department to, once a sort of
 4 battle plan, a strategy was agreed, to make sure that
 5 all other departments were doing their bit, and that was
 6 being checked and improved, if it could be improved.

7 **Q.** And could you give us, please, some idea of the amount
 8 of time that was devoted to this issue or the priority
 9 that was given to it in your department? I mean, were
 10 you on a daily basis or a weekly basis trying to focus
 11 on what practically could be done at the operational end
 12 on reducing barriers to uptake, by way of getting the
 13 message about vaccination out there --

14 **A.** Yeah.

15 **Q.** -- making the vaccine practically available,
 16 operationally available, trying to deal with some of the
 17 conspiracies and the myths and the tropes surrounding
 18 vaccination? Who was responsible for making sure that
 19 that general drive was actually being put into practice
 20 and -- (overspeaking) --

21 **A.** Well, I felt ultimately it was my responsibility as the
 22 Secretary of State, and it's something that I worked on,
 23 I'd say, almost every day. Because every day in my
 24 department -- certainly every weekday in the department,
 25 we would have, at some time in the morning, a meeting of

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1 plainly very concerned about this issue.

2 **A.** Yes.

3 **Q.** Which government department do you assess was in the
 4 driving seat when it comes to trying to drive through
 5 measures to try to reduce barriers to uptake and to
 6 increase confidence? Who was driving forward the
 7 government machinery on this, in your view?

8 **A.** I think -- well, first, I think there was a general
 9 shared responsibility, but in terms of the department,
 10 the big two that I think that were really essential to
 11 this: one was my own, and we were, rightly, I think, it
 12 was the health department responsible for the delivery
 13 of the vaccine, the uptake of the vaccine, and I think
 14 as the -- both as the Secretary of State but also all
 15 the expert advice, the CMO, the DCMO and others that
 16 worked with the department played a crucial role in
 17 building vaccine confidence. But the other department
 18 would be the Cabinet Office, because there was a --
 19 I think that's the one department that can coordinate
 20 properly across government, and that you could -- one
 21 could see a role virtually in every department how other
 22 ministers, cabinet ministers and others could play
 23 a role.

24 So, for example, you could see there would be a role
 25 in the Education Department, in the Department for Work

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1 what was -- the vaccine, sort of, delivery team. And
 2 that included our colleagues from the NHS, which we
 3 were -- who were primarily responsible for delivery of
 4 the vaccines, and also VTF and CMO and others. And
 5 I would chair that meeting, and there would be an
 6 agenda, and I would say almost every time we had that
 7 meeting, one of the agenda items would be vaccine
 8 uptake, especially in combating hesitancy, building
 9 vaccine confidence, and also discussions, especially if
 10 there had been some incident or something around
 11 conspiracy theories and issues of that nature.

12 And we would agree in those calls, the -- in every,
 13 sort of, video calls, with everyone joining in, we would
 14 agree that what would be the -- following that meeting,
 15 would be the action points. And then the next day,
 16 because we'd talk about it again, I would want to make
 17 sure that what we had agreed previously had been done,
 18 what were the results, what we were doing.

19 Also I'd hold number of meetings with groups,
 20 especially with, for example, the ethnic minority
 21 groups, with the media, and -- from -- that might
 22 represent certain communities, as I've tried to sort of,
 23 myself, do something when I was trying to reach out.

24 And then, lastly, I also felt that, not specifically
 25 with vaccines, but I felt throughout my time in that

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1 role, was that health generally, there were a lot of
2 inequalities including regarding ethnicity but also more
3 broadly based on gender, disabilities and more broadly,
4 and deprivation. And that was an area I did a lot of
5 work in. And I felt that if it was clear that this was
6 something I was and the government was taking perhaps
7 more seriously than before, that would help to build up
8 general confidence in the health system.

9 So, for example, the inquiry -- the independent
10 review I asked for from Dame Margaret Whitehead into the
11 inequalities of medical devices and instruments,
12 although that wasn't related, of course, to vaccines,
13 I just felt it would show that there were some real
14 issues around ethnicity, for example, and healthcare,
15 and the government was taking them seriously, and I felt
16 that would help build up confidence.

17 **Q.** The material before the Inquiry suggests provisionally
18 that, whilst there were a great many people and bodies
19 concerned with issues as to whether or not barriers to
20 access could be reduced, could be further reduced, and
21 confidence increased, that there was a general failure,
22 perhaps, to utilise or to focus upon greater use of
23 local-level means, practical solutions, to make sure
24 that the barriers to access in the way of ethnic
25 minority communities, disabled people, migrant groups

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1 is actually building that sort of confidence with
2 communities, you know, Traveller communities, different
3 ethnic minority communities and others, today, because
4 I think to try and sort of -- it's very hard to build
5 that confidence quickly. It needs to be built slowly
6 over time, and around healthcare more generally, in
7 peacetime. And that is why I felt the work I was doing
8 in inequalities was so important. Which, sadly, the
9 successor, sort of, secretaries of state and the current
10 government haven't continued. And that's why I did all
11 the work I did on a draft White Paper which was to look
12 at all these inequalities and issues --

13 **Q.** Was that the draft White Paper on health inequalities?

14 **A.** That's correct, yeah. Was to try to sort of build more
15 confidence with communities that I felt, in some ways,
16 had been left behind in healthcare and in consideration
17 of their health needs.

18 **Q.** A witness said very pertinently, I think, a couple of
19 days ago that if you can't see and assess the scope of
20 the problem, you can't fix it. Did you assess that
21 you -- or do you assess that you had sufficient data,
22 sufficient information, as the Secretary of State, about
23 the extent of the practical barriers to access, and the
24 particular unique needs of all of these various
25 communities, from Gypsy, Roma and Traveller communities,

35

1 and other marginalised parts of society, were -- well,
2 whether there was enough use of local methods to try to
3 reduce barriers.

4 And it was obvious that there were a great deal of
5 government departments and people concerned in this
6 issue, and, in the best of faith, doing their best. Is
7 there an argument for having a more focused, specific
8 government body, department, entity, that can focus all
9 its intention on ensuring that these important issues
10 are addressed: that vaccine confidence is maintained,
11 and barriers, practical barriers to access, are reduced?
12 It appears to be a very fragmented, disparate picture in
13 terms of the outcome of the work that the government
14 did.

15 **A.** In general, yes, there is. I think, for me, one of the
16 lessons learnt should be that even in peacetime, like
17 now, we should be preparing for the next pandemic, of
18 course, and one of those areas of preparation should be
19 a vaccine or, even more broadly, therapeutics delivery,
20 because the next pandemic it might not be vaccines; it
21 might be antivirals, for instance. But whatever that
22 pharmaceutical, sort of, intervention is, I think there
23 is a strong argument to have a unit, a group of
24 officials, experts, that are very focused on that in
25 peacetime. For example, what they could be doing today

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1 through migrants, through ethnic minority communities
2 and so on, so as to be able to formulate proper policies
3 for their resolution and to put operational plans in
4 place? Did you know enough about what it was like on
5 the ground?

6 **A.** I felt that -- well, I was told that the data that I was
7 getting was a significant improvement on what my
8 predecessor had had at the start of the pandemic, and
9 I can understand why, and -- you know, a lot had been
10 done to improve things, even by then.

11 Your question was: was there enough data points?
12 And -- and I think that could be improved, and that's
13 just a -- I think just a sort of -- in -- it's easier to
14 say in retrospect, but I think there are areas, for
15 example, in sort of behavioural science, behavioural
16 data, that could be used. And there were instances of
17 that, where I asked for such an analysis and got it, but
18 it wasn't -- I think it could -- something like that
19 could be more, sort of, a fixed part of the process.

20 So, for example, there was an idea -- and it's good
21 to look at lots of different ideas, especially what
22 other countries were doing, and I remember someone had
23 said in one of those meetings -- I referred to daily
24 meetings -- said: look -- I can't remember what country
25 it was in Europe, but they were offering young people --

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1 younger people -- teenagers, like -- in their early
 2 twenties, theatre tickets or cinema tickets to get
 3 vaccinated, like an inducement to get vaccinated. And
 4 I was sceptical about that. I just felt that if you get
 5 a vaccine, it should be for a positive reason: to want
 6 to protect your health or protect your loved ones from
 7 infection, rather than some kind of inducement. But
 8 I thought it would be -- wouldn't be right of me just to
 9 ignore it and then pretend I know better, because
 10 I wasn't an expert on it.

11 So I did ask for a -- behavioural science work to be
 12 done on that and similar ideas. And what we got back
 13 was that basically my scepticism was, I think, proven,
 14 that it could backfire.

15 So that was useful data, useful analysis, but
 16 I think having more of that kind of analysis would be
 17 helpful.

18 **Q.** So let's be clear on this. In relation to the passive
 19 receipt of data as to the reality on the ground, you
 20 think more could be done, there are always improvements
 21 that can be put into place?

22 **A.** Yes.

23 **Q.** But also, there is a case for taking more positive steps
 24 in terms of accumulating knowledge and seeing whether or
 25 not there may be incentives or nudges based on

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1 immunocompromised for booster vaccinations."

2 And over the page at page 2, JVT says in the second
 3 indent, he:

4 "... believes that there is a requirement for
 5 a clinical lead on the immunocompromised. This person
 6 needs to be able to pick up work on shielding,
 7 therapeutics, antibodies, and the vaccine agenda. There
 8 currently isn't anyone who is able to step into this
 9 space, and this is something that needs to be fixed.
 10 There needs to be further discussion with Ministers, but
 11 there is currently a gap."

12 Was this something that was brought to your
 13 attention -- (overspeaking) -- agenda?

14 **A.** I don't believe I was at this meeting --

15 **Q.** No, you weren't.

16 **A.** -- but yes, generally, I would say yes, this issue
 17 was about doing as much as we can to make sure, when
 18 we're thinking about pharmaceutical defences, it's not
 19 just vaccines, but it's -- obviously, vaccines is
 20 important for certain members of the immunocompromised
 21 community but it doesn't work for everyone, and so we
 22 were looking broadly at therapeutics and antibodies and
 23 antivirals.

24 **Q.** It's obvious that whilst vaccines had been purchased at
 25 risk, that is to say hugely expensive and fundamentally

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1 behavioural science that might improve the general lot
 2 of in terms of availability of vaccination?

3 **A.** Yes.

4 **Q.** All right. Prophylactics. When you were Health
 5 Secretary between June 2021 and July 2022, a significant
 6 part of your time appears to have been taken up by
 7 considering the issue of post-authorisation making
 8 available of prophylactics in particular, but
 9 therapeutics generally.

10 Shortly after you arrived at the DHSC on
 11 12 July 2021, there was a meeting on the topic of
 12 prophylactics. INQ000497986. And the email is from the
 13 private secretary to Lord Bethell, who was one of the
 14 ministers in the department. I don't think that you had
 15 been an attendee at the meeting, but Lord Bethell's
 16 private secretary had, as well as the Deputy Chief
 17 Medical Officer, Professor Sir Jonathan Van-Tam, and
 18 a number of other officials.

19 We can see remarks from Sir Jonathan to the effect
 20 that:

21 "... Covid will remain prevalent in the population,
 22 and that therefore those who are immunocompromised and
 23 [clinically extremely vulnerable] are concerned."

24 And he notes the fact that:

25 "... JCVI will likely prioritise the

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1 important decisions had been made about whether to
 2 procure vaccines had been taken without knowing whether,
 3 clinically, they would be effective or significantly
 4 effective. In relation to therapeutics, by contrast,
 5 whenever a decision had to be made about whether or not
 6 to pursue a particular therapeutic, there had to be an
 7 assessment of its cost effectiveness as well as the
 8 risk-reward balance, and HMT ultimately had to take
 9 a view as to whether or not it would be funded?

10 **A.** Yeah.

11 **Q.** Why was the DHSC in that position? Why could you not
 12 simply pursue a range of therapeutics, in particular
 13 prophylactic treatments, on the basis that you could
 14 purchase them at risk and then see whether or not they
 15 would be clinically effective?

16 **A.** Well, I think -- firstly, I think a lot of the decision
 17 making on that issue about how much funding there was or
 18 how that funding would be accessed for, sort of,
 19 pharmaceutical, you know, intervention in general,
 20 whether that's vaccines, therapeutics, antivirals,
 21 et cetera, they were made before I was in the
 22 department. A lot of that had been, sort of, set in
 23 train, as it were, before I joined as Secretary of State
 24 in June of 2021. But my -- from what I saw, was that --
 25 well, what I can say, because it was self-evident, was

40

1 that by the time I came to the department in June 2021,
 2 obviously the vaccine -- finding a vaccine that worked
 3 had been successful, those vaccines had started to be
 4 delivered, there were still a lot more people to
 5 vaccinate, but I think the, sort of, broadly, the focus
 6 was more shifted on vaccines and getting them delivered,
 7 because they were broadly working, albeit of course not
 8 for everyone, they weren't appropriate, and I felt that
 9 there was less focus or -- and including from the
 10 Treasury -- on having something other than vaccines.
 11 And that particularly, you know, became an issue for me
 12 in, it was around, I think -- quite early on, when
 13 I became Secretary of State, I think August of 2021,
 14 where there was an Antivirals Taskforce led by Eddie
 15 Gray, and he had spoken to my officials and then he had
 16 spoken to me and written to me, sort of, recommending
 17 the purchase of antivirals, two antivirals in particular
 18 manufactured in the US, and I agreed fully with his
 19 arguments and what he'd set out and the clinical and the
 20 medical reasons for that, and not just because I thought
 21 they could be perhaps more useful with certain groups of
 22 people where vaccines were less useful, but I just
 23 thought it would be another line of defence, because
 24 especially at that time, in August of 2021, of course,
 25 we didn't know about Omicron at that time but it was

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1 the start of the pandemic, but it felt to me the
 2 attitude had changed towards funding of pharmaceutical
 3 defences by, sort of, middle of -- the second half of
 4 2021. And just to say something, the reference that you
 5 just made to the antivirals that were eventually
 6 purchased, I -- in my arguments to get more antivirals,
 7 there were actually two distinct phases: there was the
 8 pre-Omicron phase and there was the post-Omicron phase.
 9 And in pre-Omicron I had a huge amount of resistance
 10 from Treasury, from even the Number 10 team, parts of
 11 the Number 10 team, and in that case I did manage to
 12 secure, but it was a lot less than I wanted. And
 13 I think it was collectively about 800 -- 700,000 units.

14 When Omicron was a reality, then I'd received -- I'd
 15 asked for fresh advice about antivirals and about what
 16 role they could play right on the onset of Omicron,
 17 right at the start of November, and I had fresh advice
 18 from Eddie Gray that I asked the CMO and even the CSI --
 19 the CSA, the Chief Scientific Adviser to comment on, and
 20 they all said that we should get more antivirals. There
 21 was a very strong, I thought, advice from all three of
 22 them, and they were my -- very -- they were very
 23 important advisers to me, and that is when I asked for
 24 funding for a lot more antivirals in light of Omicron,
 25 because especially at that time when I got the advice,

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1 a widespread view that the pandemic wasn't over and
 2 Covid was likely to mutate many more times and we don't
 3 know what was going to come down the line or whether the
 4 same vaccines were going to work.

5 So I also felt almost something like an insurance
 6 policy that we should have something else, but his
 7 recommendation that he gave me was for over, I think,
 8 between the two antivirals, procuring over two million
 9 units in -- and I had to have a big battle with the
 10 Treasury and with Number 10, and eventually I did secure
 11 some, but it was a lot less than I had wanted.

12 **Q.** You secured agreement for the purchase on 19 December
 13 2021 of 1.75 million courses of molnupiravir and I think
 14 a further two and a half million doses of Paxlovid. So
 15 that's absolutely right in terms of the outcome. But
 16 coming back to the question of risk. In your statement
 17 you say:

18 "I saw firsthand the approach to funding the vaccine
 19 and the willingness to take risks did not even last the
 20 length of the pandemic."

21 So from that statement, from that observation, you
 22 appear to be saying not enough was done, as it was and
 23 had been done very successfully with vaccines, to take
 24 a punt, to take a risk on the purchase of therapeutics.

25 **A.** Yeah, I felt the -- again, obviously, I wasn't there at

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1 we weren't even sure if the vaccines were going to work
 2 with a booster effectively against the Omicron and
 3 I felt that we had to go and secure whatever we could
 4 because there was a global competition for these
 5 antivirals. There were only two manufacturers in the
 6 world: they were US, meaning the US would get the first
 7 supplies, whatever it wanted, and then all other
 8 countries had to fight for what was left. And I felt we
 9 had to get orders in, and quickly. And if it turned out
 10 that we couldn't get what we wanted after we ordered it,
 11 that's not something in our control, but I felt we had
 12 to do whatever was possible and was in our control.

13 **Q.** In September of 2021, and as you say, there was what was
 14 described, in fact, by you as quite frustrating debate
 15 about whether or not the recommendations to buy
 16 antivirals would be accepted by the Treasury, and it's
 17 clear from your evidence and other evidence that the
 18 Treasury, in particular in the form of the Chief
 19 Secretary to the Treasury, Steve Barclay, was concerned
 20 about how efficacious antivirals were, and told his
 21 officials that they had to be extremely clear about
 22 whether or not the funding was justified, and to be
 23 rigorous in their approach.

24 We can see some emails between Sir Patrick Vallance,
 25 Eddie Gray, who was the Head of Antivirals Taskforce,

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1 and Sir John Bell of Oxford, INQ000399326, concerning
2 antivirals. And on the first page of 399326, we can see
3 Eddie Gray, the Head of the Antivirals Taskforce,
4 writing to Sir John Bell and Sir Patrick Vallance, and
5 saying this:

6 "We have at least stopped the DHSC trying to
7 negotiate itself down under pressure from the Treasury.
8 SOS has been impressive [that's you, of course], is
9 running with our proposal and telling officials that if
10 any compromises are to be made, he'll make them with the
11 [Prime Minister] and Chancellor, not officials."

12 Now in hindsight, do you think that there is
13 a better way of trying to get approval for therapeutics
14 in the teeth of a pandemic, than having to negotiate in
15 each case through the iron fist of the Treasury?

16 **A.** I'm not sure there is, because the Treasury is the only
17 department that has money in government, and you're not
18 going to be able to buy anything without the money. And
19 so ultimately the Treasury has to agree in one way or
20 another. I think where things can improve is that, you
21 know, the -- I felt the Treasury officials -- because it
22 was more about the officials rather than the Chancellor
23 himself at the time -- they were trying to sort of argue
24 with my officials, who were clinicians and scientists
25 and, you know, experts and -- on vaccines and

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1 the government] is most frustrating. We have ordered
2 a small amount of PF, but late and at a level that we'll
3 get no priority."

4 So that's the point you make about --

5 **A.** Yeah.

6 **Q.** -- being in the priority lane from the standpoint of
7 manufacturers.

8 "Mck [that's a manufacturer] have given us
9 a deadline of Friday and we are in danger of falling in
10 same trap. Very annoying. [The Secretary of State] has
11 supported our recommendations which is good, but getting
12 decision across him, [the Prime Minister] and [the]
13 Chancellor, ridiculously hard."

14 In relation to vaccines, Sir Sajid, there was
15 a ministerial panel which brought together, forced to
16 sit at the same table, Treasury, BEIS, DHSC and -- I'll
17 be reminded, there was one other minister there, I can't
18 now remember -- Cabinet Office -- thank you -- in
19 which -- in the course of which meetings decisions to
20 fund over the level of £150 million were taken then and
21 there, rather than having to make a case, a business
22 case -- although business cases were made for each
23 vaccine and each expenditure -- one after the other to
24 get final ultimate approval from the Treasury.

25 Why was consideration not given to have a similar

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1 therapeutics, they were trying to argue with them on the
2 science of the antivirals and whether they were
3 effective or not. And I don't feel that was their
4 place.

5 I mean, they -- by all means they can say: look, it
6 might be effective but we're not going to fund them
7 because of some other reason. That's their prerogative.
8 But I felt the arguments were -- and there were
9 arguments between officials, and that's why in this note
10 I think it refers to -- I didn't want my officials
11 agreeing that any kind of sort of backing down on the
12 requests with Treasury officials. I felt that if --
13 whatever agreement we -- ultimately was going to be
14 reached, it has to be done by me and the Prime Minister
15 and the Chancellor, so that both of my colleagues, the
16 Prime Minister and Chancellor, could see just how
17 important this was, and how important I thought it was
18 to pandemic defences.

19 **Q.** And if we scroll back out, I think we'll see a reference
20 to the difficulty of getting decisions across the
21 Prime Minister and the Chancellor.

22 Perhaps it's on the second page. Yes, at the top,
23 in the top email.

24 An email from Eddie Gray to Sir John Bell:

25 "As of now that response [that's the response from

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1 ministerial panel in relation to therapeutics, which
2 might have reduced the level of difficulty which appears
3 to have been encountered in getting decisions made and
4 authorised?

5 **A.** I think, actually, if there was it wouldn't have made
6 much difference, because the key decision is not to have
7 a sort of ministerial panel. I mean, it does -- helpful
8 in the process of making a final decision to buy
9 something or not buy something. The key decision is to
10 allocate a budget.

11 And so the ministerial panel that has just been
12 referred to, on vaccines, that was established, you
13 know, once the Treasury had already decided there's
14 a budget. In the case of vaccines, again, that decision
15 was made before I was there, but it was almost, you
16 know, unlimited budget, that "Go after vaccine
17 candidates and it's going to cost what it's going to
18 cost", and as a panel, you just sort of make the final
19 decision. But there's a budget, an overall budget
20 you've already got control of. And so there's a budget
21 delegated to that panel.

22 But if there was a panel on antivirals, but it
23 hasn't -- it doesn't -- there's no budget above it, then
24 it makes no difference.

25 **Q.** So the problem with therapeutics, including antivirals,

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1 was that there was no overarching budget?
 2 **A.** There was no budget.
 3 **Q.** In the same way that there'd been a £5 billion budget
 4 for vaccines, there was no overarching budget to
 5 which appeal could be had and recourse could be had?
 6 **A.** There was no budget, and you might recall in a previous
 7 session we talked about the spending review for the NHS,
 8 I believe in Module 1, I can't be sure, but where -- you
 9 know, around -- prior to this moment that we're --
 10 you're considering now, in sort of September,
 11 November 2021, in the summer of 2021, I had to agree the
 12 overall spending envelope for my department for the next
 13 three years. And that included a -- vis à vis the
 14 budget, it included, sort of, budget cover for -- as
 15 it's referred to, "budget cover", by the Treasury -- for
 16 vaccines and other, sort of, responses by the NHS to the
 17 pandemic, in terms of more staff and more diagnostics
 18 and so forth.

19 At that time, I was specifically asking for a budget
 20 for antivirals, and that was unsuccessful, and the
 21 decision that was made eventually was that we're not --
 22 that you're not going to get a budget for antivirals.
 23 Should you -- should the nature of the pandemic change,
 24 should there be a new variant and you need antivirals,
 25 then you'll have to come back and revisit it.

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1 programme, and given the state of clinical evidence as
 2 to the effectiveness of Evusheld, it wasn't something
 3 that could be pursued at that time, it had to go through
 4 a further technology appraisal process?
 5 **A.** Yes. Essentially, yes. That by -- so Evusheld,
 6 I believe was -- the sort of the research and
 7 development of Evusheld had begun towards the start of
 8 the pandemic.
 9 **Q.** Yes.
 10 **A.** But it didn't receive MHRA -- it took a lot longer than
 11 vaccines, and it didn't get MHRA approval until
 12 March of 2022. By March of 2022, almost every infection
 13 was Omicron. So the nature of the virus had changed
 14 dramatically. And my understanding was that all sort of
 15 testing or trials that had been done of Evusheld to date
 16 had been with the Delta and Alpha virus, and a variant,
 17 and not with Omicron. And I received the very clear
 18 advice, I think -- firstly it was in May of that year,
 19 2022, that there's not enough evidence at that point
 20 that Evusheld is going to work. I think the trials were
 21 held by a group called RAPID C-19, and the advice was
 22 that it's -- there was not enough evidence that it was
 23 effective against Omicron and more trials are required,
 24 and that's what was -- more testing was done.

25 Then in June of 2022, I had very clear advice from

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1 And I knew at the time that that will delay things,
 2 at best. At worst, it will mean, you know, there would
 3 be a real lack of funding when it was needed.

4 **Q.** So when it came to seeking Treasury approval for
 5 expenditure in relation to specific therapeutics, was
 6 there then an additional block in the flow of money,
 7 which is that you were told on occasion, or perhaps
 8 regularly: if you want funding for this particular
 9 therapeutic, you're going to have to make a cut
 10 elsewhere in your health budget.

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

12 **Q.** All right. And in relation particularly to Evusheld,
 13 about which we've heard a great deal, you received
 14 a submission on 20 June 2022 -- this is later, so
 15 post-Omicron -- INQ000497090 -- in which ministers were
 16 asked to agree that the department shouldn't deploy
 17 Evusheld in a prophylactic programme at that time, and
 18 that Evusheld should be considered through the
 19 technology appraisal process run by NICE, the National
 20 Institute for Clinical Excellence.

21 And briefly, in relation to Evusheld, was all the
 22 advice that you received from OCMO, from your
 23 department, from officials, pointing in one direction:
 24 which is that, given the background of Omicron, given
 25 the background of the success of the vaccination

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1 the CMO and others that they believe that Evusheld is
 2 not effective enough against Omicron, and therefore it
 3 would not be value for money to purchase it.

4 **Q.** Following that decision being made, there was a meeting
 5 with AstraZeneca on 4 July 2022, AstraZeneca was the
 6 manufacturer --

7 **A.** Yeah.

8 **Q.** -- for Evusheld and no doubt quite a difficult meeting
 9 ... you were at the meeting and you explain why the
 10 decision had been taken not to procure Evusheld.

11 **A.** Yes.

12 **Q.** AstraZeneca expressed obvious and understandable concern
 13 as to why they thought they were being forced through
 14 a different process.

15 **A.** Yes.

16 **Q.** Their product, Evusheld, was being put through a further
 17 clinical technological appraisal trial rather than being
 18 authorised -- sorry, being agreed to be used and
 19 procured.

20 **A.** Yes.

21 **Q.** Following that meeting, I think you resigned or fairly
 22 shortly thereafter you resigned. And then you sent
 23 a message to your successor, Steve Barclay who had been
 24 Chief Secretary to the Treasury but who became Secretary
 25 of State?

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1 A. Yeah.

2 Q. And in a WhatsApp message with him dated 13 August, you
3 said that:

4 [As read] "Just a quick on Evusheld. I wanted to
5 make sure you know that the week before I left, I agreed
6 a deal with AstraZeneca that would have allowed us to
7 generally roll out the drug to vulnerable people but we
8 would only pay if it turned to work against current
9 subvariants as defined by us."

10 le, no success, no, fee.

11 We want to know, please, whether or not you had
12 actually agreed a formal or commercial deal with
13 AstraZeneca, because the meeting with AstraZeneca on
14 4 July very clearly indicates that, of course, they were
15 very unhappy that there was no deal, and Evusheld was
16 not going to be pursued.

17 A. Yes, so in that meeting -- as you say, I wanted to be
18 very open with AstraZeneca, because I felt that -- well,
19 I think it was just the right professional approach in
20 that they, AstraZeneca, I think, first of all, in the --
21 throughout the Covid pandemic as a company had put a lot
22 of time and effort in developing vaccines and other
23 therapeutics around the pandemic. They had invested
24 a lot in Evusheld, so I felt that they deserved a full
25 explanation of the government's decision, and

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1 important, and that he should know because there might
2 be a deal to be done.

3 Q. I think -- I'm not sure about superiors not being there,
4 because the meeting was attended by Mr Pangalos, who was
5 the head of AstraZeneca, but is this the sum of it: you
6 agreed a way forward with AstraZeneca or an
7 understanding as to how you might proceed but there was
8 certainly no commercial deal or formal contract?

9 A. That's correct, yeah.

10 Q. All right. Two final questions, please. Whilst you
11 were Secretary of State you received a number of
12 submissions concerning the operation of the Vaccine
13 Damage Payment Scheme, and you were given a number of
14 options as to whether or not the scheme could be
15 reformed, and if so, whether or not the flat rate of
16 £120,000 could be increased and backdated for those
17 persons to whom payments had already been made.

18 You received a submission on the 22 March 2022, and
19 again on 27 May 2022, and actually, I think, it was the
20 third briefing in June 2022. Do you happen to know
21 whether or not there were any changes made to the
22 scheme? You had indicated your strong preference for
23 one of the options, which was an increase in payment,
24 a flat rate, and backdating. But your officials told
25 you it would cost between £1.2 million and £8.9 million.

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1 I explained that the advice was that it was not
2 effective against Omicron.

3 AstraZeneca's view was that the advice was wrong,
4 and that it is effective against Omicron, broadly put.
5 And they said that they could prove that if only it was
6 used more widely, you know, you, the government, would
7 see. And that is when I raised this idea with them and
8 said, "Okay, if you're so convinced then why don't we
9 test it, and have this, kind of, generally put, no
10 success no/fee arrangement", and the two gentlemen from
11 AstraZeneca were very positive about having such an
12 arrangement.

13 They did say, you know, it wasn't something that you
14 could, sort of, just shake a hand on there and then and
15 do it. It was -- they had to go away and think about
16 it, and see how it could be done, speak to their
17 superiors, but it was left in a sort of positive
18 position where there might be a deal to be done on that
19 basis.

20 But then, as you referred to, I think within a week
21 or a few days after that, I left that role. And then
22 Steve Barclay, as you mention, took over, and I -- and
23 maybe I shouldn't have, because it was no longer my
24 role, but I was just keen that he knew of the nature of
25 the discussion I had, because I thought it was very

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1 Do you know whether or not your recommendation was taken
2 up or whether there were any changes made generally?

3 A. My understanding is that no changes have since that time
4 been made even now. And I felt that the VDPS is
5 something that my department had inherited from, I think
6 the Department of Work and Pensions, and I was happy to
7 take it on because I felt it wasn't fit for purpose and
8 it needed a lot of focus on it. And in the paper I
9 think you just referred to, there were a number of
10 recommendations that were made, and one of the key ones
11 was the, as you said, the amount of compensation which
12 hadn't been changed for years, but also I felt it was
13 too slow, it was bureaucratic, the people working there
14 weren't, sort of, expert enough. And also, what was
15 called the disability threshold was too high.

16 And if I may say, even -- and when I left the
17 department soon after, I was -- which -- and then I had
18 a meeting with my successor as well about it, because
19 I was contacted by one of my constituents, as I was with
20 my, sort of, MP hat on, which was that the wife of
21 a constituent, my constituent's name was John Cross, and
22 I think his experience is really important here just to
23 understand how dysfunctional this scheme is, in that he
24 was a retired pharmacist, he got vaccinated in
25 January 2021 --

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1 **Q.** With respect, I'm afraid I don't want to go into the
 2 details of any individual case and I'm not sure that he
 3 would necessarily want us or you to describe his case in
 4 public.
 5 Is it fair to say, and I suspect this is where
 6 you're heading, you did form the view that this scheme
 7 required fundamental reform? You may even have been of
 8 the view that it wasn't fit for purpose?
 9 **A.** Yes, that was my view, and with regards to the case, I
 10 won't go through the case but if it's possible, I think
 11 the Inquiry should look at this particular case and I'd
 12 be happy to furnish the details of that --
 13 **Q.** I'm sorry, we can't look at individual cases, it is
 14 outside our scope.
 15 **LADY HALLETT:** It is also one of the issues that was raised
 16 by a contributor to the impact film, so I'm very
 17 conscious of it, and I can see in the public gallery
 18 there are those who are acutely distressed ...
 19 **A.** All right. Thank you, my Lady.
 20 **MR KEITH:** And I should make absolutely plain that we are
 21 asking a number of other witnesses about the nature, the
 22 scheme, and the susceptibility for reform in relation to
 23 the Vaccine Damage Payment Scheme.
 24 **A.** Yeah.
 25 **Q.** Finally, Valneva, the contract for manufacture of

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1 than the study placebo, and on that basis it would not
 2 have been good value for money for the Treasury or the
 3 government to purchase something that it was never going
 4 to use.
 5 **Q.** And if we have INQ00514013 up, finally, please.
 6 9 September, did you receive advice from the
 7 director of strategy, VTF? So the Vaccine Taskforce,
 8 recommending you:
 9 "Issue [something] ..."
 10 Something contractual.
 11 "... to Violet ..."
 12 Violet was the codename for this contract?
 13 **A.** Yes.
 14 **Q.** "... against our expectation of their failure to meet
 15 the current delivery schedule, and based on legal
 16 advice ...
 17 "Inform the company of our decision and issue the
 18 notices after Friday ..."
 19 And:
 20 "... write to the Ministerial Panel ..."
 21 And if we scroll back out, we can see over the page
 22 a great deal of data or a great deal of information
 23 about the commercial nature of the contract, but also
 24 the clinical effectiveness of the vaccines that they
 25 were seeking to produce.

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1 vaccines in Scotland.
 2 The paperwork appears to indicate that advice was
 3 given on the cancellation of the Valneva contract on
 4 9 September 2021. You were the Secretary of State for
 5 Health at that time, but the advice from, it transpired,
 6 the Vaccine Taskforce, was -- well, it concerned whether
 7 or not the merits of that contract should be pursued and
 8 whether or not the deal should continue.
 9 Was the decision to cancel the contract taken by the
 10 DHSC or was it taken by the Treasury in the form of the
 11 Chief Secretary?
 12 **A.** It was taken -- ultimately it was taken by the DHSC.
 13 **Q.** And did the DHSC take advice from the Treasury as to
 14 whether or not the contract should proceed?
 15 **A.** No, I think it would have been -- I think it was a very
 16 clear decision, and so therefore I think that we would
 17 have notified -- we would have told the Treasury of the
 18 decision, and the Treasury was very happy with the
 19 decision, and it's very important the decision was based
 20 on one absolute key factor in that I received a very
 21 clear advice in September of 2021 that the vaccine, the
 22 Valneva vaccine, was ineffective as a third dose, and
 23 that's what we were looking for at that time, which
 24 was -- the real need was for a third so-called booster
 25 dose, that it was ineffective, and that it was no better

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1 **A.** Sorry, what's the question?
 2 **Q.** The question is: was it the VTF who made the submission
 3 to the department concerning the termination of the
 4 contract?
 5 **A.** The main submission came from the VTF, that's correct.
 6 **MR KEITH:** Thank you very much.
 7 **LADY HALLETT:** Thank you, Mr Keith.
 8 A few more questions but we'll definitely complete
 9 by 11.35.
 10 Mr Wagner.
 11 **Questions from MR WAGNER**
 12 **MR WAGNER:** Thank you.
 13 Good morning, Sir Sajid. I'm over here.
 14 **A.** Good morning.
 15 **Q.** I act on behalf of Clinically Vulnerable Families, who
 16 look after the interests of the clinically vulnerable
 17 and the clinically extremely vulnerable and the
 18 immunosuppressed. I've got one area to ask you about.
 19 It's vaccination about 12- to 15-year-old children. You
 20 were asked quite a lot of questions about it by Mr Keith
 21 at the beginning.
 22 So the JCVI has said that vaccination should, on
 23 balance, benefit the person, in this case the child,
 24 receiving vaccination. That is, it would not be
 25 acceptable to advise that a child be vaccinated where

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1 the benefit was primarily to another individual,
 2 including an adult, who can be directly protected
 3 themselves, for example, by receiving the vaccination.
 4 I think you agreed this morning already that once --
 5 is it fair to say that once the agreement -- sorry, once
 6 the decision reaches government, the other factors can
 7 be taken into account: for example, the importance of
 8 education?
 9 **A.** That's right.
 10 **Q.** Yeah. Would you also agree that another relevant factor
 11 would be the benefit, if there was one, in reducing
 12 transmission of Covid-19?
 13 **A.** In certain cases, yes.
 14 **Q.** And following from that, what about the potential
 15 benefit to clinically vulnerable or clinically extremely
 16 vulnerable people who are close contacts of children,
 17 whether that's other children or adults living in the
 18 same household? Would that be something that could in
 19 theory be taken into account?
 20 **A.** Yes. And I believe the JCVI did do that.
 21 **Q.** Did you do that?
 22 **A.** Yes -- because my job was to respond to the JCVI advice.
 23 And so, for example, in August of 2021, I believe
 24 that -- it was around the same -- maybe it was the same
 25 piece of advice they gave me around 16 to 17-year-olds

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1 **Q.** Okay, thank you.
 2 **LADY HALLETT:** Thank you, Mr Wagner.
 3 Ms Morris.
 4 Ms Morris is over there, and if you could make sure
 5 your voice carries on into the microphone.
 6 **THE WITNESS:** Yes.
 7 **Questions from MS MORRIS KC**
 8 **MS MORRIS:** Thank you, my Lady.
 9 Mr Javid, I ask questions on behalf of the Covid
 10 Adverse Reaction and Bereaved groups. These groups
 11 represent those who have suffered injury or bereavement
 12 following their voluntary acceptance of the Covid-19
 13 vaccines.
 14 My Lady, to assist you, Mr Javid mentioned Mr Cross,
 15 and you noticed -- some concern --

16 **LADY HALLETT:** I did realise it was his daughter who was --
 17 **MS MORRIS:** Yes. And you'll recall, my Lady, that
 18 Mr Cross's story was featured in the impact film at the
 19 opening of Module 4, and his daughter Liz sits in the
 20 public gallery --
 21 **LADY HALLETT:** The reason I didn't acknowledge it publicly
 22 was I wasn't sure whether his daughter and the rest of
 23 his family were happy for me to name him.
 24 **MS MORRIS:** I'm grateful, and I've clarified that, thank
 25 you.

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1 in the first dose, they also addressed the issue of
 2 those over the age of 12 that had household contacts
 3 that were clinically extremely vulnerable.
 4 **Q.** Yes. So it's an important factor --
 5 **A.** Yes.
 6 **Q.** -- in those decisions?
 7 **A.** Yes.
 8 **Q.** Yes. And then finally, the JCVI's statement of
 9 4 August 2021 records reports of Long Covid in children,
 10 by that time. So that's a year and a half, I guess,
 11 into the pandemic. And those reports were coming
 12 through?
 13 **A.** Yes.
 14 **Q.** What consideration, if any, was given to that risk in
 15 the decision making around the vaccination of
 16 children's?
 17 **A.** Well, it would have been for the JCVI and the other
 18 clinical advisers that the government had, such as the
 19 CMO and others. But just as with the adult population,
 20 the risk of Long Covid or other sort of concerns would
 21 have been taken into account, and it would have been
 22 a balanced decision.
 23 **Q.** Do you recall yourself taking it into account as part of
 24 your decision making?
 25 **A.** Yes.

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1 Mr Javid, my questions are about the Yellow Card
 2 Scheme, a matter of some importance to those
 3 I represent, as you'll understand.
 4 **A.** Yes.
 5 **Q.** You said in your statement when you were Secretary
 6 of State for Health that the Yellow Card Scheme was
 7 something that didn't come to your attention and
 8 therefore you couldn't answer the inquiry's questions
 9 about whether it was effective, and you couldn't make
 10 any observations about the scheme and how it could be
 11 improved.
 12 My question is, then, how, then, was the government
 13 effectively monitoring adverse reactions if the Health
 14 Secretary, yourself, the individual responsible for
 15 overseeing the nation's health, was unaware of the
 16 primary tool designed for this purpose?
 17 **A.** Yeah, thank you. It's a very reasonable question, of
 18 course, and what I would say -- so I wasn't aware of the
 19 Yellow Card, sort of, scheme, which I, you know,
 20 I understand is -- the scheme has been there for many
 21 years, in terms of if there is -- if someone suspects an
 22 adverse effect, they can report it especially to the
 23 MHRA and make sure obviously it is taken account of, but
 24 I think, just because a Secretary of State is not aware
 25 of a particular sort of system or process within the

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1 wider department, whether it's in the NHS or to do with
2 the MHRA or the various other multiple bodies that fall
3 under the department, doesn't mean to say it's not taken
4 seriously or it's not happening.

5 The -- you'll know, obviously, the department itself
6 is the biggest department in government by its spending,
7 you know, if you take the NHS, there's well over
8 1.4 million employees and things. So there's so many
9 different processes and procedures, especially clinical
10 procedures, but especially independent procedures. And
11 I think on those, they would only tend to come to the
12 attention of the Secretary of State if there was
13 a problem or an issue or something had to change, or be
14 addressed. And this particular case as I understand it,
15 the Yellow Card, I believe, that's for the MHRA. And
16 I think that because the very important independence of
17 the MHRA, I think that's another reason why generally
18 the Secretary of State wouldn't interfere unless there
19 was a good reason to.

20 **Q.** Understood, but you said in answer to questions to
21 Mr Keith that you were having meetings about vaccine
22 delivery every day. You were the central role
23 responsible for the -- driving the vaccine project
24 forward. Would you agree that not knowing about the
25 Yellow Card system, one of the centrepiece systems for

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1 department is just too vast, especially if it's dealing
2 with a pandemic as well as normal healthcare at the same
3 time and social care, to just -- to have everything
4 landing at the Secretary of State's desk.

5 **MS MORRIS:** Thank you.

6 Thank you, my Lady.

7 **LADY HALLETT:** Thank you, Ms Morris.

8 Thank you very much indeed, Sir Sajid. I appreciate
9 you didn't realise Mr Cross's daughter was in the room
10 and I know you didn't intend to cause her any distress,
11 but that is one of the reasons why we don't go into
12 individual circumstances, but anyway --

13 **THE WITNESS:** That's right. And just to say, my Lady, I did
14 ask Christine Cross in advance if I could raise the
15 case --

16 **LADY HALLETT:** Oh, you did, right.

17 **THE WITNESS:** -- and she was very happy for me to do so.

18 **LADY HALLETT:** I understand. Well, well done you for taking
19 that precaution.

20 Thank you very much indeed for your help. I'm sorry
21 I wasn't here last time in person, but I'm really
22 grateful to you for all that you've done to help the
23 Inquiry, and for your evidence today.

24 **THE WITNESS:** Thank you very much, thank you.

25 **LADY HALLETT:** Thank you, I shall return at 11.50.

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1 adverse effect reporting, highlights a significant gap
2 in the systems designed to ensure that key decision
3 makers like yourself were informed about critical
4 mechanisms for monitoring vaccine safety during the
5 rollout?

6 **A.** I think that -- with respect, what I'd say is that I'm
7 not sure me not knowing what the Yellow Card system is
8 or was would have made any difference, in that --
9 because I'm not aware -- and it certainly hasn't been
10 brought to my attention at this point -- that there was
11 a problem with the system, there was an issue with the
12 system, and so -- and I would suspect the reason it
13 wasn't brought to my attention in those meetings that
14 you just referred to was because no one within my
15 department or the wider department thought it was an
16 issue that was important enough to bring to the
17 Secretary of State.

18 Now, that -- is it possible that it could have
19 been -- that's a mistake for someone, they should have
20 brought it to my attention because there was a problem?
21 I'm not saying that isn't the case, I just don't know
22 enough of the detail. But the fact it wasn't brought to
23 my attention or an issue is not brought to my attention
24 is in and of itself not a problem because not everything
25 can land at the Secretary of State's desk because the

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1 (The witness withdrew)

2 (11.34 am)

3 (A short break)

4 (11.50 am)

5 **MR KEITH:** My Lady, the next witness is
6 Professor Wei Shen Lim, please.

7 **PROFESSOR WEI SHEN LIM (sworn)**

8 **Questions from LEAD COUNSEL TO THE INQUIRY for MODULE 4**

9 **LADY HALLETT:** I hope you were warned that there might be
10 a delay before we got to you, Professor.

11 **THE WITNESS:** That's fine, thank you.

12 **MR KEITH:** Could you commence your evidence, please, by
13 giving us your full name.

14 **A.** Lim Wei Shen.

15 **Q.** I hope I don't embarrass you, Professor, by observing
16 that we've had plenty of knights in the course of giving
17 evidence in this Inquiry, I think the collective noun
18 for knights is a rout of knights, but anyway there's
19 been a rout, it's right to point out that you were
20 appointed an Honorary Knight Commander of the Order of
21 the British Empire, and therefore you're an Honorary
22 Knight, entitled to use the post-nominal letters KBE,
23 but not to call yourself Sir Wei Shen Lim?

24 **A.** That's correct.

25 **Q.** I think it's important giving the recognition to the

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1 JCVI and yourself, as well as many of your colleagues.
 2 You have provided, and we're very grateful to you,
 3 two witness statements, INQ000471988 and INQ000474527,
 4 dated March and October 2024. They both contain the
 5 usual declarations that they are true to the best of
 6 your knowledge and belief.

7 Professor, you are, I think, one of the founder
 8 members of NERVTAG; is that right?

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

10 **Q.** And you sat on the main committee until 2023, and you
 11 were also, and you may still be a member of -- you were
 12 a member of the National Institute for Health and Care
 13 Research.

14 **A.** So I do research that is funded by NIHR, as you say. In
 15 particular, I guess, for this, in relevance, it's the
 16 RECOVERY trial and dexamethasone. That was
 17 researched -- it was funded by NIHR, in fact before the
 18 Covid pandemic. It was funded for an influenza
 19 pandemic. And I was chief investigator for that.

20 **Q.** You were the chief investigator.

21 Would you just keep your voice up, Professor. It's
 22 very important that we can hear what you have to say,
 23 and your evidence is being recorded remotely through
 24 a stenographer.

25 For our purposes, the most important feature of your
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1 the cost effectiveness of a vaccine, the government must
 2 accept your recommendation, but in other circumstances,
 3 where you've not opined on cost effectiveness, the
 4 Secretary of State for Health and Social Care is
 5 expected to follow your advice, or place considerable
 6 reliance on it, and would need a compelling reason not
 7 to accept it; is that fair?

8 **A.** That is fair. And that's reflected in the language that
 9 is used. So in JCVI terms, if we offer a recommendation
 10 to the Secretary of State, then that reflects
 11 a cost-effectiveness evaluation, whereas if we offer
 12 advice, then it is the latter, as you describe.

13 **Q.** In relation to Wales is there a similar position in
 14 place, which is that the JCVI is regarded as
 15 a departmental expert committee which gives advice to
 16 Welsh ministers, and then, as with the Secretary of
 17 State for Health, the Welsh minister or ministers are
 18 then accountable to their own Parliamentary assembly?

19 **A.** That's correct.

20 **Q.** Scotland, there's no statutory basis for the provision
 21 of advice by the JCVI; it's up to Scottish ministers
 22 whether they accept or reject your recommendation?

23 **A.** That's right.

24 **Q.** And is the position the same in Northern Ireland?

25 **A.** The same for Northern Ireland and Scotland, yes.

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1 distinguished professional career is that you have been
 2 a longstanding member on the Joint Committee on
 3 Vaccination and Immunisation. And in April 2020, is
 4 this right, the chair of the JCVI,
 5 Professor Andrew Pollard, who is at the Department of
 6 Paediatrics at Oxford, recused himself because he'd been
 7 involved in the development of the Oxford adenoviral
 8 vaccine, and because he recused himself, you became the
 9 de facto chair from 6 May 2020; is that right?

10 **A.** That is correct.

11 **Q.** And that is why, of course, you are the witness on
 12 behalf of the JCVI today.

13 **A.** (Witness nodded)

14 **Q.** The JCVI was originally an advisory board for polio
 15 immunisation. I think it took on its current emanation
 16 as a statutory body under the NHS Act 1977; is that
 17 right?

18 **A.** That's correct.

19 **Q.** And under that statutory framework, it is an independent
 20 Departmental Expert Committee as well as being
 21 a statutory body?

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

23 **Q.** The significance of its statutory genesis is that,
 24 insofar as England is concerned, in certain
 25 circumstances, where, for example, you have opined on
 70

1 **Q.** All right.

2 **A.** And I would like to stress that JCVI is independent.
 3 Completely independent to all of the organisations it's
 4 offering its advice to.

5 **Q.** Indeed. My next question was going to be: is it
 6 functionally and operationally independent?

7 **A.** Yes, correct.

8 **Q.** It seems there were three committees set up within JCVI
 9 to deal with Covid. There is the -- there was the
 10 Covid-19 Committee, there was a Covid-19 subcommittee,
 11 and a Vaccine Monitoring Working Group Committee; is
 12 that right?

13 **A.** That's right.

14 **Q.** To what extent are the terms of reference of the JCVI
 15 agreed to by all the health departments in each of the
 16 four nations of the United Kingdom, and to what extent
 17 does the remit of the JCVI extend over the whole of the
 18 United Kingdom?

19 **A.** As far as I'm aware, the terms of reference apply across
 20 all four nations, but with the caveats that you describe
 21 about standing committees as regards England and Wales
 22 versus Scotland and Northern Ireland.

23 **Q.** Were UK health departments, that's to say health
 24 departments in each of the four nations, all made aware
 25 of the JCVI advice, and were they closely concerned with

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1 and connected to the operations -- the dealings of the
 2 JCVI?
 3 **A.** Yes, they are. And there are co-opted members from each
 4 of the devolved administrations who are at JCVI meetings
 5 as well as added observers from devolved
 6 administrations.
 7 **Q.** And does that go for the JCVI in total, as well as the
 8 committee, the subcommittees of which you've spoken?
 9 **A.** It applies to the JCVI Covid committee and the JCVI
 10 Covid subcommittee. The monitoring committee was
 11 actually for information, rather than for any decision
 12 making, so perhaps less observers attended those.
 13 **Q.** And did all the nations of the United Kingdom,
 14 therefore, through their health departments, receive
 15 committee papers, all the documents, and, as you say,
 16 attend relevant meetings?
 17 **A.** Indeed, yes.
 18 **Q.** Could we, please, have the Code of Practice. Is there
 19 a Code of Practice applicable -- is there a Code of
 20 Practice which applies to the JCVI?
 21 **A.** Yes, there is.
 22 **Q.** It is, please, INQ000145984. And if we could just have,
 23 please, page 12.
 24 "All members of the Committee and its Subcommittees
 25 must demonstrate high standards of conduct."

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1 **Q.** All right.
 2 And in your statement, if we could have INQ000471988
 3 at page 6, please. Paragraph 22:
 4 "... industry representatives are not invited to
 5 meetings and may not present to the main committee."
 6 Is that right?
 7 **A.** That is correct. And perhaps I can add there -- oh, it
 8 says here -- that the reason for constituting
 9 a subcommittee is to allow industry to present to the
 10 subcommittee.
 11 **Q.** So members of or representatives from industry may
 12 attend, and may be expected or indeed ordered to attend
 13 a subcommittee, to give an account of themselves and to
 14 present data and information, but they are
 15 self-evidently not there as a member of the committee?
 16 **A.** Correct.
 17 **Q.** All right. And on paragraph 26, at paragraph 26 on the
 18 following page, do we see that there is also a register
 19 of relevant interests reviewed and maintained, which
 20 contains everything that could possibly be relevant.
 21 And at paragraph 27, is this right, that the members
 22 and subcommittee members must declare personal pecuniary
 23 interests, personal family interests, and then over the
 24 page, non-personal pecuniary interests and then finally,
 25 personal non-pecuniary interests?

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1 We can see in paragraph 35 a reference to the Nolan
 2 Principles. Did they apply to the JCVI?
 3 **A.** Yes, indeed.
 4 **Q.** And over the page we can see references to the need for
 5 the Chair, yourself, to provide effective leadership?
 6 **A.** That's correct.
 7 **Q.** And then at 38, "Conflicts of interest". Is there a
 8 complex and rigorous structure by which conflicts of
 9 interest or perceived conflicts of interest are managed
 10 within the JCVI?
 11 **A.** Yes, these are detailed in the Code of Practice, and at
 12 the start of every meeting all members are required to
 13 declare any potential conflicts of interest.
 14 I should also add that with every of our published
 15 statements we also published conflicts of interest at
 16 the end of each of the statements.
 17 **Q.** So when we see some of the JCVI papers in a moment, do
 18 we see that, at the beginning of every meeting, there's
 19 a very long list of perceived issues, or nominal
 20 conflicts, but in truth they're not, because if they
 21 were, they would disentitle the person from attending --
 22 listed at the beginning of every meeting? And at the
 23 end of every paper there are, again, equally long lists
 24 or references of possible nominal connections?
 25 **A.** Correct.

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1 **A.** That is right.
 2 **Q.** All right. So it's a very extensive obligation, is it
 3 not?
 4 **A.** Yes.
 5 **Q.** The JCVI first met on 7 May 2020 to discuss its
 6 provisional advice on prioritisation. And we're not
 7 going to go into the details of it but there were
 8 numerous papers prepared on prioritisation. The
 9 subcommittee met in September on the 24th. And then, I
 10 think, there were a number of meetings, a very
 11 considerable number of meetings, between May 2020 and,
 12 of course, the end of the pandemic, June 2022.
 13 Give us some idea, please, Professor, of the number
 14 of times the main committee met in that two-year period?
 15 **A.** The main committee and the subcommittee for Covid-19
 16 I think we met 98 times during the period in question.
 17 **Q.** And the subcommittee?
 18 **A.** Sorry, those were the two combined.
 19 **Q.** That was the combined figure for the main committee and
 20 the subcommittees?
 21 **A.** Yes.
 22 **Q.** All right. And did you provide substantive advice or
 23 recommendations, depending how you phrase it, to the
 24 Secretary of State on 28 occasions?
 25 **A.** Yes, that's right. And these were all published

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1 clinical statements that are available publicly.

2 **Q.** And did the Secretary of State, firstly in the form of

3 Matt Hancock, and then secondly in the form of

4 Sir Sajid Javid, agree?

5 **A.** They agreed to -- yes, they agreed to the advice.

6 I should say it's obviously for JCVI to provide advice

7 to the Secretary of State and not to make the decision.

8 it is for ministers to make the decision.

9 **Q.** Ministers ultimately have the call. It's their call.

10 They decide. But, as you've already described, they are

11 expected to follow -- or at least to follow -- if they

12 don't follow, to give good reason -- your

13 recommendations, which is why it's couched in terms of

14 recommendation or advice. But they agreed on every

15 single occasion?

16 **A.** Yes.

17 **Q.** At the start of this process, why was the JCVI asked to

18 consider and to give provisional advice on

19 prioritisation, in truth some months before the vaccines

20 were even authorised, let alone rolled out?

21 **A.** As you can imagine, we were going to embark on what

22 would be the largest mass vaccination programme in the

23 UK, and that would take a lot of effort to organise, to

24 help the public understand, and a lot of information for

25 advisory groups like JCVI to get through. So it was

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1 **A. (Witness nodded).**

2 **Q.** -- NHSE, Public Health England, Public Health Scotland,

3 Wales and Northern Ireland work, let alone damage

4 payment schemes --

5 **A. (Witness nodded).**

6 **Q.** -- or vaccine donations to other countries; it's not

7 within your reach?

8 **A.** It's not within our remit. Correct.

9 **Q.** All right. The evidence before the Inquiry shows very

10 clearly that you alighted upon, no doubt after a great

11 deal of consideration, a relatively simple,

12 straightforward -- at least on paper straightforward,

13 but in practice, of course, very much more difficult,

14 but a relatively simple, straightforward, prioritisation

15 programme that focused on the clinical vulnerability of

16 recipients -- so obviously the elderly, the very

17 elderly, then the elderly, then the less elderly,

18 because they were the most vulnerable followed by the

19 less vulnerable -- and a system which simultaneously

20 focused on maintaining the health and care structures

21 around the most vulnerable.

22 Why, in brief, did you come across, or why did you

23 determine that that was the right way to proceed, by

24 contrast, perhaps, to targeting economically active

25 people and saying, well, we're going to vaccinate by

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1 important, we felt, that we provided interim advice as

2 far as ahead of time as possible to allow all these

3 processes to take place.

4 **Q.** And there was a lot to consider, was there not, from the

5 likely scientific rationale for any particular

6 prioritisation programme, issues about deliverability,

7 public acceptability, fairness, the equity of having

8 a prioritisation programme, all of which had to be

9 considered even before you knew whether or not they

10 would work?

11 **A.** Indeed. So all of that information had to be learnt, as

12 it were, by the committee, because we were dealing with

13 a new pathogen, a new disease, and we didn't know what

14 was necessarily in store for us.

15 **Q.** But the substance of what you were doing did not differ,

16 did it, from what you had always done historically,

17 which is provide advice on how to make offers of

18 vaccination and how they should be taken up, as you

19 might have done or did do with polio or something like

20 that?

21 **A.** That's correct.

22 **Q.** All right. The JCVI is not involved, though, is it,

23 with procurement, delivery --

24 **A. (Witness nodded).**

25 **Q.** -- the operational rollout --

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1 occupation or societal role?

2 **A.** So give me a few moments to explain this. There are two

3 main concepts when using a vaccine in a pandemic

4 situation, where there is constrained vaccine supply.

5 And the two main concepts are either to target those

6 people directly with a protective vaccine and protect

7 those people, or to use the indirect benefits of

8 a vaccine by targeting people who might be responsible

9 for transmission of disease, and therefore indirectly

10 protecting those most at risk themselves. Obviously,

11 I say these things as though they are two completely

12 separate, there is overlap. But those are the two main

13 principles.

14 If we want to adopt an indirect protection model,

15 ie, vaccinating, say, younger adults who are the main

16 people responsible for transmission of infection, then

17 there are two prerequisites for such a model to work

18 well. The first is you need a vaccine that will

19 effectively block transmission, hopefully, and secondly,

20 one needs a high degree of vaccine uptake within that

21 population in order to achieve the indirect benefit,

22 whereas, on the counter side, if you were to use the

23 direct effect of the vaccine, then you would choose the

24 most at-risk population and directly protect those.

25 **Q.** And in the summer of 2020, as you were deciding upon

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1 which, strategically, was the right way forward, did you
2 have a clear understanding as to whether or not the
3 vaccines would reduce transmission, or the degree to
4 which they would reduce transmission?

5 **A.** We didn't.

6 **Q.** But you knew, because you'd seen the impact of Covid,
7 that Covid killed in far greater numbers the most
8 elderly?

9 **A.** Correct, yes.

10 **Q.** So they were the ones who, on an individual basis,
11 required the greatest attention, along with the people
12 who look after them?

13 **A.** Yes.

14 **Q.** And is that the nub of why you developed the
15 prioritisation scheme that you did?

16 **A.** That is one aspect. I do want to stress the importance
17 of a limited or constrained vaccine supply.

18 **Q.** What is the relevance of that?

19 **A.** So if you have only a limited number of vaccines, then
20 using direct protection means every vaccine that is
21 given, every dose that is given, will offer protection
22 to a vulnerable person, whereas if we try to use the
23 vaccine for its indirect benefits then, as an example,
24 you would be vaccinating a 30-year old who would have
25 less individual benefit, and until you vaccinated enough

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1 **A.** Towards the latter part of 2020. So very close to when
2 the first vaccines were approved by MHRA.

3 **Q.** So presumably a great deal of work had to be done in
4 December 2020. When you realised that there were
5 vaccines coming, you had the data, the safety data and
6 the effectiveness data, in determining whether or not
7 the course you had begun to develop in May was the right
8 one?

9 **A.** Indeed.

10 **Q.** To what extent did you consider, as you drew up the
11 scheme, equity? That is to say inbuilt pre-existing
12 health inequalities, the barriers to access which are
13 embedded in society which prevent particular groups from
14 receiving healthcare, and in particular vaccines, and
15 the need to ensure that their needs were promoted as far
16 as could be, in terms of vaccination?

17 **A.** Yes, these were considered in something September and
18 November of 2020 as part of the overall strategy.

19 And I should say at this point that equity is
20 promoted if there is a simple-to-deliver message,
21 because that enables understanding across a wide range
22 of society. And that understanding then promotes
23 confidence, and therefore vaccine uptake.

24 Advice alone does not save any lives. The advice
25 has to be disseminated, listened to, and somebody has to

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1 30-year olds to block transmission, you would not be
2 directly protecting -- you would not be protecting the
3 most vulnerable.

4 **Q.** So there were two problems there: one is you didn't have
5 a -- you couldn't have had and you wouldn't have for
6 some time a clear understanding, assuming there was an
7 effective vaccine at all, of the nature of the supply,
8 how limited it would be, how difficult it would be to
9 get it into the population, and you also wouldn't have
10 a clear understanding as to how quickly the vaccination
11 of less vulnerable people would reduce transmission in
12 society as a whole?

13 **A.** Yes. And there's a third element to that, if I may.

14 Usually the uptake of vaccination is influenced by how
15 vulnerable somebody feels, and if one were to offer
16 vaccination to a 30-year old who felt that they were
17 personally not so vulnerable, the uptake may be lower in
18 that population. So that was also an uncertainty.

19 **Q.** When you began to design the prioritisation list, the
20 phase I list of cohorts, did you have regard to a great
21 deal of data concerning efficacy, transmission, and the
22 possible impacts of any future vaccine that might be
23 authorised?

24 **A.** Not until the clinical trials reported results, we --

25 **Q.** When did they start reporting the results?

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1 agree to go and be vaccinated before any lives are
2 saved.

3 **Q.** May it be put another way, Professor: if you put into
4 place a system for prioritisation and for delivery of
5 vaccines, and you reduce transmission, death, and
6 disease across the whole population, you will protect,
7 inevitably, even those persons in front of whom barriers
8 to access have been placed or, for a variety of reasons,
9 have not been able to take up a vaccine?

10 **A.** That's correct.

11 **Q.** That's the nub of it. All right.

12 Could we then look, please, at the final emanation
13 of your hard work, which was the priority list --
14 INQ000354469 -- dated 30 December 2020. There it is.

15 I'd want very briefly just to pick a some of the
16 most significant features of it, please, Professor.

17 Page 3, there's a reference there to what the
18 committee had regard to, and you made plain you've
19 reviewed published and unpublished safety data from the
20 manufacturers, both in relation to Pfizer-BioNTech and
21 AstraZeneca.

22 It was Pfizer which had been authorised on
23 2 December and AstraZeneca at the end of December, and
24 those are the two, therefore, that you focus on; is that
25 right?

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- 1 **A.** That's right.
- 2 **Q.** At the bottom of the page, there is a reference to the
3 two-dose schedule, and over the page:
4 "... the JCVI places a high priority on promoting
5 rapid high levels of vaccine uptake among vulnerable
6 persons.
7 "... given [the] data indicating high efficacy ...
8 the committee advises that delivery of the first dose to
9 as many eligible individuals as possible should be
10 initially prioritised over delivery of a second vaccine
11 dose."
12 Is this the first dose prioritisation issue?
- 13 **A.** That's right.
- 14 **Q.** And in relation to that, had there been, within JCVI,
15 debate over the previous two to three weeks, or two
16 weeks, over whether or not, notwithstanding that the
17 formal MHRA authorisation for Pfizer-BioNTech, provided
18 for a minimum of three weeks by way of a gap between the
19 first and second dose, of the issue of whether or not in
20 practice the interval could be extended so as to get as
21 many first doses into people's arms as possible?
- 22 **A.** We discussed the possibility of using a one-dose
23 schedule, even before we issued the advice on
24 3 December. It is part of JCVI's role and
25 responsibility to decide how best to use the limited

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- 1 **Q.** So you were considering that -- you were just simply
2 summarising there the debate?
- 3 **A.** Yes.
- 4 **Q.** Then we can see if we scroll rapidly over the next three
5 or four pages, particular cohorts, "Age" -- if we go --
6 not too quickly, I'm so sorry, if we go back to page 5,
7 "Age", and then over to page 6, "Older adults resident
8 in care homes", "Health and social care workers",
9 "Clinically extremely vulnerable", "Women who are
10 pregnant", "Women who are breastfeeding", "Children less
11 than 16 years", "Persons with underlying health
12 conditions", and then "Mitigating inequalities".
13 So in this report in your -- in the published
14 advice, were you there setting out your general approach
15 to each of those potential cohorts?
- 16 **A.** That's right.
- 17 **Q.** And on mitigating inequalities, page 11, were you at
18 pains to say that you had considered the particular
19 needs of those persons who suffer under inequalities,
20 health inclusion groups, ethnic minority communities,
21 and, as we'll see, homeless, those in detention, and
22 migrants -- migrant groups.
23 And in this advice, do you therefore seek to set out
24 why you've gone for the age/clinical vulnerability
25 approach?

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- 1 supplies of vaccine we had, and one of those roles is to
2 examine whether the dose schedule that is prescribed by
3 the manufacturer may indeed be the optimal dose schedule
4 in the first place.
5 And so from the very start, we were not only looking
6 at the dose schedule that the manufacturers were testing
7 in their clinical trials, but we were also looking to
8 see if we could do even better. Could one dose be as
9 effective? Could a separation in a dose be as
10 effective?
11 So these are other strategies that, as a scientific
12 body with huge amounts of expertise, we were able to
13 examine and wanted to examine, even before December.
- 14 **Q.** But the formal authority from the MHRA allowed at least
15 three weeks, and said no more. Because you were
16 concerned with efficacy, with priority, with practical
17 delivery, you said in relation to Pfizer: the vaccine
18 may be given between 3 to 12 weeks after the first dose,
19 and in relation to AstraZeneca, 4 to 12?
- 20 **A.** Correct.
- 21 **Q.** Page 5. There's a reference to the direct protection
22 against transmission reduction issue. What was that?
- 23 **A.** These are the two strategies I described just two
24 minutes ago about direct protection versus indirect
25 protection, ie, transmission.

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- 1 **A.** Yes, I think the -- perhaps one way to understand it is
2 the advice is given here about mitigating inequalities,
3 firstly, because we had examined that issue in close
4 detail. And, secondly, as an instruction, almost, to
5 deployment teams that it was very important to take note
6 of these inequalities and to do our best to mitigate
7 against these inequalities by having tailored measures
8 to deliver the vaccination programme.
- 9 **Q.** So this wasn't just an explanation of your position; it
10 was a call to deployment groups to say: "You've
11 absolutely got to be on top of this"?
- 12 **A.** Correct.
- 13 **Q.** All right. Then the list is on page 13. It'll be very
14 familiar. Phase I -- there were two phase, weren't
15 there, but this is phase I: Residents in a care home;
16 80; 75; 70 and extremely clinically vulnerable people;
17 65; anybody 16-64 with underlying health conditions;
18 then 60; then 55; then 50. And that's where the line
19 was drawn.
20 I now want to ask you some questions about some
21 particular groups of people, starting with children and
22 young persons.
23 In relation to children and young persons, there is
24 a much more difficult balance to be drawn on an
25 individual level, is there not, as to whether or not the

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1 benefit of vaccination, which must take into account
2 whether they're likely to get Covid or to suffer
3 seriously from it if they do, against the risks of
4 vaccination which may, in some circumstances, be
5 increased vis younger people in relation to mRNA
6 vaccines?

7 **A.** Yes, and if I can elaborate on that, the list that you
8 just showed, phase I, there is a line at the bottom of
9 that that says that we expect phase I to include people
10 who are responsible for 99% of the mortality from
11 Covid-19.

12 Children and young people -- we're talking, I think,
13 here, about healthy children and young people, not
14 children and young people with underlying health
15 conditions -- have a much, much lower risk of serious
16 illness from Covid-19.

17 And just to put some figures to that, the number
18 needed to vaccinate to prevent one person from dying in
19 cohort 1 was calculated by the institute of actuaries
20 as 20. In other words, if we vaccinated 20 people who
21 are residents in an old age care home, we would protect
22 one life.

23 The same number needed to vaccinate to prevent one
24 person from dying in a 65-year old cohort was 1,000, and
25 of the number needed to vaccinate -- to prevent one

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1 **A.** That's a good question. I don't know offhand.

2 **Q.** Roughly. It's to be measured in the tens of millions?

3 **A.** Yes, yes.

4 **Q.** So your prioritisation scheme was deliberately designed
5 to sweep up and protect 99% of those persons who were
6 most at risk of morbidity or mortality, serious illness
7 or death, in the whole population?

8 **A.** That's right.

9 **Q.** And that was millions of -- tens of millions of people?

10 **A.** Yes.

11 **Q.** Does it follow that as a result of that prioritisation
12 approach, sweeping up and protecting the most
13 vulnerable, the rollout of the vaccines did directly
14 avert hundreds of thousands of deaths?

15 **A.** That's right. Yes. And I should add, because this may
16 be helpful, timing is also important. By the time we
17 had vaccines that were approved by MHRA for use in 12 to
18 15-year-olds, we're talking June 2021, by that time,
19 phase I of the vaccination programme had already run.
20 So the most vulnerable people in the population had
21 already been offered not just one dose of vaccine, but
22 two doses of vaccines by this time. So they were
23 already highly protected from serious illness.

24 **Q.** Children and young persons. On 4 June 2021, authority
25 was given by the MHRA -- authorisation was given by the

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1 life -- save one life in the 50-plus cohort is 8,000.

2 So by the time we get to children and young people
3 who have no underlying health conditions, then the
4 number needed to vaccinate to prevent one adverse
5 outcome -- clinical outcome, not safety outcome -- is in
6 the many tens of thousands.

7 **Q.** Because of the prospect or the risk of serious disease
8 requiring hospitalisation, or, god forbid, death, in
9 a child or young person, is very much less than in an
10 elderly person?

11 **A.** Correct.

12 **Q.** Right.

13 **A.** And it is that benefit that needs to be weighed against
14 the potential harm that might arise from vaccination
15 itself.

16 **Q.** And then at the same time, on the reverse side of the
17 coin, there is the issue of risk from vaccination. And
18 was there a concern, which we'll look at in a moment,
19 about the potential, in very rare cases indeed, of
20 myocarditis and pericarditis in children and young
21 persons?

22 **A.** Correct.

23 **Q.** Right. How many -- or, roughly, how many people in the
24 population of the United Kingdom does that 99% of the
25 most vulnerable people amount to?

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1 MHRA to Pfizer to allow the use of its vaccine in 12 to
2 15-year-olds. So the decision then had to be made by
3 the JCVI, what advice to be given as to whether or not
4 people are actually offered a vaccine if they're 12 to
5 15.

6 You were asked by the DHSC to give advice on the
7 possible extension of the vaccination programme for 12-
8 to 15-year olds and you issued a statement on
9 15 July 2021, INQ000387481, "Statement on Covid-19
10 vaccination of children and young persons aged 12 - 17".

11 And what you decided, I think, is that 16 and
12 17-year-olds who had risk conditions, who were
13 vulnerable, should be offered vaccination, but you
14 deferred the issue of whether there should be a
15 universal call to all 16 and 17-year-olds, and you
16 deferred the issue of whether or not 12 to 15-year-olds
17 should be offered vaccination, either universally or to
18 those with a risk condition. I think that's right.

19 **A.** I want to add something to that.

20 **Q.** Please.

21 **A.** So at the start of the vaccine programme in December
22 2020, our advice was that 12-year-olds and above who had
23 certain severe neuro disabilities in a residential
24 setting should be offered vaccination, even in phase I,
25 even though they were children and the vaccine was not

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1 necessarily approved for them at that time, we, as JCVI
2 said there should be off-label use for this highly
3 vulnerable group, because we noted from the evidence
4 that there were a concentrated number of serious
5 illnesses happening in this group.

6 And I just want to raise that. We were very aware
7 of the risk to children and wanting to protect them,
8 such that we were willing to offer off-label advice even
9 in December 2020.

10 **Q.** So let's be absolutely clear about that. Although the
11 MHRA had given authorisation formally only for use,
12 I think, for 18-year-olds and above for AstraZeneca and
13 17-year-olds and above for Pfizer, it is permissible for
14 the JCVI to state in terms: on clinical advice, and
15 after speaking to your doctor, particular cohorts who
16 are vulnerable may receive a vaccine off-label, that is
17 outwith the terms of the authorisation?

18 **A.** Correct.

19 **Q.** That's the position?

20 **A.** That's the position.

21 **Q.** And that's what you did?

22 **A.** And that is what we did, and that is something that JCVI
23 has done in the past with other vaccines as well. So
24 this is something that the expert committee is -- we are
25 used to doing if we have to do it and we think it's in

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1 **A.** Correct.

2 **LADY HALLETT:** I think you said "by the end of June 2020".

3 I think you meant 2021.

4 **THE WITNESS:** Sorry, thank you.

5 **MR KEITH:** On 4 August 2021, JCVI announced that 16 and
6 17-year-olds should be offered a first dose of Pfizer
7 universally, so not just those in high-risk groups,
8 particularly high-risk groups, who had been able to have
9 a vaccine off-label, and nor was it concerned with 16
10 and 17-year-olds in high-risk or risk groups who had
11 already received the nod from the JCVI.

12 There was an extraordinary meeting of the JCVI on
13 2 September 2021.

14 Let's have, please, INQ000354535 and it was
15 concerned on the issue, page 2, of what to do about 12
16 to 15-year-olds who were not therefore in a clinical
17 risk group; is that right?

18 **A.** Correct.

19 **Q.** We can see there the heading at paragraph 2, "12 to
20 15-year-olds in a clinical risk group."

21 If we then go forward to -- sorry, if we look
22 further down the page, we can see a reference, can't we,
23 to the issue of myocarditis in paragraph 9 -- at
24 paragraphs 8 and 9 -- in fact 7, 8 and 9 -- 6 to 9.

25 **A.** Yes.

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1 the best interests of the public.

2 **Q.** There is very clear evidence that there was a great deal
3 of political pressure being applied to speed up the
4 process of giving advice about children, and young
5 persons, both now and later, as we'll see, when it came
6 to what to do about 5 to 11-year-olds.

7 Do you consider that you gave this advice on 15 July
8 as reasonably, as quick as possible -- or as reasonably
9 as soon as possible?

10 **A.** We were pre-warned as to the likely time when MHRA would
11 give approval for vaccinations -- or for the vaccines
12 for 12 to 15-year olds, and we were asked by the
13 Department of Health to give advice by the end of
14 June 2020 (sic). We missed that by a couple of days
15 because we actually gave the advice up to the Secretary
16 of State on 2 July. That was when our meeting was held,
17 and our advice was formulated. The advice was published
18 on 19 July, I believe, because of the internal
19 discussions after we had submitted our advice to the
20 Secretary of State.

21 **Q.** And indeed the paperwork shows there was a meeting on
22 6 July, attended by the Secretary of State, at which
23 your advice was considered, so that publication date,
24 which is the document that we have, actually post-dates
25 JCVI's actual decision on 16 and 17-year-olds?

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1 **Q.** Because by this stage in September, data and reports had
2 already started to emerge, particularly from abroad,
3 about the very rare but nevertheless significant
4 occurrence of myocarditis following vaccination, without
5 expressing a view as to whether or not it was
6 coincidental, caused by Covid, possibly caused by
7 a vaccine, or certainly caused by a vaccine. You were
8 aware of the issue.

9 And so was this issue of myocarditis highly relevant
10 to your determination on the balance -- risk-benefit
11 balance to be drawn for 12 to 15-year-olds?

12 **A.** Indeed, it was very relevant. You may recall, the
13 public may recall, that the US, Canada and Israel
14 started their childhood or their 12 to 15-year-old
15 programme just before the UK, because the vaccine was
16 regulated and approved in those countries earlier, and
17 when they started delivering the vaccines in large
18 numbers to younger people, they noticed this signal of
19 myocarditis, particularly from Israel. And we had many
20 discussions and meetings with our colleagues overseas to
21 understand from them what was happening with myocarditis
22 at that time.

23 Some of the -- this is obviously new for them as
24 well, and they were sharing with us hot information, as
25 it were. And some of their cardiologists were saying

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1 that while myocarditis appeared to be short-lived, they
2 didn't know the full extent of the potential medium or
3 long-term effects of myocarditis. And so some
4 cardiologists were advising children who had developed
5 myocarditis and had recovered after a few days, not to,
6 for example, do any strenuous physical exercise for up
7 to six months, because of the risk that it might trigger
8 something that is cardiac related.

9 So these were important, very important, safety
10 concerns, where the picture was only just emerging. And
11 you will understand, because the benefit to children
12 from the vaccine, direct benefit, is small, as we've
13 discussed, any safety concern in that situation would
14 need to be taken highly, highly seriously.

15 **Q.** And the position concerning myocarditis was uncertain.
16 You had data, but you didn't know to what extent it
17 would develop as a condition following vaccination, and
18 you didn't, of course, have an idea -- an accurate idea
19 as to how likely -- well, it is a very rare condition
20 nevertheless, but what the percentages were?

21 **A.** Yes.

22 **Q.** And so in that risk-benefit analysis, as you said
23 earlier, between the marginal benefits of vaccination
24 against the very rare but not to be ignored risk of
25 myocarditis, was it a more difficult balance to draw?

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1 economic benefits. That is in usual practice.

2 During the pandemic that remained the case, and
3 I had communications with DHSC to explain that the
4 educational benefits that might arise from a vaccination
5 programme were an area that was not in our usual remit
6 and would be difficult to integrate with the way that we
7 balanced risk and benefits.

8 That is not to say that we did not take into account
9 qualitatively what the impact would be. We had meetings
10 with the Department for Education to try to understand
11 what the impact would be of missing school.

12 One other aspect that I want to stress is that a lot
13 of the absenteeism from school was not due to the
14 infection itself, but due to the social distancing
15 regulations or rules or advice put around being
16 infected. As an example, we already know that many,
17 most children, potentially, who were infected with
18 Covid-19 developed no symptoms or hardly any symptoms.
19 And in the usual run of things those children would go
20 to school because they physically are able to.

21 Children who might be symptomatically infected are,
22 again, mildly symptomatically infected and may miss
23 a few days of school, but not an extended number of days
24 at school.

25 And if we then ask what can the vaccine provide in

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1 **A.** It was a very difficult balance, a hugely fine balance,
2 quite unlike the balance of an older person who might
3 have an adverse effect from vaccination.

4 **Q.** Do you also consider in the balance, health
5 inequalities, Long Covid, the impact on mental health of
6 children and young persons of being vaccinated or not
7 being vaccinated, as well as the ethics?

8 **A.** Correct. We consider all those things.

9 **Q.** And if we look at page 4, paragraph 25, we can see a nod
10 in the discussion to all the main issues which you
11 looked at.

12 Thank you very much.

13 There may be wider societal or educational benefits
14 in vaccinating children. It will allow them to go back
15 to school; for those who live in deprived conditions,
16 that's of additional importance. It may have a wider
17 societal benefit, because it will allow the day-to-day
18 running of life and society in the United Kingdom to
19 continue as normal. But were those wider potential
20 benefits and disbenefits at a population level matters
21 for you, or did you only consider, and did you only
22 allow yourself to consider, the risk-benefit on an
23 individual level?

24 **A.** In usual practice, JCVI considers the health benefits,
25 and would not consider wider societal benefits or

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1 terms of preventing absenteeism from those episodes of
2 the symptomatic illness, then it's a much more limited
3 number of absenteeism from school than it is as imposed
4 because of infection control or social distancing
5 measures.

6 **Q.** Why, then, did you refer the matter to the
7 United Kingdom chief medical officers for advice on the
8 wider education and public health benefits if,
9 quantitatively, it was something you could have regard
10 to?

11 **A.** I think -- well, quantitatively, I -- quantitatively, we
12 couldn't have regard to. We asked the Department for
13 Education specifically if they could tell us what does
14 it mean for a child or a pupil to miss five days of
15 school? And they couldn't tell us, because it would
16 depend which year/grade they were in, it would depend
17 what time of year, whether they were coming up to exams,
18 a whole host of reasons whereby five days missed of
19 school would mean different things educationally to
20 different people at different times.

21 That makes it very difficult to put quantitative
22 measurements to put into any model to decide what does
23 this mean.

24 **Q.** So a good idea was to go to the UK CMOs and ask them to
25 give a paper on the wider educational and societal

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1 benefits, which you could then feed into the mix?
 2 **A.** Correct. And I just want to maybe clarify what we did.
 3 We offer advice directly to Secretary of State, and
 4 in that advice we suggested to the Secretary of State
 5 that the Secretary of State, before he or she makes
 6 a decision on policy, may want to also take advice from
 7 the CMOs. And there are two key reasons for asking the
 8 CMOs: the first is they have a wider responsibility for
 9 health, including educational health, as well as the
 10 fact that the CMOs are much more closely in touch and
 11 have greater responsibility for the infection control
 12 measures and social distancing measures in schools,
 13 which were the main reason, we think, why children did
 14 not attend so many days at school.
 15 So they were more relevant for that aspect. And
 16 just as an analogy, perhaps, for most of the vaccine
 17 programme we were asking Secretary of State to take note
 18 of JCVI's advice and, on the pillar of JCVI's advice,
 19 make a decision.
 20 On this one occasion we suggested to the Secretary
 21 of State that he might want to take advice using two
 22 pillars of advice: one from JCVI and from the CMOs,
 23 because of the educational importance to children. So
 24 we were not passing the decision on to the CMOs, and
 25 I think that's an important point to make, neither were

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1 in greater detail what was the risk to children from
 2 myocarditis. And you will imagine that in a vaccination
 3 programme that's progressing at high speed in other
 4 countries, they would be gathering information on
 5 myocarditis every week, if not -- and every month.
 6 **Q.** And you've got to have access to all that?
 7 **A.** Correct. And that is time. There is nothing that you
 8 can do except wait until the information comes.
 9 **Q.** And at the same time, were children and young persons
 10 most at risk from Covid?
 11 **A.** No.
 12 **Q.** Indeed. Right.
 13 Pregnant and breastfeeding women.
 14 At the beginning of December 2020 when you were
 15 drawing up the final iteration of the prioritisation
 16 list, the position before the JCVI was that there was no
 17 data as to the safety of the vaccines in pregnancy
 18 because pregnant women and breastfeeding women had
 19 deliberately not been included in the trials; is that
 20 right?
 21 **A.** That's right.
 22 **Q.** And you nevertheless sought information, and as much
 23 data as you could possibly gather, in part by asking for
 24 expert bodies, including the Royal College of
 25 Obstetricians and Gynecologists to come and present to

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1 we trying to exclude or deny the importance of
 2 educational impacts. We were trying to say to the
 3 Secretary of State: these are both important, but we
 4 have to act within our remit, which is health, and that
 5 is one pillar, but one pillar only, to this decision.
 6 **Q.** Well, we've heard, of course, from Professor
 7 Sir Chris Whitty, and he describes how, exactly as
 8 you've put it, they give their advice on the wider
 9 educational basis, on the premise that, at an individual
 10 level, the benefit marginally outweighs the risk, as the
 11 JCVI had determined, and they give their views.
 12 Do you think that that seeking of the views of
 13 the UK CMOs and digging further into the issue of wider
 14 educational and societal benefit or public health
 15 benefit impermissibly delayed or unacceptably delayed
 16 the process by which the JCVI came to an ultimate view?
 17 There is before the Inquiry numerous references to
 18 political and administrative pressure to speed up the
 19 process. There are a number of interlocutors who refer
 20 to concerns about delay on the part of JCVI around this
 21 time.
 22 **A.** I think it would incorrect to characterise the advice we
 23 gave and the timing of our advice as delay. We gave
 24 advice in July and we gave further advice in August, and
 25 this is all within the context of trying to understand

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1 you, the JCVI; is that right?
 2 **A.** That's right.
 3 **Q.** And you looked for data from abroad --
 4 **A.** Yes.
 5 **Q.** -- to see whether that could provide information upon
 6 which you could reach a view. But the advice which you
 7 gave on 30 December could not positively extol the
 8 virtues of vaccination for pregnant women and
 9 breastfeeding women because you didn't have an
 10 underlying data-driven foundation sufficient to make
 11 a positive recommendation. Is that a fair summary?
 12 **A.** That is fair. I should also add the context that
 13 vaccine confidence among this particular group, women
 14 who were pregnant, as reflected in vaccine uptake rates,
 15 the usual vaccination programme is lower than in other
 16 groups. And so we were particularly concerned to pay
 17 attention to their needs and their wishes, which is to
 18 understand the safety of these vaccines.
 19 **Q.** Obviously adult pregnant women remained at risk from
 20 Covid. And so when you gave what might be thought to be
 21 equivocal advice, which is that pregnant women should
 22 discuss the risks and benefits of vaccination with
 23 clinicians, do you think -- and I emphasise in
 24 hindsight -- that that left pregnant women and their
 25 clinicians in rather a difficult position? Because they

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1 didn't have a positive recommendation to rely upon,
 2 there was no data which would have helped them resolve
 3 on an individual case whether they should be vaccinated,
 4 and that gave rise to a considerable degree of doubt,
 5 concern, and difficulty?

6 **A.** I agree. If we knew -- well, if we knew then what we
 7 know now, that the vaccines are indeed very safe for
 8 women who are pregnant, then we could have been more
 9 positive in our advice. But we were reflecting what the
 10 evidence was at the time.

11 **Q.** In March, on the 16th, there was another extraordinary
 12 meeting, one of the many hundreds or one of the many
 13 that you had, and the issue of vaccination for pregnant
 14 women was re-debated, was it not?

15 **A.** Yes.

16 **Q.** And the committee agreed that there should be
 17 a universal offer to all pregnant women of vaccines, of
 18 vaccination. By that stage, by 16 March, had more data
 19 been made available?

20 **A.** Yes.

21 **Q.** And in essence, what did it consist of?

22 **A.** These were post-approval, post-rollout data. You've
 23 heard yesterday about phase IV studies, so these were
 24 phase IV studies, data from, particularly, the US, where
 25 they had already vaccinated at least 90,000 women who

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1 **Q.** So they weren't randomised control trials; they were
 2 observational studies?

3 **A.** Correct, yes.

4 **Q.** And do you, as a result of this issue, which was
 5 obviously extremely difficult for the JCVI, do you, in
 6 one of your recommendations, reflect that pregnancy must
 7 be a key issue for consideration in any future pandemic?
 8 It is vital to ensure that relevant and significant data
 9 is developed as early as possible to avoid precisely
 10 what of course occurred in relation to Covid?

11 **A.** Exactly.

12 **Q.** Disabled people were obviously the focus of
 13 prioritisation, were they not?

14 **A.** Yes.

15 **Q.** In two regards: individuals with Down's syndrome fell
 16 within priority group 4; and there was an issue about
 17 the extent to which those with learning disabilities
 18 should fall within priority group 6.

19 Did the JCVI appreciate, particularly in relation to
 20 those with learning disabilities in group 6, whether or
 21 not an individual disabled person would know that they
 22 were entitled to receive the vaccine would depend to
 23 a huge extent as to whether or not the state regarded
 24 them as being within the terminological description in
 25 cohort 6?

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1 were pregnant, and found no safety concerns.
 2 So this was positive information on safety.

3 **Q.** As a matter of interest, that extraordinary meeting was
 4 on 16 March. I don't believe that the statement -- the
 5 position of the JCVI was made public until 16 April. Do
 6 you happen to know why there was that elapse of time of
 7 a month?

8 **A.** I don't know offhand. I can go and find out.

9 **Q.** All right. If you don't know off the top of your head,
 10 don't worry.

11 Therefore, the position remained at the end of
 12 April, or the position was at the end of April, that
 13 pregnant women were offered the vaccine but they were
 14 still encouraged to discuss the risk and benefits of
 15 vaccination with their individual clinicians. Why was
 16 it deemed necessary to add that caveat? It is not
 17 a caveat, of course, that is applied in relation to
 18 other cohorts who receive prioritised access under the
 19 schemes.

20 **A.** I think this is an acknowledgement of the confidence and
 21 the safety concerns that pregnant women express
 22 regarding vaccination. And we are relying also on
 23 evidence that is not from clinical trials, but relying
 24 on evidence that are phase IV studies about the safety
 25 of these vaccines. So --

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1 **A.** I think you're referring here to how somebody might know
 2 that they should go to be vaccinated. And you're right:
 3 there was -- and that may still be the case -- less than
 4 full identification of who is living with a learning
 5 disability. Which makes -- both analysing the data and
 6 understanding who really is at risk or not at risk, and
 7 who is taking up the vaccine or not taking a vaccine,
 8 that makes it difficult. It also makes it difficult to
 9 call up the correct people for a vaccination programme.

10 I should point out that in a mass vaccination
 11 programme, the main means of asking people to attend for
 12 vaccination should not be self-identification. It
 13 should be a patient being asked, by some system, to go
 14 and be vaccinated. Because the question of
 15 self-knowledge of medical categories of illness does not
 16 apply simply to people living with learning
 17 disabilities.

18 **Q.** But that all rests on the premise that there is
 19 a coherent and effective system for recording learning
 20 disabilities, for example, or that the NHS or GPs have
 21 medical codes in their records which accurately reflect
 22 related conditions such as cerebral palsy, which is
 23 a medical code, it gets a medical code in the system.

24 You were aware that the systems for recording,
 25 objectively, the medical condition or the disability

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1 sadly encountered by people in this cohort, did not work
2 there people well, which is why you actually wrote to
3 the DHSC yourself making -- or attempting to make
4 recommendations as to how the system would navigate its
5 way around this data-driven issue?

6 **A.** Correct, yes.

7 **Q.** And did you feel, did you assess that enough was done to
8 try to bring together, for example, learning disability
9 registers across the United Kingdom, medical codes in
10 four different NHS boards, for cerebral palsy, for
11 example, together so that everybody would know
12 reasonably whether or not they were entitled to
13 vaccines?

14 **A.** Yes, I should point out that delivery of the programme,
15 as we said, is not within the remit or responsibility of
16 JCVI. But we wanted to understand how well deployment
17 teams were doing.

18 In regard to the specifics of how people were being
19 identified, there were two means at least that were
20 being used centrally. One is to use the GP codes for
21 diagnostic conditions that would map on to somebody who
22 might be living with a learning disability. And those
23 codes are published, they are publicly available.
24 I think there are over 443 codes that are being used to
25 identify people, as well as using the GP Learning

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1 **Q.** Right. There was a considerable difficulty, was there
2 not, in defining what was meant by sole or primary carer
3 or main carer? Was that something that the JCVI was
4 able to get on top of, or was that a matter which had to
5 be left to the operational experts who were delivering
6 the vaccines?

7 **A.** That was -- the precise definition is mainly left to the
8 UKHSA and deployment teams, because the precise
9 actionable definitions need to be something that the
10 deployment teams can use to call people up.

11 **Q.** There was in the list, for the reasons that you've
12 described, no reference to any particular occupation,
13 other than care home workers in the top priority, and to
14 wider care and health workers in a lower priority.

15 But there was also no reference to particularly
16 socially excluded groups such as homeless people, sex
17 workers, vulnerable migrants, the Gypsy, Roma and
18 Traveller communities, detained people, or people who
19 have come through the wrong end of the justice system.

20 It was obvious to the JCVI that those groups were
21 likely to have poorer health outcomes, to be more
22 subject to the intersectionality of deprivation, poor
23 housing, stigma, discrimination, and so on.

24 And the committee was asked to give its views on
25 homeless groups, and it didn't put them into the group,

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1 Disability Register, as well, I should add, asking local
2 teams to also identify people as best as possible.

3 And I guess what I'm trying to emphasise, although
4 it's not JCVI's responsibility, is that deployment teams
5 were trying to do their best to identify as many people
6 as possible that will come under JCVI's advice for
7 prioritisation with as many means as possible. And
8 where we know that there are gaps in the data, then the
9 help of non-centralised bodies such as charity groups,
10 self-help groups, word of mouth, all of these are
11 important as well, because what we want is as many
12 people who can benefit to benefit.

13 **Q.** In relation to unpaid carers, at the beginning of
14 December 2020 when you drew up the draft prioritisation
15 list, there wasn't, I think, a reference to sole or
16 primary carers in the draft list. There was
17 a footnote or a reference to the clinicians' Green Book.
18 By the end of December, there was an express footnote in
19 the list which referred to main carer or sole or primary
20 carer. I can't recall which. Which was it, Professor?

21 **A.** I think in end of December --

22 **Q.** It's a memory test --

23 **A.** -- it was main carer.

24 **Q.** Main carer?

25 **A.** Yes.

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1 but it did say: operationally, you might want to think
2 about them as being in cohort 6, and, on the ground,
3 make a universal offer.

4 Why didn't the JCVI take that sort of similar
5 approach, or that sort of approach, to those other
6 marginalised or inequitably treated groups?

7 **A.** In the paper from Public Health England, as it was at
8 that time, inclusion groups -- inclusion health groups
9 include a wide range, as you've just described. The
10 most information was available for people living with
11 homelessness. That's thanks to excellent work done in
12 London by some colleagues from UCL. So we had
13 understanding of people living with homelessness, and
14 importantly, there were already efforts in influenza
15 vaccination to reach out to people living with
16 homelessness and to understand their underlying health
17 problems and their willingness to be vaccinated.

18 In that same paper that describes inclusion health
19 groups, I think it might be in the last paragraph, the
20 advice from PHE and the equity group was very clear that
21 outreach to different communities may sometimes be
22 counterproductive if it's not done in -- in a correct
23 way, and without engagement of trusted organisations.
24 And the reason why there was less information for some
25 of the other inclusion health groups is precisely

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1 because there had been less engagement previously. And
2 so we had less data.

3 The paper, actually, very much put forwards that
4 outreach teams, when they go out to offer vaccination to
5 people who live -- living with homelessness, whether
6 they could have a formal piece of advice from JCVI to
7 exercise the operational flexibility that we had already
8 described in December 2020. So this was not an addition
9 or any change; we were not making a decision to suddenly
10 move people living with homelessness as a priority
11 group. We were simply saying: yes, please exercise the
12 operational flexibility that we had already described
13 for this group of people, because, if you are reaching
14 out to them -- and we know that in flu vaccination
15 campaigns they would respond positively -- then please
16 do so. This was a formal piece of advice from JCVI on
17 that front.

18 For the other groups, we mentioned in the advice
19 that there should be concerted efforts to keep on trying
20 to engage with them in order to bring them into the
21 system and be vaccinated.

22 **Q.** All right. Thank you very much.

23 My Lady, I have five more minutes to go and there's
24 ten minutes of Rule 10s.

25 **LADY HALLETT:** Professor, would it help you if we carried on
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1 again. The first report of potential -- and it's
2 extremely rare, I emphasise, but potential adverse
3 effect of TTS first emerged at the end of February.
4 Abroad, in fact.

5 Data was received immediately from AstraZeneca and
6 from observational studies and epidemiological studies
7 as to the risks. But, notwithstanding the number of
8 meetings, it wasn't until just before the Bank Holiday
9 weekend, on 1 April, that a decision appeared to have
10 been taken as to what should be done. The MHRA took
11 a view and told clinicians and public -- primary care
12 network directors of the position, but it wasn't until
13 after the Bank Holiday weekend there was a press
14 conference and a public statement and so on.

15 Why did it take so long, from the vantage point of
16 persons who were younger and might therefore be at
17 greater risk of TTS, for a decision to be reached?

18 **A.** It's a complex decision, as you have already discussed
19 with many other witnesses. At that time, we in the UK
20 were using AstraZeneca vaccine alongside the
21 Pfizer-BioNTech vaccine in our vaccination programme, by
22 age. And at the end of February in England, I believe
23 we were just calling up people who are aged 64 years and
24 above. So still very much at high risk.

25 The amount of AstraZeneca vaccine being used at that
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1 and finished your evidence before lunch?

2 **THE WITNESS:** That would be most helpful, thank you.

3 **LADY HALLETT:** Right. Carry on, please.

4 I may be able to relieve Ms Beattie of asking her
5 question by asking it shortly in a minute.

6 **MR KEITH:** TTS.

7 **LADY HALLETT:** We'll see, see whether you think I have.

8 **MR KEITH:** We'd heard evidence from Dame June Raine and from
9 Mr Hancock concerning the TTS issue, which arose, of
10 course, between late February/early March of 2021 and
11 the beginning of April, when there was a press
12 conference given on 7 April attended by yourself,
13 Sir Jonathan Van-Tam, Dame June Raine. And in the
14 course of those few weeks it's obvious that there were
15 a significant number of JCVI meetings, meetings of the
16 MHRA, the CHM, OCMO and DHSC.

17 And in essence, what was being tackled was whether
18 or not the emerging data of TTS required either
19 authority to be withdrawn or altered at the hands of the
20 MHRA, or the JCVI to give advice as to whether or not
21 AstraZeneca should be offered to a particular age group,
22 or perhaps to specify by age precisely who should
23 receive or more pertinently who should not receive
24 AstraZeneca vaccine.

25 What we're concerned about is the passage of time
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1 time was about 50% of the programme. There's -- some
2 people have alluded to other countries where the
3 AstraZeneca product was stopped or withdrawn from their
4 vaccine programme very early on, without clear data.

5 We were left in a difficult position because the
6 AstraZeneca vaccine was such a large part of our vaccine
7 programme and at that time we were offering vaccination
8 to some of the most vulnerable people in our population.

9 And so, on the one hand, we have to balance the risk
10 of withdrawing one vaccine product, possibly our main
11 product, from the programme without sufficient data or
12 support from MHRA that this indeed was a vaccine-related
13 problem --

14 **Q.** Can I interrupt you there to say that is all
15 justification for the ultimate position on authorisation
16 reached by the MHRA on advice for vaccination given by
17 the JCVI. Why did that -- and you've said it's
18 a complex process -- why did that decision-making
19 process on your part, the JCVI, have to take from
20 25 February to 7 April?

21 **A.** We were asking MHRA for their viewpoint regarding safety
22 and who was at risk and who was not at risk. We'd had
23 earlier reports that the clusters of people where
24 myocarditis -- TTS was occurring was younger people.
25 And at that point, as I say, our vaccine programme was
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1 delivering the vaccine to older people, not younger
2 people. So the people at risk were not yet being
3 offered the vaccine.

4 I should also add that at that point we were
5 delivering vaccine doses at about 1 million or more per
6 week. If we had delayed rollout of the vaccine by,
7 just, say, two weeks, that would be 2 million doses not
8 given to people who were aged 64 and above --

9 **Q.** Professor, forgive me, again, that all goes to the
10 merit, for which there is a very strong case, for the
11 ultimate decision you reached, but, bluntly, why didn't
12 the JCVI reach a decision mid-March and give its public
13 statement at a press conference then?

14 **A.** We didn't have the information that was required to make
15 that decision.

16 **MR KEITH:** Thank you.

17 Professor, those are all my questions. Thank you
18 very much.

19 Questions from THE CHAIR

20 **LADY HALLETT:** Given the time, I'm going to try to reduce
21 the amount of time left for the questions.

22 I gave permission to the Disabled People's
23 Organisations to ask a question about the definition of
24 "carer", and we can explain why you and Mr Keith got in
25 some confusion about what was the definition, because

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1 who are the editors of the Green Book, it is not the
2 JCVI, but Mary Ramsay, who gave witness a few days ago,
3 I think she said this as well: that the clarification in
4 February was not actually a clarification around the
5 definition of carers; that was not the intended
6 clarification. The clarification was to enable NHSE to
7 identify who was being cared for. That was where the
8 clarification was intended. So I think any
9 misunderstanding regarding main, sole or primary carer
10 is just that. It's -- there is no intended narrowing of
11 the definition of "carer" by those change in words.

12 **LADY HALLETT:** Thank you.

13 Just so that Ms Beattie doesn't think I'm picking on
14 her, I'm going to ask Mr Wagner's question too.

15 I gave permission for this question to be asked by
16 the Clinically Vulnerable Families: do you agree that
17 the mRNA Covid-19 vaccine protection has been shown to
18 wane after five to six months?

19 **A.** That is information we now know, yes.

20 **LADY HALLETT:** Do you also agree that Covid-19 has not
21 transitioned into a seasonal virus like influenza?

22 **A.** That's correct.

23 **LADY HALLETT:** In which case, Mr Wagner wanted to know why
24 did the JCVI not recommend more frequent vaccinations
25 for all clinically vulnerable groups?

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1 it's explained in the question. 30 December 2020, JCVI
2 included main carers in cohort 6, but then the
3 definition was narrowed on 12 February 2021 to those who
4 are the sole or primary carer. And the question from
5 the organisations is this: Given many disabled people
6 rely on more than one carer to have an effective and
7 independent life, did the JCVI give any thought to the
8 confusion that this narrow definition of "carer" might
9 cause?

10 **A.** Just to clarify the situation, carers were included in
11 the Green Book advice at the start of December. It was
12 only also included as a footnote at the end of December
13 because there was feedback that it was difficult to find
14 the advice, and so we wanted to make it clear that the
15 advice was already there, but people needed to look in
16 the Green Book for the definition.

17 And the Green Book is indeed the place where one
18 reaches all the definitions for the very many
19 conditions. We don't list definitions within the
20 clinical statements for obvious purposes.

21 The definition that was in the Green Book and -- at
22 the start of December and the end of December, was the
23 same definition that was used to identify carers for the
24 influenza programme.

25 In February -- I'm speaking here on behalf of UKHSA,
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1 **A.** We -- clinically vulnerable groups. I'm just trying to
2 think where we are.

3 So clinically vulnerable groups were offered
4 vaccination as a primary course, and then every autumn,
5 2021 and 2022, 2023 and 2024. The phrase "clinically
6 extremely vulnerable" obviously was disbanded after
7 a while, and so it's difficult to separate out that from
8 the later programmes. They would come in under people
9 who were clinically at risk.

10 In spring 2022 JCVI I think was the first
11 country (sic) in the world to suggest that we should
12 have a spring booster campaign. And this was
13 a precautionary position for those people in whom we
14 thought their immunity might wane before the autumn
15 programme. No other country had done this. And at that
16 point we were not sure just how quickly immunity would
17 wane.

18 So we know some things now but we didn't know all of
19 them then, and so the spring booster campaign in 2022
20 was specifically directed at those who were most
21 vulnerable and most likely to lose their immunity
22 because of immune senescence, which is loss of immune
23 protection because of age or a less good immune system.
24 Hence it was narrowed to those people aged 75 and above
25 and people who have poor immune systems.

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1 **LADY HALLETT:** Thank you very much indeed, Professor. That
 2 completes all the questions we have for you. I know
 3 that we're all extremely grateful for all the work that
 4 you did during the pandemic and obviously your
 5 colleagues too. I know you'd want to share the credit
 6 with your colleagues. And we are indebted to you. And
 7 thank you very much for showing similar care in giving
 8 your evidence before the Inquiry. Thank you so much for
 9 your help.

10 I shall return at 2.10.

11 **(The witness withdrew)**

12 **(1.15 pm)**

13 **(The Short Adjournment)**

14 **(2.10 pm)**

15 **LADY HALLETT:** Mr Mansell.

16 **MR MANSELL:** My Lady, the next witness is Ben Osborn,
 17 please. If he could be sworn.

18 **MR BEN OSBORN (sworn)**

19 **Questions from COUNSEL TO THE INQUIRY**

20 **Q.** Could you give the Inquiry your full name, please.

21 **A.** My name is Benjamin John Osborn.

22 **Q.** Mr Osborn, thank you very much for coming along today
 23 the Inquiry. You have also provided a witness statement
 24 for this module of the Inquiry, it is INQ485977, and
 25 this is your witness statement provided on behalf of

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1 **A.** I did.

2 **Q.** And during your time as UK Country Manager, the role
 3 which is the most relevant, I think, for your evidence
 4 today --

5 **A.** Yes.

6 **Q.** -- your responsibilities included leading Pfizer's UK
 7 biopharmaceuticals organisation, overseeing key business
 8 and operational matters relating to Pfizer's medicines
 9 and vaccines in the UK?

10 **A.** That's right.

11 **Q.** The first topic I'd like to deal with with you, please,
 12 is the development of the Pfizer-BioNTech vaccine, brand
 13 name Comirnaty.

14 So the vaccine was created, is this right, in
 15 partnership with the German company BioNTech?

16 **A.** That is correct.

17 **Q.** And Pfizer had been working with BioNTech since 2018,
 18 seeking to develop an influenza vaccine based on
 19 messenger ribonucleic acid (mRNA) technology?

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

21 **Q.** We have heard a bit about of mRNA technology during the
 22 course of this module of the Inquiry. It's sometimes
 23 called a novel vaccines. It was the first time it was
 24 authorised as a vaccine technology, is that right, in
 25 relation to the Covid-19 Pfizer-BioNTech vaccine?

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1 Pfizer Limited; is that right?

2 **A.** That is correct.

3 **Q.** That statement is signed by you. Are the contents of it
 4 true to the best of your knowledge and belief?

5 **A.** They are indeed.

6 **Q.** Thank you.

7 You explain in the statement that Pfizer is
 8 a US-headquartered multinational pharmaceutical and
 9 biotechnology company which develops and produces
 10 medicines and vaccines in a wide range of therapeutic
 11 areas.

12 **A.** Indeed.

13 **Q.** Its UK affiliate, Pfizer Limited, was incorporated in
 14 1953 and has sites across England?

15 **A.** That's correct.

16 **Q.** Since December 2023, you have held the position of
 17 President, International Commercial Office, at Pfizer?

18 **A.** That's correct.

19 **Q.** You were previously Managing Director and UK Country
 20 Manager of Pfizer Limited from December 2018 to
 21 January 2022?

22 **A.** Yes.

23 **Q.** From January 2022 to September 2022, you held the
 24 position of Regional President, Hospital Business Unit,
 25 International Developed Markets?

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1 **A.** It was indeed, although the research and the science
 2 into mRNA vaccines had actually been ongoing for some
 3 two decades, widely across the world but in particular
 4 through our BioNTech partner.

5 **Q.** In your statement you set out vaccine development
 6 timelines. And include a useful diagram which,
 7 I believe, was originally utilised by Professor
 8 Sir Jonathan Van-Tam in November 2020.

9 We can see that, please, in your statement at
 10 page 16, if we could zoom in on that. Thank you very
 11 much.

12 And you set out here the traditional vaccine
 13 development timeline and the accelerated timeline below
 14 it. Just looking at the traditional vaccine development
 15 timeline, we can see that phases I, II and III occur
 16 consecutively.

17 **A.** That's right.

18 **Q.** The regulatory review aspect of the process occurs at
 19 the end of the clinical trial process; is that right?

20 **A.** That's correct.

21 **Q.** And then, once authorised, there is then the move to
 22 large-scale production and distribution?

23 **A.** Indeed.

24 **Q.** But overall this is a process that, as the arrow shows
 25 us at the bottom of that first diagram, takes several

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1 years?

2 **A.** Absolutely.

3 **Q.** The accelerated timeline, this is the timeline that was
4 used in relation to the Covid-19 vaccines --

5 **A.** Yes.

6 **Q.** -- including the Pfizer-BioNTech vaccine, we see there
7 the clinical trial phases, phase I, phase II and III
8 overlapping; is that right?

9 **A.** That's right.

10 **Q.** There's rolling regulatory review throughout this
11 process, yes?

12 **A.** Yes, not through -- so the way to think about it, in the
13 traditional R&D model, one would run a phase I, or
14 multiple phase I studies. Potentially there's a period
15 of time where there's then a break, phase II, break,
16 assessment, and then into phase III. Potentially then
17 a break as manufacturing decisions are made, certain
18 investments, et cetera. I think what you see in the
19 document here and in this diagram is actually how there
20 was much more parallel processing here.

21 So from a trial perspective actually we rolled
22 straight from phase I into phase II and into the pivotal
23 phase III study, which provided the evidence that we
24 submitted to the regulator.

25 And once we had that data, that's what the MHRA and
125

1 out, I think it was, early November.

2 So they had already started to assess some elements
3 of the vaccine before the major phase III study read
4 out.

5 **Q.** We can also see a difference here in the stage at which
6 the manufacturing process begins because at-risk
7 manufacturing is taking place during the phase III trial
8 process?

9 **A.** That is right. Typically we would wait until we had the
10 confirmation of, essentially, a medicine that we
11 believed would then be approved by regulators around the
12 world. We knew in this situation that if we waited to
13 those timelines, we wouldn't necessarily be able to
14 serve the global needs and the volume of vaccine that
15 would be required. So we invested over \$1 billion in
16 2020, at risk, our own financial risk, because we didn't
17 take any investment from any government around the
18 world, to essentially start that manufacturing scale-up.

19 **Q.** The process has gone from the traditional timeline,
20 taking several years, to ten months plus. With that
21 accelerated development timeline, did that come at the
22 expense of safety assessments?

23 **A.** No. Safety is absolutely at the forefront of all of our
24 decision making as Pfizer.

25 **Q.** That can come down from the screen, thank you.
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1 other regulators around the world assessed our vaccine
2 on.

3 **Q.** Is it right that there are perhaps two aspects to the
4 rolling review. You've got the aspect you were just
5 speaking about --

6 **A.** Yes.

7 **Q.** -- which deals with authorisation --

8 **A.** Indeed.

9 **Q.** -- and the information that needs to be submitted to the
10 regulator in terms of authorisation, but also, during
11 the trial process --

12 **A.** Yes.

13 **Q.** -- and getting authorisation for trials, that is also
14 something that can happen on a rolling basis and did
15 happen on a rolling basis during the pandemic?

16 **A.** So, indeed, the regulator is involved right from the
17 very start. In fact, before any patient is vaccinated,
18 before phase I, there is discussions with regulators,
19 with the MHRA and others around the world, and they are
20 then assessing our data, our protocols, our
21 manufacturing steps at all stages of the development of
22 this vaccine.

23 In terms of the rolling review to the MHRA, that
24 began in October. And as you're aware, the actual
25 pivotal phase III study, the actual results of that came
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1 You explain that two clinical trials form the basis
2 for the initial authorisation of the vaccine: study 1
3 and study 2. Study 2 included those pivotal phase III
4 clinical trials.

5 We've heard evidence about this already but there
6 were almost 44,000 enrolled study subjects?

7 **A.** That's right.

8 **Q.** The trial was conducted by Pfizer in the United States,
9 Germany, South Africa, Turkey, Argentina, and Brazil?

10 **A.** Correct.

11 **Q.** Were the same clinical trial processes followed in
12 relation to that trial, as would be followed in respect
13 of a trial taking place in a non-pandemic setting?

14 **A.** Yes, absolutely. The standards, the requirements under
15 Good Clinical Practice, GCP, were exactly the same as
16 for any other pivotal phase III study that would be
17 conducted.

18 **Q.** You mentioned GCP, are those the international, ethical
19 and scientific quality standards that are applied?

20 **A.** They are the standards essentially applied to our
21 industry and academics running such studies, yes.

22 **Q.** Is it right that no suspected unexpected serious adverse
23 reactions, or SUSARs, were reported during those trials?

24 **A.** That is correct.

25 **Q.** Now, an issue the Inquiry has been looking at is the
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1 ethnic diversity of the clinical trials.
 2 **A.** Yes.
 3 **Q.** You may have seen the evidence of
 4 Professor Prieto-Alhambra yesterday and, indeed, in his
 5 report he explains that the Pfizer phase III trials
 6 had -- 83% of the participants were white, 9% black, 4%
 7 Asian, and 2% multi-racial. Were those trials
 8 sufficiently diverse?
 9 **A.** Yes, they were.
 10 **Q.** And can you expand on that, please?
 11 **A.** Yes, as we began the development of this vaccine,
 12 diversity was absolutely critical to us and, indeed, we
 13 knew, to the population that were ultimately going to be
 14 using this vaccine. They needed to have confidence in
 15 the vaccine. We sought to ensure that our study was run
 16 across multiple sites, across a diverse population, so
 17 that the data that ultimately we submitted to the
 18 regulator for independent assessment was reflective of
 19 the population that would ultimately be vaccinated
 20 around the world.
 21 **Q.** We've seen other figures that explain that the trial had
 22 42% of global participants and 30% of US participants
 23 with a racially and ethnically diverse background. How
 24 can we make sense of the two figures side by side?
 25 **A.** Yes, sure. So the 42% is essentially reflective of

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1 **Q.** Is this right, that pregnant women and immunocompromised
 2 individuals were excluded from the clinical trials?
 3 **A.** That is correct, and certainly when it comes to clinical
 4 trials, certainly the pre-authorisation phase, it is
 5 standard procedure in the vast majority of trial cases
 6 that pregnant women are not involved at that stage.
 7 **Q.** But Pfizer conducted post-authorisation studies,
 8 including among pregnant women, but there were
 9 challenges with that, you explain in your statement,
 10 because by that point, vaccination had been recommended
 11 among pregnant women, so there was not the cohort there
 12 to draw upon for the phase IV clinical trials. Is that
 13 a fair summary?
 14 **A.** Indeed. So as part of our agreed pharmacovigilance
 15 follow-ups, so one of the PASS studies,
 16 post-authorisation safety studies, was in pregnant
 17 women, and we essentially found that across the world,
 18 many pregnant women had already started to be
 19 vaccinated, given local and national immunisation
 20 guidelines. And so recruitment became a real challenge
 21 in this situation, and ultimately the trial was stopped
 22 because we weren't able to sufficiently recruit enough
 23 women into this study.
 24 **Q.** That raises the obvious question, is there a case for
 25 including such groups like pregnant women in

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1 a black, Asian, Latino population. So that's how we
 2 essentially square that one.
 3 **Q.** So taking into account the sites in Argentina and
 4 Brazil, and the --
 5 **A.** Indeed. The Latino population were also, in terms of
 6 the overall summary, included in the 82.9% that were
 7 classified as white. So it's essentially a sub racial
 8 group within the 82.9%.
 9 **Q.** From an industry perspective, do you have any
 10 recommendations as to what can be done in the UK to
 11 ensure greater ethnic diversity in clinical trials?
 12 **A.** I think it goes beyond, actually, racial diversity here.
 13 I think it's really encouraging and helping society at
 14 large to understand the importance of clinical trials,
 15 and the role that every member of our society, no matter
 16 which group one would essentially fall into, to really
 17 understand the value of being part of a clinical trial,
 18 and what is involved as part of that.
 19 So I think it goes back to education, and really our
 20 government and others and the NHS really investing time,
 21 effort and energy in education around the value of
 22 clinical trials. And then making sure that essentially,
 23 when the clinical trials are being run, that we are
 24 reaching all aspects, all members of society with the
 25 opportunity to partake in a clinical trial.

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1 pre-authorisation studies so that you can get the
 2 randomised control trial data that otherwise you may not
 3 be able to obtain?
 4 **A.** I think that's a matter for the regulator to decide
 5 whether a population such as pregnant women and children
 6 should be included in such studies.
 7 **Q.** What about the immunocompromised? Did that
 8 post-authorisation trial complete successfully?
 9 **A.** Immunocompromised patients weren't involved because the
 10 very nature of their immunocompromised state means that
 11 they typically would not respond to a vaccine. So they
 12 required other treatments, as we've heard over the last
 13 few days through the Inquiry.
 14 **Q.** Let's turn now to authorisation and pharmacovigilance,
 15 please. You explain that following assessment by the
 16 MHRA, the vaccine was authorised under Regulation 174 of
 17 the Human Medicines Regulations on 2 December 2020.
 18 **A.** That's right.
 19 **Q.** The Inquiry is, by now, very familiar with
 20 Regulation 174 authorisation. It is not the same as
 21 a market authorisation?
 22 **A.** No, it's not.
 23 **Q.** And you observe that the legislative provisions setting
 24 out requirements for post-authorisation of monitoring
 25 medicines and vaccines are normally directed at the

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1 marketing authorisation holder, which would be the
2 company?
3 **A.** Yes.
4 **Q.** Pfizer and BioNTech in this example.
5 Because this was authorisation under Regulation 174,
6 was there less stringent conditions imposed upon Pfizer
7 as a result of that, in terms of pharmacovigilance?
8 **A.** No, they were not less stringent. I would say they were
9 incredibly rigorous. I think everyone recognised the
10 scrutiny that would be given to these vaccines. They
11 were very robust, and they went beyond what we would
12 typically see, I would say, in many cases, in terms of
13 the frequency of review. So not the standards, but the
14 frequency of data review, given the volume of patients
15 that were being vaccinated in the UK and across the
16 world.
17 **Q.** We can perhaps look at some of those pharmacovigilance
18 monitoring obligations now, please, just to run through
19 them. Is it right that Pfizer was required to submit,
20 and update when appropriate, a risk management plan?
21 **A.** That's right.
22 **Q.** Is it right that Pfizer was required to maintain
23 a global safety database containing adverse events for
24 its vaccine?
25 **A.** That's correct.

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1 frequency of submission.
2 **Q.** You've mentioned post-authorisation safety studies.
3 There was a commitment on the part of Pfizer to conduct
4 ten post-authorisation safety studies; is that right?
5 **A.** Yes.
6 **Q.** Now, you may have seen Professor Prieto-Alhambra's
7 report. He recommends that there should be greater
8 obligations on pharmaceutical companies to conduct early
9 post-authorisation safety studies with a particular
10 focus on the risk-benefit of vaccines among groups
11 underrepresented in, or excluded from, phase III trials.
12 So perhaps groups like pregnant women, we've already
13 spoken about, but he also places an emphasis on ethnic
14 minorities -- not excluded from trials but perhaps
15 underrepresented -- elderly people with frailty or
16 multiple comorbidities, and people with disabilities.
17 **A.** Yes.
18 **Q.** A greater obligation on pharmaceutical companies in that
19 regard. What is your view of how workable such
20 a recommendation is?
21 **A.** I mean, it's an obligation we take very, very seriously.
22 I think in the first instance we seek to make our
23 clinical trial programme and certainly our phase III
24 programme reflective of the population in which we
25 ultimately intend to serve. Our intention then is to

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1 **Q.** And also provide periodic safety update reports to the
2 MHRA?
3 **A.** Yes.
4 **Q.** Could you just explain what those are, please, and what
5 the reporting requirements were.
6 **A.** So essentially these are -- as you've described, we
7 collect data on a global basis, and at specific time
8 points we were required, mandated under this temporary
9 authorisation, to provide the safety update reviews
10 directly to the MHRA and other regulators across the
11 world, so that then, in the case of the MHRA, they could
12 then take this dataset that we had collated and then
13 assess that alongside those potential adverse events
14 that had been reported through the Yellow Card Scheme.
15 **Q.** Those periodic safety update reports are normally
16 provided every six months?
17 **A.** I believe so, yes.
18 **Q.** But the timescales applied were more exacting in
19 relation to the Covid-19 vaccine, I think?
20 **A.** They were indeed. They were much more frequent, yes.
21 **Q.** They were provided monthly for 11 months --
22 **A.** That's right, and then --
23 **Q.** -- the reports?
24 **A.** And then I think we went to every other month after
25 that. So it was a sustained period of increased

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1 very quickly, but in a regulated way, in line with
2 decisions directly from the MHRA and other regulators,
3 to move through the appropriate subsequent studies in
4 a phase IV setting.
5 So the PASS studies to which you're referring to are
6 agreed directly with the regulators. It is not Pfizer
7 here saying we wish to study an X, Y and Z population;
8 it is a direct agreement with the regulator.
9 **Q.** There is a commitment made to conduct --
10 **A.** In the --
11 **Q.** -- a certain PASS as part of authorisation being
12 granted -- (overspeaking) --
13 **A.** Exactly, yes.
14 **Q.** And will that be decided on a case-by-case basis,
15 a vaccine-by-vaccine or drug-by-drug basis, how many
16 PASS need to be conducted?
17 **A.** Yes, it will.
18 **Q.** And which groups it needs to be focused on?
19 **A.** Yes, it well.
20 **Q.** What about reporting timescales? Are there requirements
21 in relation to that when a PASS has to report to the
22 public?
23 **A.** I'm not aware of the details specifically on the
24 reporting timescales. My belief is that it would be in
25 line with when essentially sufficient data has accrued

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1 that a decision can be -- or data can be then submitted
2 to the regulator.

3 **Q.** I think it's right to say that two of the studies, two
4 of the ten PASS studies that Pfizer committed to have
5 been published to date; is that right?

6 **A.** That's right, yes.

7 **Q.** And the others are pending, in various stages?

8 **A.** Ongoing assessment, indeed.

9 **Q.** Pharmacovigilance monitoring. We've spoken about the
10 obligations on the company, on Pfizer, in this
11 particular case, in relation to pharmacovigilance
12 monitoring. As safety signals are assessed, as they
13 come to light, is this right: that it can lead to an
14 update of the product information?

15 **A.** It can indeed.

16 **Q.** That product information is approved by the MHRA?

17 **A.** That's right.

18 **Q.** And it is, is this right, a central way in which the
19 public and healthcare professionals are updated about
20 the safety profile of a drug, in this case a vaccine?

21 **A.** That is correct. And I think the example of
22 anaphylaxis, actually, in the very first few days of
23 vaccination in the UK, is a really good demonstration of
24 this process actually doing exactly what it should have
25 done.

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1 more severe than that seen in relation to that induced
2 by a vaccine.

3 **Q.** The first reports of myocarditis and pericarditis
4 emerged from safety surveillance in Israel?

5 **A.** That's correct.

6 **Q.** And at that stage, no signal had been validated based on
7 the data available to Pfizer-BioNTech, and no other
8 regulator had raised similar concerns?

9 **A.** That's right.

10 **Q.** Pfizer worked to determine the relevant background rates
11 for myocarditis and pericarditis, and performed an
12 observed versus expected analysis. Could you just
13 explain to us what that is, please?

14 **A.** Yes. So if we just look at the chronology here. So
15 a number of rare cases were identified on 28 December,
16 as you say, in Israel. Actually, it was in April that
17 Pfizer-BioNTech met with the MHRA to begin the
18 conversations on myocarditis, or specifically, sorry --
19 to have conversations on myocarditis. We continued,
20 then, to assess our data, as the MHRA did. What we then
21 saw in May was the Center for Disease Control in the US,
22 their data demonstrated a similar potential signal to
23 that seen in Israel.

24 At this time we were asked strictly by the MHRA for
25 further data, which included an assessment of what was

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1 So on 8 December there were a number of rare cases
2 of anaphylaxis associated with the Pfizer-BioNTech
3 vaccine. They were discussed with the MHRA and assessed
4 by the MHRA and their independent experts on 9 December.
5 And on 10 December, the SPC and the patient information
6 leaflet and subsequent guidance to the NHS vaccination
7 centres was changed.

8 **Q.** Yes --

9 **A.** Rapidly, that potential safety signal was translated
10 back into a clinical practice.

11 **Q.** People would be familiar with the 15-minute observation
12 period that was introduced as a result.

13 **A.** Exactly.

14 **Q.** You've spoken about anaphylaxis. Let's look at myo- and
15 pericarditis, please.

16 **A.** Yes.

17 **Q.** And I'm going to ask you about updates to the product
18 information regarding those conditions. But firstly, is
19 it right that myocarditis and pericarditis are
20 conditions which, as well as having an association with
21 mRNA vaccines, can also be caused by Covid-19 itself?

22 **A.** Indeed. And I think the data, as we stand today,
23 demonstrate that the frequency is actually higher in an
24 unvaccinated population who have had Covid-19, and
25 indeed the myocarditis and pericarditis is typically

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1 the baseline prevalence of myocarditis in the general
2 population and specific population, so younger men?
3 Because what they were looking to do was to identify,
4 was this a vaccine-driven event, or not? And so, by
5 understanding what the baseline incidence was, one could
6 compare the incidence rates in real life.

7 **Q.** So in terms of from the point that the safety signal
8 emerged, was there close contact and communication with
9 the MHRA about the work you had been doing and the
10 signals you were receiving in relation to this
11 condition?

12 **A.** So there was constant dialogue, as there is for all of
13 our safety assessments with the MHRA and other
14 regulators, and when the -- essentially we presented the
15 data back to the MHRA on 22 June, a decision was then
16 made on the 25th and rapidly that translated into an
17 updated SPC and patient information leaflet.

18 **Q.** You've mentioned 25 June 2021. That is the date on
19 which the -- at that point I think referred to as the
20 Regulation 174 product information was updated?

21 **A.** Indeed.

22 **Q.** We can see that, please, the Reg 174 information for
23 healthcare professionals.

24 It's INQ000507930. There it is. And page 5,
25 please.

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1 We have section 4.4 at the bottom of that page. And
2 that's "Special" -- we have "Special warnings and
3 precautions for use". And when we can move on to the
4 next page, please, page 6.

5 There's the anaphylaxis you mentioned earlier, but,
6 at the top of this page:

7 "Myocarditis and pericarditis

8 "There have been very rare reports of myocarditis
9 and pericarditis occurring after vaccination with
10 [that's the Pfizer-BioNTech vaccine] often in younger
11 men and shortly after the second dose ... typically
12 mild ... and individuals tend to recover within a short
13 time following standard treatment and rest."

14 And then what healthcare professionals should be
15 alive to --

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

17 **Q.** -- in relation to that.

18 That can come down, please.

19 Because, of course, that is the product information,
20 the Regulation 174 information for healthcare
21 professionals but we can see the information for
22 recipients at INQ000507943.

23 Page 3, please.

24 "Possible side effects", section 4. And we can see:

25 "Side effects may occur with [the] following

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1 (pericarditis) ..."

2 And the symptoms there.

3 And that can come down. Thank you.

4 So as more information had come to light and been
5 analysed, there was greater clarity about the frequency
6 of this association.

7 **A.** That is exactly right. And that's the nature of how the
8 pharmacovigilance process works: that at the time, and
9 as essentially these events are accrued and understood,
10 then the -- I guess the confidence of the event rate is
11 then able to translate into the data and the numbers
12 that we see then in the SPC and PIL.

13 **Q.** The Inquiry's expert, Professor Evans, suggested that
14 a new approach is needed to patient information
15 leaflets. We were just looking at one there. His view
16 is that they need to be updated, perhaps changed, made
17 available much more online, and split into categories to
18 make them perhaps easier to digest for recipients: what
19 you need to know about the risks before you're given
20 a medicine, what you need to know about risks while
21 you're taking the medicine, and what you need to know in
22 the event that an adverse reaction has occurred that
23 might be as a result of taking the medicine.

24 Now, from the perspective of the manufacturer, what
25 is your view of whether those are sensible suggestions

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1 frequencies ..."

2 And under "Not known", towards the bottom of the
3 page:

4 "... (cannot be estimated from the available data)."

5 And including "inflammation of the heart,
6 (myocarditis or pericarditis)".

7 So that's what patients are being told as of
8 25 June 2021 in the information provided.

9 **A.** That's correct.

10 **Q.** And then things further develop -- that can come down,
11 thank you -- and we move to 14 March 2022 when further
12 analysis has been done, you've been liaising with the
13 regulator on -- on an ongoing basis?

14 **A.** Yes.

15 **Q.** And at this stage, because I think by this point the
16 vaccine had market authorisation, it's what we know as
17 the patient information leaflet (PIL). We can see that,
18 please, INQ000507969, page 3. So this is from
19 14 March 2022.

20 "Possible side effects"

21 And:

22 "Very rare side effects: may affect up to
23 1 in 10,000 people

24 "- inflammation of the heart muscle (myocarditis) or
25 inflammation of the lining outside the heart

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1 for reform?

2 **A.** I think in terms of the characterisation of pre, during
3 post is very sensible. I think from my perspective and
4 that of the industry's, I think the most important thing
5 is that these are tested with patients. These patient
6 information leaflets are regulatory documents. They are
7 decided by the MHRA under a particular template and
8 format. This is not the discretion of Pfizer or another
9 company.

10 And I think this is perhaps a situation where,
11 actually, there's a great opportunity to involve
12 patients here. What worked for patients? There's
13 a huge range of, obviously, knowledge across patients in
14 terms of their scientific understanding of the medicines
15 which they're taking, and it needs to work for
16 everybody.

17 So I think this is an opportunity to test with
18 patients. I don't think it's for me to say what this
19 should look like.

20 **Q.** Next topic is the Yellow Card.

21 We've heard a lot about that during the course of
22 the Module 4 evidence. We're familiar with what it is.
23 In your statement you note that:

24 "During the pandemic, quick access to safety reports
25 was more important than ever, however the time lag

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1 between the data being shared via the [Yellow Card]
2 Platform and being passed on to Pfizer meant that Pfizer
3 did not have immediate awareness of that portion of
4 UK Adverse Events which were available to MHRA ..."

5 So just to sketch in some of the background here:
6 Pfizer receives information about an adverse event. You
7 have to tell the regulator.

8 **A.** That's right.

9 **Q.** The regulator, the MHRA, receives information about an
10 adverse event through the Yellow Card platform.

11 **A.** Yes.

12 **Q.** It shares that information you at Pfizer.

13 **A.** Yes.

14 **Q.** So that it can inform your picture of the safety profile
15 of the vaccine; is that a fair summary?

16 **A.** That is a very fair summary, yes.

17 **Q.** Yet you talk about time lags here. What sort of period
18 are we looking at, and what were the consequences, if
19 any, of that delay?

20 **A.** So I'm not aware of any consequences as a result of that
21 delay. I mean, in effect, unless a patient or a HCP
22 were to report in tandem to both the MHRA and to Pfizer,
23 there will, in effect, be a delay, because the event has
24 been submitted, it needs to be processed, assessed,
25 through the MHRA, before it's reported to Pfizer.

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1 can be done to make the UK a more attractive place to
2 conduct those commercial phase III trials?

3 **A.** I think the Lord O'Shaughnessy report actually captures
4 very, very clearly the approach, the strategy that the
5 UK should take. I can't do that justice this afternoon,
6 but I think there are several things. I think there's
7 a recognition of the association between the investment
8 that companies will make in R&D in a particular country,
9 and the utilisation of that. So what I mean by that is
10 making sure that we have a whole system-wide approach to
11 the pharmaceutical and biotech industry and making sure
12 there is a seamless transition between research and
13 actually those medicines, those vaccines, then
14 benefiting the population in which they've been
15 trialed.

16 So I think I note in my evidence there is often too
17 long a delay between the research in the UK and actually
18 then the routine use in clinical practice for patients.
19 Reducing that gap down so that it is a seamless flow
20 would significantly improve things.

21 **Q.** The final point I want to raise with you, Mr Osborn, is
22 one of the recommendations made in a document called
23 Breakthrough Nation II.

24 This is INQ000507914, please.

25 And this is a suggested agenda that Pfizer has put

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1 I don't know the specific details on how long that
2 delay would be, but it wasn't consequential to any
3 patient or safety assessment, because all of those
4 reports were being continuously monitored by the MHRA.

5 If any signals were identified, they were
6 immediately raised with Pfizer.

7 **Q.** Nevertheless, you suggest that the system could be made
8 more efficient --

9 **A.** Indeed.

10 **Q.** -- with an investment in technology and a strong
11 encouragement for electronic rather than paper
12 submission --

13 **A.** Yes.

14 **Q.** -- of Yellow Card, Yellow Card reports.

15 I just want to deal with a couple of other
16 recommendations with you, if I may. The first is in
17 relation to clinical trials, because in your statement
18 you make the point that the UK is falling behind other
19 comparable countries when it comes to clinical trials,
20 commercial clinical trials being conducted in the UK.
21 You point out that we're tenth in the world for industry
22 phase III trials, falling from fourth in 2017, and far
23 behind countries --

24 **A.** Yes.

25 **Q.** -- such as Spain, is the example that you give. What

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1 together for prevention, innovation and investment in
2 life sciences in the UK.

3 And we can see -- thank you -- that number 1, in
4 terms of the recommendations in that document is about
5 the "mission-led approach" of the Vaccine Taskforce,
6 which Pfizer's view, in Pfizer's view, should be applied
7 to address other major healthcare challenges.

8 That can come down. Thank you very much.

9 How was the VTF's approach different in terms of
10 industry, from where you sat in industry? You describe
11 it as a single front door for industry.

12 **A.** That's right. It was a very significant shift for us in
13 terms of our relationship and working with government.
14 It provided single points of accountability, it provided
15 a very rapid and agile decision-making approach. It
16 ensured that when there were issues, when there were
17 challenges that needed to be navigated, there was
18 a rapid access to the right expertise to essentially
19 resolve those, in a very collaborative partnership way.

20 So yeah, I think when you then look at some of the
21 big societal health challenges that we face, cancer,
22 Alzheimer's, and other such diseases, that there are
23 some significant learnings that we can take from the
24 approach of both the Vaccine Taskforce and Antivirals
25 Taskforce as well.

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1 Q. And in terms of facing the next pandemic, it's an
2 approach you would like to see replicated?
3 A. Very much so, and I think in particular, and we have
4 heard this from other witnesses: the importance of that
5 expertise that was around and involved in the Vaccine
6 Taskforce was absolutely central to the approach.

7 MR MANSELL: Thank you, Mr Osborn.

8 My Lady, those are all my questions. I believe

9 Mr Weatherby KC has a question.

10 LADY HALLETT: Indeed. Thank you very much indeed,

11 Mr Mansell.

12 Mr Weatherby.

13 **Questions from MR WEATHERBY KC**

14 MR WEATHERBY: Thank you very much.

15 Mr Osborn, I ask questions on behalf of the Covid
16 Bereaved Families for Justice UK group. Just one point
17 from me, and it rather picks up from the last point that
18 you were speaking about, I think.

19 In your witness statement, and for the record, it's
20 paragraph 38, under the heading of "Pfizer's
21 understanding of the preparedness of the [UK] for the
22 rapid development of a 'Disease X' vaccine in early
23 2020", you state, and I quote:

24 "... the focus on an influenza pandemic, together
25 with an assumption that a pandemic specific influenza

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1 A. -- in this space, and I think it's one of the key
2 learnings now as we move forward that we need to make
3 sure we're not just putting our eggs in one basket. We
4 need to look broadly across the range of technologies,
5 the range of expertise, companies, academics, that will
6 ultimately contribute to solutions for future pandemics.

7 MR WEATHERBY: Thank you very much.

8 LADY HALLETT: Thank you, Mr Weatherby.

9 Thank you very much indeed, Mr Osborn. Those are
10 all the questions that we have for you. Thank you for
11 your help in providing the statement and answering our
12 questions and thank you for your help coming along
13 today.

14 THE WITNESS: Thank you.

15 LADY HALLETT: I'm very grateful to you.

16 **(The witness withdrew)**

17 LADY HALLETT: Mr Keith.

18 MR KEITH: My Lady, the next witness is Dr Justin Green,
19 please.

20 **DR JUSTIN GREEN (sworn)**

21 **Questions from LEAD COUNSEL TO THE INQUIRY for MODULE 4**

22 LADY HALLETT: Sorry if we've kept you waiting, Dr Green.

23 MR KEITH: Can you please commence your evidence by giving
24 us your full name.

25 A. Justin Anton Green.

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1 vaccine based on existing influenza vaccines, could be
2 made available within 4 - 6 months after the start of
3 a pandemic, meant that there had been limited
4 co-ordinated investment in development of vaccines
5 against new viruses."

6 Does it follow from that, that your view is that the
7 UK Government had not done enough to facilitate research
8 and development of vaccines to address Disease X, prior
9 to 2020?

10 A. I think, as we've seen from across -- both here in the
11 UK and across the world, we weren't ready for Covid-19
12 overall. From a very specific Pfizer perspective, it
13 didn't impact the development of our vaccine or delay at
14 all. We didn't take any government money from the UK or
15 indeed across the board.

16 Q. With respect, that rather avoids my question. The
17 statement that you put in your witness statement is that
18 the focus on influenza vaccines meant that there'd been
19 limited coordinated investment in this area.

20 Do you agree that that was in fact the case, and
21 that the UK Government should have been in a better
22 position?

23 A. I think there had been less focus, both in the UK and
24 further afield --

25 Q. Yes.

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1 Q. Dr Green, thank you very much for attending today and
2 for providing the witness statement which you have,
3 dated 7 November 2024.

4 You are, is this right, a UK-qualified infectious
5 diseases and general internal medicine physician, you
6 obtained an MA from Cambridge, a BM BCh in medicine and
7 surgery from Oxford, you're a Fellow of the Royal
8 College of Physicians, you have a diploma from the
9 London School of Tropical Medicine and Hygiene and from
10 the College of Physicians of London, a PhD from
11 Imperial, and notably -- and most importantly, for our
12 purposes -- in November 2020 you were one of the three
13 global clinical product leads for the Oxford-AstraZeneca
14 vaccine.

15 A. Correct.

16 Q. I want to ask you, please, about some events that
17 occurred in Singapore in 2002-3. Were you at that time
18 working in the hospital as a registrar?

19 A. Yes, I was a clinical registrar on the wards in
20 a thousand-bed hospital, which is a big hospital, in
21 Singapore.

22 Q. And what did you have to deal with during your time
23 there?

24 A. So general infectious diseases, but for well over
25 three months, I was the -- one of the clinical

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1 registrars looking after hundreds of patients with
 2 SARS-CoV-1 in the first coronavirus outbreak in 2002 to
 3 2003, where I looked after hundreds of patients with
 4 this condition, including some of my colleagues who got
 5 infected in the hospital, two of whom died.

6 **Q.** So you've seen firsthand the impact -- well, you saw
 7 then the impact of a pandemic?

8 **A.** It was an epidemic, but yes, but certainly this disease,
 9 you know, this -- this disease.

10 **Q.** The evidence before this Inquiry demonstrates that the
 11 Oxford-AstraZeneca vaccine which was rolled out in great
 12 numbers from January 2021, and in particular during
 13 those first three months of 2021, saved thousands of
 14 lives in the United Kingdom. You're aware, I'm sure, of
 15 a mathematical modelling study which estimates that
 16 vaccinations generally have prevented over 14 million
 17 deaths from Covid in 185 countries?

18 And also of estimates to the effect that in the
 19 United Kingdom, by September 2021, the Covid vaccines
 20 had prevented more than 23 million infections and
 21 123,000 deaths?

22 In your statement you identify a number of very
 23 general reasons or explanations why the
 24 Oxford-AstraZeneca vaccine was able to be produced,
 25 manufactured and subsequently rolled out. And I just

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1 phase I data, albeit in different diseases, with the
 2 same vector that gave us confidence that there should be
 3 a high chance of success in phase I, at least.

4 **Q.** How important, secondly, to the development of the
 5 vaccine was the degree of funding for research and
 6 development, in particular from the UK Government and
 7 the bodies such as NIHR and UKRI and others, and the
 8 recruitment or the ability to recruit into clinical
 9 trials?

10 **A.** So obviously this is Professor Pollard's team, so
 11 I speak with that in mind in terms of it was
 12 a collaboration between us, us and Oxford, but I think
 13 he's made it clear that the availability of funds,
 14 particularly for what they call the CoV-1, which is the
 15 phase I study that they did, with 1,000 patients, and
 16 then rapidly moving into the CoV-2 study, was incredibly
 17 important that that was made available, and made
 18 available early, with reassurance from the other
 19 phase Is that it was a worthwhile investment to make,
 20 albeit at a higher risk than you might make at other
 21 times in -- not in a pandemic setting.

22 **Q.** And to what extent did your team find that there was
 23 a heightened degree of a greater level of recruitment in
 24 the course of planning and conducting the trials for the
 25 Oxford-AstraZeneca vaccine, and to what extent did that

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1 want to ask you about those reasons.

2 Had there been, in the years leading up to the
 3 pandemic, considerable research done on the technology,
 4 the vaccine platform, chimpanzee adenoviral Oxford
 5 platform from which the Oxford-AstraZeneca vaccine was
 6 derived?

7 **A.** Yes. Dame Sarah Gilbert's team and other teams in
 8 Oxford had worked on this platform in a number of
 9 conditions, and pertinent to this was another
 10 coronavirus called MERS, which is Middle East
 11 Respiratory Syndrome, which is very similar, and
 12 therefore that gave them confidence that (a) they had
 13 phase I data that looked at safety of this in a small
 14 number of healthy volunteers, but also that they might
 15 have a product that could give a suitable immune
 16 response against that condition, and therefore increased
 17 our confidence that that might be the case in
 18 SARS-CoV-2.

19 **Q.** And had the technology also been worked on for the
 20 purposes of trying to develop vaccines for influenza and
 21 other pathogenic diseases --

22 **A.** Yes, and other ones.

23 **Q.** -- such as Zika?

24 **A.** Zika, malaria, HIV, others. They'd done a number of
 25 phase I studies, so actually we had quite a lot of

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1 level of recruitment make a difference?

2 **A.** So those recruited very fast. I mean, I think it's fair
 3 to say vaccine studies often, even outside of the
 4 pandemic setting, but -- that these studies do recruit
 5 fast, because you've got ambulatory healthy individuals
 6 volunteering for studies. But certainly in the context
 7 of the operational team at Oxford, they were, you know,
 8 really pleased and obviously were able to recruit those
 9 very rapidly, those trials.

10 **Q.** Thirdly, you refer in your statement to what has been
 11 very clearly established by the evidence in the course
 12 of this Inquiry so far, to the effect that the MHRA
 13 permitted data in relation to trials to be submitted on
 14 a rolling basis, rather than waiting to the end of the
 15 clinical trial process to receive all the data together,
 16 and, similarly in relation to the application for
 17 authorisation, was prepared to consider the data, the
 18 paperwork, on a rolling review basis.

19 Did that help with taking an overall review on the
 20 efficacy and the speed of the process with getting to
 21 the point of authorisation?

22 **A.** I mean, undoubtedly it did. We did a data lock in early
 23 November. We provided the final clinical documents,
 24 I think the headline results were on 23 November, and
 25 then obviously the approval was in late December and,

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1 you know, that really is very accelerated and that was
 2 clearly related to our ability to submit on a rolling
 3 basis, not just clinical information, information from
 4 pre-clinical studies which had already been completed
 5 and therefore were ready to be submitted, and
 6 manufacturing.

7 **Q.** Was safety in any way compromised or reduced by virtue
 8 of that ability afforded to you by the MHRA to provide
 9 data on a rolling basis?

10 **A.** No.

11 **Q.** Finally on this topic, you pay tribute in your statement
 12 to the prioritisation by all the stakeholders, to use
 13 your phrase, involved in this process. So everybody in
 14 Oxford, at AstraZeneca, and on the part of the state,
 15 and in particular the regulatory authority, the MHRA,
 16 worked extremely hard and very fast to make sure that
 17 the process was completed within as short a time as
 18 could reasonably be permitted. I mean, bluntly, did
 19 this mean that by contrast to what had gone before,
 20 phone calls were made every time of day and night,
 21 emails were sent immediately, meetings were scheduled
 22 and held repeatedly and with great frequency? The
 23 system was made to run very, very hot.

24 **A.** I mean, I think it was very clear that the reason we
 25 were able to go so rapidly was because almost the entire

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1 going -- from a logistical perspective, was going to be
 2 incredibly advantageous for people that had a similar
 3 supply chain set-up in non-pandemic settings in order to
 4 ensure that large volumes of this product could be
 5 supplied globally as well as obviously within the UK, in
 6 the sense of going to harder-to-reach regions.

7 **Q.** Turning now to the subject of clinical trials, please,
 8 Dr Green. Are clinical trials an ordinary part of all
 9 medicines' development and manufacture?

10 **A.** Yes. Not just vaccines, obviously -- of small
 11 molecules, monoclonals, other therapies.

12 **Q.** Could you say something, please, in general terms about
 13 the degree of scrutiny directed towards the
 14 Oxford-AstraZeneca vaccine by comparison to historic
 15 vaccines, perhaps by comparison to the Covid vaccines,
 16 was it a vaccine which has been subject to unprecedented
 17 degrees of scrutiny?

18 **A.** By whom? I think everybody was scrutinising it. So
 19 I think we had a high level of scrutiny, obviously in
 20 the public domain, in the press, but also obviously from
 21 not just the regulatory agency in the UK, the MHRA, but
 22 in parallel we had submissions in Europe, so we were
 23 dealing with getting a European approval, which we got
 24 in late January. We had interactions with WHO. We
 25 had -- certainly in early 2021, we were dealing with the

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1 machinery of AstraZeneca was turned over in order to
 2 support these trials for this and our monoclonal
 3 antibody Evusheld as well. And also, the same was
 4 happening in Oxford and at the MHRA and other agencies.
 5 And there were, you know, everybody was ready to respond
 6 rapidly, but with the same level of quality in that very
 7 busy time.

8 **Q.** The effectiveness of the Oxford-AstraZeneca vaccine has
 9 been trawled over and reported upon and countless
 10 reports published on its effectiveness, but in addition
 11 to that issue, was the Oxford-AstraZeneca vaccine
 12 a vaccine which was produced and manufactured and made
 13 available without profit?

14 **A.** Yes.

15 **Q.** And was that something which Oxford-AstraZeneca was
 16 prepared to agree not just with the United Kingdom
 17 Government but with other government's around the world?

18 **A.** Absolutely.

19 **Q.** And another hugely important aspect of that vaccine was,
 20 by contrast to one particular other vaccine, was it
 21 a vaccine which was more readily transported, stored and
 22 physically delivered?

23 **A.** Certainly earlier -- early in the pandemic we knew that
 24 we had a vaccine which could be stored at 2 to
 25 8 degrees, and therefore from a global perspective, was

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1 Brazilian government and other independent regulators
 2 that were asking their questions of our data. Not all
 3 of those questions were the same, and therefore we were
 4 answering all of those during that early part of 2021.

5 I think, just to put that into some kind of context,
 6 we answered 1,500 clinical questions, and I think at
 7 AstraZeneca, of all of the products that we've got,
 8 that's three times more than any other product we've
 9 ever had.

10 **Q.** In general terms, were the clinical trials led by Oxford
 11 as opposed to AstraZeneca, or was it a shared endeavour?

12 **A.** So the University of Oxford sponsored the trials.
 13 Professor Pollard's team did a heroic effort of managing
 14 those trials and then we partnered with them in terms of
 15 then using the data that they had collected in order to
 16 support the file that we made and the authorisation that
 17 we got, but we then became what's called the market
 18 authorisation holder, and therefore responsible, after
 19 authorisation, for that product.

20 **Q.** So you made the authorisation applications, you helped
 21 with the analysis of the data and it's interpretation,
 22 and no doubt you provided software and a great deal of
 23 the number crunching as well, in support of your
 24 applications for authorisation?

25 **A.** We did, although the original analysis was actually done

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1 by Oxford and repeated by us, and that was very
 2 important for Oxford, as well as ourselves, and that's
 3 not usual, that actually we came to the same conclusion
 4 on the same datasets.

5 **Q.** So expand on that, the data having been made available
 6 from the output from the clinical trials, it was
 7 looked at by both AstraZeneca and Oxford?

8 **A.** Yes.

9 **Q.** Independently of each another in order to reach a view
 10 as to the significance of the data --

11 **A.** Well, to come to exactly the same numbers so that we
 12 were completely confident that the way it had been
 13 analysed was actually giving exactly the same numbers in
 14 terms of efficacy but also, obviously, safety and
 15 immunogenicity.

16 **Q.** All right. There were a number of Oxford-AstraZeneca
 17 trials or Oxford trials, perhaps, COV001, 2, 3 and 5.
 18 They are the ones I'm most concerned about. Some of the
 19 trials took place abroad, and in particular, COV002
 20 trial and COV001 trial took place in the United Kingdom;
 21 is that right?

22 **A.** That's correct.

23 **Q.** And just, please, help us with a general overview of the
 24 scope and the scale of these trials, the COV001 trial in
 25 the United Kingdom, roughly how many trial centres did

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1 **Q.** And is that because the MHRA standards or assurances are
 2 agreed at international level, and at least consistent
 3 with what other international regulators demand?

4 **A.** Yes, the International Conference on Harmonisation, or
 5 ICH, would say within that the MHRA standards fulfil
 6 what we consider that GCP, good clinical practice, is.

7 **Q.** Staying with the issue of diversity of trials, could you
 8 please look at the article in The Lancet, INQ000153551.
 9 This is an article dated 8 December 2020. And Dr Green,
 10 did Oxford-AstraZeneca put its data from four of its
 11 ongoing blinded randomised controlled trials, and the
 12 analysis into the public domain, through Lancet?

13 **A.** That's right. That was published, I think on the --
 14 online and is open access as well, so you don't have to
 15 pay to or be part of a library to access that. And
 16 that, we felt, was very important, that any publications
 17 were done swiftly, that they were done in high impact
 18 journals with, you know, high standards of peer review,
 19 and therefore, we were pleased that Lancet agreed to
 20 publish that paper.

21 **Q.** And is it self-evident that the degree of detail is at
 22 a very high level? The numbers, the data, the
 23 percentages, it's all there?

24 **A.** Well, there's a high level of detail here and we were
 25 pleased that Lancet gave us a little bit more space to

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1 that involve?

2 **A.** I think it was five.

3 **Q.** And roughly how many participants?

4 **A.** The final analysis was 1,077 patients.

5 **Q.** COV002 was in the United Kingdom. It was a phase II,
 6 phase III trial. Was that over 10,000 participants?

7 **A.** About 12,000, yeah.

8 **Q.** 12,000. COV003 was in Brazil -- over 10,000?

9 **A.** -- (overspeaking) -- in about seven sites.

10 **Q.** And COV005 in South Africa, and how many participants?

11 **A.** About 2,000 and then some of those were HIV positive as
 12 well, which was important.

13 **Q.** Were all of the trials randomised and controlled?

14 **A.** They were all randomised and controlled, yes.

15 **Q.** Most were single-blinded, and we now know --

16 **A.** Yes.

17 **Q.** -- what single-blinded means and one, I think was --
 18 (overspeaking) --

19 **A.** COV005 was double-blind.

20 **Q.** And were the trials carried out even though some of them
 21 had taken place abroad, in accordance with the MHRA's
 22 good clinical practice for clinical trials?

23 **A.** Yes, I mean, the way that they were conducted was
 24 certainly done to international standards, of which the
 25 MHRA's is a very good example of that, but yes.

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1 get more information in than their usual articles, but
 2 actually, what lies behind this is hundreds and hundreds
 3 of pages of documents that I helped edit and write with
 4 my colleagues that formed the basis of the readout of
 5 the clinical trial that was then submitted to the MHRA.
 6 This is a summary, and this is a précis of that summary.

7 **Q.** All right. But we can see from the findings that
 8 information is given there not just about overall
 9 vaccine efficacy, but also about the fact that in
 10 relation to -- was it one of the trials or all the
 11 trials? -- there were ten cases hospitalised for Covid,
 12 all in the control arm, and two were classified as
 13 severe Covid-19, including one death. So in the control
 14 arm. Was that across all of the trials or one of the
 15 trials?

16 **A.** No, this is a pooled analysis and so that was across all
 17 of the trials, although the -- you know, and so that
 18 gave us a really good indication that we had an
 19 excellent product here that was going to be really
 20 effective.

21 **Q.** And so we're absolutely clear, during the course of the
 22 trials, amongst the cohort of participants who did not
 23 receive the vaccine, because they were in the control
 24 arm, some were hospitalised, two got severe Covid, and
 25 one died?

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1 A. And unfortunately one died, yes.

2 Q. Had you not known with absolute certainty that that poor
3 individual who'd died had not received a vaccine, and
4 they had died without that knowledge, you wouldn't have
5 known whether or not they'd died from the vaccine or
6 from Covid?

7 A. Well, you'd know that information after you'd unblinded
8 the trial. So --

9 Q. Quite so, but --

10 A. You may, during the course of a trial, occasionally
11 understand who, particularly in the context of serious
12 safety issues, you might unblind an individual, but you
13 would only know that at the end of the trial. So you
14 would know that you'd had ten severe cases and you'd had
15 one death but until you unblinded the trial in late
16 November 2020, you wouldn't know whether that person had
17 had vaccine or not.

18 Q. But the general point is that of course people could and
19 did die from Covid itself?

20 A. Yes.

21 Q. There's a reference there to person months of safety
22 follow-up, 74,341 person months. What is that?

23 A. I mean, it's large --

24 Q. Well, what does it mean?

25 A. -- and extensive, and what it means is that, you know,

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1 had had no vaccine at all?

2 A. Yes, and the imbalance is driven mainly by the fact that
3 unfortunately they got very severe Covid and that's
4 likely to lead to a serious adverse event, because they
5 would have been hospitalised.

6 Q. And that's because many of these severe adverse events
7 appear in the community coincidentally -- (overspeaking)
8 --

9 A. Yes, I mean, if you break your leg and end up in a
10 hospital it may not be because of the vaccine but you'd
11 still have had a serious adverse event.

12 Q. Of those severe adverse events occurring in the vaccine
13 participant group -- sorry, of the total number of
14 severe events, three events were classified as possibly
15 related to a vaccine, one in the vaccine group, one in
16 the control group, and one in a participant who remains
17 masked to group allocation. So did Oxford-AstraZeneca
18 carry out enquiries in each case of severe adverse
19 events and try to determine what link, if any, there was
20 to the vaccines as opposed to the severe adverse event
21 occurring coincidentally?

22 A. Yes, usually prior to unblinding you have that
23 information and then subsequent to unblinding you look
24 at those individual that have had vaccine, and actually
25 the one in the vaccine group, because actually of those

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1 if you totalled together the number of participants and
2 how much each individual contributed to the safety
3 database, because this was an interim data readout, you
4 know, one individual could have contributed 1 month and
5 one finished could have contributed 11 months, but
6 overall, there was a cumulative amount of safety in
7 74,000 person months.

8 The median time that individuals had been followed
9 up at the time of the submission of our original file
10 was about two months, so we knew we had that very early,
11 and importantly in a vaccine study, we had information
12 where we considered the most likely time that these
13 adverse events will present that are likely to be
14 related to vaccine.

15 Q. And then turning to severe adverse events, there are
16 a number of severe adverse events amongst -- out of the
17 total number of participants, 168 people?

18 A. Yes, you'd expect that in 23,000 individuals. But
19 what's more important is the attributable ones, so the
20 ones that either the investigators prior to unblinding,
21 or even after unblinding, you felt were related to the
22 vaccine, and the number of those were very, very low.

23 Q. Eighty-four events amongst the group of people who had
24 received the Oxford-AstraZeneca vaccine, but there were
25 91 severe adverse events amongst the control group who

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1 three, only one of them ended up being in the vaccine,
2 was somebody that had a very high fever, and sought
3 medical advice for that fever, and therefore reached the
4 qualification to be a serious adverse event. But that
5 was self-limiting, and actually, we now know that
6 individuals having fever with this vaccine in the first
7 seven days of delivery is not uncommon.

8 Q. Can we just look at some other aspects of this report
9 please. Page 3, there's a reference to the COV002
10 trial, so that's one of the two trials that was in the
11 United Kingdom, we can see in the bottom left-hand
12 corner. It says:

13 "Enrolment particularly targeted individuals working
14 in professions with high possible exposure to
15 SARS-CoV-2, such as health and social care settings."

16 So as part of that trial, you were focusing on
17 particularly people in the health and social care
18 sector?

19 A. That's correct.

20 Q. Page 4, there's a reference to the COV003 trial in
21 Brazil and the COV005 trial in South Africa. May we
22 presume that because they were trials in Brazil and
23 South Africa, there was a higher or there was a more
24 diverse racial and ethnic make-up amongst the
25 participants?

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1 **A.** Yes, that's right. I mean, the ethnicity of individuals
2 in Brazil is often very mixed because of the historical
3 migration patterns, and then obviously in South Africa,
4 we had a high proportion of black individuals.

5 **Q.** But because the UK trials tended to be, I think, larger,
6 or at least one of the UK trials was quite large, in
7 terms of overall ethnicity of the trials, you've got to
8 pool all the participants in all the trials, and see
9 what the overall figures are, and so that's why,
10 elsewhere in this report, the overall figure is about
11 76% participants were white, 10% black, 4% mixed
12 ethnicity, 3% Asian and 7% other. Is that right?

13 **A.** That's correct.

14 **Q.** Right. We've learnt a great deal about
15 pharmacovigilance, and I needn't ask you about the
16 general system. It is clear that Oxford-AstraZeneca
17 appointed, for the purposes of the clinical trial
18 process and seeking authorisation, a data safety
19 monitoring board.

20 Amongst the papers before the Inquiry it's clear
21 that the trial was paused in September 2020 to
22 investigate a suspected unexpected serious adverse
23 reaction, a SUSAR, a case of transverse myelitis, in
24 fact, and the issue arose as to whether it was
25 associated with the receipt of the vaccine.

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1 context of new safety findings, you would be very much
2 looking for those conditions, and obviously all the
3 other conditions you are expecting to find, and
4 therefore it would have been agreed with the MHRA.

5 And in actual fact, because we had other
6 international clinical trials ongoing at the time, it
7 was also agreed with other international regulatory
8 agencies that we would start -- restart our trial, and
9 that they agreed with that.

10 **Q.** The safety monitoring, safety supervisory system obliges
11 a manufacturer, pre-authorisation, to provide
12 pre-clinical studies, clinical trial data, it would seem
13 almost any data or information related to safety and the
14 issue of whether or not a prospective authorisation
15 might be impacted by that event.

16 But did AstraZeneca and Oxford also receive and make
17 available reports from members of the public who'd taken
18 part in the trials?

19 **A.** So I don't think I fully understand your question.

20 **Q.** We know from the pharmacovigilance system that there's
21 a process by which members of the public and clinicians
22 can report through the Yellow Card system.

23 **A.** So are you talking about --

24 **Q.** We're post -- post-authorisation.

25 **A.** That's post, okay.

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1 Was the pausing of the trial something that would
2 have been ordered by the data safety monitoring board
3 embedded within AstraZeneca -- or Oxford-AstraZeneca?

4 **A.** No, that would be done by the study team. So usually,
5 you would consider there's a number of people that might
6 pause a trial. So the pause might come from the
7 investigator, so you would say: we're going to stop and
8 we're going to find out about this case and then we're
9 going to discuss that with the D -- what's called the
10 DSMB, which is the Data Safety Monitoring Board. It
11 could be done by the Data Safety Monitoring Board and
12 sometimes it's done by the regulator.

13 **Q.** All right. So there are different degrees and levels
14 of, I suppose, safety supervision?

15 **A.** Yes.

16 **Q.** And do you recall how it was the position was reached
17 that the trials could be recommenced?

18 **A.** Yes, there was discussion obviously between the sponsor,
19 which was Oxford, and the clinical team, which was
20 Professor Pollard's team, with our input, to the DSMB,
21 and the DSMB agreed that they felt that there was
22 insufficient evidence of causality from the vaccine, and
23 therefore, that was then -- what you do is you then
24 agree with the regulator that your position is that
25 vaccination should restart. And obviously, in the

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1 **Q.** But was there a system in place whereby, either pre- or
2 post-authorisation, anybody who had taken place in an
3 Oxford-AstraZeneca trial could get in touch with
4 Oxford-AstraZeneca directly and report suspected side
5 effects --

6 **A.** Yes.

7 **Q.** -- to you directly?

8 **A.** Yes, so the usual conduct, and the conduct in this case
9 with the clinical operations team at Oxford who ran the
10 trials, would -- was that the -- that Professor Pollard
11 had a number of staff working for him, some of which
12 were physicians, and that all of those participants
13 would have been informed at the beginning of the trial
14 how they could contact the trial site, on a 24-hour
15 basis, seven days a week, if they had any symptoms that
16 they were concerned about. And that's encouraged. You
17 know, that is part and parcel of the covenant of working
18 with people who volunteer to be in your trials, is that
19 you really give them easy access to trial staff so that
20 they can report those, even if they're late.

21 So sometimes, you know, we might even find out
22 something after someone has finished a trial. And if
23 they report that, that would then be subsequently
24 included in the database.

25 **Q.** And are these reports from those participants analysed

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1 by the company, put through your data systems, followed
2 up in certain circumstances as well as being reported to
3 the regulator, the MA, or the MHRA, whoever it is?

4 **A.** They are, and in fact we put in a number of reports in
5 terms of the clinical study report that was submitted.
6 So we put the rolling submission in in late 2020, but in
7 the second quarter of 2021 we submitted formal clinical
8 study reports of the early part of the trials, and then
9 later, we submitted final study reports which reported
10 on the totality of the safety and efficacy data of all
11 of those individuals in those four trials, followed up
12 to completion of the -- completion of those studies.

13 **Q.** Did trials continue after the date of authorisation?

14 **A.** Yes. So for many months afterwards. So we were looking
15 at, in those four trials, we were looking at everybody
16 being followed up for a year, and a large number of
17 those individuals were actually rolled into another
18 study to look at the second year of safety in a study
19 called Cov-9, which has subsequently finished.

20 **Q.** And was there a large trial, I think with sites in the
21 US, Peru and Chile, which carried on throughout 2021,
22 following authorisation, an RCT (a randomised control
23 trial) double-blind --

24 **A.** Yes, we --

25 **Q.** -- reported subsequently?

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1 delivery of particularly safety information, but also
2 effectiveness.

3 **Q.** So you set out what you propose to do if authorisation
4 is given, and how, precisely, you're going to continue
5 to monitor safety and report on it.

6 And we can see the data lock point for this document
7 is 4 November 2020, so pre-authorisation.

8 **A.** That's right. And you identify which safety issues you
9 either already know about and which ones you continue to
10 have concerns about, despite the fact that you may not
11 have seen them in a clinical trial, because there are
12 some generic understandings of doing vaccine trials
13 whereby you always are concerned about particular
14 adverse events that have been associated with many other
15 vaccines, not necessarily within the Covid space.

16 **Q.** Because, for example, in relation to some vaccines,
17 perhaps the Covid-19 vaccines, there is always the
18 possibility of a thromboembolic event, and that's one of
19 the -- it's AESIs that are identified in --

20 **A.** That's right, and -- but let's be clear that that
21 thromboembolic event would be something we would expect
22 to see in a clinical practice, like a deep vein
23 thrombosis or a pulmonary embolus and not something
24 associated with low platelets. Different
25 pathophysiology.

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1 **A.** Yes, we also started a trial in the late summer of 2020
2 which was using sites in the three countries that you've
3 quoted, and that reported in late March 2021, and, very
4 reassuringly, in a second complete dataset, so a second
5 phase III study, we demonstrated very similar efficacy,
6 almost identical efficacy, against severe disease.

7 And what was most reassuring for us at the time
8 was very similar safety profile. Although I might add
9 we did not see any cases of transverse myelitis in that
10 dataset.

11 **Q.** Another important part of the monitoring, the safety
12 monitoring process, is the provision of a risk
13 management plan.

14 Can we just have a look at this, at INQ000506071.

15 We will see a risk management plan which was
16 submitted on behalf of the Oxford-AstraZeneca adenoviral
17 vaccine, AZD1222, to the EMA, and this is -- is this
18 a document which is, in its first instance, drawn up by
19 the company?

20 **A.** Yes, you draw it up prior to authorisation or approval,
21 and often in the late stages of -- as you get towards an
22 authorisation, you would negotiate to update this, and
23 obviously then mutually agree what the contents of this
24 are, because it's critically important for
25 post-approval -- post-authorisation planning and

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1 **Q.** If we can quickly just go through pages 3, we can see
2 here the index and the sorts of issues which are covered
3 by the risk management plan: prevention of Covid, the
4 non-clinical start of the safety specification,
5 information about the trial process, who were not
6 studied in the clinical trials, post-authorisation
7 experience, identified and potential risks.

8 And, over the page, the pharmacovigilance plan
9 setting out all the things that will be done, going
10 forward, for the purposes of maintaining this high level
11 of safety.

12 **A.** That's right, and you can see there, lower down page 47
13 and below, that also requires you to complete, report
14 out and report back to the regulators the trials that
15 you've done. So that kind of is -- it's not just about
16 new activities; it's about ensuring that you've
17 completed the activities that you are undertaking at the
18 time of authorisation.

19 **Q.** And just to pick up some of the pieces of evidence which
20 the Inquiry has explored during the course of the
21 hearing, if we look at page 33 we will see, by way of
22 example, what is known as the missing information. So
23 the absence of pregnant and breastfeeding women in the
24 course of the AstraZeneca trials, as well as those with
25 a severe immunodeficiency. So you're reporting on all

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1 aspects of safety for the purposes to of the trials.
 2 Page 36. Details of the obligations to examine the
 3 data sources for signal detection, safety signal
 4 detection.
 5 Page 39, detailed information concerning the ICSRs,
 6 the case safety studies, signal evaluation, and I could
 7 go on.
 8 **A.** The -- under authorisation, the 174, I think what was
 9 made abundantly clear to us, and it's clear in this
 10 document, is that actually the commitment for
 11 pharmacovigilance was no different to what you would get
 12 in a routine conditional marketing approval. So the
 13 pharmacovigilance part of the RMP was definitely as
 14 expected for any other product in or outside of
 15 a pandemic.
 16 **Q.** We've not enjoyed acronyms, generally, by RMP you
 17 mean --
 18 **A.** Risk management plan.
 19 **Q.** All right.
 20 And then if we look at the MHRA, risk management
 21 plan, INQ000506077, I think I have engaged in an acronym
 22 there, the medicinal health -- Medicines and Healthcare
 23 products Regulatory Agency, we can see there the
 24 country-specific addendum to that risk management plan
 25 precisely for the purpose of the agency and the

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1 **A.** They have all been completed. Only one is not reported,
 2 which is unsurprising, because it's a pregnancy study.
 3 But all of the others have been completed. The clinical
 4 study reports have been completed. They are available.
 5 In the public domain. Many in almost unredacted forms.
 6 And a number of those have also been published in
 7 peer-reviewed journals.
 8 **Q.** All right. Fees. Does a manufacturer wishing to seek
 9 authorisation for the use in a particular country, or in
 10 the United Kingdom, of a medicinal product, including
 11 a vaccine, have to pay a fee?
 12 **A.** Yes.
 13 **Q.** Do you also pay fees, I think a subscription fee, for
 14 particular portals overseen or run by the regulator?
 15 **A.** Yes.
 16 **Q.** Is there any financial link between AstraZeneca and the
 17 MHRA?
 18 **A.** None whatsoever.
 19 **Q.** The authorisation was granted on 29 or 30 December 2020,
 20 and were there a number of conditions attached to the
 21 authorisation by the regulatory agency?
 22 **A.** Yes.
 23 **Q.** Did those conditions concern not just use of the
 24 vaccine, but also, the continuing obligations of
 25 pharmacovigilance?

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1 United Kingdom?
 2 **A.** That's right.
 3 **Q.** Post-authorisation, there were a number of obligations
 4 imposed on you, were there not, to provide summary
 5 safety reports, periodic safety update reports, provide
 6 scientific and medical reports which have been published
 7 in the literature, data from your database, anything to
 8 do with adverse events, as well as specific
 9 post-authorisation safety studies. Is that a fair
 10 summary?
 11 **A.** That's right, but in the context of this, this --
 12 actually it was heightened. I mean, there were
 13 twice-weekly phone calls, which is unusual. There were
 14 monthly reports, which again is unusual, and was
 15 increased for what would be expected for a normal
 16 product.
 17 But that was a reflection of fact that we knew that
 18 this was an important product that was going to be used
 19 in many millions of people very quickly.
 20 **Q.** How many post-authorisations safety studies do you
 21 recall were done?
 22 **A.** I think there are nine listed.
 23 **Q.** And were they all given to the EMA, the European
 24 Medicines Agency, and the Medicines and Healthcare
 25 products Regulatory Agency?

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1 **A.** Yes, they did.
 2 **Q.** If we can look, please, at INQ000413711, at pages 3 to
 3 4, we'll see at the bottom of the page, paragraph 23:
 4 "[AstraZeneca] must operate a comprehensive
 5 pharmacovigilance system for this product ...
 6 "[It] ... must submit to MHRA inspections to assess
 7 compliance ..."
 8 There must be:
 9 "... full product lifecycle compliance with the risk
 10 management plan ...
 11 "... promptly and regularly liaise with the HMRA to
 12 ensure the safety specification ...
 13 "... submit protocols ..."
 14 And so on.
 15 So it's a condition of the authorisation that this
 16 stringent process continues?
 17 **A.** That's correct.
 18 **Q.** All right.
 19 Another important part of it is the system by which
 20 the company produces product information about the
 21 vaccine; is that right?
 22 **A.** Yes.
 23 **Q.** And must all the product information which you provide
 24 about your product be approved by the regulatory agency?
 25 **A.** Yes.

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1 **Q.** Because this was a process under Regulation 174 of the
2 medicines regulations, did you produce for healthcare
3 professionals, and then for UK recipients, something
4 known as Regulation 174 information?

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

6 **Q.** We'll look at the healthcare professional one first,
7 INQ000413715.

8 If we go to page 2, you can see there the name of
9 the product, the qualitative and quantitative composition,
10 pharmaceutical form, clinical particulars. And does it
11 set out a great deal of detail about the nature of the
12 product, the risks, the benefits, the contraindications,
13 and so on?

14 **A.** It does.

15 **Q.** And then the information for the patient, UK recipient,
16 INQ000413716, page 2., what the vaccine is, what you
17 need to know, how it's given, possible side effects, how
18 to store, and contents of the pack and other
19 information?

20 **A.** It is. But this document particularly we were at pains
21 to try our very best to make sure that it was written in
22 a language and a style that was understandable to
23 everybody that might receive the product.

24 **Q.** The information you provided subsequently found its way
25 into what we know to be the patient information leaflet

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1 **Q.** In your statement you, very helpfully, included a table
2 listing all the changes that were made in the product
3 information, by reference to all adverse drug reactions,
4 whether demonstrated to be linked to a vaccine, the
5 vaccine, or merely associated with the vaccine, or just
6 suspected to be associated or maybe not connected at
7 all, but an adverse event about which public concern has
8 been expressed in relation to whether it is connected to
9 the vaccine.

10 And just by way of example, if you can have page 34
11 of your statement, INQ000474537, have you provided
12 a summary of how the product information was changed in
13 relation to thrombosis with thrombocytopenia syndrome,
14 TTS, called by some, VITT. It's very rare; is that what
15 the data showed?

16 **A.** Yes.

17 **Q.** The summary of product characteristics, SmPC, was
18 changed on 7 April 2021?

19 **A.** Yes.

20 **Q.** Following that Bank Holiday weekend, in fact. And
21 a description was added to section 4.8 referring to
22 "very rare events of major venous and arterial
23 thrombosis with concurrent thrombocytopenia", noting
24 that "a causal relationship has not been established."

25 That note was then removed on 15 April and I think

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1 and also the summary of product characteristics.

2 Is that information updated as you go along.

3 **A.** Yes. You update it as and when you have information
4 that you feel is important for people to understand the
5 product that they might receive.

6 **Q.** And by and large, are those changes agreed with the
7 regulator?

8 **A.** Always.

9 **Q.** Does the regulator have an ability to say, "You may not
10 want that information" or "You've got a good argument by
11 that information doesn't need to be put in or it's not
12 relevant, but we, the regulator, want it in anyway"?

13 **A.** I think what you're describing is actually quite common
14 in pharmaceutical medicine, which is an imposition,
15 which is --

16 **Q.** That's a technical -- or it's a term of art?

17 **A.** That's the technical description of what you're saying,
18 which is that we would have an opinion about
19 a particular adverse event or a particular set of
20 wording within the -- either the patient information
21 leaflet or the summary of product characteristics, but
22 ultimately, the regulator would insist on that language
23 and we would come to usually a mutual conclusion about
24 the best language for that, and that would then go into
25 that label and would be disseminated.

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1 that was the final change made, was it, to the Summary
2 of -- (overspeaking) --

3 **A.** Regarding that particular adverse reaction.

4 **Q.** TTS, all right. So that gives us a good idea. And that
5 the same approach was applied in relation to any other
6 adverse events suspected, confirmed or just argued to be
7 connected to vaccines, in this list?

8 **A.** That's right. So when we read out our US trial, for
9 example, we had a bit more information about the early
10 reactogenicity reactions, and we made adjustments with
11 that information. So you're data driven, and once you
12 have that information, you update it so you've got the
13 best summary in that document and obviously the
14 patient-facing version of that document, so that people
15 fully understand what it is that is associated with this
16 product.

17 **Q.** Finally, you've helpfully provided in your statement
18 a number of -- you've identified a number of lessons
19 learnt and made a number of recommendations and I just
20 want to very briefly run through those.

21 In relation to clinical trials, you refer to the
22 possibility of encouraging the government to ensure that
23 there be trial hubs which can be pandemic-ready to
24 support institutions with recruitment and efficient
25 operation of trials. What did you mean by "trial hubs"?

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1 **A.** Well, I think what we found in the UK I in Covid was
 2 that Professor Pollard, you know, has a lot of
 3 colleagues who very rapidly were able to mobilise
 4 clinical trial sites that either already existed or they
 5 created subsequently new clinical trial sites, trained
 6 up investigators that would be appropriate to look after
 7 participants of the vaccine. And it's really
 8 understanding that you need a sustainable system of
 9 clinical trial sites that can pivot towards a pandemic
 10 setting, but also more likely in that context, expand so
 11 that you would have the capacity, because you're not
 12 only doing clinical trials of one vaccine, you know,
 13 there were several vaccines that might want to be
 14 trialled at any one time, so you've got the best
 15 opportunity of getting one that's safe and efficacious,
 16 but also, monoclonal antibodies because monoclonal
 17 antibodies like Evusheld are critical in the context of
 18 having an armoury of products that could be used,
 19 because not everyone will respond to a vaccine, and also
 20 therapeutics for individuals that are ill with the
 21 disease and might actually have less severe disease once
 22 ill, with small molecules.

23 And all of that will require thought, will require
 24 planning, and it needs to be sustainable so that you're
 25 not suddenly doing it today having not had that capacity
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1 a different electronic system, with hospital data.
 2 And it's that if you're going to do really effective
 3 post-approval real-world evidence studies, having those
 4 three systems that can actually triangulate and be drawn
 5 into one source of information that can then be analysed
 6 would be incredibly powerful and incredibly helpful.

7 **Q.** You've referred to a study. Is this the position: that
 8 on 19 February the first set of real-world effectiveness
 9 data, the vaccine, was published by Public Health
 10 Scotland and a number of Scottish universities, but it
 11 was the only one published at that time. What you're
 12 calling for is that there be a better regulated and
 13 managed system for the provision of that sort of
 14 real-world post-authorisation data?

15 **A.** But wouldn't it have been amazing if that also had
 16 really deep and rich safety data? And we could have had
 17 that at the same time.

18 **MR KEITH:** Thank you very much, Dr Green. Those are all the
 19 questions I ask.

20 **LADY HALLETT:** Thank you very much indeed, Dr Green.
 21 Thank you to you and your colleagues for all you did
 22 to develop the vaccine. Obviously, there are millions
 23 of people around the world who are very grateful to you
 24 and your team. And thank you very much for all that you
 25 and your colleagues have done to help the Inquiry,
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1 yesterday.

2 **Q.** You've spoken about the rolling review of clinical trial
 3 data, and of the data supporting the application for
 4 authorisation. Was that process, adopted by the
 5 regulatory agency to deal with the exigencies of this
 6 particular crisis, something you would recommend for
 7 future use?

8 **A.** That was incredibly important.

9 **Q.** And finally, is there anything that you would ask the
 10 Inquiry to consider to be done in relation to access to
 11 medical health records, electronic data records, and
 12 essentially information from the NHS concerning the
 13 possibility of adverse events?

14 **A.** So post-authorisation, post-approval, the availability
 15 of real world evidence is incredibly important. It was
 16 incredibly powerful for us, because data coming in
 17 February from Scotland, from Public Health Scotland, was
 18 incredibly important in confirming how well our vaccine
 19 was working, but what we found was that we had to set up
 20 our own real-world evidence studies as well as the ones
 21 that were being done and, more importantly, is the
 22 triangulation of information that already exists. So
 23 the triangulation of primary care data, where people may
 24 well first present with disease, may have a diagnosis
 25 made, with laboratory data, which is often in
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1 producing the statement and coming on today to help us.

2 **THE WITNESS:** Thank you.

3 **LADY HALLETT:** Thank you. I hope we haven't denuded
 4 AstraZeneca, you seem to have a number of colleagues
 5 with you. Thank you very much indeed.

6 10.30 on Monday, the 27th. Thank you.

7 (The witness withdrew)

8 (3.47 pm)

9 (The hearing adjourned until 10.30 am
 10 on Monday 27 January 2025)

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