Witness Name: Sir John Bell
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UK COVID-19 INQUIRY

SECOND WITNESS STATEMENT OF PROFESSOR SIR JOHN BELL

I, Professor Sir John Bell will say as follows: -

The role of Life Sciences Strategy in preparing for and responding to major health threats, including pandemics:

1. I have been closely involved in developing a Life Sciences Industrial Strategy since my appointment as the first Chair of the Office for Strategic Coordinating of Health Research in 2006 and, subsequently, being appointed as Life Sciences Champion by David Cameron, Teresa May, Boris Johnson, and continuing in that role alongside Sir Jon Symonds since 2020. My background in biomedical research in areas such as genomics and immunology, my leadership positions in the biomedical research arena, including being President of the Academic of Medical Sciences and Regius Professor of Medicine at the University of Oxford and my close involvement with the Life Sciences industry have all provided me with the necessary insight to enable engagement of the industry by the public sector.

2. My insight into the role of industry in health care and biomedicine comes from a longstanding involvement with large pharmaceutical companies: I sat on the Scientific Advisory Board of AstraZeneca for four years up to 2001, and then as a Non-Executive Board member of Roche AG from 2002 and of Genentech since 2010 up to the beginning of the pandemic in 2020. In addition, I have been actively involved in helping to create biotech companies in the UK and have been a founder or founding director of several biotech companies.

3. At Roche AG, I participated actively on the development of a R&D strategy. The

company, including Genentech, led the development of biologic therapies and pioneered personalised medicine. The company also had a large in vitro diagnostics division, and I was active in multiple strategic discussions with this team about the future of IVD and its wider role in healthcare.

4. Together, this background gave me insights into the industry from a variety of levels, but also a strong understanding of the research and development opportunities that the UK provides.

5. The UK has had a remarkably successful history in the life sciences. It has been the home of multiple pharmaceutical companies, although only two – AstraZeneca and GSK – remain domiciled here, there are discovery sites for a significant number of other pharmaceutical companies discovering new therapeutics and vaccines in the UK. The industry is one of the significant pillars of the UK economy and is responsible for much of its Research and Development ("R&D") and economic growth.

6. I was asked by Greg Clark to lead the work on the Life Sciences Strategy in 2015/16. Life Sciences had already been a chosen sector for the UK government because of its very large footprint in the country's economy, but also the potential for inward investment from multiple different aspects of the sector. I was asked to bring together a committee involving industry, government and academia to work out how the sector could take advantage of the Industrial Strategy Challenge Fund (ISCF) and, on the back of these discussions, we wrote and published the first Life Sciences Strategy document which led to a set of very successful programmes, many of which have now been completed and all of which received substantial matching funding from industry. These programmes brought in more than £3.5 billion worth of investment, including the ICSF programmes but also inward investment for discovery sites for MSD, UCB, NovoNordisk and AstraZeneca. It also set the community up with extensive internal discussions about working together, such that the community was prepared for more joint work during the pandemic.

7. I have acted as a facilitator for the sector, meeting regularly with industry representation in the medtech and diagnostic space, small companies and large

pharma companies and have also helped to facilitate interactions with NICE and the MHRA, providing government with advice in all these domains.

8. During my time as Life Sciences Champion, I have done my best to enhance the attractiveness of the UK for inward investment in the life sciences space and many would agree that we have been successful in this endeavour. Over the course of the first Life Sciences Industrial Strategy published in 2017, four major pharmaceutical companies chose to develop significant new discovery sites in the UK. As mentioned above these included MSD, UCB, and Novo Nordisk, and AstraZeneca began creating its major research site in Cambridge. In biotech, the UK is the most successful country outside of the US in establishing and growing small biotech companies but has been singularly unsuccessful in scaling any of these to mid-sized, successful companies with products for sale. Nevertheless, it is a rich environment for this type of economic activity, with a large number of biotech and medtech companies being established here. It has developed a strong and capable workforce, good infrastructure, a world class regulator in the MHRA and a world Class R&D capability.

9. However, not all has been easy for the life sciences industry in the UK. Despite efforts of previous governments to create an attractive environment, including the creation of the patent box and, until recently, the relatively low corporation tax, the healthcare system is, by international standards, a difficult environment into which to sell novel, innovative products. Only 7% of the healthcare spend in the UK is spent on drugs where, in most other OECD countries this sits at 15%. In comparison to Europe and North America, drug prices in the UK are low and access is poor.

10. Nevertheless, the NHS does offer some significant advantages to those working on discovery and development of novel life sciences interventions. Its large population is attractive for clinical trials; although, since the pandemic, the number of commercial clinical trials has been at an all-time low, it should be possible to re-establish these at a higher level. The NHS has also become increasingly digitised, and it now begins to offer an opportunity to better understand population and public health as well as individual disease entities at a population level using digitised data. The UK is also the home of many key opinion leaders across the field of biomedicine and this is, of course, attractive to the industry which might seek out this expert

opinion. Therefore, the accumulative advantages of the UK as a life sciences hub, are ones that most companies globally would envy and has led to a successful and thriving life sciences industry in this country, going back some decades.

11. In 2022, Sir Jon Symonds and I were asked to renew the Life Sciences Strategy with a document called the Life Sciences Vision. In this we laid out a strategy for industry to work to tackle some of the big challenges that the NHS was confronting. Those Life Sciences Missions have formed a core part of the Industrial Strategy going forward, although it should be said that less progress has been made in advancing these than was expected. Nevertheless, it provides an important format for inward investment and government/industry interactions.

12. The concept of industrial strategy has caused some difficulty as it is interpreted in different ways by different governments. We have viewed the industrial strategy as a mechanism to get industry, the NHS and academic research groups to align behind things that we believe will substantially advance the field and create new innovations that will be to the benefit of patients worldwide, but also generate economic growth driven by the sector. This is not a question of government choosing winners, nor is it an opportunity for government to prop up failing sectors. Instead, it is an opportunity to help industry and the NHS to move into exciting new areas of research together, jointly share capabilities and risk and jointly resource projects that advance the industry in a significant way.

13. Our Future Health, which emerged out of the first Life Sciences Strategy is a perfect example of this. It is a large cohort designed to allow industry and government to think about how they would introduce a programme that would identify disease and intervene at an early stage with a range of prevention tools, starting with a large cohort (now 2 million people) who are consented to participate in the studies and can be characterised in great detail, both genetically and biochemically. This is a unique resource globally and was done with Innovate UK and industry sharing broadly equal amounts of the funding to allow this to happen.

Why is the Life Sciences Industry important?

14. Much of modern health care relies on the flow of innovative, new technologies including diagnostics, medtech and novel therapeutics, to create the improvement in

health now expected by the population. This has been one of the most successful scientific endeavours in the past forty years and has led to the remarkable enhancement of life expectancy of twelve years in this country and, globally, of about nineteen years, which is a remarkable achievement. The presence of an active and vibrant Life Sciences Sector is obviously helpful in general terms as it creates jobs and economic growth for the country; the Life Sciences Sector has a Compound Annual Growth Rate of 3.5% predicted over the next twenty years. Investment in this area is likely to generate prolonged and successful economic growth. However, in addition to the growth prospects associated with this industry, it also creates a number of strategic opportunities for the country.

15. Firstly, its work on new, innovative tools for healthcare, provides an opportunity for these to be trialled and tested in the UK first and then rolled out for the benefit of the UK population. Therefore, it is a key component of both the health and the wealth agendas in the UK. The evaluation of drugs, devices and diagnostics in the health care system is largely paid for by the industrial creators of these innovations and, as a result, it provides more than a net saving to the NHS; it provides a significant, positive funding. This is why the re-establishment of a strong, commercial clinical trial capability within the NHS is crucially important.

16. Secondly, the industry has the potential to provide significant onshore manufacturing capabilities, which was demonstrated to be crucial during the pandemic. This is essential for health security when there is massive global demand for products that significantly exceeds supply, and countries are likely to close borders to ensure their own populations can access healthcare resources that are in short supply.

17. The UK has not been good at supporting the creation of significant amounts of life sciences manufacturing, although this has changed in the last two years and HMG is making significant efforts to help subsidise the creation of manufacturing capabilities across the UK, a key strategic step forward. In the case of a health emergency, ready access to products including testing devices, reagents, drugs and vaccines, becomes mission critical and having onshore capacity that can be used to supply the UK population has been, and will continue to be, an important strategic issue.

18. In my first Witness Statement, I discussed the difficulties in ensuring that

manufacturing of vaccines – particularly our own UK based vaccine – occurred at the necessary pace and, although the UK managed to do this very successfully with the help of AstraZeneca, this was not the result of careful planning, but rather the fact that we had significant life sciences activity in the UK that could pick up these manufacturing challenges. In particular, British Biotechnology was a major source of domestic supply of the AstraZeneca vaccine and that capacity had been supported by the Life Sciences Industrial Strategy – not for this specific purpose, but rather because it had created the infrastructure that made it possible to be used for this requirement when the time came.

19. The importance of a further aspect of the Life Sciences Strategy became obvious in the early months of the pandemic; a domestically based life sciences industry proved to be extremely helpful in responding to and preparing the country for the challenges of the pandemic.

20. The presence of a Life Sciences Industrial Strategy meant that many people in government, and more widely across the UK, were in close contact with leaders in the life sciences industry, all of whom were anxious to try to help with this significant healthcare emergency. In order to respond as a nation to this global crisis, the ability to contact and use these individuals with expertise in exactly the right domain proved to be crucially important.

21. I advised Ministers on many occasions on how to get access to particular expertise, as well as how one could explore the procurement of particular types of life sciences products that were proving to be essential for the UK during the pandemic. That network simply included the ability to ask companies whether they would be able to help find life sciences suppliers from their global networks to provide us with anything from swabs through to tests and generic medicines. The industry was also very willing to open up its R&D capacity to help generate the reagents necessary for the development tests and, when they were approached in the right way, they were also enthusiastic about leaning into the creation of testing capabilities across the UK. There are many examples of this but, perhaps the willingness of AstraZeneca to pick up the challenge of collaborating to manufacture, regulate and distribute the AstraZeneca vaccine, initially on a not-for-profit basis, shows a remarkable commitment in the industry to stand up to the global crisis produced by the global

pandemic.

22. Similarly, colleagues at GSK helped to generate recombinant Spike protein to enable antigen testing development and helped identify global sources for other life sciences resources. This was largely done through personal contacts in the industry and, as these discussions took place, the strategic advantage of having the industry onshore became very clear to myself and Ministers.

Procurement of PPE, Oxygen Ventilators and Diagnostic Tests

23. I played no role in providing advice on or procuring PPE during the pandemic apart from procuring a container of PPE from colleagues in Hong Kong which was used at the local Oxford Hospitals. I had nothing to do with the wider procurement arrangements at the Department of Health. Similarly, I had nothing to do with procurement of oxygen. The ventilator crisis loomed early in the pandemic and, at the request of the Health SpAd at No 10, I reached out to see if I could get access to ventilators from other jurisdictions. I placed a call to Zhu Chen, the previous Health Minister in China, who ultimately got back to me and offered a significant number of ventilators for the UK. This offer was ultimately declined by HMG and the NHS managed to get through without this source of supply.

Diagnostic Tests

24. I was very closely involved in the identification and recommendations to Government as to which diagnostic tests to make available. There are several important things for the Inquiry to understand about procurement of diagnostic tests in the middle of the pandemic. Firstly, there is bound to be a limited supply of tests compared to the demand which is truly global with all countries seeking to obtain as many tests as they can. This global competition is for an increasingly limited supply of not just tests, but all the associated requirements for testing, including swabs and other forms of chemicals and reagents for PCR and lateral flow tests. Procurement becomes a particularly challenging problem because, if one attempts to procure in the conventional way, there is a very significant risk that, by the time that process is complete, products are no longer available. Therefore, during a pandemic, speed is a crucial component of procurement.

25. The second thing to remember is that one needs to think carefully about how best to

deploy diagnostic tests to ensure that the necessary supplies and capabilities are available for the end-to-end solution. During the Covid-19 pandemic, there were three basic approaches taken to testing the UK. The first was the polymerase chain reaction (PCR) tests undertaken in hospitals and healthcare settings. This proved to be helpful for the management of patients in the hospital setting, but unhelpful for the management of the pandemic at a population level. The second approach was highly centralised testing using PCR done outside of the NHS. This is a model particularly developed in the UK and subsequently replicated in other jurisdictions such as Australia and Canada. It allowed automation and scaling and ultimately led to a very large capacity for PCR testing nationally. This required significant, centralised facilities, large amounts of PCR equipment, automation and a digital infrastructure that allowed the management of flow and reporting results. These highly centralised labs proved to be enormously productive early in the pandemic and I was extensively involved in getting them established. In addition, the labs required access to very large numbers of swabs for which there was a serious global shortage, and this proved to be a significant problem early in the pandemic.

26. The approach to obtaining the swabs was developed by the DHSC team. Kirsten McLeod, who I had worked with in the Office for Life Sciences, was intimately involved in helping to establish the drive-through testing centres which allowed individuals to have samples taken which were then forwarded to the Lighthouse Labs. This was a substantial logistical challenge and one that was significantly enabled by Boots, which offered to provide support for this effort, and by the MOD; the armed forces were important in establishing these capabilities nationally. The final type of testing was that applied by individuals in the community through home testing. This was an ambition that the DHSC set out early in the pandemic but was only realised when it was clear that lateral flow tests were being made to the necessary standard of sensitivity and specificity and could provide results in a few minutes. The UK was again a leader in this space.

27. I had been involved in evaluating serological lateral flow tests that were intended to detect covid antibodies in people that had previously been exposed. This exercise demonstrated several things. First of all, there were a lot of suppliers of products out there attempting to sell them at scale, even though the products were inadequate, and the products had not undergone any effective form of regulatory approval or

evaluation. On the instructions of Ministers in the DHSC, I set up a small group which rapidly accessed positive serological samples from those exposed to Covid and utilised those to test and evaluate large numbers of serological lateral flow tests. On the whole, these proved to be inadequate but, most importantly, progress on this project was stopped when it became clear that it had not been robustly demonstrated that previous exposure to the virus, as confirmed by a serological assay, provided protection to subsequent infection. In the end, studies showed that this was largely the case and, indeed, natural exposure to the virus likely provided better protection than vaccines. However, at the time this was not certain and, as a result, progress was paused on this project.

28. The experience we had had with serological lateral flow tests led naturally to the evaluation of antigen testing using lateral flow tests which was undertaken by a group I led at Porton Down under the leadership of Alex Sienkiewicz and Richard Vipond. This team set out to develop a robust approach to evaluating the utility of lateral flow antigen testing at a time when there was scepticism about whether these would be of any value.

29. The team at Porton Down had access to a large number of frozen, stored samples of swabs from individuals who had tested positive with PCR and, using the containment facilities at Porton, were able to evaluate the test to detect their limits of detection against live virus and their ability to detect antigens on stored collections of swabs. This programme was started in late June/early July 2020, ran through the summer and through most of the following year. The outcome of this was that tests could be utilised by the population at large and, indeed, this became the standard population testing.

30. Initially, most of the lateral flow tests that we evaluated were not of a standard that could be used at a population level, but we did identify several early on in our studies that we felt met the mark of being useful at an individual and population level. These were procured by a team of civil servants who were part of the committee evaluating lateral flow tests. Dominic Cummings was an early advocate of attempting to procure large numbers of these tests as soon as they appeared to be useful. Ultimately, they were procured by the tens of millions and were distributed through Boots in packs and widely used by the population in the latter stages of the pandemic.

31. It is important for the Inquiry to recognise that the two major types of tests, the polymerase chain reaction (which were best deployed in large, centralised labs) and lateral flow tests (which were designed to be used in a distributed fashion, ideally by individuals at home), ultimately give somewhat different results because they are detecting different material associated with the virus. PCR detects viral RNA and, when the tests are appropriately designed, can detect RNA with very high sensitivity. However, what emerged during the pandemic was that it was clear that some individuals were still testing positive several weeks after the infection when there was no evidence that they were infectious to other people. It was speculated that there was residual RNA in the nasopharynx which was being detected because of the high sensitivity of PCR. As a result, the tests were associated with a certain level of false positive results if one was considering their contributions to measuring infectious virus. Nevertheless, as the gold standard test for the presence of virus, PCR was undoubtedly the optimal tool.

32. Lateral flow antigen tests detected something entirely different and that was the protein antigens associated with the virus. What became clear during the evaluation of these tests was that they were positive only at a particular level of viral infection and that viral infection correlated strongly with the level of infectiousness of the individual infected and, as a result, were an excellent tool for managing the transmission of the disease. It was often misunderstood that the test for infectiousness was a powerful public health tool and one that could be used effectively to identify people who were likely to spread the disease; it was used as such by many members of the population before they went out to join forms of social gatherings later in the pandemic. It also had the massive advantage that it could detect virus in the large number of people who were never going to be PCR tested; as a result, as a tool for managing the pandemic, the tests proved to be extremely powerful. The work on this was done by Professors Tim Peto and Derrick Crook who made significant contributions to our understanding of what lateral flow testing could provide. Once thought about in the appropriate way, it was clear that false positive rate of <1:1000 and a sensitivity for infectiousness that sat in the 90%+ range, these were extremely effective and inexpensive tools that could be deployed for populations.

33. There were other tests procured during the pandemic. The LAMP test is a thermal cycling test which, again, requires centralised facilities and the acquisition of samples from a distributed network. This test has high specificity and a similar specificity to LFTs but suffers from the significant disadvantage that it does require centralised facilities with all that goes with them, including automation and logistic support for the transport of swabs. Other individual devices were deployed to increase the number of tests undertaken, but none of these reached any material scale to have an impact on the pandemic.

PCR Testing

34. In early March 2020, I was asked by No 10 to join a small group looking at the effectiveness of PCR testing very early in the pandemic. At that stage, the predominant test being used in test laboratories were the usual 'laboratory developed tests' or LDTs, otherwise known as "home-brew". It is possible, from a regulatory perspective, for labs to make their own tests, provided they run the labs themselves and do not distribute them to other users. This is a common approach used in the NHS where diagnostic capacity has never been a major health system priority and where the labs, at the start of the pandemic, were underfunded and certainly not prepared for the wave of activity they were about to be confronted with.

35. Lab developed tests often involved the lab putting together the various test components, including a range of different supplies and enzymes as well as PCR primers to make PCR tests that could be used. In the end, these turned out to be less reliable than predicted but, most importantly, the labs were rapidly overwhelmed with testing volumes and quickly ran out of the supplies which, as discussed, were unavailable due to dramatically increased global demand.

36. In the absence of the supplies necessary to make the tests, there was a deficiency of tests available, and the totality of NHS labs drastically failed to meet the challenge of providing PCR testing for the country. The committee (I am unable to be precise about its membership, but it included myself, William Warr from No 10, Jeremy Farrar, at least one of the deputy CMOs, NHS representatives and, I believe, Kristen McLeod) brought together by No 10 was tasked with investigating this problem.

37. At our first meeting, it was indicated that the total number of PCR tests done nationally the previous day was in the order of 5,000 tests. It was agreed that this

might simply be a question of labs getting started but, when this was followed up on subsequent days, it was clear that that number was falling rather than rising and that the NHS was not going to be able to provide any material amount of testing capability. The solution was discussed by the committee and it was decided that we should attempt to create several large-scale, high-throughput laboratories around the country, support them with PCR machines and RNA extraction machines obtained from the life sciences sector around the UK (as the production of new machines would have taken many months), and that we should attempt to set up at least three of these laboratories urgently.

38. I had two significant contributions to make to this discussion. Firstly, over the previous several years I had been busy helping to create a large bioresource facility in Milton Keynes that had been funded through the NIHR as a national facility for handling and storing samples. It had an excellent team in place led by Tony Cox, and a good board led by Peter Weissberg. They were significantly under capacity before the pandemic and, with a single phone call with Tony and Peter, I agreed that they should consider becoming a hub for PCR testing for the country, something they agreed to do within a day.

39. A second opportunity arose during discussions with Chris Molloy who had been involved in setting up one of the Innovate Catapults in Manchester where I thought there might be capacity. Chris picked up the idea and rapidly positioned himself to help establish a second lab in Manchester for samples. A third lab needed to be sited in Scotland and that was left up to Scotland to eventually decide to place it in Glasgow. This is how the three Lighthouse Labs were originally selected; it was entirely opportunistic, but also incredibly urgent.

40. The next task was to find PCR machines and machines for RNA extraction that could go into these sites. The Government decided that the life sciences sector, particularly the universities, had large numbers of these machines and that it might be appropriate for them to make them available for large-scale throughput. The army was enlisted to go to universities to pick up these machines and very rapidly it was possible to populate the three Lighthouse labs with the necessary machinery. Volunteers poured in to help run the machines, usually from the local universities (I know Birmingham in particular was extremely helpful with the Milton Keynes

Lighthouse lab); protocols were established, and considerable efforts were put into identifying how to get flow from drive-in centres from around the country.

41. The other major contribution I made was as a result of a phone call I had from Claire Wallace, Vice President Life Sciences Solutions EMEA at Thermo Fisher Scientific in Renfrewshire. I had become aware that PHE had decided to procure commercial PCR tests from Roche, the world's biggest diagnostic supplier. Unfortunately, I was also aware that their manufacturing facility on the East Coast of the USA needed to be significantly expanded to meet global demand and, even then, the company was only willing to supply the tests on a pro rata basis based on population numbers. This meant that Roche could not make a significant contribution to the early PCR testing capability in the UK.

42. During the call from Claire, she explained that she had been trying desperately to get hold of PHE, but no-one was answering the phone. Thermo had a substantial capability for supplying the UK with PCR tests. She wanted to know if there was anything I could do to enable their access to decision makers at PHE or DHSC. This is a good example of the benefits of having a Life Sciences Strategy in that she knew me through my life sciences role and, as a result, was able to call me and I could then forward that message onto Government.

43. Thermo had indicated that they could rapidly provide us with up to 100,000 commercial tests a day and that they could scale ultimately to 200,000 tests a day. Access to these tests essentially rescued the country which had started with a lamentable level of testing and was now getting ready to scale through centralised PCR laboratories. The Department of Health proceeded to sign contracts with Thermo Fisher to make those tests available. Thermo became extremely important in helping to identify PCR machines and RNA extraction machines around the country that could be used for this purpose. Thermo became a close partner throughout the whole process of PCR expansion in the UK; another good example of having on shore life sciences capability.

44. At one point, there was some concern that the US would implement the Defence Procurement Act which provided them with the legal right to stop exports of medical equipment to prioritise the supply to their domestic market. Thermo had been very thoughtful, however, and had ensured that they had global supply chains for most of

these products that would enable them to continue to supply even with this particular challenge.

45. There was a wide discussion largely generated by the academic community that the best way to expand PCR testing was to allow lots of individual labs to run single machines or small numbers of machines for testing. Claire Wallace was opposed to this model, as was I, as the ability of the company to support the machines, provide maintenance and repair services to keep them all running was greatly enabled by the fact that they would all be concentrated in a few major sites. Those sites also provided an opportunity to automate the process, improving high throughput and enhancing the health and safety capabilities of Covid testing. Finally, the ability to link up a whole range of little independent labs into a digital framework that would have allowed the test results to flow smoothly, was also a potential problem and, although some academic scientists went on to establish small labs, they had no significant impact on the total testing capacity of the UK.

46. There were some additional issues that emerged, including access to swabs; it became very clear early on that the capacity for accessing swabs at the scale would be needed and was highly constrained by the absence of sizeable swab manufacturers in the UK and the difficulty of obtaining swabs internationally due to global demand. We spent some time in the lab attempting to validate the utility of different swab types. The team at DHSC were very preoccupied trying to identify swabs. It turns out that many swabs potentially could have been used but had not been properly approved by regulators. As a result, even Q-tips, which might have sufficed, were not accessible for use in this way. Ultimately, swabs were a significant limitation in the early stages of PCR testing but, as manufacturing grew globally, this particular issue became less important.

47. The Secretary of State for Health and Social Care, Matt Hancock, declared that we would be attempting to generate 100,000 tests a day by the end of April 2020. Despite this being a big reach, it was realised – although only just. However, the important consideration here was that it focused everyone on the need to dramatically expand our PCR testing capacity during March and April and left us in a strong position to continue to expand that capacity over subsequent months. With the NHS being stretched well beyond capacity, we had gone from a standing start to

having a significant PCR capacity nationally. The PCR testing programme subsequently expanded using a technique called end-point PCR which did not quantitate the product, but simply provided a digital outcome of whether there was virus in the sample or not. This is done using large reels and high-throughput facilities and had been pioneered by the Gates Foundation in the USA. This was picked up and formed the basis for a further centralised lab, The Rosalind Franklin Laboratory, in Leamington Spa. This allowed ultimate scaling of PCR testing to >500,000 tests a day by the end of the pandemic.

48. The model of large, automated testing labs did require the introduction of a large amount of automation to make these efficient. There was a remarkably impressive team at the Milton Keynes Lighthouse Lab that introduced large amount of automation and provided many of the tools that allowed the throughput to increase at pace. Help in supporting the development of this lab came largely from the life sciences industry. It should be noted that AstraZeneca also established a highly efficient lab in Cambridge which ultimately formed part of the overall network. Another significant contribution from the industry.

49. All aspects of our testing capacity with PCR were derived from the Life Science industry. They were partners in providing tests, machines, automation, some testing labs, supply chains and expertise. We would have been in real trouble without them.

Antigen Lateral Flow Testing

50. The need, however, to begin to test much larger numbers of people in the population became urgent when it was recognised first by the Covid-19 Infection Survey with ONS that a significant number of people who tested positive with PCR tests in the population were in fact asymptomatic.

51. The numbers of asymptomatic people ranged around 50% in studies done both here and internationally, hence there was a large burden of people with disease in the population who would never access tests or be requested to undertake a test, but who were still capable of spreading the virus more widely to susceptible groups.

52. The dogma in some parts of DHSC and the NHS was that the numbers with asymptomatic disease in the population were small; this view ignored data from other

respiratory viruses and was ultimately a significant problem until debunked by available data. Knowing that there was a large number of people in the population who were unable to access PCR tests or were unlikely to access tests because they were symptom free was a strong motivation for us to think about testing that would identify those asymptomatic people, particularly those who were at the stage of the disease where they were infectious.

53. We were aware that there were antigen-based lateral flow tests available from the Life Sciences industry, and we began testing to evaluate their utility. This involved a detailed set of sequential experiments at Porton Down that tested both specificity and sensitivity and evaluating their use in real-life swab samples.

54. Once several of these tests that operated at an acceptable level of performance were identified, they were then evaluated in large-scale, real-world studies. These studies were rolled out to be evaluated in a range of educational settings, including state schools in Wiltshire and the University of Durham. The team in Liverpool also then ran a large-scale population screening study led by the MOD out of the University of Liverpool and the Liverpool School of Tropical Medicine; this evaluated the real-world use of these tests in that setting. There was confusion from the beginning as to whether these could be self-use tests or not indeed, there was a lot of pressure to have people attend sites and be swabbed by professional staff for testing. This seemed to defeat the entire purpose of having these tests and, as a result, our team at Porton Down and Oxford did the necessary studies to demonstrate that the sort of deep nasal swabbing that had been recommended early in the pandemic was unnecessary and that there was sufficient virus in the anterior nose so that swabbing could be relatively easily performed by individuals by themselves, producing equivalent results to those obtained from terminate swabbing of the upper airway.

55. This was a crucial component of achieving tolerability so that these tests would be used frequently. However, in order to make these accessible to the population at large it did need regulatory approval from MHRA. The Porton Down and Oxford team undertook to write a regulatory submission for these tests for self-use, which proposed a significant difference in the IFU provided by most of the tests. Approval by the MHRA took some weeks but, ultimately, once this came through, it opened the door to much more wide-spread use of these tests on a self-use basis. Debate

then followed as to whether people would be obliged to report these results through some central system. Attempts to develop a digitised system using iPhones to record the results and log them centrally failed because NHS Digital was unable at the time to develop the necessary tech. During the process, they also managed to upset a significant number of commercial players who did have such capabilities available.

56. At the beginning of the process of evaluating lateral flow antigen tests, the vast majority of tests evaluated were not of the standard that would have made them useable for deployment across the population. Nevertheless, there were a few outstanding products that were rapidly procured and deployed, particularly in the real-world evidence studies and across educational institutions.

57. At least one company established manufacturing capacity onshore in the UK. Several other countries, including Serbia, had laid out a large-scale screening programme using lateral flow tests and they were beginning to be used more widely, but the UK was clearly at the front edge of this evolving technology, and its utility in identifying infectiousness rather than the presence of the virus was increasingly acknowledged and recognised as being a powerful way to get to the large number of people who were never going to be tested but who were spreading the virus in the population. We had excellent help in this project from Professor Susan Hopkins at PHE who was a significant contributor to the LFT evaluation committee. In addition to having several tests that were clearly deployable at scale, the quality of tests over the course of the following year improved substantially, indicating how useful this particular tool could be at scale in any infectious outbreak or pandemic.

58. The UK started in a fairly catastrophic position in terms of its ability to test for Covid-19, particularly as the NHS was not able to cope with the demand or the technological challenges of moving away from LDTs. The creation of a separate strand of testing centres through the Lighthouse Labs was a major step that was subsequently replicated in other countries which had seen how effective a large-scale automated PCR capability could be. Similarly, our deployment of lateral flow tests, initially to specific environments such as schools, universities and to NHS employees, demonstrated how useful these tests could be in allowing people to monitor the risk they pose to others by measuring infectiousness. I believe the large-scale deployment of these tests across the whole population was perhaps more effective

in the UK than any other country and undoubtedly had a significant impact on our ability to manage the pandemic in its later stages.

59. It should be noted that I made recommendations to Government on all these aspects of testing but was not involved directly in the procurement of any of these products which was done by civil servants working in the Test and Trace team at the DHSC. To my knowledge, they did an excellent job under very difficult circumstances.

60. In conclusion the Life Sciences industry which was already engaged with government through the Life Sciences Strategy proved crucial for the country as it established new and efficient approaches for testing for Covid 19. From a health security perspective the advantages of having a strong industry presence was clear and all parts of the sector played an important role in the UK response to the pandemic.

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: 24th January 2025