HOUSE OF LORDS

Select Committee on the European Union

International Agreements Sub-Committee

Oral evidence: UK-US trade negotiations

Wednesday 8 July 2020

3 pm

Members present: Lord Goldsmith (The Chair); Lord Foster of Bath; Lord Gold; Lord Kerr of Kinlochard; Lord Lansley; Baroness Liddell of Coatdyke; Lord Morris of Aberavon; Lord Oates; Lord Robathan; The Earl of Sandwich; Lord Watts.

Evidence Session No. 2 Virtual Proceeding Questions 13 - 23

Witnesses

I: Mark Dayan, Nuffield Trust; Professor Karl Claxton, Professor of Health Economics, University of York.

Examination of witnesses

Mark Dayan and Professor Karl Claxton.

Q13 **The Chair:** Thank you very much indeed for joining us. We are looking forward to the help that you can give us on our inquiry. I remind everybody that this session is being transcribed for publication on the parliamentary website. You will have the opportunity to review both questions and answers before it is finished. Members may also declare relevant interests before asking questions, but those will be brief.

We have quite a lot to get through in a relatively short time, so I ask Members to be relatively crisp in their questions. Mr Dayan and Professor Claxton, you must give the answers that do justice to the questions we have asked, but if you can keep them crisp we can get through quite a lot. I do not for one moment want to stop you giving the answers that you can, because that is important to us.

There is a great deal of complexity in how the NHS drug pricing system works. I wonder if our witnesses could start by giving us a quick overview of how the prices for drugs are evaluated and set, and how the UK's pricing system is used internationally as a reference price. Both of those are important to us.

Professor Karl Claxton: You are right; it is complex. Over time, a superstructure of complexity has been added, in my view to try to get a square peg in a round hole, which is about what the NHS can afford to pay for the benefits the new drugs offer. In short, manufacturers have every right to set any price they wish. It is then for NICE to take in that pricing, accounting for other elements of NHS cost, to decide whether it is sufficient value to be recommended for the NHS, with a funding mandate applied in the NHS such that, if NICE approves it, money has to be found to pay for those drugs.

If it is not worth while, using NICE criteria, at the price the manufacturer has chosen, the question in that appraisal process is whether patient access schemes, essentially discounts, might be offered. There is the price that the manufacturer chooses to set, with an eye to a global market and the way UK prices are used around the world. There are then potential discounts to get through the NICE appraisal process. There is added complexity when it comes to large budget impact, because now something that is approved by NICE but has a big budget impact does not necessarily get that funding mandate and there is another round of negotiation with NHS England.

Wired on top of this is the PPRS, which requires rebates to be paid should caps on total branded expenditure be exceeded, which they commonly are. Those rebates are paid back to Treasury. It is a complex picture. NICE does not have a right to negotiate or set price, but it has the responsibility to figure out, at the price the manufacturer wishes to charge, whether it is good value for the NHS.

The Chair: That is very helpful indeed. Mr Dayan, do you want to add to

that at all?

***Mark Dayan*:** No, that is a good overview of the three main layers of the system: NICE approval; the collective bargaining power of the NHS at various levels; and the voluntary and compulsory schemes for controlling total spend.

The Chair: Can I clarify one point, because I would like to understand this? Which countries will use UK NHS prices as a reference for themselves?

Professor Karl Claxton: I cannot give you detailed chapter and verse. It is quite old now, but the Office of Fair Trading did a very thorough investigation into the pharmaceutical markets in 2007. It estimated that UK prices and approvals influenced about 25% of the global market.

The Chair: That is helpful. Do you think it may be worth our while going back to that and seeing the detail in it?

Professor Karl Claxton: I do. It was an incredibly thorough piece of work. It was a huge piece of work, but it did an excellent job in picking apart exactly what influence we have in which countries, which is quite difficult to know.

Q14 **Lord Foster of Bath:** Gentlemen, good afternoon and thank you very much for coming. Professor Claxton, you have already explained that drug pricing has layers of complexity. The delivery of NHS services is also very complex because of the number of services that have commercial involvement, where there is competition for contracts and so on.

In the light of all that, could you both comment on whether the Government's negotiating objectives in relation to the NHS and drug pricing are clear enough, so that we will be able to understand at the end of the process whether we have been successful in our negotiations?

Professor Karl Claxton: I am deeply concerned. I read the report from the Council of Economic Advisers in the United States, which was accepted by the White House. It is now chaired by Tomas Philipson, who has been a long-time critic of collectively funded healthcare, such as the NHS, and of the types of analysis that NICE uses in coming to a collective decision about what represented good value. In my view, that report very clearly sets out a deal in which the US will use its weight in trade negotiations to make sure the rest of the world plays more, in return for lower domestic prices. That really worries me.

We had lots of verbal reassurances at the time, before the minutes of those meetings were made available. Those reassurances were about price, but it is so complex, as we see. You can effectively give US pharmaceutical companies what they want, not by changing prices but by restricting the way in which NICE makes its decisions or restricting the way in which the PPRS operates. The list price stays the same, but the NHS pays more. That is what really concerns me.

It also concerned me, once the minutes were made available, that the US had taken certain things off the table in those preliminary negotiations, but the UK side had not done that as clearly as it could have when it comes to the NHS and drug prices. I remain concerned. There is a door open to get what the Council of Economic Advisers wants, which is for the rest of the world to pay more to support those very high costs in the United States.

***Mark Dayan*:** I tend to echo those concerns to some extent. The DIT document setting out the UK's goals is very big on high-level promises that prices of medicines will not rise. As Karl is alluding to, you are probably not going to get a trade deal text proposed by the US side that says prices will rise. What you have seen in other trade negotiations, such as Australia and South Korea, is much more in the department of creating new rights and duties, for example rights to appeal decisions or to have certain things recognised within the pricing process, which companies can then rest on.

The DIT's rhetoric is kind of reassuring on one level, but on another level it is so far above the details of what the actual proposals are likely to be that it is hard to know exactly what is being ruled out.

Lord Foster of Bath: I know that Lord Lansley will go into the issue of NHS services in quite a bit of detail later. More broadly in relation to NHS services, do you have the same concerns about the DIT's negotiating objectives?

***Mark Dayan*:** That is a slightly tricky one to answer without knowing exactly what we are discussing. Concerns about a US trade deal leading to a dramatic increase in American companies' rights to bid for services are somewhat overblown, in my view, because they already have those rights. In general, the UK as a jurisdiction is more open to foreign companies bidding for public services than the USA is.

There are other issues that have more to do with possible obstacles to any reduction in those rights or any renationalisation of the NHS. There are similar concerns that the DIT has some quite high-level commitments. They are a bit more specific, but it is not completely clear how they line up with exactly what is likely to be asked for. I am sure we will come to that.

Q15 **The Earl of Sandwich:** Good afternoon. This is a question for Mr Mark Dayan. Seeing as you have been working on Brexit and the NHS quite recently, you are probably very up to date on this. What are the likely knock-on effects of a trade deal with the EU, if it succeeds, on future pricing for a deal with the United States? I realise that would be speculating.

***Mark Dayan*:** That is a very interesting question. On the EU side of things, the issue is often less about pricing than about costs. All else being equal, a more distant relationship with the EU will tend to mean higher actual costs for companies producing medicines and bringing them

to the UK from the European Economic Area. Most of the medicines in the NHS come from or via the EU.

There are quite live issues at the moment in negotiations about things such as mutual recognition of good manufacturing practice, to use some slightly terrible jargon, which will determine exactly the scale of the impact. It is fair to say that academic studies, and in fact the Government's own impact assessments from a couple of years back, have tended to suggest that a free trade agreement with the European Union will probably mean somewhat higher medicine prices because of the increased red tape relative to being in the single market. At the same time, whether we get a deal, and what kind of deal that is, makes a difference.

Q16 **Lord Kerr of Kinlochard:** Picking up where we were with Lord Foster's question, if you listen to the US Administration you get the impression that the rest of the world does not contribute enough to development on new drugs, treatments and devices and freerides on American R&D. If you listen to the White House, you hear from the President that "fixing this injustice" is "a top priority with every trading partner".

I have two questions. Is the charge justified in respect of the UK? Do we pay our fair share to R&D in this area? Secondly, how far will the Americans press it? It seems to me that they set off in the USMCA negotiation aiming to get a long way and got very little. The same is true of the Korean negotiation, partly because Congress does not seem to entirely share the Administration's view. I see that Congress would like to reduce the exclusivity period on new drugs, whereas the Administration want us to agree to its extension.

Professor Karl Claxton: We have done work in this area. Empirically, and I would argue very strongly, the charges are not fair at all. The issue is this: what is the long-term value of any innovation, including the patented period and, when that patent expires, the generic period or the biosimilar period? If we pay branded prices during the patented period, those are NHS costs that could have delivered health improvement elsewhere for other NHS patients. During the patented period, we may be getting zero net health benefit for that medicine and getting value only once that patent expires.

In reality, as I hope we can discuss later, the empirics suggest that during the patented period we are paying far more than we can actually afford. During the patented period, we are reducing health outcomes overall in the NHS. Those are being compensated for only post-patent. We are about to submit to journal work, based on recent NICE appraisals, that looked at what we know about the extent of patent remaining at launch, the prices of generic small molecules or biosimilars, and the switching. We find that, for very many new technologies, we are paying more than 100% of the lifetime value of those products.

We do not know what it would be appropriate to offer manufacturers, but we know that it should not be zero, because there would be no incentive.

We certainly know that it should not be more than 100%. If it is, we incentivise the development of unaffordable innovations that will damage the healthcare system. In many cases, that is exactly what is happening right now. To sum up, the charge is absolutely flawed. We are probably paying far more than our fair share of value.

The problem is that the US healthcare system has no effective demand side. That incentivises the creation of very high-cost research and development marketing programmes for products of often modest value, which are unaffordable for the rest of the world and increasingly are unaffordable for American citizens. That is the situation we are in and it is difficult to resist that argument. We are already paying far more than our share of value. We are overrewarding high-cost innovation of relatively modest value that will be unaffordable even when biosimilars come through.

The Chair: That was a very helpful answer from Professor Claxton, but what is the American charge if the charge that we are getting a free ride is without justification?

Professor Karl Claxton: Tomas Philipson wrote some time ago saying that manufacturers get only 2% of long-term value. He came to that conclusion by ignoring reality. He ascribed a very high individual willingness to pay for health outcomes and failed to recognise that social choices about how much we pay for healthcare in a collectively funded healthcare system mean that healthcare costs are not out of your pocket; healthcare costs are other people's health.

That is what it comes down to. Well, I am not sure it does. I have expressed that in a very academic way, but there is a failure to recognise that healthcare system costs are other people's health and to know something about how much health that accounts for.

Lord Kerr of Kinlochard: I suppose we also contribute quite a lot to global R&D in this area through companies such as AstraZeneca.

***Mark Dayan*:** Yes, there is another relevant point here. There is no economically rational reason why, just because companies can charge a higher price in the UK, they would lower the price they charge in the USA. They set a market price in the USA that is as high as they can get away with. If they can make still more money elsewhere, great, but there is no logical reason to reduce what they charge in the USA.

On your question about how firm US backing for this might be, it is relevant to disentangle the patents and intellectual protection side from the issues we have been discussing about the process of acceptance and reimbursement for drugs. In the example you rightly raised of USMCA, there was a lot of congressional disquiet about trying to put minimum data exclusivity standards, the time for which full whack can be charged for biologic drugs, into it, because that is a live issue in the USA. There is a sizeable contingent that would like to reduce the protections and thereby save money.

It is not clear to what extent the same is true of US demands to avoid or weaken NICE-like systems of medicines approval based on cost, partly because the USA does not have anything like that, so it is not as domestically visible as an issue. To some extent at least, the interest in provisions that might soften or weaken those systems stretches back through multiple American Administrations.

Lord Kerr of Kinlochard: Thank you very much for making that understandable. Can I add an even more general question? We are looking at a number of other areas, as well as the healthcare area, in this negotiation. We are about to talk about agriculture this afternoon. How do you rate the relative importance to the United States of the healthcare demands that it has and the demands in other sectors, particularly agriculture? How would you rate the strength of the congressional lobbies on, say, agriculture versus healthcare?

Professor Karl Claxton: I know little about agriculture and the strength of the agricultural lobby. I can say that the pharmaceutical sector has a very strong lobby. There have been and are attempts to introduce the same kind of appraisals in the United States, particularly the Institute for Clinical and Economic Review in Massachusetts, which is doing an excellent job in trying to inform private plans about the scale of benefit and of cost. It is coming under huge pressure and criticism.

I am not really answering your question, because I do not know enough about agriculture. The interests of the pharmaceuticals sector are very high on the political agenda, and appointing Tomas Philipson as chair of the Council of Economic Advisers speaks to that.

Lord Kerr of Kinlochard: On the drug pricing issue, is that because so much of the rest of the world follows the UK price?

Professor Karl Claxton: The UK is probably a target precisely because we have quite a lot of influence and NICE decisions are quite influential. In a way, it is a double-edged sword. The UK is about 3% of the global market. If the OFT is right, we influence 25%. In a sense that is great, because we can start to influence R&D priorities. In a way it is bad, because there will be huge resistance to us trying to get better more affordable deals for new pharmaceuticals, for the fear that it would influence the rest of the market.

I have one other brief point to chip in on this, related to the last question. The sensible economic rationale in a global market is to achieve price discrimination; paying the fair share of the R&D required, taking account of the fact that public funds are often doing the fundamental research. That fair share does not mean that everybody pays the same price. It would be better for everybody, both for the pharmaceutical sector and for healthcare systems, if we had price discrimination to reflect how much different countries' healthcare systems can afford to pay for the same benefit. A fair system where everybody contributed a fair share would, indeed, mean very different prices in very different countries, and basically lower prices in most countries other than the United States.

Q17 **Lord Lansley:** I wonder if I might ask Professor Claxton about the influence of the pharmaceutical industry. The fact that drug pricing in America is very high on the political agenda, as it undoubtedly is, is not simply because of the lobbying activity of pharmaceutical companies. It is because the price of drugs in America is an enormous political issue. Getting those prices down in America is far more important to them than anything else.

Mr Dayan, I am just commenting on what you were saying, but it seems to me that that is really important. If we were mysteriously to pay more for our drugs in the UK, it would not necessarily change the price of drugs in the United States. I am not anticipating what we might say at some point, but we might well suggest that it is more important for the American Government to adopt some of the techniques used in the United Kingdom than to try to persuade the United Kingdom to deregulate its pharmaceutical pricing. I do not know whether Professor Claxton might agree with that.

Professor Karl Claxton: I could not agree more. In the Council of Economic Advisers' report, we basically see an attempt at a profoundly political narrative, which is to say to the American people, "Hey, we know domestic US drug prices are astronomical. We know people face bankruptcy just by having to pay their co-payment. We know many of you do not have decent healthcare benefit packages. Do you know what? It's the fault of the rest of the world. They're not pulling their weight".

The reality is very different. The rest of the world is not the ungrateful recipient of US-generated R&D. It is in many respects the victim. The other victims in all this are the US citizens who are unable to pay their co-payments to access medicines. That absolutely is the reality. Bodies such as ICER are attempting to introduce the way in which we look at value and the reasonable price for a new drug. That, in my opinion, is one of the most optimistic things at the moment in America. They are facing a lot of opposition and lawsuits, as you would expect. There is a lot of money at stake in all this.

Lord Lansley: If the US Administration can find somebody else to blame for high US drug prices, no doubt they will take that approach. In the statement of objectives, the trade representative said that the United States will "seek standards to ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory, and provide full market access for US products".

There are a number of pieces to that. I wonder if either of our witnesses might unpick it. What specifically do you think the American side means by procedural fairness and non-discriminatory? On full market access, we know where they are; they do not like NICE's thresholds.

***Mark Dayan*:** You can probably get some idea by looking at the renegotiated US-Korea trade deal, which is a Trump-era renegotiation. There are lots of provisions in there that put extra requirements on the South Korean drug pricing and reimbursement system. They include

having to publish different steps of the process and giving companies the right to certain things, such as new duties to enable them to appeal in order to charge higher prices. South Korea has set up a review body to do these appeals, which must be independent from its Government.

In some ways, there are layers of vagueness upon layers of vagueness. There is a general provision that drug pricing decisions must "appropriately recognise the value" of medicines. What exactly that means is quite unclear and would have to be settled to some extent through dispute resolution, if companies object to measures that the South Korean Government have taken. I imagine you would be looking at those sorts of process and review requirements, and duties to take things into account, the institutional implications of which might be quite non-transparent.

Professor Karl Claxton: On the face of it, transparency and procedural fairness are exactly what NICE has provided. That has been tested through judicial review a number of times, so we might feel quite relaxed about that. I am not that relaxed. What procedures would we use to judge that as part of this agreement?

In particular, I am worried that the thresholds, criteria or norms by which NICE decides yes or no are potentially challengeable. They really should be founded on good empirics, and thankfully we have some of that empirics now. The current NICE threshold range is not really well founded on empirics. It is based on the implied values from the decisions we made in the first few years of operation. I imagine that will be the press point: they want higher thresholds.

Lord Lansley: I completely see that from the US point of view the abolition of NICE thresholds would be the objective, because they regard them as arbitrary. Presumably they will also have a go at what they perceive as the lack of transparency over NHS England's increased role in determining the pricing of drugs for the NHS. You mentioned the high-value level, Professor Claxton, but actually NHS England is trying to operate on quite a wide breadth of these things. In a sense, it is less transparent in that sense than the rest of the NICE process.

That goes right to the other question. Where do you think the US might impact directly on the way we regulate our healthcare and pricing in particular? For example, we apparently have a NICE methodology review under way. Do you think they will be looking to secure something in the deal that impacts directly on that? How might they go about it?

***Mark Dayan*:** It is very difficult to say. Previous trade deals with South Korea and Australia suggest that, rather than commenting on individual domestic processes and laws, at least explicitly, it would be more a set of principles which the UK has to sign up to and maybe bodies to be created, like the new South Korean body or the working group in Australia, which then oversee and monitor it. It would then be left potentially for some kind of dispute resolution to decide whether what the

UK has done is in compliance with the less specific commitments it has made.

Q18 **Lord Gold:** In lobbying for change to the UK's drug pricing criteria, the US pharmaceutical trade body, PhRMA, stated, "Due to long-standing market access barriers such as rigid health technology assessments (HTA), government price controls, insufficient healthcare budgets, and increasingly punitive and proactive national procurement initiatives and local barriers to uptake, the ability of UK patients to access the latest, innovative medicines can be difficult". Is it true that, under the present system, UK patients are being deprived of access to the latest innovative medicines?

Professor Karl Claxton: If NICE approves a new technology, there is a funding mandate associated with it, which means that it has to be made available. However, when NICE is appraising new technologies, at the kind of prices that are being charged, unless the manufacturer can offer discounts that make it acceptable using NICE's current criteria, NICE often restricts the patient groups they can be approved for. There is no doubt that the global price of medicines is restricting access to potentially beneficial medicines in the UK. That is a consequence of prices that are essentially unaffordable.

The solution to this is to make sure that the scale of rebate being paid by manufacturers reflects the discrepancy between the price they wish to charge and how much a particular healthcare system can afford to pay for the benefits that medicine offers. That is the kind of rebate system that I would like to see in place, which would make all new medicines affordable for the healthcare system, so long as manufacturers signed up to paying the rebates. If they did, those prescriptions could be reimbursed centrally, because the centre would know they were getting back the money.

It is right that NHS England is getting involved in price negotiations after NICE appraisal. In many respects, that budget impact hurdle reflects the fact that NHS England is acutely aware of the pain and the consequences of approving new drugs, even at NICE's current thresholds. Therefore, they are trying to put the brakes on, because they understand the local impact. That is the real problem. Even NICE thresholds are leading to substantially more harm than benefit at a local level in the NHS.

We face a fundamental problem. I have no doubt that the arbitrariness of NICE thresholds will be a key target in trying to break this apart.

***Mark Dayan*:** I agree with much of that. In the idealised version of a NICE-like system, the answer to the question of whether British patients are not getting new and innovative medicines is that they are not, and they should not if those new and innovative medicines save less life than the other things you could spend that money on. Whether we are quite at that perfect system, I am not sure, but it strikes me that, in a health system with acutely limited budgets, it is the approach you want to have. Just because something is the latest and innovative, it does not mean

that you should spend £100,000 on it if, by spending that money on something else, you would do more good.

Q19 **Lord Oates:** Could I turn to the subject of intellectual property rights relating to drug patents and exclusivity for biologic medicines, such as many cancer treatments? Is it likely that a deal will result in an increase in the UK's patent or exclusivity durations? If it does, what might the scale of the costs involved be to the NHS?

***Mark Dayan*:** I do not think it is hugely likely, for three reasons. First, as was mentioned in the USMCA example, the USA domestically is not well united behind a policy of pushing for longer or greater IP protections on pharmaceuticals. It is another manifestation of the overall concern about drug pricing that Lord Lansley spoke about.

Secondly, if you look at the DIT's assurance that the price the NHS pays for medicines will not change, in terms of reimbursement and NICE there is arguably a bit of a grey area. It is potentially unclear whether, for example, relaxing NICE cost effectiveness thresholds means that prices will rise or merely that we will accept medicines that already had higher prices. If it came to extending data exclusivity, however, the exact same medicine would indeed be likely to be more expensive. It is very hard to reconcile that with the UK's position.

Lastly, and this applies to patents more than exclusivity, we are currently members of the European Patent Office. That is intended to continue after Brexit, which is official policy. That will make it difficult, for example, to shift to a US-style model for patent extensions. Essentially, for many medicines, we do not run our own patent system. We would have to drop that whole European system, which is not current government policy. I am not sure it is hugely likely, but it should be monitored.

Professor Karl Claxton: In the work that I mentioned, which is just about to go to journal, we included biologics in the sample of NICE appraisals. Biologics are really problematic, first, because they tend to be expensive and, secondly, because biosimilars are not that cheap, to be perfectly honest, and take time to arrive after you lose exclusivity. That means that, using thresholds of between £15,000 and £25,000 per QALY, we will give away 100% of the lifetime value of a biologic. In other words, with existing NICE thresholds, even before any relaxation, we are already giving away more than 100% of the value.

If we decided that we should share the value 50:50 between the NHS and manufacturers, we would need a NICE threshold for biologics of somewhere between £4,000 and £14,000 per QALY. That reflects how out of kilter we are in how much we are paying for new medicines and especially biologics. Biologics at their current prices are a very real threat to NHS care.

The Chair: I am going to bring in Baroness Liddell of Coatdyke. In doing that, I want to make a disclosure as a partner in a practising international

law firm, given that I know what she is going to ask.

Q20 **Baroness Liddell of Coatdyke:** In our written submissions, a concern has been expressed that if investor-state dispute settlement provisions are included in any UK-US deal, US pharmaceutical companies might, through wholly owned UK subsidiaries, seek to challenge the NICE approval process on the grounds that it undermines their investment in the UK. Could this tool be used by companies to achieve increases in expenditure on branded pharmaceuticals?

***Mark Dayan*:** I can see where these concerns may have come from, because there have been high-profile cases of international pharmaceutical companies taking countries such as Colombia and Canada to international tribunals over intellectual property-related decisions. Because the NICE system already exists, it might be relatively difficult to build a case that that was in some way expropriating the value of an asset. It could come into play in the future. If we have the kinds of changes that Karl is talking about, that is a possibility.

The underlying issue is what it says in the free trade agreement, and what rights and limits on rights it gives people. That could be enforced through ISDS or merely through country-to-country arguments. Is it out of the question that President Trump would adopt such a claim on a governmental level, with or without ISDS? I am not sure it is. In some cases, such as Colombia, you saw the US state getting involved.

Those would be my thoughts on that. It is a possibility. I am not sure it would entirely apply to the existing system. That is where issues such as the right to regulate provisions that the DIT mentioned in its policy document would be important.

Professor Karl Claxton: I cannot talk about the legalities, but the issue about location of R&D, and using that to resist the establishment of NICE and the work that NICE did early on, is a well-trodden route. Those arguments have been made over many decades: "You need to pay higher prices for our drugs, because if you do not we will not invest in the UK". It is simply a negotiating threat. The location of research and development investment has everything to do with research environment and access to the right skills. It has very little or nothing to do with the domestic market, because this is a global enterprise.

In the past, it has been regarded widely as a rather empty threat. Whether that remains an empty threat with any legal levers that might be pulled in the future, I cannot comment. Certainly up until now, it has remained a rather empty threat and not credible.

Q21 **Lord Robathan:** We have talked about quite a lot of this already. Mr Dayan, you mentioned just now the right to regulate and the DIT position. Based on your knowledge of US policy, past deals and the negotiating objectives of the two sides so far, do you think that any deal we made might constrain our right to regulate public services generally? This is obviously about healthcare in particular. We have talked about

NICE, but would it make it difficult to change how NICE does things in future if we had a deal with the US?

***Mark Dayan*:** Yes, there may be that risk, because most trade deals include an investment protection section, as was raised earlier. This prevents either state party from confiscating the assets of investors in that country. The argument has been made before, and it is a known issue, that certain forms of regulatory change that reduce the value of a company's investment can be perceived as indirect expropriation. That is therefore a matter for intervention under the terms of these treaties. It is conceivable that, under certain forms of drafting, those rights would apply to things such as the value of pharmaceutical investments.

The DIT's answer to this is a right to regulate, which is a common feature in international trade agreements, largely in response to the kinds of investor claims we have been talking about. Although it is reasonably clear in exempting the NHS from procurement commitments, which is the NHS's buying and selling of healthcare from private or government-owned companies, it is a bit vague about what exactly would be covered in the right to regulate public services. Rights to regulate are usually based on the goals being pursued, for example public health. Potentially, efficiency would be in play in a NICE context. It is not completely clear what the line there is.

The Chair: We are coming to the end of our allotted time, which is a good opportunity to move from the dangers to the opportunities.

Q22 **Lord Foster of Bath:** We have spent nearly an hour talking about the concerns we have and the risks that might come from a US trade deal. It would be interesting to end with your thoughts about the positives. What are the opportunities for the UK healthcare sector? Could we, for instance, benefit from mutual recognition of qualification? Could the trade provisions enable us to provide telemedicine services to the US? What are the benefits of a trade deal such as this?

***Mark Dayan*:** Mutual recognition of qualifications could be an interesting opportunity. As you will see from my written submission, one of the legal discrepancies between most EU systems and most US systems—it is typically at state level—is that, in the EU, it tends to be whether you are registered in your home country that matters. In the US, it tends to be whether you are registered where the patient is. From the perspective of professionals crossing borders and potentially things like telemedicine, there may be advantages to a system where British practitioners of various types of healthcare could be recognised more easily in the USA.

Another area I mention in my submission is medical devices. The US has a system a kind of regulatory alignment on medical devices with some other countries. The first preference of much of the industry and the NHS would be to stay on the EU side of that, because we trade more with the EU and because that is our starting point. Our industry is adapted to it. If we could not get that, it might be worth looking at that other bloc, which is centred on the United States.

Q23 **Lord Watts:** We were talking about whether it would be possible to have affordability criteria around the world for medicines. Is that realistic? America spends far more than we do on health by GDP. Obviously, we pay less. I do not know what criteria you could use to discriminate between one country and another on prices.

Professor Karl Claxton: That speaks pretty much to my area of research. Increasingly, we do have estimates in different healthcare systems, particularly in the UK, about how much health we get for changes in NHS expenditure. That tells us something about how much we can afford to pay for the benefits of any new drug.

In the UK, we have some good data that is now well worked. It tells us that £15,000 gains you one quality-adjusted life year. In other words, £100 million avoids about 500 deaths. It gains you about 2,500 life years and about 8,000 quality-adjusted life years. If we pay more than that for the benefit of a new drug, although the drug might be beneficial the additional NHS costs mean that other NHS patients lose more health than we gain.

Do we have those estimates for other countries? Increasingly, we do. Other research groups around the world are starting to estimate similar things in their healthcare systems: Australia, Spain, the Netherlands and Sweden, but also some middle-income countries. I just reviewed Colombia, which has done exactly the same thing. Based on what we know from global data, we have estimated the impact of healthcare expenditure on mortality in different categories.

There is an empirical, evidential foundation to answering the question "How much can this healthcare system afford to pay for the benefits on offer?" In many respects, that is the bulwark against the claim that thresholds are arbitrary and the attempt to drive Trojan horses through NICE. In the UK, the evidence suggests that NICE thresholds are far too high, to be frank. NHS England understands and feels the damage done when NICE approves a medicine at £30,000 per QALY, and local CCGs have to find that from existing resources.

Lord Watts: Is this the research you told us about before that is just going to the journal?

Professor Karl Claxton: No, this is other research. This was originally funded by the Medical Research Council. It was first published in 2015 but continues to be updated and supported by the economic evaluation policy research unit at DHSC. We continue to work in this space. We also find that, among the categories of expenditure within the NHS, public health expenditure is really effective. We are looking at £2,000 to £3,000 per QALY, for example.

The Chair: Thank you very much indeed. I want to thank you, Professor Claxton and Mr Dayan, enormously for the evidence you have given us. We have covered a lot of ground. It is tricky ground, but it is very helpful indeed to have your expert insights into all the points that have been

raised. Thank you very much indeed. I am not promising that we will not find something else we want to ask you about and come back to you, but, for the moment, thank you.