Witness Name: Dame Catherine Bingham

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Dated: 4 October 2024

**UK COVID-19 INQUIRY**

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**FIRST WITNESS STATEMENT OF DAME CATHERINE BINGHAM**

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I, **DAME CATHERINE BINGHAM**, will say as follows:

## 1. Introduction

1.1 I make this witness statement in response to the request for evidence made of me by the UK Covid-19 Inquiry dated 6 December 2023 ("the Rule 9 Request").

1.2 Pursuant to the Rule 9 Request I have been asked to address various matters relating to the work of the Vaccine Task Force ("the VTF") during the COVID-19 pandemic ("the Pandemic") and my involvement with the VTF.

1.3 I have prepared this statement with the assistance of the Government Legal Department ("GLD"). I make this statement on the basis of my own personal knowledge, as refreshed by documents which have been made available to me following searches undertaken by GLD and the UK Health Security Agency ("UKHSA"). Much of it is drawn from a book by me, The Long Shot, published in 2022, which contains a more detailed account of these events.

## 2. Background

2.1 I graduated from Oxford University with a First-Class degree in Biochemistry. Following university, I worked as a management consultant at Monitor Company

between 1987 and 1989. I completed my Master of Business Administration at Harvard Business School, graduating as a Baker Scholar in 1991. From there I joined the venture capital and private equity group Schroder Ventures, out of which my venture capital biotech part was created, now called SV Health Investors ("SV"), where I specialise in building and investing in biotech companies. I remain a Managing Partner at SV.

2.2 My husband, Jesse Norman, has been a Member of Parliament since 2010, and served as Financial Secretary to HM Treasury from 2019 to 2021. However, I am not and never have been political, and have no political aspirations.

2.3 Between 16 May 2020 and December 2020, I served as Chair of the VTF.

## 3. Establishment of the VTF and the VTF External Advisory Board

3.1 I believe that the VTF was established in March 2020 by the Government's Chief Scientific Advisor ("CSA"), Sir Patrick Vallance. Sir Patrick believed that the Government needed to create a dedicated team of officials, separate from the Department of Health and Social Care ("DHSC"), that was focused on procurement, development and manufacturing of COVID-19 vaccines [see **Exhibit CB1/01 – INQ000065356**].

3.2 The VTF was established through the Department of Business Energy and Industrial Strategy ("BEIS"). It was initially made up of a small team of BEIS Civil Servants led by Alexandra ("Alex") Jones, Director of Science, Research and Innovation. The team had little expertise in the pharmaceutical industry or knowledge of recent advances in vaccine development. Nor did they have close relationships with vaccine companies. To address these gaps, Sir Patrick established a VTF External Advisory Board, of which he would be Chair, to assist him and the BEIS team. The VTF External Advisory Board was comprised of experts from academia and industry who met with the BEIS team every 2 weeks on a video call. On 1 April 2020, Alex Jones asked if I would be willing to be a member of the Board. I understand that it was Alex Jones who had included my name on the list of potential members of the External Advisory Board and that Sir Patrick had approved my nomination.

3.3 I had known Sir Patrick since 2006 when he was leading the Research and Development Team at GlaxoSmithKline ("GSK"). At SV, I had helped create two

new neuroscience companies based on GSK assets when GSK closed their neuroscience operations in 2010. Sir Patrick supported these spinouts.

3.4 In addition, in 2015, GSK were one of the founding investors to create the world's first venture capital fund - the Dementia Discovery Fund ("DDF") - focused on creating and building biotech companies developing new disease-modifying treatments for dementia and Alzheimer's disease. SV manages the DDF and Sir Patrick was a founding member of the Fund's Scientific Advisory Board.

3.5 Sir Patrick has deep expertise in vaccine technology and through working with me, knew that I was experienced in creating new biotech companies developing innovative drugs and building new teams to drive this.

## 4. Launch of the VTF and my Appointment as Chair

4.1 The VTF was officially launched by the Business Secretary, Alok Sharma, on 17 April 2020. Originally it was led by Sir Patrick and the Deputy Chief Medical Officer ("DCMO") for England, Professor Jonathan Van-Tam.

4.2 It became apparent to me as a member of the VTF External Advisory Board that the UK would benefit from a dedicated team within Government populated by professionals with industry experience, to coordinate the end-to-end process of vaccine development from discovery, through clinical trials to distribution, including both domestic and international sourcing and licensing. This was a view shared by Sir Patrick.

4.3 On 5 May 2020, I was asked by the Health Secretary, Matt Hancock, if, at the request of the then Prime Minister, Boris Johnson, I would be willing to accept the full-time position of Chair of a revised VTF to be led by industry experts. I was surprised to be offered the role of Chair and consulted my family and various experts in the field, including Sir Patrick himself.

4.4 The following day I informed Matt Hancock that I would accept the post subject to the following conditions:

- that I would have a clear mandate, with a direct reporting line to the Prime Minister;
- that I would be located within BEIS with rapid decision-making;

- that I would be able to establish a dedicated budget across Government with timelines;

- that I would have a six-month term of office; and

- that I would sign off all communications in advance.

4.5 I am not aware precisely how the process operated that led to me being selected as VTF Chair, but I believe that it was a decision largely made by the Prime Minister. I understand that there had been a process within Whitehall whereby a broad list of names, of which I was one, was considered and reviewed. I also understand that there was no formal open selection process for this temporary unpaid advisory position.

4.6 I knew the Prime Minister, who was at university with me. My mother's first cousin is married to his sister Rachel, who joined my year at school in the sixth form. However, whilst our paths had crossed, I would not describe my relationship with the Prime Minster as very close.

4.7 On 6 May 2020, having met with Alok Sharma, I spoke with the Prime Minister who informed me that the three objectives of the VTF were:

(i) to secure vaccines for the UK;

(ii) to ensure that vaccines were distributed equitably around the world; and

(iii) to make the UK more resilient in dealing with a future pandemic.

He was right to emphasise that we needed to work quickly, and that speed was of the essence – people were dying every day. The Prime Minister wanted the VTF to help develop and agree a wider long-term UK vaccine strategy, to include a broad UK biotherapeutic and vaccine manufacturing capability, so that the UK was prepared for future potential pandemics.

4.8 During those conversations the Prime Minister also told me he wanted the UK to be at the forefront of vaccine research & development ("R&D"), manufacturing and supply globally, and that he hoped that any successful first vaccine would "have a British flag on it". I told the Prime Minister that my task was to source and develop a safe and effective vaccine, wherever it originated from, that the chances of success were small but that he was nevertheless right to create the VTF which

needed to invest funds up-front *at risk* – that is, before we knew which, if any, vaccine was safe and effective – if we wanted to have any vaccines available as soon as they might be approved by the Medicine and Healthcare products Regulatory Agency ("MHRA").

4.9 On 15 May 2020, I received my official letter of appointment from Sir Mark Sedwill, the Cabinet Secretary, **[Exhibit CB1/02 INQ000069537]**. This largely reflected the conditions I had laid out and agreed with Matt Hancock. I was unpaid.

4.10 My role was to set the strategy for the VTF, build the team and empower them to deliver on the priorities set by the PM. The VTF would have the authority to make deals through the Civil Service directly with the vaccine and manufacturing companies, with large spending decisions taken by a Ministerial Investment Committee, or and smaller spending decisions taken by BEIS officials. The Business Secretary was accountable to Parliament for the work of the VTF and the funding associated with it.

4.11 Before my appointment was finalised, there was a detailed process to explore any possible conflict of interest. This included an examination by Karen Perry of the Department of Health and Social Care ("DHSC"), signed off by the Cabinet Office, of all my activities in companies and SV funds which might conceivably cause a conflict of interest. I completed a detailed BEIS conflict of interest declaration, which I updated during my tenure **[Exhibit CB1/03 INQ000421910]**. The conflict of interests testing and evaluations before I was appointed was thorough and impressive. Following this exercise (and to free up my time), I stepped off the following boards and committees of which I was a member:

- Oxford University Spin-out Enterprise Management Advisory Board,
- Alchemab Ltd Board of Directors.

4.12 I did not have any on-boarding process at BEIS that I can recall.

4.13 I was not and am not involved in prophylactic vaccine venture capital investments. As part of my appointment, it was agreed that no fund managed by SV Health Investors would be investing in COVID-19 vaccine companies while I was at the VTF. At the time SV managed a publicly listed investment trust – International Biotechnology Trust Limited ("IBT"). To comply with the restriction, SV paused any vaccine investments/divestments from IBT during 2020 and for 12 months after I

left the VTF. This restriction was potentially financially damaging to this public fund and its investors since the vaccine stocks represented a material component of the Nasdaq Biotech Index ("NBI") in 2020-2021. With this restriction IBT would not be able to balance its holdings in these stocks to retain its position of market neutrality. This is in fact what took place.

4.14 As far as I am aware, everyone in the VTF was subject to the same conflict of interest review. No one was involved with any COVID-19 vaccine companies.

4.15 As Chair of the VTF, I reported to the Prime Minister and we operated within BEIS, though given the restrictions then in place, in practice we worked virtually for much of the time. Whilst I reported to the Prime Minister I did not, in truth, have a great deal of interaction with him. I never had any reason to doubt the independence of the VTF and this was never a matter that was raised with me.

4.16 I spoke to Alok Sharma most weekends to update him on the progress of the VTF and joined him for COVID-O meetings chaired by Michael Gove and occasionally for meetings chaired by the Prime Minister. I also spoke to Nadhim Zahawi who was Parliamentary Under Secretary at BEIS with responsibilities in life sciences. I would also exchange periodic text or WhatsApp messages with the Prime Minister to let him know our progress. Throughout my tenure as Chair of the VTF, the Prime Minister offered me consistent and strong personal support. Given the lockdown restrictions, I mainly worked from home during my period as Chair of the VTF. We held 8-10am Steering Group meetings on Mondays, Wednesdays, and Fridays on MS Teams. As other departments in Whitehall became interested in the VTF, they joined the Monday meetings. On Wednesdays, it would usually be just the Steering Group and one of two outsiders depending on the issue under consideration. On Fridays, we would review the progress that had been made to date and identify future priorities.

4.17 Apart from the rules as to conflicts of interest, I cannot recall being made aware of any separate code of conduct I was required to follow in the exercise of my role of Chair of the VTF, and none was mentioned in my discussions with the Cabinet Secretary, or my letter of engagement.

## 5. The VTF Members and Team

5.1 To deliver the Prime Minister's objectives, the VTF team needed both industrial expertise and skills in science, manufacturing, and clinical development together with the more usual areas of Civil Service expertise in Government processes for contracting, project management and diplomacy. In particular, we needed to bring to the table and leverage trusted, current relationships in the biotech, pharmaceutical and the bioprocessing industries.

5.2 In parallel to my appointment as Chair, Nick Elliott was appointed as Director General of the VTF. He was chosen by the Cabinet Secretary, Sir Mark Sedwill. Nick Elliott's background was in the military and, after working for a period for Network Rail, he had most recently been seconded to the Ministry of Defence as Deputy Director of Defence Equipment and Support.

5.3 My role was to appoint the industry experts while Nick built up the Whitehall leadership team that would deal with the Government and make sure that everything the VTF did was legally and procedurally correct. Together we built the leadership team which we named the Steering Group.

5.4 Dr Clive Dix contacted me in early May 2020 to ask if he could volunteer his services and act as my deputy. I had known Clive for a number of years having backed him successfully as CEO in two of my biotech companies. He has vast experience in the fields of biotechnology and pharmaceuticals, is intelligent, well connected and has considerable scientific and financial acumen. I considered that Clive was the ideal person to bring together a small team of experts to identify the most credible vaccine candidates and to help advise me on the broad VTF strategy.

5.5 Appointed as my deputy, Clive quickly recruited a highly skilled and competent team of individuals with proven technical and industrial expertise to assist him in conducting due diligence and prioritisation of the most promising vaccines. Clive identified people from industry with a current and in-depth knowledge of how the pharmaceutical industry worked, and with the personal connections and goodwill that we thought were required for the task. This was the team that prioritised and recommended the vaccine portfolio for the UK.

5.6 Ian McCubbin was the head of the BIA Bioprocessing Group. He had been asked by Sir Patrick Vallance to join the VTF External Advisory Board. Given his long and

impressive career in advanced medicines manufacturing and his close relationships in the industry, I asked him to join the VTF Steering Group. His role was to build a team to oversee the scale-up and manufacturing of the vaccines, ensuring we had all the skills, equipment and supplies needed for the population-scale vaccines.

5.7 Dr Giovanni Della Cioppa was one of several members of the VTF due diligence team working under Clive to lead on clinical development issues. He had run clinical development for Novartis Vaccines and GSK Vaccines based in Italy. We needed someone with expertise in running industrially sponsored vaccine clinical trials and a track record in securing approval of novel vaccines from global regulators, and Giovanni brought that deep experience.

5.8 Steve Bates was the CEO of the Bioindustry Association. Steve spearheaded the BIA's bioprocessing capability review in early 2020 which led to the remarkable collaboration of UK Bioprocessing companies/academic and other contract development and manufacturing groups in February 2020 who were ultimately responsible for the scale up of covid vaccines in the UK. Steve joined the VTF Steering group to provide broad industry input and advise on the UK's pandemic resilience plans.

5.9 Divya Chadha Manek was Head of Business Development at the National Institute for Health Research ("NIHR") with strong relationships with pharmaceutical and vaccine companies who ran clinical trials in the UK. We needed someone with coal-face experience of recruitment and delivery of UK clinical trials on vaccines, so I asked that she take the lead on clinical trials for the VTF, recruiting additional support where necessary.

5.10 Madelaine ("Maddy") McTernan joined us from UK Government Investments ("UKGI") to be our chief commercial and legal negotiator and deal-doer. Maddy would lead legal contracting once Clive and the industry team had shaped out the scope of the proposed deal with each vaccine company. Maddy brought strong general experience in both the private and public sectors and built a small team in house to support her, as well as external legal counsel (primarily Stephen Reese from Clifford Chance).

5.11 Ruth Todd took the lead for VTF delivery and project management. She had worked with Nick Elliott at the Ministry of Defence. Ruth was also responsible for

the security of the entire VTF operation and worked closely with the security services and military intelligence to make sure that the UK's vaccine work was not hacked and to identify potential threats to the UK's vaccine supply. Ruth has an impressive background in running factories, programme management and delivery. Ruth built and led the VTF's programme management activity and team and was the interface between the VTF and DHSC who were responsible for deployment.

5.12 Tim Colley, a former diplomat, was appointed as the VTF lead working with countries around the world, dealing with our international intergovernmental and NGO relationships. He took on the international aspects of the VTF's agenda and had a small team working with him.

5.13 Dan Osgood, a senior BEIS Civil Servant was brought onto the VTF Steering Committee to help manage the BEIS team and to prepare the business cases.

5.14 Professor Jonathan Van-Tam was an outstanding advocate for the VTF and acted an interface between the VTF and DHSC.

5.15 In total, the Steering Group comprised of myself (Chair), Clive Dix (Deputy Chair), Nike Elliott (Director General), Ian McCubbin, Steve Bates, Divya Chadha Manek, Ruth Todd, Tim Colley, Maddy McTernan, Jonathan Van-Tam and Dan Osgood.

5.16 Senior members of the VTF were supported by a number of Civil Servants from BEIS. Each member of the Steering Group had a clear task. We did not have lots of subcommittees, but each Steering Group member was empowered to build the resources to enable them to deliver their objectives. By the end of my period as Chair of the VTF, I understand there were more than 150 people operating across the whole VTF team.

## 6. The Role and Goals of the VTF

6.1 The role of the VTF, as laid out by the Prime Minister, was to secure and deliver the best potential vaccines for the UK, to ensure that vaccines were distributed equitably around the world, and to help develop the UK's vaccine plans to improve future pandemic resilience.

6.2 In June 2020, I wrote and circulated seven headline goals for the VTF [see **Exhibit CB1/04 INQ000503508**] to achieve by the end of the year when I would be leaving

my role as Chair. These reflected the Government's known priorities of the time, and were discussed and agreed with BEIS Civil Servants and the Steering Group. Behind each of these seven goals were a page of measurable targets since I thought it would be helpful to have some quantified goals to help assess whether and to what extent the VTF had met its goals in 2020:

- Procure rights to a diverse range of vaccines which have the potential to vaccinate safely to protect the high-priority populations in the UK by the first half of 2021.

- Establish robust supply chains where necessary to ensure there is sufficient supply for the high-priority populations by the first half of 2021; build plans for longer term supply.

- Provide funding for all prioritised vaccine clinical trials to be run through NIHR with industrial scale diagnostics and MHRA regulatory support to enable rapid demonstration of clinical safety and efficacy in the high-priority populations. Ensure the pharmacovigilance systems are in place for long-term clinical follow-up of everyone vaccinated.

- Develop and evaluate detailed operational plans with DHSC for deployment as soon as a vaccine becomes available.

- Collaborate with other countries (where appropriate) to improve access to develop, supply and distribute the most promising vaccines internationally to low- and high-income countries.

- Establish long-term vaccine strategy plans to prepare for future pandemics within the long-term industrial strategy for life sciences.

- Educate and inform Government, Parliament and commentators about COVID-19 vaccine development, challenges and the science involved.

## 7. Vaccine Preparedness of the UK in Early 2020

7.1 COVID-19 was the seventh outbreak of a pandemic in the twenty-first century. Covid-19 had been preceded by SARS in 2002-3, H5N1 bird flu in 2004, H1N1 swine flu in 2009, MERS in 2012, Ebola in 2014-16 and Zika in 2015-16. There were a number of factors that stopped those outbreaks being as devastating as

Covid 19: poor infectivity (MERS), a relatively low fatality rate (swine flu) or a swift co-ordinated international response (SARS).

7.2 The previous outbreaks had led to increases in new vaccine technologies and scientists had developed vaccine frameworks to progress against SARS and MERS. These were then modified to use against COVID-19.

7.3 However, there was no apparent Government plan for the vaccine response to 'Disease X', as the World Health Organisation had described, this is a potential unknown pathogen capable of causing a disease epidemic. By 2020 the DHSC's expertise and plans in the vaccine field were narrow and constrained. As far as I understood, these plans were based too much on influenza models that offered little insight into the consequences of asymptomatic transmission of a virus about which we knew very little.

7.4 It appeared that successive Governments had failed to build or maintain relationships with innovators and key companies in the vaccine field – and it was clear to me that building relationships with innovators and vaccine companies was not a Government/Whitehall priority, if it ever had been. In fact, the reverse was the case. There was a general suspicion of industry within the Civil Service. The resultant lack of any real planning, industry relationships and skills were why the VTF had to be established at such short notice.

## 8. Identifying the Best Vaccines

8.1 We worked quickly to identify and then procure the best potential vaccine candidates. However, the scale of the challenge facing us was not lost on me or the other members of the VTF. No vaccine had ever been successfully developed to combat any human coronavirus (and no vaccine had ever been successfully developed against SARS and MERS). Vaccines typically take several years to develop, and most vaccines don't secure regulatory approval – so success was far from certain. The most advanced vaccine formats in May 2020, namely adeno-based and messenger RNA ("mRNA") vaccines, had never been approved for any indication. We knew little about SARS-CoV-2, except that it caused COVID-19.

8.2 In my first VTF Expert Advisory Committee meeting on 3 April 2020, I had asked the vaccine experts for their assessment of the likelihood of success of any COVID-19 vaccine. They told me that it was only 15% likely in each case that any vaccine

would prove effective, and then only if the vaccine was already in clinical trials. For preclinical vaccine candidates, the odds shrank to ten per cent or lower. This is similar to the success rates of new therapeutics.

8.3 Nor did we know the level of protection that could be achieved from a successful vaccine. Even if a vaccine worked there was a likelihood that, as with an average flu vaccine, it might only protect half its recipients from infection. The likely duration of the effectiveness of any successful vaccine was also unclear, especially if the virus was to mutate rapidly.

8.4 In spite of these facts, I believe that the message of how unlikely a vaccine was to succeed was not well understood within Government or some individuals within the medical profession in the Spring of 2020. Too many scientists and doctors had been paraded before the media in March and April 2020 raising false hopes as to how likely we were to secure a successful vaccine against COVID-19.

8.5 Naturally occurring vaccines have been used for centuries in different contexts, but it has typically taken many years, if not decades, to create a successful new vaccine. We could not wait years for vaccines to be developed. Fortunately, recent innovations offered quicker and more efficient ways to make vaccines.

8.6 The assessment and management of drug development risk in the life sciences had been at the core of my professional life in venture capital for the past 30 years. Since most new drugs fail, and given this experience I was comfortable with the concept of taking risk in investing in experimental ideas and innovations.

8.7 Given my long experience in the industry, as well as Clive Dix's, I felt that we had strong personal networks across the key players in the pharmaceutical and biotechnology sector in the UK, the United States, Europe and around the world.

8.8 However, when I began work as Chair of the VTF in May 2020 I discovered that the VTF officials in BEIS had already handed over responsibility for surveying the vaccine landscape and making vaccine recommendations to a high-profile management consultancy firm. This company had no specialist expertise in vaccines discovery, development and manufacturing. As VTF Chair, I told Nick that this was a task that could not be outsourced to people without the relevant expertise and relationships; it needed to be performed by the VTF industry experts that Clive Dix was assembling – and that's what we did.

## 9. Co-operation with EU Countries

9.1 Prior to my being appointed chair of the VTF, President Macron of France had suggested that France, the UK, and Germany merge their efforts to acquire vaccines. I was provided with a note entitled 'COVID-19 EMA Pandemic Task Force' later to be called the 'Inclusive Alliance' or 'E3'.

9.2 When I became Chair of the VTF I was asked what I thought about the E3 proposal. I thought there were potential benefits: each of the three countries had headquarters of multinational pharmaceutical companies developing promising vaccine candidates and each had substantial capabilities for an end-to-end vaccine approach. But no country would be fully self-sufficient as matters stood, so a division of tasks could be valuable. Moreover, there was the commercial fact that all three countries – with a combined population of more than 200 million people – would wield more collective bargaining power with vaccine companies than the UK would alone.

9.3 However, there were also disadvantages to engaging with the E3. The proposal made by France was vague in a number of aspects, including how far each of the three countries would be allowed to pursue their own agendas as well as co-operating with other countries. It was also not clear how the EU or the UK Government would react to the proposal. We did not want to limit the VTF's ability to act independently, nor did we want to lose our agility by becoming subject to a clunky decision-making process.

9.4 The E3 proposal increased in scope to include Italy, the Netherlands and Norway. However, on 12 June the European Commission announced its own plans for €2.7 billion programme to fund COVID-19 vaccination development and procurement in the EU. This put an end to the expanded E3 proposal and put the Commission in charge of procurement for the EU bloc.

9.5 Brussels' conditions for the UK's participation in the EU's vaccine procurement programme were not attractive. As I told the House of Commons Public Accounts Committee on 11 January 2021, we were not able to join any decision-making on which vaccines to choose; we had to abandon the negotiations we either already had underway or had concluded with AstraZeneca; and we were not able to talk to future potential vaccine companies that the EU may have been or would be talking

to in the future. We felt that the conditions were too tight and that we would be able to act more quickly if we did it independently. This proved to be the case.

9.6 Unlike the political rhetoric, the VTF was cooperative with the EU throughout. For example, in late 2020, we sent a team of skilled manufacturing experts to the Halix plant in Belgium to support their scale up and improvement of yield of the AZ vaccine manufacture.

## 10. The Process for Identification of the Best Candidates

10.1 The first task for the VTF was to prioritise the best vaccine candidates from approximately 190 vaccine candidates around the world to build a portfolio of vaccines for the UK. We prioritised vaccines which we believed were most likely to generate high quality data that would convince the MHRA that they were safe, effective, that could be manufactured at population scales at speed, and that had the potential to be delivered to the UK by late 2020.

10.2 There are 4 main types of vaccine: whole virus vaccines; protein subunit vaccines; viral vector vaccines; and mRNA vaccines. The latter two types of vaccine were more recent innovations and in May 2020, when I started as Chair of the VTF, no adenoviral vector or mRNA vaccine had ever been approved for use. Whole virus vaccines and adjuvanted protein subunit vaccines were well established and widely used vaccine formats, but they were slower to develop as new vaccines at scale.

10.3 Clive Dix and I agreed that we should build a portfolio with the most promising vaccines representing each of the different formats, so that we could increase our chances of securing at least one successful vaccine. (This portfolio strategy is the same approach that I use in biotech venture capital investing). Should more than one vaccine work, the Government would then be able to offer the UK population a choice of vaccines which could maximise the breadth and depth of the immune response. A choice of vaccines would also improve our chances of finding a vaccine that was suitable for the elderly, whose immune systems respond less well to vaccines. Including more traditional vaccine formats might also prove more attractive to vaccine-hesitant members of the public. If there were any surplus vaccines, these could be donated to low- and middle-income countries as part of our support of COVAX.

10.4 Deciding which vaccines to pick for the VTF portfolio fell in the first instance to Clive and his expert team. The VTF Steering Group would then discuss these rolling recommendations and would decide on the final portfolio.

**11. Number of Vaccine Doses to Buy**

11.1 In addition to deciding which types of vaccine to purchase, we had to make a recommendation to the Government of how many doses to buy. We asked the Joint Committee on Vaccination and Immunisation ("JCVI") who in the population should be vaccinated, since they were the expert group advising the Government on vaccination policy.

11.2 By July, the JCVI told us that their highest priorities were the elderly and frontline health workers. After that came adults over fifty and younger adults who had underlying medical conditions that made them especially vulnerable to the virus, the so-called 'Groups 1-9'. At that stage healthy adults and children were not a priority; indeed, no vaccines were being trialled in children in the summer of 2020.

11.3 DHSC told us to use a planning assumption that 30 million people were in the 'at risk' Groups 1-9. Most vaccines required two doses for protection.

11.4 With a target group of 30 million people at risk meant that the UK would be a small customer compared to the US, Japan, and the EU. So, we decided that the VTF's strategy should be to compete with these massive buyers by trying to make the UK the best possible client, doing everything we could to make the UK the most attractive place in the world for them to develop and manufacture vaccines.

**12. Government Approval of VTF Proposals**

12.1 Given the challenges that we faced and the number of deaths that were already occurring, I was keen to avoid a protracted approval process for the decisions of the VTF. I had explicitly discussed with the Prime Minister that the UK would need to be willing to take agreed appropriate commercial risks, acting quickly and providing upfront funding so as to build an optimal portfolio of vaccines as fast as possible, before we knew which if any of them might be safe and effective. Instead of the usual bureaucratic model I wanted the VTF to operate on a model that was closer to the more risk-tolerant and far faster investment models that were used in life sciences venture capital investing.

12.2 The structure the VTF adopted was as follows: first, Clive Dix and his team of experts would evaluate and shortlist the most promising vaccines. Then we would outline a deal with the vaccine company and bring Maddy McTernan in to negotiate the legal elements of the deal. Typically, the smaller companies wanted more help with upfront scale-up, manufacturing, and clinical development (as well as more cash up front) than the larger multinational pharmaceutical companies. The VTF team, led in this area by Ian McCubbin and Divya Chadha Manek, would then work to determine how to deliver the help that the vaccine company needed for scale-up and manufacturing, as well as the level of support needed for clinical development and regulatory approval.

12.3 In parallel to the contractual negotiations, Nick Elliott would drive the business case document preparation. This was based on a standard Whitehall Business Case Template that included a strategic case, an economic case, a commercial case, and a management case – often totalling over 100 pages. In my opinion the Whitehall Business Case template was not ideally suited to the task since it did not include a scientific case – obviously vital – to evaluate a proposal. Greater emphasis should be placed on matters such as expert due diligence, future development and manufacturing plans and mitigation of the anticipated risks in Whitehall Business Cases.

12.4 Once the documents had been completed, Nick would take them first to the Permanent Secretary at BEIS for approval as the relevant Accounting Officer, and from there to the Ministerial Panel.

12.5 The Ministerial Panel consisted of four decision makers: the Secretary of State for BEIS, Alok Sharma; the Health and Social Care Secretary, Matt Hancock; the Chief Secretary to the Treasury, Steve Barclay; and the Minister of State at the Cabinet Office, Lord Agnew. This Panel effectively operated as the VTF 'investment committee'. Meetings would be scheduled at short notice and Nick would send the business case and contract to the Committee for a decision. I would attend the meetings, together with Nick and Maddy, to answer any questions. It is important to be clear that, in line with standard Whitehall practice, whilst the VTF outside team gave expert advice and the requisite project management and negotiations were carried out by Civil Servants, it was only Ministers who took the final decisions and committed public money. Overall, I think this decision-making process worked well: it was efficient, it was procedurally robust, and it provided timely, considered decisions.

## 13. Interactions with Government Departments and Agencies

13.1 Clive Dix interacted with JCVI to update them on our due diligence and conclusions about the different vaccines. Prof. Lim Wei Shen, Chair of the COVID-19 Immunisation for the JCVI, attended some of our Steering Group meetings later in 2020.

13.2 Discussions regarding medicine regulations were held directly between the vaccine companies and the MHRA – and we were not part of these discussions. As we were prioritising the UK's vaccine portfolio, we discussed with the MHRA the scope and timings for getting MHRA approvals of vaccines manufactured around the world, including in India and China. We had Dr Kirsty Wydenbach, an expert from the MHRA, attend the early Steering Group discussions to help inform our thinking about likely timing and process for MHRA approvals.

13.3 As part of the due diligence process when selecting vaccines, the VTF reviewed relevant preclinical and clinical data, including as to safety and efficacy. However, vaccine safety issues were matters for the MHRA. We also engaged with the MHRA's National Institute for Biological Standards and Control ("NIBSC", a Government agency focused on biological standardisation) to alert them of the likely timing and nature of vaccines which the VTF was likely to prioritise, so they could build the relevant capacity and capabilities for testing the vaccines. By law, NIBSC is responsible for approving the release of each vaccine batch.

13.4 Ruth Todd acted as the interface between the VTF and DHSC teams, supported by Jonathan Van-Tam. I did not have much involvement with DHSC.

13.5 The Office for Life Sciences also provided people and expertise into the VTF team.

## 14. The Treasury

14.1 BEIS did not have authority from the Treasury to spend much money independently, so Nick Elliott had to acquire a reasonable operating budget for VTF to recruit and pay people.

14.2 We also had to make the overarching VTF Business Case to the Treasury, describing the whole programme, in order to ring fence funds to deliver VTF's goals. In early June 2020 we estimated that we would need to spend approximately £5 billion between June 2020 and the end of 2022. This figure was, however, based

on a significant degree of guesswork given the absence of hard data. At that time, we were very early in the process of doing due diligence on potential vaccine candidates and building a portfolio, but it seemed very likely that the AstraZeneca (non-profit) vaccine would be relatively inexpensive while the (for profit) Moderna vaccine was likely to be substantially more expensive. We had to estimate how many vaccines we needed to buy, at what price per dose, how many doses and when they would be delivered, the numbers of people the JCVI would recommend to be vaccinated and all the additional costs we might need to incur in manufacturing and clinical development – all of which were impossible to predict in June 2020.

14.3 In making the business case, we also had to assess the chances of success of everything we did and quantify the benefits to the UK economy if the vaccines put an end to the pandemic. All of these calculations were based on speculation. The VTF Civil Service team calculated a 'minimum' benefit to the UK economy of £10 billion and a maximum of £200 billion. In my view, this rigid Whitehall calculation methodology was not fit for purpose when dealing with the limited supply of unknown and unproven vaccines, with all its attendant uncertainties.

14.4 The VTF business case and budget was eventually endorsed by the Treasury in September 2020. Approval of the VTF's budget by the Treasury was, in my opinion, too slow and did not appear to be a priority for the Chancellor's office. Fortunately, this did not impede our work since we had authority to proceed, and formal Government consent was only needed to approve the binding legal commitments, which fell later in the process.

14.5 Members of the Treasury attended some of the VTF Steering Group meetings so they could get up to speed on the progress of vaccine selection and deal making. We had some contradictory feedback from different members of the Treasury. From some, we were encouraged to explore opportunities to build manufacturing and testing infrastructure to support long term pandemic resilience, and from others there was an aversion to any spending that wasn't immediately critical to a short-term UK Government response. Again, there was very little sign of industry knowledge, relationships, or expertise.

## 15. The Cabinet Office

15.1 Our relations with the Cabinet Office were not easy. When I arrived at VTF I discovered that the Cabinet Office required VTF officials from BEIS to send Excel spreadsheets with "status updates" twice a week, which was an unnecessary distraction and not relevant to the work we were embarking on. Cabinet Officials also kept attempting to bring senior VTF members into meetings from May 2020 onwards about how a vaccine roll-out might be organised. This was odd because such requests were being made before the team had even made decisions about which vaccines to prioritise, and the VTF was not responsible for vaccine roll-out. This too was an unnecessary distraction. Michael Gove chaired the Covid-O meetings where vaccines were discussed efficiently and well.

## 16. National Audit Office

16.1 In July 2020, Gareth Davies, the Civil Servant who headed up the National Audit Office ("NAO"), decided to launch an investigation into how the VTF was performing and to review whether VTF used its resources 'efficiently, effectively and with economy.' In his letter to us, Gareth Davies said that he: "*hoped that by undertaking this investigation now, whilst your officials are making these important decisions, his team will be able to help sharpen your thinking and bring to your attention any risks that could significantly impact on the programme. He hopes that this approach to our work will enable you and your officials to gain insights and benefits throughout the whole process.*"

16.2 Given that the VTF had only been launched a matter of weeks before, by July 2020 I did not know what they would audit, since we had not signed any contracts for any vaccines and weren't expecting to sign any before the Autumn. The VTF's primary focus at that moment was to prioritise the vaccines for the UK, to define non-binding terms for their procurement and explore how the extended VTF team could support these vaccine companies in scale up, manufacturing and clinical development.

16.3 At the time, I spoke with Nick Elliott and I objected very strongly to launching an audit at such a critical and high intensity time for the VTF team. In response, the NAO audit was postponed by one month to start instead in August 2020.

16.4 I fully recognise the importance of scrutiny, accountability and transparency. The involvement of the NAO in this audit, and the subsequent requests that they sent

over the following five-month period absorbed a significant amount of the VTF's time and resources. ```

16.5 I am prevented from expressing my views on the NAO audit process as I am advised that to do so would contravene the Inquiry's approach to the doctrine of Parliamentary privilege. I am however permitted to exhibit my letter to Gareth Davies of January 2021 [see **Exhibit CB1/05 INQ000128490**], in which I wrote

*"I am writing to highlight some serious concerns relating to the quality of the recent NAO audit of the Vaccine Taskforce (VTF) and the Government's preparations for the Coronavirus vaccine programme.*

*Let me say up front that I hugely welcome effective scrutiny and accountability, and both are ever-present features of my work as a life sciences investor and business builder. I also strongly believe in the importance of Parliamentary scrutiny of public expenditure: it is essential to democracy and in the UK the NAO has a crucial role in providing expert input to that scrutiny.*

*The NAO report into the work of the VTF provides some useful public information, which the VTF would in any case have been pleased to publish on request and in a timely way.* ***But as an instrument of scrutiny the investigation was poorly conceived in its outline and inadequate in its execution, and the report reflects both failings. To that extent, this audit has not served Parliament and the public good.***

*In the normal course it is not possible for civil servants to draw attention to these concerns. But it is important for someone to do so. The NAO's weak performance in this area demands proper review, and without that review such wider concerns would likely go unaddressed. I am sure that as Comptroller and Auditor General you will appreciate the importance of the NAO and you yourself being properly held to account…. I have no previous experience of the NAO nor of working in Government, so I do not know how its other audits have worked. I do have experience, however, of audits of public and private companies and also of charities through being a member of numerous audit committees. But, as you can see, I did not see the benefit of this particular audit…. I hope these comments can help you to focus the work of the NAO so that it can better serve Parliament and the public good in future. The NAO's performance in this case in turn raises a range of more fundamental questions, and I am copying this letter to the Chair of the Public*

*Accounts Committee, the Chair of the Health and Social Care Committee, the Secretary of State for BEIS and the Speaker for information."*

*Overall, the NAO audit had the effect of obstructing and distracting the VTF at a crucial time. An audit start date in November or December or even Q1 2021 would almost certainly have generated genuine insight, without the distraction and obstruction that occurred, raising the quality of the NAO work without in any way compromising its remit.*

*….*

*It was always unrealistic to expect that a NAO team which lacked specialist skills and understanding and a willingness to engage outside expertise would be able to offer new insights. This proved to be the case."* [emphasis added]

**17. Other Government Departments and Agencies**

17.1 Members of the VTF, at various times, liaised and communicated with officials from various Government departments and agencies. Representatives of some agencies would, from time to time, attend meetings or provide the VTF with information. Other than the comments I have made above I have nothing to add in relation to the involvement which such agencies had with the VTF in the development, manufacture, and approval process for COVID-19 vaccines.

**18. The Devolved Administrations**

18.1 I had little to do with the devolved administrations of the United Kingdom, other than writing to the Medical Officers to encourage them to take part in the NHS Registry to build a pool of volunteers who could be contacted about taking part in clinical trials. I did not have any involvement with the delivery of vaccines in the devolved nations of the United Kingdom.

**19. Reviews of VTF's Work**

19.1 Throughout my tenure as Chair of the VTF we were subject to regular external expert and Parliamentary scrutiny and review, in addition to the normal routine processes of civil service feedback and assessment.

19.2 As early as June 2020, the VTF was at risk of becoming the subject of unjustified criticism from certain parts of Government. I realised the VTF needed some protection against these attacks if we were to be able to quickly deliver the goals set by the Prime Minister. I felt we had to urgently address the suggestion that our team lacked competence. I therefore asked Sir Richard Sykes whether he would be willing to conduct an independent review of the VTF's strategy, team, and actions. Sir Richard had a wealth of industrial, clinical, and academic experience; he had been Chairman and CEO of GSK, Rector of Imperial College, London, and Chairman of Imperial College Healthcare NHS Trust. He had co-founded the Jenner Institute for vaccine research so was familiar with the work we were doing and the challenges that the VTF faced. He was also well known as a person of independent mind and character. Luckily Sir Richard agreed to do a review – and did so quickly.

19.3 Sir Richard's review "The Vaccine Task Force: an initial review by Sir Richard Sykes FRS, FMedSci" **[Exhibit CB1/06 INQ000410499]** was completed in July 2020 and shared with Ministers. It gave a strong expert and commercial endorsement of the work that the VTF was doing, concluding that:

*"The team leading the VTF is of extremely high quality and once again highlights the depth of talent and expertise we have in the UK. Time will tell as to the results, but they have made an excellent start. They are in my opinion perfectly suited for the complex task ahead, being a group of smart pragmatic highly experienced individuals. If anyone can do it, they can."*

19.4 In December 2020, Sir Richard again reviewed the VTF's work in a report published on the Government website called: UK Vaccine Taskforce 2020: Achievements and Future Strategy **[Exhibit CB1/07 INQ000128474]** which set out in detail what we had delivered in the preceding six months. He concluded by saying "*We are at the early stages of managing the pandemic and while the scientific and governmental response to this pandemic is far from over, I would pay tribute to Kate Bingham and the Vaccine Task Force for the drive, focus and creativity they have shown in getting the UK so far forward in such a short time.*"

19.5 At the end of November 2020, a review **[Exhibit CB1/08 INQ000128467]** was also carried out by the Infrastructure Projects Authority ("IPA"), which reports to the Cabinet Office and the Treasury. I found that those involved in the IPA review were well informed and had expertise in the work undertaken by the VTF. They wrote:

"*The Review Team concludes that [the VTF] success has been founded on expertise and agility. This has put the UK ahead of the curve in its thinking, planning, delivery, and creation of future resilience. The RT urges HMG to build on this through a lessons-learned exercise so that future programmes may benefit.*"

19.6 I gave evidence before Parliamentary Select Committees on five occasions during and after my six-month tenure as Chair of the VTF. I was impressed by the Select Committee process, especially the Science and Technology Committee. I enjoyed my appearances before the Select Committees since they were a good way of sharing the detail of what we were actually doing, the challenges we were facing and what we should expect to achieve in a non-political way, rather than following the "lines" given to me by the BEIS press office.

19.7 After I left the VTF I was asked to speak with Nigel Boardman, a solicitor and non-executive director at BEIS who was conducting a review on Government procurement that looked into PPE and vaccines. I was surprised to discover BEIS had not thought to share with Nigel our VTF 2020 year-end report, nor had they shared the IPA audit. Both of these reports were very informative about how we worked and reached key conclusions regarding effectiveness and the challenges we faced. It is not clear why they were not shared with Nigel Boardman, nor whether they had been read and considered by senior politicians and Civil Servants. The Boardman report was published a day or two after I spoke to him, so it felt like my meeting was an afterthought.

## 20. Selection of the First Candidate Vaccines

20.1 The average vaccine takes over 10 years to develop from the preclinical phase and the industry average likelihood of it making to market is 6% [see **Exhibit CB1/09 INQ000421914**]. We agreed at the outset that we would need a portfolio of different vaccines to maximise our chances of success.

20.2 In May 2020, there were initially around 190 potential vaccines that were being developed around the world. The team of experts led by Clive Dix narrowed down the potential candidates to 30, then 23, then 15. The longlist had included vaccines that were being developed in the UK, US, EU, Canada, and China.

20.3 A critical factor in determining which potential vaccines we would consider was whether they would enter clinical trials in 2020. If not, we did not think they could form part of the first generation of vaccines to be deployed to control the pandemic.

20.4 Another critical factor was the robustness and credibility of manufacturing scale-up plans and capabilities to manufacture population-scale quantities of vaccines, and the likelihood of early delivery doses to the UK. The manufacturing analysis was undertaken by a team led by Ian McCubbin to review the manufacturing plans, data generated to date and plans for scale-up.

20.5 We also set other criteria to select the most promising vaccines. The track record of the vaccine format and the experience of senior management teams, the preclinical and clinical safety and efficacy data against SARS Cov2 other viruses, and the level of understanding of the MHRA approval process. Price was not a driver for the VTF.

20.6 The VTF's due diligence on all vaccines was generally done in three stages. The first was a preclinical and clinical assessment to determine the likely safety of the vaccine. The second question was 'how likely is it that this vaccine will work, especially for those at most risk, and will it win regulatory approval?'. The third was the manufacturing review where the question was 'can it be made swiftly at high quality and at scale?'

20.7 We had initially thought that we would need up to 12 vaccines to build a balanced portfolio to maximise the chances of picking one that would get approved. However, having conducted due diligence we concluded that we could achieve the diversity we wanted with a portfolio of seven vaccines.

20.8 The first vaccines candidates which Clive Dix and his team reviewed were the Oxford University/AstraZeneca vaccine, which was already in clinical trials, and the self-amplifying RNA vaccine which Professor Robin Shattock was developing at Imperial College.

20.9 All vaccines were given code-names after Submarines.

**21. Oxford/Astra Zeneca (Project Triumph)**

21.1 The Oxford Vaccine Group had started work on designing a vaccine for COVID-19 in January 2020, and in just over two weeks had designed a new pathogen. In

March, the UK Government agreed to finance the £2.2 million cost of clinical trials for the Oxford vaccine. In April, the Oxford team recognised that it needed an industrial partner to scale up and manufacture its vaccine and entered into an agreement with AstraZeneca.

21.2 Sir John Bell, an Oxford professor and the Government's life sciences champion, had brought Oxford and AstraZeneca together. The alliance had been struck extraordinarily quickly, with discussions that had only started in mid-April 2020 resulting in non-binding but wide-ranging Heads of Terms signed within a week. A more definitive document was signed two weeks later. Whitehall was keen to ensure that the UK's long and short-term interests in relation to the vaccine were protected. The scope of these Heads of Terms had been defined between Oxford and AstraZeneca in April 2020, before I started as Chair of the VTF. The relationship between Oxford University, Astra Zeneca, the VTF and Government was, in my opinion, excellent.

**22. Review of the Oxford/AstraZeneca vaccine by the VTF**

22.1 Clive Dix led a team of experts from VTF along with Sarah Gilbert and Andrew Pollard from the University to review of all the preclinical and clinical data. The assessment of the Oxford vaccine was positive and suggested that the vaccine was a strong contender to prevent COVID-19. I have known Mene Pangalos, EVP Biopharmaceuticals R&D at AstraZeneca, for several years and spoke to him frequently. I knew others at AZ too since SV had sold one of our biotech companies, KuDos (which invented olaparib/Lynparza, a precision oncology treatment for ovarian, breast, prostate and pancreatic cancer) to AstraZeneca in 2006.

22.2 We spent time discussing the merits of a single high dose or lower two-dose schedule. The clinical data ultimately suggested two doses were required to protect against death and severe disease.

22.3 The manufacturing process for the Oxford vaccine was well planned by AstraZeneca, Oxford, and industrial partners. The initial scale-up projections were based on small volume bench-scale academic data. The scale-up to regulatory-quality bulk manufacturing presented challenges, however, particularly against tight time frames.

## 23. The Oxford/AstraZeneca Business Case

23.1 The Heads of Terms in April 2020 stated that the UK would buy 100 million doses of the Oxford vaccine (with 30 million proposed to be delivered in September 2020) but the contract was not finalised until late August.

23.2 AstraZeneca had volunteered to act on a not-for profit basis. The UK Government would provide upfront funding to reimburse the costs incurred by AstraZeneca and the various contractors working for them. This funding could not be recovered if the vaccine was ultimately unsuccessful.

## 24. Problems for Oxford/AstraZeneca

24.1 By June 2020 it became clear that the early best case scenario estimates for scale-up were too optimistic, and that the yields would be substantially lower than anticipated. The prospect of 30 million doses being manufactured by September receded overnight and even securing that number by the end of the year looked highly unlikely. Sadly, expectations had been raised to unrealistic levels, with best case estimates taken as reality.

24.2 The second delay came about through the effect of lockdown. In clinical trials there needs to be a sufficient number of infections to prove statistically that the vaccines provide protection versus a placebo. In the Summer of 2020, the imposition of severe restrictions reduced the number of infections which meant that it would take longer to prove that the vaccine could be protective. The early lead that Oxford had by starting its UK clinical trials so quickly was lost, whereas in the US where infection rates were high, the clinical trials were able to progress more rapidly. To ensure the vaccine was effective in different ethnic minorities, Oxford also ran clinical trials in South Africa, Brazil, and Kenya.

24.3 In September, following a Suspected Unexcepted Serious Adverse Reaction ("SUSAR") in the UK phase 3 trials, Oxford and AstraZeneca voluntarily paused the Phase 3 trials worldwide while the MHRA, all the relevant international regulators and the independent Data and Safety Monitoring Boards ("DSMB") investigated the event. It quickly became apparent to the MHRA that the SUSAR was unlikely to be caused by the vaccine but by an unrelated condition. Trials in the UK were allowed to resume. The authorities in the United States took a different approach and the FDA issued a formal notice halting the study there. Very rare blood clots have since been linked to this vaccine. According to the British Heart

Foundation, one study in the BMJ showed that for every 10 million people vaccinated with AstraZeneca there would be a total of 73 extra cases of blood clots. By contrast 10 million Covid cases would trigger thousands of extra blood clot cases.

24.4 President Macron and Chancellor Merkel made adverse remarks about the AstraZeneca vaccine and its efficacy in the elderly once it had been approved in 2021. These comments betrayed a degree of ignorance about the vaccine and appeared to be politically motivated. Amplified by hysterical headlines in the media, their effect was to slow down the vaccine roll-out on the continent; the very likely result is that many people died or suffered adverse effects from COVID-19 unnecessarily.

24.5 It may be worth adding that from my perspective, throughout 2021, the relationship between the Government and AstraZeneca seemed to deteriorate. AstraZeneca is the largest investor of R&D in the UK in any sector, yet the Government seemed to be suspicious of their motives. It took several decisions that had a negative impact on AstraZeneca, including not recommending AstraZeneca vaccines for boosters in the elderly, not paying for an updated vaccine against the beta variant which AstraZeneca had progressed in good faith based on encouragement from the Government, and not buying any Evusheld cocktails [see section 38] after the VTF's non-binding commitment in the summer of 2020.

24.6 Yet AstraZeneca had partnered with Oxford at a time of great need. In December 2021, *The Economist* reported that the fridge-based non-profit Oxford/AstraZeneca vaccine had saved more lives worldwide than any other vaccine (>6 million lives) [see **Exhibit CB1/10 INQ000421913**].

**25. A Portfolio of Vaccines**

25.1 Whilst the Oxford/AstraZeneca vaccine held enormous promise, the VTF recognised the likelihood of failure and sought a wider range of vaccines for the VTF portfolio.

25.2 Sir Patrick Vallance was a visionary in recognising that new vaccine technologies could be quicker to develop than traditional vaccine formats. Sir Patrick recognised that novel mRNA technology could be the fastest way to develop a pandemic vaccine, even though this approach was unproven, and the UK had no mRNA manufacturing capacity. He thought it was worth considering an investment in UK

mRNA production facilities, as the cost could be relatively low, and this capability could be important for long-term resilience.

25.3 In January 2020, Sir Patrick wanted to engage with those working in experimental vaccine fields and issued a rapid open call to fund new solutions, so as to embrace all vaccine approaches. These vaccine applications would be quickly peer-reviewed and funded. He also recommended starting immediate conversations with the MHRA about how to accelerate the assessment of new vaccines.

25.4 Given this, it was always likely that potential mRNA vaccines would be part of the portfolio built by the VTF. There were two main candidates, Moderna and Pfizer/BioNTech, and Curevac a little further behind.

**26. Moderna (Project Renown)**

26.1 Moderna was a relatively new publicly listed US company that had been formed to develop their mRNA technology for new vaccines and drugs. It had raised over $3 billion since it started life almost a decade before the pandemic. It had not, however, yet produced any product that had been approved for commercial use. The United States Government had invested heavily in the mRNA Covid vaccine that was being developed by Moderna.

26.2 I was told that Moderna had approached Ministers with an offer that if the UK committed to meet the whole cost of the Moderna allocation straight away then the UK could be the first country outside of the United States to receive Moderna vaccines. Such funding would be 'at risk'; so that if the vaccine failed then the entire sum would be lost. When I started as Chair of the VTF there was some expectation that we would proceed to back the Oxford/AstraZeneca vaccine, the Imperial College vaccine and would also place an order with Moderna.

26.3 Moderna was first out of the gate in January 2020 in making the case that mass vaccination was possible for COVID-19. Their vaccine codenamed MRNA-1273 was designed within two days of the release of the SARS-CoV-2 sequence. Moderna manufactured the first clinical batch of mRNA-1273 twenty-five days after the sequence design, which is quite remarkable.

26.4 However, our due diligence raised red flags over Moderna's ability to scale and deliver vaccines to Europe quickly. Being an American company, Moderna's primary focus was delivering vaccines to the USA, not for export markets. Moderna

was not a large pharmaceutical company with a track record of producing and distributing vaccines internationally. It was also reluctant to provide detailed answers to questions about scale-up and manufacturing, both generally and in relation to the specific scale-up plans in the Swiss factory in Visp from which any UK vaccines would come. They appeared to approach discussions with the VTF on a 'take it or leave it' basis. Clive Dix became increasingly convinced that the UK would not receive meaningful supplies of the Moderna vaccine until the middle of 2021 at best (correctly, as it turned out). The mRNA vaccines were inherently unstable and required a complex ultra-cold supply chain.

26.5 Moncef Slaoui, the head of Operation Warp Speed, as the American version of the VTF was named, was the former head of vaccines at GSK and importantly, had been a director on the Moderna board. He of course knew Sir Patrick Vallance well. I spoke to Slaoui about Moderna, and he was convinced that the company would be able to scale their vaccine, although timing of delivery outside the US was less certain.

26.6 Ultimately, we decided not to commit to a several hundred million dollar contract with Moderna in the summer of 2020, since we were not convinced we would get our vaccines before the end of 2021. Instead, a non-binding heads-of-terms was signed for 7 million doses (i.e. 2 doses for 3.5 million people). Of this, five million doses of vaccine would be delivered to the UK from the late spring of 2021 - the maximum amount that Moderna could guarantee. An upfront payment was made, and the remainder was subject to MHRA approval and delivery to the UK. The legally binding contract was signed in November 2020. I understand the VTF expanded this contract subsequently when Moderna's EU manufacturing process and delivery schedule were more certain.

**27. BioNTech/Pfizer (Project Ambush)**

27.1 In 2018, BioNTech and Pfizer had entered into partnership to develop flu vaccines and in 2020 expanded this agreement to develop a COVID-19 vaccine. They had launched very promising clinical trials on several potential mRNA vaccines. I had a large number of contacts at Pfizer, having worked with the company over a number of years: Pfizer was a founding investor in SV's Dementia Discovery Fund in 2015; we regularly invest with Pfizer Ventures, and SV has sold companies to Pfizer including Clive Dix's company PowderMed and Rinat. I knew the CBO/COO

Sean Marett of BioNTech well, having backed in him in a previous biotech company, so I reached out to him first in May 2020.

27.2 Clive Dix's due diligence team found both BioNTech and Pfizer accessible and candid. The due diligence convinced us that this partnership would be able to secure regulatory approval, could scale up the manufacturing to population quantities quickly and supply the UK with the quantities of vaccine doses that we needed. Clive Dix's team of experts were convinced that their approach was credible. As with Moderna, this mRNA vaccine required a complex, ultra-cold supply chain.

27.3 Non-binding heads of terms were signed with Pfizer/BioNTech in July 2020, which included price, volume and delivery dates. I don't recall the exact details, but we agreed to buy 40 million doses of the vaccine (the most they could guarantee). The UK was the first country to sign a heads-of-terms with Pfizer/BioNTech, and committed over $800 million to secure a material proportion of the initial global supply of the vaccine.

27.4 Just before we signed the term sheet, we received a call from each of Pfizer and BioNTech in July 2020 (after we had agreed a non-binding term sheet) to be told that the Trump Administration planned to invoke the US Defense Production Act to requisition all of the available Pfizer/BioNTech vaccine. We were told that if we wanted to secure our position in law then we would have to agree binding indemnity language and do so in twenty-four hours. I had attended meetings with the Prime Minister, Alok Sharma and ministers, explaining the need to be ready to sign indemnity language in our supply contracts. Officials had refined their calculations estimating the total potential liability over the last few weeks, so the necessary preparatory work had been done.

27.5 Thanks to all their recent work, Nick and Maddy were able both to mobilise Whitehall and to nail down the legal indemnity terms within twenty-four hours. As a result, the UK became the first country to sign a term sheet with Pfizer/BioNTech. The final contract was signed in October 2020.

27.6 Ruth Todd subsequently worked very effectively with the DHSC, Pfizer and her VTF team to prepare for deployment. In our interactions with Pfizer, we were keen to prove that we were quick and competent. We wanted to impress upon Pfizer

that the UK was likely to offer very early regulatory approval – and was thus a perfect location for launching the Pfizer vaccine in 2020.

27.7 In November 2020, Ruth insisted to the DHSC teams that our whole supply chain should be tested, in close co-operation with the Pfizer team, by performing dry runs involving pizza boxes, each of which was the size of the container for the Pfizer vaccine. Ruth demanded this rehearsal to expose any gaps in deployment and then fix them before we started receiving real vaccines. Every single link in the various supply chains was scrutinised time and time again, with Ruth pressing to ensure that every conceivable hitch had been identified and accounted for.

27.8 As a result of this laser-sharp focus on detail, Ruth helped ensure the UK had a very credible plan for delivery of the Pfizer vaccine; and equally importantly, had the right people in place to implement it.

27.9 On 9 November 2020, BioNTech and Pfizer announced that their vaccine was more than 95% effective in preventing COVID-19, based on a trial in over 40,000 diverse volunteers. On 2 December 2020 Pfizer informed the markets that it had obtained MHRA approval for the emergency use of its vaccine. On December 8 2020, the UK started vaccination of the target population with the Pfizer Covid vaccine, the first Western country to start Covid vaccinations.

**28. Need for other Vaccines Beyond Oxford and Pfizer**

28.1 The Oxford/AstraZeneca and Pfizer/BioNTech vaccines were unproven and based on new technologies. Neither vaccine format had ever been approved by regulatory authorities for any product. There was a good chance that they would not be successful and we needed to secure other promising vaccines that could complement them in our portfolio and increase our chances of success.

**29. Janssen (Project Astute)**

29.1 Janssen Vaccines, a Belgian subsidiary of the multinational US pharmaceutical company Johnson & Johnson ("J&J"), had developed a novel adenoviral (Ad26) vaccine that was distinct from the Oxford/AstraZeneca vaccine to be included in our portfolio. Janssen had taken a couple of extra months to optimise the spike gene sequence to maximise its immunogenicity, and this made a striking difference in preclinical experimental models.

29.2 Janssen had enormous clinical experience with its Ad26 platform having run clinical trials with this vaccine format in Ebola, HIV, malaria, Filovirus, HPV and Zika in over 67,000 people so had built a very substantial safety and efficacy database. The due diligence we completed with the Janssen team was impressive but, like AstraZeneca and Moderna, this remained a risky proposition. No Ad26 vaccine had been approved when we were doing our due diligence. In July 2020, the EU granted Marketing Authorization for Janssen's Ebola vaccine, making it the first approved vaccine to be developed using Janssen's vaccine technologies.

29.3 I worked closely with Paul Stoffels, then the Deputy Chairman and Chief Scientific Officer of J&J. He was a highly respected figure in our industry, not least for his immense integrity and longstanding commitment to global health. I have known Paul for more than ten years, having first sold a respiratory biotech company, Respivert, to him (J&J) in 2010. SV frequently invests with J&J Development Corporation. Paul was an early champion of the Dementia Discovery Fund and secured J&J's commitment to investing in it.

29.4 Through Paul's influence, Janssen was also working on a not-for-profit basis. The company was committed to providing vaccines to low- and middle-income countries and conducted trials of its vaccines based on a single dose which would be of particular benefit in poorer countries, as well as exploring the safety and efficacy of two doses. Paul Stoffels felt strongly that a single-shot vaccine, that could be kept in a fridge without a complex cold chain, was the only practical solution to protecting hard-to-reach communities, including villages in many African countries. So Janssen ran two trials, one with a single dose and the second with two doses fifty-four days apart. Volunteers from the UK participated in the two-dose trial.

29.5 Janssen's focus on providing vaccines to the low- and middle-income countries was a significant factor for the VTF given our second goal as set out by the PM: to ensure that vaccines were distributed equitably around the world.

29.6 In August 2020 the VTF signed heads of terms that would allow for thirty million doses to be purchased by the UK Government with the option for twenty-two million more such doses if necessary, enough with one dose for 52 million people, or 26 million with two doses. We anticipated that up to 3 million doses would be delivered by end Q2 2021 and the remainder by end Q3 2021. This contract required the UK

to pay $75 million upfront to support the scale-up and development. The remainder was based on MHRA approval and delivery.

29.7 One additional condition I recall was that the UK should not use the Janssen vaccines for booster shots (i.e., after the initial two doses) since Janssen was keen for this vaccine to be protecting the most vulnerable around the world and not extending protection for those in western countries who were already protected while supplies were limited. I don't think a binding legal contact was signed during my tenure as VTF chair in 2020.

29.8 Janssen received conditional approval for use in the UK on 28 May 2021. Janssen ultimately showed that their two-dose version (with a booster given 56 days after the first) provided 94% protection against symptomatic infection and 100% protection against severe/critical disease and death. This made a two-dose regimen of J&J's Janssen vaccine comparable to a two-dose regimen of Moderna's or Pfizer's. This equivalent efficacy is not a fact that is widely known.

29.9 In the end the vaccine was not used in the UK because other vaccines were already being deployed in the UK and the Government decided to focus – for reasons that are not clear and may prove to have been inadvisable – on mRNA only. As I said in 'The Long Shot,'[1] variety is vital:

*"A central feature of the VTF approach was to build a portfolio of different types of vaccines. In 2020, we didn't know which, if any, vaccine format would work against SARS-CoV-2 and its variants so we wanted to secure a breadth of different vaccination approaches*

*Disease X, where we know neither what form it might take, nor its potential mutations, presents an even more pressing need for a portfolio strategy. First, different vaccine formats such as mRNA vaccines, vector-based vaccines, the protein subunit vaccines and inactivated vaccines stimulate different immune responses and provide different levels of protection. mRNA vaccines are quick to design and manufacture but may not provide the most robust and durable protection. Not all vaccine formats are suitable for everybody. Some people may be immunocompromised, or have allergies or adverse reactions to some vaccine components making a choice of vaccine crucial.*

[1] Pages 138-139

*Second, manufacturing capabilities and supply chain infrastructure vary enormously across countries and regions. Some formats may be suitable for large-scale production, while others may be easier to produce in resource-limited settings without sophisticated cold chains. We saw this with Covid-19 where it made sense to use Pfizer-BioNTech and Moderna in wealthier nations and Oxford-AstraZeneca in poorer places.*

*Third, we should trial new technologies and approaches to vaccine design to address shortcomings of the current vaccines relating to transmission, durability, breadth, delivery and stability – as well as cost.*

*Fourth, exploration of vaccine alternatives is a solid positive for research and development. Promoting the development of various formats fosters welcome innovation and scientific advancements. It will allow researchers to trial new technologies and approaches to vaccine design, potentially leading to more effective and efficient vaccines in the future – as well as economic growth.*

*Having the flexibility to use a range of vaccine formats means that scientists and health authorities can choose the most effective and safe vaccines based on clinical trials and real-world data. With multiple options, they can optimise vaccination strategies and adapt to emerging variants or changes in the virus."*

29.10 After I left the VTF the UK Government went on to spend approximately £2bn more on the original Pfizer vaccine when we had already bought other diverse vaccines that would generate a broader immune response and to which we were already committed. In my opinion this clearly demonstrated how little knowledge there was within Government.

29.11 J&J's commitment to global health meant that they targeted their response mainly on poorer nations that had not received any vaccine at all, rather than boosting already vaccinated westerners.

**30. Protein-Based Vaccines: GSK and Novavax**

30.1 There were a large number of adjuvanted protein vaccines considered by the VTF. Adjuvanted protein vaccines are a well understood and widely used vaccine format, so our team was keen to include the best of these types of vaccine in the VTF portfolio. These vaccines do not require a complex, ultra-cold chain. In the end we selected GSK/Sanofi and Novavax.

## 31. GSK/Sanofi (Project Valiant)

31.1 GlaxoSmithKline ("GSK") and Sanofi were the number one and number two vaccine companies globally; they too had formed a partnership to provide their vaccine on a non-profit basis. GSK provided the adjuvant and Sanofi the peptide antigen which were combined to form the final vaccine. We hoped that if the adeno and mRNA vaccines failed, we could depend on GSK and Sanofi.

31.2 As I remember, Sanofi were not as quick as some other companies to develop their peptide against the spike protein in 2020. Therefore, our due diligence largely focused on Sanofi's plans to develop the peptide rather than on reviewing data already generated. Sanofi planned to manufacture the peptide antigen primarily in France and then complete drug production in Italy and Germany.

31.3 GSK had developed a very effective adjuvant called AS03 which was proven to help stimulate immune responses in the elderly. AS03 is used in flu vaccines. GSK's COVID-19 strategy was to provide this adjuvant to a number of different vaccine companies through partnerships, including the French company Sanofi. There was a large volume of data supporting the safety and efficacy of AS03 for the VTF to review. GSK did its vaccine manufacturing in Belgium.

31.4 We had numerous close relationships with GSK; Clive had been Head of Research at GlaxoWellcome, and so had recruited and worked with a wide range of GSK executives, while I had worked with GSK a lot. We also had members of our VTF team who were former Sanofi employees including Dave Watson in Clive's due diligence team.

31.5 GSK/Sanofi engaged with the VTF about running clinical trials in the UK, and ultimately did run trials here. Based on our analysis, we concluded that the GSK/Sanofi vaccine would enter clinical trials at the end of 2020. Whilst they were well behind the adenovirus and mRNA vaccine leaders, we felt that the GSK/Sanofi vaccine was a strong and reliable "book-end" candidate for our vaccine portfolio. We thought that if the "unproven" vaccine formats failed, then it was still possible that the traditional adjuvanted peptide vaccine format could succeed. And we knew that GSK/Sanofi were both highly experienced vaccine developers.

31.6 In July 2020, the VTF signed a heads of terms purchase order for 60 million doses of the GSK/Sanofi vaccine for delivery in the second half of 2021 (namely 2 doses for 30 million people). We provided ~10% funding upfront for the manufacturing

scale up. Like AstraZeneca and J&J, GSK and Sanofi had committed to provide their vaccine on a non-profit basis.

31.7 However, in December 2020 GSK and Sanofi announced that the original vaccine candidate needed to be redesigned and the earliest approval date would be 2022. By February 2022, they announced that their fridge-temperature vaccine provided 100% protection against severe disease and hospitalisation. In December 2022, the MHRA approved the VidPrevtyn Beta vaccine and in August 2023 the JCVI recommended this vaccine (among others) for booster in adults over 75 years old. Our assumptions in 2020 that the two vaccine leaders would be a reliable supplier were thus mistaken; while their vaccine was ultimately approved, it was severely delayed due to mistakes apparently made in antigen design and dosing errors. It was a salutary reminder of the risks and uncertainty involved in vaccine development, which could afflict even the largest and most experienced vaccine companies.

**32. Novavax (Project Audacious)**

32.1 Novavax is a small Nasdaq listed US company, considerably smaller than GSK and Sanofi. The company had developed a novel virus-like-particle ("VLP") recombinant technology which enabled their vaccines to mimic viruses but are not infectious. We were intrigued by their VLP approach to generate antigen derived from the coronavirus spike (S) protein which assembled into a 3-D structure like the native Sars-Cov2 virus. This was combined with the saponin-based Matrix-M™ adjuvant to make the final vaccine. The adjuvant was used to enhance the immune response and stimulate high levels of neutralizing antibodies.

32.2 Novavax's vaccines had been evaluated in fifteen thousand volunteers across different clinical trials in seasonal influenza, RSV, Ebola, MERS and SARS so there were reasons in principle to think it would prove to be safe. But in 2020 Novavax had not launched any product using this technology, so their vaccine platform had not been approved by any regulator. The VTF experts believed that the Novavax vaccine had real potential but that the company would need considerable assistance with manufacturing.

32.3 We knew members of the Novavax team and board which gave us confidence that they were experienced and understood the development, regulatory and CMC

processes. The Novavax team formed a highly collaborative and constructive partnership with the VTF.

32.4 In July 2020, US Operation Warp Speed awarded Novavax a contract for $1.6 billion for 100m doses, so they seemed well funded.

32.5 Ian and his team including Steve Bagshaw (former Fujifilm Diosynth UK CEO) worked with Novavax to secure manufacturing slots in Fujifilm Diosynth's Billingham factory from early 2021. This vaccine was made using Novavax's Sf9/baculovirus expression system platform. The adjuvant was manufactured in Novavax's Denmark facilities and fill-finished at the Wockhardt UK facility thus providing a largely UK supply chain. By the early Autumn 2020, Novavax were manufacturing their vaccine at a large multi thousand litre scale funded by Warp Speed, and they planned to tech transfer the commercial scale process to Fujifim from the start of 2021.

32.6 Divya Chadha worked closely with the Novavax clinical team who in turn worked closely with the MHRA and the National Institute for Health Research (NIHR) to run Phase 3 efficacy studies in the UK, starting in October 2020. I myself joined that clinical trial. On 30 November 2020, Novavax announced that it completed enrolment of 15,000 participants in a pivotal Phase 3 UK clinical trial.

32.7 We ordered 60 million doses for 30 million treatments (two doses per treatment). All 60 million doses were due to be delivered no later than January 2022.

**33. Whole Virus Based Vaccines: Valneva (Project Victorious)**

33.1 The vaccines outlined above were all based on generating an immune response to the spike protein. In order to provide balance to the portfolio we wanted to find vaccines which provoked a broader response to the COVID-19 virus beyond the spike protein alone – such as whole virus-based vaccines. Such vaccines could be particularly useful if the virus mutated, as well as providing an option for children (whom we did not expect to vaccinate at that time but might be vaccinated in the future) and the vaccine hesitant who might be unwilling to accept a new vaccine format.

33.2 Inactivated whole viral vaccines were widely used and trusted in vaccines for flu, Japanese encephalitis, tick borne encephalitis, polio and rabies. They had a good safety profile and have the advantage of being suitable for the general population,

including the elderly, immunocompromised groups and individuals suffering from other diseases. Variant Sars-Cov2 viruses could be grown (and combined with adjuvants) to create updated vaccines in the future. The VTF team thought it was important to include this vaccine format in the VTF portfolio.

33.3 The inactivated whole virus would be combined with an adjuvant to improve the immune response to create the Covid19 vaccine. Valneva's preferred adjuvant candidate was CpG1018 from US company Dynavax Technologies, a next generation adjuvant supported by strong data.

33.4 A suitable manufacturing and containment facility would be needed to grow up pandemic viruses to make whole-viral vaccines. Ian McCubbin identified a potential facility in Livingstone, near Glasgow that was owned by the French company Valneva, which would need to be upgraded to meet BSL4 containment standards to grow a lethal virus. The facility would not be able to manufacture vaccines in bulk until later in 2021, but we felt that the UK should have the ability to produce whole virus-based vaccines to provide an important insurance option for VTF.

33.5 Clive knew Valneva's CEO and Chairman, Thomas Lingelbach, who had previously been Managing Director and General Manager at GSK Vaccines GmbH. Clive, Ian and the team also built a strong relationship with Valneva's CFO David Lawrence.

33.6 In July 2020 the VTF signed an initial heads of terms agreement which allowed the UK to acquire 60 million doses (for 30m people) of the VLA2001 vaccine to be delivered by the end of 2021. We didn't know what the final costs would be at that point so the VTF agreed that the final price would be based on the actual cost of the product, to include manufacturing in Scotland, "fill and finish" into vials in Sweden and administrative costs, R&D costs plus the required capex, with a margin of 19.9%. We also agreed an option of additional doses at a lower price over the following four years. Payment was tranched with a small portion being paid upfront and the rest subject to achieving milestones. The funding was used to enable Valneva to sponsor UK based Phase 1 and 2 clinical trials. Phase 1 trials were scheduled to start in December 2020. In addition, in return for providing the capex to upgrade and expand the plant in Livingstone, the VTF negotiated a royalty on the sale of any vaccines sold outside the UK.

## 34. Overall Costs and Commitments

34.1 In September 2020, the Treasury approved the business case for up to £5.2 billion in funding to be allocated to the work being carried out by the VTF. In 2020, the UK Government entered into agreements in respect of the seven vaccine candidates that had the potential to provide up to 357 million doses of vaccine at a potential cost of £3.7 billion, excluding the cost of deployment. Upfront payments of £914 million were agreed in the five contracts signed up to 8 December 2020, prior to any vaccines having been approved by MHRA, By December 2020, £302 million had been committed to a range of manufacturing projects.

## 35. Indemnities

35.1 All of the COVID-19 vaccine companies with which the VTF entered into negotiations requested broad and unlimited indemnity from the Government for all losses arising from the product, including death and personal injury.

35.2 Moderna and J&J were also keen for the UK Government to pass legislation which would give them statutory immunity against any liability whatsoever. Legislation such as this had been passed in the United States in the form of the US Prep Act. However, this was a non-starter for the UK Government.

## 36. The US Defense Production Act

36.1 The US Defense Production Act enabled the US Government legally to secure any supplies it wanted from US companies, including Moderna, Novavax and possibly Janssen (as a J&J subsidiary). President Trump had threatened to use the Act to secure vaccines produced in the US, so any vaccines we selected which were owned by US companies were at risk of not being delivered to the UK should the US invoke this Act.

36.2 BioNTech (a German company) was the Marketing Authorisation holder for the Covid vaccine, not Pfizer (a US company), so we took comfort that it was unlikely that the US Defense Production Act could be used to commandeer the Pfizer/BioNTech vaccine. The fact that the manufacturing was in Belgium meant there was less risk of President Trump being able to commandeer the supply., noting that production in Belgium increased the risk that the vaccines would be kept within the EU.

## 37. The Vaccine Candidates Not Chosen

37.1 Most vaccine candidates did not make the final VTF portfolio, for many different reasons. These included not being likely to enter clinical trials in 2020, no convincing bulk scale-up and manufacturing plans, and inadequate safety and efficacy data.

37.2 Amongst those that did not make the portfolio was the vaccine that was being developed by the team led by Robin Shattock at Imperial College, London, that used a new approach of self-amplifying RNA (saRNA).

37.3 The self-amplifying RNA was attractive because it required a much lower dose than the mRNA vaccines, meaning it should be easier and quicker to scale up and manufacture. As mentioned, when I arrived at VTF it was expected that the Imperial vaccine would be one of those taken up by the UK. However, the early due diligence that was conducted on the saRNA vaccine caused our VTF experts to have too many doubts about the vaccine, both as regards manufacturing and clinical efficacy, to be convinced it could form part of the initial VTF vaccine portfolio. We were particularly concerned about the proposed, and complicated, supply chains; one for the UK and another for the EU. All the VTF experts were worried that what was being proposed looked fragile, and that even if the vaccine did emerge it would prove too hard to make it at scale.

37.4 We tried to assist the Imperial team by contacting various pharmaceutical companies to see if they would be interested in partnering with them, to provide their proven manufacturing, clinical and distribution capabilities. We tried unsuccessfully to bring GSK on board. We also worked with the Centre for Process and Innovation (CPI) to help the Imperial team. However, we reluctantly concluded that the Imperial saRNA vaccine was not an option we could pursue. [However the work done on the Imperial saRNA vaccine encouraged others to continue investing in the field to develop next-gen versions of this format.]

## 38. Focus on Vaccines, Expansion to Therapeutics and Antivirals

38.1 One of the first matters that the VTF Steering Committee considered was whether the focus of the VTF should be on vaccines alone or should also include therapeutic treatments for people who had already contracted COVID-19.

38.2 Alok Sharma was keen for therapeutics to be incorporated into the VTF's mission. I was dubious. Vaccines and therapeutics are quite different and taking on both would be a considerable undertaking that might stretch the VTF too thin. I was also aware that well managed, large repurposing trials were already under way, and I did not see the need to interfere with these. Moreover, the repurposing trials were being run by the Department of Health with different approval requirements and lines of accountability to the VTF, which sat within BEIS and reported to the Prime Minister. Having spoken to Sir Patrick Vallance and Sir Jeremy Farrar, the Director of the Wellcome Trust and a clinician scientist who, with Professor Martin Landray, had designed the world's largest COVID-19 therapeutic trials in February, I came to the view, and recommended, that vaccines should be the primary focus of the VTF. As a result, there was no tension between BEIS and DHSC in relation to the remit of the VTF and therapeutics, and no impact on the lines of accountability for the VTF.

38.3 However, I did believe that the VTF should take the lead in reviewing antibody products against COVID-19, known as antibody cocktails. It was accepted by both DHSC and BEIS that the VTF's expertise was required to conduct due diligence and to assess and prioritise antibody products, and in my engagement letter it was agreed that the VTF should take the lead on all due diligence for these antibody cocktails (both for passive prophylactic protection, which clearly fell within the VTF's remit, as well as for therapeutic treatment of those infected). At that time I felt that the procurement of prophylactics was a priority for the government and an indication of interest was agreed with AstraZeneca in respect of the Evusheld cocktail. However as I set out below (paragraph 38.13) a decision was ultimately taken not to proceed with the antibody cocktails. Apart from reaching agreeing an indication of interest, there were no other discussions with the Department of Health and the VTF at that time about the procurement of prophylactics.

38.4 These cocktails consisted of two antibodies that bind to the spike protein, basically to provide a 'synthetic immune response in a syringe.' Antibodies could be engineered to have a long (approximately 6 month) effect which could be particularly useful as a substitute vaccination for those without a well-functioning immune system. We were informed by the DHSC that there were approximately 500,000 immunocompromised people in the United Kingdom, so there was clearly a large need for these passive treatments. In addition, antibody cocktails (without

the long-acting modifications) could be used as short-term treatments for patients not responding to dexamethasone, remdesivir, or other current interventions.

38.5 Clive Dix led the due diligence to make recommendations of which antibody cocktails, if any, should be included in the VTF portfolio for prophylaxis and which would be included in the trials to be assessed as therapeutics.

38.6 Antibody cocktails were much more expensive than the vaccines (£1,000 per antibody cocktail dose as opposed to typically £10 per vaccine dose) and would also require repeated treatments – mostly intravenous infusions (iv) for therapeutic use and in AZ's case, delivered subcutaneously (SQ) under the skin.

38.7 Bulk antibody manufacturing capacity in the UK was and remains non-existent.

38.8 Clive and his diligence team worked with Jane Osbourn, the BIA Chair and world-renowned antibody developer, to review all COVID-19 antibody opportunities. Jane is also CSO of one of the SV-investee neuroscience companies, Alchemab. Jane led the BIA Antibody Taskforce, an initiative to screen and evaluate all possible COVID-19 antibodies from industry and academia in standardised screens.

38.9 Clive Dix concluded that Ronapreve, created by Regeneron and Roche, was the most advanced and effective antibody cocktail for treatment. In response to his recommendation, this cocktail was successfully evaluated in the RECOVERY Trial. In June 2021, the RECOVERY trial announced that Regeneron's monoclonal antibody combination reduces deaths for hospitalised COVID-19 patients who have not mounted their own immune response.

38.10 Clive determined that the most promising prophylactic candidate was a long-acting engineered antibody cocktail (called AZD7442, now called Evusheld) that was being developed by AstraZeneca and provided protection for at least six months.

38.11 In June 2020 the VTF agreed provisionally with AstraZeneca to buy one million doses of long-acting antibodies, sufficient for one dose of 2 antibodies for 500k immunocompromised people. The provisional agreement was discussed by the Steering Committee and was known to Alok Sharma, and was announced by the government in July 2020 **[Exhibit CB1/01 INQ000065356]**.

38.12 However, given the global supply constraints and the lack of any antibody manufacturing capacity in the UK, AstraZeneca were concerned that the size of our order meant that the UK would have a very large proportion of the total global

supply. When I went back to the DHSC to ask what the minimum level was they wanted to protect the immunocompromised, I was told that they now did not want to purchase *any* antibody cocktails at all. Their view now was that it would be easier to treat immunocompromised patients with drugs after they were infected, while encouraging them to continue shielding, rather than to protect them before they got infected.

38.13 No contract for the purchase of Evusheld was ever entered into, which I still believe was a serious mistake. I felt that the protection of high risk and clinically vulnerable groups fell within the remit of the VTF, however my role was to make recommendations, and the decision not to purchase Evusheld was ultimately one taken by government, as was the prioritisation of different groups. The decision had a further negative effect on the Government's relationship with AstraZeneca, but by far the most significant harm was caused to hundreds of thousands of immunocompromised members of the UK public. The effect was that UK was the only Western country not to protect its immunocompromised people using long-acting antibodies. It is very plausible that this decision cost lives and condemned many more people to suffer through long term shielding.

38.14 I am not clear as to who in fact took this decision, but I believe that the concern at the DHSC was driven in part by the potential cost of purchasing the requisite amounts of Evusheld. Other concerns were that there was no guarantee antibody cocktails would work, which I did not consider to be well founded as there was no guarantee vaccines would work whereas antibodies were more likely to. Also, that it would not be possible to administer them, which again I did not consider to be well-founded as the antibody cocktails were to be administered by injection, just as the vaccines were, rather than by the usual IV infusion for administering antibodies which would indeed have been impossible for 500 thousand immunocompromised people. Either way, many people would argue, as I would, that this decision should have been publicly debated and defended by Ministers.

38.15 It was peculiar to me that part of the UK's pandemic response used a rapid vaccines procurement model, and part (such as Evusheld) went through a therapeutics process which was governed by the National Institute for Health and Care Excellence (NICE) and Quality of Life Years (QALYs) which was much slower. I do not know why a different approach was taken to vaccines on the one hand and therapeutics and antivirals on the other. The Antivirals and Therapeutics Taskforce headed by Eddie Gray and Ruth McKernan did not have as clear a remit as the

VTF, having only two antivirals to look at without a lot of data. Antivirals take much longer to develop and are much less effective, hence the comparative success of the VTF. My view however is that taskforces should not be required at all. As I set out below, competent government should maintain readiness and capability by engaging in developing new technologies for antivirals and exploring new drugs and formats that could then be adapted for antivirals. The same applies to vaccines.

**39. Manufacturing of the Vaccines**

39.1 Whilst some of the vaccines that the VTF had identified would need to be imported into the UK, it would have been an unacceptable risk to rely entirely on imports. Vaccine nationalism was always a risk, and the UK would need the ability to manufacture some of its own vaccines. However, at the time of the pandemic, the pharmaceutical and chemical sectors represented only 7% of the UK's manufacturing output. Whilst the UK was home to some of the world's biggest pharmaceutical companies, most of their commercial production takes place outside of the UK.

39.2 As part of the Government's industrial strategy before the pandemic, there had been some focus by the Government on developing the UK's vaccine manufacturing capabilities. However, existing bulk manufacturing in the UK was light. Seqirus had a plant in Liverpool that made flu vaccine in chicken eggs, but the plant did not have the capability to pivot to produce COVID-19 vaccines at scale. Furthermore, the UK did not have any dedicated mRNA vaccine manufacturing capability. The UK did, however, have a number of flexible but small bioprocessing manufacturing sites and many skilled people.

39.3 In 2016 then BEIS Secretary, Greg Clark had appointed Sir John Bell, the Regius Professor of Medicine at Oxford University, to refresh the UK's life sciences policy and strategy. As a part of his work, in 2017 Sir John led a workshop that proposed that the UK should establish and fund a new Vaccine Manufacturing and Innovation Centre ("VMIC") in Harwell. The sum of £66 million had been committed to this project by the Government's Industrial Strategy Challenge Fund ("ISCF"). However, by the time that the pandemic struck three years later, the VMIC had not been built. Construction was scheduled to begin in April 2020 with a best case opening date in late 2022.

39.4 In February 2020, in response to a request from Oxford, Steve Bates (CEO of BIA) and Ian McCubbin who led the BIA Bioprocessing group, corralled the UK experts in bioprocessing to see how they could help with vaccine scale-up and manufacture. The BIA Bioprocessing group had been set up following the Ebola outbreak so that the UK could start to build a scale-up vaccine network. Nearly 40 companies, non-profits, charities, and Universities came together in February 2020 to form a volunteer 'COVID-19 manufacturing consortium' to assist the Oxford team in building the supply chain that was necessary, setting aside commercial contracts to do so. This was some weeks before the VTF had been established.

39.5 Ian McCubbin came up with the idea that the money that would have been spent on equipment at VMIC should, in addition to further money, be diverted to the cell and gene therapy manufacturing leader Oxford Biomedica so that it could acquire and commission the bioprocessing equipment to start manufacturing covid vaccines rapidly. This equipment would return to VMIC once it had been built. A specialist team had already been recruited by VMIC, and Ian planned that they would also be temporarily moved over to Oxford Biomedica to help them manufacture the Oxford/AstraZeneca vaccine. This was agreed and a further £38 million was committed to create what amounted to a virtual VMIC within Oxford Biomedica.

39.6 We also recognised that VMIC itself would need to have the capacity to produce a far higher number of vaccines than had been originally anticipated (3 million) and would need to start operating as soon as possible. A further £150 million was provided in phases to accelerate construction of the building in Harwell, and to bring forward the opening date and build its bulk manufacturing capability. Based on enlarged capability the Harwell site was now projected to have the capacity to manufacture up to 70 million doses in a matter of months.

39.7 In addition to providing the capability to bulk manufacture the vaccines, the second part of the process, where the vaccine is placed inside small bottles or vials – known as "fill and finish" - is often vulnerable to delays. Wockhardt had recently invested in a new fill and finish facility in Wrexham, North Wales. The VTF, led by Ian, recommended we reserve all the fill finish capacity that Wockhardt could offer for at least two years. It was a brilliant idea to buy more than we knew the UK might need. Although we didn't know which if any vaccine would work, or how much bulk vaccine we would receive or need to be filled, the excess capacity also acted as an inducement in our negotiations with vaccine companies overseas as fill and

finish resources were scarce worldwide. Ian also ensured that the UK had sufficient glass vials, glass tubes to make vials and even the borosilicate sand needed to make the glass.

39.8 In addition to being able to produce the Oxford/AstraZeneca vaccine, we also needed to secure or build flexible capabilities to be able to manufacture multiple different types of vaccine, including mRNA. When I was first appointed, Sir Patrick Vallance had mentioned acquiring a veterinary vaccine plant. Shortly afterwards I received an email from Susan Searle of Benchmark Vaccines who wanted to discuss whether the Government would be interested in purchasing the company's veterinary vaccine plant in Braintree, Essex. I had known Susan for years following her time leading Imperial Innovations at Imperial College. Due diligence was done, and a plan was developed to upgrade this plant for manufacture of human vaccines, to be managed by the Cell and Gene Therapy Catapult. This acquisition was completed in less than two months and provides an excellent facility for the UK to respond to any future pandemics.

39.9 The Centre for Process and Innovation ("CPI") in Darlington was the logical choice to scale up and develop mRNA vaccines in the UK. CPI was a founding member of the Government's High Value Manufacturing Catapult. Ian McCubbin planned to use the CPI to optimise the mRNA manufacturing production process and then transfer this to the Braintree plant for bulk manufacture.

39.10 The VTF acted as a broker between Novavax and Darlington-based Fujifilm Diosynth Biotechnologies. Fujifilm could start manufacturing the Novavax vaccine at the site whilst it was still in clinical trials. Ian planned to build a UK supply chain for Novavax.

39.11 Investment was also made in Valneva's site to convert it ready for pandemic whole virus vaccine production. The VTF would pay the upfront cost of upgrading the site to make Valneva's vaccine, but as a flexible state-of-the-art capacity that could then be used to manufacture any biological vaccine or drug as needed. In return the UK would receive a priority supply and discount on the price of that vaccine in the future were it to be approved and supplied, plus royalties on vaccine exports.

39.12 Thanks to the efforts of Ian McCubbin and his team, within 12 months the UK went from having a minor vaccine manufacturing base to having one capable of providing flexible, manufacturing capability for all the main vaccine formats at a

population scale. We now enjoyed the capacity to supply repeat doses rapidly to the British people, as well as to export abroad.

39.13 The VTF also recognised that the UK needed to establish bulk manufacturing capacity for antibodies. We anticipated that the scale of investment required from the Government would be substantial and there were several companies who were willing to work with Government on this. We held an Antibodies Supply Event in October 2020 to seek expressions of interest from specialist companies to work with Government to build this bulk capacity. Government would provide funding for future orders and industry would manage and run the facility.

39.14 Several companies duly threw their hats into the ring. However, although the Treasury had previously explicitly indicated their support neither BEIS nor the Treasury showed any sign of interest and this potential capability was never developed further. Very sadly, the VTF's drive to establish new bulk bioprocessing manufacturing capacity in the UK seems not to have progressed since I left. This lack of biomanufacturing capacity in the UK is a major vulnerability.

**40. Clinical Trials**

40.1 The VTF recognised that clinical trials could be a very useful bargaining chip in negotiating with the companies developing promising vaccine candidates, as well as a great opportunity to supercharge the clinical trials of the most attractive ones. The UK is a particularly good place to run trials, as everyone has an NHS number connected to electronic medical records, which means that patients can be followed to build a rich data set on the safety and efficacy of the vaccines.

40.2 In order to make it maximally attractive for companies to run their clinical trials in the United Kingdom in the extremely testing circumstances of COVID-19, we believed it would be necessary to subsidise or wholly cover the cost of trials as an upfront payment for future vaccine supply. We also needed to demonstrate that such trials could be done at speed with the utmost professionalism.

40.3 Pfizer had been clear from the outset that they did not want Government support and would not be running trials in the UK in 2020, since they correctly recognised that our levels of viral infections had dropped in mid-2020 as a result of the lockdown. Moderna had been talking about running UK trials but that stopped when the UK did not place a large order for the company's vaccines.

40.4 In order to attract the vaccine companies, Divya Chadha Manek recommended that we create a COVID-19 National Citizens Registry on the NHS website. This would allow any member of the public to consent to be contacted about taking part in vaccine clinical trials.

40.5 We started discussing the Registry project in June and wanted to be ready to launch by July in time to assemble enough people for the expected wave of trials starting in September and October 2020. The Civil Service bureaucracy needed to get this done was unfortunately rather high. We had little practical choice but to collaborate with NHS Digital, which owned the patient data. NHS Digital was a relatively new and untested institution that had never done anything like this before. Despite insisting to us that robust beta testing had been done, when the Registry went live on national TV and radio on 20 July, it quickly fell over. On that day alone over 50,000 people visited the NHS website page, which was far beyond the scope of the system that NHS Digital had built. Confirmatory emails that should have been sent instantly to over 150,000 people trying to sign up had been held in the ether for twenty-four hours. Only a small proportion of those individuals were, entirely understandably, patient enough to wait to sign up again on the following day.

40.6 We had to secure approval from Chief Medical Officers not only in England but of course in Scotland, Wales, and Northern Ireland as well if this was to be a national offering. Scotland was not cooperative and withheld consent until the eleventh hour. While it did not make a huge practical difference whether all the Devolved Administrations signed up, I thought it would make for a better pitch to the vaccine companies if we could state that we would reach the entire UK through the Registry.

40.7 It cost about £2.5 million between NIHR and NHS digital to build and launch the Registry.

40.8 In the event, 60,000 people came forward before the end of 2020 and more than 500,000 by mid-2021, of which over 1/3 were over the age of 60. We had successfully included a huge number of volunteers who were vulnerable to the disease. Nearly 50,000 volunteers took part in vaccine trials run by Novavax, GSK/Sanofi (booster trial), Valneva, AstraZeneca (beta variant covid study and proven antibody study), Medicago, (a Canadian vaccine company), Pfizer/BioNTech (CCOVID-19 maternal vaccine study), Moderna (Omicron variant vaccine study). The Registry was also used to generate data to inform further

public health policy decisions. For example: to test whether it was safe for people to have one or more of the COVID-19 vaccines alongside the annual flu jab, and if so, for whom; and what was the effect of the vaccines on pregnant women or young children? Therefore, several trials were run including COM-COV (mixing vaccine schedules), COV-BOOST (boost vaccine schedules 3rd and 4th dose) and Preg-COV (pregnancy).

40.9 Our longer-term goal, which was shared with many in the NIHR and the DHSC, was to expand the Registry beyond volunteers for coronavirus vaccine trials to include any patient with a poorly treated condition. We asked the volunteers whether they would be willing to contacted about clinical trials beyond COVID-19 vaccines and 94% said yes. Several pharmaceutical companies have since asked me how they can work with the Registry to accelerate recruitment into their trials.

40.10 However, in August 2022, I received a disturbing email saying "NHS COVID-19 Vaccine Research Registry closing down". There seemed to be little interest in NIHR to continue building what could have been a fabulous national clinical trial resource. Instead, and much more promisingly, Our Future Health has now been successfully launched at much greater scale and ambition, and this largely bypasses the NIHR. Our Future Health aims to discover what drives disease in different populations based on participation of up to five million diverse UK individuals. The health of these volunteers is reviewed regularly over decades and critically allows for recontact with volunteers so that at risk individuals can participate in relevant clinical trials.

40.11 There is one bitterly disappointing coda to this story. The volunteers in the COVID-19 vaccine trials were later disadvantaged by their participation in the vaccine trials, because their vaccine certificates were not recognised until the candidate vaccines had been approved by the Regulators, even if they had been shown clinically to be effective. In the meantime, they were prohibited from receiving other approved vaccines. This meant triallists were not able to travel or attend any venues where vaccine passports were required. They were thus penalised for their public spiritedness in coming forward to help their country and the cause of science at a moment of huge national need. It took me and others a great deal of effort to convince the Government to allow triallists to be able to receive registered vaccines on top of their unregistered ones – indeed it was only after I threatened to withdraw from the trials and publicly explain my reasons for doing so that the solution of an additional registered vaccine was offered (in the absence of any safety data at that

time on whether giving people additional vaccines was not harmful). In my opinion, where the clinical data shows that the vaccine is effective, triallists should be given a global commitment to be excluded from vaccine passport requirements.

**41. Communications support for the VTF, the Registry and more generally**

41.1 The new Vaccines Registry was central to our strategy of making the UK the best place in the world to develop the COVID-19 vaccine. It became clear that the Registry would require a different quality and quantity of communications support. We were hoping to recruit hundreds of thousands of volunteers to sign up to the Registry, but we also needed to send wider messages about the safety of any approved vaccines, and to flag UK technology leadership very publicly so that innovative companies, both large and small and around the world, would see the opportunity to run trials quickly in the UK and use the Registry. This was a core part of our whole strategy meeting the "UK leadership" goal that Boris Johnson had set us.

41.2 In June, I had a call with Dr Jonathan Sheffield (former CEO for the NIHR Clinical Research Network), together with officials from the DHSC and Lord Bethell, the Minister in charge of clinical trials and interface with myVTF team. We all agreed that a national communications campaign was needed to launch the new NHS Registry.

41.3 I asked about our communication plans to support the launch and was told that the BEIS press office understandably did not have the capabilities to provide this type of specialist support.

41.4 Jonathan Sheffield recommended a private sector group called Admiral Associates, who had recently been seconded into NIHR to provide specialist communication support. It became clear on further investigation that Admiral both understood clinical trials and were trusted by NIHR. They seemed a good resource to bring in to help us.

41.5 I spoke to the CEO there, Georgie Cameron. She was clearly experienced and shared our energy, with a laser-like focus on results, and had run national campaigns in the past. I then suggested she speak to Nick Elliott to scope out how they might be able to help us. Nick agreed this would be a key resource, so he and his team then sorted out the contract and we got going. I had had no previous relationship with Admiral or its team, and had no control over any

communications budgets, or over the legal, procurement and contracting processes. All of these were handled by Civil Servants in the normal way.

41.6 As far as we could see, there appeared to be no coherent communications strategy in this area across Government. In fact, only those working directly with the VTF actually knew the up-to-date facts about vaccines and what we were doing; government "lines" generated by the BEIS press team were frequently out of date.

41.7 In mid-July we were preparing for our first press release, where we would announce the NHS Registry to support rapid enrolment into trials as well as announcing outline terms for the initial vaccines that we had prioritised, namely Pfizer/BioNTech and Valneva vaccines and AstraZeneca antibodies for the immunocompromised.

41.8 I had a difficult time getting the tone of this first press release agreed with BEIS officials. Their press office was focused on highlighting the total number of vaccine doses that we planned to purchase, as if it was simply true that the more we purchased the better we were. However, this naïve 'numbers game' approach completely ignored the fact that we were building a portfolio of different vaccines and formats, since we expected many, if not all, of them to fail. It also ignored the uncertainties and potential for delay.

41.9 In fact, in my judgement the BEIS press team line was naïve and irresponsible in the way it raised potentially false hopes. It also left the Government massively open to the possibility that if one or more vaccines failed, as they were likely to, the headline numbers would fall, raising question marks about the whole programme.

41.10 We had planned a paid advertising campaign to support a large-scale push to drive people to sign up to the NHS Registry, and these costs had been reviewed, included, and approved in our Business Case. We were particularly keen that our targeted campaign should reach those most at risk from infection, including the elderly, those with severe underlying diseases and frontline workers. We also especially wanted to attract people from black, Asian and minority ethnic backgrounds who were disproportionally affected by COVID-19 and who the evidence suggested might be among the more vaccine-hesitant to sign up.

41.11 We spoke to the Behavioural Insights team led by Dr David Halpern and Hannah Behrendt to explore generally how to increase vaccine uptake, and specifically how

to bring these most vulnerable people into clinical trials in an effective, fair, and transparent way. The NIHR teams were also helpful on advising on translation and individual advocates for different ethnic communities.

41.12 However, the Cabinet Office then blocked expenditure from our budget for advertising the NHS Registry, even though these costs had already been approved. I still do not know how or why this happened. This ban further complicated our work, as it meant that the VTF had to try to deliver a national message without the benefit of any targeted advertising support.

41.13 Our goal for the NHS Registry was to get hundreds of thousands of volunteers to sign up in time for possible clinical trials starting in September, and it was a core part of our overall strategy to woo the best vaccine developers around the world to the UK. For that purpose, we developed a media strategy that encompassed radio and TV interviews with me – and in some cases Divya Chadha Manek for Asian radio – plus newspaper articles, podcasts and even longer quasi-academic articles. Time and scale were of the essence.

41.14 We recognised there was huge public uncertainty and, apart it seemed from within the UK Government, a massive thirst from all quarters for information about how vaccines work, how they get developed and made, the risks of clinical trials and generally what to expect. It was hardly surprising that people were not willing to sign up to volunteer for clinical trials until they understood much more about what was involved and why they *should* do this. So I spent a lot of time on broadcast media explaining the background, outlining possible scenarios and answering questions, explicitly reassuring the public that safety testing had not been curtailed, even though the overall vaccine development had been dramatically accelerated.

41.15 From the start the team and I faced a continual problem with getting official approvals for each interview and article we wanted to produce. The process required separate signoffs from BEIS and the Number 10 press teams, a process which was laborious, time-consuming and absolutely not fit for purpose for a fast-paced media environment.

41.16 Frequently, by the time we received approval from BEIS and Number 10, the opportunity would have gone. This caused tensions between Admiral and the Whitehall press teams, which we tried to fix with regular briefings and invitations

to join our Steering Group meetings; but this did not work, largely I suspect because of a lack of Whitehall understanding about or interest in what we were doing or why it mattered. And all of this was of course made worse by an evident measure of official hostility to the dedicated healthcare communications specialists which the VTF had had to bring in from outside Government.

**42. Porton Down**

42.1 An assay is a quantifiable means to measure the amount and activity of a target drug or intervention. We recognised the need to create standardised assays so we could measure the effectiveness of the various vaccines, not just against each other but also with emerging variants. This task was given to Porton Down. In September the VTF received approval for £19.7 million for industrial scale testing of variant samples to ensure that the vaccines chosen by the VTF would be effective against current and future vaccines.

**43. Humans Challenge Trials**

43.1 Clive Dix and I also secured approval to invest in a developing a new controlled infection clinical trial capability, called a Human Challenge Programme. This is a trial in which healthy young adults receive a vaccine before being deliberately infected with the virus to test it. As Sir Richard Sykes rightly noted in his report on the VTF in July 2020 **[Exhibit CB1/06 INQ000410499]**: "*Human challenge studies in flu revealed critical information and data about the infectivity of subjects prior to their showing symptoms and this was only discovered through the tightly controlled human challenge studies.*" We believed it was a key priority for the VTF to get human challenge studies up and running for the controlled testing of new vaccines, especially once the virus starts mutating and when large pivotal trials are no longer feasible.

43.2 In October 2020, the VTF announced £33 million funding for the first phase of a Human Challenge Programme as a partnership between Imperial College, London as the trial sponsor, BEIS, hVIVO and the Royal Free London NHS Foundation Trust. This initiative was successful and in July 2021, New England Journal of Medicine published a paper entitled 'SARS-COV-2 Human Challenge Studies – Establishing the model during an evolving pandemic'. This said: "*Our experience thus far indicates that a SARS-COV-2 human challenge research programme can be developed as part of the pandemic response*". I don't think we have yet taken

full value from this model since this will be the best way to understand the mechanism and biology of infection and how to protect against infection with updated vaccines and therapeutics.

**44. Delivery**

44.1 Planning for the deployment of any COVID-19 vaccines had begun in Whitehall before the creation of the VTF. The COVID-19 vaccination had been modelled on the annual influenza vaccination campaign. However, even if a suitable vaccine was found, a far larger number of people would need to be vaccinated against COVID-19 than compared to influenza, and the deployment would be far more complicated than anything that had gone before.

44.2 The VTF had to work closely with other Government departments and organisations to help shape a national deployment plan, so as to make sure that the vaccines were delivered safely and efficiently. Ruth Todd was the VTF Programme Director and took the lead at the VTF in relation to vaccine deployment and roll-out planning, albeit this was far from her only role.

44.3 Deployment of the vaccine involved a number of different Government departments and agencies. The DHSC had an extensive policy development role and was the dominant force. The JCVI was the independent entity advising the Government on vaccine prioritisation.

44.4 It was up to the VTF to ensure that wherever any vaccines came from, they arrived at a central distribution point in the UK. From there it was Public Health England's ("PHE") responsibility to transfer the vaccines to regional centres as and when needed. PHE was also responsible for ensuring that there were enough people to administer the vaccine and that they were trained for specific vaccines. The last part of the rollout rested with the NHS.

44.5 Ruth's first priority was to build the programme management capability in the VTF to support scale-up, manufacturing and clinical development of each vaccine we had selected. The VTF created separate teams consisting of a blend of external experts and career Civil Servants to work with the high-priority vaccines in the summer of 2020.

44.6 Pfizer did not want too much Government cash or interference and so largely ran its own affairs. The VTF team worked with Pfizer in planning the distribution of their

vaccine, which was required to be stored at ultracold temperatures, around the UK. Pfizer also embedded their people into our team. We had an excellent working relationship with the company.

44.7 VTF offered substantial help to the Oxford/AstraZeneca vaccine team. The supply chain was largely based in the UK which was and advantage.

44.8 There were also project management teams supporting GSK/Sanofi, Imperial, Janssen, Moderna, Novavax and Valneva.

44.9 For some time, it looked as if the Oxford/AstraZeneca vaccine might be the first available. By September it was clear that Pfizer's vaccine was the most likely to be rolled out first. PHE ramped up their preparations; a substantial number of new ultra-cold freezers were purchased and distributed; investment was made in in new, smaller, low dead space syringes; and training was given to those likely to be delivering the vaccines before it was certain which would be available.

44.10 VTF had to ensure that any approved vaccine was delivered to the main holding depot for England and Scotland. From there vaccines would be sent to the respective centres for Wales and Northern Ireland.

**45. Vaccine Approval**

45.1 Approval of new vaccines by the MHRA can often take years. The CEO of the MHRA, Dr June Raine, recognised the urgency of the situation that the pandemic presented and pioneered a new 'close partnership' approach between the regulator and the vaccine companies to accelerate the ordinary timetable for approval. The MHRA adopted a very successful rolling review process which meant that companies were encouraged to share data with the MHRA as soon as it was generated, allowing it to be reviewed much more quickly. This meant that when the phase 3 data was ready the MHRA only had to review this data, the earlier data having already been assessed.

45.2 On 9 November 2020, BioNTech and Pfizer announced that their vaccine was more than 90% effective. This exceeded all expectations.

45.3 On 23 November, Pfizer announced that it would seek regulatory backing from the FDA in the United States and the MHRA in the UK. We hoped that regulatory approval would be granted quickly.

45.4 On 30 November, the JCVI changed its recommendation on who should be prioritised for receiving the vaccine. Only a few weeks before the JCVI had indicated that it expected to recommend that healthcare workers should be vaccinated at the same time as the frail and elderly in care homes, their carers, and the over-eighties. Now the JCVI changed their position, saying that the frail and elderly in care homes should be prioritised ahead of healthcare workers. This meant that the deployment plans had to be radically changed and Emily Lawson did a remarkable job rapidly re-organising the UK's deployment plans.

45.5 On 2 December, Pfizer announced that it had obtained MHRA approval of the emergency use of its vaccine.

45.6 The process of distributing the vaccine began on 5 December with the first vaccination being given on 8 December 2020.

45.7 There were two early instances of people suffering allergic reactions to the Pfizer vaccine. It was known that these individuals were hyper-sensitive and carried epi-pens. The MHRA immediately changed the label to exclude the hyper-allergic and required a period of safety monitoring post injection. Fortunately, this matter did not appear to dissuade the public and it became clear that the take-up of the vaccine would be very high.

45.8 The Oxford/AstraZeneca team made their submission to the MHRA on 27 December 2020 and approval was given on 30 December. EU approval for the vaccine followed shortly afterwards.

45.9 In January 2021, Novavax announced extremely encouraging results for their UK phase 3 trials, showing an overall efficacy of nearly 90% and strong immunity against the 'Kent variant.' Manufacturing of the Novavax vaccine adjuvant proved to be more difficult than anticipated and securing regulatory approval for the Novavax vaccine took longer than expected. Novavax sought regulatory approval from the MHRA in October 2021 and gained approval in February 2022.

**46. Departure from VTF and Handover**

46.1 My appointment as Chair of the VTF, as agreed with the Prime Minister, had originally been for a term of 6 months. This was extended by a month by mutual agreement to December 2020.

46.2 Before I left, Clive Dix and I worked with the VTF team to prepare recommendations from the Vaccine Taskforce in December 2020 **[Exhibit CB/11 INQ000330659]**. Nick Elliott was the Director-General in post. It has been suggested to me by the Inquiry that Madeline McTernan made the decision not to publish the document but I do not believe that it was Madelaine McTernan who made that decision. I was told by Nick that BEIS had said that they would not agree to publish the recommendations because it would look as it if had come from Government, and was government policy, when it was not. I believe that the recommendations were correct at the time I wrote them. I have offered the Inquiry my thoughts on the recommendations that I believe need to be made now, in paragraph 48 below.

46.3 When I left, I handed over the Chairmanship of the VTF to Clive Dix who, as my Deputy, was extremely familiar with everything that the role entailed. As far as I know, however, Clive was never given a letter of engagement and did not enjoy the same level of authority and cooperation as I had received in 2020. He resigned from the role as a result. The subsequent systematic removal of experts from the VTF and the people with relationships with industry from the VTF by civil servants damaged the relationship the Government had with industry and reflected incredibly badly on the UK.

## 47. Conclusion – Reflections

47.1 Within six weeks of my appointment, the VTF had developed its strategy and built a team of industry and technical specialists alongside a team of Whitehall officials, expert in project management, contracting and diplomacy. We prioritised a shortlist of vaccines from over 190 candidates and signed contracts for seven vaccines across four different formats. Against very high odds those vaccines turned out to be precisely the right calls. The Government supported the VTF's work by generally making rapid and pragmatic decisions, especially about money.

47.2 Two of the VTF's chosen vaccines were approved by the MHRA in 2020. All seven vaccines chosen have now been approved by the MHRA.

47.3 The VTF created and/or benefited from a wide range of innovations that were introduced to speed up the development, procurement, manufacture, and approval of vaccines, including:

- MHRA's rolling review and constructive partnerships with vaccine companies. MHRA and JCVI's pragmatic recommendations in 2021 to increase the duration between doses enabled more people to get vaccinated early on when supplies were limited and also improved the immune response.

- VTF's innovative approach to accelerate scale-up and manufacturing of vaccines:

    - Creative and collaborative partnerships with contract manufacturers and Chemistry, Manufacturing and Controls (CMC) experts from the VTF e.g., the Virtual VMIC operating within Oxford Biomedica.

    - Proactive forward purchasing of fill-finish capacity and equipment (such as the procurement of borosilicate sand etc., to make glass vials).

    - Purchasing low dead-space syringes so that a larger number of doses could be extracted from each multi-dose vaccine vial.

- Innovative approach to accelerate the clinical development of vaccines through the launch of the NHS Registry to build a diverse pool of volunteers for rapid recruitment into clinical trials.

47.4 Above all, a venture capital mindset allowed us to set strategy, drive rapid decision-making including mitigation of risks, and recruit and empower a temporary expert team to work with Government. However, the follow-up by Government following my departure has fallen well short of what we had hoped.

47.5 First, the protein-based and whole virus vaccines we bought, astonishingly, have never been used. Instead, the Government decided to place its bets entirely on mRNA vaccines. HMG increased its Pfizer-BioNTech order from 40 million to 100 million doses in April 2021, and placed an additional order of 35 million doses in August 2021, followed by a further order in November 2021 for a total of 114 million doses of Pfizer-BioNTech and Moderna vaccine over 2022 and 2023. Recent partnerships have been struck with BioNTech and Moderna to invest in the UK, but there seems to have been no appetite to secure a broader vaccine format capability. I fear that this lack of diversity in vaccine formats is a potential public health weakness since we are not taking advantage of the broader and more

durable immunity that could be generated with a wider range of COVID-19 vaccines.

47.6 I also think that has also undermined the wider UK vaccines industrial strategy since the vaccines developed and approved by the smaller innovative companies – which were being manufactured in the UK – were ignored. We had helped to create an environment whereby vaccine companies were encouraged to work in the United Kingdom and with the UK Government. We worked positively in partnership with the private sector and achieved results. The ability of the UK to scaleup and manufacture vaccines in bulk was transformed Once I had left, this strategy appeared to be abandoned.

47.7 The Prime Minister originally set three goals: to secure vaccines for the UK; to ensure that vaccines were distributed equitably around the world; and to make the UK more resilient in dealing with a future pandemic.

47.8 I feel that the VTF largely delivered the first goal. We were successful in developing and securing vaccines and did so faster than anyone had originally imagined. However, it is also true that we were not able to protect those whose immune systems could not respond adequately or at all to vaccination. We were not able to gain Government support to buy AstraZeneca's long-acting antibodies (Evusheld).

47.9 We were less successful in achieving the second and third goals. The Prime Minister's second goal was for the VTF to ensure that vaccines were distributed fairly around the world. We made only modest progress in this regard. Despite the success of the vaccine procurement programme, in my judgement the UK Government donated too few vaccines to countries overseas. By March 2022, according to a report I read from the analytics firm Airfinity, the UK had donated only 32 million doses and was not even in the top ten percent of per capita donations worldwide. The UK provided support to COVAX, but the sharing of vaccines internationally was ultimately a political decision rather than an administrative one for VTF. COVAX was slow to get going and often did not deliver the vaccines to the countries that needed them.

47.10 I also feel that we fell short in seeking to meet the third goal. We created considerable scope for future long term UK pandemic resilience, but we did not succeed in building permanent pandemic capabilities in the UK. Again, we were not able to secure Government backing for an industry partnership to build a bulk

antibody UK manufacturing capability, despite significant interest from several companies to build new facilities including in the North of England. This is a serious matter: it means that the UK does not have a secure on-shore supply of bulk antibodies, which are an increasingly important part of our therapeutic armoury to controlling severe diseases such as cancer and autoimmune disorders.

47.11 We also failed to get the VMIC on a secure footing before I left at the end of 2020. The VMIC was then sold to a private US company, Catalent. I do not know what guarantees were sought from Catalent, or what guarantees that company has given to provide the range of scale-up manufacturing capabilities and development resources needed to explore novel vaccines in the future. In November 2022, Catalent announced that it was pausing work on VMIC – which, astonishingly, remains unfinished. A small pandemic resilience fund has been created to support innovative vaccine scale-up, focused on the North and West UK to try to address the missing "innovation" activity in VMIC. I am concerned that the sale of VMIC to Catalent, without some form of right or assurance for the Government to use the site in the event of a future pandemic, has reduced our resilience and capability to be prepared for a future pandemic. VMIC could have been used to help with the innovation side of vaccine development and bulk manufacturing but we do not have that capability now that we have sold this valuable asset.

47.12 I also feel that the positive co-operation and momentum of the Government working with vaccine companies and manufacturers has gone. This began when the VTF ended its relationship with the various industry experts which had driven its success. Worse, it seems that Whitehall has essentially re-established "business as usual", reverting to its position of officials (without vaccine expertise or relevant relationships) focusing on process and not outcomes, weak communications and challenge, and a willingness to work against one another and industry. The ethos of the VTF team, whose success derived from working collaboratively, nimbly and quickly with vaccine companies and manufacturers, seems now to have shifted from 'partner' to 'adversary', when the VTF moved from BEIS into the DHSC on my departure. I fear that the approach has become more antagonistic and bureaucratic once more. Many new Government initiatives have been labelled "VTF-like" without having the VTF DNA at its core.

47.13 As an example, the Government then inexplicably cancelled the Valneva contract three weeks before its Phase 3 trial results were received. This decision was apparently taken on the basis that Ministers believed that the vaccine would never

be approved, on what official advice, reflecting what actual expertise, remains unclear. The advice was wrong. The Phase 3 data announced in November 2021 showed that the vaccine was highly effective and safe. The premature cancellation meant that the EU terminated their supply discussions and over one hundred new jobs at Valneva were immediately lost.

47.14 When it cancelled Valneva's contract, I doubt the Government considered the needs of COVAX, which badly required stable vaccines which could be sent to low-income countries. Nor did it consider the need to build resilience in the UK's pandemic preparedness capability with a new flexible state-of-the art manufacturing plant. Nor the moral commitment it had made when it originally engaged with Valneva, very much on a company "at-risk" basis. Nor the signalling effect its actions would have on the pharmaceutical and bioscience industry. Nor the long-term economic opportunity for Scotland to build high-value advanced medical products for export. My concern is that the Government's cancellation of the Valneva contract looked like we acted in bad faith and it has thus damaged the trust and relationship between the UK and the pharmaceutical and bioscience industry. I have heard from those in the industry that they view the Government's behaviour concerning the Valneva contact as appalling. I think the Government's actions will make it very difficult for industry to be as willing to work with Government again in the event of a future pandemic.

47.15 The Government appeared to be solely focused on reducing its financial commitments during the first part of 2021. The UK contract allowed for 'at-will termination', subject to paying costs incurred up to that point. But by alleging breach of contract, the Government sought to avoid even paying for the costs which Valneva had already incurred in good faith. It certainly sent the worst possible message to any future UK industrial investor or life sciences partner. Valneva was ultimately approved by the MHRA, which justified our confidence in the company, but only after the Government had controversially, and in my view improperly, cancelled the contract.

47.16 The Government continued with its highly aggressive approach towards small innovative vaccine companies who had worked diligently and in good faith – and with our Ministerially authorised encouragement – to support the VTF and its goals in 2020. Novavax, at the VTF's request, had built a UK manufacturing capability in Darlington which provided the UK with some long-term pandemic resilience and also successfully ran their pivotal trials with 15,000 volunteers in the UK. In 2023,

Dame Jenny Harries, leading the UKHSA insisted that Novavax return $112.5 million in cash as the Government no longer wanted their vaccines, even though the MHRA had approved the vaccine as both safe and highly effective. I understand from Novavax's US Securities and Exchange Commission filing that as of August 2024, the company is in discussion with the Government about the return of the remaining upfront $112.5 million. Again, I regard this as improper.

47.17 I mentioned my concerns about the Government's treatment of AstraZeneca earlier. It is a matter of serious public concern that this behaviour has done long-term damage to the UK's reputation in the pharmaceutical and biotechnology industries, as well its future public health and pandemic resilience. I am aware of these concerns having discussed them with those in the industry.

47.18 The Government's recent rhetoric has been to try to emphasize the UK as a great destination for high-tech companies and international investment, in pursuit of its professed goal of making the UK a "science superpower". This pattern of behaviour with vaccine companies sends exactly the opposite signal. It is also noticeable that there appears to have been no serious investigation or attempt to hold Ministers or officials to account, public or private, for this poor series of decisions.

**48. Conclusion – Lessons Learnt from Working with Government**

48.1 **Focus on process not outcomes**. Officials in Whitehall are not rewarded for specialist skills or finding innovative solutions to complex challenges, but for adhering to the correct procedures. I saw an almost obsessive desire to follow the proper process and in particular to avoid any suggestion of personal error or possible criticism. Our VTF processes did not cut corners, and they worked – they delivered the outcomes.

48.2 Official and Ministerial nervousness amounting to paranoia about how to handle the media and the media's possible reaction held back the pace of execution, as did hesitancy over risk. It's much safer for officials, who focus on political and presentational risk but generally know little or nothing about actual commercial or scientific risk, to drag their heels regarding complex decisions rather than risk career suicide by pushing ahead with an even vaguely controversial task. In peacetime, no Civil Servant ever gets criticised for delaying a decision; in an emergency delay can be literally life-threatening.

48.3 **Lack of relevant skills.** In my seven months at the VTF, I was disappointed by the nearly complete absence in the Civil Service and among Ministers of scientific, industrial, commercial and manufacturing skills. If these skills are not in the BEIS, which also funds academic research, then where are they? The pressures to limit headcount in Whitehall meant that officials appeared to use strategic and operational consultants as an alternative. This had the added benefit, from their viewpoint, of providing a degree of official deniability. But such an expensive and short-term use of consultants does not help build this capability within Whitehall itself.

48.4 Very few Permanent Secretaries, the senior Civil Servants who are ultimately responsible for the commissioning of work, have STEM degrees or operational experience. Less than ten per cent of graduates entering the Fast Stream (a graduate Civil Service programme) have STEM backgrounds. Instead, Whitehall is dominated by historians and economists, few of whom have ever worked outside the official and political worlds, and very few of whom have the requisite pace of action or capability to make rapid substantive change.

48.5 **Government's fragile relationship with industry:** Even in BEIS, there seemed to be very few people who understood how the high-tech biosciences/pharmaceutical industry works, or who had any real relationships with the key companies and their leadership teams. This unfamiliarity was reinforced by an innate cultural hostility to business, with deep suspicion about industry motives. Companies were seen and treated as money-grabbing fat-cats, whose only interest was to rip off the taxpayer. Personally, I don't like being fleeced any more than the next person. But the Government appears to have no means of differentiating between rent seeking and rip-offs versus valuable corporate behaviour. This can be enormously costly. The Government showed that it was itself not immune from bad behaviour. I have given examples of this earlier.

48.6 To assist the Inquiry, I would make five recommendations.

**(1) Reward Outcome not Process**

48.7 My first recommendation is to refocus Whitehall and Government on outcomes not procedures. Professional development and promotions should focus not on rapid rotation between roles and departments as is the case now, but on contributing skills of demonstrable value. As part of professional development, I

would reward specialist science skills as much as generalist skills, and explicitly reward tempo and focus on outcomes. I would also punish for failing to act.

48.8 I would change the current system to reflect the proven practices of organisational management in the private sector. This means promoting the outperformers rapidly and quickly releasing underperformers. I would seek robust references on past performance of prospective candidates.

48.9 I would mandate that mid-level Civil Servants should not be able to climb the Whitehall ladder without at least two years of productive industrial or commercial secondments and public sector operational delivery experience. Unless they see how companies work from within, I don't see how officials can discharge their roles effectively.

48.10 I would also make changes to improve the effectiveness of Government itself. I would train Ministers in commissioning, business and financial skills and make such training mandatory for upward elevation to senior roles. Ministers should be chosen based on skills and relevant experience rather than simply on perceived loyalty.

48.11 I would introduce serious relationship management with key sectors. I would assign Ministers to manage relationships with CEOs of the leading bioscience companies operating in the UK. Sir John Bell and Sir Jon Symonds have developed a robust life sciences strategy with Government and this can help provide the roadmap. The role of Ministers should be to build closer relationships with bioscience leaders and instil new confidence that the Government is serious about working with them and supporting their work for the long term. Only by building trust with these critical organisations can we encourage them to invest in the UK, providing jobs, economic growth, and crucially resilience against future healthcare threats.

**(2) Embed Scientific Thinking and Science in Policymaking, Just Like Economics**

48.12 When we wrote Business Cases at the VTF recommending the purchase of vaccines, the Whitehall template required multiple different areas of analysis including strategy, economics, commercial, finance, management and legal. But not, astonishingly, science.

48.13 In the VTF, our due diligence provided that scientific and technical underpinning, but I would require the science case to be made for all Government decisions. The science case should be added to the Whitehall template. Scientific evidence should be central to policy and decision-making and should be just as important as economics. Creating a science case would also have the effect of stimulating wider and more in-depth understanding of science across Whitehall.

48.14 I would give the science advisers within each Government department more authority and status to influence policy and decision-making based on scientific principles. I would appoint advisers based on their industry experience and problem-solving track record. I would incentivise departments to collaborate on relevant areas of science.

48.15 Finally, I would encourage the Government to embrace the scientific method. This means enquiry, experimentation, observation and the accumulation of evidence and knowledge. Whitehall should be charged to challenge orthodoxy but be flexible to pivot and change in response to new information, data and evidence. Using the scientific method can help deal with uncertainty and manage risk.

**(3) Overhaul the Recruitment, Professional Development and Incentives of Civil Servants**

48.16 Science-related competencies, problem-solving and quantitative analysis should be essential skills for officials in today's data-based and innovation-driven economy.

48.17 I would set a target of recruiting fifty per cent STEM graduates at entry, prioritising those with research, analytical and statistical expertise. New STEM graduates should also have some training in economics so that they have a breadth of relevant skills. It is much easier to train scientists in economics than the other way round.

48.18 I would take measures to slow down the turnover within the Civil Service, so as to build up specific, valuable expertise.

48.19 I would fire half the people dealing with public affairs communications across Government. I was told that there were 120 communications people in BEIS while I was at the VTF. It is hard to see what of value they actually achieve or could achieve. I would redeploy this talent to more productive ends. This would send a

clear signal that the focus on Government is on the delivery of outcomes rather than on spinning the government "line".

48.20 In the private sector, incentives are widely used to implement change. So, one suggestion would be to delay awards of honours to Civil Servants and politicians to two or three years after the relevant period of service, or retirement, so that a better judgement could be reached of their actual achievements and effectiveness while in post.

**(4) Appoint a Senior and Permanent Pandemic Security Capability**

48.21 The reason why the VTF was required in 2020 was that there was no one to advise on this work in Government. Healthcare threats are just as serious as many aspects of national security and defence – arguably more so, given the actual risk to life and limb involved – and should be treated with at least the same importance. We invest in our conventional and special forces, we recognise the importance of developing our intelligence services, and we plan and train for a vast array of difference scenarios, yet we are neglecting the most likely and potentially most severe collective threat to the nation – the next pandemic.

48.22 I would appoint a permanent pandemic security expert from the private sector, perhaps as or alongside an experienced senior Minister, with authority for building and maintaining a co-ordinated UK pandemic preparedness capability This person must have high level, relevant relationships with industry. This person must also be protected against relentless negative briefings.

48.23 In my own case, I was the target of numerous false accusations about corruption, incompetence and cronyism from strangers repeating unfounded claims – much of which has now been confirmed to have come from Number 10 and DHSC private briefings with the media. These false accusations were often repeated by parts of the media for their own reasons. BEIS did not provide any robust protection against these attacks. This treatment of unpaid volunteers, and the lack of willingness to confront it, is not acceptable. The same is true for senior external professionals retained in sensitive roles in the future like that of pandemic security adviser.

48.24 As it does with defence and security, this capability will involve close collaborations across Whitehall as well as with companies and Governments globally. The UK will need to continue to invest in next generation vaccine and antiviral therapeutic formats, partnering with researchers and AI experts to predict future pandemic

threats as well as to design new vaccines and therapeutics. The Government will need to provide a budget for this work. I would recommend that this individual reports to the Prime Minister, as the current National Security Adviser does, and as I did.

**(5) Agree a Strong International Approach for the Future Management of Pandemics**

48.25 The Western countries were too slow to join together, and too self-interested. Of course, it is essential for democratically elected Governments to protect and support their citizens, but the COVID-19 pandemic has been made worse – including for those citizens – by the West's instinct to hoard vaccines. While the UK fared well, as matters have turned out so far, global surveillance to identify pandemic threats and emerging variants could be considerably more thorough and more joined up.

48.26 It is essential that the UK, and maybe for the G20 and other motivated countries, invests in building vaccine manufacturing facilities around the world, especially in Africa. These facilities should ideally be located in low-population countries, to mitigate the risks of their being overwhelmed by domestic vaccine needs, and so by the imposition of export bans. We collectively need to build the skills, infrastructure, and capabilities to make safe, approved vaccines, and to do so quickly in a pandemic. Such skills and facilities are relevant for all advanced medicine manufacturing, so an investment here will help build global health security as well as long-term economic growth in these countries.

48.27 This Government and other Governments must also agree a robust long-term basis for funding the provision of vaccines to low-income countries. Agreeing the scope of COVAX in 2020 was too slow, and this delay caused unnecessary deaths.

**49. Conclusion Preparations of the next Pandemic Virus / Disease X**

49.1 In terms of preparing for the next pandemic, we need to start preparing how to deal with it now, and that involves allocating money to it now. Urgent collaboration is needed across the goal to prevent a repeat of the COVID-19 pandemic[2].

[2] One recent vaccine research and development initiative launched by the Novo Nordisk Fonden would be a great collaborative partner.

49.2 We need to develop a prototype vaccine framework that could be engineered to target the specific features of future viruses across all threatening virus families. The reason that there was such a rapid global response to COVID-19 was because vaccine frameworks had already been developed as part of the process to develop vaccines against SARS and MERS a decade earlier. When COVID-19 emerged, scientists had a prototype design to start with.

49.3 I have been asked by the Inquiry to consider the "proactive vaccinology" approach and the so-called "all in one" vaccine that researchers at the University of Cambridge have developed and tested on mice. I understand that the aim of this approach is to build a vaccine before a disease-causing pathogen emerges. I have not considered the research in detail but I think that there may be the potential for it to work but until the clinical trials are run and until the data is developed, then we won't know for sure. I doubt it is the silver bullet and I consider that several alternative approaches need to be adopted in order to be ready for whatever pathogen may cause a future pandemic.

49.4 The speed of response also needs to be improved to ensure that the next outbreak will not become a pandemic. The '100 day mission' is a strategy launched by the Centre of Epidemic Preparedness Initiative (CEPI) and supported by Governments around the world to develop safe and effective vaccines and make them available within 100 days of a disease being identified. We need to be quicker in our response to vaccinate everyone, including the immunocompromised, to prevent, or at least limit, the chances of future viruses mutating.

49.5 To meet this aggressive timetable, we will need to build a large collection of different prototype vaccines for every known pathogenic virus family with pandemic potential.

49.6 Disease X, where we know neither what form it might take, nor its potential mutations, presents an even more pressing need for a portfolio strategy. First, different vaccine formats such as mRNA vaccines, vector-based vaccines, the protein subunit vaccines and inactivated vaccines stimulate different immune responses and provide different levels of protection. mRNA vaccines are quick to design and manufacture but may not provide the most robust and durable protection. In fact, we may not know which antigen to include in the vaccine to generate protection. In contrast, with Sars-Cov2 we knew vaccines should focus on the Spike protein based on the previous work with SARS and MERS. However,

with rapidly mutating flu viruses, is it much less simple and more difficult still with an unknown virus. As such, having a capability to manufacture whole virus vaccines is critical for the UK's pandemic resilience. Not all vaccine formats are suitable for everybody. Some people may be immunocompromised or have allergies or adverse reactions to some vaccine components, making a choice of vaccine crucial. The UK must have the capability to develop and manufacture a broad spectrum of vaccine formats.

49.7 Second, manufacturing capabilities and supply chain infrastructure vary enormously across countries and regions. Some formats may be suitable for large-scale production, while others may be easier to produce in resource-limited settings without sophisticated cold chains. We saw this with COVID-19 where it made sense to use Pfizer-BioNTech and Moderna in wealthier nations and Oxford-AstraZeneca in poorer places.

49.8 Third, we should trial new technologies and approaches to vaccine design to address shortcomings of the current vaccines relating to transmission, durability, breadth, delivery, and stability, as well as cost.

49.9 Fourth, exploration of vaccine alternatives is a solid positive for UK research and development. Promoting the development of various formats fosters welcome innovation and scientific advancements. It will allow researchers to trial new technologies and approaches to vaccine design, potentially leading to more effective and efficient vaccines in the future – as well as economic growth.

49.10 Having the flexibility to use a range of vaccine formats means that scientists and health authorities can choose the most effective and safe vaccines based on clinical trials and real-world data. With multiple options, they can optimise vaccination strategies and adapt to emerging variants or changes in the virus.

49.11 We need to invest in state-of-the-art systems for international surveillance of prospective virus threats. The Biden administration has funded DEEP VZN, a programme for the exploration and discovery of emerging pathogens, to identify and prioritise the most disturbing viruses. This research could and should be conducted alongside a Global Viral Genome Project to maximise its impact. It should be supplemented by the use of space science to monitor climate and environmental change that can trigger the emergence of new viruses. An

imaginative masterplan will not allow us to identify the next one with certainty, but it can help.

49.12 We must commit to equitable distribution of vaccines, invest in manufacturing infrastructure across the world and reject the vaccine nationalism that marred our responses in 2020.

49.13 One of the many tragedies of the COVID-19 saga in 2020 was that countries often retreated into silos, locked down mentally as well as physically, and failed to support any serious international plan. We need to learn the lessons of what was a major long-term policy and organisational failure, a failure which cost many lives without doubt, and we need to put in place the components that would allow us to react much more effectively next time.

49.14 The first step in this would be to build biological vaccine- manufacturing capacities in low-population countries in each continent to provide surge capacity for vaccine production at low cost. Building capabilities in low-population countries should reduce the tension between the political demands to 'vaccinate our own people first' versus treating those most in need. A world in which so much manufacturing is located in some of the most populous nations – India, China, the US – carries the risk of Governments stopping vaccine exports, as was evident during the COVID-19 pandemic. The developing world, especially Africa, needs more sophisticated manufacturing centres for future pandemics. This is easier said than done. It is not simply a matter of planting a production centre in a modestly populated country which appears to be in the right place on the map. Broader infrastructure also needs to be in place. This is not just a matter of physical facilities. To ensure that the enterprise will be safe and secure, there has to be robust training to build the expert capability needed.

49.15 As of May 2021, only thirteen lower and middle-income countries had their own national regulatory agency for pharmaceuticals (the equivalent of the MHRA in the UK, the FDA in the US, or the EMA in the EU). The MHRA is making an admirable effort to set global regulations and standards and share its expertise to support regulatory approvals in low and middle-income countries. It will take a sustained drive and dynamic leadership by regulators to bolster the rapid approval of vaccines in an emergency and in the right places. With more national regulatory agencies in place, it should be possible to conduct more clinical trials in parallel and in more countries than was the case with COVID-19. The more opportunities we

have to test vaccines in different countries, which may have different population exposure or virus variants, the better our prospects of devising vaccines with the best impact.

49.16 There can be no excuse for not being better prepared for the next pandemic. There has to be international co-ordination as to how we rehearse the response much better and more scientifically. A more intelligent and informed battle plan is essential because, even if every previous suggestion set out here were incorporated into official thinking immediately and the resources found to support it instantly, there would still be a period of time between realising that a virus with the potential to induce a pandemic had reached human beings and the deployment of mass vaccination. It is highly likely that some sort of non-pharmaceutical interventions would be needed as a stopgap.

49.17 This is some way from the remit of the Inquiry, but for the sake of completeness, I would suggest that such a battle plan should have at least the following elements.

49.18 First, there have been lots of individual studies as to the effect of various non-pharmaceutical interventions between 2020 and 2022 and there will doubtless be many more such research initiatives. We must have a central repository for the data from these studies, as there will be priceless unexplored material contained within them. This is a long term public good.

49.19 Second, we need a toolkit of different non-pharmaceutical interventions, depending on events. There has, not unreasonably, been an anguished debate around the cost–benefit analysis of shutting schools during COVID-19, when children were the least likely sub-section of the population to acquire COVID-19 and the most likely to shrug it off with minimal risk to their health if they did. There is no reason whatsoever that a future pandemic would have the same profile in terms of its impact by age – different pandemics require different kinds of lockdown. Much more thought needs to be given to the potential interactions between targeted direct financial support, the use of non-pharmaceutical interventions, and the deployment of vaccines, antibodies, and therapeutics, as part of a full future pandemic response.

49.20 Finally, there must be a single global body responsible for our response. The obvious one to take up the mantle is CEPI working closely with the WHO. We need to fund a Global Budget with contributions based on relative wealth across the

international community. There should be a Global Pandemic Treaty with clear accountability for vaccine development and manufacturing, plus the open sharing of information among scientists and clinicians globally.

**Statement of Truth**

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

**Signed:** Personal Data

**Dated:** **4 October 2024**