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Claim No: HT-2020-000442

**IN THE HIGH COURT OF JUSTICE**  
**BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES**  
**TECHNOLOGY AND CONSTRUCTION COURT (KBD)**

Date: 7 October 2022

Before:  
**MR JUSTICE WAKSMAN**

**BETWEEN:**

**THE KING**

(on the application of the **GOOD LAW PROJECT LIMITED**)

**Claimant**

- and -

**THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE**

**Defendant**

**ABINGDON HEALTH PLC**

**Interested Party**

**Joseph Barrett, Rupert Paines and Stephanie David** (instructed by Rook Irwin Sweeney LLP, Solicitors) for the Claimant

**Philip Moser KC, Ewan West, Khatija Hafesji and Niamh Cleary** (instructed by the Government Legal Department) for the Defendant

**Ligia Osepciu and Clodhna Kelleher** (instructed by Bristows LLP) for the Interested Party

**JUDGMENT**

**Hearing dates: 3-5 May 2022**

This is a redacted version of the Judgment, to be made available publicly.

The redactions are for reasons of confidentiality and are shown by square brackets

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## **INTRODUCTION**

1. This is a claim for judicial review brought by the Claimant, The Good Law Project Ltd (“GLP”) a not-for-profit organisation, against the Defendant, the Secretary of State for Health and Social Care (“SSHSC”). I shall refer to the Defendant by reference to the relevant departmental name, in other words the Department of Health and Social Care (“DHSC”). The claim concerns the award by DHSC in April, June and August 2020 of 3 contracts to the Interested Party, Abingdon Health plc (“Abingdon”) in respect of the development of antibody lateral flow tests (“LFTs”). Such tests are designed to detect certain antibodies in a sample of blood provided by the person tested. If antibodies are detected, it indicates that they have been infected with the Covid-19 virus (“Covid”).
2. The instant claim is one of a number that have been brought by GLP in respect of, in broad terms, the government’s procurement of various goods and services, all related to the Covid pandemic.
3. Because they are of considerable relevance to the issues before me (principally on the law) I refer here to some of GLP’s claims which have already been determined:
  - (1) *GLP v SSHSC* [2021] EWHC 346 (“*Unpublished Contracts*”), where Chamberlain J held that the SSHSC had acted unlawfully by failing to follow his own Transparency Policy in relation to a large number of Covid-related contracts made prior to 17 September 2020;
  - (2) *GLP v Minister for the Cabinet Office and Public First Ltd* [2021] EWHC 1569 (“*Public First*”). This concerned the direct award of contracts for the provision of focus group and communications support services. O’Farrell J rejected all of the claims save for that based on apparent bias. On appeal ([2022] EWCA 21) the Court of Appeal reversed the finding of apparent bias, and dismissed the cross-appeal with the result that the claim now failed entirely;
  - (3) *GLP and Everydoctor v SSHSC and Crisp Websites and others* [2022] EWHC 46 (“*PPE*”). Here, the challenge concerned directly-awarded contracts for the supply of personal protective equipment (“PPE”) for use in particular by those treating patients who had Covid. O’Farrell J rejected all the challenges except one;
  - (4) *GLP and Runnymede Trust v The Prime Minister and the SSHSC* [2022] EWHC 208 (“*Runnymede*”). Here, the Divisional Court held that the SSHSC had failed to comply with his public sector equality duty in relation to the appointment of Baroness Dido Harding as Interim Chair of the National Institute for Health Protection and Mike Coupe as director of NHS Test and Trace (“TT”).
4. In addition, there is *Gardner and Harris v SSHSC and others* [2022] EWHC 967. This was a decision of the Divisional Court concerned with the death of the two claimants’ fathers in care homes in April and May 2020 i.e. in the first wave of the pandemic. The Court rejected claims that policy documents issued by DHSC and others at the time in relation to residents of care homes, and the policy decisions recorded in those documents, constituted breaches of the rights of the deceased fathers.

### **Background**

5. As for the general background, I gratefully adopt the account given by O’Farrell J at paragraphs 7-17 of her judgment in *Public First*. In early 2020 the first wave of the Covid-19 virus surged through Europe. On 11 March 2020 the Director General of the World Health Organisation announced that Covid-19 had been classified as a pandemic. On 13

March 2020 there was widespread cancellation of sporting events, including Premier League football and the London Marathon. On 16 March 2020 the Prime Minister began daily press briefings, urging everyone in the UK to stop non-essential contact and travel to enable the NHS to cope with the pandemic. On 17 March 2020, the European Union closed all its external borders in an attempt to contain the spread of Covid-19. On 18 March 2020 the Government announced that most schools across England would shut from Friday 20 March 2020. The Welsh and Scottish governments also announced that they would close schools. On 20 March 2020 the Government ordered all pubs, restaurants, gyms and other social venues across the country to close. The furlough scheme was announced. On 23 March 2020 the Prime Minister, in a televised address to the nation, imposed the first lockdown, asking the British people to: “Stay at home, protect the NHS and save lives.” On 25 March 2020 the Coronavirus Act 2020 was passed, making emergency provision in connection with Covid and conferring wide powers on the Government to impose restrictions on the freedom of movement of individuals for public health protection. On 9 April 2020 the UK recorded its highest Covid-19 daily death toll in the first wave of 1,073 deaths. On 10 May 2020 the Prime Minister announced limited plans for the easing of the first lockdown. Through June and July 2020 restrictions were relaxed and replaced with social distancing rules pursuant to revised regulations.

6. By the end of 2020, the first rollout of what was to become the highly successful vaccination programme in the UK (and elsewhere) had commenced. But in early 2020, a vaccine solution to the pandemic was just a distant hope. Instead, the essential response was to seek to contain the virus by the imposition of the restrictions referred to above in order to stop its spread in particular, of course, partial or complete lockdown.
7. At that time, a major question was whether a person who had been infected with Covid was thereafter immune (“the Immunity Question”). We now know, of course, that having been infected or vaccinated is no guarantee of immunity, although subsequent infections may be less serious. But in early 2020 there was still a real hope that scientific work would show effectively that infection conferred immunity because of the antibodies produced by the virus. If it did, then there was huge potential for relaxing most or all of the social and workplace restrictions for those who had been infected. This was because they would not then pose a risk of infection to others nor would they succumb to Covid again.
8. However, to make swift and extensive use of that immunity would require the manufacture of millions of easy-to-use tests which key workers and others could carry out at home with almost instant results. The object for any test was to detect the existence of the particular antibodies associated with Covid infection and which were created as a result. Such antibodies would demonstrate that the relevant person had had Covid. Accurate laboratory tests to detect such antibodies already existed by March 2020 but they were expensive and time-consuming. They could not possibly be used on a mass basis.
9. Hence the search for an antibody LFT. An LFT combines a sample of bodily fluid or other material from the user which is then placed on absorbent material which allows it to flow, much as ink flows through blotting paper. It will then come into contact with something else and if it reacts in a particular way a positive test result will be shown. An early example of an LFT is, of course, a pregnancy test. Another, now, is an HIV test. So the basic technology was well-known. In the case of an antibody LFT, a sample of blood from a finger-prick would be used and placed in the well of the plastic surround of the LFT. The “something else” with which it needed to come into contact was a sample of the relevant type of antigen protein which is always present in the active Covid virus. If there were antibodies in the blood sample they would “stick” to the antigen and yield a positive result in terms of a line showing on the “T” (test) point of the LFT. This is a simplified account

because there are other materials used as well. The fluid would continue down the pad until it reached some more material which would then yield a further line at the “C” (control) point of the test unit which would then indicate that the test had been completed.

10. Readers of this judgment will of course be familiar with what became the most-used LFT in respect of Covid, namely the antigen LFT. The purpose there was to identify those who actually had the virus at the time of the test. It would identify whether the bodily matter obtained using a laryngeal and/or nasal swab contained the relevant antigen, by revealing its reaction with antibodies placed within the LFT.
11. Any antibody LFT that was going to be fit for mass use at home had to be extremely reliable. In other words, there could be no significant amount of cases where the test showed that someone had the antibodies (and were therefore potentially immune) when in fact they did not. Or where it showed that did not have the antibodies (and was therefore not potentially immune) when in fact they did. The success rate of a test such as that used to detect antibodies was measured by the percentage “sensitivity” and “specificity” that it achieved. Percentages in the high 90s were required. A high percentage sensitivity meant that there would be few cases where the test was negative i.e. there were no antibodies present, when in fact the true position was that they were there. This could be checked by using testing conditions where 100% of the samples provided were known to be positive i.e. the antibodies were present. The question then was how many samples were shown to be positive by the test. Cases where a positive result was not shown (but where it should have been) are referred to as “false negatives”. Conversely, the level of specificity shows the extent to which there were “false positives”. A high level of specificity meant that there would only be a few cases where the test showed a positive result (i.e. the presence of antibodies) when in fact it should have been a negative result because there were none. Here, where the test failed to identify correctly, it would produce “false positives”.
12. It is not in dispute that the various forms of laboratory test were likely to be more precise than LFTs. The chances of false positives or negatives emerging with LFTs also depended on the quality of the sample. There would be fewer false results where the sample used to analyse the test was itself from someone with a high level of antibody, perhaps because they had the infection relatively recently, as opposed to someone who had it a while ago and the strength of the actual infection in any given case could also affect the strength and detectability of the antibodies produced. In addition, the type of antigen used was important. If one adds to those variables, issues which could arise as to the quality and reliability of the underlying components of the LFT, it begins to show why the development of a successful antibody LFT was a complex process which would take considerable time and considerable resources.
13. It is not in dispute that as at March 2020 many companies from the UK and abroad who had made LFTs for other purposes claimed to be able to produce antibody LFTs. DHSC purchased many such LFTs as it were, “off-the-shelf” only to discover that they were not sufficiently reliable.
14. In the event, Abingdon was engaged to create and develop from scratch as it were a reliable antibody LFT. As at March 2020, Professor Sir John Bell was an unpaid adviser to the government in relation to many aspects of Covid. In addition, there were others at Oxford University who were involved in research into Covid.
15. The first contract under challenge was made between DHSC and Abingdon on 11 April 2020 (“the Research Contract”). By that contract, DHSC would pay to Abingdon £2.5m in order to assist it to develop the relevant test. The making of that contract was approved by the then Secretary of State himself, Matt Hancock, following a Ministerial Submission dated 2 April (“MS2”). While Abingdon was stated to be the other contracting party so that

there was, from the point of view of DHSC one entity which was clearly liable, Abingdon was in practice contracting on behalf of a consortium of other diagnostic companies (and possibly others) which was known as “UK-RTC” (i.e. Rapid Test Consortium).

16. The second contract under challenge was contained in a letter agreement made between those same parties on 2 June 2020 (the June Contract”). This followed the making of Ministerial Submissions on 13 April (“MS3”) and on 13 May (“MS4”) and was approved, this time, by Lord Bethell, the then Minister of Innovation. By this contract DHSC agreed to fund the costs of the purchase of particular required LFT components so as to enable Abingdon to make 10m tests. The amount of funding required under the June Contract was expressed to be £10.272m. That contract contemplated the making of a further contract for the actual supply of LFTs. Title to the components would remain with DHSC until they were incorporated into manufactured tests. The anticipated supply agreement would be conditional on Abingdon producing an LFT that was validated and approved by the MHRA (ie the Medicines and Healthcare Products Regulatory Agency) by 31 July 2020.
17. The third contract under challenge was made on 14 August 2020 (“the August Contract”). It was for the purchase of 1m LFTs but with the right on the part of DHSC to purchase a further 9m. By the time it was made, Abingdon had not secured MHRA approval for its test but the August Contract had provisions whereby it was conditional on MHRA approval being obtained along with a satisfactory evaluation from Public Health England (“PHE”).
18. I shall refer to these contracts collectively as “the Contracts”.
19. In the event, no MHRA or PHE approvals were obtained. In addition, the Immunity Question had still not been resolved in favour of a clear link between the presence of antibodies and immunity. The case for the manufacture and purchase of millions of tests for home use faded away. In the end, DHSC purchased only 1m tests, most of which were not used and became time expired. On 14 February 2021 the August Contract expired without being renewed by DHSC.
20. There was a dispute between DHSC and Abingdon in relation to the Research and/or June and/or August Contracts. This was ultimately settled by an agreement reached only recently, on 22 June 2022 which included the payment of substantial sums by DHSC to Abingdon.
21. In the meantime, these proceedings had commenced on 4 November 2020.

## **THE ISSUES**

### **Introduction**

22. By the time of the hearing, there were five issues for determination by me. They are set out below in the order in which I intend to take them and my description of them is based on the parties’ Agreed List of Issues. The 4 Grounds alleged by GLP are those for which permission was ultimately granted. DHSC’s point on Standing was added by way of amendment.
23. Where I need to refer to GLP’s Re-Re-Amended Statement of Facts and Grounds, I shall call it “the Claim”. I shall refer to DHSC’s Re-Amended Detailed Grounds of Resistance as “the Defence”. I shall refer to GLP’s Response to DHSC’s Request for Further Information as “the Further Information”.
24. Given that in essence this is a procurement challenge it is unsurprising that the Grounds alleged make reference to various parts of the Public Contracts Regulations 2015 (“the PCR”). However, it is now common ground that Reg. 32 (2) (c) applied because of the extreme circumstances arising as a result of the pandemic. Its application was specifically

contemplated in relation to procurement by public authorities during the pandemic by the EC Notice dated 1 April 2020 which provided “Guidance...on using the public procurement framework in the emergency situation related to the COVID-19 crisis” (see in particular paragraph 2.3). Reg. 32 (2) (c) provides as follows:

**“Use of the negotiated procedure without prior publication**

32.—(1) In the specific cases and circumstances laid down in this regulation, contracting authorities may award public contracts by a negotiated procedure without prior publication.

*General grounds*

(2) The negotiated procedure without prior publication may be used for public works contracts, public supply contracts and public service contracts in any of the following cases:—...

(c) insofar as is strictly necessary where, for reasons of extreme urgency brought about by events unforeseeable by the contracting authority, the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with.”

25. What is not common ground is what other duties or obligations within the PCR apply in such a case.

**Ground 5: Rationality**

26. GLP here claims that

- (1) the decision to enter into the Research Contract was made:
  - (a) in breach of DHSC’s own policy/process, which required consideration and approval by the Scientific Advisory Panel, referred to at paragraph 89 below (“the SAP”);
  - (b) without any or any sufficient enquiry into or consideration of Abingdon’s and other suppliers’ capability, suitability, supply chain or financial position;
  - (c) on the basis of false or incorrect advice provided to the Secretary of State; and/or
  - (d) on the basis of, or with regard to, Abingdon’s nationality;
- (2) The decision to enter into the June Contract was made at a point in time at which DHSC had not conducted any evaluation of the accuracy or reliability of the Abingdon LFTs;
- (3) The decision to enter into the August Contract was made
  - (a) at a point in time when the AH rapid AB test had only been self-certified by CE mark, with no MHRA or PHE evaluation having been conducted;
  - (b) in circumstances where the requirements of clause 6 of the June Contract (“Validation”) had not been satisfied;
  - (c) before the conclusion of the PHE evaluation; and
  - (d) in circumstances in which the accuracy of the AH tests did not comply with DHSC’s own policies and requirements.

27. GLP then alleges that if and to the extent that any of the matters above are made out, DHSC’s decision to enter into the Contracts (or any of them) was taken (i) without any lawful, sufficient, or rational assessment of relevant matters; (ii) without regard to relevant considerations; (iii) in breach of the *Tameside* duty of enquiry; (iv) based on irrelevant considerations; (v) *Wednesbury* unreasonable; (vi) taken in breach of DHSC’s own policy or process; (vii) vitiated by improper purpose; and/or (viii) vitiated by error of fact.



28. DHSC denies this claim. It denies, by reference to the evidence it has adduced, a number of the factual allegations made by GLP. But in addition, it says that each of the contract award decisions were made at a time of national crisis where there was an urgent need for antibody testing, assuming the Immunity Question was answered favourably. In this context, the decision to enter into each of the Contracts was rational, relevant considerations were taken into account and enquiries which could reasonably be made at the time were made. Further, the claims set out at paragraph 26(1)(b) and 26(1)(d) above are time-barred. It also denies that there was anything unlawful by reason of the point set out at paragraph 26(1)(d) above. See further, paragraph 37 below, which addresses the same point made in the context of Ground 6.
29. Certain elements of Ground 5, as set out in paragraph 111 of the Claim, are not now pursued (see Rook Irwin Sweeney's letter of 30 April). These are:
- (1) In relation to Ground 5, allegations that
    - (a) Professor Bell's conduct in falsely informing DHSC that the SAP had considered and approved Abingdon's proposal was unlawful and vitiated by improper purpose and in breach of his duty of DHSC's candour; this was all said by inference to have been done to ensure the appointment of Abingdon and/or avoid further enquiry scrutiny and/or publicity in relation to it (see paragraph 111 (a1) (i));
    - (b) DHSC intentionally published false information concerning the contract award process with the effect or intention of misleading other service providers and third parties or preventing them from exercising their legal rights; this was said to be the result of the actions of Ms Berry; such actions including what she said in an email to civil servants on 6 April 2020; the inference was that she was acting pursuant to an improper purpose in order to mislead other service providers etc. (see paragraph 111 (a2));
  - (2) In relation to Ground 6
    - (a) The matters pleaded at paragraph 116 (ai) and (b) and
    - (b) The matters pleaded at paragraph 116 (ag) insofar as they allege that Professor Bell and/or his team stood to benefit financially from the success of the Abingdon tests.
30. Notwithstanding the withdrawal of those specific allegations, part of GLP's case involves inviting me to find facts which differ from the evidence adduced on behalf of DHSC, in particular from Professor Bell and Ms Berry. I deal with my approach to this issue in paragraph 52 below.

### **Ground 6 - Apparent Bias, Conflict of Interest and Unlawful Nationality Preference**

31. Here, GLP contends as follows.

#### *Apparent Bias*

32. First, there was a real possibility of bias and/or predetermination arising in relation to DHSC's conduct by reason of one or more of the following matters:
- (1) The involvement (if any) of Professor Bell and/or the University of Oxford in arrangements and/or decisions relating to the Consortium;
  - (2) DHSC's decisions to contract directly with Abingdon/the Consortium without advertisement or competition, to develop a test which (on the Claimant's case)

Professor Bell's team and/or the University of Oxford developed, and in circumstances in which members of the Consortium including (on the Claimant's case) the University of Oxford and/or members of Professor Bell's team stood to gain from the arrangements and/or contracts with DHSC and/or the success of the AH test;

- (3) The nature of DHSC's transactions with Abingdon/the Consortium (and in particular the degree of Civil Service involvement therein);
  - (4) There being (on GLP's case) no other economic operators or service providers treated in a comparable or similar manner to Abingdon/the Consortium;
  - (5) Professor Bell's public statements concerning the accuracy of the tests developed by Abingdon/the Consortium;
  - (6) Any confirmations given by Professor Bell regarding the SAP's consideration of Abingdon's proposal;
  - (7) Ms Berry and DHSC's descriptions of the contract award process;
  - (8) The arrangements under the 'revenue sharing agreement' and/or the Commercialisation Agreement;
  - (9) Lord Bethell having (it is alleged) pre-determined or been apparently biased regarding the decisions to enter into each of the contracts with Abingdon.
33. DHSC denies any apparent bias on the part of Professor Bell, Ms Berry or Lord Bethell. None of the relevant facts amount to such bias.

#### *Conflict of Interest*

34. Second, it is said that Professor Bell had a conflict of interest relating to his role for DHSC, Abingdon and the Consortium. If so, it is then said that DHSC:
- (1) Failed to take appropriate measures to effectively prevent, identify and remedy conflicts of interest arising in the conduct of its procurement procedures in respect of any such conflicts of interest; and
  - (2) Was in breach of Reg. 24 PCR and/or its own policies on conflicts of interest.
35. DHSC denies that there was any conflict of interest on the part of Professor Bell and denies there were any breaches of Reg. 24 or its own policies.

#### *Unlawful Nationality Discrimination/Preference*

36. Finally it is here said that DHSC's actions were vitiated by unlawful nationality discrimination/preference, and/or breach of equal treatment, fairness and transparency, and/or irrelevant considerations, by reason of its desire to finance and develop the 'British diagnostics industry'.
37. At paragraph 7 of the parties' agreed List of Common Ground, DHSC accepts that in entering into the Contracts it took into account the fact that Abingdon was a British company. However, it says that this was not unlawful in circumstances where supply chains were fragile, there was insecure supply, and the UK diagnostic industry was not sufficiently developed to meet the UK's needs. It also contends, as a matter of law, that the non-

discrimination principle in Reg. 18 did not here apply. However, if it did, then DHSC was entitled to derogate from it.

## **Ground 2 - Equal Treatment and Transparency**

38. GLP contends that notwithstanding the application of Reg. 32 (2) (c) (see paragraph 24 above), there remained obligations on DHSC by virtue of the legal principles of equal treatment, transparency and proportionality in respect of the awards of each of (i) the June Contract and (ii) the August Contract. If and to the extent that there were such obligations, GLP contends that DHSC did not fulfil them due to:
- (1) The absence of any advertisement or competition in respect of the contracts;
  - (2) The process by which Abingdon was selected as the economic operator to be awarded each of the June and August Contracts, and in particular,
    - (a) The presence or absence of other potentially interested economic operators;
    - (b) The involvement of Professor Bell and/or (on the Claimant's case) his 'team' and/or other members of the University of Oxford; and
    - (c) The support and assistance provided to Abingdon and the Consortium.
39. DHSC contends that where Reg. 32 (2) (c) applies, as it does here, the principles of equal treatment and transparency are displaced or modified. In any event, to the extent that they do apply, there was no relevant breach on the circumstances of this case, alternatively any such breach was justified.

## **Ground 7 – State Aid**

40. Here, GLP contends that DHSC granted Abingdon State aid by reason of one or more of:
- (1) The direct award and/or terms of the Research and/or June and/or August Contracts;
  - (2) The alleged provision of support and assistance to Abingdon/the Consortium in connection with the work that they were required to carry out under the contracts and development of their business.
41. DHSC and Abingdon contend that:
- (1) There was no State aid and in any event GLP's case is not pleaded to a sufficient standard;
  - (2) In any event,
    - (a) The indicia of State aid are not made out and a private market investor would have taken the same actions;
    - (b) The allegations of State aid are based on factual errors and are, in any event, ill-founded; and
    - (c) DHSC sufficiently considered the position and verified to the necessary standard (alternatively the necessary standard in the emergency circumstances which prevailed) to ensure that the outcome corresponded to the market price and/or the outcome did correspond to the market price as a matter-of-fact, anyway.
42. An alternative contention that even if DHSC had granted Abingdon State aid, it was lawful under the European Commission's Temporary Framework is not now pursued.

## **Standing and Relief**

43. Finally, DHSC contends that GLP has no standing to raise any of the Grounds set out above and the Court should refuse it any relief on account of that lack of standing.
44. If, in the event, GLP has standing and succeeds on any of the Grounds, there remains an issue as to what if any relief should be granted by the Court.

## **THE EVIDENCE – WITNESSES AND DOCUMENTS**

45. For GLP, there was one witness statement (“WS”) from Jolyon Maugham KC dated 14 December, 2020, and Ws from Simon Mico, the Managing Director of a diagnostics company known as Bio-Diagnostics (“BDx”) and from Gemma Abbott, GLP’s Legal Director, dated 1 and 8 April, 2022 respectively.
46. For the DSHC, I had Ws from the following:
  - (1) Professor Sir John Irving Bell, Regius Professor of Medicine at the University of Oxford, dated 9 July and 22 October 2021;
  - (2) Tamsin Berry, a Partner at Population Health Partners but a Senior Civil Servant working at DHSC on Covid-related testing until 10 June, 2020, dated 8 July and 15 October 2021;
  - (3) Dr Beverley Jandziol, a Senior Civil Servant, and member of the CTT (see paragraph 63 below) but who was between March and December 2020 deployed to DHSC and working on the NHS Test and Trace programme (“NHSTT”) as Commercial Lead, dated 7 July 2021;
  - (4) Tim Brown, a Senior Civil Servant at DHSC, who was at the Pillar 3 antibody testing team between 30 March and the end of June 2020, being number two to Ms Berry, dated 8 July 2021 and 10 February 2022;
  - (5) The Rt Hon James Nicholas Bethell (Baron Bethell), Parliamentary Under Secretary of State (Minister for Innovation) at DHSC, dated 12 October 2021 and 15 February 2022;
  - (6) Christian Destombes, a Senior Civil Servant and member of the CTT at the Cabinet Office, deployed to DHSC working on the NHSTT, dated 8 July 2021;
  - (7) Stephen Hennigan, a Senior Civil Servant and a Deputy Director working on antibody testing from around 6 May to late November 2020, dated 9 July 2021;
  - (8) Dr Kay Pattison OBE, Head of Research at DHSC which role also involved strategic oversight of the National Institute for Health Research (“NIHR”), dated 30 June 2021;
  - (9) Andrea Berry, a Senior Civil Servant and a Deputy Director working in the NHSTT from March to 28 July 2020 dated 1 July 2021;
  - (10) Michael Batley, a Senior Civil Servant and Deputy Director of Research Programmes at DHSC, dated 5 July 2021;
  - (11) Ann Bishop, a Senior Civil Servant, secondment to Pillar 5 at the testing programme in DHSC, dated 8 July 2021;

- (12) Daniel Bamford, a Deputy Director, seconded to the Covid Tests Triage Team at DHSC, dated 9 July 2021;
  - (13) The Rt Hon Matthew Hancock MP, SSHC at the relevant time, dated 27 October 2021;
  - (14) Tim Locke, Senior Civil Servant who joined DHSC in April 2020 first on Pillar 2, dated 18 February 2022; and
  - (15) Sean Kelsey, one of the GLD lawyers with conduct of these proceedings on behalf of DHSC, dated 13 April 2022.
47. For Abingdon, there were WSs from the following:
- (1) Chris Yates, CEO of Abingdon, dated 12 July 2021;
  - (2) Dr Christopher Hand, Chairman of Abingdon, dated 12 July 2021 and 18 February and 1 April, 2022; and
  - (3) Scott Page, Finance Director at Abingdon dated 12 July 2021.
48. The WSs adduced by DHSC and Abingdon represent a very considerable body of evidence.
49. On 19 July and 14 September 2021 GLP applied for what amounted to specific disclosure from DHSC. There was a hearing about these (and other) matters before Fraser J on 21 September. By that stage, DHSC had already agreed to give something akin to standard disclosure (itself somewhat unusual in a conventional JR). By an order made by him dated 1 October Fraser J directed that DHSC undertake a reasonable search of relevant emails and other messages to or from Mr Hancock. It also sought further disclosure from Ms Berry. GLP was also directed to serve a third-party disclosure application on Professor Bell - neither he nor Oxford University were (or are) parties to these proceedings. In addition, DHSC undertook to serve further witness evidence from Lord Bethell and other evidence about the replacement of a mobile phone which had been used by Lord Bethell, and related matters.
50. There was a further hearing before Fraser J on 1 November 2021. On this occasion he dealt with an application by GLP to cross-examine Professor Bell and Ms Berry. No such order was made then but Fraser J did require further WSs from both of them to deal with specific allegations and matters. On that footing, the cross-examination application was adjourned. It would then be a matter for GLP whether or not to restore that application once it had seen the further evidence from Professor Bell and Ms Berry. In the event, and following service of that evidence, the application was not restored.
51. In this regard, I was referred to these paragraphs of the decision in *Gardner* (itself another Covid-related case) as follows:
- “259. It is not enough for the Defendants to rely on a general proposition that where there are disputes of fact between the evidence for the Claimant and the evidence for the Defendants in judicial review the dispute must always be resolved in favour of the Defendants. In judicial review claims evidence of the Defendant’s witnesses, particularly if it is in generalised terms, may be contradicted by contemporaneous documents or, where appropriate, by the absence of contemporaneous documents.
260. In ordinary, less pressured circumstances than those prevailing at DHSC in March and April 2020 one would expect to see a chain of documents including a written submission to the Secretary of State and either a written response on his behalf or a minute of a meeting containing his decision. It is unsurprising that this usual degree of formality was not always observed. But, as recorded

above, the Defendants have disclosed what they say are all the relevant recorded communications (including Whats App and text messages) arising from proportionate searches of communications to or from the Secretary of State or the Minister for Social Care during the relevant period. Where there is no record at all of an important issue being raised with the Secretary of State nor of his response we cannot simply assume that everything relevant was taken into consideration. We have to do the best we can with the available material.”

52. Accordingly, even in JR proceedings and even where there has been no cross-examination, it does not always follow that what a defendant’s witness says can never be contradicted. But whether an adverse inference is to be drawn from the absence of documentation depends, as one would expect, on all the circumstances. It may be appropriate to draw it, it may not.
53. GLP have made the point that DHSC should have adduced evidence from yet further witnesses. An example was said to be [A], referred to in the WS from Mr Hennigan. While it is correct that she remains with the civil service she only spent about a month on the Pillar 3 team, according to Mr Locke. Another was Mr White but he had left the civil service. In general terms, I do not think that it was necessary for DHSC to adduce evidence from yet further witnesses.
54. There has also been much disclosure given by DHSC, although GLP says still not enough. In the event, there were some 20 hardcopy bundles of documents for the hearing, amounting to over 8,600 pages. Understandably, in a highly compressed three-day hearing, it was not possible to examine all the documents relied upon by the parties nor, for that matter, the detail of the WSs produced or even the detail of some of the authorities cited. Even so, much time was taken up with considering the true meaning of, or inferences to be drawn from, many emails. I take GLP’s point that because there was a lack of formal notes in a number of instances, it has been necessary to focus on emails. However, even had there been a complete repository of formal notes, I suspect that the argument would be that whatever was said in such notes, the emails tell a different story. As it happens, this exercise (undertaken below with an unavoidable citation of emails) has had one particular benefit: it reveals on a real-time basis how highly-skilled and motivated (but often changing) teams of civil servants and medical professionals were all attempting, at great speed, to understand the pandemic enveloping the country and create methods of combating it that would all need to be established immediately.
55. In that context, it is worth remembering that this claim is not a public inquiry into the adequacy or efficiency of the measures taken in relation to the procuring of antibody LFTs. Nor is it an action in negligence. It is, as it must be, a highly specific and focused consideration of whether there has been unlawfulness on the part of DHSC that sounds in judicial review.
56. I propose here to set out the facts (and some necessary findings in relation to them) covering the whole period in question. I will then consider each of the issues referred to in paragraphs 22-44 above, making all such further findings as I need to. I should add that I have not here addressed every single point or piece of evidence referred to me. To do so would have entailed a judgment much longer than even this one. However I have considered all the submissions made and I have dealt here with all the key questions of fact, law and analysis.

## **THE FACTS**

### **A. Some Organisational and Scientific References**

#### *CE Mark*

57. In the context of Covid, it was possible to obtain a CE Mark for tests for professional use (i.e. medical practitioners, pharmacists etc.) as opposed to self-testing at home. Once a CE

Mark was obtained, it would be registered with the MHRA (see below). Although the process is described as “self-certification” it is a complex and substantial one involving the compilation of a “technical file” with more than 100 documents. That file is then subject to (if requested) review and verification by the relevant notified body which here was the British Standards Institute (“BSI”).

#### *MHRA*

58. It is worth setting out some of the organisations which are relevant, apart from DHSC itself. First, the MHRA. This is the relevant regulatory body for products such as antibody LFTs. On 8 April 2020 it published its “Specification Criteria for serology point of care tests and self-tests”. In relation to “self-tests” (i.e. LFTs), for them to be “acceptable” they had to have a sensitivity of more than 95% and a specificity of more than 98%. To be “desirable” the sensitivity needed to be more than 98%, with the specificity being the same. These criteria made up what the MHRA referred to as the Target Product Profile (“TPP”). The MHRA also had the power to “derogate” a test from the usual requirement to have a CE Mark. As Dr Hand explains (see paragraph 38-42 of CH2) it was not possible to obtain a CE Mark for an LFT self-test. That is why it was necessary for the MHRA to provide a derogation, and thereby approve it without a CE Mark.

#### *PHE*

59. This body no longer exists under the name “PHE” (Public Health England), but at the time it was an executive agency of DHSC in England whose object was to protect and improve health and well-being and reduce health inequalities. From 1 October 2021 it ceased to operate and its functions were transferred to other agencies and offices. It was not a regulatory body as such. Nonetheless it had a clear role here (see below).

#### *NIHR*

60. This is the National Institute for Health and Care Research. It was established to create a health research system supported by the NHS. The NIHR itself is funded by DHSC, and it is not a separate legal entity. The research which it funded was either commissioned by the NIHR to begin with, or was research which had been proposed to it and which it approved. Its work was directed by Dr Louise Wood, the Director of DHSC’s Science Research and Evidence directorate, and also Professor Chris Whitty, Chief Scientific Adviser for DHSC. Dr Pattison was also involved, providing strategic oversight. Funding proposals usually had their formal approval from Dr Wood. Mr Batley, being responsible at DHSC for commissioning and funding health and care research, carried out this role through the vehicle of the NIHR.

#### *NHSTT*

61. It will be recalled that a major element of government strategy in response to Covid was the NHS Test and Trace programme (“TT”). This grew out of an initial collaboration between PHE and DHSC. At a relatively early stage, the government suggested, as part of the NHSTT programme, a target of 100,000 tests per day. These were all related to lab-based PCR tests for infection.

#### *OLS*

62. The Office for Life Sciences (“the OLS”) was part of both DHSC and the Department for Business, Energy and Industrial Strategy (“BEIS”). It promoted research, innovation and the use of technology to transform the health and care service. It was itself involved in research projects relating to Covid.

### *CTT*

63. This is the Complex Transactions Team at the Cabinet Office.

### *REACT*

64. These were the "REal-time Assessment of Community Transmission" studies being carried out by Lord Darzi and his team at Imperial College.

### *ELISA*

65. This stands for Enzyme-linked immunosorbent assay which is a lab-based test for antibodies.

### *PCR*

66. This stands for Polymerase Chain Reaction which is also a lab-based test. It can be used, among other things, to test for antibodies and antigens.

### *IgG*

67. This is Immunoglobulin G which is a type of antibody.

## **B. Workstreams and Pillars**

68. By the time Ms Berry had joined the testing programme, there were 4 "workstreams":

- (1) NHS swab-based viral detection;
- (2) Commercial swab-based viral detection;
- (3) Mass antibody testing to determine immunity; and
- (4) Surveillance i.e. antibody testing to determine what proportion of the population had been infected.

69. These 4 workstreams then became part of DHSC's "pillar" strategy. The old workstream 3, dealing with the development of mass-antibody testing, now became Pillar 3. By late March, a new fifth pillar was being worked on. The 5 Pillar Plan was announced on 2 April 2020. Pillar 3 was described as: "develop blood testing to help know if people across the UK have the right antibodies and so have high levels of immunity to coronavirus". Pillar 5 was described as "Create a new National Effort for testing, to build a mass-testing capacity for the UK at a completely new scale." The 5 pillars were then set out in detail in a document called "Scaling up our testing programs" dated 4 April which I describe below.

## **C. Key parties and individuals**

### *Professor Bell*

70. Professor Sir John Bell was appointed Regius Professor of Medicine at Oxford University in 2002. He leads Oxford's Medical Sciences research strategies. He has worked in the Life Sciences industry for over 30 years and has served on a wide range of advisory panels. His own specialisms are immunology and genetics, which are particularly relevant to diagnostic testing.

71. He has advised and supported various public officials working at DHSC during the pandemic, including those working on antibody and antigen testing, immunology and the vaccine programs. He has worked very closely with Ms Berry and provided direct advice to Mr Hancock and Lord Bethell.



72. Further, and as a contextual point, Professor Bell explains at paragraphs 20 and 22 of his first WS (“JB1”) how many Covid-related projects he was involved with in early 2020. There were numerous initiatives, some of which succeeded and some of which did not. All of this reflected (a) the urgency of the situation as the pandemic grew with increasing loss of life here and abroad and (b) the fact that in early 2020, very little was actually known about the Covid pathogen (virus).
73. One of the advantages which Professor Bell had was an extensive network of colleagues and contacts in the life sciences industry and in academia, so he was able to call on various specialists who might prove useful for a particular task or project.

*Ms Berry*

74. After graduating from Nottingham University, Ms Berry became a Science and Policy Fellow at Cambridge University, after which she joined the civil service in 2008. She started in the Cabinet Office then moved to PHE in 2013. She later moved to OLS in 2015 where she was a deputy then Interim Director. She joined DHSC on 21 March 2020.
75. She makes the point (which could hardly be doubted) that by early 2020 Covid was presenting an emergency for the UK not seen since WW2. The imperative when she joined the testing programme was to work at high-speed to develop it and indeed it was being started from scratch. It took time for matters to be formalised and going forward, such was the pace and scope of activity that some processes would not be formalised or structured as they normally would be. That explained why, for example, there were not always formal notes and why a particular team or group may have different names applied to them by different people.

*Abingdon*

76. Abingdon Health Limited had been founded as a private limited company in 2008 by Dr Hand, Brett Pollard and Mr Yates. It is a diagnostics company specialising in the manufacture of LFTs and devices. Dr Hand has worked in the immunodiagnostics industry since 1986, having previously obtained a D.Phil at Oxford concerned with immunodiagnostic tests. He has worked in the lateral flow area since the 1990s. Prior to starting Abingdon he was founder and CEO of Cozart Biosciences Ltd (“Cozart”), an immunodiagnostics company making various tests and kits. According to a long letter dated 4 May 2021, sent by Abingdon’s solicitors, Bristows, to those acting for GLP (“the May Letter”) others at Abingdon involved in this LFT project all had impressive credentials and experience in the lateral flow field (see paragraphs 9-19 thereof).
77. Abingdon had by early 2020 developed a number of LFTs for antibodies, bacteria and other matters.
78. One point of fact which can be dealt with here concerns Abingdon’s involvement in an HIV LFT. GLP took issue with DHSC’s statement that Abingdon had previously developed HIV home testing kits and at-home drug testing for the Home Office. Its own “open source” research revealed that Abingdon had not actually researched or developed any HIV antibody test. Rather it had (merely) manufactured such tests for another company which had developed them, namely BioSure. The implication was that Abingdon had effectively been no more than a production line.
79. Dr Hand explains in his third WS (“CH3”) that this allegation was both simplistic and wrong:

“5. Paragraph 12 of Abbott 1 claims that Abingdon “has not researched or developed an HIV antibody test” but merely “manufactured HIV antibody tests for another company which had developed such tests, BioSure” (emphasis in original). For Ms Abbott to claim that this means Abingdon is not qualified to research and develop an antibody test suggests a fundamental

misunderstanding of the nature of contract development and contract manufacture in the diagnostics industry.

6. Abingdon developed for manufacture, scaled-up for manufacture and produced BioSure's HIV self-test according to a product requirement specification ("PRS") prepared by BioSure in collaboration with Abingdon. The PRS defines product requirements such as sample type, time for test to run, assay format and performance characteristics such as sensitivity, specificity and, in the case of HIV, performance against known sample panels. Validation studies assess stability, shelf-life, precision, limit of detection etc. Other requirements include the selection of specialist biochemicals such as peptides and the synthesis of others such as colloidal gold-protein conjugates, the selection of membranes, and other key components which form part of the 'development for manufacture' process. The product is developed in such a way to enable automated manufacture; this will include details such as membrane spraying parameters, drying times and temperatures and other environmental factors such as controlled humidity.

7. The development of the HIV product involved iterative steps, modifications of peptide formulations and optimisation of other test biochemicals. This is a process controlled by Abingdon's new product development process ("NPD") which is a component of the Abingdon ISO13485:2016 Quality Management System. It involved the provision of validation data by Abingdon to BioSure to support regulatory approvals. Abingdon then manufactured the finished lateral flow device for BioSure, and BioSure packaged the device into a box alongside other components such as a blood lancet. BioSure owned the product, its regulatory approvals and retained the title of 'legal manufacturer'.

8. The HIV test development and manufacture is one of many lateral flow tests developed and manufactured by Abingdon and its employees throughout their careers as illustrated in the May letter. Furthermore, the recent development of a fingerstick whole blood antibody test for HIV meant the Abingdon team had directly relevant expertise which could be applied to the development of a test for COVID-19."

80. Another point made by GLP is that Abingdon had misrepresented its involvement in manufacturing tests for the Home Office. This is dealt with at paragraphs 9-14 of CH3. These show that Dr Hand had indeed been involved in developing and manufacturing such tests for the Home Office while he was at Cozart where Mr Yates and Mr Baldwin were also directors at the time. Mr Baldwin was later Technical Director at Abingdon and is now a consultant there. Dr Hand also says that he did not say that Abingdon itself had done these tests for the Home Office, rather it was senior employees there (who had also been at Cozart) who had that experience. Overall, I do not think there is anything in GLP's point about Abingdon's Home Office experience.
81. At paragraph 14 of the Claim, GLP pleaded that Abingdon was a small struggling company as at the beginning of 2020 and it had only recently become a plc. Its published accounts at the time of issue of these proceedings showed revenue of £2.268m in the 18 months to 30 June 2018 and revenue of £2.277m in the year ending 30 June 2019, but with a loss of £1.24m for that year. Its income was said to be from the sale of products to monitor myeloma, pocket diagnostic products, PCR tests and antibodies for research. The largest proportion of income was said to have come from "contract development and manufacturing activities". The directors did not recommend the payment of a dividend for that year and concluded that "it is necessary to draw attention to the revenue and cost forecasts in the business plans", as there "remains uncertainty as to the level of sales that will be achieved, the amount of cost reduction that may be required and the amount of funding that could be raised from shareholders or external investors. This combination of factors represents a material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern." (This is also reflected also in the Independent Auditor's Report). Under 'Principal risks', the Directors stated that "[t]he critical challenge facing the Company is growing revenues to breakeven in a timely fashion, and securing appropriate funding from shareholders and other sources when

required.” It was also noted that “[t]he Group’s business faces intense competition from fellow diagnostics companies”.

82. In early 2020, and before its involvement with DHSC, Abingdon had received offers of additional funding from a number of venture capital companies. On 30 October 2020, i.e. after the award of all of the contracts at issue in this case, Abingdon applied to be registered as a plc which was approved on 11 November. It later announced its intention to float on the AIM market on 15 December 2020, raising £22m on an IPO. Dr. Hand had acknowledged that the framework agreement between Abingdon and DHSC was a core focal point of the IPO. Following the expiry of the August Contract in February 2021, and the dispute with DHSC, Abingdon issued a profits warning on 26 April 2021 which caused its share price to drop by 30% before later recovering.
83. The present position is that Abingdon continues to trade, with 150 employees but there was an operating loss of £6.72m. Mr Page has made the point that at the time of his WS, DHSC owed Abingdon about £6.76m for sums due under the June and August Contracts. £6.27m is now going to be paid to Abingdon by DHSC by reason of the Settlement Agreement made on 22 June 2022, but nonetheless this outstanding debt strained Abingdon’s cash resources in the meantime and indeed there were some redundancies.
84. I think it would be wrong to see Abingdon (or to see it as at early 2020) as a small struggling company on the brink of insolvency with no relevant expertise.

#### **D. The Position as at March 2020**

85. At this time, as Professor Bell explains at paragraph 26 of JB1, with the development of vaccines a long way off, the bulk of the evidence supported relying on the antibodies created by those infected with the virus as the form of protection for them against future infection. Also at that time, most immunologists believed that antibodies were a good marker for infection and there was the possibility for protection through immunity acquired as a result.
86. However, the unsuitability of lab testing for antibodies on a mass basis led to the idea of using LFTs instead. By this time, Professor David Stuart, Professor of Structural Biology at Oxford and his team had developed the sort of high quality antigen which would be needed for effective antibody testing, whether in a lab or otherwise. They created a highly purified recombinant antigen by isolating the “spike” protein of the virus and modified it for use in tests. I say more about this below.
87. However, the UK, and in particular the NHS, had very little testing capacity. There was not a well developed diagnostics industry. This is reflected by the fact that in his statement of 19 March, the Prime Minister referred to the need to find an antibody test because of the numbers who had by then been infected and who might therefore have acquired some immunity.
88. Alongside the search for a suitable test, other scientists were working to try and resolve the Immunity Question. In addition, and in any event, according to Professor Bell, a second but also valid objective for antibody testing was simply to see how many people had been infected with the virus directly at any particular point in time, what has been described as the “surveillance” use of testing.
89. Around mid-March and with offers of suitable antibody LFTs starting to come in, Professor Bell suggested to Lord Bethell that a special team be set up to assess serological tests and LFTs before any commitments were made to purchase them in large quantities. Lord Bethell agreed and this led to the establishment of the Scientific Advisory Panel (“SAP”). For this purpose, Professor Derrick Crook, also at Oxford set up a laboratory designed to

evaluate the tests being submitted. Other members of the group included Dr Sam Roberts and Graeme Tunbridge from the MHRA. Ms Berry also sat on this panel which was already in place when she joined.

90. A triage inbox was also set up to receive information about test kits being offered or proposed by interested manufacturers and suppliers. Sample kits would then be ordered and evaluated if they looked promising.
91. Draft terms of reference (“TOR”) for the SAP were produced in late March (see the different drafts at pp1150, 1153 and 1561, on or around 24 and 26 March) although it is not clear to me that any final TOR were ever approved. But what they all seemed to contemplate was a review by the SAP of new and complete testing solutions and new specifications/designs for supplies for both antigen and antibody testing which had passed an initial triage. Recommendations would then be made by the SAP and then any relevant new test recommended would be sent to PHE and the MHRA. If the products were assessed as high priority, the SAP had the authority to authorise procurement of tests/materials as they saw fit prior to PHE/MHRA evaluation being done. This was before Abingdon came on the scene and the decision made to develop an antibody LFT from scratch, as it were. The TOR seemed to assume that what would be provided would be completed tests, components etc. whether new or otherwise.
92. Various tests and samples were indeed submitted. The SAP, chaired by Professor Bell, met daily, according to Ms Berry, to discuss the various tests being evaluated and to note the results.
93. At some early stage according to Professor Bell, the SAP became the Covid New Test Advisory Group (“NTAG”) which had more members than the SAP. If Ms Berry is right in her recollection this must have happened quite quickly. Likewise, and as a separate exercise, in a document called “Covid-19 Response Documentation”, there were proposed TOR for the NTAG (among other new groups). Its scope was said to be:

“Provides rapid assessment and procurement of new testing technologies for immunity and surveillance. Operating at risk with trusted manufacturers where appropriate. Provides a decision (where required) on the prioritisation of validation (by reviewing the validation master log) and reviews results from validation testing across all UK Testing Labs, agreeing clear next steps. Will also consider novel RNA/DNA tests where they have applicability to key worker rapid testing requirement (non-lab based testing). Where required, this group should consult the Expert Panel to consult on recommendations.”
94. The members would include Professor Bell, Dr Roberts, Mr Tunbridge and Ms Berry as Chair.
95. Even though these seem to be technically separate groups, albeit with overlapping memberships, the labels SAP and NTAG were often used interchangeably. However, (and save as referred to below) nothing turns on this.
96. At this point in the chronology, it is necessary to set out in some detail, the work that Oxford University had been doing on its lab-based ELISA test, as at late March 2020. Professor Stuart was particularly involved here. Part of the reason for its success was the particular antigen or protein used to be the reagent for antibodies present in the blood sample of the person being tested. There was in fact a choice. At the outset of the pandemic, a number of antibody tests (including those developed by Roche and Abbott) used a protein associated with the RNA of the virus known as nucleocapsid protein (“NP”). A test (whether lab or LFT) using NP as the reagent will then detect the antibodies to NP present in the blood sample which resulted from the infection. However, those antibodies detected, while they would certainly indicate there had been a Covid infection, were not the antibodies which produced the immunity or possible immunity that was being looked for. In other words,

while a high success rate of antibody detection might be shown on a test using NP, its use was limited if the object was to find the antibodies that potentially gave immunity.

97. On the other hand, if the “spike” protein or antigen within the virus was used as the reagent, this would interact with any IgG antibodies present in the blood which would then indicate not merely prior infection, but the possibility of conferring immunity, because these were the antibodies which it was thought would neutralise the virus thereafter. Most vaccines in use are designed to produce the IgG antibodies for that reason. Oxford’s ELISA test used the spike protein. Reference to it is seen in some of the emails I quote below. This protein was also “recombinant” i.e. it could be “engineered” or artificially created.
98. This is the context for a statement made by Abingdon in the MOU and Side-Agreement which GLP contends shows that Oxford was assisting Abingdon to develop the very test which Abingdon had been commissioned by the Research Contract to develop and produce. This is the statement Abingdon’s intended LFT was “based on an assay initially developed in laboratory format by the University of Oxford team led by Professor John Bell”. However, and as Dr Hand confirmed in paragraphs 20-21 CH1, Abingdon’s LFT was not based on the different, lab-based ELISA test being developed by Oxford. He said that the statement made was intended to give confidence that an LFT could be developed. For his part, Professor Bell said that the statement was inaccurate because in relation to Abingdon, what Oxford had developed was the antigen, not the actual LFT which was Abingdon’s responsibility to devise under the Research Contract. There was, of course, a connection between the two tests which was the use of the spike protein. And there is an issue as to the nature and extent of the supply of that antigen to Abingdon for the purpose of developing its LFT which was going to use it as the reagent. That is a separate matter which I deal with below.
99. Also by late March, it was clear to Professor Bell and the others at SAP that most of the LFT kits sent for evaluation did not work, or did not work well. Many were not accurate enough or were only accurate when testing hospital-based samples where there tended to be more powerful antibody responses due to the severity of the infection (which is why the donor of the relevant blood samples was in hospital in the first place).
100. Further, the antigen used was often not of high quality or of the right kind, and the physical build of some of the LFT test kits was itself flimsy. Further, the ability to secure suitable tests from elsewhere was in any event limited. According to Professor Bell, “There was pandemonium in global supply chains for medical equipment and tests”. Indeed, there were bans on exports from the USA of antibody LFTs among other things, and China had halted at least one consignment of tests bound for the UK.
101. While the ELISA test proved to be very successful, there still needed to be designed and manufactured an appropriate LFT platform which was beyond the SAP (or Oxford). Initially, it was thought that the limited amount of antigen and blood samples available meant that it was possible only for the SAP to assist one company to make the test. The use of the spike protein is what was thought to give the putative LFT a much better potential success rate than other LFTs being offered, which used different antigens. This idea was suggested by SAP and Professor Bell in the context of the emergence of Abingdon as a suitable company to develop the test, as described below.
102. At the same time, and in parallel, DHSC started to buy up large quantities of LFTs without waiting to see if these would ultimately be validated. This is dealt with in detail in paragraphs 23-28 of the WS of Dr Beverley Jandziol, who had overall responsibility for

commercial activities on all 5 pillars. As with the sample “prototype” tests sent to NTAG, the LFTs purchased in larger quantities fared little better.

103. In the meantime, Dr Hand had sent an email to the Testing Triage Mailbox. It is worth reciting in full because it set out Abingdon’s position at the time:

“Subject: UK-based COVID19 Rapid-test manufacturing capability

Dear Triage Team

I am Chairman of Abingdon Health Ltd, a York based lateral flow assay development, and manufacturing company.

I have been in discussion with Professor Dusheiko of Kings College Hospital and University College London Medical School, who has in turn been advising Professor Sharon Peacock of PHE in relation to rapid tests for the COVID19 pandemic. Professor Dusheiko asked that I write directly to this address too.

I am writing to make you aware of the capabilities of Abingdon Health which can be applied to help with the need for rapid diagnostic test systems for the SARS-CoV-2 viral antigen, and tests to detect antibodies (IgG and IgM) to the virus, in those who have been infected.

We have capacity to manufacture lateral flow tests in the multi-millions per annum and are one of a small number (perhaps 2 or 3) companies in the UK that can offer this large-scale manufacture. We are in the process of doubling our manufacturing capacity.

In terms of the PHE antibody test that has been mentioned by the Prime Minister, Chief Scientific Officer and Chief Medical Officer on the daily briefings I believe all UK manufacturers of scale, including ourselves, should be brought together under one framework to make the test according to the same specifications. This would ensure co-ordination of supply chains (including UK Government guarantees for purchase orders) and also surety of supply if, for example, one site is closed due to a COVID-19 outbreak. We, along with our competitors I'm sure, are receiving numerous enquiries from overseas and if we're not careful UK manufacturing will be not have the spare capacity to cope with the required number of tests for UK-use. Furthermore, there will be an enormous demand for a "UK PLC" test from overseas e.g. India alone would be looking at testing in the millions on a daily basis. This requires immediate action and I would put myself and my colleague (CEO) forward to lead this co-ordination effort if this was helpful. It is clearly important that UK manufacturers work in the national interest to ensure supply and value for money.

Due to our expertise in lateral flow manufacture, we have been contacted by many overseas suppliers of tests or components of tests who tell us they have access to both antigen tests and antibody tests. They contacted us due to the need for appropriate skills and infrastructure and are interested in a UK site for manufacture. We can procure these tests immediately for evaluation, and indeed have samples and technical data on route to us, but believe a coordinated effort in conjunction with PHE would be more appropriate.

Please get in contact with me so we can discuss in greater detail...”

104. This offer was not actioned at the time by DHSC. But on 29 March, in an email exchange with Lord Bethell, Mr Hancock said “we are going to build the British diagnostics industry”.

105. On 30 March, Lord Bethell sent an email to his Permanent Secretary dealing with the whole question of testing strategy. In it he said this, among many other things:

“Bringing forward British champions.

We need to understand the global diagnostics industry. And have a strong view on the UK start-ups and small businesses that might be in this space.

Gap analysis of the essential piece of the diagnostic supply chain we need domestic production so that have a resilient solution eg reagents.

Figure out a way to bring on growth in the UK market. As per yesterday's paper, this could include interventions like:-

- provide cash prizes for innovators who develop viable new testing solutions, including targeted prizes for new antibody tests,
- support manufacturers in other sectors to convert equipment and technology to boost covid testing capacity,

- support smaller manufacturers to scale their production,
- support firms 'at risk' to ensure continuity of supply, and
- provide incentives for global firms to work with smaller suppliers to boost their own capacity and to base manufacturing operations within the UK.”

106. On the same day, Professor Bell (as with other members of SAP) signed off his voluntary agreement in respect of the provision of his services to DHSC, with the main point of contact being Ms Berry, for a period of 6 months. Clause 4.1 stated that he would observe the provisions of the Civil Service Code including Civil Service values and all DHSC rules policies and procedures relating to conduct and standards.

107. On 31 March a number of things happened. First, Ms Berry sent a Ministerial Submission to Lord Bethell (“MS1”). This was all about developing an accurate antibody test delivered at scale. Among other things, MS1 said this:

“12) The development of accurate antibody tests for SARS-CoV-2 is moving rapidly. We are bringing in dedicated resource, who will work closely with organisations such as the Gates Foundation & wider industry to drive forward development of accurate, home-use kits. This might not be too far into the future as AstraZeneca and the Gates Foundation are aiming to have a prototype in the coming months. Assuming these tests prove viable, we will also prepare for UK-based manufacturing at scale. This approach supports the realisation of associated benefits for the UK diagnostics industry.

Strategic implementation

13) This process needs to start fast with the development of a minimum viable process for rollout which will be iterated as the programme develops. Therefore, we believe that workstream 3 can be carried out in two stages:

a) Stage 1 is focused on the rapid rollout of existing antibody testing kits, currently available on the market. If reliable and safe, existing tests may be able to clear key workers, and other priority groups, to go back to work if they possess a level of immunity to infection.

b) Stage 2 is focused on the creation / acquisition of a bespoke and accurate Covid-19 Antibody test, which can be manufactured at scale and rolled out nationally and on an ongoing basis.

14) We are working closely with a range of stakeholders in government, industry and academia to ensure we are accessing the best scientific, communications & logistical expertise to deliver on the objective of the programme. These are detailed at Annex C.”

108. In addition, NTAG sent a note of the results of evaluating 19 LFT kits from around the world. None were approved. A further test, from Surescreen, also failed.

109. Around this time, Professor Bell called Dr Gordon Sanghera, CEO of Oxford Nanopore, a successful biotech company. He had known Dr Sanghera for 15 to 20 years. He thought it would be worth talking to him about finding someone to make the LFTs. Dr Sanghera gave him the name of Abingdon at 9:46 PM, Professor Bell emailed Ms Berry to say (with Abingdon’s website address in the header) this:

“Have a look at this. Lateral flow company developers based in Yorkshire!!”

110. Ms Berry responded:

“Let’s contact them tomorrow!”

And she also forwarded the email to others in her team saying:

“Potential UK company”

111. Professor Bell assumes that he did look up Abingdon on its website before sending the email.

## E. April 2020

112. There was another SAP/NTAG meeting on 1 April, referred to here as a “skunk” meeting. That description indicates an informal group “brainstorming” particular ideas and solutions. This meeting was mainly about the testing of various LFT kits but Professor Bell is recorded as referring to Abingdon as a potential new source of LFTs.
113. Professor Bell says that he recalled a telephone conversation with Dr Hand who said that he was confident that Abingdon could make a functional LFT. He told Professor Bell that Abingdon had made self-tests for HIV which Professor Bell thought was useful because there was a large range of antibody response strengths with HIV, just as with Covid. Professor Bell could not recall when this conversation was but from other contemporaneous documents, I think it would have been on the afternoon of 1 April.
114. At 5:30pm there was a planned meeting between Lord Bethell and various industry representatives about obtaining tests and building up a domestic UK diagnostic capacity. The brief minutes of the meeting show that the attendees included representatives of various companies including Mr Yates. This has been referred to as “the kick-off meeting”.
115. According to his permanent secretary, Lord Bethell’s proposals going forward were: “1. Adaptive design (i.e. a distributed system); 2. High quality (i.e. sensitive); 3. Resilient (i.e. can be manufactured in the UK); 4. Open source; 5. Platform for engagement (i.e. clear where companies slot in)”.
116. The agenda/introductory note for attendees at the kick-off meeting read as follows:

“UK Diagnostic's Industrial Strategy kick off roundtable

5pm-6pm 01/04/2020

Purpose of meeting

Kick off meeting with key industry partners to develop an industrial strategy for how we further leverage and rapidly scale up the UK's diagnostic industry to support the work on testing for Covid-19.

We want to understand:

1. In the short term, how we can meet current capacity challenges to testing plans through enabling large suppliers to expand existing manufacturing capacity in the UK; and scaling up of our smaller scale diagnostic manufacturing capability and companies in the UK;
2. In the medium term, set a challenge for industry consortium to develop innovative solutions to our key testing challenges; in particular, delivering national population immunity testing.

We are keen to understand potential collaborative industry actions on these, and what government incentives and support is needed for industry to scale up at speed.

Proposed Agenda

1. Intro from SoS and update from government on current testing plans (Secretary of State and Kathy Hall)
2. Roundtable discussion from industry (All)
  - a. Areas of potential expansion of capacity to support these work streams
  - b. New areas of testing work e.g. genomics and decentralised approaches that could be utilised
3. How can government support industry to unlock these? (All)

Key points to make

- We have 4 key workstreams for testing
  - Symptom testing in hospitals
  - Symptom testing in home-based and local centres
  - Immunity testing
  - National mass population surveillance



- However, testing capacity is currently limited due to the availability of supplies, driven by international competition, system capacity to administer and process test and the availability of specialist staff. We also face significant logistics challenges in transporting testing kits, and matching laboratory capacity to demand.
- Government is currently addressing these strands by working with major suppliers to understand key supply constraints, by reviewing and identifying viable new testing solutions, and by adopting a rapid procurement model. But need to go further if we are to move to national population level immunity testing.
- Therefore, want to launch a new strand - a new industrial strategy for UK diagnostics.
- I'm keen to hear thoughts on what you more you can do and what you need from government to unlock additional activity."

117. There then followed a meeting between Lord Bethell, Ms Berry, Dr Hand and Mr Yates. In short, Dr Hand and Mr Yates said that Abingdon could develop an antibody LFT and use its experience with other LFTs. They said it would normally take 25 to 30 weeks to develop but could accelerate to 5 weeks here and they would work with Professor Bell.
118. Ms Berry then had a further conversation with Dr Hand the following morning, 2 April. This would appear to be the telephone call at around 10:45am which involved Professor Bell as well. Dr Hand said that it was possible to do the design of the LFT in 5 weeks. GKN was mentioned as a possible supplier of antigen. £2.5m would be needed for development and £40m for procurement. It was not known where the "pinch points" would be in relation to the supply of components.
119. I should add here that it was suggested in oral argument (and not presaged earlier) that a statement in the notes for this meeting, namely "Tamsin will produce advice for ministers, run it past Chris" meant that what became MS2 was going to be run past Mr Yates prior to submission. In my judgment there is no basis for this and the more likely reference is Professor Chris Whitty. He was in fact copied into MS2 and Ms Berry spoke to him about it.
120. Professor Bell then emailed Professor Crook to say that:
- "...The government wants to proceed with the development of a UK lateral flow test. Abingdon Health are a respected supplier in the UK who make these tests and have had experience in infectious diseases such as HIV. They have agreed to lead but need our help. They will need access to recombinant antigen. Your call but I think you had decided on Spike. They will also need sera for verification of the test. Derrick can you help? We need to move fast. Can you link up and discuss today please? Jb"
121. Professor Crook responded by saying:
- "Sure,  
We also need to link the company Sarah Gilbert has interacted with - I'll link Sarah with Tamsin."
122. Professor Bell then responded:
- "Don't get more people involved. We need a clean plan without committees and too many actors. These guys know the business and will make to open standards so others can produce it as well, they need headroom to design the pilot, jb"
123. At just after 5pm and further to his meeting with Ms Berry in the morning, Dr Hand sent her an email attaching a proposal for the development and production of an open-source specification for manufacture of the LFT, referred to here as the "COVID 19 IgG lateral flow assay". He said that he had a technical call with Professor Bell and colleagues shortly after but looked forward to discussing his conversation with Ms Berry. The enclosed proposal explained the detailed design and construction of the proposed LFT. A timeline suggested the relevant development, evaluation and readiness for manufacturing roll-out would be achieved by the 15 May. It said that 20 different components would be required. The first one mentioned was the test line antigen with the supplier name shown as

GKN/Oxford University. Under the heading “Roll-out to Other Manufacturers” it said that the specification and design would be provided to other manufacturers. The proposal went on to say that Abingdon could mobilise within 24-hours but to proceed at speed it would need a grant of £2.5m to cover the development phase. It would also require access to government funds to source and purchase the component materials to enable rapid test development.

124. That evening, Ms Berry and her team started to draft a further ministerial submission. This became “MS2” which was sent the following day to Lord Bethell. In the course of her work on MS2, Ms Berry asked Dr Hand as to who would be the partners with whom Abingdon would work in the proposed consortium. In reply, he said that apart from Abingdon it should be Omega (Scotland), BBI (Wales) and CIGA (Northern Ireland) and that this would be a “manageable consortium”.

125. Also, in the course of that evening there was an important exchange of emails between Ms Berry and David Williams, one of DHSC’s Accounts Officers and its Second Permanent Secretary. It is necessary to set out the entirety of this exchange in the light of the issues which are said to arise from it.

126. At just after 6pm on 2 April, Ms Berry emailed Mr Williams thus:

“So I have been to asked look at whether we can partner with industry by Lord Bethell to develop and spec our own lateral flow test.

I have a proposal but before I put them to Lord Bethel as requested can I ask how we are going to fund this?

The company needs 2.5 million to develop the test working on a complete end to end process.

And then if we are to proceed with multiple manufactures making these tests in the UK they want c40m.

I just want to check what the financial approval process is for this BEFORE I advise Lord Bethell later. Can I proceed with ministerial sign off, if that is what he wants to do.

This company was at the SoS roundtable last night too.”

127. Mr Williams responded at length raising a number of questions. Ms Berry then replied to those questions by adding words in red to Mr Williams original email. For ease of reference, I am here setting out Mr Williams' original email but with words underlined indicating Ms Berry’s response to the questions he asked.

“Hi

On costs overall, as long as we can socialise with HMT, there shouldn't be a particular problem. Andrea is pulling together an overview of testing costs esp strand 2.

But step back:

• We need to explain where in the 5 pillar strategy this sits.

In my mind this is one of the critical technologies we need to roll out antibody testing and so an issue I need to fix if I can deliver the objectives of the mass antibody programme. Its part of WS3 to implement but the levers and overarching strategy sits with WS5 -that should cut across all workstreams. This should be (if successful) one of the IS strand's exemplars.

• What is the basis for picking this company as opposed to others? In our "buy any test you can find" phase the lack of competition in a seller's market and need to move at pace is acceptable. But for this - indeed for Strand 5 as a whole - being clear about the criteria on which we are choosing to use this public money for company x but not similar company y is really important

This came up. We don't want to pick one company - we want to work with ALL UK lateral flow test manufacturers. We picked this one to design the spec with because it was recommended by the Science Advisory Group who think it's the best UK one in terms of scientific development and track record of performance. Its done HIV at home testing and at home drug testing for the Home Office. (I have no counterweight to this.) The proposal is to rapidly develop with oxford a test that measures

the antibody to the spike protein to demonstrate a neutralising IgG response. Then make the specification, SOP and prototype open source and all LTF manufacturers can make it. I suggested working with a few companies but the view was it wouldn't be agile and rapid to design in this way.

• And linked to that what are we buying? Whose IP is it? What protections would we have in place to ensure we aren't just growing shareholder value but are getting something meaningful back?

The IP is open source although I suspect it would be wise to retain this in the UK?! Question for the IS strand how open we should be. We are giving them a grant to develop the design and then a grant/loan money for a central materials procurement exercise run by them to get ahead of the potential world shortages of key ingredients like cellulose strips and plastic casings.

I understand that time is of the essence but is it so critical that we could not do a quick call to industry challenge fund - pick the three most promising? I don't know how you say yes to this and no to the next 5 companies that come with a similar proposition. If we were clear that only Abingdon could do it, that would be a different calculation but that then needs to be part of the case.

I think the pressure and constraint here is time. Can we add weeks on the process to do this call? 5 weeks from now to starting to manufacture will ensure kits for the future. They will most probably be post peak of the pandemic when a vast number of people are still just getting over the virus (you take this test 2/3 weeks plus after symptoms) but still very helpful. Especially if we don't generate lasting immunity.

If you can I would work through some of these issues before going to Ministers. Ideally I would like to see a very brief cut down business case - Andrea has a 2 page template - If you have to go back tonight try to hold at a decision in principle subject to setting some of this stuff out and working through the risks and opportunities. Once this is on the table though it will be hard to walk back from it.

I know I will be pressured in tomorrow to have more answers (seems bonkers given this was only discussed last night and this morning and we've had little time to write up) but we can certainly do a short business case if Andrea you can forward the template, in the morning. Who can help on the legal?"

128. In her email containing her replies to Mr Williams questions, Ms Berry also said that she had held off until first thing in the morning and added:

“The pressure comes from creating something viable and this will take circa 5 weeks from decision to starting production according to the company.

That in itself begs the question what do we do in the meantime which is a discussion we are having with the minister tomorrow as well.”

129. In addition to all that, and no doubt bearing in mind the exchange with Mr Williams, Ms Berry emailed Professor Bell, having googled other possible LFT providers:

“I've done a quick google and these are other LFT providers... in the UK. We can work with them all -just trying to work out how to make it happen. Do we invite them to a roundtable or something to propose the plan - I'm worried they might complain as soon as they find out we are developing with Abingdon.

We could either bring them in now with the plan or we could give a couple of them the chance to also develop a design - put them in a race. Did Gordon have a view on that when you spoke to him?"

130. Professor Bell responded early the following morning:

“I would not do that. It will cause real trouble. Once we have a prototype we can bring them in so we are sure the open standard will be widely applicable.

Three of these guys provided us with dud tests so no need to worry about them. Mologic have a test we have not seen yet. We just need to move on one partner otherwise we will spend all our time managing a herd of companies some of which we already know don't get it. Jb”

131. Mr Williams then came back with this:

“If there is a strong case for a sole source, no competition approach to the company based partly on timescales and partly on their track record and recommendations then I can see that working for the upfront £2.5M to develop the spec.

I don't understand from the short email chain or the business proposal what the £40M is for. This needs thinking through and proper commercial input. I can see a model which you suggest of rapid development of an open source spec and then a challenge to a whole bunch of people to make it quickly - but why would we then get this outfit to buy the consumables? If that is for the stuff they are going to manufacture it should be part of a separate contract. If it is for others to get off them, that seems an odd route. Or are they saying they need £42.5M just to get to the spec?

I can see us moving quickly on the £2.5M for the development work while we work through what comes next - but being clear whether £2.5M gets you to a usable, shareable spec would be a necessary condition."

132. What this exchange shows is that Mr Williams did have initial concerns but Ms Berry went through them with him so that he was satisfied that they should proceed.
133. Later on Friday 3 April, at around 6:55pm, MS2, in its final form, was sent to Lord Bethell. It was copied to Mr Williams and Professor Chris Whitty among others. The formal recommendation in MS2 was to pursue development of a new LFT device with a consortium led by Abingdon with the aim of a starting wave one of antibody testing with a pilot on 21 or 28 April. Abingdon should be provided with £2.5m of funding to develop the device and an email should be written to it to that effect, a draft of which was attached to MS2. There were some other recommendations as well. In the body of MS2, the recommendation was to work with industry at speed to develop a bespoke test:

"Recommendation A: Development of Bespoke Test

16) We need to rapidly develop a test which meets our specification. To achieve this, we recommend doing the following.

Work with UK based developers & call to arms

17) In the short run, we will approach UK suppliers of lateral flow tests to create a bespoke test with secure supply chains on shore. The characteristics of this test will be sensitivity equivalent to an ELISA, home use design, digital read out by camera, 3D bar coded for tracking, use of a good neutralising antigen as the target and capability for high volume manufacturing.

18) We will start this process immediately. A Government "call to arms" next week to the UK diagnostics industry would help raise the profile of the challenge. The Oxford Skunkworks will then continue to validate new kits via the established triage process, and the moment we receive and validate an accurate test kit, we will move rapidly to pilot and rollout. Some initial research mapping the UK Lateral Flow Device Manufacturers can be found at Annex C and we will continue working with McKinsey to provide some more in-depth research into the scale-up potential of the companies in this consortium and more widely.

19) We will want to pursue opportunities arising from the call to arms. We have already received a proposal from Abingdon Health (Annex D) who suggest they can develop the test required. The Science Advisory Group have suggested that Abingdon are the best qualified UK firm to achieve this in terms of scientific development and track record of performance. They have previously developed HIV home testing kits and at home drug testing for the Home Office.

20) Abingdon would lead a consortium potentially including Omega, BBI and Ciga - other leading manufacturers of Lateral Flow Devices. They have asked for initial funding of £2.5m to support this process. This grant would allow them to develop the design and create a working test. Approximately £40m of additional funding would then be required for a central materials procurement exercise to allow them to get ahead of the potential world shortages of key ingredients like cellulose strips and plastic casings.

21) Further companies may come forward through the call to arms process who may similarly require funding. We will look to ensure there is a framework to provide funding to companies who similarly may be able to create a device that can meet our requirements.

22) We believe that an initial viable product could be potential ready for an initial Wave 1 pilot on the 21st / 28th April. We are developing the critical path now and trying very hard to make the pilot as soon as possible (See Annex E). We will work with PHE and the MHRA to ensure that a pilot programme is ready for launch on this date, and that it will have all the appropriate regulatory clearances by this point. We believe that these devices could then be available at scale in May.

23) Following development of initial kit & specification we would then make the information open source in order to exploit all manufacturing capabilities in the UK. We believe this will result in a more resilient supply chain for these tests, as well as more innovation and development. However, it is important to note that this could exacerbate issues around shortages of the materials & reagents available for UK manufacturing of the tests. We will look to ensure sufficient continuity of supply ahead of release of the specification.

24) Workstream 3 will work then closely with Abingdon and the consortia who are deemed most likely to be able to provide the accurate antibody tests providing scientific & bespoke support. Workstream 3 will then be responsible roll-out of this test, including comms, media, tech build, PMC, Whitehall management and logistics.”

134. At paragraph 48 of TB1, Ms Berry deals with an allegation made by GLP that there was some sort of memo recommending the award of a contract to Abingdon prepared by a colleague of Professor Bell. She says she was not aware of any such memo, and the recommendation to agree a contract was the subject of MS2. This had been prepared by her and her officials. There is no reason not to accept that evidence.

135. At 7pm Lord Bethell’s Permanent Secretary said that he wanted a call with the proposed consortium the following day (i.e. 4 April) to go into further detail and show some encouragement.

136. Mr Williams, for his part, sent some comments of his own on MS2 :

“Sorry me again -I have just read the draft email for Lord B to send.  
On the £40M, **I do not advise the Minister to say in that email that he is "lending his support" to this approach.** I have seen no details or follow up to my queries about whether this approach was likely to be reasonable value for money. He should not be drawn until he has had proper advice on this. The submission is misleading in suggesting that I have agreed the financial approach - I have agreed the £2.5M and that is all.

The proposed approach may make sense or it may be better for us to procure and disseminate to all the companies who then step up to the manufacturing challenge. I do not think that a decision on that is needed now to proceed at pace with the £2.5M work programme.”

137. At this point I should deal with the statement made in paragraph 19 of MS2 that:

“The Science Advisory Group have suggested that Abingdon are the best qualified UK firm to achieve this in terms of scientific development and track record of performance.”

138. A similar statement was made in Ms Berry’s email to Mr Williams on 2 April, recounted in paragraph 127 above.

139. As the person who, with the team, drafted that statement, Ms Berry has given some evidence about how it arose, in the light of the fact that GLP alleges that it was untrue. At paragraph 43 of TB1 she said this:

“I do not remember the exact conversations I had about this proposal with members of my team and expert advisors however I do know that I would have discussed this proposal, probably on the phone, with one or more of the members of the SAP. It would have been imperative to seek a wide range of views from the SAP members and internal DHSC staff before putting advice in a formal submission. I would never clear a submission without going through this process.”

and at paragraph 61:

“At this time and as I have explained, we were receiving lots of offers of antibody tests from other suppliers and manufacturers via the Testing Triage Team as well as via emails from ministers and the commercial supply teams, and we were responding to these through the triage process, with the most promising tests going forward for validation. However, the proposal from Abingdon Health and the UK-RTC was unique in my view, as they were offering not to supply an existing test but instead to work together to develop a new and hopefully more accurate test using the spike protein which was believed by the SAP/ NTAG as the most accurate way of detecting neutralising antibodies. As far as I am aware, no other company at any stage ever came forward with this type of proposal. The UK-RTC had told us that they needed a research grant in order to fund the research

and development of a suitable antibody test and they had also, as I have explained, indicated that they would need assistance with purchasing components.”

and then at paragraph 65:

“At this time and as I have explained, we were receiving lots of offers of antibody tests from other suppliers and manufacturers via the Testing Triage Team as well as via emails from ministers and the commercial supply teams, and we were responding to these through the triage process, with the most promising tests going forward for validation. However, the proposal from Abingdon Health and the UK-RTC was unique in my view, as they were offering not to supply an existing test but instead to work together to develop a new and hopefully more accurate test using the spike protein which was believed by the SAP/ NT AG as the most accurate way of detecting neutralising antibodies. As far as I am aware, no other company at any stage ever came forward with this type of proposal. The UK-RTC had told us that they needed a research grant in order to fund the research and development of a suitable antibody test and they had also, as I have explained, indicated that they would need assistance with purchasing components. DHSC's decision to go with the Abingdon Health proposal was based on advice from the SAP and following consultation within DHSC with officials copied on the submission. Sir John Bell was one of the critical stakeholders in this process given his role on the SAP but he was not the only person who advised on this proposal. My recollection is that this advice was given to me from various officials and advisors verbally in meetings and on the phone, but in any event I note that Sir John Bell confirmed in writing by email to our finance colleagues on 7 April 2020 that it had been approved by him and SAP.”

140. GLP has alleged that paragraph 43 of TB1 was itself untrue. If it was untrue, the implication must be that Ms Berry knew that it was untrue when it went into that WS. She addresses this in TB2. As GLP's allegation is so serious and underpins part of its Ground 5 claim in relation to the Research Contract, it is appropriate to quote fully Ms Berry's response in TB2:

“17. The Claimant's assumption (i.e. that, because there are no written records, I must be lying) is wholly unjustified and is false. As I explained in my First Statement (at §12), the environment in which we were working at the time was highly pressured and things were moving at an extremely fast pace and as a result I did not make a written note of every conversation that I had, and I do not remember every conversation that took place. If I had kept a careful record of every discussion, we would have never got anything done. We were working flat out in the middle of a crisis in which people were dying and billions of pounds were being spent by the Government almost every day to deal with the crisis and save lives.

18. My team prepared a submission to Lord Bethell dated 2 April 2020 which stated “The Science Advisory Group have suggested that Abingdon are the best qualified UK firm to achieve this in terms of scientific development and track record of performance”. I included this in the submission because it was true. I know that I had a conversation with someone from the SAP (or Science Advisory Group as it was also referred to at this very early stage). I cannot now recall who that individual was and, because there was no record kept at the time of the individual conversations I was having, I cannot consult any records to assist the Court with further details. I do not, however, lie to Ministers. The fact that there is no record of a particular conversation, and that – unsurprisingly – I cannot now recall who I spoke to or when – does not mean that I lied to Ministers in the Ministerial Submission.

19. This submission was copied to other members of the wider testing team and linked to the SAP, such as Dr Sam Roberts. As I explain at §18 of my First Statement, Dr Sam Roberts was one of my ‘go to’ advisors and colleague. I am confident that if she felt the Ministerial submission was inaccurate in this regard, she would have raised any such concerns with me directly, which she did not as far as I recall. I also specifically remember having a conversation with Chris Whitty, who was also copied to the submission, about the importance of this test. He told me it was very important. I do not have a record of this conversation either. The nature of our work at this time did not allow for every conversation to be documented.

20. In addition, at this time the SAP was only very recently formed. It did not have formal processes in place yet. As time went on, we became more organised but at this early stage the SAP was a group of experts convened under Sir John Bell, I think by ministers just before I started, who I had access to in order to get help and advice.”

141. In my judgment that is an explanation which is plausible to me. The lack of records in this context is not surprising. It is true that there are some records of NTAG meetings insofar (at least) as they concern the specific results of its evaluations. I have referred to one such communication in paragraph 108 above. But that is hardly surprising since there would need to be a note kept of those tests and their results. I do not here regard it as suspicious or surprising that there was no actual note of an SAP deliberation and it does not here raise an inference that what Ms Berry said in MS2 was false. Cf *Gardner* at paragraphs 258-260.
142. Nor do I think that here, there is anything in the fact that in TB1 at paragraph 43, Ms Berry said that she “would have” discussed the proposal with one or more SAP members, while in TB2 at paragraph 18 she recalls one particular conversation. In TB2, she was addressing specifically the question of the falsity or otherwise of what was in MS2 very specifically and in more detail, as required by the Court.
143. GLP has also suggested that Ms Berry may have felt it necessary to say that Abingdon was the best, because Mr Williams had said in his prior email that for the contract to go forward, Abingdon had to be the best or the only relevant supplier. In fact that is not what he said in the email cited at paragraph 127 above. Further, GLP says that Ms Berry's statement was in fact inconsistent with Professor Bell’s statement in his email of 7 April. I deal with that email in paragraph 167 below, but record here that I do not think there is anything in this point.
144. GLP also points to the fact that DHSC has not adduced evidence from any other member of SAP, for example Professor Crook, even after the allegation of falsity had been made. I see that, but DHSC had already submitted a very large amount of evidence. Moreover, corroboration (if that is the right word) for Ms Berry’s understanding comes, in my view, from the evidence of Professor Bell generally on Abingdon but also with regard to what he said in his email dated 7 April (see below) which GLP also says is false. I deal with that point below.
145. In my judgment, Ms Berry did not make a false statement within MS2, knowingly or otherwise. I now return to the chronology immediately following the submission of MS2.
146. Ms Berry makes the point that while the process of recommending Abingdon was going on, offers of help from other companies were coming in and she would direct those to the testing triage.
147. I interpose here the publication on 4 April of DHSC document called “Scaling up our testing programs” which set out in detail a description of each of the 5 pillars which came after a Ministerial Foreword by Mr Hancock and the challenges which the pandemic was posing. The Pillar 3 description was as follows:

**“Mass-antibody testing to help determine if people have immunity to coronavirus**

1.20 Antibody tests could tell people whether they have had the virus and are now immune. Such tests are done by taking a blood sample and looking for the presence of the right COVID-19 antibodies. Once proven in a laboratory setting, this testing could potentially be done at home with a finger prick and deliver rapid results - maybe in as little as twenty minutes.

1.21 These antibody tests are brand new. In fact, they are still being developed and there is not yet one that has been proven to work as we would require. No government in the world has yet rolled out a full COVID-19 antibody testing programme.

1.22 We are currently engaged with several companies and are urgently testing the quality, accuracy and effectiveness of potential tests with scientific experts and regulators. We have bought some antibody testing kit stock on the basis of minimum initial volumes to enable clinical testing. If the outcome of this is that the antibody tests do not work, no further tests will be purchased and, where possible, orders will be cancelled.

1.23 Our experts are clear that an unreliable test is worse than no test. We need to be led by the evidence. Hence, the Chief Medical Officer discourages in the strongest terms organisations from buying their own invalidated antibody tests.

1.24 Should our clinical testing prove successful, we hope to deploy antibody testing kits in their millions. In time, and subject to clinical advice, they could even be used to inform the use of social distancing measures in the future. However, this is some way off. In the meantime, we will keep the public updated on progress.”

148. The introduction to Pillar 5 was as follows:

**“Spearheading a Diagnostics National Effort to build a mass-testing capacity at a completely new scale**

1.29 Britain has an innovative, but relatively small diagnostics industry. We now need to grow it, substantially and quickly. We are calling on all British life science companies to turn their resources to creating and rolling out mass testing at scale. In the short-term, this will help meet the supply outlined in the other strands in this strategy, and then help us develop resilient, diagnostic capability in the UK capable of meeting the testing demands over the coming months and years...”

149. At 8:55pm on 4 April, Mr Hancock sent an internal email about MS2 which recorded his agreement with recommendations 2-4 of MS to and that:

“We should go hell for leather at the Abingdon project ...”

150. His views were then set out in an email from his Private Secretary to the testing team as follows:

“Thanks for this submission. SofS has commented that he agrees with the recommendations to:

- Pursue development of new devices with consortia led by Abingdon Health with aim of starting wave 1 of antibody testing with a pilot on 21st or 28th of April.
- Providing Abingdon with £2.5m in funding to develop device and writing confirmatory email from Lord Bethell to this effect (email at Annex F – last page of the submission)
- Pursuing development of a high-throughput ELISA testing programme.

He is keen we go as fast and far as we can on the Abingdon project...”

151. The meeting, which Lord Bethell had asked for the previous evening, he having read MS2, took place. By now the consortium had been arranged. Ms Berry said that she went through the plans quite robustly. It was said at the meeting that supply bottlenecks could arise and Abingdon would need assistance to get the components in the course of developing the test.

152. Ms Berry then had to develop a business case for the £2.5m funding. On 5 April, a draft business case was sent by [B], a member of the Pillar 3 Team seconded from BEIS, to Andrea Barry. She was a Deputy Director asked to oversee DHSC’s Covid Finance Team. She took the lead on the testing/TT element. This produced a lengthy email back from Ms Barry. It raised a number of points including whether any due diligence had been done on Abingdon, making reference to the notes to its financial statements for the year ending 30 June 2019, as quoted in paragraph 81 above. She said that it would be good to get some assurance through a recent financial statement that Abingdon’s position had improved and that DHSC was not risking this funding. She asked for further details in relation to the £40m for materials and said it would be useful if there could be a comparison to the price they were paying for antibody testing kits which was around £5 per kit albeit that they were not that reliable, and the costs of production. She also wanted more detail on VIP. She said this was critical as they would face significant legal challenge if they have affected the market by offering one company a competitive advantage - how were they protecting against this?

153. The following morning she had a meeting with Mr Stone. He confirmed that he had now completed the budget table in the business case so that it looks right. He noted that they were still awaiting a detailed proposal from Abingdon on the additional £40m after which they would be able to firm up an approach which would inform a separate business case to



be drafted. He also noted that he had agreed with her that the question of Abingdon's financial position was not an immediate issue for the £2.5m development funding but they may want to consider this when deciding on options for procuring materials.

154. Her earlier email to Mr Stone had in fact been leaked to the *Daily Mail* by July 2021 and she dealt with it specifically in her WS. She said that any procurement proposal from a finance perspective would raise the kind of questions which she asked about Abingdon. It did not stand out. She just needed to check that financial risks were covered and adequately addressed. She says that she was mainly concerned about due diligence in relation to the proposed £40m funding. She felt they needed to understand whether Abingdon could manage this level of cash sustainably before DHSC could agree to provide the funding. The level of due diligence normally depended on the value of the contract and the level of risk. The £2.5m research grant was a much lower risk since it was to produce a specific research output that had received scientific backing from the SAP. Even if Abingdon could not deliver on the production side (i.e. the manufacture of large numbers of LFTs) DHSC could take any research that Abingdon had produced and give it to another company to develop. The sum of £2.5m was also much more aligned with Abingdon's revenue at the time as opposed to £40m. That was why she agreed with Mr Stone that commercial due diligence would be taken forward in relation to the £40m funding.

155. Mr Williams also gave his view, having seen the email between Ms Barry and Mr Stone. He said this:

“2 quick points from me:

- I am happy that this is about the £2.5M and that we can come back to the £40M/manufacturing in a separate business case. That needn't held this up.
- I think that the NIHR route in support of diagnostics is a good avenue to explore, either if they have headroom within their Budget allocation for this or-as a route to HMT-arguing for an uplift in it to cover this. But only if going down that route doesn't add in delay.”

156. At the same time, there was email traffic about how to present publicly the funding of £2.5m for Abingdon. I will set it out first then deal with its importance or otherwise. There was intended to be a press announcement by the government on Wednesday 7 April. Ms Berry was copied in on a draft of the announcement which contained this line:

“the government is investing £2.3 million in a business consortium, Abingdon Health, to develop, test and rollout antibody tests to determine whether people have developed immunity after contracting the virus. So far, all of the antibody tests the UK have tested have not delivered accurate enough results to be safely deployed”

157. Ms Berry responded late in the day to say this:

“I think we must be REALLY careful how we pitch this so it seen as them coming to us and not the other way round.”

158. GLP has suggested that Ms Berry's proposed wording was misleading and was asking other civil servants to present an account of how DHSC came to engage with Abingdon which was untrue. This was another of the matters dealt with in TB2. Again, it is necessary to set out fully Ms Berry's response:

“11...I completely reject the allegation that I was being misleading, deliberately or otherwise, in my emails of 6 April 2020. I also completely reject the allegation that I was asking other civil servants to present an account that was untrue. Firstly, I thought then, and still think now, that the accurate version of events, which I wanted the press release to reflect, is that Abingdon Health approached DHSC with its proposal. As I have described at §31 of my First Statement, Abingdon Health, along with other companies from the sector, were invited to and then attended the Pillar 5 “kick off meeting” on 1 April 2020. At this meeting, Abingdon Health told us they could provide assistance. Naturally, we followed up with them and then received a proposal from them, as I explain in my First Statement. As far as I was concerned, they had come to us, the Department, with a proposal

and it is DHSC's decision to move forward with the proposal which is being announced in the press release. The wording of the press release that I suggested in my email reflected that fact.

12. Mr Rook states, at §53 of his Second Statement, that it was the Government who singled out Abingdon. It is indeed true, as I noted in §34 of my First Statement, that we had been in touch with Abingdon Health before the issuing of the press release. We had been in touch with lots of companies at this time. Pillar 5 in particular had been set up to engage with companies and suppliers in order to understand the market and our strategic policy options better. From my perspective, I was in regular communication with different companies and suppliers, from big pharmaceutical companies like Roche and Abbott to small biotech companies, in my efforts to find an antibody test that worked for Pillar 3. We were in the middle of an unprecedented crisis and we were not going to sit back and hope that companies would guess what we needed."

159. I agree with her analysis. It is of course true that the very first direct contact between Professor Bell and Abingdon came from him after he had been given its name by Professor Sanghera. Even here, Abingdon had in fact made an approach through the triage inbox previously, on 25 March. So it is hardly as if it was being pulled out of the woodwork. It is true that it participated in the kick-off meeting but then again, so did other companies. Finally, it was Abingdon that made the specific proposal to DHSC on 2 April. Also, the draft wording suggested by Ms Berry made clear that the government had already invested (in truth, was about to invest) in the project.

160. At the same time, Doris-Ann Williams, CEO of the British in Vitro Diagnostics Association (BIVDA) forwarded to Dr Roberts, an email she received from the CEO of a diagnostics company called The Binding Site Group. The relevant emails are as follows:

"Apologies for copying you all in but members are becoming exasperated - and their fear now is their expertise is being overlooked - the Binding Site below is a well established UK larger SME selling globally and would be a great company to involve - with manufacturing capability in the middle of Birmingham and as the name suggests, they are antibody specialists.

Regards

Doris-Ann

"....

Subject: Which of our four Queen's Awards would the minister like to see?

.....The fifth pillar is the most ambitious. We want to build in a short space of time, the large diagnostics industry that this country currently lacks. Just as our top end manufacturers have joined the national effort to build ventilators, so our life sciences companies will do the same for testing. UK pharmaceutical giants which don't have a tradition of diagnostics, are now working with our world leading but smaller diagnostics companies, to build a British diagnostics industry at scale. This new national effort for testing will ensure we can get tests for everyone who needs them.....

I'm sure I'm not alone in feeling a little aggrieved by the comment. But also understand that they've only recently come to understand what IVD actually is.

We have started our planning and collaborations with clinicians near us and in Germany.

We believe we have some particular expertise in the immunoglobulin specialties that this Ab response test requires.

If the GSK/AZ are actually reaching out, then would be happy to talk to them. Also interested in any discussions you've been having with DoH

Thanks

Charles" "

161. Another member of the team to whom these emails had been copied by Dr Roberts, Kathy Hall, commented that she could not pretend to understand all of this but "is [this] the sort of company that is going to be very annoyed re: Abingdon partnership."

162. Ms Berry then responded:

"Yes potentially!!! Its critical that the Abingdon partnership is pitched the right way as industry coming together on its own with Oxford university to form a consortium and put a proposal to government. NOT that government convened them. Any set of companies are encouraged to do this

and find academic partners to work with and we will consider whether we fund them if their proposal is scalable, end to end, supply chain resilience and based on quality science etc. We're just working on a process on how to fund the Abingdon proposal with SRE. I think we need to maybe formalise this for other proposals that come out way.

Will/ Sue something that we should to the list of consideration for WS5?

Also, I expect quite a lot of the IVD companies to say that we have to help them do everything but I think we should take an industrial strategy stance to this akin to the Sector deal process which was you (industry) come up with the proposal and we will review it. Something Will/ Annette know well from the Greg Clarke days.

Plus if they have a product that is CE marked and fits the MHRA spec, it should go through Sam's triage process for review.

Hope that's helpful.”

163. In respect of all of that, Ms Berry commented in TB2 as follows:

“14. In relation to my use of the words “pitched the right way”, emphasised by Mr Rook, I used these words because, as I have explained, Abingdon Health had come to the Government with an offer of help, and I wanted the press release to accurately reflect this fact. “Pitched” simply refers to the presentation in the press release of what had in fact happened, and “the right way” refers to ensuring the press release reflected the facts of what had occurred. To the extent that the Claimant believes the words “pitched the right way” to mean I was asking others to present an account that was untrue, this is an unjustified misinterpretation of the email I wrote.

15. It is important to note that these emails were with Will and Sue from the Pillar 5 team. This was the team that had been set up to engage with industry and encourage them to come forward and help us with the crisis. I was concerned that companies would not come forward, as Abingdon Health had done, if the inaccurate impression was given that the Department was simply reaching out to those it wished to work with, rather than relying upon the industry to come forward proactively with proposals.”

164. In the light of what I have already said, I do not think that this was some attempt by Ms Berry to spin, in a false or misleading way, the position with Abingdon. The fact that other companies might be annoyed was not actually to the point where Abingdon had actually offered to help in the first instance.

165. What does follow from all of these exchanges (both on the announcement and the references to the view taken by the SAP of Abingdon in Ms Berry’s email discussions with Mr Williams) is that she was hardly oblivious to the question of whether there should be some more general competition at this stage, in some shape or form. These communications describe why it was thought right to prioritise the work with Abingdon, not least from the point of view of the urgency of the situation. Where that goes in terms of Grounds 5 and 2, I discuss below.

166. I now turn back to Professor Bell. He, too, is the subject of serious criticism by GLP. On 7 April, James Whitehouse, part of the OLS team and a member of the Pillar 3 team who was dealing with obtaining the £2.5 million for Abingdon, emailed Professor Bell thus:

“Hi John,

We are looking to get the initial (£2.5m) tranche of funding for Abingdon Health as quickly as possible for the development of the lateral flow antibody test.

For audit purposes would you be happy to send an email back to this chain confirming that pursuing Abingdon's proposal is the recommendation of yourself and the COVID Scientific Advisory Panel?

Regards,

James”

167. Professor Bell replied:

“I am very happy with this plan. We have looked at this proposal and think it is the right thing to do now. jb”

168. This then led to a further email from Mr Whitehouse to Mr Batley :

“Hi Mike,

We have got the below from John Bell on behalf of the SAP - with that, and the business case / readout from SofS, are we good to go ahead on the funding with Abingdon?

If so is it worth us having a quick chat about what needs to be done with the research contract?...”

169. In JB1, Professor Bell said this about the 7 April email:

“I do not recall that the SAP conducted a formal review of Abingdon Health's proposal, nor do I believe that we were being asked to do so. However, I had previously discussed with members of the SAP that Abingdon Health should be given access to the high quality antigen from Professor Stuart's lab and asked to try and create a better test than we had seen to date. The SAP did not review research proposals as a matter of course and I do not recall that we had ever been asked to do something like this previously. Looking at James Whitehouse's email now, I do not believe that I would have understood this to be a request for a formal audit or anything like that, but that James was seeking some assurance that outside scientific experts had looked at the plan and thought it was a good idea. He did not attach a proposal or any paperwork for us to review. He simply asked me to confirm that the SAP were happy with the proposal, and I gave this confirmation because I believed that the SAP were happy.”

170. GLP then said that Professor Bell's evidence suggested that he did not in fact consult with the SAP or ask them to consider recommending Abingdon. If so, then the 7 April email was itself untrue. Again, his response to this, in JB3, needs to be set out:

“13. Mr Rook fundamentally misunderstands what the SAP was and how it operated in these early days of the COVID-19 pandemic. I have explained at §§41 – 42 of my First Witness Statement how in mid-to-late March 2020 the SAP was essentially a small group of scientists brought together in an emergency to provide advice to the Government on, amongst other things, serological testing for antibodies. By way of further context, sometime in mid-March 2020, Lord Bethell and I had sat down and agreed that we needed to ask Derrick Crook from Oxford University and his team to properly assess the lateral flow antibody tests that were coming in from all over the place. Sam Roberts had been given the very difficult task of triaging what came in, but she needed support. This is where the group originated from. At the time, I was working as a volunteer for the Government, as is apparent from the Volunteer Agreement ... that my Secretary has found when assisting me with responding in these proceedings.

14. At that time, the SAP as it is now known as was also referred to as a ‘skunk works’ group, and this was the name I tended to use rather than “SAP”. In general terms, a ‘skunk works’ group is a group consisting of a relatively small and loosely structured team of scientists who research and develop solutions to problems using often radical innovation. The concept is a well-recognised mechanism for generating innovative solutions to challenging problems. It originally was created by the Lockheed Martin corporation in the USA, but has been adopted and used more widely by scientific researchers (amongst others). Flexibility, agility and speed are core to the effectiveness of a ‘skunk works’ group.

15. The membership of the group changed continuously based on the problem being addressed. I cannot now say who was or was not a member on any one particular day. There were ‘core’ members of the SAP such as myself, Professor Derrick Crook (Professor of Microbiology in the Nuffield Department of Medicine at the University of Oxford) and Professor Sir David Stuart (Professor of Structural Biology in the Nuffield Department of Medicine in the University of Oxford and Scientific Director of the Diamond Light Source, the UK's national synchrotron science facility). Any reference to ‘we’ or ‘the SAP team’ or ‘the SAP group’ in this statement can be taken to refer to one or more members of this core team, as a minimum. However there were other ‘members’ that came and went depending on the issue or problem being looked at. This included many junior scientists who were helping out at the time. Therefore the ‘wider SAP’ refers to this amorphous group of people. It was an informal group, scientists who were used as part of this group were not to my memory formally invited to join, nor did they have a title. They were simply asked to help with specific projects. For example, at various times, the group incorporated scientists with expertise in infectious disease, immunology, in vitro testing, protein chemistry and structural biology, protein

expression, biostatistics and virology. As a group without a fixed membership, SAP engaged scientists when needed to solve discrete problems or to innovate. The group was mainly based around the microbiology labs associated with the University of Oxford but included scientists of different expertise and varying levels of seniority. The group tackled many issues, for example the group evaluated the utility of a wide number of swabs when it was clear that access to swabs would be limiting; it evaluated the use of anterior nasal swabbing compared to middle turbinate naso pharyngeal swabbing; it assessed viral transport media and the use of dry swabs; it considered the use of guanidinium isocyanate for sterilising virus in samples; it utilised information from the lab based ELISA test to try and improve lateral flow tests; it undertook to establish automation for Lampore testing; and, it established robust and reproducible testing of serological lateral flow tests. The group lived on well after the serological lateral flow program ended and went onto establishing antigen testing validation techniques in PHE Porton Down and described the role of these tests in testing for infectiousness, and showed they were a crucial tool for testing nationally. The group evaluated 140 of these tests to find 40 were acceptable. The national roll out of these tests was in part the result of advice from this skunkworks group. The procurement of these tests was again not the responsibility of the SAP and they had no involvement in such matters.

16. We never met as a complete group in these first few weeks and months following the outbreak of the pandemic. Moreover, at the beginning there were never any formal meetings of the group and there were no formal records of our consultations or recommendations. The SAP was not a formal committee or body and we did not have codified governance or approval processes. As a group, in the early months of the pandemic, we did not have formal in person or virtual meetings, and so there are no minutes of any meetings. We were simply providing advice to Government, through this loose assemblage of scientists, at a time of unprecedented crisis. We did not need to make decisions via any kind of majority or quorum. It was enough for a civil servant to phone one of us up and seek our advice on an individual basis. The idea was to be able to provide answers to scientific questions as quickly as possible, and as we all had different areas of expertise it may be the person who had the relevant expertise who would provide an answer. It therefore does not make sense to suggest that there should be “documents” recording our deliberations or advice. There are none.

17. As a result, as far as I am aware, there is no formal record of the SAP being consulted in relation to Abingdon Health, nor is there a formal record of a recommendation to proceed with Abingdon Health. There is no formal record of any decision taken by the SAP at this stage of the pandemic as it was entirely advisory and made no procurement decision on lateral flow serological tests or any of the other projects it undertook in the months up to June 2020. There were however active discussions amongst members of the group about the possibility of improving the lateral flow test with a set of innovations that Abingdon Health agreed to test.”

171. Professor Bell then sets out extensively at paragraphs 20-23, the background to the involvement of Abingdon. It would not have made sense to ask the SAP for a formal approval, since Professor Bell had already come up with the name (unaware of Abingdon’s earlier approach on 25 March) and had had contact with the civil servants about the matter which I have recounted above. This was not a formal process, as he points out at the end of paragraph 23. I should add that a point was made in argument by GLP that the Secretary of State was not made aware that the recommendation had originally come from Dr Sanghera and it was also said that he knew Dr Hand. It was also said that there was no evidence that he had any expertise. There is nothing in any of this: he was a trusted and respected colleague of Professor Bell and since the point was raised about any connection with Abingdon, Ms Osepciu informed me on instructions that Dr Sanghera had no such connection. It is in my judgment irrelevant whether the Secretary of State was aware of the actual source of the recommendation.
172. At paragraph 25 he said (as he had before) that he discussed Abingdon’s proposals with SAP members such as Professor Crook and Dr Stuart. In particular, he would have spoken to them about Abingdon’s proposals to use different reagents to make the test. In short, he did not lie in the 7 April email. He was very happy with Abingdon’s plan and “we” (i.e. at least some members of SAP including Professor Crook and Dr Stuart and Professor Bell himself) had looked at it and thought it was the right thing to do. The suggestion that this

was a false statement (and necessarily dishonest on GLP's case, even though it no longer alleges dishonesty) is hopeless, in my view.

173. Nor do I consider that Professor Bell's evidence is at odds with the statement made in MS2, discussed above. Both he and Ms Berry agreed that there was no formal SAP consideration or review. Both agreed that the matter was certainly discussed, but informally. I do not consider that the thrust of the statement in MS2 is materially different from how Professor Bell put it on 7 April.
174. I now revert to the chronology in relation to the approval for the funding of the £2.5m and the Research Contract itself. The funding was to be provided by NIHR although DHSC would be the contracting party. On 6 April, Ms Barry sent an email chain to Mr Batley referring to the desired provision of the £2.5 million to Abingdon. Attached were Abingdon's proposal, MS2, and the draft business case. Mr Batley's team was asked to assist with the contractual arrangements. Later in the day, he and Ms Barry were sent copies of the email setting out Mr Hancock's agreement to the recommendations in MS2, referred to in paragraph 150 above.
175. By this stage, and as explained at paragraphs 20-24 of Mr Batley's WS, the NIHR had by this time developed an urgent health prioritisation system so as to identify a relatively small number of studies proposed to it for funding. It truncated and sped up its own triage and assessment procedure in that regard. Mr Batley noted that decisions were now having to be made in the course of a week or even less. New panels and processes were set up to meet the specific requirements of Covid research.
176. At the time of receipt of Ms Barry's email, Mr Batley felt that he and his team had been by-passed since the funding decision had effectively been made over the previous weekend. Later in the day, he sent this email to Dr Wood and Dr Pattison:

"Hi Louise

To be aware.

John Bell is Chairing a Scientific Advisory Group that advises the Department (principally OLS I think) on tests for COVID-19. It has become apparent that none of the commercially available antibody tests are up to scratch and so there is an urgent need for new tests to be developed. As part of his work on that group, JB has recommended to SofS that £2.5m is awarded to a consortium led by Abingdon Health to rapidly develop an open- source test, the specs for which would then be available for anyone to use to produce the new test at scale. SofS has agreed this and I understand Lord Bethell has already written to Abingdon Health informing them of this decision. This all happened over the weekend, driven by OLS (Tamsin) without any engagement with us. In their haste, the OLS team don't appear to have had time to consider how this work might be contracted, finance approvals gained etc.

I've spoken to Finance and funding could be found for this from the overall testing pot (currently £[C], we're about to ask HMT to increase it to £[D]!).

So we're in a position where:

- SofS wants this work to go ahead at pace
- There has been a scientific review (of sorts) from the JB Chaired panel
- Funding has been identified

After discussion with Kay we can help move this on to contracting through an i4i type contract - once the paper trail has been sorted out e.g. ToRs for the John Bell panel, a clear note of the discussion, clear note setting out SofS approval etc. I've also asked for this to be run past a couple of our NIHR experts to give us further assurance from a peer-review perspective.

Hope this is all okay.

No way to do business but we are in exceptional times."

177. Dr Wood replied that she agreed that they should proceed as he suggested.
178. Despite his frustration expressed in that email, Mr Batley considered that the proposal did meet NIHR's funding criteria. While external peer review of the project proposed would normally be required he considered that given that, as he understood, it had been reviewed and endorsed by the SAP under Professor Bell's chairmanship, and given the urgency there was sufficient endorsement. He had said in the email that the proposition should be run past a couple of NIHR experts. It was because Mr Batley wanted assurance on the SAP approval that Mr Whitehouse had sent to Professor Bell the email of 7 April referred to above. There was then Professor Bell's response and then the email back to Mr Batley, referred to at paragraphs 166-168 above. That is why Mr Batley then emailed Dr Pattison and others later that day asking if Dr Pattison was happy with the due diligence on the proposal. She said that they could now move to contracting. Mr Batley said it would not have been unusual none the less to have an independent peer review because they did not know how robust or independent the review conducted by Professor Bell's panel had been. That would have been helpful. However he says that given the urgency and that everyone was working flat out and ministerial approval had already been given, it was not unreasonable to rely upon Professor Bell's confirmation that the proposal had been approved by his panel. That is why he referred to anything further as "belt and braces". While in normal times a visit to Abingdon's site operations might also have been required, in the circumstances of the pandemic this was dispensed with.

#### **F. The Research Contract**

179. Usually, the payment of an NIHR research grant would be done in arrears and against milestones. Here, the request was for a single payment in advance. This was approved by Ms Berry and Mr Williams on the basis that there was a need to expedite Abingdon's work. Also, Mr Yates had told Mr Patient, Head of Intellectual Property and Commercial and Director of Innovation Programs at NIHR that if Abingdon had to do the work and wait for payment in arrears it would be bankrupted. Ms Barry agreed to the making of a payment in advance in this case.
180. As for the Research Contract itself, it was negotiated between NIHR and Abingdon and entered into on 11 April.
181. At Part A thereof, Abingdon agreed to undertake the research project set out at Part A Section 3 ("the Research"). This was the antibody LFT project. Part C listed the Consortium Members as Abingdon, BBI Holdings Limited, Omega Diagnostics, CIGA Healthcare Limited and The University of Oxford. There is an issue as to whether Oxford was in fact part of the Consortium which I deal with below. By Section 4, DHSC would release the sum of £2.5m to Abingdon on 14 April. The Research was to be completed by 30 September.
182. There were detailed provisions about Intellectual Property Rights. In essence the "Foreground IP" and the Research Data would vest in DHSC, having been developed implemented and maintained by Abingdon. The former encompassed intellectual property ("IP") that was or had been created exemplified or developed in the course of and for the purpose of the Research. It excluded what was defined as Arising Know-how and Research Data. The latter was defined as information or data collected or generated in the performance of the Research including that which was collated or stored in searchable form. But it did not include any information or data that had been analysed, and it excluded Personal Data.
183. Clause 16.5 is significant for present purposes and provides as follows:

“The Contractor acknowledges and agrees that the Foreground IP and Research Data shall vest in or be controlled by the Authority. If the Research is successful, the Parties intend that (i) the Authority... and the Consortium shall enter into an agreement for the manufacture and supply of test kits developed using the Research for use in the United Kingdom and (ii) the Parties shall enter into a revenue sharing agreement in relation to any revenue that the Contractor receives from the Contractor’s Commercial Use of the Foreground IP and the Research Data to supply test kits for use outside the United Kingdom. The Parties acknowledge and accept that this contract does not and is not intended to address such matters.”

184. The contemplated contract there is what became the August Contract and the Commercialisation Agreement.

### **G. Matters leading up to the June Contract**

185. The testing team moved ahead swiftly following the making of the Research Contract. The funding of the proposed purchase of components for Abingdon to use in making large quantities of LFTs had already been flagged. The initial sum put forward was £40m. Ms Barry says that they wanted to have a plan to enable Abingdon to get LFTs into the market as soon as possible. They therefore did not want to wait for the outcome of the research which was the subject of the Research Contract - to wait until then (and the deadline was 30 September) there would be a delay to DHSC’s ability to impede the pandemic.
186. It was decided that DHSC should purchase the components required, either directly or through Abingdon as its agent which it would then reimburse. The recommendation in MS3 (see below) was a direct purchase although this later changed.
187. A new ministerial submission was drafted up. Ms Barry made some changes to it. In particular, she removed references to “the Consortium to ensure its goodwill” and to “the provision of funds [for procurement of materials]”. Instead she emphasised that DHSC would be purchasing the components itself, subject to HMT clearance. She says that she did this to avoid the agreement looking like the provision of State aid, which in fact it was not. Rather this was a commercial relationship with government buying the components which would then either be sold to Abingdon or would be provided to Abingdon against an agreed reduction in the price for the ultimate completed units.
188. MS3 was sent in final form on 13 April 2020. It provided as follows:

“...Abingdon Health will receive initial funding to begin development of a home-use antibody test. They are working with a consortium of other key UK diagnostics companies, including BBI, Ciga, Omega diagnostics, as well as Oxford University. We urgently need your approval to proceed with next steps on procurement of materials and manufacturing of the test.

Recommendation that you confirm you are content with the following:

- i) To approve, in principle and subject to HMT clearance, the central procurement of materials to allow for the manufacture of 40 million tests, which will be developed by UK-RTC.
- 1) ) You received previous advice on the 2nd April. Abingdon Health will receive funding of £2.5 million to begin the development of a new COVID19 IgG Lateral Flow Test with the diagnostics consortium, consisting of BBI, Ciga, and Omega Diagnostics and, in addition to the four companies, Oxford University. The consortium - known as the UK Rapid Test Consortium (‘UK-RTC’) - will develop the detailed design and technical specification of the test. Once complete, the details will be shared with the wider diagnostics industry in order to exploit the full manufacturing capability in the UK.
  - 2) In order to ensure industry is ready to move into production early, procurement of test materials, such as cellulose strips and plastic casings is required. This is an urgent issue because of a predicted global shortage of these materials.
  - 3) We could encourage Abingdon or members of the consortium to purchase the materials direct themselves. However, it is unclear currently when and where the raw materials will be required, and whether the consortium currently have sufficient cash to enter into this purchase. We are keen to



continue moving at pace in this space, and to allow the consortium to focus on product development and scaling manufacturing processes.

4) We therefore suggest that HMG should purchase the materials directly and distribute these to where the production will take place - in this case, Abingdon or the consortia members. This approach ensures that purchasing can be done at pace, avoids any up-front financial support being provided to the consortium and has the benefit of HMG always retaining a form of asset (i.e. cash or materials). These materials would then be sold at cost to the companies undertaking production and/or donated in exchange for an equivalent reduction in the future price of the tests.

5) Abingdon has provided a list of required materials with cost estimates. We suggest that we work closely with the UK-RTC and their existing supply chain, to acquire the materials. Pending discussion, Abingdon or a member of the consortia could source the materials, with HMG making the final purchase. This option is consistent with treatments of similar scheme in OGDs - particularly MOD.

6) The list shared by UK-RTC covers materials for a total of 10 million tests, with a total cost of £13.5 million, meaning the production cost for one test is £1.35. We think it is very low risk that we will need fewer than 40 million antibody tests overall. Depending on how much higher the eventual requirement is we can scale accordingly against international procurement and domestic supply. We are working urgently with McKinsey to model a robust estimate of the required number. Purchasing materials for 40 million tests would cost HMG approximately £54 million, though the final price of the tests would include additional labour costs.

7) By comparison, the antibody tests already available that failed to meet our validation standards ranged from £2.25 to £7.44 in price, with one outlier at £13.00. The approach we are now pursuing also has the advantage of providing investment to the UK diagnostics industry.

#### Discussion and Recommendations

##### Antibody Test Materials Procurement

8) The full list of required materials, suppliers and costs for 10 million tests, as estimated by the consortium, can be seen at Annex A. Given the potential for global shortages of materials and the need to avoid unnecessary delay, we recommend:

- a) all materials are sourced by industry to maximise efficiency; and
- b) making funding available now for the procurement of materials for the manufacture of 40 million tests in order to prevent subsequent supply chain issues. Based on estimates from the consortium, this would carry a total cost of approximately £54 million.
- c) HMG purchases the materials once they have been sourced by the consortium and prices agreed with suppliers.

9) If you are content with the above recommendations we will immediately pursue with HMT and UK-RTC, to secure the supply of materials as quickly as possible.”

189. Lord Bethell approved it later on 13 April in these terms:

“This is approved. Thank you. I hugely appreciate everyone working over the weekend on this and pleased to see such progress.

But I want to make it clear that this element is very important:-

"will develop the detailed design and technical specification of the test. Once complete, the details will be shared with the wider diagnostics industry in order to exploit the full manufacturing capability in the UK."

This must be done (1) promptly and if possible concurrently with manufacture, not necessarily after the event, and (2) it must be done in a clear thoughtful way that can be easily used by others, and is not the subject of criticism. This will require the expenditure of resources and the department must make sure this is suitably resourced in terms of manpower, expertise and management focus.

With thanks

Tally ho!”

190. In the meantime, the triage testing of other LFT products coming in continued. None met the MHRA TPP specifications set out at paragraph 58 above. It was decided to ask suppliers

also to confirm the antigen which they proposed to be used in their tests, since this was something that the SAP/NTAG was particularly concerned about and was familiar with.

191. On 16 April Ms Berry provided a Pillar 3 update on antibody testing in a webinar where she made the following points:

- (1) Her team was focused on at-home testing;
- (2) None of the available tests on the market had proved accurate enough but they would consider tests as they became available;
- (3) They had put out a “call to arms to the British diagnostic industry to support efforts to develop a home-grown test”;
- (4) There had already been two responses to this call, namely Abingdon and “proposals for a high throughput ELISA”; and
- (5) If they could find a test that meets the high clinical standards they hoped to deploy antibody testing kits in large numbers.

192. By 24 April, Abingdon was reporting that good progress was being made on the research with results looking positive. However this was still using lab-based samples. In addition, PHE had been asked to devise an antibody LFT evaluation test and a protocol for this had been delivered by 23 April. In a further ministerial submission (“MS4”) sent on 27 April 2020, Ms Berry recorded that the Consortium was making good progress and currently estimated that a prototype would be ready for evaluation by 15 May. If this was successful or another supply of accurate tests was sourced, they would be evaluated in the PHE pilot.

193. On 28 April, Dr Hand wrote to Professor Bell and Lord Bethell to say that while they were making good progress there was a lack of sufficient supplies of antigen. Professor Bell was able to assist with the supply of more antigen but it was still not enough. The antigen that Professor Bell and/or Oxford did supply was provided free of charge. At this particular point, the antigen supply became a major issue for Abingdon (this was the context for Professor Bell remarking “hopeless”) but subsequently Abingdon was able to source the antigen from elsewhere.

194. As for Ms Barry, she dealt with the obtaining of HMT approval for the purchased raw materials of up to £54m. She said that some of this could and should come from the refunds which DHSC had obtained from suppliers of LFTs purchased by it (in a total sum of £91m) but which did not work. She was also able to explain that even if Abingdon failed to develop a suitable LFT itself, DHSC, as owner of the components, should be able to sell them elsewhere since antibody LFTs generally required the same components and reagents. She obtained HMT approval on 20 April.

195. On 30 April, there was a meeting which included Ms Berry, Mr Brown, Mr Destombes, Mr Yates and Dr Hand. After the meeting, Mr Brown wrote in these terms:

“First, thank you for the time and effort you have been putting into this work -I appreciate that it is not easy when being asked to work outside what would be considered the ‘normal process’.

That said, that meeting was quite frankly embarrassing. It looked like we were not aware of the ask (which is bad enough) but to do so in front of a consortium that UK Government is supposed to be backing to meet our demanding targets was far worse. We are asking these guys to work at pace and at risk to be (quite possibly) the first people in the world to develop an antibody test for at home use. And yet we gave the impression of impeding and making life difficult rather than being there to help.

To be clear:

- HMT ministers have agreed the spend in relation to components for 40m devices. This is on the basis that a) the consortium is not large enough to do this themselves and b) we need to act early to make sure of supply (as many of the materials are in very high demand).
- HMG has accepted that there is a risk to Govt of spending money on materials that might not be needed (i.e. if the product fails or if we decide later we need less volume) - this fed into the discussion of various options with Ministers. The point here is that we have already done this work and agreed that we have a risk
- It has been agreed that the consortium will source the materials from their supply chains - they know what they want and who to get it from. Of course, if we can assist in that space then we should - they will ask us for that help if it is needed.
- Yes, the consortium need to be able to share a more detailed schedule of exactly what components they need to order and when - so we understand the timing and flow of money and can consider this risk against our joint development and rollout plans...

Tamsin said, we do not want to be going to SoS over the weekend to say that the delivery of antibody testing is being pushed out because of this, when CST approved the principle of funding this on 20 April. If you do not think you are the right decision maker on this then you need to escalate it today and involve the right people. The consortium are highly likely to raise this with the minister today and he will want an update.”

196. In his evidence, Mr Brown says that he sent this email because there had been disagreement between the policy team (i.e. the Pillar 3 testing team including himself and Ms Berry) and the commercial team (including Ms Jandziol and Mr Destombes) and they were not able to demonstrate a clear and agreed government negotiating position. For her part, Ms Jandziol did not accept Mr Brown’s characterisation of the role of the commercial team at the meeting and there was a call later in the day between the teams to talk about the issues in their working relationship. She also wished to ensure that both teams worked collaboratively and respectfully, while ensuring there was an aligned position with Abingdon. After that call, she says that the working relationship between the two teams improved. However, she went on to say that there were still some concerns that the commercial risks of the proposed contract had not been fully addressed. She also said that she had some concerns about how to obtain the agreement with Abingdon and the question of State aid.
197. These concerns were set out in a further ministerial submission which she sent on 13 May (“MS5”). The proposal by then (as sought in particular by Ms Berry) had been that the recoupment for the cost of the components incurred by DHSC would be through the ultimate intended supply contract. On timing, she said that the Consortium needed to make their first orders for components in the week commencing 11 May. She noted that the key risks were the release of £9.3m of funds, i.e. enough to cover 10m tests, for the acquisition of the necessary components prior to completion of the supply contract. The latter was intended to fund the advance purchase of the components which may be in short supply and/or which had long lead times, and she noted that Abingdon said that that needed £9.3m over the next 2 weeks including £600,000 on 13 May. This would enable the manufacture of tests until October with the next phase of purchasing taking place in late August. The total cash requirement for the next 12 months was estimated at £65m. The ministerial approval for the funding agreement up to £54m had included a number of conditions including that the unit price for the final product reflected DHSC’s purchase of the components and that Cabinet Office approved the funding agreement. Those two conditions had not yet been met and meeting them would be priorities in respect of the next release of funds in August. She ended by saying that those risks needed to be considered in the context of not having access to a viable antibody test available in significant numbers if production was delayed.

198. After receiving MS5, Lord Bethell called for a discussion with the policy and commercial teams. He stressed that DHSC had to mitigate its exposure to commercial risk and certain conditions had to be put into the contract. These included retaining title to the relevant components for as long as possible, exit provisions where there was a change of circumstance for example insolvency and provisions in respect of the upfront funding. On that basis the commercial team was authorised to go ahead and negotiate further.

199. For his part, Mr Destombes was also involved in due diligence in respect of the financial position of the consortium. He obtained reports from the Crown Commercial Service on each of the Consortium companies. There was a concern about Abingdon in relation to a recent change of its credit score following recent losses. Others on his team sought clarification from Abingdon's finance director and after that, there was no further due diligence sought nor any further concerns raised. Mr Destombes considered that the level of due diligence was acceptable. Mr Destombes was not troubled by Abingdon's low credit score because this was about the purchase of Abingdon's ability to develop and produce 10m tests and to put DHSC at the front of the queue to purchase them. It was buying Abingdon's knowledge and experience in device design. While there had been doubt about Abingdon's ability to continue as a going concern this was historical and more fundamentally it was operating in a sector characterised by high risk and high reward. Pharmaceutical and medical device companies such as Abingdon could wait 10-20 years for the right product which would be a success and make profits. As Mr Destombes said to Mr Richman in an email on 1 June commenting on the Dunn and Bradstreet report on Abingdon:

“it is not a very well-managed company; it made losses every year (for the last 3-4 years) but our supply contract will ensure that they stay afloat for the minimum period necessary to meet the U.K.'s needs.”

200. Ultimately, it was decided that, rather than procure the components directly, DHSC would permit Abingdon to source them and it would then reimburse Abingdon for the costs incurred. On a rolling basis, Ms Barry was happy to do this, subject to State aid and commercial rules.

201. What became the June Contract was ultimately approved by HMT and (as Ms Barry had sought) by Lord Agnew of Oulton, then Minister of State at the Cabinet Office and Chris Young, DHSC's Finance Director.

202. Meanwhile, on 19 May, Dr Philippa Matthews, a Consultant at Oxford Hospitals NHS Foundation Trust and a Professor at the University emailed Dr Hand in the context of further supplies of blood samples to Abingdon. In it, she said the following among other things:

“Further to discussions this week, we remain keen to continue to support development of the new lateral flow devices.

Current issues

1. Testing a further batch of devices

(i) Immediate testing:

For reasons of governance and ethics, we are not at liberty to share the complete sample set, but we have now confirmed access to approximately 60 convalescent samples (cases with a confirmed COVID-19 PCR diagnosis) that we could use for the next phase of testing, along with a bank of positives (we had agreed 10 of these as I understand you already have access to pre-pandemic material to use as a negative group).

We should be able to run this next batch of testing on Thursday or Friday - and Sarah will kindly find out when our lab team can support this if you could confirm that you'd like to go ahead. Please could you let us know?

(ii) Extended testing:

If you wanted access to a greater number of samples, it sounds as though that could potentially be done through a specific application. However, we suggest that a better alternative for further testing would be for us to link you up with the team in Edinburgh who are running a similar appraisal of lateral flow devices. This would provide the advantages of access to their test material, and validation through an independent group without any potential conflict of interest.”

203. Dr Hand’s response, the following day, included the following:

“(ii) The type of testing you suggest at Edinburgh would be great, when the assay has finished development, but we are not at that stage yet, but still in a research and development phase, and have so far only been able to test with eight positive samples. Third party evaluation would be key to roll out of the finished product. Before that we need to confirm performance "in-house" so access to additional Oxford based samples is important. Could you let me know how to make the specific application please?

This would need to go through the Oxford Immunology Group, chaired by Paul Klenerman. However, we are happy to discuss in principle first. We evidently have limited banks of material and there are lots of competing interests to be balanced.

It may help with ethics if there is acceptance that we are in a research phase rather than commercialisation, similar to the development of your ELISA. Commercialisation will be via supply to DHSC. I don't think there is a conflict of interest - the idea was this should be a collaborative project between Abingdon Health (AH) and Oxford University. As legal manufacturer AH will be sure that all appropriate evaluations are done in consultation with MHRA before release of the product. We do this for highly regulated products we produce such as self-test HIV kits.”

[underlined words are subsequent comment from Dr Matthews]

204. In fact, as the immediate context of those and other emails show, apart from the question of validation testing (which was indeed transferred to Edinburgh), Oxford’s involvement consisted of the supply of some antigens and samples to be used in Abingdon’s developing test. I deal further with this point in paragraphs 269-281 below.

205. It is appropriate to mention here some later references in the chronology to Oxford’s position on conflict of interest. On 20 July, Annette Rusling, an officer in the Pillar 34 team, emailed Mr Hennigan on a number of matters in which she said this:

“...• In addition to NTAG reviewing commercially available antibody tests, pillar 3 have been working with UK-RTC on a bespoke lateral flow device (with scientific input from Oxford University)

- Early on in the programme NTAG referred promising devices to an evaluation in the lab at Oxford. It became clear this was not an option for the RTC test due to i) Oxford University wishing to avoid any conflict of interest and ii) sample set depletion/ issues with ethics around samples held

- In parallel pillar 3 has been working with PHE on a study to evaluate lateral flow tests both in the lab and in users. The lab phase at its conception was additional data on a larger sample set than the Oxford set and the protocol as a whole was designed to accelerate lateral flow tests through to home use (ie self test) approvals by MHRA under derogation

- Given the concerns of the Oxford lab team and the need for evaluation of tests to be more sustainable (ie not led principally by just one lab) NTAG have suggested a process going forward where by NIBSC has a sample set manufacturers can access to evaluate tests. In the meantime NTAG asked for the Abingdon test and [three] others to go through the PHE evaluation...”

206. What was said in the email was somewhat amplified in an instant message between Ms Rusling and Mr Hennigan the following day where she referred specifically to Oxford helping the RTC with the science behind the specific protein to be used in the test. None of this really adds to what was said in the email exchange of late May.

## H. The June Contract

207. This was made in the form of a letter agreement dated 1 June but signed on 2 June.

208. The recital stated as follows:

“The purpose of this letter is for the Secretary of State for Health and Social Care through the Department of Health and Social Care (DHSC) to provide Abingdon Health Limited (AH) with funding to purchase components and materials in order for AH, under a separate supply agreement, to develop and manufacture new lateral flow test kits to be purchased by DHSC and other health bodies for testing COVID-19 antibodies (the Tests).

The parties recognise the urgent nature of the Covid-19 outbreak and the need for Tests to be manufactured and supplied as quickly and efficiently as possible. AH has established a Rapid Test Consortium comprising BBI Group Holding Limited, CIGA Healthcare Limited, Omega Diagnostics Limited and the University of Oxford (each a Subcontractor and together the RTC).

The parties agree to act reasonably and in good faith to continue to negotiate fair and reasonable terms for a supply agreement to:-

- i. provide DHSC with a significant quantity of Tests at a reasonable price which reflects DHSC’s investment in the components, provides DHSC with value for money and reflects the significant volume to be purchased by DHSC; and
- ii. provide AH and the RTC with a reasonable return having regard to the commitment that AH and the RTC have made in setting aside their normal commercial activities to develop the Tests as rapidly as possible to meet an urgent national requirement.

The parties agree that DHSC will have a right of a first refusal for the Tests.

The parties shall also enter into a separate revenue sharing agreement pursuant to clause 16.5 the Research Contract dated 11 April 2020.”

209. There then followed (among many other provisions) the following terms:

“1. Advance payments

DHSC agrees to pay for the advance purchase of components and materials as set out in the Supply Assumptions Tab in Annex 1 (as may be updated from time to time by agreement between the parties) (DHSC Components).

The flow of funds will be as follows:

- a. DHSC will issue the first purchase order for sufficient DHSC Components to manufacture 10 million Tests (totalling £10,272,590 (inclusive of VAT) to be paid in three tranches as set out in the Supply Assumptions Tab in Annex 1);....

3. Title

Title to any DHSC Components purchased using DHSC funds in accordance with clause 1 by adequate insurance with a reputable insurer and are stored separately from other goods so that they remain readily identifiable as DHSC’s property until the components are required for the manufacturing process...

6. Validation

The supply agreement will be conditional on AH producing a Test that is (a) validated and approved for use by the MHRA (or an appropriate derogation is in place) (“Validation ”); and

(b) that meets the relevant industry standards for use (in particular CE marking or r relevant derogation) and the relevant British Standards (the “Standards”). AH shall use reasonable endeavors to develop a Test that meets the Standards and is Validated. In the event that AH does not succeed in producing a Test that (a) meets the Standards; and (b) is Validated by 31 July 2020, any DHSC Components shall be returned to DHSC on request by DHSC (unless otherwise agreed by DHSC).”

210. Clause 1 also contained specific obligations upon Abingdon to give full details of components, their pricing and to use reasonable endeavours to purchase at competitive prices etc.

211. On the same day, the corporate members of the Consortium entered into a Side-Agreement dealing with their obligations as against each other in respect of the June Contract. They had previously signed a Memorandum of Understanding (“MOU”) on 6 April in relation to their development of the antibody test.

## I. Lead-up to the August Contract

212. Mr Brown took over from Ms Berry as Director of Pillar 3 on 1 June and thereafter attended NTAG meetings. By then the NTAG was meeting 3 times a week to assess the test received through the triage. Tests that looked promising were measured against the TPP.
213. Along with supplies of antigen it was necessary for Abingdon to use positive and negative blood samples. Some had been accessed from Oxford University. In late May they were able to access further blood samples from Imperial College pursuant to arrangements made directly with them, although it had been a colleague of Mr Brown, then on secondment to Imperial College, who was able to find someone there for Abingdon to contact.
214. Between April and June, the government used Oxford and PHE (which was developing its own testing protocol) to evaluate LFTs and ELISA tests. By May, the likelihood of an alternative LFT to that being developed by Abingdon had increased. Accordingly the evaluation protocols used by DHSC (through NTAG) and PHE were modified so that they could be used in respect of multiple test suppliers. These modifications were underway by 9 June.
215. At an NTAG meeting on 12 June, antibody tests from [E] and [F] were discussed (see Mr Bamford's email of 12 June). Both had performed well when tested in the Oxford lab against the TPP. Imperial College and Edinburgh University had also assessed them. Further work would be done which would include submitting them for what was being described as the "PHE RTC-LFT" pilot validation. This was the test originally developed by PHE for the consortium but now made available for other tests, as indicated above.
216. Mr Brown emailed in this context as follows:
- "Can I also just pass on a word of caution to everyone (sorry to tell you what you already know)? Whilst this is very encouraging news, I want to retain an element of realism and control about where we are at. The last thing I need is people getting over excited and pressing for fast decisions before our proper evaluation work/recommendations are complete. So can this information please be treated very carefully and not shared beyond absolute need.
- I am sure there are also significant commercial/market consequences that the manufacturers will also be worried about.
- There is also a general point here about control over validation results and how we record them, send them in emails etc. that probably needs looking at.
- Sorry for the lecture!"
217. I do not see anything surprising or unusual about that response. In particular I do not see it as some sort of dampening of other prospective tests because the Consortium was *per se* to be favoured.
218. In the meantime, on 6 June, a note setting out the agreed strategy for antibody testing as part of NHSTT was sent to the Prime Minister's office by Mr Brown. It is referred to as the "No. 10 Note - Antibody Testing" ("the Number 10 Note"). It stated the following among other things:
- "4. The key constraint we currently face is that the effect and duration of the antibody response to SARS-CoV-2, both on personal risk (immunity) and public health risk (transmission) is unknown, materially limiting the use of these tests today. As our scientific knowledge of the virus and immunity develops, antibody tests could start to play an increasingly important role in supporting the return to as close to normal life as possible for millions of people. It is important, therefore, that future deployment of antibody tests is considered in the context of the Enable pillar in the Test and Trace programme.
- The role of antibody tests in supporting 'Enable'

5. If the body generates a lasting and protective immune response to Covid-19, possibly additionally preventing transmission, antibody tests could be used to understand individual immunity status offering clinical, economic, and social benefits for individuals and for the country. How these benefits might be determined, communicated and delivered is a key part of the Enable pillar...

12. Home-based tests have the advantage that they can be delivered easily to homes, are relatively simple to use and produce a quick result and can be produced and delivered at mass scale and low cost. If they can be deployed in scale at low-cost they could be used as the gateway to lab based testing ensuring that scarce and expensive resources (labs and phlebotomy) are only used when there is a known benefit...

19. We will continue to support the development of a viable lateral flow test. The UK Rapid testing Consortium (RTC) has a test in development as we are currently planning for the requisite evaluations and regulatory approval as well as designing the logistics and digital supporting processes (utilising infrastructure from virus testing where appropriate). Other diagnostic companies also have devices in development, and we are not commercially committed to buying from RTC. The RTC estimate they will be able to produce 300,000 kits per week by the end of July rising to 1m tests a week by the end of the year."

219. Annex B to the Number 10 Note stated that 10.7m tests would be needed for key workers, assuming that each of them did one test over a six-month period.

220. On 17 June, Mr Whitehouse sought information from Mr Lee of MHRA on a number of matters. These included the question of derogation for home-use of LFTs, which was for the MHRA to authorise, or not. Mr Whitehouse wanted to know how much of an impediment to derogation would be constituted by the existing concern about the clinical [ie as opposed to surveillance] use case for LFTs, given the gaps in understanding immunity (i.e. the Immunity Question). He then went on to say this, among other things:

"3. Alternative tests

a. A couple of other LFDs have shown promising results from the REACT study. They are both already CE marked for professional use, and potentially could be ready sooner than the UK-RTC device. It would be great to get your thoughts on whether the existing PHE protocol could collect sufficient data on these devices to allow MHRA to make a decision on whether they could be derogated for home use."

221. This illustrates the fact that DHSC was hardly ignoring other LFT manufacturers in favour of Abingdon.

222. On 19 June, Lord Darzi sent a ministerial submission ("MS6") to Lord Bethell seeking approval for further REACT studies. They were by now testing a further 5 LFTs – Abingdon's, as recommended by DHSC, [G] [H] (recommended by NTAG), [I] and [J]. Abingdon, however, said that they could not supply kits for testing until the following week which meant they would not be involved in the next round of testing. On [K] (referred to in paragraph above) this was now being outperformed by [L]. These studies involve sending large numbers of different LFTs to the community including key workers.

223. By now, there were discussions between Mr Destombes and his team and Abingdon about the terms of the contemplated supply contract. Thus Mr Destombes emailed Mr Brown and others as follows on Friday 19 June:

"We spoke to Abingdon at three scheduled calls this week.

Product development. A pilot batch was being manufactured today. It will be sent to Imperial College for testing next week. Abingdon hope that it will result in design freeze next week.

Contract development: We talked to Abingdon about: price, Open Book, revenue sharing, volumes, notice period for the extension, reimbursement of advance funding.

In summary: Abingdon are reluctant to accept an Open Book approach and feel that they are receiving an unusually harsh treatment in this respect [e.g. "did you also ask Abbott for open book?"] Abingdon suggest that we do not need Open Book to demonstrate VFM: we can simply benchmark their price. Alex H will try again next week at a side meeting to see if we can change their mind.



Ideally, we need Open Book to demonstrate VFM and to calibrate the revenue sharing arrangement with confidence.

Volumes: we reiterated that we aim to buy 10 million units in the next 6 months. Any additional purchase would be through a contract extension (3 months max) or via the new PHE framework. We also said that we need to include a mechanism if we don't buy the full 10 million units (e.g. they sell the surplus to third parties, or we pay compensation for their loss if the product has no taker).

We agreed that the reimbursement of advance funding will be on a "per unit sold" basis (i.e. £0.85+VAT for each unit sold).

It seems that the unit price will be the most difficult point to negotiate. We do not have great visible leverage now, but it is possible that they get nervous at the lack of progress. We also signalled that we expect other suppliers to come strongly to the market in the next few months.

Internally: GLD have produced a first draft of the contract (for internal review); we have started to consult colleagues on precedents re. revenue sharing; we have started to consider DHSC's position on indemnities.

Other business:

Annette will advise us shortly on the validation process and, separately, on DHSC policy re. the BBI app."

224. Mr Brown responded as follows:

"Thanks for the update Christian. I spoke briefly to Chris on Friday and he was positive with the progress that was being made and certainly didn't have any moans about anything - so maybe just a reflection that this is how the game is played on these negotiations.

That said, I think useful for you to understand that there are now 2-3 other potential lateral flow devices coming into play (and maybe even a few weeks ahead of where RTC currently are). This strengthens our position because it means we may have a choice of supplier and potentially the option to buy more than one device, which lowers the risk to our supply (and maybe gets more volume in earlier). Still a ways to go before evaluations etc are complete - but RTC definitely not the only game in town (and it's a matter of weeks not months). RTC know this as I mentioned it to them yesterday so I think they will feel the pressure. But should help you push for what you think is best on the commercial side.

Of course, other products may make the pricing/benchmarking easier as well (although the other companies don't know we are interested yet so not sure how we might find out useful info). But let me know if there's anything I can do to help on that front.

The open book challenge is an interesting one - they are right that we haven't done that with the 10m tests we've bought from Abbott and Roche, now the millions we are signing in other contracts this week. And I'm guessing we wouldn't be doing it if we buy devices from some of these other providers

(?). Don't want to be in a position where we have set the bar higher for RTC than for anyone else - but I am also not going to tread on your toes at this stage."

225. On 26 June, Abingdon reached "design freeze" on its LFT.

226. On 30 June, Abingdon received a CE mark for its LFT. For this purpose, Abingdon had commissioned Ulster University to test its LFTs as an independent test which was a necessary part of the procedure here. According to Dr Hand (and Ulster's findings were published) the results were very good and achieved the TPP requirements.

227. On 24 June, Mr Hennigan sent a lengthy email to Ms Rusling. In it, he explored various options about the use of LFTs going forward. He commented that "Ministers up to now have wanted every [sic] greater testing numbers. That makes us do things we wouldn't do otherwise, like test despite no clinical use." The core immunity goal was mass-testing to discern immunity (assuming the link between antibodies and immunities was established). By then, and as highlighted in some earlier emails, this was still very uncertain. Thus Mr Hennigan here referred to "no clinical use" i.e. the LFT could not be used to determine immunity which of course would be of direct clinical benefit to the individual concerned

and others. This is also reflected in his comment later in the email as to whether there was a need “to convince Ministers that things are fundamentally changed?” Ms Rusling in her comments on that email pointed out that there would still be a need to build capacity for the winter if, by then, the Immunity Question was answered positively. But she also noted that immunity may not come from an antibody response but elsewhere. In his WS, Mr Hennigan added that in fact later on, antibody testing was considered in the question of understanding the effects of long Covid where it might have a clinical use. There was obviously also non-clinical use for example surveillance use.

228. On 3 July 2020, Imperial College reported disappointing results on its test of Abingdon’s “draft” LFT. The sensitivity was good but specificity was not, and Imperial thought that it would not qualify even for surveillance testing. In fact, Abingdon protested about this shortly afterwards, on the basis that Imperial had not followed Abingdon’s procedure but followed their own. See Dr Hand’s emails on 6 July and the detailed points made by him at paragraph 20-22 of CH2.
229. By 3 July, Mr Hennigan was starting to think in detail about the forthcoming supply contract which was already in draft. An initial question was when the LFT would be validated by MHRA for Pillar 3 purposes i.e. home-testing. A second was the quantity required which was now reflecting the uncertainty of the Immunity Question. The third was the issue of revenue sharing which was dealt with by Mr Destombes.
230. As Mr Hennigan explains, the uncertainty over the Immunity Question and the (consequent) issue as to whether the MHRA would grant derogation for home-use reduced the likely quantity of LFTs to be purchased from Abingdon. However, the strategy in the light of that was not straightforward. In his note of 16 July he postulated 3 options:
  - (1) Purchase 10m tests but make it conditional on home-test approval. However this would not fulfil the “ministerial steer” to continue to build capacity in the long-term for large-scale antibody testing where building capacity has a long lead time; (the Ministerial steer in this respect was largely from Lord Bethell);
  - (2) Purchase 10m tests conditional as before but even if there was no home-test approval use them anyway for professional testing for example by pharmacies;
  - (3) Purchase only 1-2m tests on the assumption that they could be used in social care where administered by professionals or in vaccine trials. Add to that an option to buy the remainder of the 10m later, on the basis of home-test approval if it emerged.
231. However, unit costs were likely to be more because of the smaller numbers sold and Abingdon’s need to absorb fixed costs earlier on. Further, DHSC's intended right of first refusal (on the tests not sold at the outset) might be lost and DHSC would end up effectively subsidising Abingdon to sell to other governments etc. He also referred to a key outstanding question namely “can we contract with them now without competition/are we covered by emergency legislation to do this?” (In the event, of course, they could, because of the application of Regulation 32 (2) (c).)
232. Another problem was that the intention had been that the PHE validation of Abingdon’s test would be achieved prior to making the supply contract. Indeed if it had not been procured by 30 July then, under the June Contract there was no obligation to make a supply contract anyway. In the event, it became clear that it would take too long to wait for the PHE results before entering into the supply contract.
233. In order to try and meet these somewhat conflicting considerations, and as described by Mr Hennigan and Mr Destombes, DHSC and Abingdon reached a position in negotiations

where there would be a commitment to purchase 1m tests with the ability to purchase 9m more out of a total of 10m. That further purchase would be justified (but not obligatory) if the Immunity Question was subsequently answered positively. DHSC's position was summarised in a further ministerial submission ("MS7") dated 7 August.

234. The material parts of this read as follows:

"Recommendation

Approve the signing of the contract with Abingdon Health, on behalf of the Rapid Test consortium (RTC), for 1m of their Lateral Flow Tests (LFTs), with the ability to order a total of 10m for Home Use if evidence for immunity improves and/or use cases widen. {Additional clearances, progressing in parallel, are required from Lord Agnew for this spend)

11...

b. Contractual arrangements. The contract with Abingdon Health, on behalf of UK-RTC, is structured to give flexibility on test volumes on an 8-week horizon. This allows DHSC to commit to an initial ~1 million professional use devices, but also enables us to build our capacity - up to a further ~10 million over a 6-month period - for large-scale at home testing, provided home-use approvals are granted by the regulator, which we are working with them on. This has been the goal to prepare for the event that an actionable link is found between antibodies and immunity. Should this materialise this could be particularly valuable if there is a second peak for e.g. workforce planning and broader easing of NPIs. The mechanism works as follows:

- The two parties will agree a 'Long Term Plan' of weekly deliveries for a nominal order of 10m units over 6 months. LFTs will cost DHSC £5.25 (+VAT) per unit for up to this amount.

- At any time in the contract term:

- We can't change any order for the next 4 weeks - these are committed
- We can reduce orders for the period 5 to 8 weeks ahead. If this happens, Abingdon has a 'reasonable endeavour obligation' to seek a buyer for those cancelled orders. If they can't find a buyer (or the price is too low), DHSC will compensate Abingdon for the cost of producing the cancelled orders. We estimate that the cost per unit is c.£3.12, but the exact liability per unit will depend on other factors, e.g. latest volumes estimates, contingencies. From all the inquiries which they receive, Abingdon is reasonably confident that they will find buyers willing to pay a good price.

- We can reduce orders for all orders 8 weeks ahead (i.e. with an 8-week notice) at no cost to us

Do you approve signing of the contract with the Rapid Test Consortium (RTC) for initially 1m of their Lateral Flow Tests (LFTs), with the ability to order a total of 10m for Home Use if evidence for immunity improves and/or use cases widen? Further detail on the contractual terms and DHSC liability for costs of reduced orders is in the Annex.

Risks

14...

c. Do sign:..

ii. For UK-RTC, but take delivery of the first 1 m tests without agreeing to further volumes subsequently up to the 10m over a 6-month period, then we may incur stakeholder risk and lose our preferred customer status. This would not only incur reputational risk but be key to scaling up should the immunity science become clearer."

235. The further detail in the Annex explained that DHSC would be refunded the £10m advance funding made under the June Contract via a discount of about £1 per unit sold of the 10m. The revenue sharing mechanism contemplated by the Research Contract would be effected by a payment of 40p for each unit sold outside the UK public sector, up to 5m units and 25p per unit thereafter.

236. Lord Bethell approved the making of the supply contract on 7 August.

## **J. Terms of the August Contract**

237. For present purposes, the relevant terms of the August Contract made on 14 August are not in dispute and so they can be summarised briefly:

- (1) The initial term was 6 months;
- (2) The initial order (“First Order”) was for 10m LFTs;
- (3) The unit price for the first 10m was £5.15 plus VAT and thereafter it was £4.85 plus VAT;
- (4) The payment for components made by DHSC pursuant to the June Contract would be recouped by (a) applying a discount of £0.856 per unit in respect of those components purchased by DHSC and (b) a payment to DHSC of £0.856 per unit in respect of any of the first 10m which were sold elsewhere. (By this stage, the component costs payable under the June Contract had gone down from £9.3m to £8.5m see Mr Destombe’s email to Lord Bethell of 29 May.) It follows that full recoupment of the component cost would not be achieved unless one way or another the first 10m units were sold but if they were there would be such recoupment. There were further provisions about such sales in Clause 10 of the Order Form. These included an obligation on Abingdon to use reasonable endeavours to sell the 9m over and above the 1m to be purchased by DHSC, if not also purchased by it, to third parties where the MHRA home-use derogation had not been obtained;
- (5) The LFTs to be sold to DHSC pursuant to the contract had to have been validated by PHE prior to delivery. Not only was this a term of the contract but if that validation was not obtained, DHSC had the right to cancel the initial order for 1m units;
- (6) In addition, the MHRA approval for home use was a term of the contract. Further, the expectation was that such approval would be obtained by 30 October. While the lack of that approval would not affect the first 1m units, thereafter, the lack of such approval gave DHSC the right to suspend all further orders. If it had not been obtained by a long-stop date of 25 December, DHSC was entitled to cancel all future orders;
- (7) The contractual call-off procedure for delivery of the units meant that after the first 1m, DHSC could in effect decide not to purchase any more (which is what happened);
- (8) On the other hand, if DHSC wish to purchase more than the 10m comprised in the First Order, not only was it entitled to do so but it would have priority over other buyers by reason of the “Right of First Refusal” provision in Clause 7 of the Order Form. Moreover, there was no exclusivity for purchase of LFTs from Abingdon. DHSC was free at all times to purchase LFTs from any other supplier.

238. Mr Destombes’ own view was that it was likely that over 10m LFTs could and would be sold by Abingdon worldwide if 9m were not taken up by DHSC.

## **K. The Commercialisation Agreement**

239. By this agreement, also made on 14 August and as contemplated by the Research Contract, Abingdon agreed to make a payment to DHSC in respect of tests sold to parties other than

UK public sector bodies. That payment was [L] per unit sold, up to 5m, and [M] per unit thereafter. This was designed to be a form of repayment of the £2.5m provided under the Research Contract and secondly a monetisation of the use of DHSC's intellectual property rights in the sale of tests to others i.e. an effective royalty to that extent.

## **L. Events after the making of the August Contract**

### *Evaluation Results*

240. In early August, the final LFT was sent to Imperial and the results were very much better and in line with the Ulster University results - see the emails between Mr Yates and Mr Hennigan on 25 and 26 August.
241. On 18 August, PHE produced preliminary results of Stage I of its evaluation of Abingdon's test, based on 504 blood samples which were known to be either positive or negative for Covid infection. The results were sensitivity of 95.4% and specificity of 97.7%, so just over and just under the respective "acceptable" requirements of the TPP. Stage II of the evaluation would look at 2693 blood samples with varying levels of antibody, which were likely to give a more accurate picture of the tests outside lab conditions.
242. PHE's final report was produced on 10 September. On the "known" samples, sensitivity was 92.5% and specificity was 97.9%. On an immunoassay reference standard (being a Roche LFT - see below), sensitivity was 94.2% among PCR confirmed cases. The fact that there had already been PCR tests here suggested that the relevant individuals had more severe symptoms in the first place, hence producing a higher level of antibodies. As for those with an unknown infection status, sensitivity was down to 84.7%. The key finding was that if the Immunity Question was answered favourably so that in principle, for example, key workers with antibodies showing could go back to work, using the Abingdon test would mean that about 1 in 5 of its positive results would be false. On that basis, all those testing positive would then need to have a lab test as well to produce a more accurate positive showing.
243. As with the initial evaluation results from Imperial, Abingdon challenged PHE's methodology, and raised significant concerns. At paragraph 29 of CH1, Dr Hand says that PHE compared the performance of Abingdon's LFTs with ones produced by Roche. But the Roche assay was for total antibodies to the NP and not the spike protein and had a smaller number of serum samples. He also pointed to the evaluation of the Roche system which showed an overall sensitivity of only 86%. He again pointed to the very good results obtained using large samples, by Ulster University, as explained in his paragraph 30. He added at paragraph 32 of CH1 that later in February 2021, PHE released results of a study done by its scientists, and others at Bristol, Warwick and Cambridge University using the same cohort of samples. The data produced could be used to assess accuracy (a blended percentage of specificity and sensitivity and taking account of the prevalence of Covid in the population) and he says that the highest performer was in fact Abingdon's LFT at 97.3%.
244. As for the MHRA, it is common ground that it did not award the necessary derogation to Abingdon for mass home-testing in relation to its LFT.
245. Here, DHSC and Abingdon to some extent blame each other for problems in this evaluation process. It appears to be common ground at least that Abingdon submitted a Clinical Performance Study Protocol document to MHRA which involved a trial of over 1500 individuals sitting in their own cars. The trial was supervised by Ulster University professionals. This yielded excellent results but MHRA wanted trials conducted by people at home. Abingdon then submitted results from a home-testing trial but at that point MHRA had stopped the process. The reason was said to be the absence of a "critical clinical need"

for antibody LFTs on a mass basis which MHRA said the government should have provided by that stage but it had not. A letter to that effect had to have come from DHSC, but it never did.

246. For his part, Mr Locke agrees that MHRA did need a confirmation of clinical need from the “sponsor” of the research i.e. DHSC. However, he says that DHSC never got to the stage where it was required to produce it. He said that Abingdon, first off, should not have used its previously-obtained data through Ulster University and needed to do a “raw performance” test without which the MHRA would not proceed to consider the case for clinical need. However Abingdon had not done that. Moreover, he said that Abingdon did not accept the help that DHSC was trying to give to it in relation to its engagement with the MHRA. He said this was complicated by the fact that Abingdon had not advanced a proposal for a limited use home derogation in relation to Biobank. He said that this was because once the MHRA had considered that the Ulster University results were not appropriate for the general home-use derogation, Abingdon assumed that it would also not use those results for the more limited Biobank use whereas, in fact, it could have done. Mr Locke said that all of this slowed down the derogation for the Biobank use which was eventually approved.
247. I am not going to attempt to resolve these disputed accounts of the difficulties with the MHRA which, for all I know, might involve an element of fault on the part of the MHRA itself. But the fact is that no MHRA derogation was obtained and by late 2020, while the Immunity Question was not entirely redundant, there was considerable doubt about it.
248. Following consultations with Professor Mike Ferguson, chair of the Scientific Advisory Group, it was agreed that although unsuitable for home use, the initial 1m tests ordered could be used for professional purposes i.e. surveillance. The remaining 9m could at least be used as an initial screen for the more expensive lab tests which would then only be carried out on those who had tested positive originally.

#### *Use of the 1 million tests*

249. In addition, no MHRA derogation for home use was obtained by 25 December, or at all. By then, of course, not only had the Immunity Question not been answered favourably, but approved vaccines were now being made available. That said, and as Mr Locke explains, it was not until January or February 2021 that it was clear that there would be no use for mass antibody testing through LFTs. That was because in November 2020 it was thought that there might be great demand for antibody testing to see the results of the vaccine and in particular how much protection it gave over time. Indeed, at one point, Baroness Harding (then Head of NHSTT) said that it might be necessary to test the majority of the population up to 3 times after they had been vaccinated. Ultimately, however, all of this fell away for various reasons.
250. Back in September 2020 there had been discussions with the charity UK Biobank, which wanted 500,000 antibody tests to study the effects of Covid on bodily organs. This was to help scientists to understand the phenomenon of long Covid. Biobank wanted these tests urgently because they would not be of much use once all or most of its patient base had been vaccinated. DHSC agreed to provide them with the tests. Although a form of derogation from MHRA would be required even here, it was in a significantly limited form and would be much easier to achieve than the general home use derogation. To move forward, in February 2021, derogation for Biobank use was granted and DHSC provided 450,000 tests to it. In the end, Biobank only used 200,000 and the other 300,000 came back to DHSC.

251. Between September 2020 and February 2021 relations between DHSC and Abingdon deteriorated. Mr Locke was overseeing its performance. Problems arose in various areas. These included Abingdon's interactions (or not) with MHRA to obtain home use derogation, its participation in the PHE evaluation and working to ensure its ability to deliver 500,000 units to Biobank. There was also a commercial dispute between the parties in relation to in particular, whether Abingdon still had a contractual obligation to manufacture 10m units even when DHSC was not going to take them itself. There were other concerns about Abingdon's ability to deliver on a mass basis. At the same time, growing differences between individual consortium members were perceived.
252. Mr Locke deals with all of this in his WS. It is not necessary for me to rehearse it here. Suffice to say that, having not taken up the supply of any tests beyond the original 1m (which was done by simply ordering zero further units beyond the 1m, at the relevant time), DHSC wrote to Abingdon on 11 January 2021 saying that it was cancelling all future orders. The August Contract then expired without renewal on 14 February.
253. There also arose a dispute about how much DHSC did or did not owe Abingdon. In that regard, in late November 2020, Ankura Consulting Europe Limited ("Ankura") was engaged by DHSC to audit aspects of Abingdon's operation. This included its purchase of components for the tests and its procurement processes. Ankura's interim report was produced on 24 December 2020 and it continued to work, to an expanded scope (including auditing Abingdon's accounting of the expenditure it incurred under the Research Contract), until production of its final report on 17 March 2021. Its findings provided the basis for DHSC's position taken in relation to how much it said it owed Abingdon.
254. To conclude on the LFTs supplied to DHSC by Abingdon, I have referred to the 450,000 supplied to Biobank above. The unused ones which were returned became time expired. DHSC made significant efforts to find "homes" for the other 500,000 (see paragraph 64 of Mr Locke's WS). In the end, none of those plans came to fruition and accordingly those tests remained with DHSC until they, too, became time expired.

#### *Figures and Settlement*

255. Taking the figures (all exclusive of VAT and all rounded) from the final Ankura report, as at 17 March 2021, DHSC had paid to Abingdon a total of £[N], made up of £[O] pursuant to the Research Contract and £[P] for components, pursuant to the June Contract.
256. As against that, Abingdon claimed the following further sums were due:
- (1) £[Q] for the supply of 1m tests, and
  - (2) £[R] in respect of further component costs
- making £[S], or £[T] inclusive of VAT.
257. Ankura recommended [U].
258. The dispute was finally resolved in the 22 June 2022 Settlement Agreement. Under it, DHSC had to pay the VAT inclusive sum of £6.27m by 22 July. Of that sum, £1.5m had to be ring-fenced by Abingdon once received, and secured by a fixed charge in favour of DHSC. This was a fund which would be used to discharge any sum which this Court might order Abingdon to repay to DHSC. In particular it would operate if any payment made under the Research Contract was held to be State aid (i.e. Ground 7 below). If not, or if the claims were dismissed, this sum would be released back to Abingdon. It was also agreed that the Research Contract had expired on 30 September 2020 and the June Contract had expired on 14 August 2020 with the August Contract expiring on 14 February 2021.

Further, ownership of the purchased components would now rest in Abingdon. The Commercialisation Agreement would continue but only for another year and now at an overall reduced rate of [V] per unit.

259. In the event, therefore, but with the benefit of the other terms referred to above, Abingdon received significantly less than the £8.9m which it asserted in its Press Notice of 28 June 2022.
260. I should add that on 30 June 2022, following the hearing in this case, and having seen the Press Notice, GLP's solicitors alleged that DHSC was in breach of its duty of candour, by failing to disclose the Settlement Agreement. There is nothing in that point - it had publicly announced the settlement on 28 June and the Settlement Agreement itself was added to the confidentiality-ring papers by 4 July.
261. Nor do I see the Settlement Agreement as adding to the debate on State aid. The mere fact that it recognised that the Court might rule that there was State aid (as explicitly recognised in the Research Contract) does not add anything. Absent an allegation that the Settlement Agreement was itself bogus (not made) either there was or there was not State aid in respect of the relevant contracts. That is a matter I deal with below.

### **M. Some Other Factual Matters**

262. A number of other factual matters are addressed here because they feature in one or more of the Grounds. They are as follows:
- (1) Whether Oxford was in fact a member of the Consortium;
  - (2) The nature and extent of any assistance provided by Oxford or Professor Bell to Abingdon;
  - (3) The nature and extent (if any) of Professor Bell's involvement in the development and/or evaluation of the Abingdon LFT;
  - (4) The nature and extent (if any) of any interest on the part of Professor Bell, Ms Berry and Lord Bethell in Abingdon or the Abingdon test;
  - (5) The Commercialisation Agreement.

#### *Was Oxford University a member of the Consortium?*

263. This is a sub-issue which achieved some significance in this case because of the allegations concerning apparent bias and/or conflict of interest on the part of Professor Bell.
264. In the first instance, the consortium proposal came from Abingdon which, from the outset, had seen this project as involving more commercial entities than just itself. Hence its suggestion of the other companies. On any view, Oxford University was not in a position itself to start mass-production of LFTs, whatever else it might do.
265. Nonetheless, there was clearly some confusion at the outset because Oxford was named as a Consortium member in the Research Contract and in the June Contract.
266. However, Oxford is not listed as a Consortium member in the August Contract. Moreover, the original MOU dated 6 April and the later Side Agreement dated 2 June 2020 listed as members of the Consortium, only the different commercial members and it did not refer to Oxford.
267. Dr Hand notes that while, as at April 2020, Abingdon and the others were under the impression that Oxford would join the consortium, "that did not happen". Further, as far as



Professor Bell himself was concerned, he was not aware of any formal arrangements for Oxford to be part of the consortium.

268. On that basis, there is simply no reason on the materials before me to say that Oxford was in fact a Consortium member at any time.

*The Nature and Extent of any assistance provided by Oxford or Professor Bell to Abingdon*

269. The first question is whether Oxford University or Professor Bell assisted Abingdon to develop the LFT itself. There is no evidence that this is so and Dr Hand has denied it. He has explained, as recounted in paragraph 98 above, the relevance of Oxford's ELISA test and the spike protein. In CH2 at paragraphs 14-16 he expands on this to explain that Abingdon had already been in discussions with Birmingham University about the possible development of an antibody LFT using spike protein.

270. It is correct that at paragraph 32 of JB 3, Professor Bell said, among other things, that:

“Not only did the SAP agree to work with Abingdon Health in respect of its serological test proposal, but SAP actually contributed almost all the key differentiating components to the project, ELISA expertise, recombinant spike and convalescent sera.”

271. This was all in the context of Professor Bell's denial of GLP's allegations about his allegedly false statement of 7 April, which I have considered at paragraphs 166-173/172 above.

272. However, Dr Hand disagrees with it and it is fair to say that Professor Bell had not, in JB1, set out in detail the particular contributions of substance that he suggests in paragraph 32 of JB 3. In any event, there is no reason to doubt the specific evidence of Dr Hand on what Oxford did or did not actually do with or for Abingdon.

273. I should add that Professor Bell said that he himself was not involved in the development of the antigen or the formula supplied by Oxford. This was undertaken by Professor Stuart and his team at Diamond Light Source which is different from Oxford although Professor Stuart has posts there as well.

274. Having now dealt with the question of assisting the development of the LFT, the other area of potential contribution was in the supply of the components themselves. There are two areas where this could have happened. First, in the context of developing the LFT under the Research Contract and seeing if it worked through no doubt many iterations. The second is the question of component supply required for production of the LFTs in large numbers.

275. As explained at paragraph 22 of CH1, Oxford did provide some control materials, blood samples and small samples of the spike protein antigen initially. In fact, for evaluation purposes, Oxford could only provide 19 blood samples when Abingdon needed 200 positive and 200 negative ones to do the tests for compliance with the TPP.

276. For manufacturing purposes, in the context of up to 40m LFTs, Dr Hand said in paragraph 6 of CH2 that Abingdon would need [W] which is [X]. Ultimately, Oxford supplied less than [Y] which is less than 0.2% of what was needed. Another 5mg came from the Crick Institute. In the end, Abingdon was able to source antigen made in Germany but which came through an English company BioServ (UK) which was already known to Abingdon. Those antigens were assessed and then prices were agreed. In oral argument, GLP referred to a number of particular emails suggesting some greater assistance from Oxford for example those at pages 3595 and 3700. They do not seem to me to add anything.

277. Abingdon also sourced blood samples for the purposes of product development and evaluation. It was CIGA which introduced Abingdon to Ulster University.

278. Otherwise, and despite some references in emails to the contrary (for example Ms Rusling’s email dated 20 July 2020 referring to “scientific input” from Oxford), there is in fact no evidence of assistance other than that referred to above.
279. Indeed, after April 2020, Professor Bell largely dropped out of the picture apart from giving some assistance to DHSC (not Abingdon) and the provision of limited amounts of antigen and sera referred to above.
280. I have discussed in paragraphs 202-206 above, the issue of conflict of interest that arose with Oxford University. However I do not see how that changes the question of what assistance Oxford did or did not give Abingdon. Moreover it was assistance which in fact it also gave to others. Other recipients of the antigen and its formula included AstraZeneca, Thermo Fisher and GlaxoSmithKline and some academic institutions including Stanford University. As Professor Bell put it “It was just part of the general effort to keep the wheels moving during the worst bit of the pandemic.”
281. It is worth adding here that, nor was this a case of Oxford “marking its own homework”. Oxford did not assess Abingdon’s LFTs - as already noted, Ulster did and so did Imperial and then there was to be the putative assessment by PHE and MHRA.

*The nature and extent (if any) of Professor Bell’s involvement in the development and/or evaluation of the Abingdon LFT*

282. As distinct from Oxford, there is no evidence of other assistance provided by Professor Bell to Abingdon in his own right, as it were.

*Professor Bell’s interest in Abingdon or the Abingdon test*

283. Now that any alleged financial interest in Abingdon (which did not exist) has been disclaimed by GLP, all that remains is a supposed reputational interest in seeing Abingdon succeed and the same for Oxford. But that is a very vague notion; the fact that Professor Bell, as one who had certainly been invested in the idea and importance of developing antibody LFTs for mass-use as a response to the pandemic, was certainly keen to see the Abingdon test succeed hardly indicates an “interest” in it for apparent bias purposes.

*Ms Berry’s interest in Abingdon or the Abingdon test*

284. As for Ms Berry, there is no evidence of any interest in Abingdon on her part, financial or otherwise. Insofar as her alleged false statements about SAP approval of Abingdon are said to give rise to or evidence such an interest, that point goes nowhere in the light of my findings at paragraphs 139-145 above.

*Lord Bethell’s interest in Abingdon or the Abingdon test*

285. As for Lord Bethell, the first point is that he has provided a detailed account of his involvement with Abingdon and the relevant Contracts in his second WS, NB2. The key points are these:

- (1) He was indeed very keen to find a group of companies which could produce an effective antibody LFT at high-speed; but he was “utterly agnostic” as to which it was, or was not;
- (2) He himself had no prior connection with Abingdon or any other consortium member and had not heard of Abingdon before Professor Bell raised it at the end of March;
- (3) At all relevant stages, the decisions he made were based on the Ministerial Submissions presented to him which have all been recounted above;

- (4) He has set out to the best of his recollection all the contacts he had with Abingdon and all were attended by DHSC officials;
- (5) Nor did he set up the Consortium. As shown above, the particular members were all suggested by Abingdon and they made their own internal agreements i.e. the MOU and the Side-Agreement;
- (6) Nor, for his part, was he aware of any factually incorrect published statements which, in any event, were not actually false or misleading - see above.

### *The Commercialisation Agreement*

286. It is very hard to see how the Commercialisation Agreement could indicate some financial interest in Abingdon of the kind which could give rise to apparent bias or pre-determination. As explained above, this agreement was a mechanism designed to provide some recoupment to DHSC in the event that the Abingdon tests were successfully manufactured and sold. Of course, therefore, DHSC would want to see Abingdon's test succeed. But none of this prevented it from considering other options and it had secured its Right of First Refusal in relation to Abingdon. There is no separate allegation that the Commercialisation Agreement was itself unlawful in some way.

### **N. Telephones and records**

287. In this context I should deal with GLP's contention (see paragraph 91 of its Skeleton Argument) that there have been:

“failures by D to comply with its duty of candour, which have led to material gaps in the factual picture before the Court. In particular, (i) following numerous inconsistent explanations, it has now been confirmed that Lord Bethell engaged in conduct which led to his WhatsApp messages being deleted and unavailable for disclosure; (ii) Ms Berry's work devices were ‘wiped’ by HMG following the commencement of proceedings;...”

288. As to this, Lord Bethell devoted his first WS (NB1) entirely to a detailed history of the various mobile phones he used and the extent to which he used WhatsApp, along with other messaging platforms. He does not accept that any earlier explanations of such matters had been inconsistent. But whether they were or not, the point is that he has given a clear and detailed account in NB1.

289. He also deals with an allegation made by GLP (and hinted at in paragraph 91 recited above) that he put his original phone beyond the reach of disclosure. Unsurprisingly, he denies this and having read NB1, I agree with that denial.

290. As for Ms Berry, serious criticisms are made of the fact that her work telephone was erased after she had handed it back prior to her leaving the civil service, and at a time after proceedings had commenced. As Mr Kelsey of the GLD acknowledged, this was a serious failure to prevent the loss of data but (lest it be suggested) that does not mean that there was some deliberate wiping of the phone's data because of these proceedings. GLP also asserts that it was unsatisfactory for the GLD not to take steps to search Ms Berry's personal mobile phone, on the basis that she said that she did not use it to discuss matters relating to Abingdon, even though she had accepted that she did use it for work purposes including communicating with Lord Bethell. I do not accept that this was unsatisfactory and the GLD was entitled to take Ms Berry's word for it.

291. In my judgment, all of the debate about phones and records has got quite out of hand. This is not a fraud trial. GLP is of course entitled to make serious allegations in the context of a judicial review - provided there is a basis for them. I am not assisted at this stage by

allegations which seem to me to suggest that there is some foul play at work in relation to data not now available to the Court.

## **THE LAW**

292. For the most part, I shall set out the law relating to a particular Ground when discussing that Ground. However, I wish to deal here with the law relating to the various provisions of the PCR which have been invoked under Ground 6 and Ground 2. This includes the interrelationship between Regulation 32 (2) (c) and Regulation 18, which was the subject of debate before me.

### **Relevant PCR and related provisions**

293. I first set out the relevant Regulations (repeating regulation 32 (2) (c) for convenience):

#### **“Principles of procurement**

18.—

(1) Contracting authorities shall treat economic operators equally and without discrimination and shall act in a transparent and proportionate manner.

(2) The design of the procurement shall not be made with the intention of excluding it from the scope of this Part or of artificially narrowing competition.

(3) For that purpose, competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators....

#### **Conflicts of interest**

24.—

(1) Contracting authorities shall take appropriate measures to effectively prevent, identify and remedy conflicts of interest arising in the conduct of procurement procedures so as to avoid any distortion of competition and to ensure equal treatment of all economic operators.

(2) For the purposes of paragraph (1), the concept of conflicts of interest shall at least cover any situation where relevant staff members have, directly or indirectly, a financial, economic or other personal interest which might be perceived to compromise their impartiality and independence in the context of the procurement procedure.

(3) In paragraph (2) —

“relevant staff members” means staff members of the contracting authority, or of a procurement service provider acting on behalf of the contracting authority, who are involved in the conduct of the procurement procedure or may influence the outcome of that procedure; and

“procurement service provider” means a public or private body which offers ancillary purchasing activities on the market.”

#### **Use of the negotiated procedure without prior publication**

32.—

(1) In the specific cases and circumstances laid down in this regulation, contracting authorities may award public contracts by a negotiated procedure without prior publication.

General grounds

(2) The negotiated procedure without prior publication may be used for public works contracts, public supply contracts and public service contracts in any of the following cases:—

...

(c) insofar as is strictly necessary where, for reasons of extreme urgency brought about by events unforeseeable by the contracting authority, the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with...”

294. A related provision is Article 52 of the Treaty on the Functioning of the European Union ("TFEU") which provides that:

“The provisions of this Chapter and measures taken in pursuance thereof shall not prejudice the applicability of provisions laid down by law, regulation or administrative action providing for special treatment for foreign nationals on grounds of public policy, public security or public health.”

295. In this case, the original Ground 1 was that Regulation 32 (2) (c) did not in fact apply. That claim was rejected as unarguable by O’Farrell J who expressed it thus in the order of 3 March when she dealt with the question of permission on paper:

“Ground 1 (no basis for making a direct award under regulation 32(2)(c)) is not arguable:

i) The global pandemic was unforeseeable.

ii) There was extreme urgency. At the beginning of June 2020 the UK remained subject to stringent social distancing restrictions that had an ongoing adverse impact on the freedom, well-being and economic health of the population. Lateral flow antibody testing for self-use at home had been identified as a potential solution but the UK did not have such testing capability.

iii) The time limits for a conventional public procurement could not be complied with. The development of accurate and reliable lateral flow antibody testing capability was needed immediately. There was a shortage of the components of lateral flow devices and demand was high.

iv) The alternative procedure was strictly necessary. Having made the decision to procure the development, manufacture and supply of lateral flow tests, pursuant to the national testing strategy, the urgent requirement for such tests justified use of Regulation 32(2)(c).”

296. At the oral renewal hearing before me on 29 March, I refused permission for Ground 1 for largely the same reasons as O’Farrell J. See paragraphs 28-37 of my judgment.

297. In *Public First* there was a direct challenge to the applicability of Regulation 32 (2) (c) to the procurement exercise actually carried out. If it did not apply, then the full panoply of the PCR provisions governing the required open competition would apply. However, O’Farrell J held that it did apply and this was upheld on appeal. There was before her no discrete challenge based on Regulation 18 and she refused an application to amend so as to bring it in.

298. However, as to the allegation of apparent bias, she held that the application of this concept was not excluded simply because of the operation of Regulation 32 (2) (c). At paragraph 153, she said this:

“The permitted departure from the usual procedural requirements of the PCR 2015 did not constitute a circumstance giving rise to apparent bias as alleged by the Claimant. However, in the absence of a tender competition, it was incumbent on the Defendant to ensure that it could demonstrate that the procurement was nonetheless fair and impartial, namely, by producing evidence that objective criteria were used to select Public First over other research agencies.”

299. Importantly, on appeal, the judgment of the Court said this, having upheld the Judge on the applicability of Regulation 32 (2) (c):

“41 The judge’s answers to the questions arising under Regulation 32(2)(c) had a significant effect on the remainder of Good Law’s challenge.

42 They meant that there was no need for the Minister to engage in the call for competition, which lies at the heart of the Regulations. It is unnecessary to set out all the Regulations which depend, directly or indirectly, on the procedures and processes triggered by the call for competition. In a situation of extreme urgency, however, none of those Regulations would apply, because the Minister was entitled to award a contract by a negotiated procedure without prior publication instead. Furthermore, they also meant that, if a negotiation with just one supplier could be shown to be strictly necessary, there was no requirement for any sort of comparative tender exercise at all. That is what had happened in *Salt International*.

43 As an example of the effect of the judge’s conclusions about Regulation 32, it is instructive to consider Regulation 67, to which Mr Coppel KC, for Good Law, drew our attention. This sets out

complex provisions relating to what the tender documents need to contain by way of contract criteria and how the competing tenders are to be ‘marked’ by the contracting authority. Many procurement challenges under the Regulations relate either to the contract criteria themselves or to the contracting authority’s failure fairly to adjudge the competing tenders by reference to their own contract criteria. Mr Coppel suggested that this was a Regulation which would still apply in full even if it was a situation of extreme urgency.

44 We disagree. Its complex provisions might be thought to be the antithesis of urgency. Regulation 67 presupposes that there was a competitive tender process which the judge concluded did not need to happen. The extent (if at all) to which Regulation 67, or any of the other Regulations in Part 2, will apply in a situation of extreme urgency will always depend on the facts. But if a negotiated procedure without prior publication with a single economic operator was justified under Regulation 32, because in all the circumstances that was what was strictly necessary, many of them will not apply at all.

45 In this way, a conclusion such as that reached by the Judge on Regulation 32 leads to a significant departure from the ordinary position under the Regulations.

47 Good Law has no pleaded claim, even indirectly, by reference to Regulation 18 because, although it sought to make a late amendment raising Regulation 18, that application was refused by the judge. However, Mr Coppel maintained that, even in a situation governed by Regulation 32(2)(c), Regulation 18 would still apply and that this would be part of the background against which the challenge on the grounds of apparent bias fell to be considered. This argument appears to be artificial, at least in the context of circumstances where only one service provider has been considered for a job.”

300. Pausing there, DHSC contends that the effect of those paragraphs is that the Court of Appeal was definitively holding that Regulation 18 is ousted where Regulation 32 (2) (c) is held to apply. Regulation 18 was not referred to by the Court of Appeal again after the passages cited, and to that extent it appears to have rejected GLP’s indirect reliance upon it as a background feature on the apparent bias challenge. Nonetheless, as a direct claim, Regulation 18 was not argued and I do not feel able to say that I am therefore bound to approach Grounds 2 and 6 on the basis that Regulation 18 is simply not applicable at all.
301. I should, however, record that I do agree that when, on the face of it, a particular procedure which consists of a direct award to one operator qualifies under Regulation 32 (2) (c), it is difficult to see how any other Regulation which presupposes an open or some other competition between a number of economic operators can apply.
302. Of course, in a vacuum, one might ask, rhetorically, why the concepts of equal treatment, non-discrimination, proportionality and so on should not continue to apply. But on a close analysis here, the entirety of Regulation 18 seems to me to presuppose that there is in fact a competition. This is so that if there is a competition, it should then be conducted fairly as between the competitors in particular in the ways set out. Indeed, all of the cases cited by O’Farrell J earlier in her judgment in the context of Regulation 18 (see paragraphs 312-3 to 5) are concerned with the competitive involvement of more than one operator.
303. Nor does it follow that if Regulation 18 does not apply, there is some kind of procurement free-for-all. Some Regulations will still apply (for example the obligation to publish a Contract Award Notice under Regulation 50, as held by Chamberlain J in *Unpublished Contracts*). Moreover, as the case before me well demonstrates, if there are grounds to suppose that the contract or contracts at issue are nonetheless tainted by unlawfulness, such as irrationality, those challenges remain available.
304. I accept, as the Court of Appeal did, that the mere application of Regulation 32 (2) (c) does not cast out all of the Regulations. It all depends on the circumstances of each case including the procurement that is itself now justified as not requiring the usual competition.

305. In this regard I should refer to the helpful analysis set out in O'Farrell J's decision in *PPE*, itself handed down just before the decision of the Court of Appeal in *Public First*. It is appropriate to quote a number of paragraphs in full because they are highly relevant here:

“333. Where regulation 32(2)(c) of the PCR is lawfully engaged, as in this case, regulation 32(1) provides that the contracting authority is relieved of any obligation to publish a call for competition by way of a contract notice. Therefore, it is not required to run a competitive tender process. The wording of regulation 32 does not require the contracting authority to justify, on an incremental basis, each degree of departure from the process steps in the procurement that would otherwise apply; it permits negotiation without a contract notice. The consequence of such relaxation is that the contracting authority is not required to publish the nature and scope of the procurement, the selection or exclusion criteria, minimum requirements or the criteria on which any contract will be awarded. Further, it is unnecessary for the contracting authority to follow any of the prescribed procedures in the PCR (open, restricted or competitive procedure with negotiation), or the stipulated time limits, the inability to comply with the same being a prerequisite to the application of regulation 32.

334. However, regulation 32 does not set out the alternative procedures that are, or are not, permitted, no doubt because extreme urgency may require a number of different approaches, depending on the circumstances arising on the facts of each case. It is therefore necessary to consider whether there are any constraints on the permissible approach by a contracting authority when acting under regulation 32; in particular, whether there is an irreducible minimum standard of objective fairness that applies to such procurements, even in the absence of open competition.

335. The general principles in awarding contracts are set out in regulations 56 to 69 of the PCR...

336. Regulation 32 does not expressly disapply the general principles imposed on the award of contracts set out in regulations 56 to 69. The question that arises is whether there is any implicit exclusion or modification of those provisions arising from operation of the negotiated procedure without notice.

337. It is reasonably clear that some of these provisions would not be applicable because they would be inconsistent with the freedom to conduct the procurement without a competition... However, a number of the other provisions in principle could be compatible with the operation of regulation 32. There is no obvious rationale for not applying the mandatory exclusion set out in regulation 57, although it is noted that even this provision may be disregarded on an exceptional basis, including overriding public health needs (regulation 57(6)), emphasising the flexibility afforded to contracting authorities where necessary. The urgency of any procurement would not necessarily justify abandonment of the principles of selection criteria that are related and proportionate to the subject matter of the contract, such as suitability of the bidder, financial standing, and technical ability (regulation 58). In the absence of express exclusion of any specific regulation, or implied exclusion based on inconsistency with regulation 32, such general principles would continue to be applicable to a procurement pursuant to regulation 32.

338. Likewise, the operation of regulation 50, imposing an obligation to publish contract award notices, would be unaffected by the urgency justifying reliance on regulation 32(2)(c)...

339. Further, regulation 84(1)(f), requiring a written report in respect of every public contract awarded under the PCR, expressly provides that for negotiated procedures without prior publication, such report should contain the circumstances referred to in regulation 32 which justify the use of such procedure.

340. Regulation 18 provides that contracting authorities shall treat economic operators equally and without discrimination and shall act in a transparent and proportionate manner. Regulation 32 does not expressly disapply the obligations set out in regulation 18. As above, the question that arises is whether there is any implicit exclusion, or modification, of this provision arising from operation of the negotiated procedure without notice.

341. It is reasonably clear that where there is only one economic operator who can provide the works, supplies or services, the principle of equal treatment can have no application. Where there is no alternative source, there will be no comparative exercise carried out and no question of any discrimination arises. However, where the contracting authority considers bids from more than one economic operator, whether at the same or at different times, there is no obvious rationale for disregarding the principle of equal treatment in terms of the criteria used to decide which bidders

should be awarded a contract. Dispensing with a competition does not justify arbitrary or unfair selection criteria where more than one economic operator could satisfy the demand.

342. The Defendant's primary position is that once regulation 32(2)(c) is engaged, the contracting authority has a freedom of action that is constrained in only very limited and specific respects and the principles of equal treatment and transparency have no further role to play during the process leading up to the award of the contract. Reliance is placed on Article 52 of the TFEU, which entitles Member States to derogate from the Treaty freedoms, including the derivative principles of equal treatment and transparency, where essential for public policy, public security or public health: ...

343. This freedom of derogation may extend to the provision of health services and medical provisions:... Further, it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. This carries with it a considerable margin of discretion and, where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent:...

344. However, a strict approach is taken to any derogation from the otherwise applicable principles in the context of procurement; a contracting authority must justify, not only the use of any derogation, but also the extent of such derogation:...

345. Therefore, Article 52 of the TFEU provides support for the operation of regulation 32 in the circumstances of the COVID-19 public health crisis but does not provide guidance as to the circumstances in which, or the extent to which, the obligations found elsewhere in the PCR, including regulation 18, may be disregarded. The above case law indicates that objective justification is required, not just for any derogation under Article 52, but also for the extent of such derogation. The circumstances in which extreme urgency might arise, and the procurement process that might be justified in those circumstances, on an objective basis, are likely to depend on the facts of each case.

346. The Defendant submits that, as he was not constrained to implement any competitive tender process, it was lawful for the Defendant to elect to approach an economic operator of his choice and negotiate directly with such economic operator for the purposes of awarding any individual public contract. In those circumstances, it is submitted, the principle of equal treatment did not apply. In my judgment that submission goes too far. It would be open to the Defendant to justify the selection of one economic operator but only: (i) where he could bring himself within the conditions set out in regulation 32(2)(b), for example where only one economic operator could source the required PPE; or (ii) where he could justify the extent of such derogation from the principles in regulation 18 under regulation 32(2)(c), for example where only one economic operator could source the PPE within the required timescale. That interpretation is consistent with the guidance issued by the European Commission on 1 April 2020.

347. The evidence does not suggest that there was only one supplier of PPE who could have satisfied the requirements of the Defendant within the very tight timescale; on the contrary, it was envisaged that there would not be a single supplier who could meet the demand for PPE amidst the global shortage. Therefore, there is no factual basis for this argument in this case."

306. Where there is only a single award, I do not think that O'Farrell J's conclusion applies. However the overall position at the moment seems to me to be unclear. While, for my part, I would hold that on the facts of this case, Regulation 18 does not apply at all, I will proceed on the basis that it can. In oral argument, Mr Moser KC placed reliance on the observations of the Court of Appeal in *Public First*. I think he was entitled to do so and in fact, although Mr Barrett objected to DHSC now taking a point on whether Regulation 18 would apply at all, he did in fact address me on the issue and the effect, or otherwise, of what the Court of Appeal said. In the end, this issue is academic, given the approach I have taken.
307. In *PPE*, the essential exercise carried out by O'Farrell J was to assess whether any of the processes operated by DHSC were in breach of the equal treatment and transparency obligations. She held that they did not, save for the operation of the "High Priority Lane". She found that this was unlawful. There was no separate Article 52 consideration.
308. Before me, and where Regulation 18 was invoked under Ground 6 and Ground 2, both parties concentrated on whether there was an objective justification for departing from it



under Article 52. That is not quite how O’Farrell J put it in paragraph 346 of her judgment in *PPE* although there, of course, she was not dealing with the case of a single award.

309. It seems to me that, logically, on the footing that Regulation 18 can apply here, there are essentially two questions:

(1) Is there a breach of any part of Regulation 18?

(2) If so, is that breach justified?

310. I shall take that approach where the Regulation 18 issue arises.

311. I should add that the application of the concept of apparent bias in the Regulation 32 (2) (c) context was also the subject of observations by the Court of Appeal. I deal with that in context below.

## **GROUND 5**

### **The Law**

312. So far as the rationality and *Tameside* enquiry challenges are concerned, there is no real dispute as to the law. In *PPE*, O’Farrell J set out a list of the relevant principles and it is appropriate to repeat them here since, in both cases, there is a rationality and *Tameside* challenge in the context of Regulation 32 (2) (c) procurements relating to Covid-related products. She said this (I have omitted her references to particular cases):

“441. In a case concerning decisions made by the Defendant, where it was required to make difficult and technical judgments, the purpose of which was to safeguard front line workers in a public health crisis, the court must accord proper respect to the fact that the decision-maker was much better placed to carry out the assessment than the judiciary by way of judicial review:...

442. The court will interfere with the decision of a public body only if the decision is outside the range of reasonable decisions open to the decision-maker or there is a demonstrable flaw in the reasoning which led to it:...

443. The decision-maker must take into account all legally relevant considerations and avoid taking into account those that are irrelevant. That requires reasonable steps to be taken to provide the decision-maker with the relevant information to enable it to make a rational decision:....

444. The scope and content of the *Tameside* duty is context specific; it is for the decision-maker and not the court, subject only to *Wednesbury* review, to decide upon the manner and intensity of the enquiry to be undertaken into any relevant factor:...

445. The decision-maker must be briefed on everything that is relevant, namely, enough to enable an informed judgment to be made; fairness requires that the issues are put to the decision-maker in a balanced way so that a decision may be made on a rational basis:...

446. The question of what is a material or relevant consideration is a question of law, but the weight to be given to it is a matter for the decision-maker, subject only to *Wednesbury* review:...

447. The court must not substitute its own decision for that of the decision-maker; there is a high threshold for a challenge based on irrationality:... Where a decision is made by a responsible decision-maker after consultation with those who have material knowledge and expertise, it is not to be lightly overridden:...

448. Finally, the margin of appreciation accorded to the decision-maker may be particularly wide in the context of a national emergency, such as the COVID-19 pandemic:..”

313. It follows that issues of rationality or what it was rational for DHSC to require by way of information to satisfy its *Tameside* duty, must be assessed by reference to the constraints imposed by the urgent need to respond as swiftly as possible to the pandemic.

### **Analysis: The Research Contract**

314. There are essentially two allegations here. First, it was irrational or otherwise unlawful to proceed on information which was false. That concerns the status or view of Abingdon as expressed by Ms Berry and Professor Bell, discussed above, including Abingdon's role in the HIV test made by Biosure. Second, DHSC failed rationally to ensure that it had the information necessary to make a decision about entering into the Research Contract.

#### *False Information*

315. It is said that because the relevant statement made in MS2 was false, therefore the Secretary of State made his decision to approve the Research Contract based on incorrect advice. However, and as found in paragraphs 140-145 and 166-173 above, I do not consider that it was a false statement.

316. I should add that even if the reference to Abingdon being "the best" was in some way misleading, the counterfactual would be Professor Bell's opinion which was more than positive enough. In other words, even if the statement about "best" had not been used it would not have made any difference to the outcome.

317. Accordingly, there is nothing in this first part of Ground 5 in relation to the Research Contract.

#### *Failure to conduct a rational enquiry*

318. The backdrop here is the making of a Research Contract at limited cost and where the IP would be owned by DHSC. As Dr Pattison explains in paragraphs 40-50 of her WS, the concern with this kind of contract was centred on obtaining the necessary IP rights rather than guarantees of manufacturing capacity. It was appropriate to take some risks where the potential benefit was to the NHS which could be lost in the absence of the contract. She also recounts that the negotiations proceeded in a way which ended up with DHSC being properly protected in terms of the IP rights. Much the same evidence is given by Ms Berry at paragraph 28-30 of her WS.

319. In fact, Abingdon's financial position was considered; see paragraphs 152-153 and 178 above.

320. Nor is it possible to identify any precise internal policy which was broken. Reference was made to the TOR of the SAP but in fact it is not possible to say whether a definitive document was produced. Compare the drafts at pages 1550 and 1153 of Bundle E of the trial bundle. Moreover, as Professor Bell said the SAP acted very informally.

321. Looked at in context, I do not see how it can be said that overall, a rational enquiry of Abingdon was not made.

#### *Limitation*

322. I should add that in paragraph 180 of its Skeleton Argument, DHSC takes a limitation point on two elements of the Ground 5 claim in relation to the Research Contract which had been added by way of amendment on 12 October 2021. I do not consider that I need to deal with this point. First, it is academic since Ground 5 on the Research Contract has failed. Second, usually, once a plea is amended (which appears to have occurred by consent here) any claim therein "relates back" to the date when the claim was started. DHSC's main timing point was by reference to the date of the 12 October amendment or that made in April 2021.

### **Analysis: The June Contract**

323. The key allegation here is that it was irrational or otherwise unlawful for DHSC to have entered into the June Contract without any evaluation of the accuracy or reliability of the

Abingdon LFTs. Similarly, by 2 June, no such tests had yet been produced or tendered for evaluation by anyone following the Research Contract. In truth, this allegation is that DHSC should have waited before entering into the June Contract until it or others could evaluate the LFTs.

324. The reason why DHSC decided not to wait is set out in the evidence already described. It was that it was not possible to delay preparing the ground for extremely large orders of tests (up to 40m of them) should they prove to be suitable and there remained a need for them. That is because there was likely to be a rush for essential components at that time. Of course, there was a risk that the tests might not be suitable or that the Immunity Question would remain unresolved or answered adversely. However, in the unparalleled circumstances existing in April and May 2020 it was in my view plainly rational for DHSC to work on the assumption the tests would be validated and the demand would be there in due course. The problems of sourcing antigen alone demonstrated that components could be in short supply.
325. In that context, it needs also to be borne in mind that it was not as if DHSC was simply spending the money on components all at once. The first (and as it turns out only) transfer was a total of £10.272m (being £8.56m plus VAT) needed for the manufacture of 10m tests. Ownership would remain with DHSC if they were not used in the making of the tests, and there was at least some prospect of using them elsewhere if the LFT failed. According to Ms Berry, this is what assuaged the commercial concerns raised in relation to the June Contract prior to it being made.
326. Accordingly, this element of Ground 5 also fails.

#### **Analysis: The August Contract**

327. It is correct, as GLP alleges, that the August Contract was entered into at a time when there was as yet no MHRA derogation-approval or PHE validation and when (it follows) DHSC was not contractually obliged to enter into the August Contract at all at that stage.
328. However, and as recounted above, at the time, there was good reason to enter into it nonetheless, especially on the terms obtained. These included a binding commitment to purchase only 1m tests but a right of first refusal, should DHSC end up wanting more than 1m. It also provided a mechanism at least, for the recoupment of the component costs already incurred. Yet further, it did not follow that there was no prospect of the MHRA approval or PHE validation being obtained. In the meantime, timelines were set out for them with corresponding cancellation rights as set out above.
329. It is far from clear that there would have been any other supplier who had at least the potential to deliver the antibody LFTs at that time who would have been prepared to contract on the particularly flexible terms (for DHSC) given by Abingdon.
330. Still further, all of this was against a backdrop where the need for mass home-testing was far from rejected. There was uncertainty on the Immunity Question but the point was that if it did resolve positively, there would be a “mad rush” to obtain tests and components. That is why the August Contract had to be entered into then. Or at least (and this is what ultimately matters) it is impossible to say that DHSC was acting irrationally in taking the view that it did. The documents referred to above show graphically how the various members of the commercial and policy teams discuss the conflicting options all under extreme time pressure. As paragraphs 52-60 of Mr Destombes’ WS make clear, he was well aware that by reason of Clause 6 of the June Contract there was no obligation to enter into the August Contract but there were good and pressing reasons why they should do so anyway.

331. Insofar as may be necessary, I would refer also to the points made about the August Contract in the context of Ground 2, at paragraphs 392-405 below.

332. There is therefore no viable JR challenge in respect of the August Contract.

### **Conclusion**

333. For all the reasons given above, the Ground 5 challenge fails.

### **GROUND 6**

334. There are 3 strands to this Ground, namely

- (1) Apparent Bias;
- (2) Conflict of Interest; and
- (3) Unlawful Nationality Preference/Discrimination.

335. I deal with each in turn.

### **Apparent Bias**

#### *The Law*

336. There is no dispute about the legal test for apparent bias. As recited by the Court of Appeal in *Public First*:

“64...The relevant test is now well-established: the court must first ascertain all the circumstances which have a bearing on the suggestions that the decision maker was possibly biased. It must then ask whether those circumstances would lead a fair-minded and informed observer to conclude that there was a real possibility that the decision maker was biased (see *Porter v. Magill* [2001] ...

65 The fair-minded and informed observer is someone who reserves judgment until both sides of any argument are apparent, is not unduly sensitive or suspicious, and is not to be confused with the person raising the complaint. This observer considers the evidence carefully, having particular regard to the specific factual circumstances, taking a balanced approach and appreciating that context forms an important part of the material to be considered...”

337. As for the role of apparent bias in the context of a negotiated procedure under Regulation 32 (2) (c), the Court said this:

“69. Turning to the present case, however, there was very specifically (and, as the judge held, justifiably) no competitive procurement process or, for example, an application by Public First as part of an adjudicative procedure of any sort. Rather, the Minister was entering directly into a private law services contract with Public First. It is difficult to see how any analogy can be drawn between the award of such a contract and the adjudicative context in which the rules against bias have hitherto been engaged. Unlike in a competitive procurement process, even one conducted outside the Regulations, the Minister was not assessing one or more applications and then making a determination. The Minister was thus not carrying out any adjudicative (and obviously not a quasi-judicial or judicial) function.

70 The lack of appropriate analogy can be demonstrated by a consideration of waiver: it has long been held that a party may waive his objections to a decision-maker who would otherwise be disqualified on the ground of bias:... Here there was no relevant third party for the purpose of considering whether or not to waive any alleged bias. Instead, Good Law assert that the process was biased against other potential providers of the service and, in particular, the two identified in the pleading:... Yet the evidence was that neither was a suitable candidate:...

71 The judge and the parties proceeded on the premise that the common law principles of apparent bias were applicable to the facts of the instant case. We are in some doubt that the common assumption was correct. But that issue is not before us as part of the appeal. What follows assumes in Good Law’s favour, however, as the judge did, that the common law principles relating to apparent bias are properly engaged.

#### Analysis and conclusion

72 The central context for an assessment of the fair minded and informed observer's belief is the emergency conditions arising out of the pandemic which, in turn, led to the engagement of Regulation 32. There is a tension between the judge's finding on the one Hand (for the reasons set out in [124] of the judgment) that the Minister was entitled to rely on Regulation 32 in awarding the contract, and on the other Hand the conclusion (at [164]) that the Minister was nevertheless required (i) to consider other research agencies by reference to experience, expertise, availability and capacity and (ii) to keep a clear record of the objective criteria used to select Public First over other research agencies as part of the process in order to avoid an appearance of bias.

73 Regulation 32 allowed the Minister to proceed without a competition. That conclusion effectively disposed of the allegation at paragraph 32(ii) of the Amended Grounds: there was no obligation on the Minister to carry out any form of competition. The allegation pleaded in paragraph 32(iii) (ability of others to perform the contract) was not established on the facts; and there were no adverse findings in relation to the amount (in fact the maximum value) payable under the contract. At [167] of the Judgment, the judge said that the amount was irrelevant to the question of apparent bias.

74 That left only the first allegation (pleaded at paragraph 32(i)), namely the relationship between the directors and owners of Public First and Mr Cummings and the Conservative Party. The judge found in terms that the relationship did not create any apparent bias. Having regard to the specialised nature of the public policy and communications research industry, it was unsurprising that those involved at Public First might have developed professional and/or personal friendships over the years working within government departments. This finding disposed of the claim, at least as pleaded, or as Sir James put it, on the basis of that conclusion there was no "springboard" for a consideration of apparent bias.

75 The effect of the judge's conclusions was to find breach on the part of the Minister of an unspecified obligation to carry out a process that involved a formally documented consideration of other research agencies (by reference to experience, expertise, availability and capacity) which gave rise to apparent bias.

76 This conclusion is, we suggest, at odds with the finding that the Minister was at the same time justified in using a negotiated procedure without prior publication, something which did not require consideration of any other agencies. The question of identifying and evaluating the capacity and suitability of other tenderers in these circumstances did not arise at all. We are unable to accept that in these circumstances the impartial and informed observer would, in effect, require the creation of a common law "procurement regime-light" in the absence of which he would think there was a real possibility of bias. This is sufficient to determine the appeal."

338. The Court went on to hold that the Judge's approach to the evidence was itself flawed and then overall found no apparent bias.
339. In argument before me and notwithstanding the observations of the Court of Appeal, DHSC accepted that the concept of apparent bias was engaged here. I accordingly decide the matter on that basis, but had the point of the application of apparent bias been raised directly, I would have been disposed to hold that it was not applicable for the reasons given by the Court of Appeal. In the event, that issue is academic because of my findings on the facts.

#### *Analysis: Professor Bell*

340. For the reasons given in paragraphs 263-283 above, there was no interest in or assistance given to Abingdon on the part of Professor Bell which could give rise to any apparent bias. Nor do I consider that it could arise by virtue of Oxford's connection with Abingdon such as it was, on the basis of the facts found in those paragraphs.
341. The only other point relied upon by GLP relates to certain statements made by Professor Bell in the press. As to these:
- (1) An article in the *Daily Telegraph* of 3 July 2020 quotes him as saying: "all I can say is we hope and think this Rapid Test Consortium test is the real deal, a game changer, if you like" and "I foresee an antibody test appearing before the end of the

year, and this may well be the one we've been waiting for." Professor Bell says that he was not sure what words he actually used but he had heard promising reports about the Abingdon test from others and was impressed that this had been achieved in such a short time, from a "standing start" as he described it. Any expression of hope or that this may be the test they were waiting for would reflect his views at the time; but given the circumstances and the need to come up with an LFT, those are entirely understandable views from someone like him without denoting the appearance of any particular interest or predetermination towards Abingdon;

- (2) An article in the *Guardian* on 18 July referred to the *Daily Telegraph* as having quoted Professor Bell as saying "this rapid test appears to be truly amazing, and it shows we can do this ourselves." His reference to "truly amazing" was repeated in a later article in the *Guardian* dated 27 August. As to that, Professor Bell has said that both of the *Guardian* articles contained some inaccuracies but in any event he was simply reinforcing the idea that to make a test that works well from scratch in such a short time was an amazing achievement. In the event, of course, PHE concluded from its evaluation that Abingdon's LFT's sensitivity was too low and no derogation was given by the MHRA, although Dr Hand has shown that it did achieve high levels of specificity and sensitivity (see above, including paragraphs 241-243). But I do not see how the view expressed by Professor Bell indicates some predisposition.

342. It is not clear whether GLP is still maintaining the point that the alleged support and assistance given by DHSC to Abingdon is a mark of apparent bias, as opposed to forming part of its now extended argument on State aid, being Ground 7. I deal with all of those questions of support and assistance in the context of that Ground but record here that I do not consider that there was any significant support or assistance that could in anyway suggest that DHSC was favouring Abingdon as opposed to other potential suppliers which could amount to apparent bias.
343. I cannot see how the fair minded observer, with the attributes noted in paragraph 65 of the judgment of the Court of Appeal in *Public First* (see paragraph 336 above) and in particular with a full knowledge of the facts, could possibly conclude that there was a real risk of bias here.

*Analysis: Ms Berry*

344. Given the matters referred to at paragraph 284 above, I cannot see any basis for apparent bias on the part of Ms Berry.

*Analysis: Lord Bethell*

345. Equally, on the basis of the matters set out at paragraph 285 above, I cannot see any basis for apparent bias on his part, either.
346. GLP made reference to an email from Mr Brown to Ms Berry and Ms Rusling on 7 May 2020 which referred to Lord Bethell wanting the consortium to massively increase their manufacturing plans and having told Abingdon that "money is no object" - this was after the making of the Research Contract; in any event, context is important. This was at the height of the pandemic, when there was still a real belief that antibody LFTs might be the way forward in combating Covid, and there was perceived to be an urgent need for them. I do not see how this indicates apparent bias on his part.
347. GLP has made reference to several other emails said to evidence apparent bias on his part. By way of example, there was an early email referring to "incessant pressure" from Lord

Bethell. While he was undoubtedly very keen to push the antibody LFT project forward I do not see that this indicated apparent bias in favour of Abingdon. Likewise, reliance is placed on the view of Mr White in an email of 27 November 2020 in relation to MHRA saying that he had “more chance of riding into Downing Street naked on the back of a horse than suggesting UKRTC be binned...”. While this sounds dramatic, the fact is that by the end of November, DHSC was firmly in dispute with Abingdon, the Immunity Question was still very doubtful and DHSC in fact ordered no more than the original 1m units. Neither did it purchase antibody tests from any other manufacturers, save from Fortress to satisfy the commitment to Biobank in case the Abingdon tests would not be adequate (see paragraphs 61 and 82 of Mr Locke’s WS). Such emails therefore do not assist GLP in establishing the case of apparent bias here.

348. Moreover, in relation to all three individuals said to have shown apparent bias, there is no evidence of any motive on their part for such bias.

### **Conflict of Interest**

349. DHSC had a conflict of interest policy. Its 2015 document entitled “Conflicts of Interest” provided that any potential conflicts of interest must be declared. Its “Code of Business Conduct Policy and Procedure” document dated 28 February 2020 provided that staff had to declare conflicts of interests and there are detailed provisions at paragraphs 14-20 about this. It is not suggested here that Professor Bell would not have been bound by these policies. He was not an employee of DHSC but he had agreed to abide by relevant policies in his Voluntary Agreement of 30 March.
350. In addition, there is Regulation 24, quoted at paragraph 293 above, dealing with conflicts of interest at the procurement stage.
351. GLP contends that (a) Professor Bell had an actual or potential conflict of interest in relation to Abingdon and (b) DHSC should have ensured that he declared it and prevented it and by not doing so, it was acting in breach of its own policies and/or Regulation 24 which was therefore unlawful.
352. So far as Regulation 24 is concerned, it is hard to see how it applies here, since it relates to the procurement stage, whereas the supposed conflict is said to arise at a later stage. Certainly, the conflict perceived by Oxford University post-dated the Research Contract.
353. However, it is not necessary to dwell on points such as this. In my view, on the facts, no possible question of conflict of interest arises. Professor Bell had no relevant interest in Abingdon. Nor was he personally involved in evaluating Abingdon’s LFTs which would be irrelevant anyway if he had no interest. And as I have already found, Oxford was not in fact a member of the Consortium and Professor Bell was not personally aware of anything to the contrary. Otherwise, I refer back to my findings at paragraphs 265-283 above. In the light of those findings there simply was no actual or potential conflict on the part of Professor Bell to be declared and so there was no breach by DHSC of its own policy or of Regulation 24.
354. The fact that Oxford perceived a conflict of interest (with which Professor Bell disagreed) does not itself prove that he was conflicted.

### **Unlawful Nationality Preference/Discrimination**

355. This part of Ground 6 relies on a breach of Regulation 18. The argument is that Abingdon was selected in a discriminatory fashion (as opposed to other operators) because the reason for its selection was the fact that it was a British company. It is not in dispute that discrimination on the grounds of nationality would constitute a breach of Regulation 18, assuming (as I have) that this provision is applicable here. I was also referred to paragraph

203 of the judgment of HHJ Lloyd KC in *Harmon v. The Corporate Officer of the House of Commons* [1999] EWHC Technology 199, in which he said that:

“...quite apart from the provisions of the Treaty the principles of equality, fairness and transparency require that a contracting authority should not allow national preferences to intrude into the procedure for inviting tenders or selecting contractors...”

356. I do not think that this adds anything since he was here talking about the context of a competitive tendering process.
357. As already noted above, DHSC accepts that in making the Contracts it “took into account the fact that Abingdon was a British company.”
358. GLP’s central contention is that in reality this award to Abingdon was based on a desire to promote British companies and little else; or at least an opportunistic attempt to do so, given the circumstances of the pandemic.
359. The first contextual point is this. There is clear evidence that the British diagnostics industry was small and underdeveloped. However, it was not going to be easy or straightforward to obtain the design and supply of tests simply from the global supply chain, not least because there would be demand from all over the world. Further, the tests which had been purchased from abroad were not satisfactory. The Supply Table provided by DHSC is a good indication of this. The answer would be to develop the ability for such tests to be designed and manufactured here. All of this has been dealt with above.
360. That said, it would be misleading to say that DHSC’s objects were limited to a UK company. Obviously, a company located in the UK that had the development and/or manufacturing capacity would be advantageous. But the point is somewhat more nuanced. A good contemporary illustration of this is the note for the 1 April kick-off meeting referred to at paragraph 116 above. The point was to scale up the diagnostic and manufacturing capacity in the UK. That was not limited to companies actually incorporated in the UK. Foreign companies with bases here would equally qualify. The concession referred to at paragraph 357 above was not a statement that in fact only British companies could be considered.
361. On that basis, and in these extreme circumstances, I cannot see why a policy which favours a company with a base in the UK (whether incorporated here or not) which had the facility to develop and manufacture some or all of the necessary tests was not plainly justified on the grounds of public health.
362. At paragraph 106 (4) of its Skeleton Argument, GLP refers to what it says were the “true objects” of Lord Bethell and Mr Hancock i.e. simply to build up the British diagnostics industry, quite removed from the exigencies of the day, as explained by the witnesses. A number of references are given. They are demonstrably out of context. I give some examples to show this, below.
363. The words “our own LFTs” (underlined in the extract below) are taken from an email sent by Ms Berry. The relevant part of the chain is this:

“Abingdon health only 200k capacity moving to 400k a week but looks like a good option.

BJ

Excellent. Talk tomorrow. I am zoomed out!

I bet you are! Talk tomorrow.

If we are going to make our own LFTs, we better start buying up the ingredients like plastic, cellulose strips etc. CO procurement can't. I was thinking army or AZ? What do you think? If we use Gavin's high thru put option we also need to start buying consumables for that don't we. Can we grab 5 mins?”



364. In other words, at an early stage, Ms Berry and Professor Bell are discussing practicalities in the context of the putative engagement with Abingdon. If it was going to be Abingdon, it would be “our own” tests because they would be made here. None of this indicates that at the outset, the whole point of the exercise was a government venture with British industry alone or UK companies alone.
365. GLP also relies on an email reference to “joint-venture”. In the event, of course, there were the Contracts but that hardly makes GLP’s point here. The reference to “joint-venture” comes in an instant message from Mr White on 2 November i.e. after the August Contract had been made, and which was all about production schedules with Abingdon. It was in the middle of the various disputes which were emerging. What the message actually said was this:
- “Its a difficult one because this whole thing looks, smells and feels like a Joint Venture between us and the RTC but legally its a Supplier/Customer model and we shouldn’t be getting involved any more than where are our test kits please.”
366. In other words, even if DHSC was trying to assist to solve the problems which had arisen it should stand back. Mr White was right about the relationship not being a joint-venture. See clause 28.2 of the General Terms of the August Contract. This has nothing to do with any claimed overriding policy in favour of a British company, in my view.
367. Reliance is also placed on the exchange between Ms Berry and Mr Williams noted at paragraph 127 above. It is correct that Ms Berry said that the Abingdon initiative fell within Pillar 3 but also Pillar 5. There is nothing in that. Pillar 5 was not some freestanding policy aim about the general promotion of British industry or even the British diagnostics industry, in a vacuum. Rather, it was about building a mass-testing capacity for the UK at a completely new scale in order to deal with the Covid challenge. See also the detailed description in the document published on 4 April, referred to at this paragraph 148 above.
368. There is then a reference to a few words of MS3 namely “the advantage of providing investment to the UK diagnostics industry” as if this was what the June Contract was all about. However, when one looks at this phrase in context in paragraph 4-7 of MS3 (quoted at paragraph 188 above) it is clear that the true position is that all of this was a justification as to why DHSC should fund the purchase of components including where previous purchased LFTs had failed. What is also, crucially, missing from the quoted phrase is the word which comes before it, namely “also”.
369. I regard the use of quotations in this selective way as unhelpful.
370. As for the references to public statements made by Professor Bell, I have dealt with these in paragraph 341 above.
371. In relation to components, it is true that in the end, components like antigen had to be sourced from abroad anyway. However, at the time, there were concerns being expressed generally about the supply chain. This is shown in paragraph 17 of MS2, quoted at paragraph 133 above. Unless it is being said that this concern was being put forward falsely or disingenuously, it seems to me to show that there was genuine concern at the time.
372. On that footing, it is hopeless to suggest that there was an unjustifiable preference on the basis of nationality under Regulation 18. Following the observations of O’Farrell J at paragraphs 343-345 of her judgment in *PPE* (see paragraph 305 above) it seems to me that in the context of the level of public protection or precautions which DHSC considered necessary, there needs to be a significant margin of appreciation afforded to it. That hardly needs to be said, given the circumstances of the pandemic. But on that basis, and on the perceived problems of overcapacity and development in the UK and the need to serve the UK population, the course of action taken in respect of Abingdon was plainly justified.

373. As for the extent of the derogation, it will be recalled that at all stages, DHSC was hardly shutting its eyes and ears to other offers of tests, and indeed retained the right to deal with companies other than Abingdon. It kept receiving and testing other LFTs through the triage. So the particular extent of the derogation was also justified.

374. Reference was also made to an email to Lord Bethell from Ms Williams of the BIVDA on 16 April. This said as follows:

“Thank you for your note -the IVD sector very much values being kept informed of activity. However yesterday's webinar raised as much concern as it did provide information. Manufacturers are now bringing serology tests to market and the impression they have taken from yesterday is that there is a reliance on the 'Oxford ELISA' to do mass testing alongside a lateral flow test if this can be achieved.

While it is a great ambition to strengthen the UK manufacturing base for our industry in the medium term, the fact remains that the sector is globalised and the best serology tests will come most rapidly from the multinational players. Some of their UK subsidiaries are already being asked what stock allocation they need for serology tests announced this week. We need to be able to give them confidence that these are required or stock may not be available to the UK.

I have confidence that these tests could easily be managed in the numbers required with the expertise of our colleagues in the NHS Pathology Service, who also feel their role is being under-utilised.

As a sector, the IVD industry has always worked in partnership with NHS pathology and I would hate this combined force not to be seen as a major factor in the efforts to produce the diagnostic information so desperately needed about infection rates and population immunity.

I hope you will receive this communication in the positive spirit intended and I assure you that we will continue to do all we can to support in any way.”

375. As to that, first, a number of LFTs had come from international companies, whether with a UK base or not, and second, not many were using the spike protein which was regarded as so important. See the WSs of Dr Hand.

376. I entirely see that had the work done by Abingdon resulted in an antibody test which was then going to be used on a mass basis, it would be likely to result in a better developed and bigger British diagnostic industry than before. But that consequence hardly means that the exercise was unjustified from an Article 52 point of view to begin with. The need for a British solution if possible had already been appreciated by DHSC prior to the emergence of Abingdon, by 26 March, being Day 4 of the emergency lockdown. See paragraph 27 of Ms Berry's TB1. Indeed, that is why Professor Bell was pleased to have found a potential UK source in Abingdon. Lord Bethell at paragraph 10 of NB2 makes the same point: about a concern over reliance on overseas global markets. See also paragraph 23 of Mr Destombes' WS and paragraph 29 of Mr Brown's first WS.

377. Accordingly, this final element of the Ground 6 claim fails also.

## **Conclusion**

378. On that basis, no part of the Ground 6 challenge succeeds.

## **GROUND 2**

379. Permission was given on paper for this ground for the following reasons:

“Ground 2 (breach of the EU principles of equal treatment and transparency) is arguable:

i) Justification for use of the Regulation 32(2)(c) procedure does not confer automatic immunity against the obligations to treat economic operators equally and without discrimination, and to act in a transparent manner.

ii) Use of the Regulation 32(2)(c) procedure to award a contract without advertisement or competition does not necessarily amount to a breach of the principles of equal treatment and transparency.

iii) The online portal provided an open invitation to economic operators to submit proposals against the published specifications to achieve the targets set out in the national testing strategy.

iv) However, it is arguable that failure to publish the criteria against which the contracts in question were awarded to Abingdon, as opposed to any other entity, amounted to a breach of transparency obligations.”

380. As it turns out, and following amendments to its case, the Ground 2 challenge is not really about lack of transparency or criteria. It is all about an alleged breach of equal treatment in that, for both the June and August Contracts (a) there was no justification for going to a single source (as opposed to multiple sources) and (b) in any event there was no justification for engaging with Abingdon as opposed to some other operator.

### **The June Contract**

381. The complaint about DHSC using a single source is not a complaint that there should have been a competition to arrive at a single source. Instead it is a complaint that DHSC should have contracted with a group of suppliers instead of just Abingdon, under the June contract. That actually makes little sense when, at the time of the June Contract the Research Contract had already been made and had itself contemplated a supply agreement with Abingdon. It is important to note that there is no Regulation 18 challenge to the Research Contract.

382. But on that footing, it is very difficult to see which other operator had been “unequally treated” unless it is the entire group of operators who might have been able to develop at short notice and who, on this analysis, had already started developing a test and were now ready to commence production.

383. Moreover, other potential suppliers had been notified by the kick-off meeting and the triage managed by NTAG was receiving and testing numerous LFTs over this period. So it is wrong to suggest that only Abingdon had access to DHSC in this regard.

384. GLP gives no clear answer to the question as to which group of operators were unequally treated. GLP does not identify any particular supplier who was in a position to deliver a suitable LFT test at the time and on short notice. If the answer to that is that DHSC should have advertised so as to draw them out, that is tantamount to requiring a competition which was not required here.

385. There was, in general terms, a readiness to deal with anyone, because:

- (1) There was an invitation through the kick-off meeting to operators to join in the general process;
- (2) The triage system operated by NTAG continued over the period June-August and beyond;
- (3) DHSC retained the right at all times to deal with any operator who produced a suitable test and retained the IP in any test made by Abingdon, for others to use;
- (4) This is in circumstances where the Research Contract itself is not said to be in breach of Regulation 18;
- (5) The fact then is that there was no other operator already developing the LFT with the spike protein prepared to deal exclusively with DHSC.

386. All of those factors emphasise that in effect, there was no defined group to be treated “equally” with Abingdon.

387. However, lest that be wrong and Regulation 18 is somehow violated, one then turns to objective justification. All GLP says is that it was not justified to deal with only one operator since (a) the only reason for doing so was short supply of antigen and yet (b) certainly by June, any operator would need to look beyond Oxford to supply it. Reference is made to paragraph 102 of the Defence which in turn refers back to paragraph 34 thereof which does refer to the supply of antigen. I agree that certainly by the end of May, DHSC knew that Abingdon was sourcing the antigen from suppliers other than Oxford which did not have anything like enough, although Dr Hand says that he had been led to believe otherwise. See paragraph 8 of CH2.
388. However, paragraphs 35-39 of the Defence are also important. Speed was regarded as vital here once the decision had been made that as matters stood it was necessary to have a bespoke LFT this needed to be done in a very short timeframe. That militated against dealing with numerous operators. Better to have one “lead” supplier who could put together a consortium, which is what happened. See, for example, in this regard, Professor Bell’s email of 3 April quoted at paragraph 130 above. See also Mr Brown’s email after the 30 April meeting where he said that one reason for purchasing the components was because it was important to act early to be sure of supply and of course, DHSC had considerable buying power.
389. GLP also suggested that the recipe for the antigen could be supplied to a number of different suppliers; in fact the recipe did not belong to DHSC but Oxford University and in fact it was supplied to a number of other operators. See paragraph 73 of JB1.
390. In my judgment, all of the above was quite sufficient to justify a decision to proceed with a contract in the form of the June Contract with a single operator especially where it was contemplated that ultimately other operators may well be involved once the LFT had been developed and where DHSC was continually open to new offerings. Moreover, the extent of this derogation from Regulation 18 was justified; it was limited because of the potential for other operators to be involved.
391. The second element of challenge in relation to the June Contract concerned the choice of Abingdon as the sole operator. Again, insofar as this also amounted to a breach of the equal treatment principle, all that GLP relies upon are the facts relating to the allegedly false presentation of SAP approval, the expertise of Abingdon and so on. But I have already dismissed those points above so there is nothing in this second element.

### **The August Contract**

392. At this point in time, the Immunity Question remained unclear. However it is hard to see why there should have been more than one operator at this stage where it certainly looked less likely that 40m units would be needed, hence all the protections for DHSC given in the August Contract. At this stage, it is not about whether other operators might have been available to develop a test and supply it; it is about how many units were needed. Now it looked in reality to be less than 10m.
393. In my judgment, the real complaint here is the second element, in other words concerning the choice of Abingdon as the single contractor.
394. The first point to note is that it was in fact a very good deal for DHSC because of all the options and protections which it felt had to be obtained. It is not at all clear that any other operator would have contracted on that basis and GLP has not shown any operator prepared so to contract. This was certainly Mr Hennigan's view; see paragraph 69 of SH1.
395. At the same time, there was still thought to be a use for gateway testing as well as for surveillance. This was set out at the time in the Note for No. 10, referred to at paragraph

- 218 above. In addition, there was a possible use for testing vaccines according to Mr Destombes - see paragraph 65 of his WS.
396. Other points here rely on the supposed assistance to Abingdon which have been considered and rejected above.
397. A further point is that there should have been no contract with Abingdon anyway because of poor test results prior to the making of the August Contract.
398. I have referred at paragraph 228 above to the initial results back from Imperial which were disappointing, and Dr Hand's explanation at the time for this which was all to do with the way in which Imperial carried out the tests.
399. As also noted above, Abingdon sent a further batch to Imperial by Abingdon at around the beginning of August as anticipated by DHSC – see, for example, Ms Duncan's email to Mr Hatwell dated 30 July. The results were very much better and in line with the Ulster results - see the emails between Mr Yates and Mr Hennigan on 25 and 26 August. I appreciate that this came after the making of the August Contract, as indeed did the PHE results and the lack of an MHRA derogation. On both of these latter matters Dr Hand has put in evidence. But for present purposes, the point is that I do not consider that any uncertainty as to performance or need, meant that resort to Abingdon as the operator, by means of the August Contract was unjustified, especially given its terms.
400. In this regard it is worth recounting Dr Hand's evidence on the other antibody LFTs which, according to Ms Abbott's researches, were said by her to have been available at the time with a similar specificity and sensitivity. At paragraph 24 of her WS, Ms Abbott refers, by way of example, to 70 LFTs which were authorised over a period from May-December 2020.
401. As to this, Dr Hand has reviewed the authorisation letters and the available data in relation to those tests. At paragraph 19 of CH3, he says that they are not true comparables for the following reasons:
- (1) These are tests approved for lab use where moderately or highly complex tests can be performed; they are not for use outside the lab;
  - (2) None would have met TPP because their samples were too small and they did not in any event consist of 200 known positive and 200 known negative cases;
  - (3) The tests measured for IgG and IgM antibodies, and it was not appropriate to extract just the specificity and sensitivity for the IgG antibodies which would have been the relevant ones for our purposes; many of the tests were designed to detect antibodies to NP as well as to the spike protein; however, the best way to measure IgG antibodies was only by reference to the spike protein. In addition, no test used the “full trimeric spike protein”;
  - (4) Many of the tests required more than a simple finger prick for the extraction of blood and could involve a high degree of sample preparation.
402. There may be counter-arguments to what Dr Hand has observed but at the end of the day, GLP did not produce its own scientific evidence on the point. In my judgment, it is not possible to conclude, as GLP effectively invites me to do, that at all material times, there was a host of readily available relevant LFT tests “out there” from other manufacturers which could have done the job that Abingdon was tasked with and moreover (presumably) without needing to do any development first, and in the same timescale.

403. GLP has referred to paragraph 77 of Mr Destombes' WS on the basis that it suggested that if Abingdon would only take a price above a certain level, DHSC would simply buy from other suppliers, and that this indicated that there were other relevant suppliers already there. However, what Mr Destombes said was that he made clear to Abingdon that DHSC would not accept a price above a certain level and he made reference to some of the prices from the suppliers which DHSC had purchased from as leverage in the negotiations. Of course, at the time, the other suppliers were not in fact producing antibody LFTs which met all the relevant requirements testing only by reference to the spike protein etc. Mr Destombes said that he told Abingdon that if they did not meet the expectations on price, the other companies would "probably become realistic alternatives in due course". I do not think that this exchange indicates that there were other relevant tests already available prior to the making of the August Contract.
404. Insofar as necessary, I would refer also to the points made in the context of Ground 5 at paragraphs 327-332 above.
405. Overall, I do not consider that either element of the Ground 2 challenge in relation to the August Contract is made out.

### **Conclusion on Ground 2**

406. It therefore follows that this Ground of challenge fails.

## **STATE AID**

### **The Law**

407. Article 107(1) TFEU provides that:

"Save as otherwise provided in the Treaties, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market."

408. Abingdon's Skeleton Argument makes two general propositions which I did not understand to be controversial:
- (1) Whether action by the State amounts to State aid is a "*global question*" which must be considered in the round (*R v Customs & Excise Commissioners ex parte Lunn Poly* [1999] STC 350 at [360]; *C-357/14 Electrabel and Dunamenti Eromu v Commission* EU:C:2015:642, [101] – [104]); and
  - (2) State aid has well-recognised characteristics: see *R (British Academy of Songwriters, Composers and Authors and Ors) v Secretary of State for Business, Innovation and Skills* [2015] EWHC 1723 (Admin) at [286]:
    - ...(i) First, there must be an aid in the sense of an economic advantage.
    - (ii) Secondly, the advantage must be granted directly or indirectly through state resources and must be imputable to the state.
    - (iii) Thirdly, the measure must favour certain undertakings or the production of certain goods (selectivity).
    - (iv) Fourthly, the measure must be liable to distort competition and affect trade between Member States."
409. Pausing there, there is, in my judgment, no live issue as far as affecting trade between Member States ("ATBMS") is concerned. It was pleaded but the parties have not substantially addressed it in their submissions and in any event the threshold for establishing it is low. See paragraphs 81-82 of the decision of the Court of Justice in

*Altmark* 24 July 2003 C-280/00. And as it happens here, there was, at least in general terms, an international European dimension to the potential manufacturers for antibody LFTs. Accordingly, I shall proceed on the basis that if the requirements for State aid were otherwise made out, the claim would not fail because of a lack of ATBMS.

410. Next, the burden is on GLP to establish the existence of State aid - see the judgment of Falk J in *Credit Suisse v HMRC* [2019] EWHC 1922 at paragraph 8.

411. There is a separate question as to the burden of proof in relation to the operation of what is known as the Market Economy Operator Principle (“MEOP”) which I deal with below.

412. Both sides have referred extensively to the EC Commission Notice on State aid 2016/C262/01 (“the Notice”). The Commission, obviously, has a role here as a result of its duties and powers under Article 108. Paragraph 1 of the Notice provides that:

“...the Commission wishes to provide further clarification on the key concepts relating to the notion of State aid as referred to in Article 107(1) of the Treaty on the Functioning of the European Union, with a view to contributing to an easier, more transparent and more consistent application of this notion across the Union.”

413. Obviously, this is not a binding provision and it is largely a very detailed and useful summary of the relevant cases. A number of points may be drawn from it.

414. Paragraph 51 points out that

“The transfer of State resources may take many forms, such as direct grants, loans, guarantees, direct investment in the capital of companies and benefits in kind. A firm and concrete commitment to make State resources available at a later point in time is also considered a transfer of State resources. A positive transfer of funds does not have to occur; foregoing State revenue is sufficient. Waiving revenue which would otherwise have been paid to the State constitutes a transfer of State resources...”

415. Paragraph 68 makes the same point, stating that the precise form of the measure is irrelevant in establishing whether it confers an economic advantage on the undertaking. Relief from economic burdens will suffice.

416. Paragraph 67 states that:

“Only the effect of the measure on the undertaking is relevant, and not the cause or the objective of the State intervention. Whenever the financial situation of an undertaking is improved as a result of State intervention on terms differing from normal market conditions, an advantage is present. To assess this, the financial situation of the undertaking following the measure should be compared with its financial situation if the measure had not been taken. Since only the effect of the measure on the undertaking matters, it is irrelevant whether the advantage is compulsory for the undertaking in that it could not avoid or refuse it.”

417. Section 4.2 of the Notice deals with the MEOP. In the light of the arguments, I need to cite verbatim a number of its general provisions:

“73. The Union legal order is neutral with regard to the system of property ownership and does not in any way prejudice the right of Member States to act as economic operators. However, when public authorities directly or indirectly carry out economic transactions in any form, they are subject to Union State aid rules.

74. Economic transactions carried out by public bodies (including public undertakings) do not confer an advantage on its counterpart, and therefore do not constitute aid, if they are carried out in line with normal market conditions. This principle has been developed with regard to different economic transactions. The Union courts have developed the ‘market economy investor principle’ to identify the presence of State aid in cases of public investment (in particular, capital injections): to determine whether a public body's investment constitutes State aid, it is necessary to assess whether, in similar circumstances, a private investor of a comparable size operating in normal

conditions of a market economy could have been prompted to make the investment in question. Similarly, the Union courts have developed the ‘private creditor test’ to examine whether debt renegotiations by public creditors involve State aid, comparing the behaviour of a public creditor to that of hypothetical private creditors that find themselves in a similar situation. Finally, the Union courts have developed the ‘private vendor test’ to assess whether a sale carried out by a public body involves State aid, considering whether a private vendor, under normal market conditions, could have obtained the same or a better price.

75. Those tests are variations of the same basic concept that the behaviour of public bodies should be compared to that of similar private economic operators under normal market conditions to determine whether the economic transactions carried out by such bodies grant an advantage to their counterparts. In this Communication, the Commission will therefore refer, in general terms, to the ‘market economy operator’ (MEO) test as the relevant method to assess whether a range of economic transactions carried out by public bodies take place under normal market conditions and, therefore, whether they involve the granting of an advantage (which would not have occurred in normal market conditions) to their counterparts. The general principles and the relevant criteria for applying the MEOP test are set out in sections 4.2.2. and 4.2.3.

76. The purpose of the MEOP test is to assess whether the State has granted an advantage to an undertaking by not acting like a market economy operator with regard to a certain transaction. In that respect, it is not relevant whether the intervention constitutes a rational means for the public bodies to pursue public policy (for example employment) considerations. Similarly, the profitability or unprofitability of the beneficiary is not in itself a decisive indicator for establishing whether or not the economic transaction in question is in line with market conditions. The decisive element is whether the public bodies acted as a market economy operator would have done in a similar situation. If this is not the case, the beneficiary undertaking has received an economic advantage which it would not have obtained under normal market conditions, placing it in a more favourable position compared to that of its competitors.

77. For the purpose of the MEOP test, only the benefits and obligations linked to the role of the State as an economic operator — to the exclusion of those linked to its role as a public authority — are to be taken into account. Indeed, the MEOP test is normally not applicable if the State acts as a public authority rather than as an economic operator. For example, if a State intervention is driven by public policy reasons (for instance, for reasons of social or regional development), the State’s behaviour, while being rational from a public policy perspective, may at the same time include considerations which a market economy operator would normally not consider. Accordingly, the MEOP test should be applied leaving aside all considerations which exclusively relate to a Member State’s role as a public authority (for example social, regional or sectoral policy considerations).

78. Whether a State intervention is in line with market conditions must be examined on an ex-ante basis, having regard to the information available at the time the intervention was decided upon. In fact, any prudent market economy operator would normally carry out its own ex-ante assessment of the strategy and financial prospects of a project, for instance, by means of a business plan. It is not enough to rely on ex-post economic evaluations entailing a retrospective finding that the investment made by the Member State concerned was actually profitable...

81. In certain cases, several consecutive measures of State intervention may, for the purposes of Article 107(1) of the Treaty, be regarded as a single intervention. This could be the case, in particular, where consecutive interventions are so closely linked to each other, especially having regard to their chronology, their purpose and the circumstances of the undertaking at the time of those interventions, that they are inseparable. For instance, a series of State interventions which take place in relation to the same undertaking in a relatively short period of time, are linked to each other, or were all planned or foreseeable at the time of the first intervention, may be assessed as one intervention. On the other hand, when the later intervention was a result of unforeseen events at the time of the earlier intervention the two measures should normally be assessed separately.”

418. It is necessary to say something more about paragraphs 76-78. First, it is clear that the mere fact that the advantage conferred by the State is rational, indeed perhaps laudable, from a public policy point of view, is irrelevant. The question is not policy rationality but the effect on the undertaking concerned. Equally, when applying the MEOP test, policy



considerations which might, for example, support a financial provision which is otherwise unjustified, must be ignored.

419. Second, paragraph 78, read by itself, might suggest that in all respects the MEOP test must be conducted as at the time of the impugned financial provision, and without regard to later events. GLP relies on paragraph 78 for its general proposition that in relation to each of the Contracts, they must only be considered from a State aid point of view at the time of their making, without reference to any later matters. Thus, by way of example, the fact that the August Contract provides a discount to compensate DHSC for its provision of components pursuant to the June Contract cannot be taken into account when assessing the question of State aid in relation to the latter.
420. In my view, that reliance is mistaken. The case cited in the Notice to support paragraph 78 is *Commission v EDF* C-124/10. EDF was, at the time, a state-owned company. The French State embarked on a restructuring of EDF's balance sheet in 1997 through a series of complex measures. Their overall effect was to provide a capital injection into EDF. Part of this involved the French tax authorities effectively granting a waiver over tax otherwise payable by EDF. Looking at that waiver in isolation, the Commission said that this was itself State aid and made a decision that the value of the waiver (over €888m) should be repaid to the French State. In its analysis, the Commission concluded that since all of this concerned tax liabilities, the French State was acting *qua* public authority and accordingly there was no basis for the application of the MEOP test because it was not acting *qua* economic operator.
421. The General Court reversed the Commission's Decision and the Court of Justice agreed with the General Court. The essential question was the proper characterisation of how the French State was acting-whether as a public authority or as the shareholder in EDF. Here, the Court took the view that the overall transaction needed to be considered, not just the tax waiver. In relation to that threshold question, the court said this:
- “81 The applicability of the private investor test ultimately depends, therefore, on the Member State concerned having conferred, in its capacity as shareholder and not in its capacity as public authority, an economic advantage on an undertaking belonging to it.
- 82 It follows that, if a Member State relies on that test during the administrative procedure, it must, where there is doubt, establish unequivocally and on the basis of objective and verifiable evidence that the measure implemented falls to be ascribed to the State acting as shareholder.
- 83 That evidence must show clearly that, before or at the same time as conferring the economic advantage..., the Member State concerned took the decision to make an investment, by means of the measure actually implemented, in the public undertaking.
- 84 In that regard, it may be necessary to produce evidence showing that the decision is based on economic evaluations comparable to those which, in the circumstances, a rational private investor in a situation as close as possible to that of the Member State would have had carried out, before making the investment, in order to determine its future profitability.
- 85 By contrast, for the purposes of showing that, before or at the same time as conferring the advantage, the Member State took that decision as a shareholder, it is not enough to rely on economic evaluations made after the advantage was conferred, on a retrospective finding that the investment made by the Member State concerned was actually profitable, or on subsequent justifications of the course of action actually chosen (see, to that effect, *France v Commission* [2002] 2 C.M.L.R. 41 at [71] and [72]).”
422. Pausing there, it is plain from the context that the obligation on the State was to establish that it had acted as economic operator (i.e. here as shareholder). But this is only in cases where its capacity was in doubt. If it was not in doubt, because it plainly was acting *qua* economic operator, there is no special burden. And certainly, paragraph 82 of the judgment

does not mean that the burden of proof in relation to the application of the MEOP test itself is generally on the State as opposed to the Commission (or other claimant). Accordingly, the burden of showing that the finance provided did not accord with ordinary market conditions is still on the claimant.

423. Moreover, and as explained below, this is not a case where there is any doubt as to the capacity in which DHSC was acting. It was plainly acting as an economic operator, buying goods and services.
424. Third, and in the same context, it is clear that paragraph 85 of the judgment (which in turn is used by the Commission as support for paragraph 78 of the Notice) is all about the question of characterisation; it is not about the logically next question which arises if the correct characterisation of the State is as economic operator. Put more simply, if, at the time of the provision, the State was acting as a public authority in injecting funds into a company, the fact that later on, it transpired that the company made profits which benefited the State, so that it was a successful “investment” this does not alter the characterisation of how the State was acting at the time of making the financial provision. It would not turn the State retrospectively into a shareholder. Accordingly, to the extent that paragraph 78 of the Notice suggests that *EDF* provided that the analysis of the effect of the financial provision could only concern circumstances up to and as at the date of that provision, this is an incorrect statement of the law.
425. Indeed, as paragraph 81 of the Notice says, sometimes a number of interventions will be looked at together, especially if they are so closely linked as to be regarded as inseparable.
426. On that basis, I do not consider that a barrier to the court’s consideration, as it were, falls down as soon as the relevant provision is made-or agreed to be made.
427. As to the detailed application of the MEOP test, the Notice first provides as follows:

“97. If a transaction has been realised through a tender or on ‘pari passu’ terms, this provides direct and specific evidence of compliance with market conditions. However, if a transaction has not been realised through a tender, or if the intervention of the public bodies is not ‘pari passu’ with that of private operators, this does not automatically mean that the transaction does not comply with market conditions. In such cases compliance with market conditions can still be assessed through (i) benchmarking or (ii) other assessment methods.

(i) Benchmarking

98. To establish whether a transaction is in compliance with market conditions, that transaction can be assessed in the light of the terms under which comparable transactions carried out by comparable private operators have taken place in comparable situations (benchmarking).

99. To identify an appropriate benchmark, it is necessary to pay particular attention to the kind of operator concerned (for example a group holding, a speculative fund, or a long-term investor seeking to secure profits in the longer run), the type of transaction at stake (for example equity participation or debt transaction) and the market or markets concerned (for example financial markets, fast-growing technology markets, utility or infrastructure markets). The timing of the transactions is also particularly relevant when significant economic developments have taken place. Where appropriate, the available market benchmarks may need to be adjusted according to the specific features of the State transaction (for instance, the situation of the beneficiary undertaking and of the relevant market). Benchmarking may not be an appropriate method to establish market prices if the available benchmarks have not been defined with regard to market considerations or the existing prices are significantly distorted by public interventions.”

428. As for other assessment methods, paragraph 101 says this:

“Whether a transaction is in line with market conditions can also be established on the basis of a generally-accepted, standard assessment methodology. Such a methodology must be based on the available objective, verifiable and reliable data, which should be sufficiently detailed and should reflect the economic situation at the time at which the transaction was decided, taking into account

the level of risk and future expectations. Depending on the value of the transaction, the robustness of the evaluation should normally be corroborated by performing a sensitivity analysis, assessing different business scenarios, preparing contingency plans and comparing the results with alternative evaluation methodologies. A new (ex-ante) valuation may need to be carried out if the transaction is delayed and it is necessary to take into account recent changes in market conditions.”

429. The detail of this paragraph seems to me to contemplate essentially something like an investment by the State in the beneficiary undertaking which, of course, is not the case here. However, the detailed provisions of the Notice on the application of the MEOP test cannot be regarded as exhaustive.

### **The Context here**

430. First, as already noted, DHSC was plainly acting as economic operator and not as a public authority. On any view, the Contracts were all economic transactions concerned with the provision of goods and services to DHSC. There is no *EDF*-type problem here.
431. Second, the background was of course extremely unusual. It is difficult to find a comparable private economic operator here because, typically, it would be the relevant State entity which was acquiring the goods and services (rather as the NHS does for the mass-purchase of drugs) not private entities. But that fact by itself cannot render the Contracts as State aid and GLP does not so contend.
432. Nonetheless, the application of the MEOP test must involve assuming market conditions which include (1) the urgent need for the development of an effective antibody LFT that could be used for mass home-testing, (2) some uncertainty as to whether that test would be developed in time, and (3) the risk that even if it was, the need for it in very large quantities might disappear. It cannot be said that these were policy considerations which have to be disregarded.

### **Analysis: the Research Contract**

433. Essentially, GLP makes one allegation here which is that in reality, the Research Contract was nothing more than a grant or subsidy in the sum of £2.5m. I disagree for the reasons set out below.
434. First, there is nothing surprising about the fact of a Research Contract. Making such contracts is what the NIHR was all about. It is plain from the format and content of the Research Contract which is a detailed, 54-page document, that much of it is in standard form. It expressly contemplates the possibility that it might be classed as State aid and it has provisions to deal with that eventuality (I suspect that this is itself a standard term but it makes no difference to my analysis if it was not). This explains that part of the Settlement which deals with the “escrow” of £1.5m. See paragraph 258 above. That, of course, does not mean that I should class it as State aid without more.
435. Second, it is true that at an earlier point, there was a suggestion in the emails that the £2.5 million might be a straight grant. But in the event, this is not what happened.
436. Third, there was clear value given to DHSC for the £2.5m, namely the Foreground IP and the Research Data. This would enable it to licence the specification to other potential suppliers and indeed it was sent out for potential manufacture by Asia Pacific - see the emails of 20 and 24 November 2020.
437. It is correct that there is no actual valuation evidence as to the worth of the IP Rights given to DHSC. But I think that is unrealistic, given the uncertainties at the time and the need for very swift action. The rights could clearly have been extremely valuable had the global way forward to combat Covid been the use of such tests to demonstrate immunity. In the event it probably was not worth very much.

438. I also agree that Abingdon obtained an irrevocable worldwide licence which was of potentially great value to it. But as against that, the Research Contract contemplated the making of a revenue-sharing agreement (along with a supply agreement)-see paragraph 16.5 thereof cited at paragraph 183 above. This became, of course, the Commercialisation Agreement (see paragraph 239 above). This has to be taken into account, and I do not accept that I cannot do so as a matter of law. Moreover, it was specifically contemplated in the June Contract. Had Abingdon sold 9m LFTs, then the £2.5m would have been recouped by DHSC, with an additional £0.5m return, as it were. DHSC says that this could equate to a 20% return which would be in line with average private equity fund returns since 2000. I agree with DHSC that the Research Contract was consistent with a market investor risking an initial investment in return for IP Rights and if successful, a recoupment based on a realistic sales assessment.
439. As for the actual sum of £2.5m, I accept that this was the figure requested by Abingdon, and it was saying that effectively, it could not afford to do the research without it. But given that clear (and realistic) consideration was given to DHSC under the Research Contract, I do not think this takes the matter any further. It might have done if, on any view, the figure of £2.5m was plainly excessive. But there is really no evidence from GLP that it was. Moreover, according to Mr Yates, at paragraph 22 of his WS, other companies abroad were being paid significantly more to develop such tests. In addition, the profit margin was less than what it would usually have been for Abingdon and had its work been assessed on a day rate basis, the price would have exceeded [Z]. The fee of £2.5m was lower than what Abingdon would typically receive. It is to be recalled that this test was to be developed at very much higher speed than usual. Abingdon communicated this to DHSC - see paragraph 117 above. And at paragraph 20 of his WS, Mr Yates confirmed that the usual development period would be 9-18 months; here they used shifts from 8 AM to 10 PM and at weekends.
440. A further point made by GLP is that MS2, which requested the £2.5m, shows that the Research Contract was being postulated by reference to illegitimate (for these purposes) policy considerations. I disagree. The relevant text is quoted at paragraph 132 above. It is all about the urgent need for the research as the precursor to obtaining a speedy supply of possibly millions of tests. In my judgment, if those considerations were to be excluded, then any application of the MEOP test becomes meaningless.
441. For all those reasons, I consider that the Research Contract did not amount to State aid.

#### **Analysis: the June Contract**

442. GLP's essential argument here is that the June Contract was simply an interest-free loan of around £10m (so as to pay for components for the first 10 million tests) and potentially more, in circumstances where such a loan could never have been obtained by Abingdon from a private lender. As part of that argument, GLP characterised the fact of ownership of the components by DHSC as simply security for the loan.
443. I do not think that this is a correct characterisation. It is not as if DHSC gave £10m at the outset to Abingdon to use for components (or other things) later and to be repaid at a certain point. Instead, DHSC was purchasing the components (procured for it by Abingdon) for itself at the outset. They would remain its property until incorporation in the manufactured tests. And if Abingdon's LFTs were not successful, DHSC was free to use the components for the manufacture of LFTs by others. Mr Yates says at paragraph 30 of his WS that a number of the components were generic. It seems to me that if Abingdon failed to develop the test, but others later did, and they were still needed, the components would have had real value. GLP again says that there was no valuation of the components but I do not see why this was necessary when Abingdon was obliged to (and did, according to the Ankura report) only buy components at arms length and on reasonable terms.

444. All of this was intended to be part and parcel of the contemplated supply agreement, since that would provide a mechanism for returning to DHSC the cost of the components through the discount of the LFTs' sale price. Again, I consider that I can take the contemplation of the supply agreement and the making of the August Contract into account here. Indeed, the June Contract again refers specifically to a supply agreement along with a revenue sharing agreement in its preamble. I accept, of course, that the June Contract was intended to provide advance funding to Abingdon in respect of the acquisition of components because it required DHSC to put Abingdon in funds at the time in respect of the purchase of the components (although in practice, DHSC was in arrears-see paragraphs 255 and 256 above). However, the advance supply to manufacturers of components is not uncommon, according to paragraph 32 of Mr Yates' WS. It was not unusual for customers to provide some of the components necessary to make the LFTs. He says that a number of Abingdon's largest customers provided components free of charge. Mr Page, in his WS, has exhibited documents showing one customer providing almost [AA] components and another providing quantities of [BB] different research reagents, both free of charge. So it is not as if the payment for components was such as to be regarded as unmarket-like, as it were.
445. Of course, in the end, only 1m LFTs were made by Abingdon and DHSC cancelled its requirements for any more and yet DHSC has had to pay for the components which had been bought. However, I do not think this affects the essential analysis.
446. In all those circumstances, I do not think it right to see the June Contract simply as an interest-free loan. I do not accept that in terms of its content it amounted to State aid.

#### **Analysis: The August Contract**

447. GLP's core allegations here are that (a) there was no or no appropriate benchmarking exercise on the question of price, (b) the price agreed (£5.15 per test and not the £7.50 originally asserted by GLP) was excessive.
448. The question of the benchmark exercise carried out at the time is dealt with in detail at paragraphs 73-83 of Mr Destombes' WS. The salient points are that despite the urgency, there were several weeks of negotiations on price and Abingdon's effectively "costs plus" model (according to which it had sought a price of £6.25) was deemed not workable because it would not recognise DHSC's contributions by way of advance funding thus far and it was vulnerable to escalation. Mr Destombes and Ms Doyle said that benchmarking could be done against the headline price of LFTs. It is correct that DHSC had tried an "open-book" approach with Abingdon so as to determine a price on the basis of all of its relevant costing data. But Abingdon refused and DHSC could not force it to change its stance because it did not have enough commercial leverage. GLP says that this illustrates that the agreed price was not market-price. I do not agree. Mr Destombes said that the alternative of benchmarking on the price of other products was common in markets for these goods. Not all customers permitted an "open-book" review. It therefore does not follow that meant that there was no relevant assessment of price.
449. However, there was an obvious problem (which affects the whole State aid claim to some extent) which is that there was no comparable case of private operators buying the tests fit for mass home use. But the absence of prices paid by private operators cannot itself mean that the MEOP test fails. The negotiating team could and did look at the prices offered by other manufacturers of antibody LFTs, albeit not validated for home use. As to the latter, first, there were the prices actually paid by DHSC for the LFTs purchased earlier in the year. Second, the team wanted to consider two other "promising" LFTs from OrientGene and Bioamerica but there was no pricing information available. The list of purchased LFTs and their prices showed the following:

Company	Volume (million)	Unit Cost
Abbott UK	12.5	[BBa]
SD biosensor	1	[BBb]
Nal Von Minden	1	[BBc]
Fortress	0.5	[BBd]
Cigahealth (Wondfo)	1	[BBe]

450. It can be seen that the cheapest was [CC] at [DD]. However, Dr Hand makes the point at paragraph 159 of his WS3, that it is not clear whether this price included individual packaging. Also, this was a test which detected both IgM and IgG antibodies in one line, as to which see paragraph 401(3) above. In this regard, Ms Abbott refers to one part Professor Darzi’s email of 7 March. This is set out below with the underlined words being those quoted by Ms Abbott:

“ • The [EE] test is performing well in the lab, almost as well as the top tests in the literature (which we also procured and are testing).

• Results in the clinic are not as accurate and we are trying to find out why -this is not in the literature and would be an important finding.”

451. It can be seen that a reference to the first sentence but not the second is selective and misleading. The concerns about clinic results for [FF] are set out in more detail in the report which Professor Darzi attached to that email. There he says that in the clinical setting (which is the important one) there may be issues with the accuracy of [GG].

452. Mr Destombes also created his own price calculation and financial modelling spreadsheet from which he worked out that Abingdon’s profit margin would be [HH] on the basis of producing 10m tests at a price of [II]. As we know, that price was approved at ministerial level along with the other elements of the August Contract. The final model done by Mr Destombes was of course his; these calculations did not come from Abingdon.

453. I cannot see that the benchmarking done by Mr Destombes and his team was illegitimate because it did not involve any purchases made by private companies. There were no such purchases, at least not for the purposes of an antibody LFT designed for mass home-use. It is very hard to see what could be considered other than the selling prices from the relevant manufacturers.

454. GLP however makes the further point that in any event all the prices from competitors were “existing prices [which] are significantly distorted by public interventions”. But it is difficult to see how that point operates here when, almost by definition, the relevant purchasers will consist of public bodies, and there is no “intervention” as such. It is just that one of the background features is a potentially very large demand and a need for urgency.

455. Turning to the price itself, GLP contends that relevant antibody tests could have been purchased for around £3. Its initial contention here was based solely on an anonymous quote in an article in the BMJ dated 16 November 2020 which said that “at these volumes the government should be paying closer to £3”. Actually, the quote went on to say “(compared to approximately £10)” which of course was not the price under the August Contract. In any event, this hardly constitutes evidence and there was no material to suggest

that this postulated £3 test was equivalent to Abingdon's LFT in terms of antibodies targeted, protein used, extent of packaging etc. Abingdon's own understanding was that there were no other tests "out there" meeting the TPP requirement. In fact, not much was made of the BMJ article in the oral and written submissions.

456. Instead, GLP now relies on the matters discussed in Ms Abbott's WS at paragraphs 19 and 20.
457. First, she refers to the precursor to the Ankura report, namely NHSTT's request for a firm to conduct the audit of the dealings with Abingdon. A number of concerns as to the conduct of the consortium were here expressed. One of them was that it was benefiting excessively. It said that the manufactured value of the LFTs supplied by Abingdon was around [JJ] and the "market value of the device should in reasonable benchmarking be quoted [KK] per device". It is not clear where this came from.
458. Part of Ankura's work which was the product of that request, concerned identifying the margin made by Abingdon. The other elements of the work concentrated on a detailed cost analysis in relation to the Research Contract and then the question of the costs of components purchased under the June Contract. The relevant table here is Table 11. This shows that in relation to the actual production of the 1m LFTs, the direct costs were [LL] which equates to [MM] per test. But on a crude basis, if that document thought that a market price of [NN] was justified on the basis of [OO] direct costs, then, if the direct costs are [PP], it would generate a price of around [QQ]. Interestingly, that is where Abingdon started in negotiations but of course they ended up with considerably less. Ankura does not really comment further on this issue of margin. Neither party addressed me on Table 11 but doing the best I can, it does cast considerable doubt on the [RR] referred to in the brief. I do not consider it takes the matter any further in favour of GLP's case.
459. Next, GLP relies on a document produced by Ms Jandziol and Ms Laguarde dated 10 November 2020, being an overview on Testing Technologies. This is all about tests for antigens, not antibodies. So references to prices here (and as at November 2020 not earlier) are not useful.
460. Of more potential relevance is a document which was prepared for a without prejudice meeting between DHSC and Abingdon called "Talking Points" and setting out each sides position on a number of matters. In the "Financial" section, Abingdon's position was that [SS]. On DHSC side, its position included the statement that "T&T and UK has confirmed that the industry benchmark for the test is circa [TT] and HMG is paying [UU]. The RTC audit shows the cost of manufacture should be readjusted to [VV] from the current [WW]...." The [XX] cost figure is more or less the same as the [YY] figure referred to in the Ankura final report. It is unclear where this [ZZ] benchmark came from. If it was the benchmark for antibody LFTs then Abingdon would certainly be not making a profit. Nonetheless, as Mr Barrett fairly pointed out, DHSC did not put in any reply evidence to deal with this point even though it put in some reply evidence (being that of Mr Kelsey to deal with the question of GLP's standing) and even though Ms Jandziol had produced a WS. On the other hand, apart from the disparity over costing, this was a figure put forward in the context of a dispute with Abingdon and in addition, it is not clear whether this was the apparent price in November, when the Talking Points document was produced, as opposed to August when the August Contract was made. A figure of [ZZa] is close to the references in the Testing Technologies document but that was dealing with antigen tests. The only other reference to £3 is in the tender document for Ankura but as already discussed, this is unreliable. Finally, the prices observed by Mr Destombes when benchmarking and the other prices referred to below do not support a market cost of [AAA].

461. Ms Abbott also refers to an antibody LFT produced by Mologic with a price ceiling of £1.25. Actually, the Deloitte and Reuters articles relied on here referred to Mologic's plans to roll out such an LFT. It is not clear whether it was ever produced - certainly there is no evidence that it was.
462. Mr Yates is criticised for not dealing with two of Ms Abbott's points in his WS. There is nothing in this since the relevant documents had not yet been disclosed when he made it.
463. Dr Hand also refers to the WS from Mr Mico of BDX, which was adduced on the question of standing. Though not dealt with in that WS, a May 2021 newspaper article said that the BDX test required a blood sample to be analysed in a lab and then returned within 72 hours, at a cost of £99.95. In April 2022, BDX's website advertised the same product for £49.95 or £33.95 for health workers. Finally, as Mr Mico said, BDX's product was not an LFT itself but rather a platform "like an LFT".
464. Ms Abbott also refers to Mr Destombes' email of 17 May on price, saying that unit prices were currently estimated in the range[BBB]. He then said "This technology is supposed to be low-cost so we should be able to achieve a price closer to the bottom of the range." That is not quite how Ms Abbott put it in her paragraph 20 (c). Further, that range is not dissimilar to the one set out in paragraph 449 above. It is also noteworthy that Ms Barry's response was to say that they should perhaps fall back on the benchmark of the average price for buying LFTs from abroad which was [CCC] (which tests were not in fact suitable).
465. In its Skeleton Argument, Abingdon also noted that its own estimated margin ([DDD]) was less than the publicly stated gross margins for BBGI, CHF43 and CHF42.
466. Another point made by Ms Abbott was that CIGA, one of the consortium partners, specifically requested DHSC's approval to sell Abingdon's antibody tests at a price of[EEE]. In fact, this was part of a chain of emails in January 2021 when DHSC and Abingdon were firmly in dispute. Mr White had noted various points about the liabilities of consortium members. He noted that CIGA had no liabilities but "do have sufficient interest of sales at a reduced price of[FFF]" and on that basis required DHSC's approval. Mr White said that save for the Commercialisation Agreement which said that they could not be sold for lower than[GGG], "it's all a bit moot". The context appears to be that someone was interested in purchasing antibody tests at a reduced price which is hardly surprising since, by January 2021, it was fairly clear that the Immunity Question was not going to be answered positively. None of that assists as to the market price in August 2020.
467. Finally, Mr Yates, at paragraph 37 of his WS, said that he compiled a list of alternative antibody tests available on the open market on the basis of publicly available data. The prices ranged from £69-70, down to £4.25. It was not clear if these were exact comparables and Dr Hand gave examples of how they might not be. Of the Roche and Abbott purchased by DHSC, Mr Yates also pointed out that those were with liquid reagents and with bulk packaging kits for testing 100 or more samples in the lab.
468. GLP makes the further point that an estimated margin of [HHH] (as perceived by Mr Destombes) being comparable to other gross margins of other companies does not assist because there is no detail of the other companies' quotes. I see that but at least it is a broad indication, especially where, on the analysis above, a price of [III] is well within the range of prices from others (assuming their tests were indeed comparable to Abingdon's).
469. GLP says that such matters needed expert evidence which in fact DHSC sought to adduce but it was refused. That is not a very attractive point since it was GLP which objected to such evidence at the time. But in any event, I disagree. In my judgment, looked at as a whole, it is quite impossible to say that a price of [JJJ] was outside the range of market prices at the time (and it is not required to be the lowest) especially on the basis of the



favourable (to DHSC) terms of the August Contract and the requirement to conform to PHE and MHRA requirements.

470. Accordingly, the State aid claim in relation to the August Contract fails also.

### **DHSC Assistance to Abingdon**

471. By an amendment made on 12 October 2021, GLP introduced a new allegation, namely that various acts of assistance given to Abingdon in the performance of the August Contract and related matters themselves amounted to State aid.

472. I express the allegations as follows by reference to their latest iteration in paragraph 131 of GLP's Skeleton Argument. It is said that DHSC

- (1) Purchased 1m tests for which in fact there was no use ("No use for tests");
- (2) Facilitated and procured the provision of key components to Abingdon namely blood samples and antigen ("Provision of components");
- (3) Provided a Chairman of the consortium namely Dr John Allis ("Provision of Chairman");
- (4) Provided extensive support to Abingdon in its seeking to obtain PHE and MHRA approvals ("Approvals Assistance");
- (5) Procured Abingdon's involvement in scientific studies ("Studies Assistance"); and
- (6) Facilitated sales by Abingdon to third parties ("Third-party Sales").

473. I deal with each in turn.

#### *No use for tests*

474. This has to be considered as at the time of the commitment to buy at least 1m tests which was part of the August Contract. Having regard to the facts surrounding that Contract, it cannot seriously be suggested that at the time there was no use for the 1m tests.

475. Of course, by late October and November, the position had changed in that there was still no PHE validation for home use or MHRA home-test approval in which case the possible use for the LFTs was more limited. That is the context for the statement from Mr Locke which GLP has relied upon at paragraph 131(1) of its Skeleton Argument. As an examination of his email, dated 27 October 2020, in context, shows, the problem by now was the lack of MHRA approval. This turned out to be a difficult and contentious process as outlined in paragraphs 244-247 above.

476. This is what led DHSC to question how it could use the 1m tests already ordered and soon to be delivered. As the emails show, Mr Locke and others certainly did not want to be in a position where DHSC now had 1m "useless tests". But that hardly means that there was no intention to use them back in August. See Mr Locke's evidence at paragraphs 145-149 of his WS. Indeed, logically, GLP's case would have to be that even in entering the Research and June Contracts, DHSC knew that it would have no need for at least 1m LFTs. That is an absurd contention. It completely goes against the history of the perceived need for such tests recounted above.

477. There is a line of EU authority to the effect that where there is a purchase of goods on normal trade terms but for which, at the time of purchase, the State had no use, this can constitute a disguised form of State aid. See, for example, the "ferry vouchers" case of *BAI*

*v Commission* [1999] ECR-II-39. This is completely different to the case before me and irrelevant.

478. There is nothing in this allegation.

#### *Provision of Components*

479. There are two short answers to this. First, as already recounted, the amount of blood samples and antigen actually supplied to Abingdon by Oxford was very small. Second, Oxford is not DHSC. Any reduction in Oxford's resources in this very limited regard is not a reduction in the States resources. So there is nothing in this point either.

#### *Provision of Chairman*

480. It is correct that DHSC recommended that there should be a Chair of the consortium to assist in its internal management. But I cannot see how that led to any diminution of State resources; it is not the case, for example, that DHSC provided a Chair to Abingdon at a cost which it bought. Indeed, for its part, Abingdon did not think that the consortium needed a Chair.

481. There is a more general point, however. That is that if there is a contract between DHSC and a supplier which (be it assumed) is not itself State aided, it is very hard to see why any steps taken by DHSC as one contracting party to assist the other the better to perform its contractual obligations could constitute State aid. DHSC had a general interest in the latter. In commercial life under ordinary market conditions, this is a normal feature of an ongoing contractual relationship. This general point applies equally to the next allegation.

482. GLP points to various benefits to the consortium of having such a Chair, as perceived by DHSC (see paragraph 131 (3) of GLP's Skeleton Argument). Quite so, but this still has nothing to do with State aid.

483. This allegation also fails.

#### *Approvals Assistance*

484. It was obviously in DHSC's interest to assist Abingdon to obtain relevant approvals. Again, this is not State aid. In fact, the PHE approval process did not really involve DHSC. As for MHRA in fact, at least from Abingdon's point of view, DHSC actually failed to do that which only it could do, namely to provide a clear statement of urgent clinical need for mass-home testing, again dealt with above.

485. I should add that part of GLP's complaint here is that the alleged assistance was on a "discriminatory basis" as compared to other providers who did not get the same support. As to that, (a) the extent of any actual support is highly questionable (see above), (b) if given, it was unexceptional in the context of a contractual relationship and (c) it seems to be a re-run of the argument that DHSC should have approached other suppliers in addition to or in substitution for Abingdon, which I have already rejected - see above. This is also relevant to the next allegation.

486. As noted, the point in paragraph 481 above applies equally here.

487. Thus, this allegation fails, too.

#### *Studies Assistance*

488. The studies concerned were carried out by the Wellcome Trust and Imperial. As to the former, Wellcome approached Abingdon to take part in its study and Abingdon felt that contractually, it needed DHSC's permission. It is not actually clear that the studies in fact took place. See paragraphs 18-20 of Dr Hands WS2.

489. As for Imperial, it is correct that Abingdon did submit its LFTs to it. What happened is set out in paragraphs 228, 240 and 398-399 above. Moreover, according to Mr Locke (at paragraph 152 of his WS) DHSC did not actually “facilitate” Abingdon’s introduction to Imperial. In any event, it is hard to see how this conferred any benefit to or value upon Abingdon.
490. It is impossible to see how any of this amounted to State aid, and again the point made in paragraph 481 above applies equally here

#### *Sales to third parties*

491. This seems to be an amalgam of paragraphs 121A (f) (vii) and (viii) of the Re-Amended Grounds. As for facilitating sales to third parties, such parties are set out at paragraph 89 (3), (4), (7), and (9) of GLP’s Skeleton Argument. Save for the last, these are all about statements referring to the UK diagnostics industry. I have dealt with that allegation above. I fail to see how it could amount to State aid, since there is no reduction in State resources, apart from anything else. And if the Contracts themselves amounted to State aid these statements could hardly make a difference. The references in paragraph 89 (9) of GLP’s Skeleton have been dealt with in paragraph 476 above.
492. As for “laudatory public statements” the reference is found in paragraph 89 (1) of GLP’s Skeleton Argument. Emphasis is placed on Mr Destombes’ reference to the objective of creating “a UK Champion”. But again, if the Contracts are not State aid I fail to see how this can add anything.
493. There have been cases where a State has publicly announced forthcoming State aid in the future so that the State aid rules could be engaged at that point. See, for example, *Bouyges v Commission* EU:C: 2013;175. But that is not this case.
494. Thus this final allegation fails, too.

#### *Other Points*

495. I should add that in the Re-Amended Grounds, it was also said that there was State aid as a result of DHSC failing to require the repayment of State aid otherwise provided, itself as State aid. This makes no sense; if there is State aid I fail to see why there is a further breach by not requiring repayment thereof. And if there is no prior State aid, as it were (which is the case here) the point falls away.
496. Nor is there anything in DHSC is somehow giving more money to Abingdon than it was entitled to under the Contracts. The Settlement followed Ankura’s suggestions as to what was due or not. In any event, this is simply part of the resolution of a commercial dispute.

#### **Conclusion on State aid**

497. Accordingly, Ground 7 fails entirely. This means that all of the Grounds have failed.

## **STANDING**

### **Introduction**

498. Since none of GLP’s substantive claims have succeeded, this issue is academic. However, since the point has been fully argued and lest the case goes further, I should deal with it.
499. The standing of GLP was only challenged recently by DHSC, by means of an amendment made in the light of the observations of the Court of Appeal in *Public First*, referred to below.

## The Law

### Introduction

500. The starting point is, of course, Section 31(3) of the Senior Courts Act 1981 which provides that:

“No application for judicial review shall be made unless the leave of the High Court has been obtained in accordance with rules of court; and the court shall not grant leave to make such an application unless –  
(a) it considers that the applicant has a sufficient interest in the matter to which the application relates, ...”

501. Having regard to the relevant case-law, it seems clear to me that the question of sufficient interest, which of course goes to the court’s jurisdiction, is a multifaceted one. It involves (at least) consideration of the following factors:

- (1) The merits of the underlying claims;
- (2) The particular legislative or other context of the claim being made;
- (3) How, if at all, the claimant might be affected by the unlawfulness alleged;
- (4) The gravity of the allegations or findings made;
- (5) Other possible claimants; and
- (6) The position of the actual claimant.

502. The nature and extent of these factors, and how they are to work in practice, require some discussion.

### Merits

503. One might have thought that, as standing goes to jurisdiction, it would be sensible to deal with it at the outset, most naturally at the permission stage. After all, the context for the claim is known by then and if there is no standing, that disposes of the matter entirely even if the underlying claim was arguable.

504. However, the case-law does not support that approach. Generally, it requires leaving the question of standing over until some stage after the grant of permission - usually the main hearing itself or, occasionally, (as we shall see) at the hearing of a preliminary issue. See, for example, paragraph 77 of the judgment of Arden LJ in *Chandler v Secretary of State for Children, Schools and Families* [2009] EWCA Civ 1011 quoted in paragraph 511 below.

505. Indeed, that approach plainly emerged from the decision of the House of Lords in *IRC v National Federation of Self-employed and Small Business Ltd* [1982] AC 617. The claimant here sought to challenge a decision of the Inland Revenue to waive any claim for historic unpaid tax (which had been evaded) in the context of an agreement for tax collection going forward, in relation to 6,000 casual workers in Fleet Street. At an *inter partes* hearing on the question of leave (i.e. permission) the Divisional Court held that the claimant had no standing and dismissed the claim for that reason. By the time the matter came to the Court of Appeal, extensive evidence had been filed by the Inland Revenue demonstrating, according to it, that there was no conceivable case of unlawfulness anyway. The Court of Appeal did not enquire into the merits but held, assuming that they existed, that the claimant did have a sufficient interest. In the House of Lords, all their Lordships considered it unfortunate that the question of standing was effectively taken as a

preliminary point. It should have been heard within the context of the claim itself. That said, the individual judgments are somewhat nuanced, as Professor Craig has pointed out at paragraph 20-017 of his *Administrative Law* 8<sup>th</sup> Edition. Lord Wilberforce, Lord Fraser and Lord Roskill emphasised the fact that the underlying legislative context was such that there was no room for a party such as the claimant which was not a taxpayer affected by the decision-unlike, for example, ratepayers who were affected by unlawfulness on the part of rating authorities. On the other hand, Lord Diplock and Lord Scarman placed much more emphasis on the fact that the underlying claim was hopeless in the light of the evidence submitted by the Inland Revenue. As a result of this case, Professor Craig thought that to some extent the question of merits understanding had become “fused”, as it were.

506. Indeed, in the Divisional Court case of *World Development Movement Limited v Secretary of State for Foreign and Commonwealth Affairs* [1995] WLR 386, Rose LJ considered that “the merits of the challenge are an important, if not dominant, factor when considering standing” – see p395G.
507. Equally, in *Runnymede*, the Divisional Court considered that sometimes standing will be closely connected with the legal and factual merits of the claim - see paragraph 17 of its judgment.
508. Since I have found no merit in any of the underlying claims, it might be said here that this is a short answer to the question of standing: there is none in the circumstances. Perhaps unsurprisingly, neither side took that point, since it could not be said at the stage of submissions what the ultimate outcome would be. Nor can I be confident that the question of merits is always such a powerful factor that if the relevant claims fail, it necessarily follows that there was no standing, as opposed to that question now merely becoming academic. So I do not base any decision here on the merits as such. However, what is clear is that the context of the claim is highly relevant. I turn to that now.

#### *The Particular Legal Context*

509. Neither side suggests that context is irrelevant. Moreover, GLP does not deny that in the context of a public law claim alleging unlawfulness under the PCR, the obvious and “natural” claimants would be the economic operators whose interests are the subject of the PCR.
510. However, that does not mean that a person other than an economic operator can never be a public law claimant here.
511. In *Chandler* itself, a claim concerned with the earlier 2006 PCR, the question of the claimant’s standing was decided, along with the merits of the claim. At first instance, the judge had held that there was no substantive claim and also that the claimant had no standing. The Court of Appeal upheld that decision. It follows that its observations on standing was strictly unnecessary and therefore *obiter* but they have often been quoted in subsequent cases and I set them out here:

“77 Forbes J...accepted the submission that a failure to comply with any of the 2006 Regulations gives rise only to a private law claim. Such a conclusion has potentially far-reaching implications. It means that a person who is not an economic operator entitled to a specific remedy under regulation 47 can never bring judicial review proceedings in respect of that failure unless he can bring himself within the exceptional type of claimant in the Law Society case. We consider that the judge’s proposition goes too far. The failure to comply with the 2006 Regulations is an unlawful act, whether or not there is no economic operator who wishes to bring proceedings under regulation 47, and thus a paradigm situation in which a public body should be subject to review by the court. We incline to the view that an individual who has a sufficient interest in compliance with the public procurement regime in the sense that he is affected in some identifiable way, but is not himself an economic operator who could pursue remedies under regulation 47, can bring judicial review proceedings to

prevent non-compliance with the 2006 Regulations or the obligations derived from the Treaty, especially before any infringement takes place:... He may have such an interest if he can show that performance of the competitive tendering procedure in Directive 2004/18 or of the obligation under the Treaty might have led to a different outcome that would have had a direct impact on him. We can also envisage cases where the gravity of a departure from public law obligations may justify the grant of a public law remedy in any event...

78 However, in this case the observations of Richards J in *Kathro's* case are particularly apposite. Ms Chandler states in her witness statement that she is sceptical about academy schools. She fears that they select the most gifted children as pupils. She is concerned that academy schools are run more like businesses than schools. Her first choice would be for her children's school to be run by the local education authority. What Ms Chandler wants to happen is that there should be a competition to determine who should run the new school in Camden and she suggests that she should have the right to be consulted if the public procurement regime applied. In fact there would be no consultation of the kind she seeks. Ms Chandler is not challenging the Secretary of State's decision because of any interest that she has in the observance of the public procurement regime but because she is opposed to the institution of academy schools. She is thus attempting, or seeking, to use the public procurement regime for a purpose for which it was not created. In all the circumstances, it would, in our judgment, be outside the proper function of public law remedies to give Ms Chandler standing to pursue her claim."

512. While not seeking to read paragraph 77 as if it were a statute, especially as it is strictly *obiter*, one can see that, at least, in the two exemplar cases, the Court of Appeal thought that a non-economic operator might have standing. The first is where they were affected in some way and the second is where the relevant breach was grave. The latter observation probably means where the breach, as found, is grave, rather than as alleged.
513. In *Unison v NHS* [2012] EWHC 624, Eady J dealt out a preliminary stage with standing and delay. He found against the claimant on both. On standing he considered that the claimant could show neither that it had been affected by the breach nor that it had the quality of "gravity".
514. In *Wylde v Waverly BC* [2017] PTSR 1245, the question of standing was considered as a full preliminary issue. Dove J held that a key issue was the legislative context which was again, the PCR. He considered that this regime was such that the availability of a public law claim to a non-economic operator should be strictly confined to those who "can show that performance of the competitive tendering procedure... Might have led to a different outcome that would have had a direct impact on him". He then found that it would be difficult here to show that any competitive tender would have produced a different outcome. Second, the claimants could show no direct impact. At paragraph 44, he said:
- "Far more centrally in relation to the issues which arise in respect of standing, these claimants are unable to demonstrate any direct impact upon them which would arise from the conduct of a competitive tendering exercise. Not only are they not economic operators, but they are not remotely approximate to any economic operator, nor could they begin to demonstrate any interest in the procurement process which might be akin to or a proxy for status as an economic operator. Whilst, therefore, I have no doubt that the concerns and objectives of the claimants are entirely genuine and expressed by them in the public interest, that observation, and their interest as either council tax or rate payers or as members of local authorities, are not sufficient to establish that they were within the Chandler test and thus they do not have standing to bring this claim."
515. It is worth adding that Dove J did not consider the question of "gravity". I apprehend that this was not because he did not have it in mind, but because it was not one relied upon by the claimants as an alternative basis for standing.

#### *Effect on the claimant*

516. Little more needs to be said about this factor. It is clearly relevant. Further, in the current context, it is not suggested that GLP was affected by the alleged unlawfulness any more

than any other member of the public (as distinct from economic operators who may have such a claim).

### *Gravity*

517. For my part, I would not reject the ability of a putative non-economic operator to argue “gravity”, even in the PCR context. But of course, by itself, it would not be determinative.
518. Again, in my judgment, this is another way of showing a basis for standing. In *Unpublished Contracts*, Chamberlain J found that the breaches alleged (indeed as found by him) related to contracts worth billions of pounds and the failure to notify any of them, a fundamental matter, was a deliberate policy on the part of DHSC.

### *Other Possible Claimants*

519. In the procurement context, and indeed the other public law claims raised here, there are parties who might be regarded as the obvious claimants, namely economic operators. In some cases, a factor in favour of standing has been said to be that while there were economic operators who could theoretically bring a claim, they were unlikely to do so because the outcome was speculative or it would be too expensive. See, for example, the observations of O’Farrell J in *Public First* at paragraph 180 and in *PPE* at paragraph 505. However, in my judgement, this point cannot be taken too far. Otherwise one would end up saying that the very fact that economic operators who were potential claimants decided, for whatever reason, not to litigate, would be sufficient to confer standing on someone else who was prepared to. Or at least that would be a strong factor in their favour. That cannot be right.
520. Moreover, such an argument runs against the approach taken by the Divisional Court in *Runnymede*. Here, there were two claimants, GLP and the Runnymede Trust. They contended that the government had a policy whereby people were appointed to important positions as part of its response to Covid, only if they had a political or personal connection to the decision-makers; also, the positions were unpaid. This was said to constitute indirect discrimination on grounds of race or disability and also a breach of the government’s Public Sector Equality Duty (“PSED”). The standing of each claimant was directly challenged by DHSC, among other things.
521. On the indirect discrimination claims, the Court held that neither claimant had standing. First, not all members of the public were equally affected. This was important because a “public interest” challenge is said to require the facts to be such that all members of the public were equally affected. In *Runnymede*, that requirement could not be shown because there were individuals directly and personally affected by the impugned policy who could have come forward. Second, the natural persons to bring a claim would be the ones with the protected characteristic put at a disadvantage. Third, practical considerations pointed against standing because the appropriate tribunal in which to bring such a claim would be the Employment Tribunal. The Divisional Court did not consider whether it was realistic to expect the “natural” claimants in fact to make a claim. It was enough that they were “out there”.
522. And after all, in our context, if there had been an economic operator willing to litigate, then the whole issue of standing would disappear since there would now be a claimant who clearly possessed it.
523. In my view, therefore, and consistent with *Chandler* and *Wylde* the Court should concentrate more on the question of the effect on the actual claimant or gravity, than on why the natural claimant did not in fact litigate. That is, unless, the claimant was bringing an “associational” claim, that is to say where it is suing on behalf of its members or a

“surrogate” claim on behalf of others who may not be well placed to bring it. See paragraph 20 of *Runnymede*. GLP does not contend that it brings either of those claims, rather it is a “pure” public interest claim. I, of course, accept that the question of the absence of claims brought by the “natural” claimants is not wholly irrelevant.

524. Where it was thought to be particularly relevant was in the Court of Appeal decision in *Child Poverty Action Group v Social Services* [1990] 2 QB 540. Here, the claimant sought judicial review in relation to the fact that there were insufficient adjudication officers made available to deal with individual benefit entitlements, therefore causing delays in payments to those who should receive them. For the purpose of the appeal, the defendant did not in fact dispute standing although it reserved its position should the matter go further. However, in the course of dealing with the claim, which the Court of Appeal rejected, Lord Woolf LJ said that the application had been made by the CPAG because it raised important issues of social welfare which were not ones which individual applicants for supplementary benefit could be expected to raise. Moreover, the CPAG played a prominent role in giving advice, guidance and assistance to such claimants. I see the force of those points in that case, albeit that standing was not strictly in issue, and I note that the Divisional Court in *World Development Movement* referred to this passage. However, it seems to me that this is a very long way from the facts of the case before me.

#### *The Position of the claimant*

525. Neither side disputed that this is of some relevance. For example, it is well-accepted that if the claimant is a mere “busybody” or has some form of ulterior motive in the outcome (see paragraph 78 of *Chandler*, quoted above), this can be enough to disqualify them. Usually, however, the claimant’s own position is not considered in a vacuum it has to be assessed in the context of the case as a whole.

#### *Other Points*

526. First, what the above factors show is that the question of standing is acutely case-sensitive. That is especially important where, as here, the claimant is an organisation which has brought many claims. The fact that it may have standing in one, does not mean automatically that it has standing in another.
527. Second, neither party disputes that the mere fact that there is a public interest in the issue to be litigated does not inevitably mean that the actual claimant has standing. An allied point is that the fact that the actual claimant brings the claim sincerely does not itself confer standing.
528. Third, some recent cases questioned standing (one can put it no higher than that) in the sort of procurement cases brought by GLP. I start with *Runnymede*, which at paragraph 54 conveniently sets out the relevant observations of the Court of Appeal in *Public First*:

“Mr Coppel points out that in several cases which have now come before the courts, it has been recognised that the Good Law Project does have standing: e.g., *R (Good Law Project Ltd) v Secretary of State for Health and Social Care* [2021] EWHC 346 (Admin)... per Chamberlain J at paragraph 104. We consider that caution needs to be exercised in relation to such dicta in the light of the judgment (delivered after the hearing in the present case) in *R (Good Law Project Ltd) v Minister for the Cabinet Office* [2022] EWCA Civ 21, on which we received written submissions from the parties. At paragraph 6 of his judgment, Lord Burnett of Maldon CJ said: “No challenge or complaint was ever raised to the award of the contract by any potential competitor of Public First. The judge held that Good Law had sufficient standing to bring proceedings for the purpose of section 31(3) of the Senior Courts Act 1981 and rely upon the Regulations, as might a commercial entity which considered that it had been deprived unlawfully of the opportunity to bid for the contract. She also concluded that Good Law had standing to mount the public law challenge based on apparent bias despite having no interest in the letting of the contract. The Minister has not appealed that part of the judge’s decision. It was based, so far as concerns the Regulations, on the obiter dicta



of this court in *R (Chandler) v. Secretary of State for Children, Schools and Families* [2009] EWCA Civ 1011 at [77] and [78]. They were summarised in *R (The Good Law Project Limited and others) v. Secretary of State for Health and Social Care* [2021] EWHC 346 (Admin) by Chamberlain J at [99]. The arguments on standing below did not distinguish between the claim based on the Regulations and the public law challenge based on apparent bias. The question of standing for complete strangers to the procurement process with no commercial interest both under the Regulations and on public law grounds is a question ripe for review when it next arises.”

529. That view was repeated in *GLP v Pharmaceuticals Direct* [2022] EWCA Civ 355. This was an appeal from an interlocutory decision of O’Farrell J concerning late or defective service of a claim form for judicial review and an application for retrospective authorisation of service at an alternative place. At paragraph 70, Carr LJ observed thus:

“70. Further, I do not consider the public interest factor relied upon by Good Law to be an independent compelling reason in favour of granting the application... The court at this stage does not embark on an assessment of the merits of the claim. Amongst other things, the SSHSC raises a serious challenge to Good Law’s standing to bring the claim, alongside his substantive defences. The question of whether Good Law had standing to bring judicial review proceedings, albeit not in a procurement context, was answered in the negative very recently by the Divisional Court in *R (Good Law and another) v The Prime Minister and another* [2022] EWHC 298 (Admin). In the procurement context, whether or not a complete stranger to the procurement process with no commercial interest (such as Good Law) has standing was described as “ripe for review when it next arises” (see *R (on the application of the Good Law Project) v Minister for the Cabinet Office* [2022] EWCA Civ 21 at [6])...”

530. Fourth, and particularly in the context of the Ground 2 claim, GLP relies on the fact that in a number of cases (including this one) GLP was granted a costs-capping order (“CCO”). In this regard, s88(7) of the Criminal Justice and Court Act 2015 sets out the elements of “public interest proceedings” which have to be shown as a precondition to the making of a CCO, namely:

“(a) an issue that is the subject of the proceedings is of general public importance,  
(b) the public interest requires the issue to be resolved, and  
(c) the proceedings are likely to provide an appropriate means of resolving it.”

531. The fact that this requirement has been satisfied is invoked to say that particularly in the PCR context, it would be wrong to limit challenges to those where the claimant was directly affected or grave cases. However, I do not see that this follows, especially as the question of standing is supposed to be decided at the main hearing or at least not at the very outset. The question of standing is a separate matter and needs to be examined in its own right at the relevant time.
532. Against that legal background I consider the question of GLP’s standing by reference to each of the claims.

## **Ground 2**

533. First, it cannot be said that GLP was affected in any tangible way by the award of the Contracts. This is especially important in the context of Ground 2 where there is a clear “scheme”, designed, essentially, to protect economic operators.
534. That then brings one to the fact that there has been no claim brought by economic operators. In this context, I need to refer to the witness statement of Mr Mico. He is the Managing Director of Covid projects at BDX. He says that his company had a platform similar to an LFT. He says that had its offer of help to the government been taken up, it could have very significantly helped to reduce many of the worst impacts of the pandemic. His company did not challenge DHSC's conduct in relation to the contracts, however, because the lack of information would have made such a challenge impracticable. Also the legal costs would have been too much. I see that, but this does not mean that a larger economic operator (and

many of the putative economic operators here were very substantial companies) could not have brought such a claim if they wished to do so. Certainly, some operators made complaints at the time about what they saw as a preference for Abingdon. As already noted, it is not as if GLP is acting as a surrogate for operators like Bio-diagnostics.

535. For the reasons already given, while the failure to litigate by the economic operators is of some relevance, I do not think that it is of substantial weight here. And as already noted, it is not as if the Divisional Court in *Runnymede* looked into why the obvious claimants for indirect discrimination did not in fact bring their claims. Insofar as that approach is inconsistent with that of O’Farrell J in *Public First* and *PPE*, I would respectfully suggest that the former is now to be preferred over the latter.
536. As for gravity, this was not a case of contracts involving billions of pounds deliberately not being publicised. Nor does this claim deal with something as fundamental as the basic obligation to notify the public, not just economic operators, of the existence of the contracts - see *Unpublished Contracts* at paragraphs 102 and 104. It concerned a single operator in contracts worth in the end around £15m. I do not consider that this was a “grave” claim for the purposes of standing. I should add that in this regard at least, GLP appears to accept that the question of gravity does have to be measured against the findings in relation to the claim. At paragraph 44 of her WS, Ms Abbott states that the Court’s assessment of whether the breaches in issue were grave would depend on its findings on the substance of the case. If the grounds of challenge or even some of them were made out it would follow that very significant sums of money had been spent on the basis of serious and significant breaches of legal obligation. That, in the event, is not what I have found.
537. As for the position of GLP itself, I deal with all of the submissions which it makes here in the context of Ground 2, even though it has emphasised those matters in connection with grounds 5, 6 and 7. Its submissions really go to all of the claims.
538. As to this, GLP makes, and has in the past made, some general points about its status and function in relation to this type of claim. Such general points were first considered, and rejected, by the Divisional Court in *Runnymede*. Because it is so relevant, I should set out its finding in full:

“55. In the present case, the question of the First Claimant’s standing is a live issue and so we will address it in more detail than appears to have occurred in other cases. The Good Law Project Limited (GLP) is a private company limited by guarantee. At the request of the Court, we have been provided with the Articles of Association which were adopted on 24 July 2018, by a special resolution. The date of that resolution is also recorded as being 27 July 2018 but that may simply be a typographical error. The resolution was passed by Mr Jolyon Maughan “being the sole person entitled to vote on the resolution on the circulation date”. Article 3 of the Articles (‘Objects’) simply provided that:

“The Company is established for the purposes expressed in the Memorandum of Association.” This Court has not been provided with a copy of that Memorandum of Association, but it is cepted that the objects were not set out in the terms which they now are in the current version of the Articles which we have been shown.

56. We are told that the organisation was still in its infancy in 2018, when the first set of Articles were drafted, and they did not in fact define its objects. Those were the Articles which were in place at the time when this claim was first issued. The current set of Articles were drafted during 2021. They were approved by the GLP Board on 30 November 2021 and were formally adopted on 15 December 2021 (coincidentally, that was the final day of the hearing in this court). The Articles were registered at Companies House on 20 December 2021. Those Articles define the objects of the GLP as follows:

“2.1 to provide the sound administration of the law and to challenge injustice and inequality;

2.2 to uphold democracy and promote changes to the law and public administration with the aim of improving social justice, equality and inclusion;

2.3 to uphold high standards in public administration in accordance with democratic principles;

2.4 to enable and promote access to justice and the law, particularly for those whose access is curtailed because of poverty, social or economic disadvantage or discrimination;

2.5 to protect and preserve the environment for benefit of mankind now and in the future;

2.6 to advance education and research into good application and development of the law and of administrative practice;

2.7 to promote compliance with the law by public and private actors and to address imbalances of economic power in the application of the law; and

2.8 to further any other philanthropic or benevolent purpose ancillary to the above proposes.”

57. No individual, even with a sincere interest in public law issues, would be regarded as having standing in all cases. We do not consider that the position differs simply because there is a limited company which brings the claim. It also cannot be right as a matter of principle that an organisation could in effect confer standing upon itself by drafting its objects clause so widely that just about any conceivable public law error by any public authority falls within its remit.

58. In all the circumstances of this case, we are not persuaded that such a general statement of objects as is now set out in the GLP’s Articles of Association can confer standing on an organisation. That would be tantamount to saying that the GLP has standing to bring judicial review proceedings in any public law case. This can be contrasted with the approach which was taken by the Divisional Court in the case of *D*, where even a statutory authority (the Mayor of London) was not regarded as having a sufficient interest in the matter in issue in that case. It cannot be supposed that the GLP now has *carte blanche* to bring any claim for judicial review no matter what the issues and no matter what the circumstances.

59. In the circumstances of the present case we have reached the conclusion that the obviously better-placed claimant for judicial review for the purposes of the public sector equality duty challenge is the Runnymede Trust, an organisation which exists specifically to promote the cause of racial equality. We consider that the Runnymede Trust has standing to bring the public sector equality duty challenge, but the Good Law Project does not.”

539. As to all of that, GLP says that there is an important difference which is that the relevant claim in *Runnymede* was concerned with the government’s PSED, not the PCR as such. I do not consider that this is a relevant distinction. Both that claim and the one before me are, broadly, in connection with the award of contracts or posts by the government in respect of Covid-related matters. Another point made by GLP was that in reality, it was only denied standing in *Runnymede* because there was a better-placed claimant, namely the Runnymede Trust. The implication is that had the Trust not been a claimant at all, then GLP might well have been given standing. I do not agree. The point was that the Runnymede Trust demonstrated a sufficient interest which GLP did not. I fail to see how GLP could acquire a sufficient interest if the Trust was not there.
540. Next, in his WS, Mr Maugham KC says that GLP exists to bring public interest litigation concerned with “ensuring no one is left behind”, “the environment”, and “governance”. I regard these as very general aims. While they may not cover every public law claim, they would certainly cover a very large number of them and are too general, in my view, following the approach taken by the Divisional Court in *Runnymede*.
541. However, the matter does not end there because a set of further points is made by Ms Abbott in her WS. First, she says that the public procurement regime serves important public interests. I agree, but that in and of itself does not confer standing on GLP as opposed to a relevant economic operator. Second, she points to the fact that GLP has brought a number of claims in connection with the government’s Covid-related spending. It has been

able to do so because of the substantial amounts of money provided to it by crowd-funding and particular donors. I accept that this does at least show a particular interest in such matters which GLP has been keen to pursue. I also agree that by dint of this litigation experience, GLP might be said to have acquired particular insights into what may be described broadly as procurement-related claims. But such points only go so far where GLP has not itself been directly affected and where there is no surrogate or associational claim. Further, at least in this case, the significance of the Contracts was much attenuated by external circumstances in the end, namely the failure to answer the Immunity Question in the affirmative. Moreover, GLP's recent Covid-related claims failed entirely (ultimately) in *Public First*, almost all of them failed in *PPE* and in any event no declaratory relief was given in the latter, and the claims before me have failed. Accordingly, in this case, I think that only very limited weight can be attached to GLP's "experience and expertise" notwithstanding the relevance attributed to that factor on standing in *Unpublished Contracts*, *Public First* and *PPE*.

542. GLP further argues that even if not affected by DHSC's alleged unlawful conduct, it had "reasonable concerns" which should result in standing. It was not a mere busybody. Again, "governance" is relied on here which is very broad, as is the aim of "upholding democracy". Ms Abbott also refers to issues of unfairness and discrimination which have consequences for the general public. Indeed they do, but standing based on such general points as this flies in the face of *Runnymede*. She also refers to GLP's sincere interest in securing the accountability of government. I am sure that it has such an interest but again, without more, this is hardly sufficient to confer standing.
543. A further point is that GLP has produced content for newspapers. However, but much of this seems to have been generated in order to support its legal challenges. Mr Maugham himself has said that GLP exists to bring and support public interest litigation.
544. Accordingly, and for all the reasons set out above, I consider that standing has not been established in relation to Ground 2.

#### **Ground 5**

545. Here, of course, the PCR is not itself invoked. Nevertheless, context is important. In truth it is all about procurement and again there were (on GLP's case) economic operators who were potentially disadvantaged by DHSC's decisions.
546. In my judgment, all the factors militating against standing under Ground 2 apply here as well.

#### **Ground 6**

547. This involves, to some extent the provisions of the PCR. But overall, this makes no difference to the question of standing. Whether invoking particular PCR provisions or not, this is again very much a procurement-related matter where it cannot be said that all individuals were affected equally.
548. Again, and for all the reasons stated above, I would refuse standing here.

#### **Ground 7**

549. Finally, as for State aid, this is again a case where the "natural" claimant would be a commercial undertaking which had not received the State aid, not GLP. Moreover, this is an area of law where there is a defined mechanism for making a complaint to the Commission which it may act upon, or where it acts on its own. Neither of these have happened here.

550. Otherwise, again, I see no reason to take a different view of standing here from that taken in relation to the other Grounds.

**OVERALL CONCLUSION**

551. All of the claims must therefore be dismissed. I am most grateful to Counsel for their very helpful written and oral submissions.