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TRANSCRIPT

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"The Lenacapavir Partnership and the Evolution of U.S. Foreign Assistance"

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FEATURING

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Katherine E. Bliss:

Hello. I'm Katherine Bliss, senior fellow and director for Immunizations and Health Systems Resilience with the CSIS Global Health Policy Center. And I'm your moderator for this panel on The Lenacapavir Partnership and the Evolution of U.S. Foreign Assistance. On behalf of the CSIS Global Development Department and the Bipartisan Alliance for Global Health Security, it's my pleasure to welcome you to today's discussion, which is part of the CSIS Futures Summit on A New Era of Development Cooperation.

Now, the last 15 to 16 months have seen considerable flux in the HIV world. And this has been particularly true with respect to the U.S. President's Emergency Plan for AIDS Relief, or PEPFAR, historically the largest program commitment by a single donor country to address a specific infectious disease globally. Now, key fluctuations in 2025 included an initial pause on PEPFAR services and programs overseas as part of a broader review of U.S. foreign assistance; major reductions in force at the Centers for Disease Control and Prevention, a key PEPFAR implementing agency; the eventual termination of U.S.-supported programs delivering HIV prevention, testing, and treatment; and the dissolution of USAID, one of the core PEPFAR implementing agencies.

Now these program changes and uncertainties about funding, supplies, and personnel fueled concerns that millions of people could miss HIV testing and medications, and raised the risk – or, raising the risk, potentially, of renewed transmission or drug resistance in countries whose health systems could ill afford it. The personnel and funding cuts particularly to laboratory services also raised concerns about broader disease surveillance and detection capabilities, given the importance that PEPFAR-supported labs had played in identifying and responding to outbreaks such as Marburg, Ebola, and even COVID-19.

But in the last year and a half, there have been a number of positive developments, particularly in the area of HIV prevention, and the effort to promote greater access to effective long-acting methods for limiting HIV transmission for populations at greatest risk. Now, since 2019 uptake of a daily oral pill offering pre-exposure prophylaxis, originally introduced in some of the higher income countries around 2010, had begun to really increase globally with significant new initiations in low- and lower-middle income countries, in 2023 and 2024.

In 2024, a bi-monthly injectable form of PrEP that had been approved just a few years earlier began to see more significant global uptake. And also in 2024, clinical trials at multiple sites in Africa, Latin America, and Europe showed that a new twice-yearly injectable, Gilead's lenacapavir, could prevent transmission among groups at high risk for HIV, while at

the same time eliminating some of the challenges of adherence to a daily pill that had been observed.

Now, given the promising results around lenacapavir, in December of 2024 the U.S. and The Global Fund had announced a plan to reach 2 million people with the PrEP product once it reached regulatory approval. In June of 2025, the FDA approved lenacapavir for PrEP. In August, the European Commission granted market authorization for the product. And a few months later, WHO pre-qualification followed, setting the stage for its introduction in countries around the world. Then, in September 2025, the U.S. Department of State, Gilead Sciences, and The Global Fund to Fight AIDS, Tuberculosis, and Malaria announced an advanced market commitment to purchase and distribute lenacapavir in a select number of countries where the burden and incidence of HIV infections is high.

Now, through this agreement the U.S. and The Global Fund procure doses of lenacapavir for distribution of up to 2 million people in high-burden countries over the next two years, while Gilead also works with a group of generics manufacturers to transfer the lenacapavir technology and enable them to produce the product at even lower cost. This partnership has emerged as a core element of the department's America First Global Health Strategy, released at the end of September and which places a very high priority on increasing access to innovative U.S. products.

In November, the first doses of lenacapavir were delivered to Zambia and Eswatini, marking a significant achievement: The availability of a new, highly effective form of HIV prevention in Africa the same year it became available in the U.S. and Europe, not years later as we saw with the daily oral pill and even the bimonthly PrEP injectable cabotegravir.

But while highly, highly encouraging, the U.S.-Global Fund-Gilead partnership is not without challenges or controversies. There have been concerns, including concerns that the goal of reaching 2 million people over two years is not ambitious enough, both because of the potential number of people at risk and also because of the significant program cuts, loss of personnel, and missed testing and treatment over the past year could mean that more people than before are at risk for HIV.

There have also been concerns expressed that the partnership's explicit emphasis on pregnant and breastfeeding women, at least as stated back in the fall, can overlook the vast number of adolescents and women at risk and not currently pregnant but who could become pregnant, or women who may wish to remain protected from HIV even after their

child weans from breastfeeding. It does not explicitly mention other key populations at high risk for HIV in the current context as well.

Now, another set of questions has to do with some of the countries to benefit from the partnership. The initial list included Zambia and Eswatini, with market authorizations requested for a number more. South Africa, at least early on – which has the highest population or the greatest number of people living with HIV – was explicitly excluded. But a recent press release on April 10th from the U.S. embassy in South Africa suggests that the country may now be receiving doses of lenacapavir, perhaps as part of this partnership. And as negotiation of bilateral compacts under the America First Global Health Strategy continues, we may see more information as those compacts are made available and released.

Now, the partnership has also been the subject of at least some confusion or at least conflicting information. The United States has underscored the importance of getting global health commodities to countries while kind of reducing the role of NGO-implementing middlemen, but there have been conflicting reports just lately about the fate of the global health supply chain mechanism for delivery of HIV commodities and little information for how the U.S., at least in the future, will seek to channel HIV products to countries for distribution.

Similarly, the America First Global Health Strategy highlights The Global Fund as a key partner and committed $4.6 billion to the Fund in the eighth replenishment, but the recent budget released by the administration for 2027 appears to eliminate disease-specific program funding. So it would be helpful to hear how far into the future U.S. funding for HIV can be expected to continue.

So these – I mean, these are, I think, issues that could potentially ultimately point to the potential for a crisis in confidence. We know from the days of the COVID-19 pandemic that confusing or contradictory information can undermine public trust and confidence even in the highest-quality health services. So I think it will be important to continue to assess the extent to which the partnership is able to play a role in building trust between countries and global entities. And it will be important to sustain community engagement and commitment in order to understand, you know, how this can really build confidence and trust and work towards HIV prevention.

So today we are fortunate to hear from three people whose institutions have been at the very center of the lenacapavir partnership to accelerate the production, financing, and delivery of long-acting HIV prevention products. They are not quite in the order that I think they are presented

on the information, but we have to my immediate left, Jeremy Lewin, senior official for the Office of the Under Secretary for Foreign Assistance, Humanitarian Affairs, and Religious Freedom at the U.S. Department of State. Peter Sands, executive director of The Global Fund to Fight AIDS, Malaria, and Tuberculosis. And Daniel O'Day, chief executive officer at Gilead Sciences. And I'm not sure who came in earlier, or – I know you both came – traveled from far away, and are dealing with different time zones. So thank you for being here with us at this early time this morning.

So today we'll have a chance to discuss how and why the lenacapavir partnership is different, the extent to which it points to a new vision for U.S. foreign assistance and development cooperation, why it's important to focus on innovation at the current juncture, and how to measure success in this current venture. We'll hear ideas on how to kind of reconcile the emphasis on partnership with countries, on the one hand, and these budget proposals that kind of eliminate disease-specific funding on the other. And we'll talk about ways the partnership is grappling with the challenges and gaps in meeting the need, the high need and demand, for high-quality, long-acting HIV prevention. And we'll talk about what's at greatest risk if the promise of this partnership for accelerating access to innovative HIV prevention is not fulfilled.

So, Jeremy Lewin, I'd like to start with you, and ask you to share your thoughts on the significance of this partnership for advancing U.S. goals under the America First Global Health Strategy. Back in the fall, back in September when this was being rolled out, there were references also to the role of a new innovation fund in really kind of moving forward engagement on global health. So why is this partnership integral to U.S. foreign policy approaches to health and health security? And can you say a bit about how the innovation funds, or fund, are being leveraged to support the lenacapavir partnership?

Jeremy P. Lewin: Yeah, absolutely. And so I'm really excited to be here, obviously, with Peter and Dan, again. And I think we collectively have an announcement, which I think by virtue of going first I'll get to say first. (Laughter.) But Peter and my institutions are upping our financial commitment to support additional doses. So we hope now to reach 3 million people with the two-dose regimen. (Applause.)

And, look, obviously that's, you know, great news for a million more people that are going to receive critical prevention. I think it's also – and as we've said when we started this whole partnership – it's also a demand signal. You know, Gilead is producing this medication not for profit. I mean, you know, largely because of their humanitarian work and commitment to helping, you know, people with HIV, particularly in

high burden and developing countries. And so having that market-shaping commitment, and that financial commitment allows them to scale production and allows them to do it quickly.

You talked about it, and Dan will know more, but, you know, the transfer of technology to generics, having the financial commitment is very important. So I think part of the message, at least, you know, from our perspective, is 3 million doses is, you know, a fantastic number. We'd like to see even more. We'd like to see countries fund doses. We'd be willing to fund additional doses as we get that manufacturing capacity ramped up. And so I think one other thing is as part of that financial commitment we're also funding programs to make sure that we're reaching the right people, that we're measuring impact, that we're training people on how to administer the medication, and everything else. Because obviously it is a huge sea change.

If you'll permit me to speak about some of the broader issues a little bit, since you mentioned them in the beginning. Just a little bit of an update on where we are in the America First Global Health Strategy. So we announced it in September. Since then we sent negotiating teams out to dozens of countries. We've signed now 30 bilateral compacts worth, I think, $21 billion. The co-investment commitments from the country is the largest mobilization of African domestic resources for health, ever. You know, and we're working with the countries on implementation plans right now that have signed the MOUs. So, you know, those are 200-page-plus plans. And I think a lot of them – some of them hired – I know, you know, some foundations paid for them to have McKinsey and such, but the countries that did it on their own did a fantastic job.

You know, I think one of the key myths – and this is one of the reasons why we started with a focus on self-reliance and I'm working with the governments – is – one of the key myths is that these governments are not, you know, competent or don't have the capacity to do health care work.

I think that's not true. In our experience with them, they are highly competent. They understand the issues very, very well. We're not in the situation that we were 20 years ago where the countries had a lack of capacity.

We did a great job with PEPFAR over the last 20 years, transferring a lot of knowledge, and now they actually know how to take care of their own populations pretty well.

So for the countries that have signed MOUs, we're pretty advanced in the implementation process. So by, you know, the end of this fiscal year

so by September 30th, those countries will all be onboarded onto new mechanisms that align with the commitments and focuses in the America First Global Health Strategy and the bilateral compacts we've signed with those countries.

That's number one. I think we're going to finish negotiating a few more compacts and a few more will roll in this month. One note about the number of compacts, because a lot of people have keyed to that.

So, you know, the funding in PEPFAR and all of our health programs has always been highly concentrated. So, you know, the top 20 countries usually account for more than 80 percent of the funding. So we prioritized and have made deals with one or two exceptions that have unique circumstances all of those top countries, and so we've accounted for more than 85 percent of the budget already.

And so the MOUs that are coming in now are smaller MOUs, countries that – it doesn't mean they're not important, but where we're giving $10 million a year or something like that. For some of those countries, an MOU is a really important way to actually grow our health cooperation, to get them to make commitments. A lot of these are in the global health security space, working with countries in Asia and Latin America that don't receive large numbers – amounts of foreign assistance but, you know, for which the partnership with the United States on these issues can be important.

Some of those countries will instead be moved to a multi-year plan. It doesn't mean that we failed to get an MOU, but for a country that's receiving $8 million in assistance, it may just be one award and it may not make sense to sign an MOU.

And so we're being thoughtful in that. We think we're going to get close to 40 MOUs by the time we're done with it, but we're not, like, hunting for additional MOUs at the expense of what makes sense. So the countries that don't get an MOU will get on a multi-year plan, which is going to align with the principles of the America First Global Health Strategy but make more sense for, you know, our government and their government.

So that's where we are in the negotiation of the compacts. You know, at the same time, we're continuing to work on all these other initiatives. This is – you know, the foundation of our innovation fund continues to be our partnership with Gilead, but we have more stuff coming in malaria and other diseases soon, we hope.

We put out a program statement and request for proposals in the global health security space. We intend to use that to evaluate proposals and do additional investments. So, you know, we're moving on those issues as well.

I think for the next few months, a lot of the focus is going to be on actually getting those implementation plans right, because you mentioned multi-year budgeting and multi-year planning. These are five-year MOUs that we're signing, and so the planning that we do right now. That's why we've been kind of heads down.

You mentioned maybe not doing as much with the community. I think part of that is we're trying to prioritize the work right now and get the plans right. It's a lot of work to work with these countries on these plans, and it's hard to do in the public eye. You know, you've got to do that with a level of trust with the governments.

So we're making a lot of progress on that and we hope to also, you know, get the contracting mechanisms and everything else stood up.

On supply chain, I think it's worth dispelling a couple of myths. I mean, a lot of people saying that we've allegedly canceled some – that the supply chain contract – that's all not true. Nothing has been canceled. Nothing has been stopped. We haven't made any sort of decision about that.

What we have said and we've been consistent about this – it's in the America First Global Health Strategy – is that as we move countries to a path of self-reliance where they take more responsibility for their own health care system, where they're the ones who are seeing the orders, placing the orders to the maximum extent possible, we're going to be working more with a different sort of supply chain architecture that allows them to do that.

Right now, you know, we pay for a contractor to do everything from purchasing the orders to getting it around the country, and there are many steps in that chain where the country, in order for them to become self-reliant, needs more ownership.

And so what we're separating out – and we're going to do this thoughtfully over the next few months. This is not something that we're going to – some people were saying by May we're going to stop placing orders in the – that's not true.

This is something that's going to take a few months, a year, to get done, and we're going do it disease by disease, country by country. So we've done a ton of analysis to look, this country is capable of taking on XYZ

function. You know, maybe there's a partner that can help with this function, you know, and we have fail-safes and everything else like that.

But we're basically going to say, look, the purchasing of the medication is different than getting it to the country and then is different than the in-country distribution, and so to the maximum extent possible with in-country distribution, that should eventually be going to the national ministry. That's the sort of core of the self-reliance.

The Global Fund is an important partner with pooled procurement on the procurement of the actual medication. They don't necessarily do a lot of that in-country stuff at this moment. We're working together on it. But they have a mechanism that allows the countries to place orders and to use their co-investment for that. And that may be an important, you know, mechanism that we leverage more in the next few months and years as well. So it's something that we're thoughtfully looking at. We're continuing to place orders on the existing supply chain contract, and will continue to do so until the backup system, the new system, is fully online. And obviously, we're committed to ensuring that there are not pipeline breaks or anything else like that.

You know, I think you also mentioned some of the questions around, you know, data and what happened over the last year. I think, not to get ahead of the team, we will be publishing some PEPFAR data very soon. I think people will be surprised at, you know, I think how resilient our health programs are and have been. I think, particularly for PEPFAR, the numbers are very, very good. And that's before we've had all the positive developments, you know, really come online through this partnership and through the America First Global Health Strategy. So, you know, I think it's an exciting time. We're really just heads down on the work in terms of the strategy, finishing up negotiations this month, and then from April through September really getting everything online so that by the end of this fiscal year we'll be in a position where, you know, all of our health funding is really on the America First Global Health Strategy compacts.

One note about the budget before I talk about, you know, what, we're here today to discuss. The president's budget proposal, you said, eliminated disease-specific funding. That's because the way that we have funded our global health programs is incredibly inefficient, and it's siloed. You've got tons of directives. And you have money that's locked up for particular diseases. So what the president's budget proposed is having an account that's more flexible. In some years and in some places we have more HIV money than we know what to do with. And we'd like to put it on – use it on global health security, or on malaria. I mean, if you asked epidemiological experts, they would mostly tell you that we

spent too little on malaria and too much on HIV, if we're actually focused on saving lives, right?

And so giving more flexibility to policymakers to make those decisions doesn't mean that we're eliminating HIV funding, or seeking to do that. It means that we want more flexibility, something we're working with Congress on. The MOUs that – our America First Global Health Strategy is the first plan that actually unifies funding across disease areas. We used to have different programs for malaria, TB, HIV, sort of uncoordinated in countries, overlapping mechanisms, overlapping implementing partners. The countries need to, and we think about, as a country, our health-care system as a holistic whole. And so I think one of the key things with the MOUs is that they include all the disease areas in the same agreement.

And so when we think about aligning funding and budget cycles to that, it's important to have funding that is more flexible so that we can make sure that – right now, you appropriate a very high level of funding, but a lot of it ends up getting kind of wasted or stuck. We can't use it for the purposes that we want to use it, or the highest and best use of the funding, which is a challenge. There's a bunch of funding that's appropriated for – basically, I mean, if you look at our foreign assistance architecture, writ large, you're paying a bunch of multi-year mortgages from the last 20 years. And so one of the things that we did, through the sort of creative destruction of the last year, was free up resources for things like this. I mean, we're here today to talk about something that really is a tremendous innovation. And we don't have the same tools that we had 20 years ago. Lenacapavir is one of the best examples of that.

But until you sort of free up budget space by getting rid of some of those older commitments that maybe have sentimental value but don't deliver when you look at the reality of today's world, we can free up space to make really transformative, big bets on things that matter. Which brings us to – me to what we're doing here today, which is talking about this tremendous partnership. You know, I think Gilead has been – for many years developed, particularly in the HIV space, a lot of these innovative medications. And I think it's – you know, lenacapavir is an example of American excellence in biomedical innovation. And we're very grateful that they continue to promote access globally, particularly in high-burden countries. And I think, for Peter and my institutions – I don't want to speak for him – this is a really exciting opportunity to actually bend the curve of the epidemic and get past what we've – you know, for the first period of sort of PEPFAR and global HIV action, it was a total five-alarm fire crisis.

And I think the programs did a really good job of containing the outbreaks, at getting people on treatment, at getting, you know, health systems, particularly in African countries, in a place to manage it. But we've sort of been in a period of stagnation and sort of how do we – we've contained the problem, but we haven't really eliminated it. And I think something like lenacapavir is one of the best ways to actually have a chance at ending it. And so we focused a lot on mother-to-child transmission. President Trump has a goal of ending mother-to-child transmission of HIV by the time – by the end of his second term. And it's only with medications like lenacapavir that we're going to – we're going to, you know, achieve that goal. And so we're going to continue investing in that.

I think it's also a testament to the fact that, you know, despite the upheavals of the last year, the partnership between the U.S. and The Global Fund remains very, very strong. We are proud of our pledge that I announced at the eighth replenishment. And, you know, I think we continue to work closely with Peter. They've been an important partner in, you know, helping the countries think about self-reliance for the first time, and are aligning a lot of their programming as well. Not just in HIV, but in malaria and other diseases. And so, you know, I think, you know, everyone is unified together here to try to get this innovative drug to as many people as possible, as quickly as possible. So.

Dr. Bliss: Thank you.

So, Dan O'Day, I want to turn to you. You know, Jeremy has really highlighted some real changes in the relationship with some of the countries that, you know, have been – that are part of this partnership. And, of course, one of the big changes is that they're actually going to be able to access lenacapavir in the same year that countries around the world are. It's not 10 years later, it's not two years later, it's really within the same year.

And so I wanted to ask you to say a little bit about, you know, kind of, like, why in the past has it sometimes taken so long for that process to unfold, and where we really see uptake kind of increasing in the lower and lower-middle income countries? And, you know, Gilead has been thinking about this process for several years. I think, with lenacapavir, even before the regulatory – before the trials and the regulatory approval. And so why has this been, you know, a real focus of the company in this period?

Daniel O'Day: Well, thank you. I'm delighted to be here with my colleagues here. I think there are three words that come to mind as I answer your question. I think we all have decades of experience between our two –

our three institutions, of really thinking, how do you end diseases and epidemics? And I think there are three words that come to mind. One is partnership. You can't do it alone. Second one is commitment. Takes a long-term commitment to achieve this. And the third one is investment. And I'm really pleased – thank you, Jeremy and Peter – for your additional commitment for another million people. We obviously want to get to tens of millions of people, but this is really important to get this started.

Look, I think for Gilead – we've been in existence for almost four decades now. And from the very start, our contribution to society is we come up with science that really ends and transforms diseases. And so we've been working in HIV for more than three decades. Our scientists came up with the cure for hepatitis C. But specifically related to lenacapavir, just to bring these points together, how did it all come together?

lenacapavir is a medicine that is 17 years in the making, just to put that into context. So when we talk about partnership, commitment, and investment, on our side the commitment to really coming up with groundbreaking medicines that can transform epidemics takes a long time and a long commitment. Thousands of molecules were screened for this. My scientists call this a unicorn of a molecule. The fact that you could get a molecule that is nearly 100 percent effective at preventing HIV, given every six months, is quite extraordinary.

And, very importantly, the five-month time period between FDA approval and the first delivery of the medicine in Eswatini and in sub-Saharan Africa was equally important to us from the very beginning. So as soon as we knew we had – even before we knew we had a molecule, the partnership that the three of our organizations have been working on for decades started to go into effect. We needed to plan well in advance of the clinical trial results.

First of all, we needed to work with our community partners on the ground to design the trials in a way that would be appropriate so the data was there for regulatory approvals and that the uptake would be there within the countries. And that started with the first trial being all amongst cisgender women in sub-Saharan Africa. And that was the one that showed 100 percent of women taking lenacapavir did not contract HIV. It was quite extraordinary. But it was important that we started with those populations from a clinical trial perspective in order for us to achieve that 17-years, five-month objective.

And then, working really closely with the State Department, PEPFAR in particular, and Global Fund to say, OK, let's assume this is successful;

how do we make this sustainable and how do we get this to people as quickly as possible? And it was essentially a two-part strategy.

One is we know the way that we get to hundreds of countries and tens of millions of people is through a sustainable, high-volume generic supply. So, unprecedented. You know, we identified generic suppliers, really, right after the clinical trial results, and that program is underway. And we expect that to deliver in the '27-'28 timeframe at really significant scales.

But equally important was working with the colleagues in the State Department and in Global Fund to manage this interim period, which was really, as Jeremy mentioned, Gilead supplying lenacapavir at no profit to Gilead to be able to create the demand and to prepare the countries for this very large-scale, self-sufficient supply over time. And so I just want to acknowledge, you know, the partnership that we have with Peter and with Jeremy and with their organizations, because – back to partnership, commitment, and investment – (laughs) – it takes all of us and more to be able to achieve ending an epidemic.

And the reason we feel so passionate and urgent around this may be obvious to everybody in this room, but we have 1.3 million new cases of HIV every year, the vast majority in sub-Saharan Africa; 41 million people living with HIV. I mean, it's – in addition to the human plight, it's an unsustainable – (laughs) – health economic, public-health situation. And the only way that we get at that is by preventing disease in the first place and, of course, treating people who have the disease. But you have to bend the arc of those 1.3 million to be able to get to a stage where the three of us and others can say, you know, this disease is now under control and we can, you know, relegate it to the history books.

And let me just say that it was a great pleasure to be on the ground with both the organizations represented here in Eswatini last November to see the supply of lenacapavir on the shelf of a clinic for some of the greatest people in need for this medicine. And we have much more to do, but everything has to start somewhere and that was an important starting point.

Dr. Bliss: Well, thank you. I mean, it sounds like, based on what you're saying, I mean, this is – this partnership, you've kind of described it as a bridge but it's kind of like a special period of a period of, you know, really kind of laying the groundwork for a much greater rollout later.

Mr. O'Day: Yeah, yeah.

Dr. Bliss: I want to come back to that.

But, Peter Sands, I'd like to ask you to say a bit about the significance of this partnership for The Global Fund. And I ask that because The Global Fund is itself a partnership, right? It's public-private, governments, other organizations. And so I guess I'd like to ask you to say a bit about what makes this partnership unique for the Fund and if you could outline some of the steps that are being taken to measure impact and kind of stay on – stay on track, given all the other partnerships and issues that you worry about.

Peter Sands: I mean, the first thing that makes us unique is it's not often you have the opportunity to make a dramatic change in the trajectory of a disease that has killed over 40 million people, and that's what makes this extraordinarily exciting. And it's great to be with both Dan and Jeremy here because I think this partnership is kind of making it happen. And I – we are hugely appreciative of the U.S. support as our biggest donor. The $4.6 billion pledge was a huge moment in our eighth replenishment. But also we're very, very appreciative of the deep operational and strategic coordination that's happening not just in Washington and Geneva, but more importantly in individual countries and working with ministries of health and people on the ground.

And then hugely appreciative, I mean, to start with, coming up with the drug. That's no small – (laughter) – no small achievement. We wouldn't be here if we didn't have the amazing innovation of Gilead Sciences. But also the commitment to affordable access, both through the branded product, producing it on a not-for-profit basis, and also the work you've done on really accelerated introduction of generic, because I don't think people realize quite how remarkable that is. Not only did we – were we able to get the product to low- and middle-income countries in the same year it became available to high-income countries and within a matter of months of FDA approval, but next year we will be seeing generic production, which is a very, very short timeframe from launch of the branded product to generic production.

It's also a dynamic partnership. So, back in November '24, we thought 2 million was a good starting point number. But the experience we've got so far suggests that actually if we really want to make the most of this we have to go bigger, and we have to go bigger faster. And that's why I'm delighted alongside Jeremy to be committing to taking our original three-year target of 2 million to 3 million, and I will be happy to be able to push it up again when we – (laughs) – when we – but we – I think we have to do it in a measured way because this isn't just about the money; it's also about the implementation practicalities. Because this isn't one of these things where you just kind of, you know, give it to everybody;

you have to test. You're testing in high-incidence populations, which means some people will test positive. So you have to be linked to enrollment or treatment. And then you have to ensure that this is the right prevention product for the populations and for the individuals that test negative. And so it's part of a program that has to be well-designed and well-executed.

So where are we on this? So far there have been deliveries of lenacapavir in Africa to nine countries. It's about 135,000 – doses isn't quite the word because it's a couple of – but 135 sort of people-doses, thousand doses that have been delivered. Six of those countries have launched their rollout programs, and the others will – are in the advanced stages of training staff and getting all the kind of programs in place. And the plan between GHSD/State and us is to get to around 24 countries by the end of this year.

There's always a tension whenever you roll out something quite as game-changing as lenacapavir between sort of giving everybody a little bit and concentrating it, and we've taken a deliberate decision to focus on the places where it can have most impact and to ensure that there are programs in place that will actually put the various elements – the testing, the enrollment on treatment, the enrollment on lenacapavir – that the follow-up to ensure that people who take it now are also going to take the next injection in six months, it's really important that we don't do this in a way that is kind of half-baked; that we – that we deliver the real impact from it. But it's happening.

And the thing that I found most exciting – I was in Eswatini in November. In February, I was there for the arrival of the first lenacapavir doses in Kenya. Next week I'm in Mozambique; they already have the delivery, but they're launching the program next week, so that's going to be really exciting. The thing that I found most interesting is that it's all very well for the scientific and clinical people like Jeremy and me to be excited about it, but what's really exciting is when you meet final-end health workers and they are buzzing, and they are absolutely – in fact, they're sort of saying, you know, when did you say we're getting it – you know, how quickly?

I mean, just to give you a very specific example, I was in Kibera, the big informal settlement/slum outside Nairobi, with a bunch of mother mentors. These are usually HIV-positive mothers who have gone through the experience of prevention of mother-to-child transmission, they have HIV-negative children, and they're now sharing that experience as mentors with newly pregnant women who are HIV-positive to ensure that they're on treatment, that they adhere to the various protocols around to ensure – and these programs are incredibly

successful. The group of – the team I was with had not seen a positive HIV child in their program for four years. They basically had a hundred percent success rate. However, they had a problem, and their problem was that they tested every newly pregnant mother, and most of the mothers were negative, and they didn't really have an answer as to how to protect the negative – HIV-negative mothers. And what they said is that what was sometimes sad is that they would meet the same woman two years later and they would be positive.

And when – the reality is oral PrEP doesn't really work in this kind of environment. It's stigmatized. It's often interpreted as being antiretroviral treatment, and you get all that stigma associated with it. Or it's also seen sometimes by partners as being a signal of distrust or lack of confidence, and can lead to sort of violence. And so the take-up rates on oral PrEP have been incredibly low.

So the mentor mothers were immediately on to me, saying, what's this about lenacapavir and when are we going to get it? Because this is the missing bit of the puzzle, because at the moment we don't have anything terrible sensible to say or to give to the many mothers we test who are HIV-negative in an environment where, to be – you know, to be frank, women are not in a position to totally control what happens around sex. There is forced sex, rape. There is transactional sex. These are very difficult environments for particularly younger women. And lenacapavir can make a massive difference in that kind of context.

So as I say, it's the – the thing that gives me great confidence that what we're doing in scaling up this is the fact that those who are most in touch with what is happening are buzzing over this. They are seeing it as a real game-changer, something that fills a gap in the tools that they have.

Other things that are happening. We need to ensure that the generics come onstream as fast as possible, because much as Gilead has done a fantastic job in scaling up production, if, you know, we really want to fulfill the ambitions of what we can do with this tool, we need that broader manufacturing base.

So one thing we did last week is we launched an expression-of-interest process for what we call expert review panel, ERP. Essentially, this is an expedited process for providing regulatory approval for the generics products, and the idea is to ensure that we get a seamless kind of introduction of generic products to complement the branded products as quickly as we can. And we're talking kind of middle of '27, so not very long away. Of course, there could be various manufacturing or

regulatory factors that might shift the timetable a little bit. So this is a really exciting moment.

I just want to emphasize one other thing that we're learning – mention one other thing we're learning which I think sort of goes to the broader impact. I mean, the obvious thing that lenacapavir does is protects people, right? That's the obvious thing. What we are also seeing, though, is it's beginning to change the incentives around getting tested, because one of the – one of the problems – we've got two real challenges. You mentioned the 1.3 million people. Lenacapavir very directly can help us reduce that. The other problem we have is that of the 41 million-ish people who are HIV-positive, only about 32 (million) are on treatment – 32 million are on treatment. So we've got 9 million people who aren't, and disproportionately these are men who are not getting tested. Now what we're beginning to see – and it's early days – is that they're thinking, oh, it might be worth getting tested if I could get this lenacapavir thing because it's – this is a prevention tool that, you know, would be good. Now, that's great if it gets them protected. It's also great if it helps us identify more HIV-positive people, because if we can simultaneously reduce the 1.3 million and reduce the 9 (million) then you could actually see HIV/AIDS coming to an end much faster than we ever dreamt of. And that's the kind of prize that we are – we're really, really excited about.

To your monitoring and impact point, we are working with various partners on how do we – how do we do that? I would say it's incredibly early days, because you literally – you know, we're launching this product in different countries. But it is going to be really important to have a rapid feedback loop on what we're learning and what we can do better. And this point about the importance of lenacapavir in changing incentives around testing, and helping us reach people for treatment that we would otherwise not have reached, is a good example of something that we're learning. And I think we will want – we will want now programs not just to see that as a sort of a nice accidental byproduct, but actually by thinking quite kind of systematically about how we use lenacapavir in a way to reach – to find more positive people, as well as to protect negative people.

Dr. Bliss: Thank you. So, Dan O'Day, I want to come back to you. You know, Peter has just talked about incentives. In this case, around, you know, people being incentivized to do more testing. But you brought up the issue of the transition to generics production and, you know, the way that that can really kind of lead to significant production. So I wanted to ask you a little bit about the incentives that the generics producers have. I feel like I've heard it kind of described as a little bit of a chicken and an egg problem, that you have production, the generics producers are kind of

looking to see demand, but if there's not enough production or demand – so they're all kind of looking for different signals. Could you just say a bit – not necessarily getting into numbers or anything like that, but kind of what the process is that the generics producers will be looking for in order to kind of go for the production that is expected by 2027?

Mr. O'Day: Yeah. Thank you. I think it's really important, this concept of incentives. I mean, generic companies are businesses. So they need to be able to see a sustainable model at a high volume of delivering a medicine that makes sense for their populations overall. So Gilead had pioneered voluntary licensing decades ago with some of our first HIV medicines. And we realized it wasn't enough. You pointed to the two-year gap and other things. But there are two things I think we think about, or we thought about, relative to lenacapavir in a very unprecedented fashion. We took our past lessons, we thought about the partnerships, and we said, how can we – how can we really decrease the time it takes to get generic volume at scale?

And there are two things, I think, associated with that. One is speed. It simply just takes time for generic manufacturers to learn how to make a medicine. And the second one is reducing their risk that the investment they make will not be a good investment. And how do you – how do you reduce that risk? You reduce that risk by making sure you have volume already established as they roll their products out the door.

Let me just say a few things about speed because, back to what we've learned as a company and with our partners, is that you have to act very fast on the technology side. And our scientists and our team did extraordinary things with lenacapavir. Again, based upon the profile of the medicine. And we realized we had in our hands one of the most important advances to end the HIV epidemic. So we thought about this very differently. As soon as we got the clinical trial results, as soon as they read out, within two weeks – which is pretty extraordinary, obviously a lot of prework – we had signed six voluntary licenses with six generic manufacturers. Royalty free. No obligation to us. We do all the tech transfer. That was done within two weeks. That's extraordinary.

Before we filed to the FDA, and we filed to the FDA very quickly, within about four months, we had actually completed the technology transfer. So our technical scientist had gone to the six volunteer licensing companies and established the work processes that it would take for them to produce this. Is this a sterile product. This is not something that, you know, is a very simple manufacturing product. But that was done before we even applied for approval of the FDA. So, you know, I just – I can't say enough good things about our voluntary licensing partners and our team in terms of how fast we worked with that.

But we also realized, the second piece of it, that without volume established, without commitments, without partners helping those generic manufacturers, we would never achieve our sustainable model. And so we immediately went to work with our partner organizations. Peter pointed out one in particular that he's – you know, they're working with the regulatory side of several generic manufacturers to accelerate that process. There are other organizations, like CHAI and the Gates Foundation, that have supplied minimum commitment requirements to generic manufacturers. So even if there wasn't a ban, which there will be, they have a commitment from different NGOs to make sure that their economic model works.

And then, very importantly, the work that the three of us are working together to drive this demand. Of course, it's critical to stop any person that has the potential to get HIV from getting HIV. But beyond that, creating that demand across multiple countries is really what's important eventually to a sustainable model for generic manufacturers. So I just want to, again, applaud the State Department, PEPFAR, and The Global Fund for moving from 2 million to 3 million. We at Gilead are not supply constrained.

We have a – we have a lead time, because it's a sophisticated product, but as we go from 2 million to 3 million we will meet that. If it goes beyond that, we'll meet that. We are fully committed to meeting all the supply needed before – and there'll be a – there'll be a handover process between what we produce and what generic manufacturers produce. Not all six generic manufacturers will come on board at the same time. Their volumes will need to increase. We'll continue to support and supplement that until the generic manufacturers can be independent. And then obviously PEPFAR and The Global Fund can work directly with them. But we are fully committed to that. I think that's who we are.

And then you have a sustainable model. Then you have a sustainable model for the countries to make sure that they can get it to the people that need it within the markets at a very low price, at a very high volume. And, again, this is what we do at Gilead. You know, we have a model where we – where we support the developed world in a different way, but for the developing world this is our model. And it's the only way, with an infectious disease, you can end an epidemic. If you don't end it everywhere, you don't end it anywhere – including the United States. (Applause.)

Dr. Bliss: So, Peter and Jeremy, you know, Dan has really talked about the relevance of the tech transfer and the importance of the generics companies, you know, having that technology and building that capacity.

We've also heard, Peter, you talked about demand. Demand is already there in many quarters. But, you know, the need to continue building demand. But, of course, financing, even for the generics production, is also an important element. And I wanted to ask each of you to just – from your perspective as a donor country or organization – you know, to reflect a little bit on the role of financing in continuing to build that generics capability.

Mr. Sands: Jeremy.

Mr. Lewin: Yeah. I mean, it's obviously very, very important. You know, as Dan was saying, there's a lead time on this. The generics need to have sort of a certainty of orders and such. I mean, this is – a lot of the leading foundations have been doing market shaping work for a long time. This is the first time that I'm aware of that PEPFAR and the U.S. government have done market shaping work in the global health space. I think it's very important and will continue to be a big part of – you mentioned the innovation fund – what we do. A lot of it will be market shaping investments.

I think it's important because of the catalytic effect, because we are catalyzing the countries to be able to come in. We're catalyzing other foundations and donors. You know, I think we're ultimately, you know, catalyzing reductions in manufacturing costs that will help developed country customers get it at a lower cost too. And I think we're looking at a horizon where, once the generics are fully online, lenacapavir will be more cost effective than oral PrEP, potentially, which is tremendous. I mean, and so what we're doing right now is helping to bridge that by financing it when it's a newer medication, to help Gilead help bridge to the generics, help get that manufacturing capacity up. But the guaranteed order base is incredibly, incredibly important.

It's also important, as Peter was mentioning, you know, is we go out to the communities and get them comfortable with it, we train them on it. They get to see the results of the medication. We help them understand how to target it, how to use it. That's also incredibly important to getting domestic demand from these countries, and getting, you know, sort of people able to uptake on the medication. So all of that, I think, is incredibly important. You know, our goal is to have this – it's already, by many metrics, been by far the fastest rollout of, you know, a global health medication in the developing world.

We're talking about the time from FDA approval to the first doses in the field in Eswatini. Peter was talking about the country's developing programs. That's groundbreaking in and of itself. Dan was talking about how quickly the generics can be able to come online. That's

groundbreaking too, and also a result of Gilead's generosity, you know, in transferring the technology so quickly and working with the generics so well. But we want this also to be the fastest scale up. And so that requires a lot more work. It's why it's important. We're putting in an additional financial commitment. It's not just the money itself that does this. It's also the momentum. And then, you know, I think it's also those programs that we have in the field to get the countries, and the way we're aligning through the America First Global Health Strategy.

I think this is a test case for how important working directly with the ministries is. Because now all these countries that have signed MOUs with us, we're able to work with – we have a much closer relationship. And Peter's team does too. We're able to go together as the two largest sort of donors in these countries and say, look, we want you to help develop a plan for this at a national scale. We're able to get the medication to them, get national distribution. You know, we're able to – they're able to do co-investment through us, with us, to get additional doses to the field. So as we build those systems, and, you know, Peter said a goal of 24 countries, that's going to create a really durable demand. Which will, in turn, create a positive effect for the manufacturing base and bring the price down.

So all of those things are really important. And that's a part of what we're doing here with this partnership. Which is, you know, I think why it's so important that we're working together, and with the urgency, recognizing that this is really a groundbreaking medication. And if we can get it to the field at scale, six months, a year, two years faster than we would have otherwise done it, that makes – that's a real difference for certainly millions of people, and also, ultimately, you know, the curve of the epidemic. I mean, from our perspective, the money that we're spending on lenacapavir is an incredibly, incredibly good investment, because if we can scale this quickly and help bend the curve of the epidemic, we're going to ultimately save all of these donor countries a tremendous amount of money, not to mention the lifesaving impact, you know, for people who otherwise would have had HIV.

Dr. Bliss: Peter, your thoughts on the financing? And also, I'd be curious just to hear you say a little bit more about how the Fund is engaging with community groups to kind of continue to accelerate that demand.

Mr. Sands: First of all, I'll pick up on Jeremy's last point, which I think is incredibly important. Which is that if you look at the challenges of transitioning responsibility and leadership of HIV/AIDS programs from heavily externally supported models to ones which are domestically led, domestically financed, that challenge becomes a lot easier if you've basically cut off the flow of new infections. Because then what you're

handing over is – yes, it's a long-lasting problem. People – in a sense, it's a good problem to have because people will live out their natural lives supported with antiretroviral treatment. But it's not a growing problem. If you're handing over a still-growing problem, that's a very different problem – a very, very different thing. And so lenacapavir can actually make transition a much more viable prospect then it has been in the past.

More generally, when I look at this – and I'm not a clinician or scientist by background. I'm a banker. So I kind of tend to look at the numbers here. If you can stop – if you can protect a 17-year-old, 18-year-old young woman from getting infected with HIV by providing lenacapavir with two doses, the economic benefit of that, quite apart from the human benefit – which is obviously the major – but, I mean, because if a 17-year-old gets infected you're looking at 50-60 years of antiretroviral treatment, viral load testing, all that kind of – all the surround services that come with that. Which, in one way or another, somebody is going to have to pay for. Up to now, a lot of it has been externally funded, but increasingly it will be domestically funded. But that's a big burden on overstretched health systems and budgets. So the sheer economics of preventing infection are enormously compelling.

And to your question on communities, I mean, we are very much engaged with community-led organizations. And this is an important part about how we maximize the impact of lenacapavir. We have to follow the epidemiology. We have to go and ensure that the communities which are most at risk get access to the most powerful tools. Some governments are quite good at that. Some governments are less good at that. And where they're less good at that, the answer is to work through community-based organizations who are better at reaching out to and serving those communities. There isn't a kind of single recipe here. Indeed, the epidemiology of HIV/AIDS is really quite different in different parts of the world.

But the key is to make sure that every dollar we spend and we invest on tools like lenacapavir is as impactful as possible. And particularly in these kind of early days of the rollout we're really keen to make sure that we're having as much impact, and therefore, in a sense, building confidence and demand by showing how much difference it makes. It does take money. And I would come back to the recognition of the fact that certainly for the Global Fund we can only play our part in this through the generosity of donors, led by the United States. And the United States bilateral money as well comes together for that. We are working, as Jeremy said, already, with countries on how they take up the baton themselves in financing lenacapavir, particularly when the generics come on board.

And I do want to underscore the point that the generic manufacturers can only deliver at the kind of numbers, at the kind of price points we're working with them on, because we are investing at scale now. Because the really expensive thing, if you're a generics manufacturer, is building the market. If the market has been built already, you can come in at scale. And your economics work from day one. And that's why there is a really strong connection between the level of ambition we're setting now and what's feasible to do later, even if much of that is actually – is funded by domestic money, as opposed to external money.

Dr. Bliss: All right. Well, Jeremy, I want to come back to you because, you know, you have said here today, and written elsewhere, that that this partnership and others envisioned in the America First Global Health Strategy should really serve as a model for new forms of U.S. foreign assistance. In fact, the title of this session is, the evolution – or – lenacapavir Partnership and the Evolution. So could you say, you know, what aspects of this partnership will be serving as a template or a model for other forms, whether in global health or, you know, other kinds of development cooperation? What should we be looking for?

Mr. Lewin: Yeah. I mean, I think the points that we're talking about right now are an example of that. I mean, we're talking about using foreign assistance money as a catalyst to bring in, you know, private sector money, foundation money, mobilize domestic resources. We're working with a partner. You know, we're focused on – just the point that Peter and I have been making, and Dan has been making, about thinking about the way that we build a base for something, think about economics, think about the economics of prevention versus treatment, all of those other things are, I think, really important shifts in the mindset in the global health space. Thinking about the way that we allocate money and that we orient our programs.

I mean, we talked about the importance of country ownership in this, which is obviously the hallmark of the America First Global Health Strategy and a lot of our foreign assistance reforms writ large. So I think those are really important shifts in and of themselves. I think obviously we're championing American innovation and excellence. We're very proud, you know, Gilead is an American company, proudly so. And, you know, the impact that this medication is delivering is going to be an American innovation. So I think those are all sort of important features of it. You know, and I think the speed, honestly. You know, I think we're making a big bet in this.

I mean, in the past – I mentioned this before – our foreign assistance architecture, we've got this heavily earmarked bill and all these

accounts, and you're paying – I mean, in the non-health accounts you're paying all these, like, Great War on Terror, like, mortgages and all these, you know, programs – 8 million, 3 million (dollars) a year here for some program that may have made sense 15 years ago but has grown into something, you know, unto itself, right? And so you don't have a lot of money, flexible pots of money, to make these big, huge shifts. And, like, we're not talking about dollars here today, but this is expensive stuff. We're not going to lie. Like, I mean, these are big, significant financial commitments for both Peter's organization and mine.

And we're proud and happy make them, and I think we're talking about why it's so important and why we think this is such an important moment in, you know, global health. But we have the firepower to make that in part because we're sort of reorienting our strategy around those types of investments, so I think that's a sea change as well.

You know, and I think the number-one thing – the United States used to pay for a lot of stuff that no one else would pay for or there wasn't a clear justification for. Maybe less in the global health space, I mean, I think, but there were certainly programs that I think were hard to justify. I think the key thing here is that we're investing in stuff that other people want to invest in – we're investing in stuff that private-sector companies want to invest in, we're investing in stuff that leading foundations and other organizations want to invest in, that the countries want to invest in, that the local health-care workers want. Those are all really important features. So, you know, I think beyond global health, obviously, things are a little different and we have pots of money that have no sort of lifesaving impact, right? I mean, you know, I think a lot of our strategic investment is really focused primarily on advancing American strategic interests, you know, and the global health money is, obviously, different and has a different purpose. You know, even here, again, we're very grateful to be supporting an American, you know, company, and we're very grateful to be supporting, as Peter articulated better than I could, what we really think is a key tool towards self-reliance for the countries, which is obviously important. We can't, you know – we don't want to be funding, and it's not in a country's best interest, for us to be funding this perpetual dependence on external financing. So all of those factors in the global health space are important, but obviously in some of our other pots of money the strategic, you know, angles here are going to be the primary function of the assistance.

So, you know, I mean, I think we also have a number of similar partnerships and things that we're going to announce in other disease areas, hopefully, in the global health space. And then, you know, announcing strategic investment. We're trying to compete with the

Chinese in ports and telecom for the first time. We're working with American companies on that. We're working with American investors on projects in critical areas. You know, and we're reforming our security assistance to be reoriented with America's 21st-century, you know, security challenges. You know, and also doing FMS reform so that, you know, we put our security assistance on cases faster, that it could be used to purchase things like software; that's important.

In the humanitarian sector, I signed an agreement with Tom Fletcher a few months ago that sort of reorients the way that we fund that system, removing duplication, making it more efficient. For the first time, they're measuring impact. I mean, in the humanitarian sector the idea that there's actually – you're measuring outputs rather than just impacts is a huge sea change and one that's very controversial, I know, in the humanitarian sector.

So we're working a lot of different things. But this partnership, I think, is very, very unique, and I think particularly in the global health space continues to be one of the things that I'm most proud of and excited about, so.

Dr. Bliss: So government to government, direct relationships, innovation, flexibility, and some new metrics that we may see coming forward.

Well, we've had so much to talk about that I know we've gone a little bit over time. So I had some other questions, but hopefully we'll be able to ask each of you to kind of wrap up with some – I was going to ask you both about your greatest concern and your most – you know, what you're most looking forward to in terms of measuring. But I think what I will start with or what I will ask you is to reflect, like, how – from your organization's perspective how you will know – what you would look for five years hence how this has been successful. So, from your particular organization, like, what that – what that measure of success looking back would be. So, Dan O'Day, I'll start with you.

Mr. O'Day: Sure. We may have similar answers here. (Laughter.) But I just want to comment on one thing that Jeremy also said. I love the word "catalyst." You'd expect from a company with chemists we would like the word "catalyst." (Laughter.) But I do think – but I do think that both – look, we're 30 years into the HIV epidemic and crisis. The world needs a success story. And I think both the combination of the breakthrough science in lenacapavir, but equally important the partnership, this catalyst nature of what the three of us represent up here and so many other circles of support that make this happen, is so important to emphasize. And I just – you know, our measure of impact is really on country-by-country uptake. And most importantly, you mentioned the

five-year timeframe, that that 1.3 million number is coming down, period. I mean, it's the only way we get to ending the epidemic.

Dr. Bliss: OK. Thank you.

Peter.

Mr. Sands: Well, that's got to be the acid test, is if we can get that 1.3 million number dramatically down. That changes the nature of the AIDS epidemic, and we can really start thinking about the end of AIDS. And I think that's in our grasp, which is – which is why, just from a personal perspective – and it's great to be with both Jeremy – this is – this is one of the most exciting things I've ever done in my life. (Laughter.) I mean, I'm serious. This is – you don't often get the chance to do something that can really make so much impact and affect so many people's lives in so many parts of the world. So it's – we are sort of all in on this. And really, really want to make it all work.

Dr. Bliss: Thank you.

Jeremy, the last word.

Mr. Lewin: Well, you know, I think, particularly within that 1.3 million new case number, we're focused on mother-to-child transmission. That has continued to be a central part of our strategy. We'd love to get all cases down, but particularly if we can really make headway towards our goal of ending mother-to-child transmission by the time President Trump ends his second term, that would be fantastic. And we think this is the way to do that. So that's one of the metrics. And then, obviously everything else that Peter and Dan said. Just getting that medication out to the field.

If we could be in a position in two years from now where the countries have much more durable, nationally controlled health-care architectures, they have a supply of generic doses, the price has come down. I mean, I'm looking for when the price gets competitive with oral PrEP, because this is so much more effective, and convenient, and just better in pretty much every way medication than oral PrEP. So if we can, through our efforts here, to get it out quickly, not only bring down cases in the short term but get it out at scale and get that price down, it's going to be a huge sea change over the next 10 years in HIV prevention around the world. So I think that's what we're looking for.

Dr. Bliss: All right. Well, thank you. So, Jeremy Lewin, Peter Sands, Dan O'Day, thank you for taking time out of your week here at the World Bank

spring meetings and everything else going on in town this week. But thank you for joining the CSIS Futures Summit. And good luck to your three organizations, and the many others that are involved in this, as you continue to implement and develop the catalytic Lenacapavir partnership. Thank you to our audience for joining today. And we are adjourned. (Applause.)

(END.)