HOUSE OF LORDS

Select Committee on Science and Technology

Corrected oral evidence: Life Sciences and the Industrial Strategy

Tuesday 17 October 2017

11.05 am

Watch the meeting

Members present: Lord Patel (The Chairman); Lord Borwick; Lord Colwyn; Lord Hunt of Chesterton; Lord Maxton; Baroness Morgan of Huyton; Baroness Neville-Jones; Lord Oxburgh; Lord Renfrew of Kaimsthorn; Baroness Young of Old Scone

Evidence Session No. 5 Heard in Public Questions 27 - 31

Witnesses

Mark Campbell CBE, Senior Manager, Randox Laboratories Ltd; Ian Staples, Chief Executive, Matoke Holdings Ltd; Bryn Sage, Chief Executive, Inhealthcare Ltd.

USE OF THE TRANSCRIPT

This is a corrected transcript of evidence taken in public and webcast on www.parliamentlive.tv.

Examination of Witnesses

Mark Campbell CBE, Ian Staples, Bryn Sage.

Q27 **The Chairman:** Good morning, gentlemen. Thank you for coming to help us with this inquiry. You, as a group, represent several others in your industry, but it is extremely important to learn from you what you think the life sciences strategy will deliver and particularly how to grow companies like yours. When you start, can you introduce yourselves and, if you have any opening statements to make, please do so and then we will get on with the questions.

Mark Campbell: I am Mark Campbell. I am the senior manager of Randox Laboratories. We are a Northern Ireland-based life sciences and diagnostics company. We grew from two people in 1982 to about 1,300 people, including 400 scientists and engineers. We wish to keep ourselves at the cutting edge of life sciences and diagnostics, in particular.

Ian Staples: I am Ian Staples, chief executive of Matoke Holdings. We are a bioengineering technology company and an SME. Our focus is totally on the antimicrobial resistance issue. Statistically, 70,000 people will die this year—but that does not count all the legs or feet cut off—because of soft tissue infections, and it is a hurricane developing. With our teams of scientists—and we work with a lot of top people in Manchester University, Southampton University, Birmingham University and the University College of London—we have developed a technology base which is pretty effective at knocking out all the serious bacteria, whether they are gram positive or gram negative, and it disrupts and destroys biofilms. We have another team working on the fact that it stimulates tissue regeneration, so we have an exciting technology. As an SME, getting from that stage through to market and making a difference to world health is like hitting a massive forest.

The Chairman: You might expand on that in a minute.

Bryn Sage: Good morning. I am Bryn Sage. I am the chief executive of Inhealthcare. We are based in Harrogate in north Yorkshire and we specialise in a sector called digital health. I guess I am here because we shared our frustrations in response to your written request because we see this sector being stymied by a lack of adoption by the NHS. If I can use as an analogy the fintech sector, it has been announced recently that it has created over 60,000 jobs in recent history and is generating £20 billion of revenue for the UK market. That is because it has been adopted by the City of London and the financial services sector in a way that the NHS does not adopt digital health-type technologies. If the NHS picked up this challenge and used the technology to reduce capacity in hospitals and GPs' surgeries, it could make a huge difference to the performance of the NHS and to the well-being of UK plc. I would ask you to task the Government to set the NHS and industry a challenge to reduce outpatient appointments by 50%, which could be easily achieved using our sort of technology in combination with other technologies from the life sciences sector.

The Chairman: Thank you very much for those very interesting comments. In some of the questions later, we will come back to the NHS and its take-up. You obviously started and have grown to the levels you are, and each of you might say what the size of your company is, but where do you go from now?

Mark Campbell: We are in a position where we are a privately owned company and have never taken any venture capital into the company whatsoever. We started off with two people and have expanded now to around 1,400. The biggest share of our turnover committed to research and development is 16%, and routinely it is in the 10%/11%/12% area. We are able to do that because we have a single owner who is utterly committed to transforming diagnostics and we do not have external stakeholders who are seeking to take resource out of the company.

We are at a very interesting point where we are now upscaling significantly. In the last three years, we purchased a piece of ex-Ministry of Defence real estate in Northern Ireland—47 acres, 400,000 square feet—which we are now turning into the Randox Science Park, which will allow us to conduct much more efficient and upscaled engineering research and development and manufacture. We are positioning ourselves, we want to upscale and want to be one of these large companies that Sir John has identified within his paper.

The Chairman: So you are one of the companies which the paper says in 10 years will be a £10 billion company?

Mark Campbell: Absolutely the potential is there, but I would make one very important point to cover my colleagues' comments. As an organisation, we have developed a clear strategy of doing today's diagnostics and reinvesting all the profits from today's diagnostics into innovative diagnostics. If we had to survive on the income from innovation, we could not do it. The issue is one of the NHS in the UK and its ability to adopt quickly. We do not depend on the UK as a market—95% of our product is exported globally—but the UK is where we conduct the vast majority of our research and development, and it is problematic to go overseas and export as UK plc when you have to stumble over the answer to the question, "How has this been adopted in the United Kingdom?"

I would make one point, if I may, and then pass on to my colleagues, with regards to the comments earlier on. We have a very strong view that if you were to look out of your window at a highly innovative, dynamic environment, it would not be a heavily centralised, monopolised environment, which is what we consider and talk about when we reflect on NICE and so on—and there are very good reasons why that is there.

One of our asks would be the chance for a highly diversified, innovative environment where individual trusts or groups of trusts were empowered to undertake and adopt innovations in a decentralised centralisation piece, where you would have to report to the centre and everything would be monitored and so on, to give SMEs and smaller companies, which do not have the income stream to sustain long-term, non-productive innovation, a much better chance to work with local clinicians,

convince local clinicians of the acceptability of this technology and get it adopted locally, which gives you the chance to work on diffusion while at the same time giving you an export platform.

The Chairman: Mr Staples?

Ian Staples: I take a very simplistic view of the world. We are at this side of the forest and we need to get to that side of the forest, and until we get through that regulatory process we can make no difference to global health. For us, the complications of the regulatory process, the lack of guidance and end-to-end accountable support is a major barrier. Grants are important, but the grant structures are so fragmented and so complex that I would favour having a very simple objective on the regulatory programme and I can raise the money through private investors.

I get very irritated every time Dame Sally Davies, the WHO or a peer paper talks about the AMR crisis, because they continue to define the size of the crisis but they do not deal with the solutions, and nor do they identify companies with potential solutions and fast-track those companies through. It is great describing a problem, but it is a really poor show not addressing the problem.

The Chairman: Mr Sage?

Bryn Sage: Like the other companies, we are privately owned, so all our money comes internally and we do not go out to the market for any money whatsoever. Although we have been in business for about 30 years, my part of the business has been around for five years, trying to sell these solutions to the NHS, and it has been tough and extremely expensive. We are persevering and think we can get some traction in the NHS and are finding programmes, such as the Test Beds and the initiatives around STPs, showing some glimmer of hope. Ultimately, if the NHS does not adopt it, we will have to take it elsewhere. We are seeing signs that other areas in western-type environments—Australia, Spain and the US—are looking at our technology and seeing if it is something they can use, so we would have to put our focus and emphasis elsewhere.

Lord Oxburgh: Mr Staples, are you at the stage of clinical trials with your technology?

Ian Staples: Yes, we have accumulated a huge amount of in vitro, in vivo and clinical assessments and now we want to move to full RCT trials to demonstrate superiority, addressing multi-resistant and pan-resistant bacteria in a soft-tissue environment.

Lord Oxburgh: What is stopping you doing that, or is there nothing stopping you?

Ian Staples: It is simply having a defined programme that is agreed with timescales. None of us pays ourselves, but running an SME is a very expensive operation and there is no urgency, there is no fast track and, as the problem continues to accelerate, more and more people are dying and losing legs when there is an issue to resolve. Therefore, it needs a

tough regulatory programme and somebody who takes ownership with us from end to end to drive that through, not just writing reports describing the scale of the problem.

The Chairman: So what you are saying is that the regulatory regime that we have now does not engage with small SMEs like you which have a potential product that may be beneficial?

Ian Staples: I would suggest that the future of the British economy is very dependent on SMEs going from that stage to that stage. No, it does not.

The Chairman: So we require a regime that engages with SMEs because they would not have the same degree of resources as a big pharma would have?

Ian Staples: Yes, 100%.

Lord Hunt of Chesterton: Having been involved in some small companies—and sometimes these companies have a product to which the Minister has even said "This is the answer" in the House of Commons—to get the civil servants to recommend a company's product as being the solution is a very difficult part of the Civil Service cultural way in which that is transmitted—and the way you are describing it is very clear. Lord Sainsbury, when he was Minister, went to Japan and said, "Isn't there a British company that can do this?" and they said, "Oh Minister, it would be very unwise to comment on Company A rather than Company B"—so of course nothing happened.

Ian Staples: I am not suggesting change as you cannot change an animal under any circumstance. You can identify companies with potential solutions and identify steps they have to pass, and it can be done in a hands-off but nevertheless accountable way.

The Chairman: I think I get it; what we need is a mechanism where small companies which have a product that has the potential to improve healthcare are able to go to somebody and say, "Can I talk to you now and can you help me take this forward?"

Q28 **Baroness Morgan of Huyton:** I think you have partly covered my question because I wanted to ask about the barriers to you growing further and we have heard quite a bit about that. Can I probe you a little bit on financing because my impression, certainly from Mr Staples, is that, in a sense, you are saying that financing is not an issue, whereas in previous sessions we have heard that the availability of capital to grow from a relatively small start-up to the next stage is a bigger problem in the UK than in some other countries. Is there anything you want to add in relation to finance and the wider barriers that you have already described? It seems to me that you are not just talking about regulation in the way that we would understand it, which is quite defined in terms of NICE or whatever, but you all seem to be saying that there needs to be a process that involves regulation which is probably wider than that in terms of taking relatively small-scale innovations to the next stage. Can you elaborate a bit more for us?

Ian Staples: I will answer on the grant front because you need a degree in cunning to understand the grant profile. The work done by Sir John Bell only mentions AMR once. It may put more grants on the table, but it does not simplify the route. The whole forest of getting through from this side to that side through grants is so complex, with so many different rules and limitations, that it is not worth the effort; it is a waste of our time. If we had a clear route through the regulatory programme that says, "In three years, we expect you to be there, and these are the boxes you need to tick", we can raise that money privately.

Baroness Morgan of Huyton: So it is the whole process?

Ian Staples: If, from the grant viewpoint, the British Government take a vested interest in growing SMEs to being significant, that is a big plus, but we are not going to hang around through that grant mire. I do not believe that Sir John Bell's life sciences report will make a jot of difference to SMEs.

Lord Oxburgh: Have you had any contact with Innovate UK?

Ian Staples: We have a guy working full-time, all unpaid. We have met the NHIR and every single body, and it gets more confusing and more difficult.

Lord Oxburgh: Including Innovate UK?

Ian Staples: I would put Innovate UK in the middle of the table. Do not believe it is simple for an SME to get through that route. I am reasonably clever, but I have really clever people in my team.

Baroness Morgan of Huyton: But you think you could raise capital?

Ian Staples: We can raise capital, if we can go to investors, because we have raised various millions out of our own pockets. We do not pay ourselves. We are very passionate about an outcome and if we have a real programme we can say to investors, "This will take three years. This is the first step and, if we do not pass the first step, don't spend any more money". We can raise capital. Capital is not the issue; it is clarity of objective.

The Chairman: Mr Campbell and Mr Sage, do you agree with the comments about not being able to grow the SMEs and that the life sciences strategy does not address this issue?

Mark Campbell: There is a lot of very positive stuff in the strategy, and we would certainly welcome it: the flow of capital and so on that is there, and the various initiatives to incentivise—perhaps we can come on to it later—to reduce the likelihood of individuals selling a company on at a certain point and growing it much more fruitfully.

I would come back to the regulatory issue. I think it is common that, when you are dealing with these issues and going through the regulatory process and dealing with some bureaucracy that is not quite sure what to do next, the easiest question to ask is, "Could we have some more evidence?", as there is always more evidence that can be gathered, and, "When can you make a decision?"

There is a core issue for young companies coming through with innovations into a mature health service that works on guidelines. By definition, innovation is not incorporated within the guidelines and guidelines are well behind the innovative age, so how can we encourage and enable a clinical service to step outside well-embedded and trusted guidelines to engage with innovation, which is not yet embedded within the guidelines? There is a whole piece about the management of risk, with a small "r", because innovation, by definition, must involve some risk because it has not been used before. If I had a penny for every time a clinician said to me, "That's really great. Where else is it being used? I'm not going to use it until it is used somewhere else", I would be exceptionally well-off.

The Chairman: Mr Sage, a quick comment.

Bryn Sage: There is private sector funding available certainly in my part of the marketplace. The United States is awash with money that is looking for a home. Regarding public sector funding and innovation funding, it is an absolute waste of taxpayers' money while you have a broken market for it, which is the NHS. I have examples where people have been to Innovate UK or SBRI, got funding, created a product and then the NHS does not adopt it—they approve the trial and then no one wants to buy it, so it is a waste of money. Fixing the market for UK-focused SMEs is as important as funding innovation, in my opinion.

The Chairman: To carry on this discussion—Lord Hunt, you have a question.

Q29 **Lord Hunt of Chesterton:** The question is about smaller and larger companies. You have been talking about two companies growing, but to what extent is it in the UK, and is it desirable to have them taken over by larger companies?

Ian Staples: Companies go through different cycles of requirement. An SME is an innovative body and it is prepared to put a huge amount of its own wealth at risk and willing to cut through everything it can to be successful. When it gets to another stage, it probably needs different skills, which might be being part of a big pharma company, or it might grow and develop those skills. I do not over-worry about that. Our first job is to get from this side of the forest to that side of the forest and see where that develops. We have seen the development of a management team, which gobsmacks me, basically, because they are excited by the technology. That SME might continue to be a big pharmaceutical company in the future because it can attack a global market of antimicrobial resistance. The British Government should be leading that charge, not writing reports on the scale of the problem. Britain is a really innovative place and it should be seen as being innovative.

Mark Campbell: There are clearly some life sciences companies that start with the intention of selling themselves on, and it is part of, generally, a five-to-seven-year strategy. The sadness is that, when they sell on to an overseas company, we lose that capability within the United Kingdom.

We were formed in 1982 in Northern Ireland on the basis that the founder of the company, as a postdoc chemist, could not find any employment for himself or his colleagues within Northern Ireland, so was absolutely committed to forming a company that would add value to our economy, both regionally and nationally.

Certain pinch points come, which Ian has mentioned, particularly at the point we are at now of upscaling, where you need significant resource in order to upscale and bring through your products effectively. If you cannot find the resource to upscale, that may be a critical point. In a strategy, we need to look at how we can assist that upscaling piece, and there are a number of studies that indicate that real economic value does not come from funding start-ups but from enabling scale-up. If we can get that scale-up model right, we will not have so many concerns.

Lord Hunt of Chesterton: The answer we were given to the question earlier today was, in fact, the science/finance culture. The combination of that is very strong in the United States but, in Britain, you have finance people and technical science people and those two do not come together. Do you subscribe to that?

Ian Staples: No, not at SME level.

Mark Campbell: No, it is our job to bring them together.

Ian Staples: As chief executive, I recognise where there are skills shortages and you put those skills shortages in. We have a team of 50 people and not one of them, not one of the directors, gets paid, but we have built enormous skills at the pharmaceutical level, at the research and development level, at the corporate finance level, and every single one is an equity holder in the business, without exception.

The Chairman: To take Lord Hunt's point further, it is the message we had before—that there is a lack of understanding from financiers that investment in life sciences is worth the investment. Many others, particularly scientists—and we have an evidence session coming up with the scientists—say, "I found it difficult to get venture capital for my ideas until I left to go to the United States" or somewhere else.

Bryn Sage: It is fair to say that North America or the States values businesses in a different way by many multiples from the UK financial sector—that is for certain—and every SME is different. In our business, it is all about the innovation in whichever sector we have been in and, when it comes to the optimisation of the service, there are other people with better skills who can do that, whether it be a big corporate globally or a national company. They have the skill sets to take the idea from its base level to mainstream, and our organisation has done that many times over the past 30 years. My boss and my major investor's stock line is that he likes building bikes but does not like riding them. Everybody is different in the SME sector.

The Chairman: Baroness Neville-Jones, you might want to expand on this.

Q30 **Baroness Neville-Jones:** I have two questions. Mr Staples, I was rather

impressed with your rather flat statement that was in the brief that Sir John Bell's strategy would not make—what was it?—a jot of difference.

Ian Staples: I would not be so rude. I think I put "fiddling" on my note.

Baroness Neville-Jones: I think it was the phrase that you used.

Ian Staples: I only look from my perspective as an SME.

Baroness Neville-Jones: Well, let me finish my sentence: "a jot of difference for SMEs". Is that because you think it will not be implemented or because you believe that, even if it is implemented, it still will not make a jot of difference for SMEs? There is a big difference between those two propositions and I do not know what lay behind the statement that it is not going to make a difference.

Ian Staples: If you were sitting in our position, that field of grants is incredibly complex and one grant does not lead to the next and to the next.

Baroness Neville-Jones: Do you think that the implementation of this strategy, if we assume it is implemented, will not change?

Ian Staples: No, not at all, because there is no ownership from the beginning to end of that particular programme; it goes from one body to the next body to the next body.

Baroness Neville-Jones: You are not assuming that implementation would lead to any kind of join-up of these various things?

Ian Staples: There is no indication.

Baroness Neville-Jones: We have not had an implementation plan, have we? I am suggesting that you are being unduly pessimistic about the prospect.

Ian Staples: Having worked really hard on the grant process, with some very, very good people involved, it is the toughest process you will have ever been through.

Baroness Neville-Jones: I think you made that point extremely effectively and it is well taken, but could I ask the other two members of the panel whether you actually agree with this rather negative assessment of the likelihood of the strategy being of any use to you, as SMEs?

Mark Campbell: I beg to differ. I would say I am optimistic about the strategy and there are very good things in it. In some ways, and I may agree to disagree on this, we have the ownership and do not want anyone else to have the ownership. We want to have a clear system that we can work our way through and navigate through. We have dedicated people to it

Baroness Neville-Jones: What would you want out of the strategy to get that? This is a "How do I get my pathway?"

Mark Campbell: We can find a pathway. It comes back to how we start at this point. If we do all this work and do not have a customer at the end

of it, there is no point in doing the work; that is the fundamental issue. My one question with Sir John's paper would be that the adoption piece seems to be very centralised and top-down. If top-end pharma companies struggle to deal with that, an SME does not really have a hope.

Lord Hunt of Chesterton: It is quite different in the United States, is it not, from the picture you are presenting?

Baroness Morgan of Huyton: Sorry to interrupt, but that is top-down too, is it not? It is just that there is fast adoption, once it is agreed at the top.

Mark Campbell: Yes, there is faster adoption. It is top-down and can work very quickly. Because there is a mix of public and private, the private will adopt it much more quickly, which is a much larger market in the United States, and, therefore, you will have an income stream more readily.

The Chairman: Mr Sage, do you have any comment?

Bryn Sage: I focus on the NHS part of it, which is Section C.

The Chairman: We are coming on to that.

Bryn Sage: If they can fix the customer, everything else will fall into place. In tinkering with markets and things like that, it does work occasionally, but it has unforeseen consequences. Getting the customer, because we are stuck with one customer in the UK, in effect, is the bit that needs to be addressed: the adoption and spread.

The Chairman: Lord Borwick, a quick question and then I will move on.

Lord Borwick: Mr Staples has talked about the difficulties of getting grants, and I entirely understand it, but there are companies which go ahead with the development of their products without applying for grants. When you said that raising money is not difficult from outside, would it not be easier to raise money from outside than from government grants?

Ian Staples: Yes.

Lord Borwick: Why then do you worry about the complexities?

Ian Staples: I am not. I am just saying that it is incredibly tortuous and does not catalyse the system. It does not make the system easy, which it should do.

Lord Borwick: That is certainly right, and I understand that.

Ian Staples: On every issue you have a question of IP. I will give you a specific where we got a small MRC grant, a tiny grant, for a major project. We had already spent millions of our own personal money. For a few thousand pounds' grant, the MRC thought they would earn the IP. Tough. We would prefer to pay for that work and earn the IP, because that is our value. We are aggressive about IP and spend a huge amount of money on intellectual property and that is our only value, so you get a grant and you say, "Well, stuff it. It isn't worth the bother". It would be nice if the grant system made our life easier and accelerated the

programme. What is more important is to get that regulatory programme accepting that people are dying from antimicrobial resistance and you fast-track that regulatory programme to make a difference with some very clear milestones that have to be passed. If I see another report on the television about the AMR crisis when I do not see any urgency to address it, I cannot watch the news without getting very cross—justifiably so. I rattle my cage.

The Chairman: You are obviously quite worked-up about this, and we have got that.

Ian Staples: But sometimes you have to care. We have done a lot of work in Kenya and Uganda and have seen people get repaired. When I see people getting repaired, I get excited, so it is not worked-up because I am interested in making lots of money—that does not turn me on. What turns me on is seeing people get repaired, not the frustration of the delay in getting through that mire to make a difference to global health. That is what turns me on.

The Chairman: Your comment that you do not think the implementation phase of the strategy will do anything to help SMEs might not be founded on good evidence, because that is the stage when one hopes that the conversation will be had as to what needs to be done at the implementation stage which will drive up our SMEs further. I will leave that point on the record. Baroness Young.

Baroness Young of Old Scone: Perhaps I can backtrack to look in a slightly more positive way at the American experience. What makes it that, once a drug has had approval, for example, it is in place virtually immediately? Is it the insurance market saying, "If you don't use the best-practice drug, you will be liable to medical legal complications"? What is it that makes the American thing happen more quickly?

Bryn Sage: It is not a market I am familiar with, so I could not comment.

Mark Campbell: We have some experience with it and it is not always perfect. On the diagnostics side, for example, there is a test, high-sensitivity troponin, which is a critical heart attack test, which was implemented in an unusual way about 10 years ago in the United Kingdom and has only just been approved in the United States 10 years later—so they have their gaps and vulnerabilities as well.

I suspect there is an element of the private nature of the market and the insurance-led piece, and so on, which will follow the resources. If you have an impressive case that this will save money, the insurers are more likely to act on it more rapidly than we would see the NHS do.

Baroness Young of Old Scone: If you could turn the switch and think of some way in which more rapid uptake right across the NHS would happen, what would fix the market that Mr Sage said was broken?

Bryn Sage: If you think about how the market is, it goes back to the Health and Social Care Act where you have a quasi-market, so people are paid for activity and not for outcomes. It creates perverse incentives

where people are not incentivised to keep people away from hospital and, if you walk through the hospital door, it raises a bill to the commissioners, so you have that problem. In the bit I am in where people do the diagnostics and self-testing at home under the supervision of an app, let us call it, the hospital is penalised if you do not turn up to the outpatient clinic because they cannot bill the CCG for the activity—so the fact that people pay for activity causes a delay in adoption.

If you think that that activity is probably contracted on a block contract for three years when no one knows what technology is going to be around in 12 months, never mind three years, it stops people penetrating into that marketplace. You might have a new drug or new way of doing things that saves the NHS a fortune in the budget for prescription drugs because you do not need as expensive drugs or as many of them to treat a patient, but the provider, who is paying for the service, cannot benefit from the reduction in the prescription budget, so he says, "Why should I bother?"

The next bit is that a clinician might have his favourite drug that costs £800 a year when one worth £27 a year will do the same thing and there is no way of stopping him prescribing it because he does his own thing because he is in one part of the NHS and the commissioner is in another bit and so on. That is why it is all broken; there is no overall control. As I touched on earlier, if we get an accountable care organisation where someone has a holistic view of the spend, what is best practice and the best outcomes, they can make that choice and save the NHS money overall as opposed to people worrying about siloed budgets, if that makes sense.

Baroness Young of Old Scone: Would you take that one stage further and have top-down prescriptive mandating of best practice?

Bryn Sage: I was shocked that I agreed with the big pharma that was in before me who said that we need a top-down approach. I do not think, even in this room, we have enough influence on anybody wanting to change how the NHS is managed and operated. If you can get it down from 210 CCGs and 340 trusts to 43/44 STPs/accountable care organisations—which might look like the old strategic health authorities, but you have someone who has control of the social care budget, the healthcare budget and everything—that would give us a glimmer of hope and at least give us 40-odd people to sell to as opposed to 500.

Baroness Young of Old Scone: Your colleague from Northern Ireland is looking uneasy at this point.

Bryn Sage: You wanted a diverse view.

Baroness Young of Old Scone: I agree with you, but he is looking uneasy.

Mark Campbell: I express a contrary view. We conducted a very significant trial with an NHS trust on a marker called a heart-type fatty acid binding protein to improve the management of chest pain patients in A&E. The outcome was very successful and about 80% of individuals within A&E were not having a heart attack and the majority of them were

admitted and discharged a day or so later. If you can identify those and discharge them very early or put them on an alternative path, there are huge benefits.

We worked with the trust and the data was very impressive, but then we went into the central process and got lost. That trust and that group of trusts would have taken it on, but they immediately deferred to the higher authority. It comes back to the point I made earlier that an innovative, dynamic, exciting environment is not centralised with a big monolith in the middle of it. Can we not have more diverse decision-making points and a more diverse ability?

The Chairman: So where was the block?

Mark Campbell: The block moved into central decision-making.

The Chairman: What is your central decision-making organisation?

Mark Campbell: Within this particular area, it was a central group in Northern Ireland. If you go into NICE and so on, you come into the evidence base and the evidence that relates to that particular cohort of individuals in that geographical area—and is that truly reflective of the national cohort? So let us spend another £3 million and do a whole national study and so on and so on. My colleague mentioned hitting a forest, and we hit a forest.

Baroness Neville-Jones: My question was on this because you said earlier on that you preferred a decentralised approach. Do you see any drawbacks, however, if one moved in that direction rather than a top-down centralisation?

Mark Campbell: Are we serious about being at the cutting edge of taking forward highly innovative capabilities? If we are, we have to think how best to do that. The current system is failing. Big pharma has struggles with it, so where are SMEs going to go? We need a model of decentralised centralisation where you give authority for defined periods of time against that defined evidence base to proceed in a local area and then report back to central areas where you look at diffusion across the rest of the country.

Baroness Neville-Jones: Would you regard that as being, in effect, a pilot? In the logic of your position, would that NHS trust go ahead anyway using it, even if, having reported back, it did not get the go-ahead more generally? Otherwise, it is of limited value, is it not?

Mark Campbell: It may be of limited value, but you are getting your innovation from these companies engaged within the NHS and being used.

Baroness Neville-Jones: You could have pilots incorporated in a more centralised system, could you not?

Mark Campbell: "Pilot" tends to be a very defined term and we have to be careful about exactly what we mean by it. At the minute, we are faced with a top-down approach, which is not true anyway, that everyone in the UK must have the same standard of care. The risk you would run with

that is that different parts of the country would get different standards of care—which, frankly, is true today.

Baroness Neville-Jones: Anyway, yes.

Q31 **Lord Borwick:** I am wondering if this is inevitable—the conflicts between small and medium-sized enterprises and big government—in that big government likes stability and to have long contracts, if it possibly can, and to have as few things changing as it can because that means uncertainty, whereas you, as a small company, like change because change means opportunities. Does it not mean that it is very difficult for an SME to thrive in the health industry with it being so dominated by the NHS, and does that not imply that you should be looking for other regulatory markets as well as the UK to expand into?

Mark Campbell: Again, we could not survive based on our UK market. As I said, 95% of our product is exported overseas, but yes, you are quite right. In the diagnostic world, where we are experienced, until recently there were roughly 250 hospitals with major laboratories. Decisions were made recently to concentrate those into 29 major spokes. Conventionally, contracts are let to one provider for seven plus seven years, so one provider locks the system for 14 years, potentially. It is a very hard market to work your way into and, unless you have a particular niche product, you will not break into that. The bureaucracy and the business structuring makes it very difficult for the small, innovative player to operate within it.

Lord Hunt of Chesterton: This idea of having bigger companies as opposed to SMEs is in other areas of the MoD and the Department for the Environment and I would not say it was special to the Department of Health. In fact, are some of these generic problems of technology and SMEs being used by government?

Baroness Neville-Jones: In the UK, anyway.

Mark Campbell: I have experience of the Ministry of Defence, and the general trend was for bigger contracts let for longer to provide the stability and so on that you want. If I go back to that diagnostic example, how much change is there going to be in diagnostics in the next 14 years? It is likely to be exponential, yet many of our hospitals are tying themselves down to a single provider for the next 14 years, who will have some of that exponential increase but not all of it by any means.

Lord Maxton: That raises much bigger political questions, but I leave that aside.

The Chairman: It seems that, Mr Campbell, you have a product that you feel you are not able to get into the healthcare system in this country. You, Mr Staples, have a product that is not yet accepted and has not gone through the necessary trial and assessment system to say that it is a product that will benefit healthcare, although you truly believe it will.

Ian Staples: I will qualify that. I do not believe it would; the research teams working with us do.

The Chairman: Yes, but it has to go through the trial system to be proven as effective.

Ian Staples: I have no problem with that at all.

The Chairman: So you are finding a block at a different level. You, Mr Sage, are the same as Mr Campbell in the sense that you have a product that you believe is effective, but you are not able to get it into the system. Am I summarising that correctly?

Bryn Sage: In effect, the system works against you for adoption.

Lord Oxburgh: Is not Mr Staples' problem that, going through this, he has no guaranteed market for a product that has cleared all the hurdles?

Ian Staples: No, it is getting over those hurdles.

Lord Oxburgh: It is still the matter of the hurdles?

Ian Staples: Yes, because you may have the evidence in an assessment with a lot of clinical work, but you have to go through that full randomised control trial. That is very expensive, and we accept that, but it is having that defined on timescale, on cost and on what is required so that it is very clear.

Mark Campbell: We do not so much have a product as a change of philosophy as to how diagnostics should be conducted. In our view, diagnostics is something largely on the wing of healthcare where you go and see your clinician and your clinician refers you to diagnostics. We have a view that the diagnostics should be the hub.

The Chairman: Can you describe very briefly what it is that you have?

Mark Campbell: We have spent £250 million on developing what is called "multiplex technology". It is a small white chip, a British invention, with which, currently, we can conduct 49 tests simultaneously. The average patient has six or seven tests run on them currently, and shortly we will do 100 simultaneously and 1,000 is possible. One of Sir John's recommendations is to look for screening for asymptomatic chronic conditions, and that will only be achieved through wide-scale biomarker analysis of the individual, much more broadly than we are doing. If we do not make that shift, we will keep a health service that is not a health service but a sickness management service and we will not promote better health, and we need to move on to that.

Baroness Neville-Jones: Can you continue with what you were saying earlier on, that you reverse the order of activity as a result of that? Is that what you are saying?

Mark Campbell: If you do this at scale, it becomes efficient and cheaper. Interestingly enough, we know from certainly the general practice level that about half the people, they say, are social welfare cases, so you need to screen them out to a social welfare piece. If a healthcare service started off with the bloods and then, as a result of the bloods, you were directed to the most appropriate clinical authority, you can go with evidence and a scientific base for the subsequent discussion

rather than the discussion and clinical judgment and so on that is required at the moment.

The Chairman: Thank you very much, gentlemen. You have been most helpful and we have gained a lot of information about SMEs and the barriers, et cetera, and I hope that our report will reflect that. Thank you very much indeed for coming.