Center for Strategic and International Studies

The Bio-Pharma Industry and Society

Keynote Address:
Sir Andrew Witty,
Chief Executive Officer,
GlaxoSmithKline

Panelists:
Margaret Hamburg, M.D.,
Foreign Secretary,
Institute of Medicine

Ezekiel Emanuel, M.D.,
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J. STEPHEN MORRISON: Good morning. Thank you all for joining us on such a beautiful day. I'm Steve Morrison, senior vice president here at CSIS, and I'm director of our global health work here at CSIS.

And we're really delighted today to host Sir Andrew Witty, chief executive officer of GlaxoSmithKline. He's been with GSK for 32 years, almost nine years in the role of CEO. Today, with the release of the 2015 Annual Report for GSK, we've also had the announcement of a formal search now beginning/underway for Andrew's successor, expected – that person expected to enter that role in about one year's time. So you've been liberated, Andrew, to speak much more broadly and widely this morning than might normally be the case. And we might want – you might want to use some of your – might want to free up some of your time to help us with our Supreme Court nominations – (laughter) – and, you know, maybe healing our Republican Party.

We're delighted that you've come here today to examine the steps that GSK and others are undertaking to restore the trust of patients around the world. Be focusing on several core areas – marketing and sales, data transparency, R&D, affordable access.

This occasion here builds on a couple of partnerships and collaborations. In the past, we had the honor of hosting, in December '14, Moncef Slaoui, president of GSK Vaccines, together with Tony Fauci and counterparts from MSK and J&J in December '14 to talk about the accelerated efforts to develop an Ebola vaccine, which was a profound and unprecedented effort. And we're just talking about what the – some of the lessons learned form that have been, both positive and negative. We've also had the good fortune that Phil Johnson (sic; Thomson), GSK's VP for communications, has joined our task force – CSIS Task Force on Women's and Family Health, and will be joining us April 25th in the Senate for the next major session of that.

Before I say a few words about Sir Andrew and turn the podium over to him for his opening speech, I want to offer special thanks to Shira Kilcoyne and Jenni Ligday from GSK for all their support and advice in putting this event together; and to my colleague, Sahil Angelo, who really worked indefatigably to pull this event together, aided by Anya McDermott (sp). Thank you, Anya (sp).

A few words about Sir Andrew as both an individual and a leader. One of the reasons we were so delighted to have this opportunity is that he is such an outlier. He is such an unusual CEO in this particular biopharmaceutical industry, who's adopted a highly public profile as a public intellectual in that industry and willing to adopt often quite provocative positions. He's time and again gone against the grain of opinion and of accepted wisdom, and changed and shaped the discourse and orientation going forward. He's forced us to begin thinking beyond short-term pressures from Wall Street and elsewhere to look at structural and political changes, and normative changes that are emerging globally in a very rapidly changing environment.

Just a few quick examples of things that have most impressed me. He's taken the position that pharma should be able to charge far less for new drugs if it can become more efficient in its own R&D practices – that the notion of a $1 billion price tag for the development

of new drugs is a myth, and that you can lower the rate of late-stage failure and change the pricing formulas.

The restructuring that went on in 2015, with the $20 billion swap with Novartis, was somewhat radical in swapping out vaccines for cancer drugs, and looking for high-volume, low-margin preventative tools in emerging markets versus focusing overwhelmingly on small supplies of highly priced specialized drugs in Western markets. That's a sea change in strategy and outlook about what the world is presenting and opportunities.

There's also been a sort of – he's also shown us a sort of sober and realistic view of what's happening here in the United States, where we continue to have a firestorm around price – around prices. The term was the weather is turning, and that we're going to see this – these changes unfold.

CSK has not been without – GSK has not been without its challenges and its stumbles. But in looking back over 15 years, there's been a process of learning and recovery from those.

After there were major confrontations in the naught decade over HIV/AIDS drugs, particularly with South Africa, that led to leadership on tier pricing and product development partnerships.

After the scandal in China in 2013/14, there were, you know, major changes undertaken. There was an apology to the nation. There was a very overt admission of errors, personal prices paid by senior executives, but then you began a deliberate process of discussion around the kinds of – the package of reforms that we're going to hear about today.

I've also been most impressed by the degree in which GSK, over the years, has engaged in good faith with MSF around just most recently on the GAVI replenishment and the announcement of the 10-year freeze on price reductions for countries that are graduating.

And now – and we'll hear more, I hope, today – is the Secretary-General's High-Level Panel on Access to Medicines. This is a very timely and sensitive and controversial effort. It's on a very compressed timeline, to produce results by June, has 16 members. It's spurred by the – by the onset of the Sustainable Development Goals and by the awareness of how much is changing. And Sir Andrew Witty chose and volunteered really to be the single industry representative among those 16 members, and to really tackle these questions around whether it's possible to bring to scale innovative, pragmatic solutions – patent pools, PDPs, advanced market commitments, whether it's possible to really de-link the R&D costs from prices looking forward.

So I think we're all in your debt, Andrew, and appreciate all of the different ways in which your leadership has changed the discourse in this industry beyond just what is of importance to GSK at one moment or next.

So Andrew's going to come deliver a speech. That'll go for 25 or 30 minutes. And then what we'll do is we'll move into a second phase of our program, which will be a roundtable discussion.

We're joined today by Peggy Hamburg, former Food and Drug administrator, currently foreign secretary at the National Academies of Medicine, and a – and a long and dear friend of ours here at CSIS.

And Zeke Emanuel, vice provost for global initiatives at the University of Penn, where he's also a professor, former White House adviser on health reform, and also a good friend and another member of our Task Force on Women's and Family Health. Thank you, Zeke, for coming today to be with us.

Andrew, if you could just come up. There's a step over here.

SIR ANDREW WITTY: Well, good morning, everybody. And, Steve, thank you very much for the kind introduction.

Peggy, Zeke, thanks so very much for coming along and attending this, and I'm looking forward to the discussion after. It's lovely to see you both.

Thank you, everybody, for coming along to listen to me.

Yes, so I announced this morning my intention to retire, so I do feel quite liberated. (Laughter.) And we've got a couple of GSK PR guys at the front who are incredibly nervous about what I'm going to say. (Laughter.) And they probably should be. (Laughter.)

But my brief or my request, or the request given to me, was just to reflect a little bit on what needs to be done essentially to try and – or what might be some ideas to try and navigate in a more positive way forward from where some of the impasses in health care politics generally, health care finance, and then of course – of course – within the pharmaceutical sector specifically. But I'm going to keep coming back to the point of health care more generally, not just pharmaceuticals. Because pharmaceuticals have many challenges, many issues which I'm going to talk about, but many of them are reflected elsewhere in the health care value chain. And while it's a trite thing to say that a relatively small fraction of the total health bill is made up of drugs, it is true. Many of the same challenges that we see in our part of the sector are seen elsewhere in the sector. I'll come back to that specifically toward the end when I make some comments around the U.S. more directly.

In terms of thinking about trust and how – and how to build credibility, you know, over the years I think I probably made a speech on trust for the first time in this sector maybe 14 years ago, and it probably has some symbol of my lack of efficacy that I'm still making speeches on trust 14 years later. (Laughter.) I wonder whether actually whether or not a better description isn't trust, but modernization: How do we make an industry modern and relevant to the society in which we now live, not the society in which it was originally spawned?

And the health care industry and the pharmaceutical industry in particular really owes its origins in large part to the '50s, '60s, '70s, '80s, '90s, really really. That's what's characterized the modern health care industry, certainly characterizes the current pharmaceutical business and

many of its practices – many of its practices, which are still dominating and are believed to be sacrosanct are products of that era. And they're products of that era when, in fact, the industry wasn't an industry, it was a cottage business. These were labs.

When I joined Glaxo in 1985, I think we were the 35th biggest drug company in the world. We employed something like 150 sales representatives in the U.K. Hardly anybody had ever heard of us. The policy of the company was just keep off the radar, nobody's really interested in what we do. And over the subsequent 15 years, it became the world's biggest drug company. Within 10 years, the U.K., we have I think a thousand sales representatives. We had 50,000 sales representatives worldwide and we were operating in 150 countries. But that – in a way, the behaviors, the culture almost grew from that cottage-industry beginning into what became a global industry, and our company was no different to any other company in that era.

And I'd argue, actually, that doctors and hospitals are the same. When I started in this business, 100 percent of the doctors I met were independent, single-handed physicians. I was in North Carolina three months ago; I think there's one left. (Laughter.) Everybody now, they're all part of corporates. Hospitals were independent hospitals run by a strong doctor, and quite often a strong matron, how they ran those facilities. But now they're big, integrated health systems.

But in a way the question is, have they modernized their ways of thinking and the structures and everything else to accompany the growth of scale that has been delivered over this period? And I think at its core in health care, and certainly in pharmaceuticals, the answer is no it hasn't.

And what happens over that period – and if you look outside of our industry, health care, into other industries, what tends to happen – banking's a very good example – is that those modernization points actually is where you get regulatory stress points and scandals. And they start to create – it's where those historic things which looked OK at the time suddenly aren't OK. They're not OK because they're visible. They're not OK because they're big versus kind of small and non-material. They're not OK because the world changed.

First 20 years of my career – I have an international career – I flew everywhere, like everybody. Get somewhere, you get on a plane. For 20 years I spent my entire time trying to get a seat not behind the smoking row. (Laughter.) And actually, the focus was, how do you get the seat which doesn't inhale directly from the guy in front. But the world was loading millions of people a year into metal tubes to get them to inhale cigarette smoke. Now we'd say that was shocking, but then it was kind of normal. It's an example, right, of how minds change, and industries have to change with the change of mind.

So modernization, for me, is what I'm going to focus on in these comments, rather than just trust. So what does modernization mean in my industry? I'm going to start with commercial relationships of the pharmaceutical business with their customers, with their doctors, with the people we should be trying to help make good decisions.

We've, over the – I'm incredibly proud of what we've done over the last two or three years at GSK. And I'm going to explain to you very, very briefly because I have a lot I'm going to try to get through today, and dispersed in here are the two or three things I'm going to say which are new new, and which these guys at the front are terrified of. So I'm going to just sprinkle those so they may not notice it when it comes along, but I'm sure you will. (Laughter.)

The changes we've made over the last two or three years in commercial are in two specific places.

Number one, take away the sense that all we care about is generating a prescription at any cost. How do we do that? We stop paying our sales representatives incentives based on the creation or the sale of the product. For the last year and a half, and in the case of the United States for the last five years, not a single representative globally employed by GlaxoSmithKline is paid an incentive to generate a prescription. We are the only company in the world to do that.

That is something which fundamentally transforms how you work with your sales representatives, because the question is, how do you measure them? And you measure them based on their knowledge, on their quality of ability, on what their customers say about them.

Having done all of this – by the way, there are plenty of people in my industry who think this is madness, that the world will stop turning the day you stop paying reps incentive comp. It doesn't stop turning. Actually, what happens is you start to have intelligent, mature conversations with your employees about what value really means to customers; what do your customers really need in a world where they are under pressure; how do you help a customer, a doctor make a better, more appropriate decision. And you know what the message is we're sending to our people? We don't mind if the right drug is somebody else's drug. We have confidence that our drugs are the right drugs sometimes, but we only want them used on the times when we're the right drug. And if, in our conversations, it turns out some information we give to the doctor actually clarifies that we're the wrong drug, then we have done a good thing that day. Better that we make sure they know we're the wrong drug than to have them prescribe it.

That changes it. That's why GSK is the number one most trusted salesforce in America as voted by physicians. Might not be the most aggressive, but we're the most trusted. That is one example.

The second example is a global prohibition on payments to doctors to speak on behalf of the company. If you look here in the United States, there has been an industry grown up over the last 15 years – I think the Holiday Inn – if this was adopted by the whole industry, the Holiday Inn would probably go out of business. Average life expectancy of chickens in America would quadruple because the number of chicken dinners would collapse, right? (Laughter.) So we said we're not going to do this anymore.

Why are we not going to do this anymore? It's not illegal. And in fact, you know, here in the U.S., there's a massive contracting world that's grown up about how you make sure these things are done properly and it's all appropriate. And of course, at that level it passes that test.

The real test it has to pass isn't a lawyer test, it's a society question: Is it right that the company who's selling you the product is paying you to talk about the product that they're selling you? Does that feel right? Does it create a perception? And our conclusion was that it did create a perception, and our conclusion was it was right to stop.

It, of course, also creates the risk of abuse, and scandals come from risk of abuse. And unfortunately, we can hire as many lawyers, as many compliance folks as possible. We can have the best rules in the world, but eventually somebody's going to do something to break the rule, and then you're going to have a scandal, and then you're back into a situation you don't want to be into.

How do you stop those things? You take the fuel away. So a secondary reason for doing that, just take the fuel away. It makes life so much easier. So we haven't – we don't do any of that anymore, anywhere in the world.

We have also made it a requirement that any company that collaborates with GSK has to adopt those two policies. So if you are a co-marketer of GSK, a licensor of GSK, we're not going to – that's not a clever way for us to avoid this. We are totally committed to it.

Now, the real reason for doing a cessation on payment to doctors isn't really what I just told you. The real reason for doing the payment – cessation of payment to doctors was to force my organization to realize we're living in 2015 and the world is digital. Because really, really modern doctors want to live in a world where, to be educated on a drug, they have to give up their Thursday night to go to the Bethesda Holiday Inn to eat cold chicken, to listen to some buy talk about a drug? Really? Or wouldn't they rather be in a situation where they could, when they need that information, go online and have a direct interaction with a highly qualified GSK physician who can give them the information they need 100 percent within the framework of the regulation?

So actually the shift we're making is, rather than saying we want to come and tell you about stuff which you may or may not be interested in on the day we're available to talk to you, we're saying we're going to replace that with a massive digital capability where we are going to make all of our knowledge accessible to you at your convenience. And if your convenience means 1 a.m. on Sunday morning, we'll be there. If that's when you wake up in the night worrying about how to treat that asthmatic, we're there. That is modernization. And what that's driven in my company is a huge shift in the way we think about how to be convenient – how to be there when the doctor needs us, not how do we force ourselves into the doctor's world whether they want to hear from us or not.

That's not that different, let's face it, from where Amazon, where the banks, in normal life, real world, we've all shifted our ways of working into that much more convenient space, exactly what we're trying to do here. So it reduces risks, it takes away perception risk, and it forces a modernization of the way we engage with customers.

Last week we ran across 20 countries a 90-minute webinar with 16,000 doctors in attendance. On average, we're getting 83 minutes' dwell time on our interactions. We have

higher standards of engagement, follow up, questions in the new world than we've ever had in the old system. Why? Because it's the way we all want to work. We're trying to modernize it. So that's the first area, couple of examples.

We're absolutely committed to this. We're beginning to hear signals of other companies beginning to follow. We've just seen a big company in China adopt our approach there. I suspect that will be a signal, more to come. We'll see what happens. I'm going to refer a minute to what happens in terms of some of this – is it good to lead on these things or not.

Let me quickly move to transparency because a lot of what I just touched on there is starting to lead you to the sense of openness of information and the like. Transparency for the industry has been an Achilles' heel. In the old days, Glaxo was – or GSK was hurt through transparency criticism.

We made a strong commitment – a couple of strong commitments, actually. We said we will publish every single clinical trial we ever do in this company, good, bad or ugly, and we do that. Every single one. Phase one, anything in a human gets published. Fails, drug gets terminated, whatever the conditions, that data gets published. We do that completely.

We also said we would make available patient-level data. The day I announced that, I was told by somebody in this industry that I was killing the pharmaceutical industry by committing to that level of transparency. Unbelievably, I think that was four years ago, and actually the sun still came up this morning. (Laughter.) All right? Because transparency doesn't stifle innovation. Transparency encourages innovation.

And then we made a further commitment where we said we will go – we will not just publish prospective trials, we will go back and we will publish every single clinical trial this company has undertaken since it was created. And I'm very proud to tell you that last month we put on our website the 1,700th, and final, clinical trial from that work. Unbelievable amount of effort to go back and take data from microfiches, from all pre-the new systems, get it all restructured into a readily available format so that researchers can now get access to that. And as of today, we've had 63 research teams access that data repository to do their own analysis.

And you know what? If they find in there that we missed an efficacy signal, great. And if they go in there and they find that we missed a toxicity signal, I won't be happy, but good, because if it's there I want to know about it. So there's no downside for us, I don't think, in that mix. And if it's used by somebody to avoid one patient going into a redundant trial, good. If it's used by somebody to help refine a protocol so the protocol has a 1 percent higher chance of success, great. That's what we get from this transparency. So that's an area where we believe it's crucial – and I'm very proud that despite the fact that I was told on the day we made that commitment that this would destroy the industry, I think now we have 12 major companies similarly moving down the same path.

R&D. How do we develop new medicines for the non-obvious, for the difficult things, for the things where the market doesn't work very well? How do we stimulate those sorts of things? And that's an area where I think companies have to think, really, like portfolio

managers. It's very easy to say let's just do the big stuff and make lots of money. But there is an obligation, I think. If you own technology, insights, skills, and you have organizations of intellectual firepower, you have to have, in my view, a societal obligation to deploy that in a balanced way against a broad portfolio of research issues, not simply the money maker.

That's why, since 1982, GSK has spent over half a billion dollars developing the world's first malaria vaccine – 1982. There aren't many government research programs that survive that long, let alone inside a private company. But we did it, we succeeded, we have the vaccine approved, and we're working with the WHO on how that deployment happens. And we've made a commitment that that vaccine will be a not-for-profit vaccine. The company will never strive to make a profit from that vaccine. Why? Because the people who need it can't possibly pay a profit. It's part of the portfolio of the way we operate.

We continue to research in malaria. And I'm delighted to tell you we have a molecule now in advanced phase two with a 90 percent cure rate single-tablet treatment in vivax. Breakthroughs are coming in the neglected diseases. They're not just coming in the diseases that we're fixated on in the West. And we, as owners of intellectual firepower, should be just as keen to deliver those breakthroughs as we are elsewhere.

An area which captures huge imagination is the unexpected rare pandemic threat – the Ebola, the Zika type of threat, flu pandemic. These are huge challenges, and it's an area where GSK has been extremely active. I've been personally involved in anthrax, SARS, swine flu, Ebola, and of course now Zika. We'll maybe talk more about this through the Q&A. The slightly scary thing I'm going to tell you is the world's responsiveness is deteriorating, not improving. So, having been through all of those, each one is more chaotic and more challenging than the last, and something needs to be done.

Companies are struggling to see how they can really continue to deploy to help because it's such a challenging environment, where relatively little is done in preparation and everything has to be tried to be done in the crisis. We repeatedly waste the peacetime and overstress the war, and that is an issue that needs to be resolved.

We've made a very substantial commitment at GSK to provide on a permanent basis to the world's governments – and that is a big phrase; we say that very deliberately, "to the world's governments" – a permanent standing research capability; not virtual, physical; based here in the U.S. Very substantial vaccine research capability, including its own bioreactor trains, all of its own laboratories, dedicated to developing vaccine after vaccine for the likely but unpredictable Ebolas of the future. And I hope we're close to getting that agreed with the governments around the world. But we're going to need to get serious in this space around doing something. And as a company, we are absolutely committed to do that.

I want to talk – a couple of things very specifically around R&D. So this notion of de-linkage. So now let's move a little bit more into the Western world. How do we start to think about novel pricing models for products?

And at the moment, of course, what happens is R&D is charged – essentially amortized across the pack price of every product which comes to market. All failures are amortized into all successes, which is why Steve's right that, you know, I don't subscribe to the view that all drug developments are these gigantic numbers. The gigantic number is the total number of – the total amount spent on everything divided by the number of successes. So the biggest driver of economics in drug discovery cost is fail less often.

Nonetheless, it's an expensive business, so you need to get a return. Now, we're the only company in the world where we have clearly publicly declared what our target rate of return is. It's 14 percent. We strive to generate 14 percent return on the R&D dollar that we spend. We publish this every two years. As of today, we're running at about 13 percent. When I took over, we were running at 7 (percent). So we've made big strides.

How have we done that? We fail less often and we have less costs tied up in fixed infrastructure, frankly. You don't need the kind of labs that were built in the '80s. You need much more virtual environments. You need to be much more connected with academia. The way you do R&D is totally different to the way you did R&D 25 years ago. The cost structures that we inherited aren't fit for purpose. They just – they just weigh down the economic efficiency of the R&D programs. We're fixing that through those mechanisms.

But we are exploring – and I think rare disease may very well be the place to do this – we are exploring de-linking the R&D charge from the pack price. What does that mean? It means being very upfront, to say this is what it cost to develop this – to develop this product, this is what the return is we need to essentially ensure that shareholders continue to put money at risk in this type of research field, and then here's what the cost of production of this product is. And you actually have a pack price – you have a pack price at one level and you have lump sum, if you can conceptualize it that way, of the R&D charge. It's entirely possible two different parts of the system pay for those two different things. And government maybe pays for one. Patients pay for another. What does that mean? It means that you – once you've paid the R&D charge you don't pay it forever. And I think that that is something we should really start to explore as an idea.

I'm sure there are 5,000 people who can give me 10,000 reasons why we shouldn't try it, but they'll be the same people who told me transparency was a terrible idea. I think it's the sort of space where we've got to start increase thinking. And we're certainly doing that. And as I've said, rare disease. And we're very close to getting approval in Europe for one of the world's first gene replacement therapies for ADA-SCID. And it may very well be in ADA-SCID that we look to try something a little bit different here to see whether or not we can, indeed, get some traction.

What we're going to need, though, is regulators and governments to be prepared to think about a different system. This is a whole interesting conversation about how flexible regulators and governments are themselves to modernize the environment in which they want to operate. It's actually very easy to criticize components of the system. It's not that often you see the owners of the system try to self-change the system as a signal to the players. You need more of that. That's an important area.

How do we get these – how do we get these vaccines and products then to people in the world who can't afford them? That's a challenge. But there are some evidence points that we're making progress. This was a horrific story in the late-'90s around HIV, South African scenario. But there has been the most gigantic progress made – pediatric death rates dropping in sub-Saharan Africa after the introduction of rotavirus and pneumococcal vaccine. Really stunning heath care interventions being achieved. You're seeing deaths from malaria drop through bed net intervention as well as pharmacological intervention. Many, many good examples.

We should – and this is one of the big questions at the U.N. panel I'm on, of course, if focused on. And it's terribly easy in these sorts of environments to think about, well, there is no simple fix, but maybe there should be. Or maybe there's a simple problem that gets in the way, like IP. The easiest thing in the world. Get rid of all IP and it would be like Nirvana. Get rid of IP everyone in the world will get everything they need it would be so great. But, you know, you get rid of IP, what happens? Seventy-five percent of essential drugs today on the WHO essential drug list have no patent protection. And yet, you think everyone in the world gets essential drugs? No.

You go to country after country where companies like GSK don't file patents, but the drugs aren't available. It's not IP. If you get rid of IP, I have a 23-year-old son, a 19-year-old daughter. You think they're going to go to university for eight years and then spend 10 years researching a really cool idea for a new medicine if they didn't think there was a patent at the end of it? Would you? Would you tell your kids that's a great future, to go be a researcher to develop something? Do you think Steve Jobs would have spent his entire life thinking about creating Apple if there was no way that he could have ever conceptualized capturing the value at the end? No chance.

IP is there to protect the innovator. But IP does not give you, as an innovator, the right to charge any price you want. That is a completely different part of the process. And it needs to be challenged and thought through really hard. And if people who are IP owners are not in step with society around pricing, then they will pay the price accordingly. They won't get used and they'll get squeezed out of the system, and the system should react in the way it wants to react. But be very careful to conflate IP with access. They are two very completely different parts of a value stream. The unintended consequences are enormous.

How have we tried to start to move this forward? A couple of really good examples of things that are working really well. Advanced market commitment. So death rates falling in sub-Saharan Africa, thanks to the arrival of things like rotavirus and pneumococcal vaccine. Why is it that GSK within four years of getting Synflorix registered are in a position to be selling 70 million doses of pneumococcal vaccine to countries with essentially no health care budget?

It's because of the GAVI AMC contract. Because of that contract, we committed to spend $600 million U.S. to build a state-of-the-art vaccine facility specifically to build that kind of volume to go into those markets. That's why the poorest countries in the world have access to the most modern vaccine almost simultaneously to the richest countries in the world. That is a first in human history. Normally, they had to wait 20 years. When we'd all got what we needed,

then we let the poor countries have a go. It's not like that anymore. It's wrong and it's not like that anymore.

And so we've been very active in AMC. The way AMC works is it gives you a guaranteed price with a tail price. Some of you will know there's increase in demand for these vaccines around the world. We're seeing continuous increased demand for GSK's Synflorix, the pneumococcal vaccine, as well as rotavirus. But just I'm very happy to tell you today that we see this as a very dynamic environment. And I want to just use that as an example of the soul of this company and what we really believe.

So we signed up to the AMC. We signed up to the AMC to go to GAVI countries. And we've made – built our factory, we sell the 70 million doses. We then said – we began to pick up an anxiety from some of the countries which were beginning to do better economically. What happens when I graduate from GAVI and I'm no longer a GAVI country. Do I lose the benefit of the AMC? Am I going to get this kind of step effect price increase? That's why we came out and said, no, we'll give you a 10-year grandfathering. So that actually go ahead, knock yourself out, grow, grow, be as successful as possible. There isn't going to be a penalty from the vaccine because of your success. We didn't have to do that. No pressure to do that. But it's the right thing to do.

Because we're seeing so much volume, our economics on pneumococcal vaccine are running better than expected. As a consequence of that, I'm very happy to tell you today, although it's not contractually required, there is no pressure, I have a contract that I can enforce forever, we are announcing today that we're reducing the price of Synflorix for the GAVI countries by a further 10 percent, right, which takes it down from about 3.40, 3.45 to 3.05 dollars per dose. And I will reiterate what I've said publicly before.

If we continue to achieve economic benefit and/or if we continue to achieve technological innovation, we will reduce it further because the goal is to get that standard of high quality vaccination to as many people as possible in the world. And we want to be part of that. So we will do that. And I'm very proud to tell you that Synflorix is the cheapest, lowest-cost vaccine for pneumococcal disease in the world. For a vaccine which has essentially 10 valencies conjugated and has 650 quality control release tests, I think $3.05 is a remarkable achievement.

So that's the second area that I wanted to touch on. Now, the third area that's working in terms of how to open up access in the developing world, medicine patent pool. First, really conceptualize – interestingly enough, there were two medicine patent pools that started more or less at the same time. One was started by GSK, actually, where we said we would put all of our intellectual knowledge, IP and otherwise, into a patent pool around neglected tropical disease.

That then became – so we launched that as POINT. It then became part of the WIPO program. And I'm thrilled to see there's now more than 10 companies have gone in there and pooled all of their IP. It's another great example. The day we did it the guys with white coats were headed my way. Five years later, we've got a whole series of people signed up to that. And it clearly works. We're seeing research groups spawned on the back of that easy access to that knowledge, more work being done in diseases of a developing world.

There was a second patent pool which was started about the same time by UNITAID, the Medicines Patent Pool. And the Medicines Patent Pool focused initially on HIV, although now it has a medicine in it for HCV and it also has a medicine in it for TB. We made a decision when we were developing our new HIV drug Dolutegravier, which I think is widely regarded as a very fundamental breakthrough in terms of standard of HIV medicine available, has become an extremely successful medicine for GSK.

We made a commitment before we launched that, that at launch we would immediately put Dolutegravier into the Medicines Patent Pool, so that right from the beginning everybody in the least-developed and low-middle income countries could, though the Medicines Patient Pool, get access to that medicine. And that has worked well. The low-middle income countries play a very small royalty, but the LDCs pay no royalty. I mean, it's essentially another reflection of our tiered pricing culture, but we do it through the Medicines Patent Pool.

I'm working on at the moment, and this where these guys are all – I'm working on at the moment what we do next with that Medicines Patent Pool. And I think in the next few weeks it's highly likely that GSK will announce further significant shifts in terms of the type of medicines that it thinks might be appropriate to go into the Medicines Patent Pool. And I think oncology is high on that list. And I think it's time the industry started to do something really serious about how to drive access to oncology agents around the world.

Now, everybody knows we sold our old oncology business. So you're probably thinking, really? That's really a gift, right? He sold his business, now what's he saying? We sold our old oncology business, but we kept all of our discover and development. So the products I'm talking about aren't old products. I'm talking about our OX40 inhibitors. I'm talking about epigenetics program. I'm talking about the next generation of breakthrough meds in oncology, potentially going straight into a patent pool for access for the least developed countries.

I think that speaks directly to the heart of the fear that sits in those countries. As they get wealthier, as they get more and more concerned about the same kind of diseases that we've been dealing with in the West. And so those are a few examples of tools. And I think the response to this broad set of issues on access are really around having a selection of tools to deploy against bespoke problems. The malaria problem is different to the pneumococcal problem. The pneumococcal problem is different from oncology. And you need different approaches to do it.

As a business strategy, we are absolutely committed to a global presence. So when I talk about high volume business, it's really reflecting a business which achieves a product offering, a contribution to health care, regardless of your buying power. I think our lowest-priced pack anywhere in the world for GSK is 11 U.S. cents for oral polio. So that's where we start. And we operate a culture in the business where we should be striving to have a meaningful contribution in every country, even if those countries can't afford the same level as the richer countries.

So that really covers off, I think, a big issue of modernization of commercial relationship, transparency, how do you develop medicines for kind of the difficult spaces, and then how do you think about access? The elephant in the room is the U.S., where we clearly all understand

that affordability and access are just as big an issue today here as they are in many of the least-developed countries in the world. There really wasn't the debate 10 years ago, but it's become the debate. And something has to change.

I'm British, so the last think I'm going to do is get anywhere close to your politics. (Laughter.) So that, for sure, is not smart. So to the extent I haven't already upset somebody in the room, that's the quick way – surefire way of doing it. But I just want to make a couple of observations, and maybe this will come up more in the Q&A and discussion, but I'll finish off with them. I want to reflect, actually, some of what I've just talked about most here on LDCs and the rest of the world directly into the U.S., is pricing.

We're a drug company. We make a lot of money here in the U.S. But we also invest a fortune here. Our U.S. R&D is phenomenal. U.S. buyer tech environment is phenomenal. The U.S. is an enormous beneficiary of the world research engine, absolutely massive beneficiary. The U.S. is the game-caller of this global industry. The FDA is the head of the system, whichever which way you want to look at it. They set the standard. The U.S. – this is a U.S.-designed system globally. Incredibly important.

We do very well here. Sometimes we do better. Sometimes we do worse. We're in a cycle of launching a lot of new products. We've had more – thank goodness – we've had more approvals by U.S. FDA in the last five, six years than any other drug company on the planet. The last five years, ever single drug approval submitted from GSK – and this is why I'm going to do this – was passed for a cycle review. I think that reflects a commitment to quality from GSK in terms of meeting the standard that was asked of us. I'm very proud of that.

In the next five years, we believe we have 20 filings. We have high 40s in late-stage clinical development. Eighty percent of those drugs are first-in-class molecules. We have the most extraordinarily exciting portfolio of drugs in cell and gene therapy, in rare disease, epigenetics oncology, immuno-oncology, respiratory, immune-inflammation – all of these areas. I'm proud that we're one of the last-standing drug companies to do industrial-scale research in antibiotics. I'm proud that we're close to filing a first-in-class antibiotic here in the U.S. And I'm proud that we're working with the U.S. government already on stockpiling that antibiotics for potential terrorist or pandemic threat.

That is what our research business is about. The U.S., American scientists in academia, biotechnology, and in our own labs, play the most extraordinary role in all of that. But it doesn't mean we shouldn't pay attention to the affordability and the price issue here in the U.S. The last six drugs that we've launched in the U.S., we've launched at or below the prices of the generation of products we aim to replace – not at or above, at or below. In the last six years, GSK's average net price increase, CAGA (ph), 1.7 percent. In the last two years, negative. So our overall net price in the U.S. is dropping. Now, I know that's not true for every company in America – we all know it's not true for every company in America. But it's true for GSK.

Now, why is that? Is that because I'm an idiot? Is that because I'm, you know, some sort of hippie, you know, leave money on the table kind of guy? No. It's because I'm trying to get us in step with where I believe the weather is going in the U.S. And we have to be focused on

having value for money. Now, I'm going to just point to one thing now. It's not easy to make progress when you cut your prices in the U.S. in health care. You know why? Because there's absolutely no transparency in the system. Nobody knows what the prices are. And not just with drugs.

So think about the health care system in the U.S. – and this is where I'm a Brit, I'm going to get on the plane tonight, you can stick pins in me – (laughter) – take it or leave it. You guys, America, 17, 18 percent of GDP. But in all honestly, you don't know the price of anything you're buying in health care. How can you – how can you dream that it's going to be efficient? Average discounts in a company like my company, 40, 50 percent. You might see a headline price go up 5 percentage points. I just told you my net prices are coming down because discounts are going up quicker than gross prices are going up. But nobody knows that.

So people focus on the list price – oh, it cost a hundred bucks. Oh, my god, it costs a hundred bucks. We must do something about that. Let's attack that hundred bucks. But what if you knew it actually was only costing you 30? Would you do the same thing? Or would you say, actually, that 30 sounds about right. I need to focus somewhere else in the system to find the efficiency. And actually at 30, I might want to use more of the product, because the economics of this product make really good sense at 30. If only I knew it only cost 30. It does cost 30. It's just that you don't know it.

And the same is true in the hospital system, in the physician system. Transparency is in the way here. Seven years ago – and I have a guy sitting here in the front row who has worked with me all through this period – I came back. I used to live her. I came back as CEO to our U.S. company. I hadn't been involved in the U.S. company for 10 years or so. I came back, we had a brand-new product to launch. I said, we're going to launch this drug 25 percent below the price in the market. And they all said, it's a terrible idea. And they were right. I launched it 25 percent below and the market in the U.S. said, no, because actually the discount rate we get from other guys on the higher price gives me more discount. I like getting discount. (Laughter.) Think I'm kidding? (Laughter.) That's how the U.S. system works. No transparency. Massive amounts of intermediary discount operation.

Why am I saying all of this to you today about the U.S.? It's not because I want to make enemies of anybody, really. But this is an existential issue for United States. Eighteen percent of health care – sorry, 18 percent of GDP and health care as two concepts couldn't get more serious politically, right? Scale and health care obviously gigantic. So there has to be, surely, a moment where the whole health care environment has to be rethought so that you end up with what the U.S. is capable of creating, powerful, breakthrough innovation, that becomes visible and understandable in an economic context, and then gets to the patient who needs it as fast as possible, without having so much kind of sclerotic material, you know, kind of gunking up the system which makes every decision difficult to see, makes it slow, makes wrong decisions get taken.

Money gets put in the wrong places. The reward for innovation doesn't actually go to the innovator. It goes to somebody else. I mean, right now there are companies in America making – the cost discount rates are more than 50 percent. Just to state the obvious, the companies who

are negotiating the discounts are getting more for the innovation than the innovator. Just to be obvious, right? Once the discounted rate is higher than 50, the extractor of the discount rate is getting more of a reward. Now, the payer at the end is saying, I'm OK paying high prices for new drugs because I'm rewarding innovation. Well, actually, you're only partly rewarding innovation. You're rewarding somebody else in the system. And so that's an area I think has to be relooked at. Now, that is not easy, but is it – nor is it unique. It's not the first time in history that a country has had to rethink its value stream within health care. But that's where I hope we will start to see some real focus.

Now, within that the opportunity for the kind of break-through technology that we have, the opportunity for that technology in the hands of managers and decision-makers who are prepared to make long-term, sensible, societally in-step pricing decisions, to recognize that we're prepared to change our prices according to new information, if the medicine is superseded or whatever else, and to think about novel ways of interacting, in the way that I've just described – that is the beginnings of a new relationship. That is the beginnings of a modern compact between an industry that we absolutely need – and I'm not saying that as the CEO of a drug company. I'm saying that as somebody who probably, 99 percent likely, is going to one day wake up and say, god, I hope somebody's discovered a drug for this disease I've just been diagnosed with. We need that innovation.

But we have to find a compact to modernize the relationship between all the players of this health care system so that we don't inadvertently react to the pressure and the tension and the anger that exists today around the 18 percent and the word health care and do something where we trigger off incredibly negative unintended consequences, and we undermine innovation, we send a signal to our kids it's not cool to discover drugs, we send a signal to our kids that you don't want to do biology, we send a signal to our employees that what they do isn't valued. We need a new compact. Transparency is the first place to start. It's hard, but just like transparency that we've led in GSK, you know what? The sun does come up the next morning. It does work out. And you can survive very, very well in a transparent system.

I hope that those comments, while they've been reasonably wide-ranging, haven't left you completely confused or frustrated. It's been an absolute pleasure to come and talk to you this morning, and I look forward, Peggy and Zeke, to continuing the discussion. Thank you so much. (Applause.)

MR. MORRISON: Thank you, Andrew, for that sweeping and powerful and eloquent and very rich speech. It's really given us an enormous amount to think about. What I would like to do is ask Peggy and Zeke to open this segment of the program up with some response, some thoughts.

Peggy.

DR. MARGARET HAMBURG: OK. Well, a lot of ground to cover. I guess I first have to say, you know, thank you for the leadership you've brought. And I just learned, as others did, that you're planning to step down. It is liberating, I can tell you. (Laughter.) You can suddenly say things that otherwise your minders watch for. (Laughter.) I also, you know, you were one of

the first CEOs that I met when I took on the role of FDA commissioner. And I mistakenly thought that most CEOs were as progressive and forward-leaning, and compassionate as you are.

But you know, I think you laid out today a lot of things that we hope we will have a chance to talk about, and be part of national and international discussions going forward as well. Let me focus on just a couple things that are closer to the world that I was living in for the last six years or so. You know, the importance, and I think you touched on it, of thinking about how do we deliver on the promise of advancing science, and really make sure that we are translating it as efficiently and effectively as possible, so that all people everywhere can benefit, and the fact that that really takes a new model and a new means of collaboration, and the fact that we are in an enormously exciting period because, as you were talking about your pipeline, that reflects that new knowledge and new scientific tools and approaches are really enabling us to develop drugs in new ways that will make a huge difference.

So let me just touch on a couple things, and you, you know, knock me when I'm saying too much. I mean, first of all, the whole notion of trust and credibility is so important at every level. That was a huge part of my focus at FDA in terms of trying to restore trust and confidence in the work of FDA. And I think that trust and confidence in the work of FDA with industry and with all stakeholders is essential to success. And the work that you've done to enhance transparency and create a model in industry I think aligns with what is needed now more than ever, both to enhance the science and to, you know, really build this continuing sense of credibility in the work being done, at a time of more and more skepticism and more and more demand to know, and the need for really quality information to be out there for the public and policy makers in a way that hasn't always been the case.

I think that when you combine more transparency in the context of data availability with new models for doing R&D, I think huge progress can be made, and we're starting to see that already. I think one of the critical things from the perspective of the FDA and the regulator as a partner with the broader scientific enterprise, is that we can really bring down the time, the cost, the risks to patients of the whole R&D process, and in turn the risks to industry, if we do it in a more coordinated and focused way. We had a fragmented system where everyone sort of sat in their corner of the landscape and did their piece serially.

But we actually learned early in the AIDs epidemic the value of all stakeholders coming together at the table and really working together to shape what was the research agenda that needed to be done, to ensure that there was the clinical trial infrastructure to support that in an efficient way, and to really engage patients in critical ways, both to understand the nature of the disease and the experience of the disease and the interventions from a patient perspective, but also to get them to want to participate in the clinical research. And I think a lot of lessons were learned as, you know, people struggled to address HIV/AIDS in the early days, but, you know, this approach clearly made a difference. And we kind of lost it and went back to our separate corners.

But we know now, I think, looking at the recent experience, that when there is a greater awareness of the regulatory framework, what are the critical questions that are going to have to be asked and answered in the development process? When we're thinking about academic

researchers, industry scientists, and government as collaborators and partners in new ways, you can really streamline and modernize the process – the process in terms of identifying what studies should be done, how they should be done, early on.

And we did an informal look at new approvals at FDA over a period of a couple of years and it was clear that, with early and continuing engagement, that several years could be taken off the R&D process, not doing anything to affect the rigor of the science but just making sure that the right studies were done, also working together to think about what are the innovative approaches to doing the critical science: innovative clinical trial designs, developing the field of toxicology in new, more modern ways so that, as you noted, if it's going to fail it can fail early.

And so developing the field of predictive toxicology, using existing data through, you know, what everybody likes to call big data techniques but to really be able to look at information that at a previous time we might not have been able to glean but now we can as we learn more about subpopulations of responders, et cetera, but also collecting data in the future in ways that enable more cross-analysis and a deeper dive into important questions, taking advantage of data that's being collected.

So there's – you know, I think that this notion of really opening things up and collaborating is a little bit trite but it really matters. It's been demonstrated to make a difference and I think it's the way of the future.

MR. MORRISON: Thank you. Why don't we ask Zeke to offer some thoughts here?

Travis (sp), is it possible to – there's a bit of an echo here.

DR. HAMBURG: Yes, I was noticing that.

MR. MORRISON: Is it possible to bring that down a little bit, please?

MR. : (Off mic.)

MR. MORRISON: Zeke?

EZEKIEL EMANUEL: So, Sir Andrew, I was a little disappointed I didn't hear the word "tax inversion" once. (Laughter.)

SIR WITTY: You're never going to hear that word out of my mouth. (Laughter.)

DR. EMANUEL: Well, that was my point, which is this was a substantial speech about the science access. And it wasn't about profitability as the primary focus. It was really about how do we create interventions that are actually going to change people's lives? And I just wanted to tell one brief story.

The first time I think I met you I was in a hotel lobby in this town. I was working for the White House. And you wanted to meet because you wanted to keep me updated about your

malaria vaccine initiative, and you were already thinking about how do we make this drug – this vaccine cheap enough for worldwide distribution, and how do we do that in an accelerated way so that we're not spending two years after we get approval to think about getting it out to the frontline? And I thought it was at that point, I think, three years before you actually got approval and – but you were already thinking about this issue of access and worldwide affordability, and I was duly impressed by that. So let me just make a few points.

I do think this emphasis on how to reduce both the costs of innovation and de-risk innovation. We can't get it to zero. You know, it's not research if it's no risk. But there are lots of things – and I do think, as Peggy just mentioned and as you mentioned, this issue of getting affordability and the approval process more harmonized is going to be critical for the industry to continue to make investments.

And I think we're still having those conversations in silo, certainly in the United States. We talk about drug pricing and we talk about FDA, but we don't talk about them in the same room. What could the trades be, you know, for changing some of the FDA processes to get – to translate into more affordability? And I think your emphasis on those links is critically important. I certainly hope the new administration, whoever they come in, will broaden this discussion about drugs in that way. And I greatly appreciate it.

You know, I can't say enough about the initiatives you've taken in the developing world. I would add one other issue, which I do think is important, and I don't know how GSK is addressing it, which is we do have this major, major problem of counterfeit, ineffective drugs. And so all the availability, all the cheap prices, et cetera, certainly helps with that but does not, as you know, eliminate it.

And sort of related is the drug resistance problem, which, you know, some recent research has shown is very heavily – certainly in India – concentrated in places where you have generic makers dumping their product – I'll use the – put "dumping" in quotes – and you get resistance literally where they're putting their product. That is a worldwide problem but I think it's especially a problem for a company like GSK and other companies that are trying to get high-quality medications out there and also prevent the resistance – you know, the antibiotic resistance, the resistance to anti-malarials, et cetera.

When we come to the American domestic market, I think, you know, we have a framework. We're not going to – we're not going back to the trough about changing the American health care framework. The ACA is the framework for the next 30, 40 years. I do think your call for more transparency on pricing is important although it's – given the discounts, given the multiple players, I'm not sure transparency is going to be the solution. So I wanted to ask you – or to push you on this issue of value-based pricing.

Now, a previous generation of CEOs of American companies had embraced value-based pricing, even if they didn't use that phrase. Some CEOs dance around it now and maybe are going to embrace it; they're not sure if they know what it is. I don't know how GSK is thinking about it but, I mean, it does seem to me that we need to get companies that are saying, look, we are willing to embrace value-based pricing. In the United States it's not an end in – it's not

supposed to solve all our problems, but it is a way to get to affordability that makes sense and it is something we are willing to embrace.

Now, value-based pricing, you know, you can't do it once because you get new data, it changes the value –

SIR WITTY: Right.

DR. EMANUEL: – of a product, right?

SIR WITTY: Right.

DR. EMANUEL: I mean, when you launch you have the least data. Three years later you have a lot more data about efficacy, effectiveness and side effects. Anyway, it does seem to me that's something, you know, GSK might want to – needs to take stand on. And I'll – (inaudible).

MR. MORRISON: Zeke, for the purposes of our audience, could you just quickly explain –

DR. EMANUEL: So value-based pricing is the idea that, you know, the price reflects the clinical impact on it. It doesn't reflect – oh, let's pick a number. You know, what are our competitors doing and we'll do 10 percent more, or whatever – however pricing is made in oncology, which is my field.

The last thing I want to raise with you is – I'll kindly put it this way: You have a problem. You're a – as I think Steve appropriately said – a leader, a visionary, someone who takes a different value set in this field. But as you know, your company is in, you know, you might say a bad neighborhood. You have neighbors, you have other people – and you're tainted.

I mean, look, every drug company has been tainted by Valeant, right, or Turing, but you're also tainted by some of the behaviors of your large competitors, colleagues, whatever you want to say, fellow PhRMA members. And I think that's a problem for the industry, right? I often say it's an amazing industry. You create lifesaving drugs and we think you're no better than cigarettes.

SIR WITTY: Right.

DR. EMANUEL: How can that be? It's an amazing, you know, alchemy. And I do think this is an issue for the industry itself and for GSK maybe in particular.

SIR WITTY: Yeah.

DR. EMANUEL: And, you know, your speech could not be given – and I could name, you know, three or four other – would never be given by three or four other CEOs. That's a problem for the industry. And I don't know how, you know, one company gets out of that

problem except continuing to lead. But, you know, 99.9 percent of the American public – you know, what's the difference between GSK and – you know, we could name the others.

SIR WITTY: Right.

DR. EMANUEL: We'll save them from embarrassment. And I'll save myself from hate mail. (Laughter.)

SIR WITTY: So do you want me just to respond just real quick?

MR. MORRISON: Yes, please.

SIR WITTY: So listen, thanks very much for the comments.

Certainly in terms of the regulatory – and the whole area of scientific openness I think, again, is part of modernization. You know, we're now crowdsourcing chemical problems that we come across. We just solved a tox issue with a crowdsource. I think we had something like, you know, 5,000 people come online, I think 30 semi-reasonable ideas. And I'll not say that's bad.

DR. EMANUEL: That's huge.

SIR WITTY: I mean, this is something where we spent five years going nowhere. So it was like, you know, anybody's – anybody who could come up with a good idea, it was good. And I think, of those, five were really tractable and in the end we solved that. That was a straight-out fundamental open crowdsource: This is the problem. Help. So we're pushing that way.

I definitely think the alignment with – the increase in alignment and, frankly, the big step up that you led, Peggy, at FDA of scientific expertise at FDA – huge. The FDA has to have the smartest people in the building. They have to be, right, because they have to – and they have to be smart enough not to learn today's technology but what could be coming and how it goes forward. And I think we've seen over the last decade a really massive step forward in that regard. And it's opening up all sorts of solutions base, so we will be very, very highly energized for that.

And we do see – I mean, ultimately, open innovation, that's really an interesting concept, right? So you can sit in a room on your own and invent something and you'll own 100 percent of it. But what's the probability of you, on your own, inventing it? Or you find a way of opening and you increase the chance – the probability of finding something, but maybe – but of course you share the benefit. But actually, you multiply the two together – one of the guys down here knows I'm obsessed with area under the curve – massive amounts of decision making in industry and business.

People don't talk about area under the curve. They talk about the vertical, the price or the percent – you know, my share. But actually, the area under the curve isn't a function just of the

price. It's a function of essentially time, the price and the probability of something happening, right? And actually, if you start to think about that, it starts to cast – it opens up enormous amounts of solution space in drug discovery, because actually it's okay to be open. You're just going to share a bit. But if you double the chances of success, you give a lot away.

I mean, in my company – I'll tell you, my head of R&D, Patrick Vallance – phenomenal guy, super top, you know, researcher – he's thrilled because – you know, I think we lead on genetic target validation. And, you know, he's been very passionate. We're a founder of Singer (ph) program, all the stuff at the Crick, all of these collaborations to get ourselves in a lead position on genetic target validation. And he said: Andrew, we have doubled our success rate in drug discovery. And I'm like: Great. So now we fail only – we fail only 96 percent of the time, because we've doubled our success rate from 2 (percent) to 4 percent. That shows you how hard it is, but to double your success rate has the most gigantic economic success.

Everything we do in genetic target validation is completely open. And we drove that. We drove – we want it as open as possible because we want as much in there with as many smart people. And then you back yourself to be the company who can spot the opportunity and make the development step. And then maybe we're the people who can do the most efficient manufacturing process. Maybe we can get – you know, on average we do drug development 20 percent quicker than our competitor. So if we're 20 percent quicker, actually we're prepared to be a lot braver on being open, right, because that's how you create the opportunity. So very, very, very positive about that. And I think the more FDA can keep driving us in that direction, phenomenal.

Value-based pricing, I'm a huge believer. You know, again, I've been giving speeches on value-based pricing for a long, long time. It's very – it's crucial. It's how we set our prices. That's how we try and figure out what the drugs are worth. Here are the problems: Bluntly, this is a relatively easy, although can be challenging, conversation with a government like the French. So the French government has a system of operating where they're very engaged around value-based pricing, actually. The Transparency Commission has, for a long time, been very thoughtful and impressed by evidence of what you can and cannot deliver in the system.

The problem in the U.S. is, A, people want to know what the price is. And the first question is, what's the discount rate? Because you're not selling to the people who own – actually, you're not selling to the organization which owns the cost structures that your drug is going to release value from, number one. The debate is completely – it's like you turn up speaking German and they're speaking Japanese. I mean, it's very difficult to engage in that conversation.

Now, the evolution of accountable care organizations in the U.S. – and it's a very interesting evolutionary opportunity – depending on how they choose to develop their procurement skills, that is the audience to have that conversation with, because as they become more accountable directly financially – and as, predictably, HHS starts to, for example, say, actually, we don't really care what happens in this intervention; it's a fixed fee; you make a mess of it, it's, you know, the same fee as whether you do it brilliantly – there's massive incentivization for that organization to go down a value-based pricing route, because they're

going to say, wow, if you've got this technology, Andrew, which can save me all these downstream costs in other areas of the health care system, this makes sense. But it's about the accountable care organization, and the question for the U.S. is how quickly that dialogue goes and is there enough incentivization for the ACOs to really want to play that game?

The third issue – which is what is a big problem in Europe, where you would think this would be super simple because you've got single payer systems – it's incredibly hard to extract the savings from the budget line, because ultimately the demand on health care is infinite.

DR. EMANUEL: Right.

SIR WITTY: So I give you a drug which gets a patient out of a bed two days early, saves you $12,000, I can justify – that is like, wow, fabulous. The problem for the system is the system will fill that bed – (snaps fingers) – with a new patient. So there isn't a dollarized reduction in the budget. There is an increasing output.

So the question is – and there is an increase in service provision and there is an increase in value, but it's a different type of value. It's actually transmitted in an extra person being treated rather than the release of dollars, which, again, when you're coming from a world of its price and discounts, you're now in a world that actually you're creating capacity rather than dollarizing the benefit is where you get stuck in these conversations, none of which says we shouldn't be doing that.

So we are a huge – if you said to me: The president's just, you know, issued an executive order, and value-based pricing is the order of the day, United States, you know, I'd be – I'd be dancing down the street, right? I mean, it would be, I think, fantastic. What can we do? There should be some real thought given to how regulators start to think about creating safe havens in the U.S. environment to allow more experimentation on this type of thing.

One of the other issues you have in the States is, because you've got such an overlap of – it's a very almost unique situation where you have a 100 percent public system with many guises overlapped with a 100 percent private system. Normally you end up with a 90/10 or a 10/90, but very unusual to see these complete overlaps. They're all controlled by multiple regulatory sets, which all – because ultimately everything is geographically local, all the regulatory sets actually hit all the zip codes, right? So you operate in a zip code, you have to comply with all those regulatory sets, whatever your block of business, and some of them cross-link with each other, right?

So to be blunt, you discount a bit more in the private sector. Government automatically gets the benefit through best price. That has an enormous chilling effect on price competition in America, because the consequences of being price-competitive are much bigger than just the price competition you're dealing with. And there are many other examples of that.

So I think a reflection on how to create safe havens to allow experimentation and pilots, in collaboration with – I don't mean, you know, some kind of crazy, you know, off-the-reservation thing but in collaboration with government, really needs to be thought through here,

because I think what we're going to struggle at here is how to get from – how to get from – we're all going to be pretty good at saying we have a problem. We're all going to be sort of aligned around trying to diagnose what that problem really is. And then we're going to get stuck around what the practical step is to develop the treatment, because it's so complex, it's so big. So safe havens, pilots, starting to think about what the ACOs really change in the system.

Just to your last point – you know, listen, I want to stand up for the industry here. I'm not in the business of – you know, I'm proud of – I'm incredibly proud of GSK, but GSK, listen, we've had some bad raps. We've made some mistakes. We've done some things that shouldn't have happened and we paid the price for it. You know, Steve was very generous, and I think – I hope you're right. We dream we'll never make a mistake but, god, if we do, we will learn from it. We will absolutely learn from it.

And we will learn from it not just in a case of, well, we'll just control a bit better and we'll hope it won't happen again. We will really fundamentally get under what went wrong and how do you fundamentally change everything to avoid it ever happening again? And actually, ideally, you know, something good comes from it. But, you know, I am not going to stand here and say we're some kind of, you know, perfect group of people. We're not and we've had our issues. And, you know, we'll have them in the – for sure. I mean, it's a big organization, a complex world; things go wrong. And that's true of other companies as well.

I would say to you that the big companies, the companies who look like GSK structurally, they – much of what I've said today there would be – not everything I've said today, but much of what I've said today there would be empathy. People like Ken Frazier at Merck, these are really standup guys. They are really thinking about how to try and help move things forward. I think you're seeing at PhRMA the beginnings of a move in terms of the sentiment of PhRMA. I think the industry is moving. And, you know, does that mean I agree with everything? Would they agree with everything I've said? Of course not. You know, it's a competition and we're all trying to do it.

The last thing – I spent a lot of time living in Africa and there's a great – when I lived in Africa there was this great phrase: If you want to – if you want to travel fast, travel alone. If you want to travel far, travel as a group. And I think that's very, very apposite in this conversation. And actually, I think it's not a choice; it's a sequence. So actually, you need to go on your own to start. So to make a break, somebody has to go. That's why I did transparency. That's why I did the patent pool. It's why I cut my prices in LDCs. It's why we've done the AMC. It's why we're going to do something big around medicine patent pool on new diseases. And it's why we've been so – we've been so strong about being responsible prices in America for the last five years.

But gradually, in all of those cases, others have followed. And in all of those cases it's moved from being one company doing something a bit weird and a bit, you know, "Really?" to something which is becoming increasingly a standard. And I think we have to be OK with that. It would be great if other companies did some of – you know, some of the lead in. And they will, and they do in different fields, but that's the model we've got to be encouraging.

Encourage the people who are brave enough to break out. Swing behind them. Make it a good experience to the extent you can. That's going to incentivize other people to break out, and then the group is going to follow. Trying to mobilize a group from a standing start, good luck. (Laughter.) You need to put some pressure in the system, and that's all about a breakout. And that's what we've – that's the strategy we've deployed, and I think so far it's broadly worked.

MR. MORRISON: We've got just about two minutes. (Laughter.) Peggy, do you want to – do you want to offer some closing thoughts or comments?

DR. HAMBURG: You know, just – I mean, this is really a critical time. I think that, as Zeke was saying, you know, I think that industry does need to, you know, really step forward. And I agree with your image of, you know, needing to have the breakout of the group.

And I think, you know, part of the problem is that we really don't understand what this ecosystem looks like, what all the elements are, you know, as we break down the silos. You know, what are the incentives that work? What are the things that really help to support the breakthroughs in science? What are the things that are going to keep companies working on hard problems where the market isn't entirely going to drive the system? And how do we keep, you know, the trust and confidence of the public with us when we're doing this? And how do we make sure, at the end of the day, that what we're all about is delivering on the promise of science in terms of real-world care, wherever it is?

But I think we – I mean, I don't know what the answers are. And I had the luxury when I was at FDA of saying, well, we don't do pricing. But, you know, now I don't have that luxury – (laughter) – and now I see this is one of the most pressing concerns in our country and around the world. And I can't figure it out in terms of how the different parts of the system align. And I learned some things from you today that I'm now going to have to go back and study up on.

But I just think that this is – this is so essential. And it's essential for the delivery of care but it's also, I think, you know, that this is a time when the whole industry, you know, is at a crossroads, and, I think with it, the world that I used to know, the regulatory context, you know, is with you at that crossroads.

SIR WITTY: Right, right, right.

MR. MORRISON: Thank you.

Andrew, I think one really strong value in having this discussion this morning is that in our own political context here we are in such a confused, turbulent condition right now, and people are incentivized to lay low and watch and not speak up as strongly as they might otherwise. And so having you come here and talk to us about what is possible and where to concentrate our efforts as we look forward, I think that's very refreshing. And thank you.

SIR WITTY: Thank you.

MR. MORRISON: Thank you for your leadership and thank you for coming and being with us this morning and offering so many thoughtful directions for us.

SIR WITTY: Thank you.

MR. MORRISON: Please join me in thanking – (applause).

(END)