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1	Wednesday, 22 January 2025
2	(10.00 am)
3	LADY HALLETT: Mr Keith.
4	MR KEITH: Good morning, my Lady. The two witnesses this
5	morning are, please, Professor Stephen Evans and
6	Professor Daniel Prieto-Alhambra, if they could be
7	sworn.
8	PROFESSOR STEPHEN EVANS (sworn)
9	PROFESSOR DANIEL PRIETO-ALHAMBRA (affirmed)
10	Questions from LEAD COUNSEL TO THE INQUIRY for MODULE 4
11	MR KEITH: My Lady, if it meets with your approval,
12	I propose to call and deal in detail with
13	Professor Stephen Evans' report first because he deals
14	primarily with the systems and processes to do with
15	safety. But where we get to areas on which
16	Professor Prieto-Alhambra has opined, I will bring him

So perhaps I could commence with asking you both to identify yourselves and then we'll deal with your qualifications and expertise.

For the record, Professor Evans, could you give us, please, your full name.

into the forensic debate, and then we will deal with the

majority of Professor Prieto-Alhambra's report after

PROFESSOR EVANS: Stephen James Weston Evans.

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Tropical Medicine to become head of the epidemiology unit at the UK Medicines Control Agency, now the MHRA. You were an honorary professor of medical statistics at the London School of Hygiene and Tropical Medicine, as well as LHMC -- I'm sorry, I think I referred to LHMC as the London School of Hygiene and Tropical Medicine, but it is in fact the London Hospital Medical College.

You became professor of pharmacoepidemiology at the London School of Hygiene. You were on a number of EU committees on medicine safety between 2006 and 2018, a member of the WHO Global Advisory Committee on Vaccine Safety, chair of the Royal Statistical Society Medical Section and a host of other qualifications.

Importantly, for the purposes of the subject matter of your report, did you also have considerable involvement in the OpenSAFELY data programme, the collaboration from 2020, and also, during the course of the pandemic, did you give some limited advice to the Vaccine Effectiveness Expert Panel in the Cabinet Office and the vaccine effectiveness expert working group, organised by Public Health England?

22 PROFESSOR EVANS: I did.

23 Q. I think you participated as a volunteer in one of the 24 trials, is that right?

25 PROFESSOR EVANS: I did, in the AstraZeneca trial.

Q. And Professor Prieto-Alhambra, your full name, please. 1

PROFESSOR PRIETO-ALHAMBRA: Professor Daniel 2

3 Prieto-Alhambra.

4 Q. Thank you very much both for the provision of your 5 expert reports, in your case, Professor Evans, dated 6 6 November 2024, and in your case,

Professor Prieto-Alhambra, September 2024.

Both are very significant, lengthy documents, and we're very grateful to you for the evident hard work and time that has gone into those reports.

May we take it that both reports are the product of your own work, although, as we'll see in a moment, you've been greatly assisted by a number of other professionals and experts, and that the contents are true. I'm sure they are.

Dealing with your qualifications firstly, Professor Evans, your first degree was from Keele University in physics and chemistry, you have a long list of post-graduate qualifications but you were, from 1979, a senior lecturer, then the reader, then professor of medical statistics at LHMC, the London School of Hygiene and Tropical Medicine (sic). You were a member of the working party of the Royal Statistical Society on statistics and drug regulation.

You then left the London School of Hygiene and

Q. And are you also, as it happens, a convener of the 2 statistics expert group at the Infected Blood Inquiry 3 under Sir Brian Langstaff?

4 PROFESSOR EVANS: Yes.

Q. Professor Prieto-Alhambra, you, is this right, are an 5 6 expert in pharmacoepidemiology. What is the discipline 7 of pharmacoepidemiology, succinctly?

8 PROFESSOR PRIETO-ALHAMBRA: Yeah, it's a specialty of 9 epidemiology where we study the use, the safety, and the 10 benefits of medicines and vaccines in the general 11 population or in wide populations.

12 Q. And is the element of epidemiology in

13 pharmacoepidemiology reflective of the fact that you're 14 dealing with the impact of medicines and vaccines, and

15 their safety at population level? You're looking at

16 trends, you're looking at the reality of the impact of

17 the medicines and the vaccines.

PROFESSOR PRIETO-ALHAMBRA: Indeed, that is right. And also 18 19 the use of observational data, typically, rather than 20 randomised control trials.

21 Q. Have you trained and practised for many years as 22 a medical doctor both in general practice, also in

23 musculoskeletal sciences and rheumatology, and therefore

24 you've got considerable experience of the clinical

25 diagnosis and management of the some of the conditions

1 upon which you opine in your report?

2 PROFESSOR PRIETO-ALHAMBRA: That is correct.

- Q. You very properly raised with the Inquiry the fact that,
 during the pandemic, you spent some time supervising
 a PhD student who was embedded within the UK Health
 Security Agency. You also did some consultancy work
- 7 providing AstraZeneca with general advice on how to
- 8 design observational studies for the monitoring of
- 9 vaccine safety, but you are at pains to point out, quite
- rightly, that you didn't conduct any studies for them or
- 11 studies funded by them in relation to Covid-19 vaccines,
- 12 and you obviously, therefore, weren't involved in any
- shape or form in AstraZeneca's take on the production,
- 14 manufacture, authorisation of their Oxford-AstraZeneca
- 15 vaccine or the issue of TTS or thrombocytopenia and so
- 16 on.

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17 PROFESSOR PRIETO-ALHAMBRA: That is all correct.

- 18 Q. In your case, Professor Prieto-Alhambra, have you been
 19 greatly assisted by a number of co-authors, all of whom,
 20 I think, are at the Nuffield Department of Orthopaedics,
- 21 Rheumatology and Musculoskeletal Sciences at Oxford?
 22 Dr Annika Jödicke, Dr Edward Burn, Dr Xie and Dr Li.
 - They have all helped you in relation to some parts of
- 24 your report and provided information and data, but the
- 25 report is your work?

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- 1 not proceed through to clinical trials?
- 2 PROFESSOR EVANS: Very large numbers.
- 3 Q. And in very rough terms, what is the purpose of the
- 4 pre-clinical trial process? Does it focus on safety?
- 5 Does it focus on whether or not the product works?
- Whether or not it has unexpected side effects? What is
- 7 the purpose of the laboratory angle?
- 8 **PROFESSOR EVANS:** The laboratory angle is really to
- 9 understand the way it is likely to work in the human
- 10 body, and in particular, what kind of dose of the
- 11 product is likely to -- what sort of dose range among
- 12 the vast possibilities. It doesn't really look at
- 13 efficacy or safety at that stage.
- 14 Q. And, therefore, only if the tests are satisfactorily
- 15 completed at that stage may the product then be tested 16 on humans?
- 10 On numans?
- 17 **PROFESSOR EVANS:** Yes, they will look in animals for things
- 18 like cancers that might only take a few weeks to develop
- in an animal, whereas in a human being it might take
- 20 tens of years.
- 21 **Q.** And then the clinical study phase, does that comprise
- 22 three phases, in fact, pre-authorisation, phases I, II
- 23 and II?
- 24 **PROFESSOR EVANS:** Yes, those are labels that -- there are
- overlaps between them.

- 1 PROFESSOR PRIETO-ALHAMBRA: Indeed, and with the review of
- 2 the literature, which was substantial.
- 3 Q. With the review of?
- 4 **PROFESSOR PRIETO-ALHAMBRA:** The literature, the published evidence.
- 6 Q. Ah yes, we'll come to that in a moment.
 - Yes, there we are.
- 8 So we're going to start, please, Professor Evans,
- 9 with your report because you focus on the systems and
- the processes and we need to address those first and get
- 11 them in our minds. And we are going to start with the
- 12 issue of trials.
- 13 The scientific process of trialling vaccines starts
- in the laboratory, does it not, with what are known as
- in vitro studies? What are they? Are they clinical
- 16 trials carried out on people or are they laboratory
- 17 tests?
- 18 **PROFESSOR EVANS:** They're laboratory tests.
- 19 $\,$ **Q.** And can a manufacturer, hoping to produce a medicine,
- 20 whether it's a vaccine or not, proceed to the clinical
- 21 trials without having passed successfully through the
- in vitro, the laboratory aspect of the trial process?
- 23 **PROFESSOR EVANS:** They have to go through that, and through
- 24 animal studies as well.
- 25 Q. And do many products, many studies end at that stage and

- 1 Q. Is phase IV a term given to such trials as may be
- 2 conducted post-authorisation --
- 3 PROFESSOR EVANS: Yes.
- 4 Q. -- focusing of course on clinical use?
- 5 PROFESSOR EVANS: Yes.
- 6 Q. Because post-authorisation the medicine will be in
- 7 general use or in use, and therefore can be given to
- 8 patients?
- 9 PROFESSOR EVANS: Yes.
- 10 Q. All right. So just focusing, then, on phases I, II, and
- 11 III, could you broadly delineate between them, please,
- 12 Professor? Phase I, what does it focus on?
- 13 PROFESSOR EVANS: Phase I is going to focus on whether we've
- 14 got the dose right, usually in healthy volunteers,
- 15 particularly for drugs, you will not be using people who
- have got the disease that you're targeting, but for
- 17 vaccines, healthy people are your target. So you test
- 18 whether the dose seems to cause a really nasty adverse
- 19 effect or not, because you won't necessarily know that
- 20 beforehand.
- 21 Q. Phase II?
- 22 PROFESSOR EVANS: Phase II, you're beginning to -- you're
- 23 moving up the scale and you're beginning to be able to
- 24 understand whether the drug has the effect or the
- 25 vaccine has the effect you expect it to have, and you

- 1 will generally be measuring biochemical things within
- 2 the body's response, the so-called immune response to
- 3 the vaccine, to see whether that is happening in the way
- 4 you expect it to in phase II. And again, ensuring that
- 5 you narrow down the dose that -- you will have started
- 6 with a potentially very wide dose range, and you
- 7 gradually narrow it down to the optimal dose range.
- 8 Q. So phase II proceeds on the premise that the vaccine has
- 9 broadly the desired effect, but it's a question of
- 10 measuring more precisely its impact --
- 11 PROFESSOR EVANS: Yes, you're --
- 12 Q. -- particularly for the purposes of deciding dose?
- 13 PROFESSOR EVANS: You're measuring the effect of biochemical
- things happening, the immune response in the body,
- 15 rather than the response to the virus.
- 16 Q. At the phase II stage, what size, in general terms,
- 17 might the participant group be?
- 18 PROFESSOR EVANS: Typically in the tens to perhaps in the
- 19 hundreds.
- 20 Q. And in all the phases, is the closest attention paid, of
- 21 course, to the consequences of providing the vaccine or
- 22 medicine -- and I emphasise the vaccine is just form of
- 23 medicine -- to the participant?
- 24 PROFESSOR EVANS: Yes.
- 25 Q. So these are very, very closely scrutinised procedures?
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- 1 that randomisation a reflection of the giving on
- 2 a random basis of the proposed medicine to some
- 3 participants, but a placebo or a control to others?
- 4 PROFESSOR EVANS: Yes, the idea is that you can be certain,
- 5 within probability limits, that two groups, or more than
- 6 two groups, are the same in every respect, whether you
- 7 can measure those things or not.
- 8 Q. And so the outcome, the figures, the results, will be
- 9 indicative of the impact, they will reflect the impact
- 10 of the proposed medicine?
- 11 PROFESSOR EVANS: Yes.
- 12 **Q.** Because that is the only basis upon which there can be
- 13 a difference of outcomes?
- 14 PROFESSOR EVANS: Exactly.
- 15 Q. And how important is it that a randomised controlled
- trial approach is applied in terms of eliminating bias
- 17 or rogue figures, or erroneous outcomes?
- 18 PROFESSOR EVANS: It is absolutely vital because otherwise
- 19 you don't know whether the people who get vaccinated are
- 20 the same, either in their characteristics or in their
- 21 behaviour, as those who are unvaccinated. So when I was

- 22 a participant in the trial, I didn't know what I was
- 23 getting, and I thought I was getting the placebo because
- 24 I didn't have any strong reactions. In fact I got the
- 25 real thing. But had I known what it was, I might have

- 1 PROFESSOR EVANS: Yes.
- 2 Q. Phase III, what is the difference with that? What
- 3 does it focus on?
- 4 PROFESSOR EVANS: For vaccine trials, you then will be
- 5 interested in whether people get the infection that
- 6 you're trying to prevent, so if it's Covid-19, you
- 7 actually test them to see whether they get that, rather
- 8 than simply whether their body is producing antibodies.
- 9 Q. So whether it works in practice?
- 10 PROFESSOR EVANS: Whether it works in the way that will make
- 11 a difference to the diseases in the population.
- 12 Q. And is safety and the possibility of side effects
- 13 something that is even more closely scrutinised in
- 14 phase III'
- 15 **PROFESSOR EVANS:** Yes, I would say they're probably of equal
- 16 scrutiny
- 17 Q. And in terms of participant numbers, what sizes may
- 18 a phase III trial amount to?
- 19 **PROFESSOR EVANS:** In drugs it will still typically be in the
- 20 hundreds or perhaps into the thousands but with
- 21 vaccines, particularly more recent vaccines, it's in the
- 22 thousands and ten thousands.
- 23 Q. You refer repeatedly throughout your report to what is
- 24 elsewhere known as the gold standard of trial
- 25 procedures, namely a randomised controlled trial. Is
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- 1 changed my behaviour.
- 2 Q. And you might have misreported perhaps even your
- 3 symptoms or any kind of reaction?
- 4 PROFESSOR EVANS: I might have behaved in different ways.
- 5 Q. That was a blind trial, because you didn't know whether
- 6 you were receiving the vaccine or a placebo. What is
- 7 a double-blind trial?
- 8 PROFESSOR EVANS: A double-blind trial is where the
- 9 participant and the investigator giving it to them do
- 10 not know.
- 11 Q. So who knows whether each participant is receiving --
- 12 PROFESSOR EVANS: It will be a statistician like me who has
- 13 hidden away the list of which treatments it is, and the
- 14 pharmacist or the manufacturer who has got the code that
- 15 says, "Bottle number 23 has the real thing".
- 16 **Q.** I now simply can't recall whether I've asked you to
- opine on the general size of phase III trials.
- 18 **PROFESSOR EVANS:** Yes.
- 19 **Q.** I have?
- 20 LADY HALLETT: Different for drugs and different for
- 21 vaccines.
- 22 MR KEITH: Thank you very much.
- 23 In the context of the three Covid-19 UK vaccines
- that we're focusing on, and they are the AstraZeneca --
- 25 Oxford-AstraZeneca, the Pfizer BioNTech and the Moderna

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1 vaccines only, were there phase III trials in the 2 majority or exclusively randomised controlled trials?

3 PROFESSOR EVANS: Yes.

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Q. Were they double-blind or blind?

5 PROFESSOR EVANS: They were in some instances double-blind,

in some instances single-blind. That was that the

investigator did know in principle what the -- whether

8 it was the real vaccine or a control being given.

9 Q. With that size of phase III trial in mind, why can they 10 not be even larger?

11 PROFESSOR EVANS: The problem is that you will run the trial

and generally there will be a data monitoring board that

13 will look at the key outcomes. In the phase III trial

it will be clinical infection. And you will ethically

need to stop the trial, or stop recruitment to the

16 trial, when you have convincing evidence of efficacy,

because otherwise, you are subjecting your control group

18 to no treatment or a treatment that is -- we know would

be ineffective, when we know that there is an effective

alternative. And that is regarded by most people as

21 unethical

22 Q. Essentially, it is unfair on the participant to oblige

them to continue to take part in a trial that's ongoing

when it's obvious that the vaccine which is being

25 trialled can actually provide a real-world solution to

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- 1 evidence that there could be a problem, to investigate 2
 - things more carefully, and the data monitoring board
- 3 will be an adviser to the investigators who don't know
- 4 what the results are showing, saying is it efficacious
- 5 or not? Is it ethical to continue randomising new
- 6 patients to this trial?
- 7 Q. And what sort of people generally make up the data and
- 8 safety monitoring board? You said it's independent, but
- 9 are --

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- PROFESSOR EVANS: They're independent but they are typically 10
- 11 about five people, maybe six people. They will
- 12 generally have a very experienced clinician who is chair
- 13 of it, but occasionally, it can be a statistician who is
- 14 chair of it. I have chaired data monitoring committees
- 15 in the past, but you require somebody who, as
 - Professor Chris Whitty said, it's important to get the
- 17 people right, and getting the people right is a key
- 18 component. So you have people with experience in
- 19 vaccines but you will also usually have a statistician
- who can help you with the numbers. 20
- 21 You also refer to a different body, a trial steering
- 22 committee, which appears to conduct the trial or be
- 23 responsible for the conduct of the trial. By contrast,
- 24 is it staffed by not just independent scientists but
- investigators and representatives of the manufacturer? 25 15

the terrible pathogenic disease -- (overspeaking) --

2 PROFESSOR EVANS: That's a subtly different point about the

3 continuation, it's a question of whether you recruit new

people. Is my new person going to come in and be likely

5 to have the placebo when there is an effective

6 treatment? And that would be regarded as unethical,

7 generally.

Q. We're going to turn a little later in more detail to the very important issue of whether it is at all likely that 10 very rare, serious side effects will be revealed by 11 a trial consisting of participants to be measured in the

tens of thousands, but I will come back to that.

12 13 In your report you set out much about the way in

14 which major trials are conducted, and you refer to the

15 existence of something called a data and safety

16 monitoring board. You've already referred to it already

17 this morning. What is that?

PROFESSOR EVANS: It's a group of independent people who 18

19 will have access to the data that nobody else has access

20 to, and will look at the results and say, for example,

21 is there an adverse effect occurring with the vaccine

22 that is occurring at such a rate that it suggests

23 a significant harm? And if that were a serious adverse

24 effect, then they may want to entirely stop the trial.

They may pause the trial if there is just slight 25

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PROFESSOR EVANS: Yes.

- 2 Q. And is it that body, the trial steering committee,
- 3 which, as it says on the tin, steers the progress of the
- 4 trial and hopefully to its conclusion?
- 5 PROFESSOR EVANS: (No audible response).
- 6 Q. As a general rule, indeed as a principle, will there
- 7 ever be a representative from the manufacturer, the
- 8 investigator or somebody else in the company, present at
- 9 the data and safety monitoring board when that board is
- 10 discussing matters such as unblinded data, ie who gets
- 11 the placebo or the vaccine, and talking about highly
- sensitive issues concerning the -- (overspeaking) --12
- PROFESSOR EVANS: I cannot say that that never happens but 13
- 14 I'd never participate in a board in which the
- 15 manufacturer was present. It must be extremely rare if
 - it does occur. I can't say never.
- 17 **Q.** And the presence and the role of the data and safety
- 18 monitoring board is reflective, is it not, of the
- 19 extraordinary importance which is placed on safety and
- 20 monitoring safety, and observing the possibility of side
- 21 effects in the course of the trial process?
- 22 PROFESSOR EVANS: Yes.
- 23 Q. Right. Elsewhere in your report, page 31, in fact, but
- 24 we needn't go to it, you refer to the fact that
- randomised trials for the Covid vaccines were conducted 25

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1 in many countries and many regulatory authorities were 2 involved. The three Covid-19 UK vaccines were trialled 3 in some cases in the United Kingdom and abroad, and 4 I think in one of the cases exclusively abroad?

PROFESSOR EVANS: (Witness nodded).

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- 6 Q. But between, as between the trials conducted in the 7 United Kingdom and those conducted abroad, were there 8 any significant differences in terms of the structures 9 that were applied, the presence of a data and safety 10 monitoring board, the use of blind and double blind 11 randomised controlled trials, and the safety set-up for 12 the regulation of those trials?
- 13 PROFESSOR EVANS: No, they're all done in exactly the same 14 way according to a very rigidly set-out protocol. It is 15 the different centres that exist within a single trial.
- 16 Q. And we'll hear a bit more from Professor Prieto-Alhambra 17 a bit later, but were in fact some of the thresholds, 18 some of the scientific requirements, for example, the 19 degree of confidence in the efficacy of a vaccine, the 20 way in which the products were to be trialled and 21 investigated, agreed between certain western European, 22 American and Canadian regulators?
- 23 PROFESSOR EVANS: Yes, international regulators agree.
- 24 International regulators. So the whole process of the 25 safety monitoring, the trialling and the authorisation
- 1 level, so that you get enough people who, on the control 2 group, sadly, will get the infection. And you will then 3 hope that the people on the vaccine will not get it, and 4 you need to have sufficient numbers that say I've got 5 convincing evidence that there is a real difference 6 here, and that the vaccine is effective.
 - Q. And in your professional opinion, were the numbers involved in each of these three vaccines at the requisite level?
- PROFESSOR EVANS: Absolutely. 10

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- 11 Q. Efficacy. The effectiveness of a vaccine.
- 12 Plainly, there is little point in developing and 13 manufacturing a vaccine that is safe but not effective?
- 14 PROFESSOR EVANS: Absolutely.
- Q. It serves no purpose. At which part of the clinical 15
- 16 trial process is efficacy generally determined? 17 PROFESSOR EVANS: For example, in the trial I was involved 18 in, then every week I had to take a swab from my throat 19 and my nose and send it in the post to a laboratory to 20 see whether I had had Covid infection. In other cases, 21 some of the trials would only do that for people who felt ill and who might have Covid and so you had to 22 23 record whether somebody got the infection or not, or 24 whether, in the other trials, it was a clinically

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relevant infection.

- 1 of all these vaccines was very much an international 2 enterprise?
- 3 PROFESSOR EVANS: Very much.
- 4 Q. Regulated nationally, but based upon agreed structures, 5 approaches, standards and thresholds internationally?
- 6 PROFESSOR EVANS: Yes.
- 7 Q. All right. Elsewhere in your report, on the subject of 8 trials, you refer to the trial sizes and you make the 9 point, and you've already made it this morning, that 10 once efficacy has been shown, continuing to recruit 11 sufficient numbers would be unethical.

What determines the precise size of the trial in respect of a particular medicinal product or vaccine? We note that although all trials were, I think, between 20 and 30,000 at phase III level, some of them had more trials in more countries than others. What determines that?

- 17 PROFESSOR EVANS: There are practical considerations as to 18 19 how many countries are involved but what you want to 20 ensure, in terms of vaccine trials, is in phase III in 21 particular, you're trying to prevent the disease. So if 22 the disease is not occurring, if the virus is not 23 circulating in the country, then you don't want to do 24 a trial in that country. You want to do the trial in 25 the place where the virus is circulating at a high
- 1 Presumably, a vaccine as with many medicines, will have 2 an impact on the body at a number of different levels. 3 In the context of a vaccine, what a vaccine in general 4 terms tries to do is to provoke the body into producing 5 antibodies to fight the infection. But the body's

antibody system is, no doubt, a very complex one.

- 7 I think there are B cells, T cells, and any number of
- 8 different levels of response. Is that -- is the nature of that response clinically examined in great deal, as 9
- 10 part of the clinical trial process?
- PROFESSOR EVANS: Yes, and it's important, as you say, that 11
- 12 the vaccine is there to train the body to provide
- a means of fighting the virus. A drug doesn't do that. 13
- 14 A drug attacks a virus, or some other element of the
- 15 disease, directly. A vaccine does not have an effect 16 directly on the virus.
- 17 Q. It can't be very straightforward to measure the antibody 18 response of the human body?
- 19 PROFESSOR EVANS: It's not -- these days, it's not that 20 difficult.
- 21 Q. It's not that difficult but is there, nevertheless, a 22 system by which one can say how confident one is as to 23 the degree of effectiveness or efficacy?
- 24 PROFESSOR EVANS: When you first start with a new vaccine, 25 you aren't absolutely sure that the antibodies you

1	measure will reflect the clinical reality of preventing
2	clinical disease. But after you've done a few trials,
3	you then find that there are measurements of antibodies
4	that will predict the clinical disease, and those are
5	the ones that you concentrate on measuring in the
6	future.

- Q. And coming back to the issue of what was agreed at the international level, was agreement generally reached as to the process by which degrees of confidence could be expressed or had to be expressed publicly about the
- 11 degree of effectiveness?12 PROFESSOR EVANS: Yes, it's -- (overspeaking) --
- 13 Q. We can see in the paperwork: vaccine X is 80% effective14 with a confidence level of between X and Y?
- PROFESSOR EVANS: Yes, and the idea is that when you didn't know anything, you kind of assume that it would be similar to a flu vaccine effectiveness, and so most of the regulators required at least 50 and possibly even 60% vaccine efficacy. But you needed to be sure that it
- 20 wasn't below a certain level and in Europe and America
- they had slightly different views on how low the uncertainty could be.
- 23 **Q.** Safety. Conceptually, is safety something that is open

to objective measurement?

- 25 **PROFESSOR EVANS:** It's very difficult. Safety is 21
- Q. And is that why there are what is known as
 pre-authorisation safety studies and post-authorisation
 safety studies?
- 4 PROFESSOR EVANS: Yes.

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- Q. Because after authority is given, and once the product
 is being rolled out, there is a flood of new and
 important data concerning the clinical use of that
 product in real-world conditions?
- 9 PROFESSOR EVANS: Yes.
- 10 Q. All right. And is that why the post -- it's known as
 11 the post-authorisation monitoring process, or safety
 12 process, is so very important?
- 13 PROFESSOR EVANS: Yes.
- 14 Q. I think we've seen somewhere that within two days of the
 rollout of the Pfizer BioNTech vaccine in the
 United Kingdom, there were more vaccines delivered than
 there had been in the entirety of all preceding clinical
 trials?
- 19 **PROFESSOR EVANS:** Yes, I believe that to be true.
- Q. Right. All medicines, including vaccines, may give rise
 to a side effect, that is to say something that's
 undesirable, not what is intended?
- PROFESSOR EVANS: I know of no effective medicine that does
 not have unwanted effects, usually adverse.
- 25 **Q.** We've seen in the paperwork references to a number of 23

1 a euphemism, I think, for harm. We can only measure

2 harms, and safety is the relative absence of harm. So

3 we look for harms. And when we start out, we think

4 there will be a certain kind of harm for a vaccine.

5 Most people will get a sore arm when they get the

6 injection, some will get a headache, some will get

a slight fever, but you will check very carefully that
 there aren't very many people getting a very high fever,

and the district very many people getting a very might lev

9 39 degrees or 40 degrees, and potentially causing

serious illness. And so you check very carefully for

11 those things.

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drua.

Q. So it simply cannot be said of any product, let alone
a vaccine, it is safe or it is not safe. What is
required to be done is to analyse the relative safety of
the product by examining the benefit and comparing it to
the risk?

17 PROFESSOR EVANS: Absolutely. And this also develops over 18 time. Our knowledge basically increases. I've talked 19 about this as a map, and that we're trying to explore 20 the entire territory of the effect of a drug. And at 21 first, we only know a little bit about that map, but 22 gradually, as we use it more, have bigger trials and 23 then start to use it, we will extend our knowledge and 24 we'll have mapped the knowledge of that area of the

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descriptions and a number of terminological phrases,
adverse events of special interest, serious adverse
reactions, adverse effects, adverse reactions, adverse
drug reactions and suspected unsuspected serious adverse
effects.

You won't, I think, agree with this proposition, but by and large we're talking about side effects?

PROFESSOR EVANS: Yes.

Q. Right. Coming back to the trial process, if a side 9 10 effect, that is to say something that is not sought, it's not what the purpose of the product is, and it's 11 12 undesirable, if it is rare or very rare or extremely 13 rare, and the MHRA defines each of those words by 14 reference to the statistical likelihood of them 15 occurring, one in 10,000 for rare, I think one in 16 100,000 for very rare, and fewer than one in 100,000 is 17 generally regarded as being extremely rare.

18 If a side effect is rare, very rare or extremely 19 rare, is it likely to appear in a trial consisting of 20 around 30,000, 40,000, 50,000 participants?

PROFESSOR EVANS: Simply put, the very rare and extremely
 rare will not be seen, even, in the trials generally,
 unless by chance.

Q. Because obviously, if a side effect will only appear one
 in every 100,000 cases, a trial of 50,000 will not reach

that point at which, statistically, the occurrence is likely to occur?

PROFESSOR EVANS: Yes. We can say what the probability of having one in that 50,000 -- even if it occurs generally at one in 100,000, in the 50,000 it might occur, but you wouldn't get -- it would be very unlikely that you got two occurring in 50,000.

8 Moreover, and perhaps it's even more difficult 9 a concept, if a person takes a vaccine, receives 10 a vaccine, and there is then a medical condition that becomes apparent, a reddening of the arm, or some 11 12 medical condition, the issue immediately arises as to 13 whether or not that appearance is coincidental or was 14 caused by the taking of the vaccine, or, I suppose, 15 might have been the result of Covid-19 itself, in this 16 case, because a person might be infected with Covid 17 unknowingly and then be vaccinated. So can you ever 18 immediately tell from the mere existence or presence of 19 a medical condition that it was necessarily caused by

the vaccine?

PROFESSOR EVANS: Very difficult indeed, in individual cases. And that's why we have a randomised trial in which we can have a large number of people, and when there is an excess in the vaccinated group and we do the statistical analysis on it, we can find that there is

Q. And how long, in general terms, do those sorts of
 reactions or conditions take to appear and disappear?

PROFESSOR EVANS: They take generally from hours to a very
 few days. Generally less than a week.

Q. What can be done about a condition or a reaction that
 may, in the human body, take weeks or months or maybe
 even years to develop and therefore appear?

8 PROFESSOR EVANS: For weeks and months the trials will go on following up people. And even when a trial stops
10 recruiting, and as in the case of the AstraZeneca trial
11 I was in, the licensed vaccine became available, and
12 I asked to be unblinded to see whether I had. But I was
13 continued to be followed up for another year or more to
14 see whether there were adverse effects of any serious

15 16 Q. And what can -- or further, or moreover, be done about 17 what is known as the multi-hit impact, that is to say 18 a person taking a vaccine and suffering already from 19 other conditions, comorbidities, perhaps, or being 20 subject to environmental factors which means that the 21 combination of taking a vaccine, alongside their 22 pre-existing or to-be-developed condition externally, 23 brings about an unexpected, or unlikely consequence?

PROFESSOR EVANS: These are the very rare reactions that wewill not be able to study easily in a randomised trial.

1 convincing evidence.

And the randomised trial means that other factors
that might explain it will not be a possible
explanation, whereas in observational studies, it is
much more difficult.

Q. Presumably, there are some responses to the taking of a vaccine in particular, which has to be injected, known as reactogenicity or conditions associated with reactogenicity, which are obviously connected to the vaccine because they might be a reddening of the arm or having, I don't know, flu-like symptoms within an hour of taking the vaccine.

13 In relation to that sort of side effect, are they14 generally ever severe or serious?

15 PROFESSOR EVANS: Almost all vaccines, if they've got as far
 16 as being trialled in phase III, will not have a high
 17 rate of the higher, more severe reactions. But that is
 18 what the phase III trial will be looking for: to check
 19 that there isn't a high rate of the more severe forms.

Q. Can you say whether or not the vast majority of the side
 effects or reactions to the vaccines in the phase III
 trials were of that type?

23 PROFESSOR EVANS: Yes.

24 Q. Mild, momentary, reactogenicity-type reactions?

25 **PROFESSOR EVANS:** Yes.

26

Q. And so what is done about them in terms of
 post-authorisation monitoring?

PROFESSOR EVANS: Well, we need to have very large numbers
 of people vaccinated, and we need to see what their
 health effects are, both immediately after, and also

6 months and perhaps years after the vaccine.
7 **Q.** And in light of all that, do you conclude for the record, at page 16 of your report, that whilst it is

9 relatively easy to detect frequent and rapid onset 10 adverse effects, it is much more difficult to detect 11 rare and serious or delayed side effects?

12 PROFESSOR EVANS: Yes.

13 Q. And that is why so much scrutiny must be paid to the
 post-authorisation, post-marketing surveillance as it's
 known.

Quality. We needn't, I think, spend a great deal of time on quality. It's not within the scope, in fact, of this module, but presumably a significant part of the authorisation in the trial and the checking processes, as well as the regulatory scrutiny, focuses on quality. So not just effectiveness or safety, but whether or not it's good quality.

23 PROFESSOR EVANS: Yes.

24 Q. And on that point, does each regulator, and including
 25 the MHRA, test medicinal products including vaccines for
 28

I		their quality?
2	PR	OFESSOR EVANS: Yes.
3	Q.	And is there a process by which laboratories, in the
4		MHRA's case, the what were known as the National
5		Institute for Riological Standards and Control

6 laboratories, test each batch?

41- - !-- --- - 1!4- -0

PROFESSOR EVANS: Yes, they're the world leaders in thefield.

9 Q. Can that testing test for safety and effectiveness or10 does it -- can it only test for quality?

PROFESSOR EVANS: It can only test for quality but some
 aspects of the quality will lead to adverse effects.
 Impurities may well lead to infections.

14 Q. Just give us some idea of the scale of this, please,
15 Professor. How big is a batch? How many doses does
16 a batch have?

17 PROFESSOR EVANS: Well, with vaccines, a batch is made as 18 a biological process rather than a chemical process, and 19 so they're rather variable in size. I'm not an expert 20 in that field but I would understand that typical 21 batches will have between a few thousand doses and a few 22 hundred thousand doses. It doesn't have millions of 23 doses generally, nor does it have tens or hundreds, but 24 it's thousands to tens of thousands, and probably

25 typically, I would have thought, about 50,000 doses. 29

across the world, by any number of different regulators?

PROFESSOR EVANS: They may well have been, yes.

Q. The authorisation process, please. All countries, by

and large -- well, I've just detracted from my own - departed from my own question. Do most countries
 regulate the marketing and supply of medicines?

7 PROFESSOR EVANS: Yes.

8 Q. In the case of the United Kingdom, and it's the whole of9 the United Kingdom, is it the MHRA?

10 PROFESSOR EVANS: Yes.

11 Q. The MHRA is nominally part of government, but is it infact an independent regulator?

13 PROFESSOR EVANS: I think they would fiercely --

14 Q. They would object to that description, would they?

15 PROFESSOR EVANS: -- object to the idea that they were part
 16 of government. They are --

17 **Q.** They are part of the state, maybe?

18 PROFESSOR EVANS: They are part of the state but they arevery much independent.

20 Q. They -- I think, actually, nominally, they regard
 21 themselves as being part of the DHSC, but yes --

22 PROFESSOR EVANS: Yes, administratively they come under the

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Department of Health, but this is a separation of

24 powers --

25 Q. So operationally --

1 But it may be rather larger.

I also understand, but I'm -- as I say, I'm not an
 expert in that area, but as the experience with the
 manufacturing process improves, then the batch size may
 become steadily larger.

Q. Do you understand, and there is clear evidence that the

7 MHRA's laboratories test every single batch, that the 8 batches that are tested are the product of the same 9 manufacturing process in respect of each vaccine? So if 10 you test every batch, you haven't got a position in

10 you test every batch, you haven't got a position in

which half the batches are being made by an offshore different manufacturing process than the other half?

13 PROFESSOR EVANS: They're meant to be made under exactly the
 14 same process. But it's a biological process and that's
 15 why particularly with vaccines it's important to check

16 their quality.

Q. And presumably the batch testing is something which is
 also open to international regulation and agreement and
 scrutiny, and therefore the MHRA's processes for batch
 testing would be very much aligned with the near

identical or very similar processes being conducted by other regulators?

23 PROFESSOR EVANS: Yes.

Q. Does it follow that the UK Covid-19 vaccines would
 therefore have been tested, because they were rolled out

PROFESSOR EVANS: Their operation and their powers are
 independent of government.

Q. Yes. And in the case of the UK Covid-19 vaccines, are
you aware of how they ramped up the number of staff and
the scope of their functions and what they were doing in
order to be able to deal with the unprecedented
authorisation process?

8 PROFESSOR EVANS: Yes.

9 Q. You've already mentioned, along the way, something about
 10 the skill and the standard of the MHRA. Where does it
 11 stand in the world rankings in terms of skill,

12 diligence, robust overview?

13 PROFESSOR EVANS: I think in terms of its size, it is
14 certainly in the top five. At one stage I think it
15 might have been regarded as the world's premier
16 regulator but probably most people would regard the FDA
17 in America, the Food and Drug Administration, which is
18 a massive body with enormous amounts of funding, as

being the world premier regulator.
 Does, in fact, the MHRA not just regulate and authorise
 medicinal products and medicines in the United Kingdom,
 but scrutinise and check, and study medicinal products

23 and medicines from elsewhere in the world, and I think

24 provide semi-regulatory or scrutinising processes for

25 other people?

- PROFESSOR EVANS: Yes, though the European Medicines Agency 1 2 does rather more of that.
 - Q. All right. And we'll hear more from Dame June Raine later, but the MHRA is greatly assisted, is it not, by
- 5 what is known as the -- a committee known as the
- 6 Commission on Human Medicines which provides expert
- 7 advice and we've seen from the paperwork that in
- 8 relation to every aspect of safety regulation in this
- 9 case, there are very, very learned, detailed papers
- 10 produced and meetings held in respect of giving advice
- 11 to the MHRA on safety issues?

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- 12 PROFESSOR EVANS: (No audible answer).
- 13 Q. How important are the expert workings that fall within
- 14 the scope of the Commission on Human Medicines?
- PROFESSOR EVANS: Inevitably any finite group of people 15
- 16 can't have all the expertise, and so having expertise
- 17 for particular areas such as vaccines, they won't -- on
- 18 the main CHM, it won't have all vaccine experts on it,
- 19 but the vaccine working group is a specialist group and
- 20 they will all have expertise in vaccines. So it's a way
- 21 of broadening the depth, as well as the range of
- 22 expertise available to the MHRA.
- 23 Q. When the MHRA looks at safety, and quality and
- 24 effectiveness for the purposes of deciding whether to
- 25 authorise a medicinal product, is it concerned with cost
- 1 Q. And there's a significant section in your report which
- 2 emphasises that there are bodies across the
- 3 United Kingdom, NICE in England and Wales, the Scottish
- 4 Intercollegiate Guidelines Network in Scotland, and the
- 5 Scottish Medicines Consortium, and in Northern Ireland,
- 6 NICE is applied through their devolved structures, which
- 7 are concerned with the issue of whether or not
- 8 a particular medicinal product should be offered to
- 9 members of the public clinically, but they have no role
- 10 whatsoever in the issue of safety, do they?
- PROFESSOR EVANS: No. 11
- Q. The authorisation in relation to the UK vaccines was 12
- 13 granted under what's known as Regulation 174 of the
- 14 Human Medicines Regulations. A number of people have
- 15 observed that that is a UK legal provision, it's a UK
- 16 regulation, 174, and it is not the legal structure which
- 17 was and is applied at the European level at the European
- 18 Union, to which -- of which we were part until 11 pm on
- 19 31 January 2020.
- Is the regulatory system under 174 in fact derived 20
- 21 from a European directive or regulation?
- PROFESSOR EVANS: Yes, it was a European regulation, 22
- 23 effectively, that was allowed under European law in
- 24 public health emergencies, for any member state to take
- 25 their own action for a public health emergency, and

- or the practicalities of delivery? 1
- 2 PROFESSOR EVANS: No.
- 3 Q. In this case, in relation to the three Covid-19 UK
 - vaccines, the MHRA authorised each vaccine with varying
- 5 conditions?

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- 6 PROFESSOR EVANS: Yes.
- 7 Q. So the MHRA cannot just authorise a vaccine, it can put
- 8 conditions on --
- 9 PROFESSOR EVANS: Yes.
- 10 Q. -- the scope of the authorisation?
- PROFESSOR EVANS: Yes. 11
- Q. And by and large, we needn't look at them in detail, 12
- 13 there were conditions placed by the MHRA in relation to
- 14 age, in relation to dosage interval, and in relation to
- 15 whether or not certain sectorial groups should be,
- 16 subject to the advice of the JCVI and the government,
- 17 offered a vaccine?
- PROFESSOR EVANS: Those would be called the indication and 18
- 19 they do that all the time for all medicines. There may
- 20 be additional conditions when the knowledge on something
- 21 is rather more limited, and they specify that extra
- 22 studies must be done, and it requires those to be done
- 23 before they get a full marketing authorisation, and that
- 24 specific post-authorisation safety studies may need to
- 25 be carried out.

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- 1 Hungary did the same, and they were part of the EU and
 - still are, for the moment at least.
- 3 Q. And Regulation 174 existed prior to our departure at the
- 4 end of the transition period --
- 5 PROFESSOR EVANS: Yes, it was under the 2012 law.
- 6 **Q.** And it continued to exist following our departure?
- 7 PROFESSOR EVANS: It did.
- 8 Q. Northern Ireland, as it happens, remained after the
- 9 transition period part of the European medicinal
- 10 regulatory structure, but did Regulation 174
- 11 nevertheless apply to Northern Ireland, and was
- 12 available to be utilised in the context of Northern
- Ireland? 13
- 14 PROFESSOR EVANS: That is my understanding. I'm not
- 15 a lawyer.
- Q. All right. 16

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- 17 PROFESSOR EVANS: But I think one of the other things is
- 18 that there is a European procedure, and the Pfizer
- 19 vaccine was authorised under European law prior to the
- 20 end of 2020, and the consequence was that the UK had
- a marketing authorisation under European law that was 22 then carried over into 2021. So it's a very complex
- 23 legal issue caused by Brexit in that instance.
- 24 Q. But because of the use of Regulation 174, a consistent 25 approach could be applied in terms of the level of

- 1 scrutiny and legal authorisation across the whole of the 2 United Kingdom, and secondly, was there any difference 3 in substance --
- 4 PROFESSOR EVANS: No.
- 5 Q. -- between the UK regulatory authorisation process, and 6 the Europeans'?
- 7 PROFESSOR EVANS: No.
- 8 Q. Finally, then, on this topic, when authority came to be
- 9 considered in respect of each of these vaccines, it's 10 plain from the evidence that an issue had arisen in
- relation to AstraZeneca, in July and September of 2020, 11
- 12 of a very, very small number of cases of what is known
- 13 as transverse myelitis appearing. The existence of
- 14 those handful of cases paused in both occasions -- on
- 15 both occasions, the trial process, but they were
- 16 recommenced, and they didn't prevent the authority being
- 17 given, ultimately, for the use of the vaccine,
- 18 because -- and we needn't go there -- it's clear that
- 19 the MHRA and the CHM, the Commission on Human Medicines,
- 20 determined that they were not causatively the result of
- 21 the vaccine.
- 22 Putting that issue aside, did any vaccine 23 manufacturer in any of these three cases report, during
- 24 the trial process, a SUSAR? That is to say the adverse
- 25 effect, the serious -- sorry, the suspected unexpected
- 1 PROFESSOR EVANS: Yes, it's usually in the manufacturer's
- 2 interests because they have to pay a big fee when they
- 3 ask for an authorisation, and so they wouldn't want to
- 4 submit until they're sure they've got a product that
- 5 works, because it's going to cost them a lot of money to
- 6 have it assessed.

- 7 Q. In relation to the authorisation process, was there
 - similarly a rolling review whereby, as a result of very
- 9 close, daily, hourly liaison between the MHRA and the
- 10 manufacturers, the data was constantly provided rather
- than being delivered in one fell swoop? 11
- PROFESSOR EVANS: Yes. 12
- 13 Q. In your opinion, did that more expedited and tweaked
- 14 process have any impact at all on the degree of
- 15 scrutiny, on the MHRA's understanding of the levels of
- 16 safety in the clinical trial process, or in relation to
- the authorisation process? 17
- PROFESSOR EVANS: No, I think the scrutiny is likely to have 18 19 been greater than in a single op.
- 20 Q. Could you elaborate on that? We, of course, are dealing
- 21 with the trial and authorisation process for vaccines
- 22 which are subject to incredible public scrutiny.
- 23 I mean, it was a matter of the greatest importance to
- 24 everybody. I mean, Covid presented almost, I suppose,
- 25 an existential threat. Can you express a view as to the

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- 1 serious adverse effect.
- 2 PROFESSOR EVANS: Adverse reaction, yes.
- 3 Q. Adverse reaction?
- 4 PROFESSOR EVANS: As far as I know, they did not.
- 5 Q. Right.

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- And is it your opinion, therefore, page 32 of your
 - report, that the authorisation process in the
- 8 United Kingdom was appropriate to the circumstances, was
- 9 based on a great deal of data, and in fact was
- 10 completely aligned to the approach of authorisation
- 11 considered and granted in other countries?
- 12 PROFESSOR EVANS: Yes, I would agree. And even if there had
- 13 been a few SUSARs, that wouldn't have affected it.
- 14 Q. Do you know of anything that the United Kingdom missed
- 15 in comparison with other countries at that time?
- 16 PROFESSOR EVANS: No.
- 17 Q. It is well known that in order to apply a more expedited
- 18 process, the MHRA altered its procedures for the receipt
- 19 of data in relation to the trial process and in relation
- 20 to the application for authorisation?
- 21 PROFESSOR EVANS: Yes.
- 22 Q. So in relation to the trial process, it allowed data to
- 23 be provided on a rolling basis rather than delaying the
- 24 whole system by waiting for the manufacturer to produce
- 25 all the data at the end in one fell swoop?

- 1 reality of the degree of scrutiny and care and attention 2
- that was applied by regulators across the western world?
- 3 PROFESSOR EVANS: I think there's no doubt that they were
- 4 aware that if they authorised a vaccine that was bad, 5 either in not being effective, or having serious adverse
- 6 effects at a sufficient rate to make the vaccine
- 7 regarded as useless, they were in real trouble. And
- 8 I think they are public spirited, and they worked every
- 9
- hour there was in order to carry out the assessment.
- 10 And by doing it in this rolling way, they became 11
- very familiar with the data. They were doing this 12 almost exclusively. There was almost nothing -- they
- 13 weren't doing work for the European Medicines Agency at
- 14 the time, and so I -- you'd have to ask Dame June Raine,
- 15 but I think that virtually everybody in that agency was
- 16 concentrating on doing it, and so the scrutiny was very
- 17 intense indeed
- Q. Professor Prieto-Alhambra, we're at the point where your 18
- 19 report, which deals largely with the more forensic issue
- 20 of particular side effects caused by the vaccines, or
- 21 associated with the vaccines, or which coincidentally
- 22 followed the receipt of the vaccines, but nevertheless, 23 you've expressed some views in an overall sense on the
- 24 regulatory and the authorisation process.
- 25 At paragraph 3.16 of your report you say:

"... it is my view that the modifications made to the ... safety regulatory system in response to the pandemic ... did not negatively affect the ability to effectively identify and respond to safety issues ..."

By that reference to modifications, are you referring to the way in which data was received in respect of the trials, and also the way in which data was received in relation to the applications for authorisation?

10 PROFESSOR PRIETO-ALHAMBRA: Indeed, Yes.

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Q. You too make the point that of course, given the scale of the trials, none of the potential serious adverse effects which were subsequently identified as being associated, that is to say, without expressing a view on whether they were causatively connected to the vaccines, none of those were known about at the time because they were all too rare to be detected even in a very large clinical trial?

19 PROFESSOR PRIETO-ALHAMBRA: I think Professor Evans 20 explained that elegantly with numbers.

21 **Q.** So you agree with what he said in relation to that?

22 LADY HALLETT: Professor, you have a very soft voice.

> I don't know if you always have a soft voice when you're speaking to your students but you do here. If you could

speak up, I would be grateful.

1 scientific literature which provides low quality, or low 2 to moderate quality, evidence for the proposition that 3 there is an association between vaccines and transverse 4 myelitis?

PROFESSOR PRIETO-ALHAMBRA: Indeed, that's our conclusion.

Right. I'm afraid that's all I'm going to ask you for the moment, Professor. We're back to Professor Evans.

Could we now spend a little time, not very long, dealing with the general obligation on manufacturers to tell regulators any information in their possession which relates to the safety of the product, or which might impact upon, post-authorisation, the conditions of the authorisation or the grant of authorisation itself. What can you say about the general extent of the obligation on manufacturers?

PROFESSOR EVANS: It's a legal requirement. 16

Q. Does that legal requirement extend to -- well, how far does that legal requirement extend, in terms of information relating to the safety of the product under manufacture? Is it anything to do with safety or is it anything which might impact upon the grant of authorisation? How is it assessed?

23 PROFESSOR EVANS: I think that one has to realise that it 24 isn't the manufacturer who is really doing the trials; 25 it is being done in hospitals or in general practices

PROFESSOR PRIETO-ALHAMBRA: I will do.

2 MR KEITH: Obviously that observation must exclude, of 3 course, the bringing to the attention of the MHRA and 4 the CHM, in July and September 2020, the handful of 5 cases of transverse myelitis in relation to AstraZeneca. 6 But that was a condition at that time, which was 7 presumably addressed in very great detail. Was a view 8 ever reached as to whether or not a causative connection q could be established between that handful of cases of 10 transverse myelitis and the vaccine, or was it 11 coincidental or perhaps associated with Covid-19 itself?

12 PROFESSOR PRIETO-ALHAMBRA: I think transverse myelitis is

13 one of these, I see, adverse events of a special 14 interest that we know, from previous experience with 15 other vaccines, could be potentially related to

16 vaccination. So it was greatly monitored very closely

17 by the MHRA and any other international regulators.

18 Despite that, the quality of the evidence on a causal

19 association is low, maybe moderate. There's a number of

20 studies, some of them good quality, with inconsistent 21 results.

22 Q. So there is -- and we'll look in more detail at the 23 nature of the literature review that you did, but

24 without going into it in detail, your overall view was

25 that there is material in the public domain by way of

around the world.

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2 Q. Well, that's phase IV.

PROFESSOR EVANS: No, but even in phase III, it's -- you are -- I was recruited through Southampton University Hospital, and so I was studied within an academic centre. And so even in phase III trials, they're being done with the real patients in the real world, but they're under very controlled conditions. And so those clinicians know that they have an absolute requirement 10 to report adverse effects to the investigators, who then 11 have to report it, and it's reported on to the data 12 monitoring board and to the manufacturer.

> And so the whole process means that if Stephen Evans got a really severe adverse reaction, there will be a nurse who starts with it and then a doctor and so on, and it will eventually end up at the MHRA through at least one mechanism, and very often there's multiple mechanisms whereby it can reach the MHRA.

So there is very considerable pressure on companies to keep to any legal requirement they have. It's possible that they will interpret the law in a slightly different way in different circumstances, but generally, my experience is that they're very good in that.

24 Q. And just so we're clear about this, and I won't awry my 25 question to you, the phase IV trials focus on the

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1 receipt of a vaccine or a product in clinical use.

2 PROFESSOR EVANS: Yes, so once --

- 3 Q. Because it's --
- PROFESSOR EVANS: Once it's been authorised, that's the 4
- 5
- 6 Q. It's been given to the public?
- 7 PROFESSOR EVANS: Yes.
- 8 Q. But hospitals and academic institutions and so on and so
- 9 forth will encourage members of the public to
- 10 participate in the phase III trials pre-authorisation?
- PROFESSOR EVANS: Exactly, exactly. 11
- Which is why members of the public --12
- 13 PROFESSOR EVANS: Yes.
- Q. -- would receive the vaccine?
- PROFESSOR EVANS: Yes. 15
- 16 Q. Right. I won't ask you the detail of it, we'll deal
- 17 with it with Dame June Raine, but a manufacturer is
- 18 obliged to produce a number of documents throughout the
- 19 trial pre-authorisation stage by way of case safety
- 20 reports, update safety reports, periodic safety update
- 21 reports, and make provision for something known as risk
- 22 management plans, that's to say how you intend to go
- 23 about addressing and monitoring safety
- 24 post-authorisation?

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25 PROFESSOR EVANS: Yes, that will be part of an enormous

1 and you may need to have trials in them. But if I have 2 trials in, let us say, people from Southampton, then 3 they're likely to be similar results to London, and 4 they'll be similar results to Paris, and they'll even be 5 similar results to Cape Town, in terms of efficacy.

> With safety, it is a little more difficult. In general, they will be similar, but not quite as -- and they're certainly not identical. So diversity in the trial for efficacy reasons is not usually a major consideration. It becomes more of a consideration when

harms might be associated with different groups. 11

12 Q. In relation to ethnic minority communities, in general 13 terms, did any of the three Covid-19 UK vaccines give rise to different results, different outcomes, during 14 15 the trials, in terms of the risk of adverse reactions or

side effects in the case of ethnic minorities?

17 PROFESSOR EVANS: Not as far as I'm aware. Look, one of the

- 18 problems, of course, is that you would -- if you were to
- 19 be really sure of it, you would need to have 30,000
- 20 people from one particular ethnic minority in order to
- 21 be sure, and that would need to be repeated across
- 22 others. So we're back to the ethical problem of: do we

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- 23 carry on doing randomised trials with hundreds of
- 24 thousands of people, and --
- 25 And such a trial, would it be as equally Q.

1 dossier -- you know, piles of paper, if it's all on

paper, that are several feet high -- that are submitted

- 3 to the regulator.
- 4 **Q.** Does it follow that from the provision of information
- 5 during the trials, that the regulator will have a very
- 6 good understanding of the levels of diversity in the
- 7 trials, whether or not there is a degree, an untoward
- 8 degree, of bias in the trial process, and whether or not
- 9 the trials are being tried across all sectors of the
- 10 population who may, ultimately, benefit from the
- 11 product, or perhaps, necessarily, have to include groups
- 12 such as pregnant women or the immunosuppressed or those
- 13 with comorbidities?
- 14 PROFESSOR EVANS: The MHRA will be aware of all that, yes.
- 15 Q. And in relation to the Covid-19 vaccines, in terms of
- 16 diversity, do you have a view as to the degree of
- 17
- PROFESSOR EVANS: In nearly all trials the degree of 18
- 19 diversity is not ideal for a whole host of reasons. But
- 20 in terms of efficacy, it is very rarely the case,
- 21 extremely rarely the case, that major groups will have
- 22 different efficacy, though that tends to be more of
- 23 a case with young children. Young children will behave
- 24 -- are not young adults, they will not behave in the
- 25 same way. And so their response may be quite different,

- 1 unrepresentative of the population which is intended to
 - be benefited?
- 2 PROFESSOR EVANS: Yes. So major efforts are made to be 3
- 4 diverse, and that's one of the reasons why you may go to
 - multiple centres and multiple countries. So for the
- 6 AstraZeneca vaccine, a great deal of the data arose from
- 7 South Africa. With trials in America, the ethnic
- 8 diversity was -- was -- they made efforts. It still
- 9 wasn't representative, but there was considerable effort
- 10 made to include people from different racial
- 11 backgrounds.

- 12 I want to ask you about that in a moment but before we
- 13 get there, just on the question of the representative
- 14 nature of the trials generally, so in relation to
- 15 safety, where there is a real issue in terms of the
- 16 position of members of the ethnic minorities, the ethnic
- 17 minority communities, is not in relation to whether or
- 18 not the possible impact upon them genetically, by virtue
- 19 of a suspected adverse side effect from a vaccine, it's
- 20 about confidence. The great need to ensure that trials
- 21 are representative of the population is to encourage
- 22 confidence that they are proper trials, that they've
- 23 adequately got on top of all the safety issues, and that
- 24 the vaccine is something which can -- (overspeaking) --25 PROFESSOR EVANS: Yes, it's an issue of confidence but

1	you're also interested in the data, if there is anything	1	properly representative of the population, one must
2	startling that you notice, and that's part of what	2	remember, is this right, that the trials were being
3	a data monitoring board would do, it will look at	3	conducted outside the United Kingdom as well as inside
4	subgroups and look at individuals, and so it will raise,	4	the United Kingdom?
5	hey, we might have a problem here.	5	PROFESSOR EVANS: Yes.
6	Q. But obviously, if you're a pregnant woman or you're	6	Q. All right. And just finally, then, please on this
7	a child, there is a greater likelihood that there will	7	topic, Professor Prieto-Alhambra, at pages 19 and 20 of
8	be a different outcome in terms of safety than other	8	your report, under the heading of "Diversity in clinical
9	sectorial groups.	9	trials", you say that, on this topic of sectorial
10	PROFESSOR EVANS: Not necessarily.	10	representation:
11		11	"The initial AstraZeneca trials included a lower
12	these vaccines, as you say, in respect of at least two	12	than desirable number of elderly people [which] led
13	of them, there were or well, in fact all of them	13	to some criticism about the potential efficacy of [the]
14	there were trials outside the United Kingdom?	14	vaccine in older populations.
15	_	15	"Sex representation was approximately balanced"
16		16	But pregnant women were, as we've heard, excluded
17		17	from all phase III trials.
18		18	And:
19		19	"Most ethnic groups were included in Phase III
20	·	20	trials for all three vaccines, albeit in lower
21		21	proportions in their representation in the overall
22		22	population."
23	, , , , , , , , , , , , , , , , , , , ,	23	But is that in relation to UK trials?
24		24	PROFESSOR PRIETO-ALHAMBRA: That is in relation to UK
25	·	25	trials, yes.
_0	49	20	50
		4	AID KEITH.
1	Q. And but you say:	1	MR KEITH: I'm so sorry, one gets to the stage where I'm
2	"Given the rarity of the later identified serious	2	afraid one just has to cut to the heart of it.
3	adverse events, it is unlikely that including a higher	3	LADY HALLETT: No, no, it's all right. I'm not being
4	proportion of people from specific ethnicities would	4	serious. 11.35, please.
5	have affected our ability to identify specific safety	5	(11.21 am)
6	issues."	6	(A short break)
7	What do you mean by that phrase?	7	(11.35 am)
8	PROFESSOR PRIETO-ALHAMBRA: I think it's very much in line	8	LADY HALLETT: Mr Keith.
9	with what Professor Evans was saying, given the rarity,	9	MR KEITH: Professor Evans, after authorisation is granted
10	• •	10	for a vaccine, in this case the three vaccines,
11	•	11	presumably there is a mass of data which is accumulated
12		12	and made available, based upon the or drawn from and
13		13	reporting on the pre-existing phase III trials on
14		14	members of the public and on the clinical rollout of the
15	rather inelegantly, to put to Professor Evans, that	15	vaccine.
16		16	In the case of the United Kingdom, are there in fact
17	the need to improve diversity is because it will improve	17	a great deal many data sources reporting on, broadly,
18	•	18	the issue of safety of the vaccines?
19	vaccine hesitancy amongst those underrepresented groups?	19	PROFESSOR EVANS: Yes.
20	PROFESSOR PRIETO-ALHAMBRA: That is indeed one of my points	20	Q. I'm going to look in a moment on the MHRA's four pillars
21	in the report.	21	and their post-authorisation approach, and I'm not
22	MR KEITH: My Lady, if that's a convenient	22	concerned about the manufacturers' obligation to report
23	LADY HALLETT: Your leading question has got the answers	23	and to continue to report on safety and related matters,
24	MR KEITH: Yes.	24	but focusing on the data, are there a number of data
25	<u> </u>	25	management tools across the United Kingdom based very
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- 1 broadly upon GP records, NHS records, the academic and 2 health institutes which carry out the trials, as well as 3 management tools relating to the delivery, the actual 4 immunisation process?
- 5 PROFESSOR EVANS: Yes.

- 6 Q. In your view, does that data process, however disparate it might appear to be, did it provide a proper, thorough 8 overview, or process by which safety related issues and 9 problems and side effects could emerge?
- 10 **PROFESSOR EVANS:** Some very clever and determined people 11 managed to bring those data sources together to do that, 12
- 13 Q. And did they include observational studies which took 14 place both before and after authorisation?
- PROFESSOR EVANS: Yes. 15
- 16 Q. How good, how thorough, were those observational studies 17 in producing data, accurate data, which would give the 18 regulator and the public a good understanding of the 19 reality of the position?
- 20 PROFESSOR EVANS: Non-randomised studies are subject to 21 biases in the way that randomised trials are not. The 22 quality in the UK of such studies was as high as 23 anywhere in the world, and it provided enormously 24 important data.
- How important, in terms of giving rise to real-world 25 Q.
- 1 rates.

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- And so this was the first, basic paper that was able to do that. They subsequently were able to link to vaccination records to not only death records but some hospital admission records, and a variety of other things. They were never able to link to occupational records. But OpenSAFELY has produced and has gone on producing many papers that were of international as well as UK importance.
- 10 Q. And to get some idea of the scale, properly anonymised 11 and properly produced data in the case, I think, of tens 12 of millions of people, was accumulated and amalgamated and analysed by this OpenSAFELY process; is that right? 13 14 PROFESSOR EVANS: Yes. And the key thing was "SAFELY". It 15 enabled the research to be done protecting any knowledge 16 of any individual participants from any of the 17 investigators. So, as an investigator, I couldn't tell 18 whether Mr Hugo Keith was included in my analysis or 19 not, whether you -- and you may well have been, but 20 I wouldn't be able to identify you at any stage. And 21 the care that was taken to do that is part of the 22 "SAFELY": it's not to do with the safety of medicines,
- 23 it's to do with the safety of the data of the 24 participant. So that requires very clever computing 25 skills to do that. 55

- data, are electronic health records kept in the 1
- 2 United Kingdom?
- 3 PROFESSOR EVANS: They're absolutely vital. The general 4 practice system is the bedrock of this. Linking to
- 5 other records is possible and was done in the pandemic, 6 but isn't always simple.
- 7 Q. Is there a national system for the retention of 8 electronic health records, or is there a trans-UK
- 9 system?

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- 10 PROFESSOR EVANS: Some of the GP systems cross the different 11 countries. Most are either well represented in Scotland
- 12 or in England.
- 13 Q. Could you tell us something, please, about the 14 OpenSAFELY observational study that was carried out.
- 15 How important was that in terms of providing useful,
- 16 safety-related information?
- 17 PROFESSOR EVANS: I'm biased because I was a participant in
 - that. It went from idea between Ben Goldacre and
- 19 Liam Smeeth, who were in Oxford and the London School of
- 20 Hygiene and Tropical Medicine, to a paper that was
- 21 published in The Lancet subsequently in 42 days, and it
- 22 was quite extraordinary. But the idea was that, based
- 23 on one of the largest providers of GP records, they
- 24 decided they could track people who had Covid tests and
- 25 who had got Covid, and be able to look at their death
- 1 Q. And is the aim of such a data system to try to identify 2 trends, occurrences, events, in terms of the appearance 3 of side effects and safety-related issues, which are of 4 significance?
- 5 PROFESSOR EVANS: That was one of the objects, yes.
- 6 Q. Right. And were there, in fact, a number of other data 7 links -- I think you refer to something called the 8 "Clinical Practice Datalink", there were data links put
- 9 into place by GP service providers, so there was a mass
- 10 of data out there?
- 11 PROFESSOR EVANS: Yes, OpenSAFELY began with one GP provider 12 and then included the other major one, such that they 13 had 95%. But Professor Prieto-Alhambra was involved in 14 other studies, and in a number of instances, these were 15 done across national boundaries, so that he could talk 16 about a study done in Spain as well as the UK.
- 17 Q. Well, that's extremely helpful, because you can now give 18 evidence for him as well.
- 19 Professor, your report at page 14, if we could have 20 that up, please, at paragraph 3.19 you extol the virtues 21 of the pseudonymised NHS records and linked data, data 22 from the National Immunisation Management System 23 registry. Did those systems allow quality and timely 24 research on safety to be done?
- PROFESSOR PRIETO-ALHAMBRA: Indeed, I think that's UK NHS 25

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- 1 pseudonymised records were world leading in the 2 investigation of safety of Covid vaccines, and the 3 NIMS registry specifically made this possible for us to 4 see a complete exposure to vaccination, which is 5 extremely important to be able to identify people who 6 were, or were not exposed to the vaccines. 7
- Q. By comparison to the amount of data accumulated by 8 manufacturers pre-authorisation, what can you say about 9 the scale of the data that was accumulated 10 post-authorisation?
- PROFESSOR PRIETO-ALHAMBRA: So post-authorisation we 11 12 accumulated an order of magnitude of more numbers of 13 patients. The nature of the data and the way it is 14 collected is fundamentally different, though, because 15 pre-authorisation data would include randomised control 16 trials, whilst the post-authorisation data is mostly 17 observational and collected in routine practice, meaning 18 that you need to be more careful with the quality of 19 that data and also with the biases arising from the fact 20 that it's observational and not randomised.
- 21 But there was very much more of it?
- 22 PROFESSOR PRIETO-ALHAMBRA: Yes.
- 23 Q. It's obviously a complex system, and there were a number 24 of data sources, were there not, both related to 25 observational studies carried out on the population, but
- 1 and, let's say, informal collaboration and conversations 2 that made that transfer of certain pieces of information 3 possible, but of course, not being -- formally sitting 4 in the same table might have limited access to certain 5 pieces of information. When I then go in my report, one 6 by one, with the different adverse events, I do not 7 think there was a big impact of that in how, I think, 8 were managed, but clearly I think a learning for the 9 future should be that we should make sure that we have 10 a more formal collaboration and a better flow of data, 11 if possible.
- 12 Q. The second point you make, at a different part of your 13 report, page 11, paragraph 3.6, is that there needs to 14 be a system by which the studies known as 15 post-authorisation safety studies, PASS, can be 16 organised and managed. And one difference you say, 17 particular difference between the European Medicines 18 Agency and the FDA, Health Canada, and us, in the form 19 of MHRA, is availability of a process by which PASS studies can be easily or straightforwardly commissioned. 20 21 Why does that matter, given the mass of data which 22 appears to have been available?
- 23 PROFESSOR PRIETO-ALHAMBRA: So it matters because generating 24 evidence, or knowledge from these masses of data 25 requires very specific expertise, and the regulators, in 59

1 also based on the records kept of the immunisation 2 process itself. So, for example, you referred to the 3 Vaccination Management Tool in Scotland and also to 4 NIMS, the National Immunisation Management -- service?

PROFESSOR PRIETO-ALHAMBRA: System.

Q. System, thank you, in England. In your assessment, were those systems for the accumulation of data efficient and

9 PROFESSOR PRIETO-ALHAMBRA: They could always improve.

10 So if you look at my recommendations, I do think 11 that we can make sure that there are systems to link the 12 data more quickly and more efficiently, but they were, 13 as I said, world leading and much better than the data 14 that many other countries had available.

15 Q. Well, there are two aspects to which you refer in that 16 context. One is, of course, following the departure 17 from the European Union, at the end of the transition 18 period, the United Kingdom no longer sat on, by right, 19 the European Medicines Agency or had direct access to 20 any of its data sources. Do you think that that absence 21 of a link, direct link in the absence of a formal 22 presence at Europe made a difference in terms of the 23 MHRA's oversight of the data which was available, the 24 reality of immunisation, and the safety system? 25

PROFESSOR PRIETO-ALHAMBRA: I believe there was very fluent

1 this case MHRA, need to have that expertise available 2 in-house but also they need to have access to it through 3 commissioning of these kind of studies. If you look at 4 the examples that I mentioned in my report of, for 5 example, Sentinel for the US FDA, C-NODES for Health 6 Canada, or DARWIN EU for the EMA, they are structured 7 systems that enable the rapid commissioning and 8 execution of such studies. And I think it would be beneficial to have a similar system here. 9

10 Q. All right. That's data. Another important part of this 11 jigsaw, is the continuing obligation on manufacturers to 12 produce safety-related information.

Professor Evans, is there a general obligation continuing on manufacturers after authorisation to continue to make available safety-related information? PROFESSOR EVANS: Yes, the frequency with which they have to

17 do so changed over time. It was -- it's generally, for 18 most medicines annually, but it became six-monthly, 19 three-monthly, and even monthly, obligations put on them 20 to update the regulators with their safety information.

Q. And in general terms, did they have to provide not just pre-authorisation case safety reports, that's to say particular instances where safety-related issues had arisen, but periodic safety update reports, post-authorisation safety study protocols, final study

reports, as well as, you said earlier, risk management plans?

3 PROFESSOR EVANS: Yes.

- 4 Q. So a complex and somewhat byzantine process of5 reporting.
- 6 PROFESSOR EVANS: Byzantine is not the word I would use.
- 7 I think that it sounds bureaucratic but in a number of
- 8 instances it has real clinical and public health
- 9 benefit, but at times, it can be bureaucratic. I'd
- 10 sympathise with you.
- 11 **Q.** Byzantine was not meant to be pejorative, I deliberately
- 12 didn't use the word "bureaucratic". It's quite complex.
- 13 PROFESSOR EVANS: It is.
- 14 Q. But overall, in your assessment, does it work in
- ensuring a high level of confidence that any relevant
- 16 knowledge in the possession of the manufacturers is
- 17 brought to the attention of the regulator?
- 18 **PROFESSOR EVANS:** Yes, I think in general it does work.
- 19 Q. Then we come on to the obligation on the MHRA to
- 20 continue to assess safety, and Professor Evans, the MHRA
- 21 extols the virtues of something called its four pillars
- 22 of review. Without asking you to identify them one
- 23 after the other, they consist of the Yellow Card system
- 24 with an added-on monitoring system, two analytical
- 25 systems by which they assess trends and the theoretical
- 1 that there are, to me, two important differences or
- 2 possibly even three, in the data. The first is the
- 3 passive things, the Yellow Card system, which relies on
- 4 people in the general public, doctors, health
- 5 professionals in general, and patients reporting to the
- 6 MHRA. Then there is a looking at electronic health
- 7 records in general, to look for problems. And then
- 8 there are specific studies, using electronic health
- 9 records.
- 10 Q. Just dealing firstly, then, with the Yellow Card system,
- 11 that passive system, because it requires members of the
- 12 public to get in touch and say, "This has happened to me
- and I'm reporting it," did it have an add-on or an
- 14 additional aspect to it, which was that during the
- pandemic, the MHRA invited people to put themselves
- forward for monitoring, having identified themselves in
- 17 the Yellow Card system, so that they could be followed
- 18 up?
- 19 **PROFESSOR EVANS**: Yes.
- 20 $\,$ Q. Do you have any idea of how many people were invited to
- 21 be monitored and how many people --
- 22 **PROFESSOR EVANS:** Of the order of a million.
- 23 Q. And how many people in reality agreed to be followed up?
- 24 PROFESSOR EVANS: My recollection is that it was of the
- 25 order of 50,000.

- and the hypothetical possibility of things happening,and therefore, if something happens, they realise it's
- 3 out of kilter, and also, the obligation to continue to
- 4 assess material provided by the manufacturers.
- Do, in your assessment, those four pillars work in terms of ensuring that everything that can be done to make sure that side effects and safety-related issues
- 8 are picked up?
- 9 **PROFESSOR EVANS:** In totality, yes.
- 10 $\,$ **Q.** They say -- well, they have four elements. One of them
- 11 is the formal epidemiological studies which are carried
- 12 out. Are those studies which are carried out, do they
- overlap with the sorts of studies that we've been
- 14 discussing generally in terms of the provision of data?
- 15 PROFESSOR EVANS: Yes.
- 16 Q. Or are they particular studies directed --
- 17 PROFESSOR EVANS: Both.
- 18 Q. -- and managed by the MHRA?
- 19 **PROFESSOR EVANS:** The MHRA will do relatively few studies of
- 20 its own. They interact mainly with manufacturers, and
- 21 they require the manufacturers to do the studies. The
- 22 manufacturers may then get either independent
- 23 organisations or academics to do them, and the sort of
- 24 things that Professor Prieto-Alhambra said are examples
- 25 of those studies. But I think you should understand
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 - **Q.** So in the context of the issue about the importance of
- 2 ensuring that population and the public have confidence
- 3 in these systems, there is a process by which they can
- 4 materially contribute to it?
- 5 PROFESSOR EVANS: Absolutely.
- 6 Q. But in terms of the monitoring system, it wasn't an
- 7 opportunity that was greatly availed of?
- 8 PROFESSOR EVANS: I don't -- my personal view is that it was
- 9 not of enormous utility. The Yellow Card system itself
- 10 was very useful but there are biases in that, and the
- 11 biases in the monitoring system, because it's only
- 12 50,000 who respond out of a million, are potentially
- much greater. Electronic health records are a much
- 14 better source for making decisions on whether an effect
- that you might have seen in the Yellow Card system is
- 16 causal.

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- 17 Q. Professor Prieto-Alhambra, at paragraph 3.17, your view
- is that, by and large, the Yellow Card Scheme did allow
- the MHRA to identify safety issues in a timely manner
- and to produce swift guidance and documentation. So you
- think, by and large, it did work?
- 22 PROFESSOR PRIETO-ALHAMBRA: (Witness nodded).
- Q. Do you have a view as to the efficacy of the monitoringadd-on system?
- 25 **PROFESSOR PRIETO-ALHAMBRA:** I think that the Yellow Card

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1	system worked really well, as it has always done, and
2	it's always, or typically always, the main source of the
3	first signals. The monitoring add-on did not add much
4	in my opinion or in my knowledge.

- Q. The second aspect, second pillar, is what is known as
 the rapid cycle analysis. Could you describe in lay
 terms what that was? What did the MHRA do in terms of
 trying to analyse pre-defined events and draw
 conclusions?
- 10 PROFESSOR EVANS: Rapid cycle analysis was developed probably in America, where they used electronic health 11 12 records to very rapidly look at whether there was an 13 excess of a particular effect of interest using those 14 electronic health records, and the MHRA adopted that 15 kind of strategy this time. I think that is very 16 useful. It doesn't cover everything, but it covers the 17 things that have risen above the mêlée that you become 18 aware of.
- 19 Q. And the third pillar, ecological analysis. So it's said
 20 to be "proactive analysis of trends within particular
 21 populations". What is that? It may in fact be part of
 22 the third pillar, but it appears to be a separate sort
 23 of study.
- 24 PROFESSOR EVANS: It's the sort of thing that you may be
 able to do without individual records. You look at

1 regulatory decisions.

I think, for the pandemic, phase IV trials as such,
 certainly the randomised ones, had a small
 (overspeaking) --

Q. So, in truth, the majority of the trials conducted
 post-authorisation concerning members of the public were
 studies --

8 PROFESSOR EVANS: Yes --

9 **Q.** Non --

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10 PROFESSOR EVANS: They were not --

11 Q. Not randomised trials?

12 PROFESSOR EVANS: And they were of enormous value, yes.

13 Q. Because presumably they were at scale and therefore were
 14 better placed to bring to the attention of the MHRA any
 15 safety-related issues.

And one last question, then, on the topic of signal detection, Professor Evans, may we presume that the very sophisticated software and data processes are used by the MHRA, and other regulators, to try to identify and evaluate the trends and significance of events occurring in the general population?

in the general population?
 PROFESSOR EVANS: The analysis of signals, and a signal noticing that you think it is possible that a particular adverse event is associated with a particular vaccine or drug and the numbers flag this up. What you need to do

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totals of things that are reported through the Office
 for National Statistics, whether there are death rate
 trends and things of that kind.

4 It's a very weak pillar. It is a pillar that's 5 reasonable to look at provided it's not absorbing lots 6 of resources, but its utility is limited.

7 **Q.** Then finally on this topic, you've referred to it
8 already, but could you express your view on the
9 efficacy, the impact and the usefulness of the phase IV
10 trial process. So, to remind ourselves, the trials that
11 took place post-authorisation, phase IV, in clinical
12 use, members of the public. How wide were they?

PROFESSOR EVANS: The nomenclature there I think is a little

14 bit confusing. Many of the so-called phase IV trials 15 are not randomised, and I think that the randomised 16 trials gave enormous help in very particular areas, such 17 as whether having a Pfizer vaccine after an AstraZeneca 18 vaccine among adolescents had certain gains or losses. 19 And many of those trials were carried out by academics 20 rather than the industry. I'm not aware of -- and they 21 were randomised. And they were supported by academics 22 and the UK system for supporting academic research.

I'm not aware of any such trials done by the manufacturers, and I'm not fully aware of -- you'd have to ask Dame June Raine -- as to what impact they had on

is then evaluate that carefully, and I think that the
MHRA's system of doing that, both in the detection of
the problem in the first place, based largely on passive
surveillance, with its limitations, I think was done
very well.

Q. Is it therefore the conclusion that you reach in your
 report, overall, that post-authorisation, safety
 surveillance, monitoring, flagging up, assessment,
 evaluative process, was a good one?

10 PROFESSOR EVANS: Yes.

11 Q. Professor Prieto-Alhambra, your opinion?

12 PROFESSOR PRIETO-ALHAMBRA: Yes, very similar opinion.

13 Q. And in reality, were they any different in substance or
 14 in output and value of use from our European neighbours
 15 and the American system?

16 PROFESSOR PRIETO-ALHAMBRA: Very similar, I would say.

Q. Professor Evans, there are then a handful of discrete points that have been raised by the Core Participants, amongst other people, and I want you, please, just to express succinctly your views on these various points, they've been very helpfully addressed in your report, but it's important that we hear what you have to say about them.

Some suggest that the mRNA and also the viral, the adenoviral vector technology underpinning, respectively,

- 1 the Moderna and Pfizer vaccines and the AstraZeneca 2 vaccine, are regarded, or should be regarded, or are --3 and I think this is not meant as a compliment, but 4 pejoratively -- gene therapies, that in some way they 5 operate to alter the genetic make-up of the body and/or 6 are therefore prone to have serious genetic side 7 effects.
- 8 PROFESSOR EVANS: Absolutely not.
- 9 Q. At [page] 60 you deal with the issue of the UK reporting 10 of myo/pericarditis, which you recall of course, was an 11 issue which brought itself to the attention of the MHRA 12 along with other regulators in Europe?
- 13 PROFESSOR EVANS: Not only Europe, it was probably of even 14 greater concern in the US and Canada.
- Q. And Canada -- Israel, was it or is that --15
- PROFESSOR EVANS: Yes, I believe, that the first signs were 16 17 seen in Israel.
- 18 Q. Ah. Do you believe that the MHRA responded in an 19 appropriate manner, in terms of substance and time, to 20 the emerging reports of myo and pericarditis?
- PROFESSOR EVANS: Yes. 21

22 Q. You've already spoken about the Yellow Card system. In 23 an overall sense, do you believe that, subject to such 24 amendments and recommendations as my Lady may formulate 25

inside the brain of the health professional to detect

- for its continued use, it is overall, an effective
- 2 that they have got a suspicion? I think you want to 3 make it as easy as possible for them to do so, but 4 I think that the notion of mandatory reporting for 5 health professionals, is not good. For manufacturers, 6 yes, they've got to report anything that they receive, 7 but for health professionals who are seeing a patient, 8 I think we want to make it as easy for them as possible, 9 but the evidence we had from the 1990s where it was 10 mandatory in France for health professionals to report, they reported at a lower rate than the UK where it was 11
- 12 non-mandatory. 13 Q. Many people have, particularly from the Covid Bereaved 14 and Injured groups, expressed concern about the 15 operation of the coronial system which is, of course, 16 wildly out of scope for us. But there is an overlap 17 insofar as, of course, there will be many people who --18 a significant proportion of those persons who suffered 19 serious side effects, who then died, will have been 20 through, or their families will have been through the 21 coronial process. Do you happen to know whether or not 22 there are any cases in which the coronial system 23 identified and considered deaths, fatalities, caused by 24 vaccines --
- PROFESSOR EVANS: Yes, they --25 71

- system for allowing members of the public to notify the 1 2 regulator of side effects?
- 3 PROFESSOR EVANS: It's probably not as effective for members 4
 - of the public, but is generally pretty effective for
- 5 health professionals, and they are the ones who report
- 6 most of the serious adverse effects. Members of the
- 7 public will tend to report less serious ones that, in
- 8 most instances, are of less public health importance.
- 9 It is the serious ones that are not likely to be seen in
- 10 the trials. The less serious ones are often seen in the
- 11 trials, and so we don't, if they're frequent, we
- 12 don't -- we know about them.
- 13 Q. So the vast majority of reports from members of the 14 public tend to focus on, perhaps, points of
- 15 reactogenicity, as opposed to the more serious, which
- 16 are, of course, very much fewer in number?
- 17 PROFESSOR EVANS: They may well do, and the data seems to 18 suggest that.
- 19 Q. The suggestion has been made that it should be mandatory 20 for healthcare professionals to report suspected adverse
- 21 reactions via the Yellow Card system; what do you say to 22
- 23 PROFESSOR EVANS: Well, I think the answer is in the words 24 you used, "suspected adverse reactions". How can it be
- 25 mandatory to report a suspicion? Are you going to get
- 1 Q. -- where those cases had not already been detected 2 through other means or been within the knowledge of the 3
- PROFESSOR EVANS: I don't know whether the cases were. 4
- 5 I think -- because I don't have knowledge of individual 6 cases. Dame June Raine may be able to answer that. But
- 7 the effect, the adverse reaction, I am not aware that
- 8 the coronial system found any new adverse reactions.
- 9 They reported on things that were already known.
- 10 Q. You've already helpfully described the position
- 11 concerning the impact on Britain's access to the EU
- 12 database, concerning safety. There is a database, is
- there not, called EudraVigilance? 13
- A. (No audible answer) 14
- 15 Q. What impact do you think the lack of access to 16 EudraVigilance from January 2021 has had, if any?
- 17 PROFESSOR EVANS: It meant that our immediate knowledge of
- 18 very rare events was less than it might have been.
- 19 Q. From your analysis of the information before the 20 Commission on Human Medicines, the MHRA, the DHSC, the
- 21 JCVI and so on, and OCMO, does it appear that any of the
- 22 European regulators were privy to safety-related
- 23 information, significant information, when we weren't?
- 24 PROFESSOR EVANS: I cannot give you an example.
- Q. You specifically address the issue of TTS, so thrombosis 25

1 with thrombocytopenia, so that's thrombosis with 2 thrombocytopenia syndrome. This was an issue which 3 arose in the spring of 2021. Have you reached a view, 4 and we'll look at this in detail with Dame June Raine, 5 but have you reached a view as to the appropriateness or 6 not of the way in which the MHRA responded to that issue 7 being brought to its attention, and the speed with which 8 it responded?

9 PROFESSOR EVANS: My judgement is that they did. It was one 10 of those things that, as was mentioned previously, could 11 be caused by Covid as well as by the vaccine. And so it 12 becomes quite difficult to disentangle the effects.

Q. Professor Prieto-Alhambra, pages 15 and 70 of your report, you also opine on this, and we'll receive, please, your view on that out of turn with the other conditions which you look at later in your report.

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What is your view on the appropriateness of the regulator's response and the speed of response on TTS in spring of 2021?

20 PROFESSOR PRIETO-ALHAMBRA: As I explain in my report, 21 I think it was an appropriate response. It was -- the 22 signal was detected a bit later, but when I say "a bit", 23 I'm talking days or weeks. And that could be caused 24 also by the fact that the AstraZeneca vaccine was used 25 in younger populations in continental Europe when

Q. Another subject, please. A source of continuing concern, and it's something about which a great deal many views have been expressed, is the question of whether or not vaccines themselves caused excess death. That is to say, whether vaccines killed people in significant numbers.

Bearing in mind that there were obviously, in very, very rare cases, a number of fatalities, and, in slightly less rare cases, serious side effects, was there nevertheless a general impact from vaccines on overall mortality rates?

12 PROFESSOR EVANS: As far as one can see, the studies that looked at mortality demonstrated that vaccines reduced mortality, and did not increase it in any way.

> Looking at ecological studies, we call them, looking at the totals and not being able to identify whether deaths are occurring in vaccinated or unvaccinated individuals is not the best way of deciding whether vaccines are likely to affect the public health. Looking at totals can be affected by so many different things that they are very biased in making causal attribution of the effects.

23 Q. Professor Prieto-Alhambra, at your report at page 23, do 24 you look at both the numerous studies which have been carried out, the estimates from a variety of different 25

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1 compared to what we were doing in the UK, and that led 2 to earlier identification of that signal.

3 Q. At page 68, Professor Evans, you say something about the 4

public funding of vaccine studies in the context of

5 phases I to III. We had understood that the studies 6 were generally publicly funded, alongside, obviously,

7 the management and the funding by the manufacturers

8 themselves, but is there room or more public funding, in

9 your opinion?

10 PROFESSOR EVANS: I think they -- room for more public 11 funding in the post-authorisation studies, I think --

Q. So phase IV? 12

13 PROFESSOR EVANS: Yeah.

14 Q. Post-authorisation. But the way in which -- I mean, it 15 looks as if, from these many trials or studies, sorry, 16 which were carried on, that there was a great deal of

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public input by funding and participation? PROFESSOR EVANS: Yes. 18

19 Q. Are you talking now about post-authorisation, randomised 20 control trials?

21 PROFESSOR EVANS: I would like to see more of those, so that 22 there --

23 Q. So formal control trials?

24 PROFESSOR EVANS: Yes. And if it's in phase IV, it's likely 25 to be comparisons between, say, Pfizer and Moderna.

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1 bodies but also, as Professor Evans has said, the 2 mathematical models, and conclude that there is best 3 quality evidence, good quality evidence, available to 4 suggest that the vaccines, far from killing people in 5 significant numbers, saved millions of lives?

6 PROFESSOR PRIETO-ALHAMBRA: All the good quality evidence 7 I could find suggests that the vaccines saved hundreds 8 of thousands or millions of lives globally.

9 Q. And to get an idea of the scale of your analysis, how 10 many studies, estimates, mathematical models, as well as 11 empirical studies, that is to say simple reporting of

12 numbers of deaths and rates of deaths, compared against

rates of vaccination, are there now in the public

14 domain?

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15 PROFESSOR PRIETO-ALHAMBRA: So the best evidence I could 16 find includes the cohort studies, where one follows 17 a group of people over time and observes how many of

18 them die, so that's at the individual level, and there

19 are many of those suggesting a reduction in mortality, 20 as well as more global analysis of mathematical models

21 that take the estimate of how effective the vaccine is,

22 and then compute how many lives were saved by the

23 vaccines. There's many, many studies in that regard,

24 and the most recent one says that the vaccines saved 25

over 14 million lives globally.

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Q. Professor Evans, due to the exigencies of time, I've not asked you in detail about the last final figure about which the safety system is maintained, namely the way in which information about safety is given to members of the public through what's known as patient information leaflets and documents produced by the manufacturers called summary of product characteristics.

But in your report at page 73, do you have something to say about the PIL system, and do you observe that one of the problems, one of the rods that we've created for our own back as a country is there are so many ways in which members of the public can get access to information, from government websites, DHSC, Public Health England, MHRA, social media, the press, friends family, whatever, that a way to increase confidence might be to have a single site or a more clearly identified source of specific, scientific, medical safety-related information for individual medicinal products?

20 PROFESSOR EVANS: That, in a sense, is what the SPC and the 21 PIL do. When there are alternative manufacturers of 22 drugs, they can sometimes give slightly different 23 information, because it's under the control of the 24 manufacturer, but for the vaccines, I think that the PIL 25 and SPC are a good way of standardising that information

1 to be high. Medicines are not like soap products. 2

People can just put them on the market with very little

regulation, but I think we need to have regulations for

4 medicines.

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5 **Q.** You say at (B) there need to be more randomised trials.

6 Is that in the context of the point you made earlier,

7 which was to the effect that post-authorisation, there

are huge numbers of studies in the population at large,

but by comparison, fewer formal randomised controlled

trials, they need to be more at that level?

PROFESSOR EVANS: I think we need to make the authorisation 11

12 of trials easier, and I have been an advocate for

introducing vaccines through randomised trials,

especially when there's shortage of vaccines, and using

15 what's called cluster trials, so that you randomise

Southampton to get Pfizer, let us say, and you randomise

17 Portsmouth to get AstraZeneca, and then study the

effects, and you then know that you've randomised and

19 you've got groups that are similar.

20 Q. And finally on the question of data, is it your view

that whilst there are numerous data sources, and it

would seem from your evidence today, a profusion of

23 information -- I mean, there's a mass of data out

24 there -- there is nevertheless an unacceptable degree of

fragmentation, that there is insufficient linkage 25

and ensuring that good information is there. 1

2 Q. Then, finally, another topic raised by a number of

3 people is whether or not -- and this is page 74 of your

report -- persons who have reported through the Yellow

5 Card system could be updated by the regulator or some

6 other government body in respect of emerging safety

information related to the particular vaccine upon which

8 they have reported. Do you think that's a sensible way

9 of proceeding?

10 PROFESSOR EVANS: I think it's impractical. I think it

11 might also discourage reporting because some people wish

to report anonymously, and I think trying to have

13 a system that got back to individuals is simply

14 impractical.

15 Q. And then trying to draw all those threads together, do 16

you make -- and there are four I want to focus on, four 17 recommendations at page 76 onwards, Professor Evans --

18 not, I think, by way of trying to identify, overly

19 prescriptively, particular things that in your opinion

need to be done, but perhaps more by way of calling

21 generally for focus to be paid -- more focus to be paid

22 to them, (A), you extol the importance of having trials

that are as sufficiently powered, as large as they can

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25 PROFESSOR EVANS: Yes, and I think the trial quality needs

1 between, for example, GP records and occupational

records between the four nations of the United Kingdom

3 and their health boards, and between GPs and, for

4 example, hospitals. There needs to be a great deal more

thought given to try to integrate the system to make it

6 work better.

7 **PROFESSOR EVANS:** Absolutely. There is a tension between 8

the availability of that kind of thing and personal

9 privacy, and I think we need to have privacy-preserving

10 linkage of data, as is done in OpenSAFELY.

Q. And Professor Prieto-Alhambra, you therefore may have 11

12 the last word on this point. Do you also say in your

13 report, page 70, paragraph ... I think I've lost the

14 reference. I think it might have been 6.2. But you say

15 that there needs to be thought given to the more rapid

16 dissemination of data, and again, the drawing together

17 of some of these quite fragmented systems or sources?

PROFESSOR PRIETO-ALHAMBRA: Yes, I think that's -- what 18

19 I want to recommend is that there is routine linkage of

20 all those datasets, pseudonymised as necessary, of

21 course, but then also with the addition of expertise to

22 analyse that data made available to MHRA on a regular

23 basis.

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24 MR KEITH: Thank you very much.

Professor Evans, those are all the questions I have

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1		for you.
2		Professor Prieto-Alhambra, can we now focus on your
3		report.
4	PR	OFESSOR EVANS: I think I might take a break is that
5		permitted while leaving Professor Alhambra here?
6	LAI	DY HALLETT: Certainly. We'll call you if we need you.
7		Or come back when you're ready.
8	PR	OFESSOR EVANS: I'll come back.
9		(Professor Evans left the hearing room)
10	MR	KEITH: We can deal much more shortly with the first part
11		of your report because many of the areas have been
12		flagged up already, very helpfully, by you in the course
13		of Professor Evans' evidence.
14		At page 2, you set out your general approach to what
15		you did and what your report is concerned with.
16		The Inquiry did not seek to ask you to opine upon
17		the objective safety of any individual vaccine, not
18		least because safety is not something amenable to an
19		objective classification or characterisation. Nor did
20		we ask you to opine upon conclusively, in
21		a determinative way, or pharmacoepidemiologically,
22		whether any given vaccine gives rise to any given
23		adverse effect, side effect.
24	Would it have been extremely difficult to express	
25		any view on the objective level of risk of a vaccine or
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1		(Professor Stephens returned)
2	PR	OFESSOR PRIETO-ALHAMBRA: That is correct. I might add
3		that we focused we tried to focus on those
4		publications and reports that were available during the
5		period of interest to the Inquiry because we thought
6		those would be the ones that were of highest interested.
7	Q.	And if we look at page 8 of your report, are there
8		degrees of quality of the evidence which you found, upon
9		which you then reached a view as to whether or not it
10		may sensibly be said there is actually an association of
11		some sort between the vaccine and the medical condition?
12		So the quality of evidence might be very low, low,
13		moderate, moderate-high, or high?
14		And briefly dealing with these first few pages, do

And briefly dealing with these first few pages, do you identify the particular type of vaccine, so the mRNA vaccine, Pfizer and Moderna, and the adenoviral vector vaccine, AstraZeneca?

If you say "yes" or "no" for the stenographer, that would help.

PROFESSOR PRIETO-ALHAMBRA: Yes.

21 Q. Thank you.

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And do you agree with what Professor Evans has said about the lack of genetic consequence of the use of all those vaccines and that any notion that they have genetic impact is unfounded?

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the likelihood of any individual side effect eventuating from its use, given the absence of a conclusive position scientifically, the relatively small amount of time which has elapsed since the pandemic, and also because it is extremely difficult to determine in any one given case whether or not the side effect is actually caused by the vaccine or is coincidental or is caused by Covid; is that a fair summary?

PROFESSOR PRIETO-ALHAMBRA: That is fair, yes. 9

10 Q. So what you've done instead is, in order to assist those 11 persons who suffered side effects in these very rare cases, seriously, following vaccination, is you've 12 13 scoured the public domain and the scientific and 14 academic literature which is in it to see what level of 15 evidence there is to support the proposition in every 16 single case, whether or not that particular 17 condition/side effect appears to be associated with 18 a vaccine?

19 PROFESSOR PRIETO-ALHAMBRA: (Witness nodded)

20 Q. So that they may have some succour, they may know what 21 the reality of the position appears to be.

22 PROFESSOR PRIETO-ALHAMBRA: (Witness nodded)

23 Q. And so the state can see, through this Inquiry, what the 24 scale of the problem, if there is a problem, is.

Is that a fair summary?

1 PROFESSOR PRIETO-ALHAMBRA: I agree with Professor Evans' 2 statement on that topic.

Q. [Page 11], you express your views on the general position about the regulatory structures and you draw favourable comparisons between us and the EMA, the FDA and Health Canada, and you've raised the guestion of the commissioning of PASS studies. I therefore don't need to deal with that in detail, but at page 13 you make the point that, again, like Professor Evans, safety cannot 10 be characterised in objective terms, it is relative, and it's all about risk-benefit. 11

> In terms of the risk-benefit and the obligation of the regulator to determine whether or not the benefit outweighs the risk, by what margin, in your view, must the MHRA be satisfied that the benefit exceeds the risk? Is it an equivocal balance or does the -- must the benefit greatly outweigh the risk?

PROFESSOR PRIETO-ALHAMBRA: I think they must be very

19 satisfied that there's a lot of evidence that the 20 benefit outweighs the risk. And I would say for 21 vaccines, that's even more so, because of course we are 22 not treating sick people but preventing sickness.

23 Q. Effectiveness and intended effects, does the scientific 24 and medical evidence available, which you've reviewed,

25 suggest, demonstrate, that the Covid-19 UK vaccines were

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(21) Pages 81 - 84

1 effective at the time that they were authorised?

2 PROFESSOR PRIETO-ALHAMBRA: Yes, and this is one of the few 3 analysis where we have really high-quality evidence

4 coming from large phase III trials.

- 5 Were the -- is the evidence consistent between all the 6 vaccines, all three vaccines, as to their effectiveness,
- 7 and also as to the levels of effectiveness in each case?
- 8 PROFESSOR PRIETO-ALHAMBRA: They are consistent and they are 9 well above the threshold set out by most of the 10 regulators internationally.
- What does the evidence say about the levels of 11 12 effectiveness in specific population subgroups?

So is there a mass of information of real-world data, that's to say the reality of the rollout of the vaccines, and the intended effects becoming reality?

Were the vaccines of less efficacy significantly in

17 relation to any particular population subgroup?

PROFESSOR PRIETO-ALHAMBRA: Not to my knowledge. I think 18

19 what's important to realise is that some of those 20

subgroups of the population were not included in the

trials, but data was generated using these electronic

22 health records and observational studies, and suggested

a similar level of effectiveness to that observed in the

trials for the other part of the population.

25 Q. And do you have there particularly in mind pregnant

- 1 Q. What was the general impact of the variants of the 2
- SARS-CoV-2 virus on the effectiveness of the vaccines?
- 3 PROFESSOR PRIETO-ALHAMBRA: So what the data suggests, and
- 4 I think UKHSA and the equivalents in the devolved
- 5 nations did a great job at this, is that as new variants
- 6 emerged, the effectiveness against symptomatic Covid
- 7 declined, also combined with the waning of the vaccines
- 8 themselves. However, there is very strong data
- 9 suggesting that the vaccines still work to prevent
- 10 severe outcomes, poor outcomes, like hospitalisation or
- 11 death

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- 12 Q. So they continued to protect against the worst outcomes,
- 13 death and hospitalisation, but were less effective in
- 14 terms of preventing you from getting infected and being
- 15 possibly symptomatic?
- PROFESSOR PRIETO-ALHAMBRA: And potentially also they lost 16
- 17 their ability to prevent transmission, we believe,
- 18 because of this inability to prevent infection in the
- 19 first place.
- 20 Q. Long Covid. Was -- it may seem self-evident --
- 21 Long Covid was identified once we'd begun to try to deal
- 22 with Covid, and to live with it, as being a medical
- 23 condition consequent to the virus itself. So it
- 24 couldn't have been studied in the trials for vaccines.
- 25 But what does the data and the evidence say now about 87

- women, breastfeeding women, who were excluded from the 1
- 2 trials but who subsequently, in large part due to data
- 3 emerging from America, in fact, large-scale data, were
- 4 offered the vaccines?
- 5 PROFESSOR PRIETO-ALHAMBRA: (Witness nodded).
- 6 Q. And do the results and the data thereafter show that the 7 vaccines worked?
- 8 PROFESSOR PRIETO-ALHAMBRA: Yes, specifically with pregnant
- 9 women, they were not underrepresented; they were
- 10 excluded, by design, from the trials and therefore it
- 11 was extremely important that we had data on the efficacy
 - or the effectiveness of the vaccines for them, also
- 13 because they were having very severe outcomes when they
- 14 got Covid. And, indeed, the data that I've seen to
- 15 date, and I know there's more data being published
- 16 because I've seen it in conferences, and results is all
- 17 consistent with a high protective effect against severe
- 18 Covid, even more recently.
- 19 Q. Children were excluded from trials. What does the
- 20 real-world post-authorisation data say about the
- 21 effectiveness of the vaccines on children?
- 22 PROFESSOR PRIETO-ALHAMBRA: Children were excluded from the
- 23 initial trials but then there were trials conducted
- 24 specifically for children where we did observe a similar
- 25 efficacy. So there is trial data on children.

- 1 whether or not the vaccines helped protect against
- 2 developing Long Covid?
- 3 PROFESSOR PRIETO-ALHAMBRA: Yes, so indeed Long Covid was
- 4 not an outcome in the trials, but there is good quality
- 5 cohort studies and observational studies suggesting that
- 6 the existing vaccines prevent or helped to prevent
- 7 Long Covid, through the prevention of infection in the
- 8 first place and also through the prevention of the
- 9 development of persistent or long-persisting symptoms.
- 10 The effects that they might have on people who already
- 11 have Long Covid are less clear.
- 12 It is well known that, at the end of December 2020, the
- 13 United Kingdom, against, I think, the trend elsewhere,
- 14 determined that extending the dosage interval was a good
- 15 idea, and not least because the prioritisation of the
- 16 first dose meant more people could get some protection,
- 17 rather than giving absolute full protection to a smaller
- 18 number of people.
- 19 PROFESSOR PRIETO-ALHAMBRA: (Witness nodded).
- 20 Q. Does the data and the literature which you've examined 21 show -- is it good quality evidence to the effect that
- 22 that was the right decision, that the increase in the
- 23 dosage interval had a generally beneficial impact?
- 24 PROFESSOR PRIETO-ALHAMBRA: Yes -- so I think there's two
- 25 levels to this. At the personal level, most of the

1 trials had a shorter interval between doses than what we 2 did in the UK, but there was at least one trial of the 3 AstraZeneca vaccine where they observed a higher 4 protective effect when the doses were a little bit 5 farther apart. So at the personal level, that's all the 6 evidence we had. At the population level, the fact that 7 we could deliver one dose to double the population 8 within a certain timeframe has proved very beneficial in 9 terms of limiting the impact of the virus on people's 10

> So, overall, I think there's good evidence to say that that strategy worked really well.

- 13 Q. Transmission of the virus. There are two levels at 14 which one must consider transmission, are there not? 15 Firstly, how likely is it that you're going to get 16 infected, but, secondly, how likely it is that you might 17 then infect another person; is that right?
- 18 PROFESSOR PRIETO-ALHAMBRA: That's correct.

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19 And did you consider those two issues separately?

20 PROFESSOR PRIETO-ALHAMBRA: They are related, of course, not 21 completely independent. They are related. But the 22 likelihood that someone might get infected, even 23 asymptomatically, was studied in the trials, whilst the 24 transmission of the virus was not. So the quality of 25 the evidence for the former is higher than for the

1 been established to have been in any way connected with 2 the vaccines, but side effects which have been brought 3 to the attention of the authorities by members of the 4 population who believe, rightly or wrongly, that they 5 have been associated with the vaccines?

PROFESSOR PRIETO-ALHAMBRA: Yes, and unfortunately our science doesn't allow us to identify a causal association at the individual level, but we tried to focus on those adverse events that we thought could have changed how we managed the rollout of the vaccines.

Q. And so in each case, or in each -- in relation to each 12 medical condition, have you looked at the degree of, or 13 the amount of evidence and underlying data which 14 suggests that there is an association with the vaccine? 15 You've identified how much material suggests that the 16 condition may in fact also, or alternatively, have been caused by the Covid virus itself, and you've also opined 18 on -- or you've expressed a view on whether, in light of all that material, as it was known about at the time, the MHRA responded in an appropriate way when being informed of the problem?

21 22 PROFESSOR PRIETO-ALHAMBRA: That is correct. I think when 23 it comes to the quality of evidence, we tried to combine 24 the quality of the studies that we identified with their 25 consistency, because if you had good quality studies but 91

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2 Q. But in both cases, what does the evidence and the data 3 upon which the evidence is based generally show in 4 relation to the effect of the vaccines in reducing 5 transmission?

6 PROFESSOR PRIETO-ALHAMBRA: The data suggests that the 7 vaccines reduced transmission, at least during the early 8 days of the vaccine rollout. That might have changed 9 after there were new emerging variants, as I mentioned 10

11 Q. Now, the bulk of your report is on the topic of vaccine 12 side effects and, as you've described, you've looked at 13 the literature, and have you -- give us an idea of the 14 nature of the exercise that you undertook. You and your 15 colleagues -- and you were greatly assisted by your 16 colleagues in this exercise --

17 PROFESSOR PRIETO-ALHAMBRA: Mm.

18 Q. How much material have you looked at here, Professor?

19 PROFESSOR PRIETO-ALHAMBRA: We read hundreds of published 20 manuscripts and tens of reports from different 21 regulatory authorities.

22 Q. And presumably covering the whole scope of vaccine side 23 effects, of which, of course, there are very, very many 24 to be mentioned, in the hundreds, and, I emphasise, not 25 in terms of side effects or medical conditions that have

1 they were inconsistent or had conflicting results, then 2 of course that would tell you there is less evidence for 3 association.

4 Q. So if we could have, please, page 32 of your report up 5 on the screen.

> My Lady, unless you wish me to deal with it in another way, I'm going to focus exclusively on the very helpful summaries for each condition that Professor Prieto-Alhambra has identified.

These summaries, you've drawn for our benefit the text and the substance of your report, which runs to -pages 30 on to 80 or thereabouts, into summary boxes for each of the conditions, so -- for ease of understanding.

14 Myocarditis and pericarditis, you conclude that 15 there was moderate-high quality evidence suggesting an 16 association between those conditions and the Pfizer or 17 Moderna vaccines, and it's "or" because they are both 18 mRNA vaccines; is that right?

19 PROFESSOR PRIETO-ALHAMBRA: Correct. That is correct.

In terms of the severity of outcome, this, would you describe as very -- as a rare condition, a rare adverse event, gave rise to some cases of hospital admission -is there any material to suggest that there was anything other than extremely rare fatality or, indeed, some studies suggest no associated fatality?

1	PROFESSOR PRIETO-ALHAMBRA:	There's many, many reports of
2	myocarditis or pericarditis follow	ving the vaccines, with

3 very few fatalities, and of course it's hard to know

- whether those were related to the condition in the first
- 6 Q. But the studies themselves don't talk in terms of even
- 7 there being the possibility of large numbers of

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- 8 fatalities being associated with the mRNA vaccines. The
- 9 evidence and the data, even at the highest point, puts
- 10 the number of possible fatalities at a very low level.
- PROFESSOR PRIETO-ALHAMBRA: A very low number indeed. 11
- 12 Right. And does the data suggest, in fact --
- 13 paragraph 5.16 -- that whilst there is a risk of
- 14 myocarditis after vaccination, the risk was much lower
- 15 compared to that seen following Covid infection in the
- 16 unvaccinated. And, I should say, that's the conclusion
- 17 of one particular study to which you refer. Was that
- 18 outcome, that proposition, consistent with the
- 19 generality of the material you looked at?
- 20 PROFESSOR PRIETO-ALHAMBRA: That is correct. And I would
- 21 say this study, in particular, by Patone et al, is
- 22 probably one of the best quality studies on this topic.
- 23 Q. Turning, then, to the system response and the way in
- 24 which the condition of myocarditis and pericarditis
- 25 emerged, do you reach the view that the MHRA's response
- 1 you would be potentially causing harm.
- 2 Q. You're allowing people to die?
- 3 PROFESSOR PRIETO-ALHAMBRA: Yes.
- 4 Q. So your assessment of the appropriateness of the
- 5 regulator's response, coming back to Professor Evans'
- 6 evidence, has to take into account this risk-benefit.
- 7 You must weigh up the number of deaths and the
 - likelihood of deaths which would occur if you don't
- 9 vaccinate against a very rare possibility, in the case
- 10 of myocarditis, of hospitalisation, from the vaccine?
- PROFESSOR PRIETO-ALHAMBRA: That is --11
- 12 Q. That's the balance?

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- PROFESSOR PRIETO-ALHAMBRA: That is correct. There are, of 13
- 14 course, other actions that a regulator can take and did
- 15 take, including making the public aware of this problem
- 16 so they could seek care when they felt unwell, or
- 17 monitoring more closely the data on particular -- in
- 18 particular subgroups for myocarditis, pericarditis, we
- 19 know that there is evidence that there was a higher risk
- 20 for younger men after the second dose, for example. So
- 21 all those things are important, and they do not cause
- 22 any harm.
- 23 Q. TTS, thrombosis with thrombocytopenia syndrome. Did the
- 24 material and the data show that there was an
- 25 association, in rare cases, with AstraZeneca? 95

- was appropriate, given the nature of the safety signals 1 2 which were then emerging?
- 3 PROFESSOR PRIETO-ALHAMBRA: Indeed, I think it was
- 4 appropriate, partly because both the virus you were
- 5 preventing with the vaccine and the vaccine itself could
- 6 potentially cause this condition but also because, of
- 7 course, the Covid vaccines also prevented many other
- 8 problems, including, of course, heart failure and
- 9 respiratory failure due to the infection. So the
- 10 benefit-risk seemed to be consistent and balanced. And
- 11 the actions taken were also very much in line with those
- 12 taken by many other regulators, internationally.
- 13 Bluntly, if a country is in the course of a vaccination
- 14 campaign and the vaccine is known and obviously prevents
- 15 death, in the case of Covid, vaccination prevented
- 16 deaths on a daily basis, and is now recognised to have
- 17 saved hundreds of thousands of lives in the United
- 18 Kingdom, if you stop a programme, do people -- will
- 19 people start dying in greater number because they have
- 20 not got the beneficial effect of the vaccine?
- 21 PROFESSOR PRIETO-ALHAMBRA: So, of course, the
- 22 counterfactual of vaccination is, in the case of Covid,
- 23 with its transmissibility, getting Covid without being
- 24 vaccinated, and therefore, when you stop, if you stop
- 25 a vaccination programme like this based on that signal,
- 1 PROFESSOR PRIETO-ALHAMBRA: Yes, again we have moderate to 2
 - high quality data suggesting an association.
- 3 Q. TTS can sometimes be fatal, can it not?
- 4 PROFESSOR PRIETO-ALHAMBRA: It is, and it's also said, and
- 5 there is evidence to say that it was more severe or more
- 6 fatal at the beginning when we started learning about
- 7 these effects and it probably got more treatable as we
- 8 learned more about it.
- 9 Q. How rare is it as a condition?
- 10 PROFESSOR PRIETO-ALHAMBRA: Yes, so looking at the Yellow
- 11 Card reports from the MHRA, it says it's around 22 per
- 12 million doses in people below the age of 50, and about
- 13 half of that in people older than 50.
- 14 Q. So 21.8 cases per million, and 11.3 per million in those
- 15 aged 50 or older, and then a proportion of those very,
- 16 very rare number of cases led to fatalities?
- 17 PROFESSOR PRIETO-ALHAMBRA: Yes, I think the MHRA estimates
- 18 are about one in four overall.
- 19 All right. And the quality of evidence, I may have Q.
- 20 asked you already, showing or demonstrating an apparent
- 21 association is good or high?
- 22 PROFESSOR PRIETO-ALHAMBRA: It's very similar to the quality
- 23 of evidence on myocarditis/pericarditis, so it's
- 24 moderate-high, meaning that we have cohort studies and
- self-control studies with adequate control for 25

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- 1 confounding and -- and biases.
- 2 Q. Can blood clots, however, be caused by Covid itself?
- 3 PROFESSOR PRIETO-ALHAMBRA: There is similar quality of
- 4 evidence suggesting that blood clots, including the rare
- 5 blood clots of the brain, also known as CVST, can be
- 6 also caused by Covid disease.
- 7 Q. And are your conclusions and is your view similar to the
- 8 view taken or rather, is the evidence and the data
- 9 you've looked at similar to that which is available in
- 10 Europe, as far as you're aware?
- 11 PROFESSOR PRIETO-ALHAMBRA: Yes. Very similar. This is
- 12 a point in my report where I think I make
- 13 a recommendation that a better or more formal
- 14 collaboration could help, because the fact that the
- 15 AstraZeneca vaccine was used for a very different
- 16 population in Europe made it -- gave an opportunity for
- 17 a sharing of data earlier on.
- 18 Q. The -- not every European country adopted a rollout
- 19 prioritisation system in the way that we did by focusing
- 20 on the very elderly first, along with their carers, and
- 21 working down through the ages.
- 22 PROFESSOR PRIETO-ALHAMBRA: Most of them did, but the
- 23 AstraZeneca vaccine, as I mentioned earlier, was --
- there was less representation of very elderly people in
- 25 the trials, and some countries like France or Spain, for 97
- 1 **PROFESSOR PRIETO-ALHAMBRA:** This one is classified as a very
- 2 rare side effect.
- 3 Q. And can it be caused by Covid itself?
- 4 **PROFESSOR PRIETO-ALHAMBRA:** And it can be caused by Covid itself, and there's good evidence on that as well.
- 6 Q. Paragraph 5.60. Is there a greater risk, indeed, that
- 7 it might be caused by Covid as opposed to the vaccines?
- 8 PROFESSOR PRIETO-ALHAMBRA: So again, there is at least a
- 9 very good quality study, in fact two in this case,
- 10 suggesting that the excess risk is even more following
- 11 Covid in the unvaccinated people than following the
- 12 vaccination with the AstraZeneca vaccine.
- 13 Q. No trials were stopped or paused on account of the
- 14 emergence in study cases of Guillain-Barré syndrome, and
- 15 it wasn't, I think -- there was no time, was there, when
- 16 cases of Guillain-Barré syndrome started to emerge which
- 17 led to specific consideration by the MHRA of whether or
- not to pause authorisation, by comparison to the debate,
- 19 which we'll look at with June Raine, about TTS and
- 20 myocarditis; is that right?
- 21 **PROFESSOR PRIETO-ALHAMBRA:** I don't think so.
- 22 Q. All right.
- 23 PROFESSOR PRIETO-ALHAMBRA: Not to my knowledge.
- 24 Q. Bell's Palsy, page 44, is a rare weakness or lack of
- 25 movement on one side of the face, so you described it as 99

- 1 example, tended to prioritise the use of the AstraZeneca
 - vaccine for younger people because they thought they
- 3 didn't have enough evidence that it would work in the
- 4 older populations.
- 5 Q. And is that why certain medical conditions started
- 6 appearing in Europe first, because generally speaking,
- 7 AstraZeneca was given to a different age cohort than it
- 8 was being given in Britain?
- 9 PROFESSOR PRIETO-ALHAMBRA: I speculate in my report that
 - that might be the case because, indeed, this condition
- 11 was more common, as I mentioned, in younger people, and
 - those were the ones being vaccinated with this vaccine
- 13 earlier on in those countries.
- 14 Q. Page 41, Guillain-Barré syndrome. What is that
- 15 syndrome?
- 16 PROFESSOR PRIETO-ALHAMBRA: So Guillain-Barré syndrome is an
- 17 autoimmune and inflammatory condition of the central
- 18 nervous system that leads to muscle weakness, and it can
- be life threatening. It can be quite severe.
- 20 Q. What was the quality of evidence suggesting an
- 21 association with AstraZeneca, and in fact Janssen?
- 22 **PROFESSOR PRIETO-ALHAMBRA:** Again, very similar to the
- 23 previous. So this would be moderate-high, meaning that
- there are good quality observational studies.
- 25 Q. Rare, very rare, or extremely rare?

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- 1 rare. Rarely serious or fatal. It may not always
- 2 resolve completely. Is there evidence to suggest an
- 3 association with the AstraZeneca, Janssen, Moderna, and
- 4 Pfizer vaccines?
- 5 PROFESSOR PRIETO-ALHAMBRA: Yeah, again, this is what we
- 6 classified as moderate-high quality evidence, meaning
- 7 that there is good quality observational studies, in
- 8 this case with a little bit less consistency across
- 9 them.

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- 10 Q. And can you draw -- do you have a conclusion as to the
- 11 comparative levels of risk between getting Bell's palsy
- from a vaccine as opposed to from coronavirus itself?
- 13 Paragraph 5.67.
- 14 PROFESSOR PRIETO-ALHAMBRA: Yes, there is again a number of
- 15 studies that suggest there is an association between
 - SARS-CoV-2 or Covid and Bell's palsy.
- 17 Q. Transverse myelitis. We recall that there were three or
- four, I think, cases of suspected transverse myelitis in
- 19 the course of the trials for one of the vaccines. Is it
- 20 a very rare or extremely rare medical condition?
- 21 **PROFESSOR PRIETO-ALHAMBRA:** This is sitting somewhere
- between very rare and extremely rare, with a likelihood or a rate of around or below one in 100,000 doses.
- 24 **Q.** No regulator, did it, reached the conclusion that the
- 25 transverse myelitis cases which emerged in the course of

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- 1 the safety trials was in fact causatively connected to a 2 vaccine, did it?
- 3 PROFESSOR PRIETO-ALHAMBRA: No, there was -- as we discussed 4
 - before, there was the halting of one of the trials in
- 5 the UK because of a case, but then that was resolved and
- 6 the trial continued later on.
- Q. And is that reflected in the quality of evidence 7
- 8 suggesting an association with any vaccine, but
- 9 particularly AstraZeneca and Janssen, is the quality of
- 10 evidence suggesting any association good, bad or low --
- or good -- very good, good or low? 11
- 12 PROFESSOR PRIETO-ALHAMBRA: Here we thought it was low or
- 13 moderate at best, because there's good quality studies
- 14 but they're not consistent; some of them find
- 15 association, some of them don't.
- 16 Q. Page 48, immune thrombocytopenia. Is this a condition
- 17 which, in the past, has been associated with previous
- 18 vaccines?
- 19 PROFESSOR PRIETO-ALHAMBRA: It is, and it was, therefore.
- 20 monitored again, as an adverse event of special interest
- 21 by most regulators internationally, including by the
- 22 MHRA
- 23 Q. And post-authorisation, has it identified itself as
- 24 a rare or extremely rare condition?
- 25 PROFESSOR PRIETO-ALHAMBRA: The data I have seen says it's
- 1 of this condition going forward.
- 2 Q. Capillary leak syndrome, you conclude on page 50 that
- 3 the quality of evidence suggesting association with the
- 4 vaccines is low. Acute disseminated encephalomyelitis,
- 5 page 51, an extremely rare condition, you say the
- 6 quality of the evidence suggesting association is
- 7 low-moderate.

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And anaphylaxis, which is the severe allergic reaction, page 53, you say the level of evidence

suggesting an association is, again, low quality.

So the material doesn't appear in each of those cases to suggest -- or at least there's only low quality evidence to suggest that there is an association of any type with a vaccine, let alone causative.

Could we have up paragraph 5.119, please.

Did you go through all the Core Participant witness statements and identify a very long list of medical conditions and health issues to which they refer, draw them up in your paragraph 5.119, and then scour the academic and scientific literature for what they said about these conditions and reach a view as to whether or not the literature showed a sufficient degree of

- 23 association as to merit, in your view, further enquiry?
- 24 PROFESSOR PRIETO-ALHAMBRA: So we were provided with that

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25 evidence, and there's a long list indeed, of -- I think

- around ten per 100,000, so that would be rare.
- 2 Q. And is it a condition which can be caused by Covid 3
- 4 PROFESSOR PRIETO-ALHAMBRA: It is, again, a condition that
- 5 we have good evidence can be -- suggests it can be 6
- triggered by Covid itself.
- 7 Q. In relation to immune thrombocytopenia, did the expert 8 working group of the Commission on Human Medicines in
- 9 fact give advice on this condition in the spring and
- 10 autumn of 2021 to the MHRA?
- 11 PROFESSOR PRIETO-ALHAMBRA: There are discussions in
 - April 2021 on this topic already, yes.
- 13 Q. And in light of the risk-benefit analysis and the
- 14 overall benefits of the vaccination programme, did the
- 15 MHRA on both occasions determine that vaccination should
- 16 proceed, albeit notification and publications concerning
- 17 the vaccines were amended?
- PROFESSOR PRIETO-ALHAMBRA: That is correct. 18
- 19 Q. And was that an appropriate cause to take, in your view?
- 20 PROFESSOR PRIETO-ALHAMBRA: I think it was an appropriate
- 21 course, again in line with that taken by many other
- 22 regulators, including neighbouring European Medicines
- 23 Agency. The MHRA I think also, importantly, consulted
- 24 consultant haematologists and tried to work on an
- 25 operational case definition to facilitate the monitoring

1 it is 80 or 81 conditions in my report, for which we

3 and tried to identify where we could see any evidence of

conducted a quick review of the literature in PubMeds

4 an association, and then go on to make recommendations

5 on which of these conditions could potentially merit

further research.

I want to add that it is -- the fact that for some of these there is no published evidence that doesn't necessarily mean that there isn't an association; it

10 just means that maybe they are too rare or too complex

11 or nobody has investigated them. But of course the

12 absence of evidence doesn't equate to evidence of

13 absence of an association in this case.

14 Q. But it says something about the degree or scale of the 15 problem, if there is one.

16 And you identify, if you go back to [pages 56/57], 17 14 of that long list, I think there's -- perhaps even

18 110 conditions you've looked at, but 14 of them, chronic

19 obstructive pulmonary disease, varicella-zoster-virus

20 reactivation, ie shingles, seizures, shoulder injury

21 related to vaccine administration, tinnitus, autoimmune

22 connective tissue disease, rheumatoid arthritis,

23 systemic lupus -- I'm not sure I can go on, I'm bound to

24 fall into error if I try to pronounce any more of

25 these -- fibromyalgia, Graves' disease, depression,

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2		there is some material to suggest an association, and
3		therefore they are conditions which would merit from
4		further investigation by, in particular, the MHRA?
5	PR	OFESSOR PRIETO-ALHAMBRA: Indeed, I just want to add that
6		some of those in fact, some of those published
7		manuscripts do suggest no association. So it's not true
8		that all of them had an association. It is just true
9		that there is some evidence, or some literature study
10	Q.	There is at least one study
11	PR	OFESSOR PRIETO-ALHAMBRA: Yes.
12	Q.	that says something about the possibility of an
13		association?
14	PR	OFESSOR PRIETO-ALHAMBRA: Yes, and in some cases like, for
15		example, COPD, that study was neutral saying there is no
16		association. So I then go on to review each one of them
17		in the summary box in page 55 (overspeaking)
18	Q.	In the remainder of that very long list you found
19		nothing
20	PR	OFESSOR PRIETO-ALHAMBRA: (overspeaking)
21	Q.	and therefore you don't even suggest that there is
22		a further inquiry into those other conditions?
23	PR	OFESSOR PRIETO-ALHAMBRA: I do not think I think we
24		should prioritise the ones where we do see at least some
25		evidence of an association, currently.
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1	Q.	Excess deaths, you've already expressed your view on
2		thank you very much, page 68. And then you make a
3		number of recommendations at page 70. I just want to
4		pick up just three of them.
5		At A you refer to the regulatory rolling review
6		which was in place, but you say it should be replicated.
7		B, you make the point you made earlier, as did
8		Professor Evans, there needs to be a better joining up
9		of data to track vaccine risks and benefits in real
10		time.
11	PR	OFESSOR PRIETO-ALHAMBRA: Mm-hm.
12	Q.	D, this is the point you made earlier about PASS studies
13		being commissioned or rather not being commissioned by
14		us but being commissioned by the FDA and the EMA, there
15		needs to be a mechanism for the commissioning and
16		funding of specific studies for post-marketing vaccine
17		safety, and perhaps, Professor Evans would say, if I can
18		speak for him, of a randomised control nature.
19		And then E, you identify the 14 conditions which you
20		looked at and which you suggest there should be further
21		consideration of.
22		And H, there must also be a continuing focus on
23		proper diversity in vaccine clinical trials.
24		Are those the most important of your
25		recommendations?
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optic neuritis, and heart failure, you conclude that

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Q.	All right. And then finally, in relation to menstrual
	disorders, page 63, you say there is no good quality
	studies to suggest evidence of a long-term impact of the
	Covid vaccines on menstruation.
	Page 65, you make what might be thought to be a very
	obvious point, which was there were multiple mild and
	temporary side effects identified in the trials, as

Professor Evans has said? PROFESSOR PRIETO-ALHAMBRA: Yes. 9

10 Q. But also apparent from real-world data, injection site 11 reactions, fever, fatigue, and flu-like symptoms?

Q. And then there were a number of publicly-reported

PROFESSOR PRIETO-ALHAMBRA: Correct. 12

14 alleged side effects which, on investigation, you were able to satisfy yourself could not be confirmed, that is 15 16 to say they did not appear to be right. One, that there 17 was any adverse effect on pregnancy, there was no 18 support, no material, to suggest any adverse effect on 19 pregnancy.

20 PROFESSOR PRIETO-ALHAMBRA: No good-quality data suggesting 21 that, no.

22 Q. Page 67, no good-quality material -- in fact, you said 23 no study to date to demonstrate an association between 24 Covid-19 vaccines and fertility in male or female form?

25 PROFESSOR PRIETO-ALHAMBRA: Correct.

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1 PROFESSOR PRIETO-ALHAMBRA: I think so, yes. 2 MR KEITH: Thank you very much. And those are all the 3 questions I have. 4 LADY HALLETT: Thank you. 5

Ms Morris, I think you have couple of questions for Professor Evans.

Questions from MS MORRIS KC

MS MORRIS: I do, my Lady, thank you. 8

Good afternoon, Professor Evans. I ask questions on behalf of the Covid vaccine Adverse Reaction and Bereaved groups, just so you understand the context of my questions, and I have two questions on two discrete topics, please, one about the patient information leaflet, and its use at the time of the pandemic; and the second, a more forwarded-looking question about adverse effect reporting. Okay?

So my first topic, patient information leaflets. One of the observations you made in your report was that one study you'd considered found that nearly 20% of individuals had never read the patient information leaflet, and you said that over half of the respondents in that study, 56%, never sought more information about the possible side effects of medicine.

So my question is going to be about accessibility and the information provided. Just as a point of

2	or any studies as to now many of those vaccinated	2	I think, if I may just add a comment, that I would
3	actually received a patient information leaflet? Is	3	wish to express my enormous sympathy with those who
4	that data available?	4	died following vaccination, and I think there are
5	PROFESSOR EVANS: I'm not aware of that. The UK, as	5	undoubtedly cases where a vaccine has led to death.
6	I understand it, from one of the manufacturer's	6	There are deaths following vaccination that may no
7	evidence, was one of the few states to demand a paper	7	be as a result of the vaccine, but I think, as
8	patient leaflet that could be given and made available	8	a community, we have to acknowledge that that does
9	at vaccination centres. In many instances, there was	9	happen in extremely rare cases, and that such people
10	simply a QR code which enabled somebody with a mobile	10	need to be looked after properly, and their relatives
11	phone to scan it and go to a website, and find the	11	and those who are bereaved need proper treatment. A
12	information. From the manufacturer's point of view,	12	so anything I've said about those things, I'd want to
13	that meant that everything was always up to date,	13	acknowledge the pain and the loss in those
14	whereas a paper leaflet may not be up to date, and	14	circumstances.
15	keeping a paper leaflet up to date when you're dealing	15	Q. Thank you for those comments. And I'm sure that exter
16	with millions of vaccinations is very difficult.	16	to those that have been injured by the vaccine?
17	I am not I think it's very likely, and from my	17	PROFESSOR EVANS: Yes, absolutely.
18	own experience very likely, that the majority of	18	Q. Yes, thank you.
19	patients getting Covid vaccinations did not read a PIL.	19	Just returning back to the information leaflet
20	Q. Thank you. But in terms of whether they had them or	20	LADY HALLETT: I think you're going to have to move on,
21	not, I only ask that because, from the one of the	21	Ms Morris. You've asked questions for which I didn't
22	groups I represent, the evidence that they've provided	22	give permission, and if you want to get in a second
23	to the Inquiry is that only 19% of that particular group	23	question, I'd suggest you ask it now.
24	were actually given I wonder if there was any data on	24	MS MORRIS: Thank you.
25	that, any studies that have been completed? 109	25	The forward-looking question I wanted to ask you, 110
1	Professor, was about the ability for vaccine injury to	1	Ethnic Minority Healthcare Organisations, and FEMHO
2	be reported. One of the things the Vaccine Injured and	2	concerned that there is an underrepresentation of black
3	Bereaved have suggested is that the NHS app, so the app	3	Asian and minority ethnic people during
4	that we can download onto our phones, includes a feature	4	pharmacovigilance monitoring, and that raises question
5	that allows individuals to report vaccine injury	5	about whether there was underreporting of race-related
6	directly through that app. You've talked a bit about	6	adverse outcomes in vaccine usage. That's the genera
7	data and connectivity; is that something that would have	7	premise.
8	your support as a proposal?	8	Sickle cell anaemia is a blood disorder that
9	PROFESSOR EVANS: There has been an app to report adverse	9	primarily affects black, Caribbean, and African people.
10	reactions, a Yellow Card app, since 2015. And so	10	Are you aware of any targeted pharmacovigilance
11	I don't see adding it to the NHS App is a key element.	11	monitoring of the performance of vaccines for this
12	That would lead to complexity. The NHS App is not	12	particular subgroup?
13	designed to connect to the Yellow Card system. Perhaps	13	PROFESSOR PRIETO-ALHAMBRA: I am not aware of a targ
14	to have on the NHS App something that tells you about	14	pharmacovigilance activity for people with sickle cell
15	the Yellow Card app may be more practical.	15	disease or sickle cell anaemia. I would say this is
16	It sounds a great idea, but practicality and	16	a case where I would expect the vaccines to be
17	existence of an existing one I would say is better.	17	potentially more beneficial even than for the general
18	Q. A single point of access is important?	18	population, given the likelihood that these people might
19	PROFESSOR EVANS: Not necessarily.	19	get more severe outcomes when they catch Covid, and
20	MS MORRIS: Okay, thank you.	20	I think they could and should be included in
21	Thank you, my Lady.	21	post-marketing authorisation studies.
22	LADY HALLETT: Ms Banton.	22	Q. So you would say that, in your view, there is value in
23	Questions from MS BANTON	23	the targeted pharmacovigilance monitoring, like in the
24	MS BANTON: Thank you, my Lady.	24	sample of sickle cell sufferers?
25	I appear on behalf of FEMHO, the Federation of 111	25	PROFESSOR PRIETO-ALHAMBRA: In the form of

information, can you assist with, is there any analysis

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PROFESSOR EVANS: I'm not aware of that. I think, if I may just add a comment, that I would ress my enormous sympathy with those who have ing vaccination, and I think there are ly cases where a vaccine has led to death. are deaths following vaccination that may not sult of the vaccine, but I think, as ity, we have to acknowledge that that does extremely rare cases, and that such people looked after properly, and their relatives who are bereaved need proper treatment. And I've said about those things, I'd want to ge the pain and the loss in those ces for those comments. And I'm sure that extends at have been injured by the vaccine? VANS: Yes, absolutely. you. turning back to the information leaflet --: I think you're going to have to move on, You've asked questions for which I didn't sion, and if you want to get in a second d suggest you ask it now. Thank you. ward-looking question I wanted to ask you, ority Healthcare Organisations, and FEMHO is that there is an underrepresentation of black, minority ethnic people during rigilance monitoring, and that raises questions ther there was underreporting of race-related tcomes in vaccine usage. That's the general cell anaemia is a blood disorder that fects black, Caribbean, and African people. are of any targeted pharmacovigilance of the performance of vaccines for this ubgroup? RIETO-ALHAMBRA: I am not aware of a targeted rigilance activity for people with sickle cell sickle cell anaemia. I would say this is ere I would expect the vaccines to be more beneficial even than for the general

1	post-authorisation studies, observational studies
2	I think I make a generic recommendation in my report,
3	I think it's recommendation I, where I say we should
4	make sure that there is good monitoring of vaccine
5	effectiveness in people who have been underrepresented
6	or literally excluded from trials, like pregnant women,
7	the minute the vaccines are rolled out. And I think
8	this is an illustrative example of precisely that,
9	a group that could benefit from that kind of study being
10	done when the vaccines are approved.
11	MS BANTON: Thank you so much, Professor.
12	If I may my I adv may I ask the same question of

MS BANTON: Thank you so much, Professor.
If I may, my Lady, may I ask the same question of
Professor Evans, just on the same point in relation to
sickle cell?

15 LADY HALLETT: I don't think we need it, do we? Thank youvery much.

17 **MS BANTON:** Thank you very much, my Lady.

18 LADY HALLETT: I think I've got the point.

19 MS BANTON: Thank you.

20 LADY HALLETT: Very well, that completes the questions we have for you, Professors. I'm really grateful to you for your help, you've obviously done a huge amount of work, and you explained it in ways that I could understand and, I hope, that those following could understand. So thank you both very much indeed for all

questions about your professional background. You are, as is well known, the chief executive of the Medicines Healthcare products Regulatory Agency, or MHRA as we're going to call it from now on.

You were, a while back, within the medicines division of the Department of Health as a senior medical officer. And then I think you were principal assessor to the Medicines Commission, and then director of post-licensing division of the Medicines Control Agency. So you've got many years' experience in the field of safety processes, if I may put it in that very general way; is that right?

13 **A.** I have.

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Q. And were you, in fact, specifically responsible for the operation of what we know to be the Yellow Card scheme about which we'll be -- which we'll be looking at in some detail later this afternoon, when you were in the post-licensing division of the Medicines Control Agency?

19 **A.** Yes, I was.

Q. Were you also chair of the pharmacovigilance risk
assessment committee of the EMA, the European Medicines
Agency, and have you been a member, and are you
subsequently still a member of, and I think you may be
the co-chair now, of the WHO's advisory committee on
safety of medicinal products?

1 your assistance and for your time today.

The Internet says 1.10, so I shall return at 2.10.

3 (The witnesses withdrew)

4 (1.10 pm)

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(The Short Adjournment)

6 **(2.10 pm)**

7 MR KEITH: My Lady, this afternoon's witness is Dame June

8 Raine. If she could be sworn, I'd be very grateful.

DAME JUNE RAINE (sworn)

10 LADY HALLETT: I hope you haven't been waiting too long,11 Dame June.

12 THE WITNESS: No, your Ladyship.

13 Questions from LEAD COUNSEL TO THE INQUIRY for MODULE 4

14 MR KEITH: Could you commence your evidence, please, by15 giving us your full name.

16 A. My name is June Munro Raine.

17 Q. Thank you very much, Dame June. And thank you very much
 18 for your attendance today and also for providing the two
 19 witness statements which you have, dated

20 11 September 2024, and then, in response to a particular 21 query raised of the MHRA by us, a second statement dated 22 20 December 2024.

We're very grateful to you for assisting us with the provision of that evidence.

25 I'd like to just start, please, by asking you some 114

A. May I correct that. I have recently stepped down from that role.

Q. Well, I'm very pleased to hear that you've eased upsomewhat on the extent of your professional functions.

Dame June, you will have been aware from the opening to Module 4 of the scope of this module, and the general approach which it is applying to the consideration of the matters which are within the scope of its review in this hearing.

I don't propose to ask you very many questions about the structures and the processes concerned with safety and side effects, because I opened them at length, we've heard a lot in the expert evidence from other witnesses about what they amount to and what they consisted of. But what we're interested in is focusing on particular aspects of the systems for which the MHRA was responsible, in order to learn from your evidence what went well, and what didn't go quite so well, and focusing on what matters, rather than the generality of the position. Do you follow?

21 A. Thank you.

Q. And so we're going to focus on a number of discrete but
 important issues which have been raised in part in the
 course of this hearing by the Core Participant groups in
 particular.

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- 1 The MHRA is the UK's regulator of medicines, medical 2 devices, and blood components for transfusion, is it 3 not?
- 4 A. Yes.
- 5 Q. And so in very general terms, is the MHRA the body 6 responsible for ensuring the safety, as well as the 7 quality and the effectiveness of all those medicines and 8 medicinal products?
- 9 A. Yes, it is, though I would perhaps phrase that our role 10 is to ensure that these healthcare products, vital products, work and are acceptably safe. 11
- 12 We'll look at that in a moment but that obligation to Q. 13 ensure they are acceptably safe lies at the heart of 14 your functions?
- 15 A. It does.
- 16 Q. Although you are an executive agency within the DHSC, is 17 that correct, are you nevertheless operationally 18 independent?
- 19 Α.

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- 20 Q. What does that mean, in practice, being operationally 21 independent?
- 22 A. It means that the decisions on safety, quality, 23 efficacy, based on evidence, are solely the 24
- responsibility of the agency. And, as I'm sure is clear 25 from what other witnesses have shared with the Inquiry,

1 health ministers. Therefore we were wanting to assure 2 that health ministers had all appropriate advice.

Q. And we'll look at the CHM in a moment, but thank you for that.

In addition, to ensure the reality and appearance of independence, because the DHSC was of course intimately involved through the Vaccine Taskforce and other bodies in the purchase and deployment of vaccines, did you put into place a system whereby the Licensing Minister, to whom you have referred, was a separate government minister to the Secretary of State and the other ministers involved in deployment and delivery and so on?

- We did, and we felt that was extremely important, that 13 14 the decisions on which we offered advice, and on which 15 the Commission on Human Medicines offered advice, were 16 entirely separated from decisions of procurement and any 17 financial considerations.
- Q. Is the MHRA a UK executive agency, a UK regulator? 18
- 19 Α.
- 20 Q. And therefore, were the decisions that you took made on 21 behalf of all the nations within the United Kingdom?
- 22 A. Yes, and it meant that we would, as we normally do, 23
- engage closely with the devolved governments to ensure
- 24 that there was a good understanding of our activities, 25
 - processes, and likely directions.

1 the independence of those decisions is basically our 2 licence to operate.

3 Q. Normally, and in many cases, the MHRA will take 4 a decision, in the scope of its functions, on behalf of 5 the Secretary of State of Health and Social Care. But 6 in the context of Covid-19, we've seen from the evidence that a UK minister in fact acted as the final decision 7 8 maker on authorisation, as the Licensing Minister.

> Why, in the context of Covid-19, did you put this particular provision, this particular process, in place?

Clearly, operationally, the agency's responsible for 11 12 many decisions at any one time, but the significance of 13 novel products that would be used in many people meant 14 that the independence and rigour of the decision making 15 needed to be beyond any question.

> The agency, in fact, is the executive arm of the licensing authority, health ministers, for all of its decisions, but this clearly was a very special set of circumstances and it seemed very appropriate that the licensing authority, the Health Minister, the Secretary of State, should be in a position to exercise that full power.

And I would just add that the independence provided by the expert advisory system, which is a statutory system, the Commission on Human Medicines, is advice to 118

- 1 So, in fact, does your statement demonstrate that you 2 met with the Scottish, Northern Irish and Welsh 3 ministers for health, their chief pharmacists, and 4 officials, very, very regularly?
- 5 A. We did.
- 6 Q. In the actuality, the regulation which was relied upon 7 for the purposes of the decisions to authorise each of 8 the UK vaccines, was 174 of the Human Medicines Regulations. Is that a UK legislative instrument? Is 9 10 it a power, a legal power, that applies across the whole 11 of the United Kingdom?
- 12 A. It is, and it reflects the permission in European law to 13 use such an act, such a basis for action, in the event 14 of a public health threat.
- 15 Q. By that you mean there are regulations that were based 16 upon and drawn from, when they were initially drafted, 17 a piece of EU legislation called an EU Directive, and 18 then latterly, a regulation.

So they apply these regulations equally to England, Scotland Wales, and Northern Ireland, but in fact, prior to 11 o'clock on the last day of December 2020, the regulatory system which was then in place was, in fact, the European one. When we left the European Union, we reverted back to exclusive reliance upon our own legislative foundations, but not in the case of Northern

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1 A.

Yes.

1		Ireland. Is that right?
2	A.	That's correct.
3	Q.	Because Northern Ireland remained within the
4		EU regulatory framework until later when the Windsor
5		Framework came to be agreed. But did that matter, given
6		that the regulations upon which the MHRA, were relying
7		was that UK-wide piece of legislation, Regulation 174?
8	Α.	It didn't matter for 174, but when European decisions
9		were made, they would have effect in Northern Ireland
10		and our decisions for Great Britain, and our goal was to
11		ensure equitable access right throughout the
12		United Kingdom.
13	^	And so in reality, there was no difference. The
14	Q.	
		lawfulness and the substance of every decision taken on
15		safety and authorisation applied equally to the citizens
16		of Northern Ireland?
17	Α.	Yes.
18	Q.	But as it happened, for a while, decisions taken at
19		European level by the EMA, for example, to authorise
20		a particular vaccine, had direct effect in Northern
21		Ireland but it didn't matter because you were taking
22		decisions on behalf of Northern Ireland anyway through
23		Regulation 174?
24	A.	Yes.
25	Q.	Have we got it right?
		121
4		Sir Patrick Vallance.
1	^	
2	Q.	
3		just being independent but being seen to be independent
4		operationally?
5	Α.	Absolutely.
6	Q.	1 7,
7		Medicines, to which you've already referred, technically
8		gives advice to the Secretary of State on medicinal and
9		regulatory matters, and works incredibly closely, along
10		with its expert working groups to the MHRA, it is also
11		an independent body or independent from the MHRA; is
12		that right?
13	A.	It is.
14	Q.	And is the MHRA also independent from the Joint
15		Committee on Vaccination and Immunisation, the JCVI?
16	A.	Yes, it is. Their roles and functions are entirely
17		separate.
18	Q.	But you all work incredibly closely together, of course?
19	A.	Yes.
20	Q.	In the public domain, there has, unfortunately, been
21		much said about potential conflicts of interest within
22		the MHRA. What degree of complexity or robustness does

the MHRA's conflict of interest policies have? I mean,

They're indeed extensive, and rigorous. And rigorously

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are they extensive?

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Α.

2 Q. Good. 3 On the subject of operational independence, did there come a point in the autumn of 2020 when the MHRA 4 5 decided not to have even a representative sit on the 6 Vaccine Taskforce? Why was that? 7 A. It was important that the Vaccine Taskforce were well 8 aware of the regulatory framework, and our whole 9 approach in the times of the early phase of the pandemic 10 was to ensure preparedness. So our goal was to ensure 11 that those who were working in the taskforce fully understood what the regulatory standards would be, and 12 13 that they would be commensurate with our normal 14 scientific standards. 15 A particular focus was to ensure that the Vaccine 16 Taskforce understood that the grant of an authorisation 17 and approval is really a milestone, it's not an endpoint, and that there would be really important work 18 19 still to be done to evaluate benefit-risk in clinical 20 21 The person who was withdrawn had completed the task 22 as our representative of advising on regulatory matters, 23 but when the work of the taskforce came to look at 24 specific products, then withdrew, and that was with 25 clear agreement of Dame Kate Bingham and the then 1 applied. Our staff adhere to a rigorously applied 2 policy and every year attest that they have no interest 3 in the pharmaceutical medical device industries. 4 And we updated our policy for our experts following 5 the independent review of the safety of medicines and 6 medical devices. 7 Is that the "do no harm" review -- (overspeaking) --8 A. -- exactly --Q. -- for later. And in very rough terms, I don't want to 9 spent time going through chapter and verse, no member of 10 11 staff in the MHRA can hold any direct financial interest in the industries that the MHRA regulates, whether 12 13 they're pharmaceutical or medical products; is that 14 right? A. That's the case. 15 Q. And, of course, are your staff subject to Civil Service 16 17 codes, in particular the Civil Service values of -- core 18 values of integrity, honesty, objectivity and impartiality? 19 20 Yes, the Nolan Principles, absolutely. 21 Q. The Nolan Principles. 22 We will see, Dame June, later, because we'll look at 23 a particular Commission on Human Medicines document, 24 that at the start of CHM meetings, certainly, and 25 perhaps also MHRA meetings, endless time is taken by

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1		every single person sitting in that room declaring any
2		interest, however seemingly tangential, to any of the
3		areas under discussion. And there's long lists every
4		time of who knows who and who does what and who has had
5		some sort of past historic connection to any of these
6		complex moving parts; is that right?
7	A.	Yes. I've dealt, I hope, with the financial aspect but
8		clearly there could be other interests of a scientific
9		nature, and it's very important to know that these are
10		possibly present.
11	Q.	The review to which you've just referred I think was
12		Baroness Cumberlege's review of July 2020, "First Do No
13		Harm".

Although the report and the review focused on three particular medical treatments, including, I think, pelvic mesh and anti-epileptic drugs, it was a review which focused in part upon the MHRA's management of any potential conflict of interest; is that right?

19 Α. Yes, it did. And for that reason we reviewed and 20 consulted on new proposals to strengthen our Code of 21 Practice.

22 Q. And were they put into place by 2021 -- or when were 23 they put into place?

24 A. I believe so, but I'll probably have to give you the 25 precise date.

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1 Innovations, CEPI, so there are some other sources, but 2 about 86% is from the regulated sector, the industry. 3 Q. Do you ever in fact charge government or state bodies

4 such as the DHSC, for any of the functions that you 5 perform?

6 Α. Not to my knowledge.

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7 Not to your knowledge, all right.

> In your statement, and we'll have it up, please, so you can see it on the screen, Dame June, INQ000474337, page 7, you've identified in a very broad sense the main functions of the MHRA, paragraph 12:

"Ensuring that medicines, medical devices and blood components ... meet applicable standards of safety, quality and effectiveness;

- "... the supply chain ... is safe and secure ...
- "... Promoting international standardisation and harmonisation ...
- "... Helping to educate the public and healthcare professionals ...
- "... Supporting innovation and research and development ...
- "... Influencing UK and international regulatory frameworks ..."

Linked to many of those primary responsibilities, appears to be the proposition that much of what you do 1 Q. All right. But as far as you're aware, they were 2 certainly in play by the time that the MHRA was involved 3 in the guts of the pandemic response in 2021?

4 A. I would like to give you the precise date.

5 Q. All right.

6 A. Another suggestion that finds some prominence in the 7 public sphere is the notion that the MHRA is directly 8 funded by pharmaceutical companies, and therefore has 9 its integrity and independence undermined by virtue of 10 that money flow.

11 Manufacturers plainly pay a fee, do they not, for 12 applications that they make to the MHRA for which they 13 are seeking authority?

14 A. Yes. And I would say, just to add to that, that the 15 recovery of costs for work done from the regulatory 16 sector is a common principle for regulators, and the UK 17 is not -- the MHRA -- in any way different in that 18 respect.

19 Is all your expenditure recovered or paid for by way of 20 the fees that you charge anybody who applies to you for 21 authority for whatever it is, or in fact is some of your 22 funding sourced from elsewhere?

23 A. Some of our funding comes from the Department of Health 24 and Social Care, and some is from grant-giving bodies 25 such as the Coalition for Epidemic Preparedness

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1 needs to be judged by reference to standards or 2 international thresholds, or international regulatory 3 requirements. Does that mean, in lay terms, that much 4 of the standards which you impose upon yourself are set 5 and agreed by other people, by other regulators or at 6 the international level, or by a process of what's 7 called assurance?

8 Δ It's correct to say that much of what we do relies on agreed standards, and after all, the industries that we 9 10 regulate, generally speaking, are international, global 11 industries. But the goal of the agency is to influence 12 the appropriate setting of those standards via our 13 participation in the International Conference on 14 Harmonisation, for one example. And therefore, those 15 standards are developed with our input, and then, if they're internationally applicable, they are ways in

16 17 which a global industry is kept to the highest

18 standards.

19 Q. How many decades of experience does the MHRA and its 20 predecessor body have in the identification of 21 appropriate standards, and in the performance of the

22 statutory functions which you carry out?

23 A. It is many decades, although predecessor organisations, 24 not always called the MHRA, but our UK influence has 25

helped to shape, for example, the International

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- 1 Conference on Harmonisation.
- 2 Q. Just remaining focused on some of the moving parts
- $3\,$ within the MHRA, an important function that the MHRA
- 4 carries out is product control testing, is it not?
- 5 A. Yes, it is.
- 6 Q. And for that, do you have access to laboratories?
- 7 A. We do. We have a science campus, the National Institute
- 8 for Biological Standards and Control merged with the
- 9 Agency in 2013, and presciently so because its
- 10 capability was fundamental to the delivery of vaccines
- 11 in the pandemic.
- 12 Q. And under myriad international agreements and perhaps
- 13 regulatory frameworks, the MHRA's laboratories are known
- 14 as the Official Medicines Control Laboratory. So they
- 15 are the United Kingdom's laboratory facilities in this
- 16 sphere?
- 17 A. Yes, they are.
- 18 Q. And putting it as simply as I am able, in the context of
- 19 vaccine testing and authorisation and including,
- 20 therefore, the three Covid-19 UK vaccines with which
- 21 we're primarily concerned, do those laboratories test
- 22 each batch of vaccine made available to the public?
- 23 A. Yes, they do, and they test them for purity and potency
- so that every person who has a vaccine will get one that
- works and doesn't have impurities.

- 1 more? Is that what you meant by "relevant"?
- 2 A. Yes, I think that would be an appropriate understanding,
- 3 your Ladyship.

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- 4 LADY HALLETT: Thank you.
- 5 MR KEITH: Some have suggested that the batches which were
- 6 delivered to the United Kingdom for use amongst its
- 7 population, which were then handed out, were not the
 - same batches, or rather were batches that were produced
- 9 by a different manufacturing process on the part of the
- 10 manufacturer, as has been -- as had been tested by the
- 11 MHRA? So bluntly, the suggestion has been made, you
- 12 tested and authorised and certified a certain number of
- 13 vaccines made by process, manufacturing process A, and
- 14 then the manufacturers actually delivered vaccines to
- 15 British population produced as a result of a different
- manufacturing process, and one, by inference, which had
- 17 not been tested. Is that right?
- 18 **A.** Well, my understanding is that the manufacturing process
- 19 would have been the same.
- 20 Q. When manufacturers engage in the development of
- 21 a vaccine or a medicine, and they're carrying out
- 22 initial research and development, will they necessarily
- 23 have built up to scale the manufacturing process which
- 24 might be needed in the event of a successful development
- 25 of that product?

- 1 Q. So nobody can receive a dose, a vaccine, unless it is
 - from within that batch, each batch of which is tested by
- 3 the United Kingdom's Official Medicines Control
- 4 Laboratory, and a certificate issued to that effect?
- 5 A. Yes.

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- 6 Q. Is that testing independent to the testing done by the
- 7 manufacturer?
- 8 A. It is.
- 9 Q. Roughly how many doses are there in each batch?
- 10 A. An earlier witness, Professor Evans, was talking around
- 11 perhaps tens of thousands. It may be as many as
- 12 a million, and of course, it's not possible to test
- every single one of those. It wouldn't be appropriate.
- 14 So a relevant sample is tested and rigorously assured
- 15 for purity and potency.
- 16 Q. So a number of doses in each batch, I'm going to presume
- that you don't just test one vial in a single batch of
- a million doses, but a number of doses in that batch are
- 19 tested, and every single batch is tested?
- 20 A. Absolutely.
- 21 Q. All right.
- 22 LADY HALLETT: Sorry, just to interrupt. You say a
- 23 "relevant" number tested. Is that relevant to the
- number of doses there are in the batch? In other words,
- 25 if it were a million doses in a batch, would you test

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- 1 A. They might not have, but our inspectorate, who look at
- 2 the manufacturing sites in great detail for the
- 3 standards that will be applied, were working with likely
- 4 manufacturers very early on, so that those issues could
 - be dealt with at the time of scale-up.
- 6 Q. And when the manufacturing processes came to be scaled
- 7 up in the case of the vaccines which did prove to be
- 8 successful, and therefore could be authorised and rolled
- 9 out, was the MHRA alert to any changes in the
- 10 manufacturing processes?
- 11 A. Yes, we would have been.
- 12 Q. And therefore, does it follow that if there were any
- changes which had any potential at all of impacting upon
- 14 the quality, the effectiveness or the safety of the
- 15 vaccine, you were aware of it and alert to it?
- 16 A. Yes.

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- 17 **Q.** All right.
- Some of the papers before the Inquiry, some of the
- 19 papers talk about a particular batch or three
- 20 AstraZeneca batches made by the Serum Institute of
- 21 India. Did there come a time in February 2021 when the
- 22 MHRA carried out an assessment as to the safety,
- 23 efficacy and quality of the particular batches made by
- 24 the SII?
- 25 **A.** We would -- we clearly had that in mind when we sent our

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- 1 inspectors to look at the -- actually inspect that site.
- 2 Q. So you actually sent inspectors to India?
- 3 A. Yes.
- 4 Q. Is it normal in the case of a vaccination programme, or
- 5 a vaccine authorisation application, to send inspectors
- 6 to manufacturing sites outwith, outside the United
- 7 Kingdom, ie abroad?
- 8 A. It might be. There are -- a point I might make that we
- 9 do have agreements with other regulators to exchange
- 10 reports, and what would have been a factor in any
- judgement on the need of an inspection would have been 11
- 12 how recently the site had been inspected.
- 13 Q. But if the merits of a particular case or scenario or
- 14 issue require it, the MHRA can inspect factories abroad,
- 15 if the manufacturer is seeking UK permission for
- 16 authority to deliver vaccines to the United Kingdom?
- 17 A.
- 18 Q. Just to close off your evidence in relation to the MHRA
- 19 generally, is the MHRA also responsible for carrying out
- 20 applied research, it also holds the United Kingdom stem
- 21 cell bank, and has the MHRA itself developed and
- 22 produced over 90% of the world's biological
- 23 international standards in use? That is to say, you've
- 24 been instrumental in setting the standards across the
- 25 world for bioindustrial regulatory and authoritative --
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- 1 Most certainly. But I would like to thank them for the
 - diligence and commitment shown at any time to respond to
- 3 requests for advice.
- 4 Q. Well, we'll see in due course a lot of what they did.
 - And does the Commission on Human Medicines concern
- 6 itself in particular with the collection and
- 7 investigation of information relating to adverse
- 8 effects?

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- 9 A. It does, for the purpose of being able to make those
- decisions or give that advice on safety, quality, and 10
- 11 efficacy.
- Which then enables you to decide whether you authorise 12
- 13 a medicinal product and, if so, whether or not you
- 14 attach conditions to that authority?
- A. That's correct. 15
- Q. Is the Commission on Human Medicines staff made up of 16
- 17 the same individuals as the MHRA or are they corporately
- 18 different people?
- 19 A. The Commission on Human Medicines, the commissioners are
- 20 called from specialities that are pertinent to the kinds
- 21 of products that the advice will be given on, and they
- 22 are very separate individuals from the MHRA.
- Q. You said earlier that one of the primary 23
- 24 responsibilities of the MHRA is to ensure that vaccines
- 25 and medicines are acceptably safe. And vaccine is just

- or authorising standards? 1
- 2 A. Yes. And it was particularly important to have
- 3 standards as new products, whether they were actual
 - biological medicines or indeed tests, that those
- 5 standards were available internationally.
- 6 Q. The Commission on Human Medicines, can we just revert to
- 7 that, please. You've said that it's the government's
- 8 independent scientific advisory body. It gives advice,
- 9 does it, to ministers -- or technically it gives advice
- 10 to ministers, but in practice, will it in fact give
- 11 advice to the MHRA directly, or does it send its minutes
 - and its memos and its advice papers to you both?
- 13 A. The MHRA, as I've touched on, is an executive arm of the
- licensing authority, and because of the many decisions
- 15 that are made, we take a delegated authority to act on
- 16 behalf of ministers.
 - So the independence of the advice of the Commission on Human Medicines is absolutely protected, although the
- 19 Agency runs its secretariat to make sure there is an
- 20 efficient turnaround.
 - I hope that's addressed your point.
- 22 **Q.** Does it have a number of expert working groups?
- 23 A. It does.
- 24 Q. And were they hard pressed and hard worked during the
- 25 course of the pandemic?
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 - a form of medicine, at its heart. What is meant by the
- 2 phrase "acceptably safe"?
- 3 A. The focus is always balance of benefit and risk, because
- 4 no healthcare product, whether it's a vaccine,
- 5 a medicine, or a medical device, is perfectly safe.
- 6 There is always a degree of risk. And that balancing of
- 7 benefit and risk needs to be undertaking on the basis of
- 8 all available evidence, understanding to the perspective
- of patients, the public, as members of our expert 9
- 10 advisory committees, as to whether that balance has been
- 11 achieved in a positive sense.
- To what extent must the benefit outweigh the risk, the 12
- 13 downside, for the MHRA to conclude that it is acceptably
- 14 safe and authority may be given?
- 15 There is no hard and fast number. There have been
- 16 various attempts to put numerical work into this,
- 17 because risk is in a context, and therefore, with
- 18 something like a vaccine, given to healthy people, the 19
- benefit-risk balance would be extremely favourable, 20 whereas if it is a medicine for something serious, like
- 21 cancer, there might be a higher tolerability of risk.
- Q. So, just to pause there, if I may, what you're saying is 23 that where, for example, the issue is whether you give
- 24 a vaccine to somebody who is not suffering from any
- 25 condition and isn't suffering in a way that requires

- 1 medicinal input, you've got to be more satisfied that 2 there is a greater benefit in giving them that
- 3 vaccine --
- 4 A. Yes.
- 5 Q. -- as opposed to the risk?
- 6 A. Yes.
- 7 Q. But if you're dealing with somebody who is seriously
- 8 ill, perhaps, and requires medical intervention to help
- 9 them with that, then there is a slightly different
- 10 balance that is struck?
- 11 A. Yes.
- 12 Q. So do we take it from that that in the context of
- 13 vaccines, which is a prophylactic given to healthy
- members of the public in most cases, by way of
- protection against a prospective infection, you had to
- 16 be more satisfied than is usually the case that the
- 17 benefits outweighed the risks?
- 18 A. Yes.
- 19 $\,$ Q. In your statement you refer to something called critical
- 20 appraisal in the context of the MHRA's approach to how
- 21 you conduct this benefit-risk balance. What is critical
- 22 appraisal?
- 23 A. Our assessors are expert in bringing together a lot of
- 24 different forms of evidence and looking at the
- 25 robustness and applicability to a particular decision,
- 1 them a vaccine and what the risks of the vaccine are,
- 2 compared to another disease which has a lesser degree of

- 3 mortality and perhaps transmissibility?
- 4 A. Yes, that's correct.
- 5 Q. All right. And in general terms, when the MHRA takes
- 6 a decision whether or not to authorise, and if so, what
- 7 conditions it attaches, does it take into account just
- 8 the data from the pre-clinical and clinical trial
- 9 process from the manufacturer or a host of other
- 10 information from the private and public domains, data,
- 11 trial material, other trials, study, observational
- 12 studies, as well?
- 13 A. Yes, and we expect an applicant to make available all
- 14 information, evidence, that they're aware of or can find
- 15 for and against their product.
- 16 Q. You describe in your statement the nature of the
- 17 phases I, II, and III of the clinical trials and we
- 18 needn't, I think -- we needn't look at that. Could you
- 19 just describe for us, please, in general terms, what
- 20 obligation there is on the manufacturer to disclose to
- 21 the MHRA information and data arising from those
- 22 clinical trials at phases I to III?
- 23 A. It is the obligation to make all available data as part
- 24 of their submission, and indeed, if there's
- 25 a presentation that they need to give to our expert

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- 1 and it is done in a properly critical manner, and
- 2 I would say one of our bastions of independence is if
- 3 there is a negative view in any sense, that brings in
- 4 the independent committees. By law, they must then take
- 5 a look. So the word "critical" is then, in that sense,
- 6 leaving no stone unturned.
- 7 Q. If I may observe, that is a much more useful and helpful
- 8 phrase. You leave no stone unturned in analysing the
- 9 degree of benefit, the degree of risk, and weighing one
- 10 against the other?
- 11 A. Absolutely.
- 12 Q. And when you do so, do you have regard to perhaps quite
- 13 a significant number of issues, including what the
- impact might be on an individual person if they receive
- no vaccine, ie that they are liable to become infected
- with a particular pathogenic disease that you're seeking
- 17 to protect them against?
- 18 A. Clearly our view is at population level, but we need to
- 19 take into account that impact on an individual, and our
- 20 committees benefit hugely from the independent voice of
- 21 patients in those discussions.
- 22 Q. So dealing with a particular disease, if it's got a high
- 23 transmission rate and a high risk of mortality, bluntly,
- 24 it's going to kill people, there is perhaps a different
- 25 balance to be struck in relation to whether you give
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- 1 committees, they're asked to give that assurance
- 2 verbally as well.
- 3 Q. Do they report generally, in general terms, anything
- 4 which might impact upon your decision, prospective
- 5 decision? So anything to do with the safety of the
- 6 product, as well as anything which might impact upon
- 7 whether you give authority, and if so, on what basis?
- 8 A. Yes, they do.
- 9 Q. Do they have to report what is formally known as
- 10 a suspected unexpected serious adverse reaction, so an
- 11 adverse event?
- 12 A. (Witness nodded).
- 13 Q. And are they also obliged to provide, after authority,
- 14 periodic safety update reports, protocols dealing with
- 15 post-authorisation safety studies, and final study
- 16 reports, that's to say final reports, into the data
- 17 arising from the trials into the product?
- 18 **A.** Yes, there's very rigorous requirements, and timelines
- 19 around them.
- 20 Q. In the case of the Covid vaccines, so the United Kingdom
- 21 Covid-19 vaccines, AstraZeneca carried out trials in the
- 22 United Kingdom as well as, I think, Brazil and South
- 23 Africa; Pfizer, Europe and America; Moderna, American
- company, mostly trials in America. Is that right?
- 25 Roughly. I think we've got it --

- 1 A. I think that's roughly right.
- 2 Q. -- roughly right.
- 3 A. There might have been some in this country for Moderna.
- 4 Q. What obligation was there on the three manufacturers to
- 5 produce to the United Kingdom and the MHRA safety data,
- 6 information and anything that was relevant from trials
- 7 conducted outside the United Kingdom?
- 8 A. They have to report everything in the United Kingdom,
- 9 but if it's relevant, that they would inform us of
- 10 events elsewhere.
- 11 Q. In reality, is there anything different between what
- 12 they might give you from the UK trials as opposed to
- 13 what they give you in relation to non-UK trials?
- 14 A. Not to my knowledge.
- 15 Q. In this scheme of monitoring and assessment, are
- 16 manufacturers also obliged to produce at least the basis
- of, and perhaps the final version of, a document called
- the patient information leaflet, and the summary of
- 19 product characteristics, the SmPC?
- 20 A. Yes. Although clearly that will change in the process
- 21 of decision making, and in particular, any
- 22 post-authorisation requirements that need to be
- 23 introduced.
- 24 **Q.** And as it says on the tin, perhaps, who is the patient
- 25 information leaflet aimed at?

- 1 that were there?
- 2 A. -- through that route, yes.
- 3 Q. All right. They're obviously different outputs, they're
- 4 different locations and different means of vaccinating.
- 5 Is it all coordinated by PHE, or UKHSA as it's now
- 6 known?
- 7 A. Yes, with the Department of Health.
- 8 Q. All right. And then the SmPC, the summary of product
- 9 characteristics, who is that aimed at?
- 10 A. That's aimed at the healthcare professional.
- 11 Q. So is it more complex and more detailed?
- 12 A. Yes.
- 13 Q. The authorisations for the three vaccines. We've heard
- 14 evidence from Professor Prieto-Alhambra and
- 15 Professor Evans on the number of participants, so
- 16 I needn't ask you about the detail of them. But was it
- 17 the MHRA's view that the phase III trials, in respect of
- 18 all three vaccines, had the required and proper number
- 19 of participants, and was not out of kilter with any
- 20 other prior trials conducted in relation to past
- 21 historic vaccines?
- 22 A. They were sizeable, and I would have said of a better
- 23 size than some previous trials.
- 24 Q. Pfizer had around 43,000 participants, and I think the
- 25 trials were conducted in the US, Germany, South Africa, 143

- 1 A. It is the user, the patient, the member of the public in
- 2 the case of a vaccine.
- Q. And who distributes that in the context ofa population-level vaccination programme?
- 5 **A.** The first step is for the MHRA to publish this. In the
- 6 context of a vaccination programme, there's very close
- 7 liaison with the UK Health Security Agency, or PHE as it
- 8 was during the pandemic, to ensure that materials,
- 9 information leaflets, produced through that route are
- 10 entirely consistent with the MHRA statutory leaflet.
- 11 Q. And is the statutory leaflet something that you produce
- which broadly contains the same information, important
- willon broadly contains the same information, importa
- 13 safety-related information, including contraindications
- 14 and possible adverse effects?
- 15 A. It does.
- 16 Q. So there is consistency between your regulatory leaflet
- and the PIL and also the summary of product
- 18 characteristics?
- 19 A. Yes.
- 20 Q. And who, bluntly, puts the PIL in the vaccination
- 21 centre, or in the GP surgery, or the mobile unit, or the
- 22 pharmacy, or makes it available online? Who does that?
- 23 A. That would be the immunisation function, it wouldn't be
- 24 the MHRA, PHE -- (overspeaking) --
- 25 **Q.** So it would be the vaccination centre and the staff who 142
- 1 Turkey, Argentina and Brazil. Was that regarded as
- 2 quite a broad range of trial processes?
- 3 A. Yes

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- 4 Q. In terms of diversity, do we take it that -- from the
 - fact that those trials were conducted in countries with
- 6 varying degrees of ethnic and racial make-up and
- 7 background, that overall, there was a higher degree of
- 8 diversity?
- 9 A. There was a degree of diversity. It's an area that we
- 10 are concerned to improve and strengthen for the
- 11 confidence of everyone who is likely to receive
- 12 a vaccine. And so although we looked very carefully at
- this, and thought it was satisfactory, we could do
- 14 better and would wish to do better.
- 15 Q. And let's not beat around the bush, South Africa
- 16 obviously has a majority black population.
- 17 **A.** Yes.
- 18 Q. In terms of diversity, trials in South Africa,
- 19 therefore, have a higher degree of diversity, in the
- sense that they're not mainly white British. However,
- 21 you may have a difference in the number of participants
- in each trial in each country, so those figures on
- 23 diversity might be dwarfed by a very much larger trial
- 24 in another country where there's a great proportion of
- 25 white people?

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1 A. Yes.

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Q. Right. Let's have a quick look at the process by which
 you authorised -- well, you authorised the Pfizer
 BioNTech vaccine.

Can we have INQ000110129, please.

This is dated 30 November. It's a submission to ministers. It -- because of the process that you've described, the [CHM] has looked at the issue, the MHRA has obviously looked at the issue, but because the Licensing Minister has the final call, a suggestion has to go to ministers as to whether or not Pfizer, as with all the other vaccines, can be authorised; is that correct?

14 A. Yes.

Q. So we can see there if we go to page -- we're on page 2, the background, the discussion. Permission is sought under Regulation 174. Full trial data is yet to be published and peer-reviewed but obviously a great deal of results and data have already been produced. And there's a reference to the JCVI's role.

And then if we look over the page:

"The MHRA has undertaken a rigorous scientific assessment of all the available evidence ... The final data package was received ... over the weekend of 28/29th November ..."

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1 Q. At paragraph --

A. That's exactly a rolling review -- I'm sorry tointerrupt.

- 4 Q. It was a rolling review?
- 5 A. It was a pre-emptive dialogue.
- 6 Q. A pre-emptive dialogue, all right.

At paragraphs 7 and 8 we're can see there reference to the CHM advice. The MHRA sought the advice of the CHM, the body to which you referred, and it consulted its own expert working groups, and no doubt there was very close liaison between the MHRA and the CHM. And you were all looking at the same material, were you not?

13 **A.** Yes.

Q. And over the page, we can see that you were all
considering in your different ways efficacy, clinical
safety, pre-clinical testing, quality and surveillance,
and the debate centred around, in fact, the sorts of
conditions which needed to be applied to any
authorisation, is that right, paragraph 10?

20 A. That's correct.

Q. And over the page, page 5, the MHRA was cognisant and aware of the approach that would be taken by other
 regulators who were, of course, considering exactly the same application by exactly the same manufacturer in relation to exactly the same vaccine?

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1 Is that because you put into place a system by which 2 the manufacturers could produce data on a rolling basis?

Did that process by which you were prepared to start looking at the paperwork, as it was produced, in any way impact the rigour of your scrutiny or the degree of safety -- (overspeaking) --

6 safety -- (overspeaking) -7 **A.** Absolutely not. Absolutely not. And I think in the
8 words of an earlier witness, it may have actually
9 increased that rigour. Although it's important to
10 always take a holistic view when it comes to the
11 Commission on Human Medicines.

12 **Q.** Because you were receiving documents hourly, informationday and night, you were over the manufacturers like

14 a rash?

15 A. Yes.

16 Q. Right.

Did you also apply a rolling review of -- a rolling review in relation to the authorisation process for clinical trials, to speed up the overarching process?

A. We offered, if you like, a pre-assessment. There was an intense dialogue. We actually asked -- invited
 researchers to come and talk to us, so that by the time
 they had their application it was likely not to raise
 issues, and publish guidance, in fact on more than one

25 occasion, for Covid-19 trials.

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A. Yes.

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Q. In relation to Pfizer, there were no SUSARs, suspected
 unexpected serious adverse reports, reported in any of
 the data given to the MHRA?

5 A. Not to my knowledge.

6 Q. All right.

And then the decision letter which formally comes from the Licensing Minister is at 410479.

INQ000410479.

10 Lord Bethell:

11 "Thank you for your letter ... which sought the 12 Licensing Authority's authorisation for the vaccine 13 [for] Pfizer ..."

There's the link to Regulation 174.

"After taking the advice of the Commission On Human
Medicines [because they formally advise the minister],
and considering ... [the three issues as you've
identified of] quality, efficacy and safety ... I have
decided to approve the ... supply ..."

And then there are conditions attached.

21 And was the same process adopted in relation to 22 Oxford-AstraZeneca?

23 **A.** Yes.

Q. Some 20,000 or more participants in their phase I to IIItrials?

- A. 1 Yes.
- 2 Q. And their trials, I think, took place in the
- 3 United Kingdom, Brazil, and South Africa. The non-white
- 4 ratio in South Africa was 87%; Brazil, 31.4%; and UK,
- 5 7.1%. So not representative of the UK population in the
- 6 United Kingdom trial. But overall, what did the MHRA
- 7 conclude in relation to diversity of the whole trial
- 8 process for AstraZeneca?
- 9 A. That it was satisfactory.
- 10 Q. In July and September 2020, the Oxford-AstraZeneca
- vaccine trials were suspended or halted due to possible 11
- cases of transverse myelitis, which is, we've heard, the 12
- 13 condition concerning inflammation of the spinal cord.
- 14 In such a scenario, in the course of clinical
- 15 trials, when the MHRA becomes aware of an issue,
- 16 a safety-related issues, is it normal for the trial
- 17 process to be suspended whilst you investigate?
- 18 Yes. Not common but it is something that --Α.
- 19 Q. It happens?
- 20 A. -- needs to be done. It happens.
- 21 Q. And was the MHRA obliged at each point on those two
- 22 occasions to reach a view as to whether or not those
- 23 cases of transverse myelitis were coincidental, caused
- 24 by the virus, or caused by, arguably, at least, or
- 25 reasonable grounds for supposing it was caused by the 149
- 1 a number of witnesses that because no proper and ethical
- 2 trial could ever be of such a scale as to give rise to
- 3 any likelihood that a rare or very rare or extremely
- 4 rare condition would be identified, it's extremely
- 5 important that after authorisation, a very close eye is
- 6 kept on the issue of safety and side effects; is that
- 7 right?
- 8 A. Absolutely.
- 9 Q. And does the MHRA have in place a number of processes,
- 10 or pillars, by which you monitor, very closely,
- 11 post-authorisation safety surveillance?
- 12 A. Absolutely, the four pillars you mention were actually
- 13 designed very carefully, with expert input, well in
- 14 advance of the approval, any possible approval, of 15 a vaccine, so as to be in a state of complete readiness.
- 16
- The passive reporting, as we've heard, of the Yellow
- 17 Card Scheme, is historically a mainstay of 18
- pharmacovigilance. But in this case, rapid matching 19 with the observed reports against expectedness was
- 20 introduced. And clearly, we may want to talk about the
- 21 rapid cycle analysis using real-world data, the vaccine
- 22 monitor, which was a -- tremendous support from members
- 23 of the public to be followed up, and of course work with
- 24 epidemiologists to conduct specific studies.
- 25 On this topic of rapid cycle analysis and ecological Q. 151

- vaccine? 1
- 2 A. Yes. Clearly we would have interacted and encouraged
- 3 the applicant to interact with their data safety
- 4 monitoring board or data monitoring committee, and also
- conduct -- consulted the Commission on Human Medicines. 5
- Q. And does the paperwork show in fact that the CHM met on 6
- 7 10 and 11 September to discuss precisely that issue of
- 8 transverse myelitis, in fact, on that occasion, in the
- 9 UK trial?
- 10 A. Yes.
- 11 Q. Other than those issues, the suspensions in July and
- September, were any SUSARs reported, let alone any cases 12
- 13 of cerebral haemorrhage or blood clotting?
- 14 A. I think you'll find in the papers, counsel, that there's
- 15 one case of migraine.
- 16 Q. Migraine, all right. No, you've got me there, I didn't
- 17 know that. Thank you.
- 18 Moderna. Were trials largely undertaken in the US?
- 19 A. Yes
- 20 Q. And did the Moderna trial in total involve more than
- 21 30,000 people?
 - 22 Α.
 - 23 Q. And were any SUSARs reported?
 - 24 A. No.
 - 25 Q. All right. Now, we've heard from Professor Evans and
 - 1 analysis -- and forgive me if I don't do them full
 - 2 justice -- are they concerned with trying to work out
 - 3 what medical conditions might, in the general scheme of
 - 4 things, appear, closely identifying what conditions
 - 5 actually appear, and resolving, therefore, or
 - 6 determining that they are unexpected? They don't
 - 7 normally arise in the course of the population in life,
 - 8 and therefore there might be a link to the vaccine; is
- 9 that what it --
- A. Yes, it might be attributable. It's really important to 10
- know what our background rates are of many of these 11
- 12
- 13 Q. Right. So it's looking at the context --
- 14 Α. Yes
- 15 Q. -- trying to see if there's something out of the
- 16 ordinary, and identifying trends?
- 17 Α. Yes

- 18 Q. Right. Alongside the Yellow Card Scheme with its
 - monitoring add-on, and also, we've heard from
- 20 Professor Evans, a profusion of formal -- or not many
- 21 trials, randomised control trials, but many, many
- 22 epidemiological studies?
- 23 A. Yes.
- 24 Q. All right. Let's have look at a Yellow Scheme (sic)
- 25 report.

- 1 INQ000502035, please.
- 2 Is that the report which was in place in 2021?
- 3 A. Yes.
- 4 Q. So we can see that it's -- well, it's self-evident. It
- 5 allows a person to report a suspected adverse drug
- 6 reaction, to give details of the patient, the vaccine,
- 7 the suspected reaction, any other drugs they might be
- 8 taking, details of any clinician, and I think that's --
- 9 is there a second page? No. That's the envelope -- oh,
- 10 auidelines.

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- Did the MHRA, having received during the course of the pandemic response a very large number of Yellow Card
- 13 reports, publish weekly summaries of the reporting?
- 14 Yes, we did, and I hope it's okay for me to thank Α.
 - everyone who reported. I think it was absolutely vital.
- 16 Of the close on half a million reports, 80% were from
- 17 members of the public vaccine recipients, and it was
- 18 a tremendous assistance to us in our signal detection
- 19 function.
- 20 Q. Was the vast majority of reports concerned with mild or
- 21 temporary matters such as reddening from injection site,
- 22 flu-like symptoms, headache?
- 23 A. (Witness nodded)
- 24 Q. That sort of thing?
- 25 A. The general reactogenicity-type events that may resolve
- 1 been coincidental or caused by the virus. And you made
- 2 the point that the overwhelmingly majority of reports
- 3 relate to mild or temporary matters. Yes?
- 4 A. Yes.

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- 5 Q. Page 6 -- no, that's what we're on, sorry. Page 12 and
- 6 13, the MHRA talks about ADRs. Are ADRs the reports
- 7 which found the basis of the Yellow Cards or are they
- 8 something different?
- 9 A. An ADR is simply an adverse drug reaction and the Yellow
- 10 Card captures suspected ADRs that a person considers may
- 11 be linked with a particular intervention, whether it's
- 12 a vaccine or a medicine.
- Q. And in the middle of the page you'll see a reference to: 13
- 14 "Up to and including 23 November ... the MHRA 15 received and analysed a total of 52 UK reports of
 - suspected ADRs to the COVID-19 vaccine Novavax."
- 17 And I'm just using this by way of an example.
- 19 through them and try to identify the important ones, the

When you receive the Yellow Card reports, do you go

- 20 ones that require follow-up, and require analysis, which
- 21 then get followed up?
- 22 A. Yes. There were special provisions during the pandemic,

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- 23 particularly in relation to the vaccines, to look every
- 24 day at any trends, and to advise on next steps. So
- there was a dedicated team doing this. 25

- within a day or two. 1
- 2 Q. But also within the reporting where reports concerning
- 3 suspected serious adverse events, serious side effects?
- 4 A Yes

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- 5 Q. Could we look, please, at -- just by way of an example,
- 6 an MHRA document talking about the summary of the Yellow 7
 - Card reporting, INQ000421360.
 - Can we just go back to the first page, just to get our bearings, if you'd be so kind.
- 10 It's a printout of the website. We can see that
- 11 it's archived because obviously time has passed. But
- 12 this in fact is a version of a report from the MHRA
- 13 updated, as it then was, on 8 March 2023. I'm sure you 14 recognise the format.
 - If we go to page 5, then, you can see that the MHRA provides details of the number of Yellow Cards for each vaccine; yes?
- 18 A. Yes.
- 19 Over the page, it's thinking about the significance of
- 20 the data and it makes the point that obviously, the fact
- 21 that somebody has reported a suspected adverse event
- 22 does not mean to say of itself, it was caused by the
- 23 vaccine?
- 24 A. No.
- 25 Q. It may have been caused coincidentally, it may have just
- 1 So the Yellow Cards were looked at and your data sources 2 from wherever they were, were looked at every day --
- 3 A.
- 4 Q. -- and things that brought themselves to your attention 5 which mattered were then followed up?
- 6 Δ

- 7 Page 37, you deal with, of course, the issue of possible 8 fatal outcomes. We see at the bottom of the page:
- "MHRA takes all reports of the fatal outcome in 9 10 patients who have received a Covid-19 vaccine".
- 11 If a member of the public wrote in on a Yellow Card
- 12 saying, "My loved one or relative has died, and we
- 13 suspect that there is a connection to or an association
- 14 with, or the death was caused by the Covid-19 vaccine",
- 15 what does the MHRA do?
- 16 A. It considers the report in very great deal with great
- 17 care, seeks to follow up with any clinical source of
- 18 data, particularly if there has been a post mortem
- 19 examination and we might touch on our special
- 20 relationship with coroners as well.
- 21 Q. Do you, can you go to the NHS or to a GP and see what
- 22 happened and whether or not they sought clinical help
- 23 and what the views of the NHS or the GP were?
- 24 We certainly can, and obviously we do, but in the
 - pandemic time, one had to take account of how hugely,

- 1 you know, busy, overwhelmed, many clinicians were.
- 2 Q. Did you, in the generality of cases where fatal outcomes
- 3 were reported to you, take steps to follow up and try to
- 4 find out what had happened?
- 5 A. Yes.
- 6 Q. And did that include speaking to health services?
- 7 A. In the generality. There may have been cases where if
- 8 it appeared that there wasn't an association likely,
- 9 that was not done.
- 10 Q. All right. So your position is you can't say that it
- 11 was done in every single case, but the expectation was,
- 12 and by -- in general terms, a fatal outcome reported to
- 13 the Yellow Card system would be researched and followed
- 14 up through relevant health services?
- 15 A. Generality, yes.
- 16 Q. All right.

- 17 Can we just go over the page to page 38, please?
- 18 This report, which was updated, as I say, in
- 19 March 2023, gives figures for the number of fatalities.
- They were, therefore, and nothing I say is intended to
- 21 detract from the individual tragedy that each fatal
- 22 outcome, of course, amounts to.
 - No, no, I didn't want the table, just the paragraph
- 24 at the top of the page, please.
- 25 The number of fatalities overall by March 2023 were 157
- 1 of the number of papers considered by the Commission on
- 2 Human Medicines expert working groups between
- 3 December 2020 and September 2022, and the number of
- 4 specific meetings held to discuss signal -- safety
- 5 signals over that time. Give us some idea.
- 6 A. In terms of papers, I would have thought in the high
- 7 hundreds, and numbers of meetings, around 100.
- 8 Q. One of the pillars you've mentioned is the Yellow Card
- 9 system which had a facility for monitoring attached to
- 10 it. We've heard evidence from --
- 11 LADY HALLETT: Take the document down, please.
- 12 MR KEITH: -- Professor Evans that whilst half a million or
- 13 maybe a million invitations were sent out to members of
- the public saying, "Would you be prepared to be
- 15 monitored and followed up following your Yellow Card
- 16 report?", only a proportion of people were prepared to
- 17 be so monitored; is that right?
- 18 A. Yes, it was about 36,000. And, again, thank you to them19 for sharing their information, because it has been
- 20 relevant and included in all our functions.
- 21 MR KEITH: All right.
- 22 My Lady, is that a convenient moment?
- 23 LADY HALLETT: Yes, certainly. I shall return at 3.35.
- 24 (3.17 pm)
- 25 (A short break)

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- 1 measured in the low thousands, in total -- yes?
- 2 A. Yes.

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- 3 Q. And therefore, what you're reporting here is not that
 - this is the number of deaths caused necessarily by
- 5 vaccines, it is the number of deaths reported as being
- 6 suspected to be caused by vaccines through the Yellow
- 7 Card system?
- 8 A. Yes.
- 9 Q. All right.
- 10 A. Although, if I may add, I'm sure in this document
- 11 elsewhere there's some context given in relation to how
- many deaths would be expected in a population of this
- 13 size over this period.
- 14 Q. I was just about to ask you. You spoke earlier about
 - the risk-benefit analysis. When the MHRA receives
- 16 a report of a fatality, in addition to seeing what
- 17 happened in that individual case, you have to assess,
- don't you, how likely it is that that condition and the
- 19 death would have occurred anyway, coincidentally,
- whether or not it might have been caused by the virus,
- 21 and also how many deaths are being prevented by the
- 22 beneficial impact of the vaccine. Those are all things
- that need to be considered?
- 24 A. Yes, they do.
- 25 **Q.** All right. And standing back, can you give us some idea
- 1 (3.35 pm)
- 2 LADY HALLETT: Mr Keith.
- 3 MR KEITH: Dame June, earlier I asked you some questions
- 4 about the monitoring process which came under the
- 5 general heading of the Yellow Card Scheme, and
- 6 I suggested to you that the monitoring system worked by
- 7 way of people who had made a Yellow Card report then
- 8 being invited to consider registering to be monitored
- 9 and followed up. I have been corrected by one of our
- 10 legal team.
- 11 Is this the position: that it was open to members of
- the public to express an interest, through the NHS, if
- they'd attended hospital, or thorough their GP, in being
- 14 monitored. It wasn't just for those, or may not even
- 15 have included those people who had actually made
- 16 a Yellow Card report?
- 17 **A.** Yes, it was separate from those who had made a report,
- 18 but I believe we did invite some people -- well, who
- 19 wished to participate.
- 20 Q. So it included people who'd made a Yellow Card report
- 21 who may just happen to have heard that -- or they might
- 22 happen to receive an invitation to consider being
- 23 monitored by way of a follow-up?
- 24 **A.** Yes.
- 25 **Q.** All right. I now want to ask you briefly about a number 160

of discrete areas and issues which have been raised in the course of the Inquiry, for the MHRA's position and response to be made plain.

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Firstly, on the question of information, there's obviously a significant number of ways in which information about the risk of a side effect or safety information relating to a vaccination might reach the public domain, and you've talked about how there's a weekly update of Yellow Card reporting, and we've seen that the authorisation letter and all the paperwork concerning authorisation may also refer to safety issues, but were there other routes by which information about a vaccine and the risks and the benefits and the risks of taking the vaccine were available to members of the public?

16 A. An important point, of course, is at the moment they're 17 queueing and going into their vaccine centre to have 18 a vaccine, and we made a great effort to ensure that 19 that was commensurate with the regulatory position, that 20

> I think we should also mention the regular press briefings and opportunities to give realtime, or as close to realtime as possible, updates on the benefit-risk

Q. So, there's the patient information leaflet, the press

1 vector technology would cause damage or harm on the 2 genetic plane? 3

A. It's a key aspect of the consideration, a very rigorous scientific consideration on how a vaccine might affect the body, the person who has taken it. And I can say that there was no hint at all, no evidence that this would be the case for the mRNA technologies.

Q. There are many people who suggest that they weren't aware, sufficiently aware, of the Yellow Card Scheme, and that not enough was done to raise awareness of the scheme. And many people, it would appear, say that it wasn't easy to use, particularly if you believed that you had been injured as a result of the vaccine and you were wishing to report a suspected adverse event.

Do you think the Yellow Card Scheme is amenable to improvement in terms of raising its awareness and making it more straightforward and easier to use?

A. Yes, I do. I would stress, though, that over the 18 19 years -- and it has been in operation in fact for over 20 60 years now -- there have been a lot of efforts not 21 simply to make it easier to use, with different ways of 22 reporting, electronic, by phone, as well as by paper, 23 and also to have local representation, and our six 24 Yellow Card centres do a very great deal of outreach in 25 their local areas.

1 release is issued by the MHRA and perhaps other bodies?

I mean, did the CHM or the DHSC or Public Health England

3 issue any kind of statements at any time concerning

4 safety?

2

A. Yes, clearly we worked alongside the JCVI, and Public 5 6 Health England coordinated those statements, but they 7 would have come one from the MHRA, one from JCVI.

8 Q. Yes. My question was, were there other routes, 9 non-MHRA-related, by which information about the safety

10 of vaccines reached the public domain?

11 A.

12 Q. On multiple occasions?

13 A. Yes.

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14 Q. Frequently?

15 A. Perhaps I wouldn't say "frequently", but at key 16 milestones in evaluating benefit-risk.

17 Q. Thank you. Concerns have been raised by some as to 18 whether or not the modalities, to use the technical 19 phrase, of vaccines, the technology, the nature of the

20 particular vaccines in the United Kingdom, engaged,

21 unacceptably or impermissibly, novel technologies liable

22 to cause damage, in particular, whether or not they

23 would cause genetic damage, by way of improper gene

24 therapy? Was there any material at all before the MHRA

which suggested that either the mRNA technology or the 25

Q. And what are they? They're all over the United Kingdom, are they?

3 Yes, Scotland, Wales, Northern Ireland, northern, north, 4 Midlands, we've got outreach very close to where people 5

6 Q. They process reports but do they play a role in bringing 7 the existence of the system to the attention of the 8 people locally?

9 A. They do the latter. They no longer process, because, 10 with electronic reporting, that automatically comes to our database. But local outreach is critically 11 12 important, and in fact in Wales there were some very 13 good examples of champions of the Yellow Card Scheme 14 having a very measurable impact on reporting.

15 I think it has to be borne in mind, though, that the 16 reporting, close to half a million, 80% from members of 17 the public, is actually testament that there was doing 18 growing awareness, but I do take the point that more 19 could be done in peacetime, as it were, to ensure that 20 everyone knows, perhaps through school education, that 21 a downside needs to be informed to the authorities if 22 they've had a product that hasn't had the -a completely safe effect on them.

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24 Q. Some have suggested that there should be a mandatory 25 obligation, if that's not tautologous. There should be

- 1 an obligation on healthcare professionals to report any 2 occasion on which they come across something that they 3 believe to be a suspected adverse event?
- 4 A. We've looked at this very carefully, and most recently
- 5 with the International Coalition of Medicines Regulatory
- 6 Authorities, around the world, some countries have
- 7 mandated health professionals to report, others not.
- 8 And we don't see a measurable difference.
 - There is a lot of value in health professionals, if you like, being so motivated as part of their clinical practice, as deemed by the professional bodies, that
- 12 they see it as part of care rather than a legal
- 13 requirement.
- 14 Q. All right. TTS, thrombosis with thrombocytopenia 15 syndrome.
- 16 Thrombotic events were not, were they, identified in 17 the course of any of the clinical trials?
- 18 A.

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- 19 But in February 2021 did the MHRA start to receive
- 20 Yellow Card reports of suspected thrombosis and, on
- 21 occasions, associated thrombocytopenia?
- 22 A. Yes. And we were looking for any reports that might
- 23 affect the blood system, knowing that these were adverse
- 24 effects of special interest. Some vaccines in the past
- 25 have been associated with, for example, low blood 165
- 1 and begun examining the basis of the reports, what had
- 2 happened in each of these individual cases, and what
- 3 conclusions should be drawn?
- 4 A. Certainly the Vaccine Benefit Risk Expert Working
- 5 Group --
- 6 Q. That's the expert working group --
- 7 Very aware.
- 8 Q. -- one of the expert groups in the CHM?
- 9 A. Of the CHM.
- Q. All right. 10
- 11 Was the MHRA able to determine, between February and 12 the Easter Bank Holiday weekend in early April, whether or not those cases of TTS did have an association of 13 14 some significant type with vaccines, ie whether they
- 15 might be reasonably thought to be the result of
- 16 vaccination, as opposed to being coincidental or perhaps
- 17 caused by Covid itself?
- A. The level of evidence was growing. After a press 18
- 19 briefing on 18 March, there were many more, you know,
- 20 general Yellow Cards submitted and we then started to
- 21 see more reports of the TTS.
- 22 Q. Was it possible for the MHRA, between February and
- 23 6 April, to reach a final position, a determined
- 24 position, as to whether or not vaccines were or
- 25 AstraZeneca was causing TTS, and if so, what should be 167

- 1 platelets. So it was something we were very alert to 2 and looking for.
- 3 Having said that, the complexity which was added was 4 that Covid itself could have such effects.
- 5 But was the possibility that TTS was being caused by 6 vaccines under investigation by the MHRA actively from
- 7 when they first started receiving Yellow Cards?
- 8 A. The first three reports in February 2021.
- 9 Q. In early March 2021, a number of European member states 10
 - suspended use of the AstraZeneca vaccine. Were those,
- 11 as far as you understood it, decisions taken by their
- 12 regulators or by the state bodies responsible for
- 13 prioritisation and rollout?
- 14 A. They were decisions taken by the bodies responsible for
- 15 the immunisation rollout.
- 16 Q. Was there at any time a suspension at the hands of
- 17 a regulator in Western Europe of the AstraZeneca
- 18 vaccine?
- 19 A. No.

25

- 20 Q. Thank you.
- 21 And the MHRA engaged, did it not, it began to
- 22 engage, with the Licensing Minister. You put
- 23 a submission up on 17 March on this issue.
- 24 From February, when you first became aware, had the
 - Commission on Human Medicines also looked at this issue 166
- 1 done about it?
- 2 It wasn't possible to reach a final position.
- 3 Q. Why?
- 4 A. The considerations we apply are very much related to
- 5 a general evaluation of that growing evidence for its,
- 6 if you like, robustness of an association. So although
- 7 the evidence was growing, it wasn't conclusive.
- 8 Q. At the same time, was the vaccination programme
- 9 continuing?
- 10 A. Yes, it was.
- 11 Q. And was that programme materially contributing to saving
- 12
- 13 A. It certainly was. And the issue of age, I'm sure we'll
- 14 touch on. By that weekend, the Easter weekend, I think
- 15 the cohorts below the age of 50 had not yet been
- 16 invited
- 17 Q. Can you just explain the significance of that? Under
- 18 our JCVI-mandated prioritisation process, vaccines were
- 19 first given to the elderly. Is the issue that TTS, if
- 20 it's linked to AstraZeneca, has a higher rate of
- 21 occurrence in the young than the old, or the much
- 22 younger than everybody else?
- 23 A. Yes.
- 24 Q. And therefore, it was less likely that there would be
- 25 any such cases, because we hadn't yet got to the stage

- 1 where we were beginning to vaccinate the young on 2 a general basis?
- 3 A. On a general basis, although there would have been some
- 4 cases in younger people who, for their -- for other
- 5 reasons, had been vaccinated.
- 6 **Q.** For health conditions they might have been vaccinated?
- 7 A. Yes, that's correct. And it might be worth saying that
- 8 in contrast, in the European member states such as
- 9 Denmark, there had been more use in the young.
- 10 Q. So they vaccinated more of their young people than we
- had, and therefore, that's why there were -- and there 11
- 12 were only a handful of cases, but there were more cases
- 13 in Denmark than there appeared to be in the
- 14 United Kingdom?
- A. It's one of the reasons. 15
- 16 Q. And an issue arose before the Bank Holiday weekend as to
- 17 whether or not a public statement should be issued by
- the MHRA setting out its conclusions and its views on 18
- 19 this, on TTS; is that right?
- 20 A. Yes.
- 21 Q. And a debate arose as to whether or not it should, or
- 22 whether or not you should stay your hand until after the
- 23 Bank Holiday weekend, because it was important to allow
- 24 other bodies with interest in this issue, the JCVI, the
- 25 DHSC, Public Health England, to clarify their own 169
- 1 A. Yes.
- 2 Q. Did the weekly summary before the Bank Holiday weekend
- 3 refer to the TTS issue?
- 4 A. I'd like to check that.
- 5 Q. All right. Could you do that, please?
- 6 A. I will.

- 7 Q. Some have suggested that the period of time from early
- February when you first became aware of the possibility 8
- 9 that extremely rarely, TTS might be caused by a vaccine,

a number of considerations that mean that that was

- 10 and the Bank Holiday weekend was too long a period to
- 11 allow this issue to rumble on; what do you say to that?
- 12 A. I can understand that perspective, but there were
- 14 actually a very appropriate period of time to reach
- 15 a very considered decision and to work very closely with
- 16 the haematological community who were instrumental in
- 17 picking up what was a very complex picture to resolve,
- 18 given that we were looking at the concern about low
- 19 platelets in isolation, and thrombosis in isolation.
- 20 Bringing those together was a more complex picture to
- 21 understand, and needed expert advice from that clinical
- 22 community.
- 23 Q. Because TTS, with or without thrombocytopenia, can be
- 24 caused -- can occur in the general population?
- 25 Very rarely. Α.

- positions and to get their statements in order; is that 1
- 2 the nub of it?
- 3 A. I think there's a consideration, an important one, that
 - if an announcement leads to public concern, the access
- to medical advice or healthcare professional advice 5
- 6 isn't there in the Bank Holiday period.
- 7 Q. So you've got to get the advice right before you
- 8
- A. Yes. 9

4

- 10 Q. And not everybody else was ready?
- 11 A. I think that's a good argument.
- 12 Q. Did, nevertheless, the MHRA -- I'm sorry. Before the
- 13 Bank Holiday weekend, was any information on the part of
- 14 the state put into the public domain concerning TTS?
- 15 A. Yes, there had been.
- 16 Q. What was it?
- 17 **A.** I believe there was a letter through the immunisation
- network to relevant healthcare professionals. 18
- 19 Q. Was there a letter to the NHS and to primary care
- 20 networks? Clinical directors in the NHS and to primary
- 21 care networks?
- 22 A. That's my understanding.
- 23 Q. Had, the week before the Bank Holiday weekend, the MHRA
- 24 undertaken its normal practice of issuing a weekly
- 25 summary of Yellow Card reports?

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- 1 It can be caused by Covid?
- 2 Yes.
- 3 Q. And you needed therefore to know the context; how likely
- 4 was it going to occur generally before you could assess
- 5 whether or not the number of cases that were appearing
- 6 might therefore be caused, by contrast, by a vaccine?
- 7 A. Yes.
- 8 Q. All right. And were there a number of bodies and people
- 9 looking intensely at this issue?
- 10 A. Yes, there were, and the British Society of
- 11 Haematologists was instrumental in collecting a very
- 12 important case series.
- Q. Did the DHSC look at it? Did the JCVI look at it? Did 13
- 14 the CHM look at it?
- 15 A. Yes.
- Q. Did the CHM's working groups look at it? 16
- 17 A. Yes, they did.
- 18 Q. All right. And then the submission, the position
- reached by the MHRA is INQ000494385, it's a submission 19
- 20 to Mr Hancock on 7 April.
- 21 Page 2, paragraph 2, so INQ000 -- thank you very
- 22 much, 7 April.

25

- 23 We can see your name in the top right-hand corner.
- 24 It has been cleared by you. If you could just scroll
 - back out a second. It's a minute -- a submission to the

1 Secretary of State, top left, copied to the private 2 secretary for one of the DHSC ministers: The MHRA has 3 concluded its initial investigation into TTS, 4 specifically blood clots, suspected to be associated 5 with AstraZeneca. The CHM met in extraordinary session 6 and then on the -- on the 4th and then on the 6th, and 7 you tell Mr Hancock that you intend to update UK 8 information for healthcare professionals and vaccine 9 recipients in line with the CHM advice.

> But your weekly update, depending on what the answer to my question was, may already have referred to it and you'd already written to primary care networks and clinical directors in the NHS.

Page 6, please, paragraph 3.

Hmm, my reference is clearly wrong. Can we go back to --

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17 LADY HALLETT: Page 2 because the first page was page 1.
18 MR KEITH: Ah yes, thank you very much, it's paragraph 6 on

18 **MR KEITH:** Ah yes, thank you very much, it's paragraph 6 on page -- paragraph 3 on that page:

"We were advised later that day that AstraZeneca had produced a new global dataset."

Whenever there's an issue, a safety issue, requiring the MHRA's consideration, do you engage with the manufacturer and seek to accumulate as much data as you possibly can on this issue?

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Then page 4, paragraphs 9 to 11, we can see there summarised the CHM advice. They considered it on 4 and 6 April, and they obviously gave intense consideration to whether there should be a specific cut-off age, to what the data showed, to what degree there was an association. That's not to say a causative link has been established, but there is something requiring further investigation?

9 **A.** Yes.

10 Q. All right.

Then page 6, paragraphs 15 and 16, "Next steps".

You've agreed to update the PIL, and the summary of product characteristics, and paragraph 16, there needs to be "clear and co-ordinated public communications", it's "essential to inform the public and retain confidence in the vaccination programme".

So there was no question of not telling the public. What was important was to make sure was that there was a unified message and that all the people who would be communicating with the public got the facts right and could be precise about what they were saying?

could be precise about what they were saying?
A. Yes. And I would like to also highlight that the time
was not time elapsed without extra work being done on
how well this could be communicated. The Winton Centre
in Cambridge was very helpful indeed in enabling really

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A. Yes, we do, and we do expect them to have, at theirfingers tips, the global picture.

Q. And did AstraZeneca provide on a number of occasions
 data?

5 A. Yes, they certainly did.

6 Q. During those weeks?

7 A. Yes.

8 Q. And towards the end of the process, by 4 April, did new9 data become available which you then had to consider?

10 A. It did, and my recollection is that it made the issue of11 age less amenable to setting precise levels.

12 Q. So if I can seek to reformulate that, consideration was

13 being given to whether or not the authority for

14 AstraZeneca should have a condition attached, namely

don't use for a certain age group?

16 A. Yes.

2

17 Q. But then the data showed that actually it was much more18 difficult to delineate between ages in terms of risk,

19 and therefore you couldn't apply a condition, or it

wouldn't be sensible to apply a condition; all you could

do was raise the issue and allow it to the individual

22 judgement of patients and clinicians?

23 A. At that point in time.

24 Q. At that point in time. So it's a rolling process,

a rolling consideration of more and more information.

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1 quite concise information, by age, on the risk of

getting Covid and its consequences, such as ITU

3 admission, versus any risk of having a case of TTS.

4 Q. We haven't got it in the system, so I don't think I can

5 bring it up, but you gave a press conference on 7 April

6 and you produced a diagram from the Winton Centre which

7 had a bar chart on it which showed, very broadly, the

8 level of risk stratified by age.

9 A. In the context of how frequent the transmission was and

10 how likely it was to get an infection with Covid. And

11 it was, if you like, to guide individual decisions, and

12 also to give a bit more factual context to the JCVI

13 considerations.

14 $\,$ **Q.** Then on 7 April, INQ000408453, did you issue the new

advice to which you refer in that submission, in which

16 you concluded that there was "a possible link between

17 COVID-19 Vaccine AstraZeneca" and this "extremely rare"

18 condition, TTS?

19 **A.** Yes.

24

25

20 Q. If we look at page 4, we can see the guts of the advice.

21 "Anyone who experienced cerebral or other major
22 blood clots ... after [the] first vaccine ... should not
23 have [a] second dose."

Pregnant women "should discuss with a healthcare professional whether the benefits of having the vaccine

outweigh the risks".

And you make the point, which you've made elsewhere, second-last paragraph: of course it can be caused by the vaccine, and it can occur in unvaccinated people.

Myocarditis and pericarditis. May viral infections generally cause myo- and pericarditis?

7 A.

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- 8 Q. And so in the MHR's (sic) consideration of whether or 9 not there was a possible association between myo- and pericarditis and mRNA vaccines, was your job made very 10 11 much harder by the fact that it occurs naturally in the 12 population amongst unvaccinated people?
- 13 A. Yes. And in this case it was very important to look at 14 accruing evidence internationally on a potential link.
- Q. And on 25 June 2021 did you put up a submission to the 15 16 Licensing Minister -- INQ000494303 -- agreeing with 17 the -- suggesting that they, the Licensing Minister, 18 agree with the Commission on Human Medicines' advice to 19 issue a precautionary warning about the very rare risk 20 of myocarditis and pericarditis following vaccination 21 with Pfizer or Moderna?
- 22 A. Yes. And to get that, if you like, decision made 23 promptly so that we could issue advice on the same day.
- 24 That's dated 25 June. You'd first sought the advice of Q. 25 the expert working group on vaccine benefit-risk within
- 1 medicines are accompanied by a leaflet because the 2 packaging permits that. In an immunisation rollout it's 3 not as amenable, and what we do is work with our UKHSA 4 colleagues to ensure that at that point suitable and 5 compatible information is given compatible with the 6 regulatory position.
- 7 Q. You have already given extensive evidence about the 8 various routes by which safety-related information might 9 reach the public domain and they've included the MHRA's 10 publication of drug analysis profiles, the weekly Yellow 11 Card summary update, press conference, online leaflets, 12 email updates, drug safety update bulletins, CAS alerts. 13 Is there an argument or perhaps a strong case for having 14 a more visible single point of information concerned 15 with safety-related vaccine information?
- 17 the other hand people source their information in 18 different ways, so it is an area that would be worthy of 19 further reflection in the context of this Inquiry. 20 Q. Finally, the MHRA, of course -- and all your evidence 21 has been premised on this basis -- is concerned with 22

A. I think that is a case that can be made, and although on

medicines generally not just vaccines, and therefore, 23 were you also responsible for giving authorisation for 24 the supply of the six new Covid-related medicines in the 25 United Kingdom, and the two previously authorised but 179

- the [CHM] on 4 February relating to peri- and 1
- 2 myocarditis. Do you consider that that elapse of time,
- 3 between February and June, was appropriate or required
- 4 or inevitable?
- 5 A. I think it was probably inevitable, given the rate at
- 6 which evidence accrued. And the fact that we had a more
- 7 extended dose interval than in Israel or in the US meant
- 8 that we were rather reliant on data from other
- 9 regulatory authorities.
- 10 Q. Some concern has been expressed by some people in
- 11 certain quarters that either the pharmaceutical
- 12 companies have not published all relevant
- 13 post-authorisation trial data or that the MHRA has sat
- 14 on post-authorisation trial data and not released it.
- 15 Is either proposition correct?
- 16 A. No, and there are studies being done on any long-term
- 17 consequences that will be rigorously examined as soon as
- 18 they're available.
- 19 Q. Patient information leaflets were not always given to
- 20 patients at the point of vaccination. They may
- 21 alternatively have been available. Is the issue of
- 22 whether PILs reached the attention of individual
- 23 patients a matter for the MHRA? Is the process
- 24 monitored?
- 25 **A**. It isn't a monitored process. In general terms,

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- 1 repurposed therapeutics?
- 2 A. For the approval of these, the benefit-risk
- 3 consideration, not for the supply.
- 4 Q. Did I not say "authority", or did I use the word 5
 - "supply"?
- 6 **LADY HALLETT:** "Authorisation for the supply".
- 7 A. Sorry. So its authorisation --
- 8 MR KEITH: Authorisation.
- A. -- that's the 174 terminology. 9
- 10 Q. Yes.
- A. Thank you. 11
- 12 Q. And you gave authority for Veklury, remdesivir,
- 13 Ronapreve, Lagevrio, Xevudy, Paxlovid, and Evusheld?
- 14 Α. Yes
- 15 Q. And then the repurposed drugs -- dexamethasone, of which 16 we have had much, and tocilizumab?
- 17 Α. Yes

19

- 18 Q. In relation to Evusheld, we've heard much evidence on
 - the reasons why no advance purchase of Evusheld was
- 20 made, prophylactically in 2021, and why, ultimately in
- 21 2022, the RAPID C-19 committee did not recommend the
- 22 purchase of Evusheld. Was the MHRA in any way involved
- 23 in that process of giving advice as to whether it should
- 24 be purchased -- or commenting on the outcome of the
- 25 clinical trials, such as they were, or, I don't know,

- 1 the operation of the pharmacovigilance system?
- 2 A. No involvement in decisions about purchase, simply
- 3 safety, quality, efficacy, and an awareness of what the
- 4 implications would be once variants were widely
- 5 circulating, variants of the Covid virus.
- 6 Q. And you'd authorised Evusheld?
- 7 A. Yes.
- 8 Q. And lastly, under the heading of therapeutics,
- 9 hydroxychloroquine. Did the MHRA authorise the use or
- 10 supply of hydroxychloroquine?
- For the treatment or prevention of Covid? 11 Α.
- 12 Q. For Covid?
- 13 A. No, and nor did any regulator.
- Q. What, you mean in western Europe or America? 14
- There was an emergency use in the US that was removed. 15 Α.
- 16 So hydroxychloroquine can be used for non-Covid
- 17 conditions, some conditions?
- Rheumatic or malaria. 18 Α.
- 19 Q. For which it had been authorised?
- 20 A. Yes.

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- 21 Q. But you had to consider whether or not it should be
- 22 authorised for Covid?
- 23 A. We considered the clinical trials for that purpose.
- 24 Q. And what did they tell you?
- 25 A. During the running of the clinical trials, further

- 1 MR KEITH: Thank you very much, Dame June.
- 2 Those are all the questions I have for you.
- 3 LADY HALLETT: Just a few more questions, Dame June.
- 4 Mr Odogwu over there is going to ask some questions.

Questions from MR ODOGWU

- 6 MR ODOGWU: Good afternoon. I ask questions on behalf of
- 7 the Federation of Ethnic Minority Healthcare
 - Organisations. I have two questions relating to the
- 9 Yellow Card Scheme.

Dr Salman Wagar, who is the president of the British Islamic Medical Association, has described the Yellow Card system as lacking transparency and failing to build trust with ethnic minority groups.

13

You mentioned at paragraph 374 of your statement, that's your first statement, that the system was updated in February 2022 to improve functionality. How, if at all, did the updates to the system address or improve trust building with marginalised communities?

19 A. Thank you for your question. It's a very important one.

> The system has been updated to improve the ability to interact with all those who report, but I do take the point that's being made that, indeed, the ability of people from minority communities to use the system with confidence and with trust needs more work.

I did a certain amount, such as I was able to do, 183

- 1 evidence became available whereby the investigators were
- 2 asked to justify continuing, given a question about
- 3 safety. And clearly -- I'm sorry to continue, the
- 4 RECOVERY trial did continue to very good effect for
- 5 treatment and gave us a definitive answer.
- 6 Q. And the definitive answer was?
- 7 That it was not effective for the treatment of Covid.
- 8 Q. And in your recommendations section, do you make number
- 9 of recommendations, which I won't trouble you with now
- 10 because they are plain from the face of your statement,
- 11 concerning frameworks for international collaboration?
- 12 You endorse, and you would ask to be able to do again
- 13 the rolling review process relating to clinical trials
- 14 and the authorisation process. You would like to see
- 15 greater diversity in clinical trials, and a more robust
- 16 surveillance strategy for special groups such as
- 17 pregnant women, and vulnerable populations?
- 18 I think we would like to really focus on the area of
- 19 clinical trials, from the point of view of diversity,
- 20 because if we start with representative trials, then
- 21 there's a much greater trust from those receiving the
- 22 vaccine that it's been tested in people like me, as was
- 23 normally asked of me, and I think that the clinical
- 24 trial area is one there for really important further
- 25 regulatory improvement.

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- 1 during the Covid pandemic, but now is the time, in
- 2 peacetime, to take this to a really improved level. And
- 3 I'm grateful for those comments.
- 4 Q. Do you have any observations about what work could be 5 done, in terms of recommendations for such a feedback
- 6 scheme?
- 7 A. I think it can use different languages, it can make it
- 8 simpler, and it can actually go from a provision of
- 9 information to a greater level of dialogue. And I think
- 10 that all of those things will make a difference to this
- very important area. 11

12 Q. Thank you.

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My last question is, FEMHO has emphasised a need for collaboration with community leaders and organisations to promote Yellow Card participating and reporting amongst ethnic minorities. Did the MHRA work with such stakeholders during the pandemic to increase awareness and participation among ethnic minorities, and if not, can you explain why?

20 A. Thank you again.

> We did. I can speak for myself to have worked with Vaughan Gething, in Wales, to try to have outreach there, in different communities, and I know working with colleagues in the Department of Health, this was a key factor.

1 I think our efforts were limited by availability, 1 2 2 given the various important calls on our time, and, as 3 3 I say, the cure I think is probably to create better 4 outreach when you're not in the throes of trying to 4 5 deliver new vaccines and therapeutics. 5 6 MR ODOGWU: Thank you. 6 7 LADY HALLETT: Thank you very much, Mr Odogwu. 7 8 8 Ms Morris. consequences of a vaccine. 9 9 Behind you, but if you could make sure you keep your 10 voice against into the microphone. Ms Morris won't be 10 offended. 11 11 12 Questions from MS MORRIS KC 12 13 MS MORRIS: Not at all, thank you, my Lady. 13 what people were offered. 14 I ask questions on behalf of the Covid Adverse 14 Q. Thank you. 15 Reaction and Bereaved groups, and these groups represent 15 16 those who have suffered injury or bereavement following 16 17 their voluntary acceptance of the Covid-19 vaccines. Of 17 18 18 course, those I represent have many questions, but I'm 19 going to focus my questions this afternoon on two 19 20 topics, the first topic around the decision to authorise 20 21 21 the vaccines. the MHRA or by other agencies? 22 The Inquiry has heard thus far from witnesses 22 Α. 23 including Dame Kate Bingham about the significant UK 23 24 investment in research and development, and supporting 24 25 the development of multiple vaccine candidates prior to 25 185 1 and the very important vehicle for this was the leaflet 1 2 that everyone got when they got their vaccine. But I do 2 3 accept that awareness of the scheme, which should be 3 4 part and parcel of using a medicine safely, could always 4 5 be improved. 5 made. 6 MS MORRIS: Thank you. 6 7 7 Thank you, my Lady. 8 LADY HALLETT: If I allowed Ms Morris a follow-up question, 8 9 I think it would be: but can we ensure that everyone got addressed. 9 10 MS MORRIS: I'm grateful. a leaflet? 10 MS MORRIS: Yes. 11 LADY HALLETT: Thank you, Ms Morris. 11 LADY HALLETT: We can't, can we? 12 12 13 13 A. I think that's a question that might well be put to 14 colleagues who were involved in the actual vaccination 14 15 process. Thank you. 15 MS MORRIS: My Lady, thank you, and the follow-up to 16 16 17 follow-up might have been: is there any way of 17 18 evaluating that process within the scope of the MHRA or 18 19 other agencies? How can they tell if anybody is 19 approach as "superb". THE WITNESS: Oh, thank you, my Lady. 20 receiving or not receiving the leaflet? 20

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LADY HALLETT: Is there any system in place for ensuring

that -- you act on the basis that patients will be

My Lady, it's meant to be supplementary to the

healthcare professional, not the sole source of

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informed by a paper leaflet.

the authorisation. My question is, how much influence, if any, did the fact that there'd been a significant cost incurred by the UK in procuring the Covid-19 vaccines have on the MHRA's decision to authorise the A. Thank you. May I say again that I want to offer the deepest regret that any person has suffered the adverse In terms of influence of the kind that you've mentioned, there was no influence whatsoever on the regulatory decisions of matters relating to UK investment procurement or other financial aspects to My second topic, on the Yellow Card reporting. Mr Keith has already asked whether there's any room for improvement around the publicity of the Yellow Card Scheme. Do you agree there was a lack of publicity around the Yellow Card and the actions to be taken by an individual, if one did suffer an adverse reaction, by We did make very great efforts to make sure that people were aware of the offer to report, and that every reaction reported to us would be treated as a very important contribution to our understanding of safety, information, and in fact, as a result of the Cumberlege review, there has been a legal change to oblige a leaflet. As you know, in a pharmacy, sometimes the medicine comes in a white box. So that change has been I think in the specifics of vaccines, there's probably some research that could be done to helpfully calibrate or quantify are there gaps that need to be I think that completes the questions for you, Dame June. I don't know if you followed Dame Kate Bingham's evidence yesterday, but I congratulated her on her extraordinary achievement, but as she was the first to acknowledge, it wouldn't have been possible without the immense hard work and the willingness to show flexibility of people like you, and she described your LADY HALLETT: So we owe you a debt of gratitude. 21 22 THE WITNESS: Thank you, my Lady. It's my agency, actually,

it's every member of staff, but I will convey that to

LADY HALLETT: I appreciate it's you and your colleagues.

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