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FEATURING

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Katherine E. Bliss:

In the nearly three years since the first cases of what has come to be known as COVID-19 were reported, there have been an estimated 6.6 million deaths, and 634 million confirmed cases worldwide, with multiple waves of new viral variants. Vaccines intended to prevent infections have been developed and distributed at record speed. But they can have adverse effects for some people, and they don't prevent all infections. At the same time, even though the global distribution of COVID vaccines has improved, in many places people still can't access the vaccines or they haven't wanted to, for a variety of reasons.

In this context, therapies to treat COVID-19 have emerged as a critical tool in the pandemic response toolbox. Like vaccines, therapies to treat infections and reduce COVID-19 symptoms have been in development since the very earliest months of 2020. Some are older drugs, repurposed for treating COVID-19, and others have been developed specifically for treating coronavirus infection. And now, three years into the pandemic, a number of new monoclonal antibodies and oral antivirals, as well as antivirals delivered by infusion, have been granted emergency use authorization or fully approved.

They serve as critical components of the COVID treatment arsenal, alongside older approaches, such as the delivery of oxygen. Like COVID-19 vaccines, new therapies have been developed and made available through multisector partnerships involving industry, governments, philanthropy, and multilateral organizations. For the people most vulnerable to severe COVID symptoms, including elderly populations, people living with other underlying conditions, or those who haven't been vaccinated, therapies have the potential for transforming what could be a health crisis into a manageable event. By preventing the most serious complications, therapies can help prevent the surge of hospitalizations that can overwhelm health systems, as we saw in the early part of 2020 when there were very few medical countermeasures available.

But despite the rapid development and great potential of COVID therapies, their uptake, particularly in low- and middle-income countries, has been mixed. Agreements between pharmaceutical manufacturers and the medicines' patent pool have led to licenses for generic production of antivirals in more than 100 countries, but we haven't yet seen widespread prioritization of therapies by national governments. And we haven't really seen a coordinated international commitment to accelerate the purchase and distribution in low and middle-income countries, at least not on the scale that we saw for vaccines with COVAX, for example.

I'm Katherine Bliss, senior fellow and director for immunizations and health systems resilience with the CSIS Global Health Policy Center. And from

October of 2021 through September of this year I had the pleasure of overseeing the efforts of a working group on COVID-19 therapies, under the umbrella of the CSIS Commission on Strengthening America's Health Security. Over a series of meetings between 2021 and 2022, a subset of commissioners, along with other experts, met to investigate, discuss, and often debate current challenges and promising ways forward.

Specifically, we came together to consider how we came to have effective therapies in a relatively short period of time, why continuous investment in innovation and research and development for new products is important, where there are gaps in terms of global access to COVID-19 therapies, who should be leading the push for global coordination in this area, and what is likely to happen if we don't see greater financing, international coordination, and demand for therapies now, or as we prepare for the next pandemic.

So on behalf of the CSIS commission and its director, CSIS Senior Vice President Steve Morrison – who regrets that he's not able to be with us today – I'm pleased to welcome you to today's discussion about the state of COVID-19 therapies, the role of the United States in supporting equitable access to COVID therapies globally, and how we should be thinking about therapies in planning and preparing for future pandemics.

Now, before I delve into this discussion with our distinguished panelists, let me invite Shira Kilcoyne, director for government affairs international at GSK – which has generously supported this working group – to offer remarks about GSK's vision for therapies and innovation in the context of pandemic preparedness and response. Shira, please.

Shira Kilcoyne: Can you hear me? Is this OK? Low enough? Sorry, much shorter than Katherine. (Laughs.)

Thank you, Katherine, for inviting me to share brief thoughts, and congratulations on all of the work the team has done over the past year, convening highly regarded experts from a wide breadth of public and private institutions to create the publication we are here today to launch. When we first started having the discussion that you – that you referenced, a little over a year ago, to discuss how adding a workstream on therapeutics could fit into the work the commission was already doing on the pandemic, the global response was at a very different place.

Governments were rightfully focused on the development and delivery of vaccines, testing, and trying to get resources into overstretched health system – health-care systems, to deal with the magnitude of severe illness.

As novel and innovative therapeutics were being developed and authorized at the height of the pandemic – which has proven to have a significant impact

on the severity of the illness many patients faced – there was a need to rapidly incorporate these interventions into the proverbial toolbox governments were using. As many of my colleagues here in industry today, and at GSK, we are incredibly proud of the contribution of Xevudy to patients, which constitutes a – which contributes to play a role in the global pandemic response.

As governments and public health officials were, and now, are recognizing the need for therapeutics to be part of their response, there are three critical success factors that I will focus on today. Many more can be found in the report. And I'm sure many will be discussed by my colleagues, the panelists. The first one that – the first one that I'll focus on is funding from and end-to-end perspective. The rapid innovation we have seen during the pandemic is unprecedented. The development and deployment of novel treatments is necessary to get ahead of current and future pandemics. To continue this pace, we, as industry, will need to work closely with all stakeholders to make sure there is sustainable funding in place to support end-to-end development of new and innovative treatments.

The second one is optionality. COVID has been anything but predictable. Different treatments have been effective for different strains. We expect governments and health systems will continue to need a diverse arsenal of vaccine and therapeutic options as COVID evolves. And the third, and most important, is regulatory cooperation. Regulatory authorities have gone to extremes to improve vaccines and therapies at an unprecedented rate. This is critical to ensure that innovations are available to patients during the pandemic. Industry and regulatory authorities need to continue to engage to make sure that we can streamline these processes so that there are not hurdles that delay the introduction of novel therapeutics.

GSK and the industry are supportive of the work this group has done, as the goal of putting therapeutics front and center during the pandemic has been instrumental in managing the most difficult circumstances. The U.S. has been and can continue to be a leader in ensuring a global initiative on therapeutics moves forward. We are prepared to continue to partner with all stakeholders in creating the best pathway forward for the policy recommendations found in the report. And once again, I just want to thank Katherine and the team for your tremendous efforts over the past year.

Dr. Bliss: Shira, thank you so much for your participation in the working group, and thanks very much to GSK For supporting this effort over the past year.

I'd now like to invite our two panelists who are here in person to come up and join me on the stage. And we'll be joined by Nahid Bhadelia, senior policy advisor for global COVID-19 response on the White House COVID-19 response team, and Jenelle Krishnamoorthy, vice president and head of

global public policy and international affairs at Merck and Company. And we're joined online virtually by Gary Edson, president of the COVID Collaborative. So if you could please come join me now.

So I'm really pleased to welcome our three panelists to this conversation this afternoon on the state of COVID therapies, what needs to be done to encourage greater investment in research and development, how to incentivize global collaboration – or, greater global collaboration to ensure their distribution, and how we can take lessons from the development and distribution of therapies under COVID-19 to apply to future efforts of pandemic preparedness and response.

So, as you know, today's conversation aligns with the release of the commission's working group report, final report. Which came out – or, was posted yesterday, and is available online and in hard copy as well, along with three videos that really center around a set of issues discussed in the text. And the report really offers five recommendations. One is to continue research and development into a diverse set of treatment options to ensure innovation, innovative products are designed with the intent of being available simultaneously to populations in high-income countries, middle-income countries, and low-income countries at the same time.

A second is really to accelerate U.S. leadership and diplomacy to mobilize adequate new resources for global distribution of COVID-19 therapies. A third, to prioritize the development of a global coordination mechanism, to finance, scale, and monitor the international mobilization for COVID-19 therapies and future pandemic rapid response. To intensify the focus on strengthening health systems, particularly primary health care, in order to improve the capacity of health facilities to diagnose COVID-19 infections and to deliver innovative therapies, and finally to accelerate the development of a comprehensive communications strategy – both to combat misinformation, but also to provide accurate and accessible information, independent information, to patients and providers.

So we developed these recommendations over the course of a year, from October to, you know, September of this year. But this is a very rapidly moving field, and there are always new developments that are being announced. So I want to start by asking each of you, you know, reflecting both on the last three years but from your perspective in government, and industry, and in the nongovernmental sector, where do you see therapies playing a role in the current response to the pandemic? And, you know, how

do you see that evolving over the next few months? Nahid, let me start with you.

Nahid Bhadelia: Thanks so much, Katherine. And thanks to CSIS and the commission for the work that you're doing, which is timely, and important, and reflects what remain the challenges in the current moment of the pandemic.

Three years ago, almost, three years ago when this pandemic started, we had no tools to prevent the ability of this brand-new pathogen that none of us had immunity against, that we had no proven therapies against. And in the span of those three years, we have made some progress, as you mentioned. The vaccines have actually had a pretty remarkable impact. We could – you know, we should be doing more, and can always be doing more on equity. And I'll talk a little bit more about that a little later. But even since the beginning of the February response till now – Director General Tedros today in a press conference talked about the fact that we've had a 90 percent drop in mortality. We've gone from around 75,000 deaths a week to about 10,000 deaths a week globally.

But this virus evolves. We now know that we need vaccines probably a lot more regularly than a booster series potentially being updated. And we need to ensure that for those who for whom vaccines may not work because they may not be able to mount an immune response, for those who are high risk, for those who are at high risk of severe or deaths, that there are therapies available that keep people out of hospitals, that prevent deaths. And this is particularly important for those parts of the world where there are already constrained health-care systems, where there is already diminishment in the health-care force after three years of working on this pandemic.

And this is in line with – you know, in September of this year, the White House COVID response team and the National Security Council put out an updated Global Recovery and Response Framework. And the goals of that remain that we have come to a point where we have to start thinking of COVID as a long-term battle. How do we still meld with its, you know, twists and turns, the more transmissible variants. But the goals of that are to reduce cases, hospitalizations, and deaths, to integrate COVID-19 response activities into existing health systems while ensuring impacts on other health services are diminished, and to strengthen the global readiness for future pandemics.

And the vaccines – as I mentioned, the vaccines are out there, but the distribution – so far, about 68 percent of the global population, as of today for our world in data, has been vaccinated. Only 24 percent, 23.4 percent, in

low-income countries. So the benefits are not the same in all places. The therapies will help those health systems that could be most affected by severe disease avoid a potential – the ongoing and a potential new onslaught. So far, oral antivirals that we've had seem to have done – still seem to retain

clinical efficacy. And these could be powerful tools as we continue to try to bridge a potential adult life course for support for vaccinations for COVID moving forward for all populations around the world.

So I think that's going to be important. I think there'll be lessons from global vaccination that we need to apply urgently, immediately to therapies. And there are differences between vaccines and treatments, which probably require a different route. And I'm sure Gary will talk a little bit about the experiences that they've had as they've approached this. I think the timing is important because we want to ensure that if a new surge comes out there that these therapies are out there as quickly as possible. And we need a long-term plan. We need a long-term plan beyond just where are the doses today, and how can you get them into communities as fast as possible? Thank you.

Dr. Bliss: Thank you.

So, Jenelle, you're at Merck, a research and development manufacturing organization. Where do you see therapies in the current context?

Jenelle Krishnamoorthy: Well, I really agree with my fellow panelists on this that, you know, this is a long-term play. I mean, we're seeing today as our health systems here in the United States are being stretched with RSV and flu. And thank goodness, because of many times either the combination of high vaccine rates plus the therapies, many of our health systems are able to deal with some of these seasonal activities that are – you know, we have to – that come unexpectedly throughout the globe.

So I think our therapies can really help be belts and suspenders to the vaccines which, first and foremost, is the first thing that should be there. But unfortunately, there's still – and even here in the United States, where we have access to our boosters and to our vaccines – many are not taking those. And so we do need to have a backup plan to that as well. And so, I think, as we've seen data in the U.K., vaccines are working really well. People are not getting to the hospitals. But then from Israel and from other places, that we see the therapies may even potentially be reducing the number of days that people are dealing with COVID, in addition to the severity. So I think as we have new variants, the therapies is, again, another powerful tool – again, with diagnostics, surveillance, and vaccines – that we really need to look at using as we move forward.

Dr. Bliss: All right. Thank you.

So, Gary, thank you for joining us remotely. You're with COVID Collaborative which was, you know, really started during this pandemic to galvanize advocacy and a focus on, you know, addressing the public health challenges

that we're facing. Where do you see therapies in the current pandemic context?

Gary Edson: First, thank you. And thank you for the tremendous work in the report, which I think will be very impactful. I apologize for appearing, I think, to loom over this conversation, but I appreciate being plugged in remotely.

I agree with all the good points that have been made. I would simply say that I think that therapies are going to have an increasingly larger role to play in the current pandemic, for a couple of key reasons. First, as noted, as we transition from an emergency response to sustainable pandemic control, therapies are going to be critical in preventing severe illness, hospitalization, and death, and protecting fragile health systems during surges. Secondly, while emerging variants are demonstrating some immune evasion to current vaccines, oral antivirals so far has retained their effectiveness. And that's important.

And third, I think it's important to recognize that we can expect that vaccine-mediated immunity will wane in many countries, due to low booster uptake over time. So treatments for high-risk populations will become even more important. And of course, as we, COVID Collaborative, and others have argued, what we need is a vaccination-plus strategy. We need to continue to grow our arsenal of tools to fight COVID-19. And therapies are going to be central to that portfolio.

Dr. Bliss: So I think you all have really laid out very clearly, therapies are an important element of a multifaceted approach to a long-term process of dealing with this pandemic and, potentially, really serving as a platform for thinking about how we might address or prepare for future pandemics as well.

So, Jenelle, I want to – I want to turn to you to tell us a little bit about, you know, the process of, you know, what we've seen, this really rapid development of therapeutic approaches over the past three years. What are some of the factors that led to a relatively rapid approach during this period? What are some of the steps that have been taken to ensure availability of new products that, you know, in previous decades might have taken quite some time to be distributed globally? And why is it important that we keep undertaking this innovation, now during COVID but, you know, as we look ahead to future pandemics as well?

Dr. Krishnamoorthy: Yeah, I appreciate that question. I mean, I think, first and foremost, I think across the globe we realize the responsibility we all have in all of the different sectors, from industry to public health, education – everyone needed to come together. And I think what helped us an industry quickly was the collaboration, and how everyone rolled up their sleeves. We looked

at our libraries. What do we have? You know, how can we try to help? And I – you know, that was the first step.

As we all were identifying what needed to happen, I think we also knew the responsibility we had. That's great, and really hard. We had, I think, two vaccine – or, three vaccine failures for COVID. But then finally, we were able to come up with a therapeutic. But in phase two, we knew we had to develop an access plan. And that's not something you can develop once you have something that can be out there and that has approval. So before we knew it would even work, we knew it would take collaboration. Because that's great to have this tool, this drug, but if it's not getting to the people then that's not helping much.

And so that's where we really did, had to reach across the aisle to UNICEF, to MPP, to several generic companies in India, and say: How can we partner so we can make sure that we're covering the globe in this distribution? I think, you know, we'll talk about some of the challenges and lessons learned but, you know, even when you have the partnerships and the supply, again, it's how – do you have the funding that was mentioned in the opening comments to then – for governments to be able to get it to the people? And so I think that's still – I know we have reserved several thousand of medicine courses that have not been delivered yet, because there has not been the capacity to deliver that.

And so I think, you know, this is something that is an end-to-end issue, that you think about from the research and development, to the access, to the partnerships, and to the delivery. So I think that's how we think about it.

Dr. Bliss: So really, you know, instead of getting to the end of the product design and then, oh, how are we going to figure out how to deliver this in different kinds of health systems, you are trying to make an approach now to start that design from the beginning and have those conversations.

Why is it important, do you think, that there be many different kinds of options? I mean, we have the monoclonal antibodies. We have the oral antivirals. Where do you see, you know, as we look ahead, and especially at distributing in different kinds of health systems, what's the – why do we need different kinds of products?

Dr. Krishnamoorthy: Yeah. And this is an area – I'll put in there also, like, antibiotics that we are very strongly in favor – we want more the merrier. Like, more people, more companies need to be developing therapies. Not just for the various health systems that are there that may be able to ease of delivery of these different medications but, secondly, the variants, as we've discussed, are going to change. And also, people are – have different preexisting conditions, are on different medications. And so there it's nice for the primary healthcare

provider to be able to have many arsenals in their toolkit here to make sure that the person who is in front of them can get the best medicine that meets their needs.

Dr. Bliss: Thank you.

So, you know, we've got a number of different options available. There are more in the pipeline, Nahid. In the U.S., we've seen the rollout of a test and treat program. We've seen uptake of the antivirals that are available in different cities and rural communities around the country. Globally, we haven't seen quite as much of a – at least a concerted effort. Jenelle has mentioned that many of the course of Lagevrio, a Merck product, are available but haven't yet been delivered in some of the countries around the world. We know UNICEF has procured several million courses of antivirals. The Global Fund has an arrangement to deliver antivirals. But, you know, in addition the United States has announced a set of priority countries where it'll be working with countries to set up those delivery mechanisms.

So, yeah, I wanted to ask you to say a little bit about, you know, why the United States has prioritized test and treat approaches overseas, how that's going to roll out. Do you see that a mechanism, kind of like COVAX, will become necessary in order to, you know, really kind of take that to the next level, I guess, in terms of distribution of therapies. And what role do you see the United States playing as this global effort moves forward?

Dr. Bhadelia: Yeah. Thank you for that.

I'll take your middle question first. In some ways, ACT-A is already starting to fill that role, right? In their updated strategy.

Dr. Bliss: This is the Access to COVID Tool Accelerator.

Dr. Bhadelia: Sorry, the Access for COVID Tools Accelerator. The ACT-A update for October to March lays out a set of plans for the medium term. In which one of the highlights is how do we move forward on the therapeutics component? And their strategies in there are to support these test or treat initiatives. It is to continue the procurement. And I think that's a – they're

going to be – this is going to be important over the next course for the reasons that Gary talked about, that Jenelle sort of highlighted as well.

But part of the goal of this is going to be to move towards integrating treatments within health-care systems. So as opposed to vaccines, right? I think when you think about the success of vaccines, one of the reasons we – to the point we've been able to get as many vaccines as possible, shots in arms so far – is that they were done through campaigns. You – and this is –

many countries have a lot of experience holding mass campaigns and getting a lot of folks vaccinated.

With treatments, what it requires is that it's an integration to a point where a person may get sick, can have access to testing, is able to get access to that treatment for a limited amount of time. And that requires – and we know where the patients are who qualify for those treatments, right? Currently the oral antivirals, for example, it's over 50, high risk, immunocompromised, and other categories. First and foremost – and I think the numbers are much smaller, but the strategy is potentially something that requires a bit more integration and thought.

And the reason why the numbers are potentially smaller is that when you look at the – you know, the average life expectancy in low-income countries, it's 62. Many people still are not getting diagnosed for the chronic diseases that they have. How do we ensure that those who do qualify, that's where we position the treatments and testing. And that requires that we go to where patients are, rather than having a mass campaign. So that integration, I think the funding for that, the planning around that, is going to be important.

And it requires not just the supply side of the equation, right? I think global health sometimes tends to be more supply side. This has to be a demand side as well, and having people know that they have access to these tools, that they should ask for it, they should know where to access it. And all of that requires public health work beforehand for generation – demand generation as well. So I think ACT-A's going to serve that role immediately.

What should the U.S. do? I think there are a couple of, you know, places already in recently released policy documents where you can see where some priorities are. So the National Biodefense Strategy, for example, you know, stresses our role in investing in innovation, in R&D, in ensuring not just for this, but future pandemics, that we are able to meet that need.

And there are documents such as the American Pandemic Preparedness Plan's update – the annual plan that was released in September, the one-year plan, by OSTP. And in that, it talks about not just innovation, but innovation

with an eye to equity. The ability to create products that are created from the very beginning that are able to sort of be met. The demand can be met in many different health-care settings. And that's one place where I think the U.S. can and should and we hope will be able to take that role.

The other is the direct work, that you mentioned, that we're doing. USAID has test to treat pilots that are already in place in 10 countries, that they're starting to, at different levels of development, already starting to provide

treatment. And third, I think that we have to potentially start thinking about how we come together as a global community to start coordinating what the scale-up from pilots to national plans looks like. And I think that the work that we're doing through our agencies, as well as coordination with our multilateral partners, can play a role there.

Dr. Bliss: And so it sounds like the focus – with the focus on health system strengthening, you know, you're really envisioning therapies – you know, you're not going to a special unit in a hospital or in a pharmacy, but you're going to your regular care provider, getting those therapies. But that potentially that can then link that person to other kinds of care, whether for chronic diseases or other kinds of problems.

Dr. Bhadelia: Yeah, and I think Gary's point about vaccines is a good one. This has to be linked to vaccines. I mean, I think that people need – we need to make sure vaccines are out there and, also, when people that are coming in for their vaccines, say you also have access to this treatment. So it is – it is multiple. And I think one of the lessons from global vaccine campaign, right, and the U.S. has donated, I think, over 660 million doses currently to 116 countries. And we continue to be there to donate. But one of the – what we've realized through that campaign, it's not just the doses.

Critically important with that, as we've always known in global health, is also shots in arms, and ensuring that the infrastructure is there. And the work that's being done currently matches that for vaccines. But what's come up is, if COVID vaccine is an annual vaccination, then what you need is an infrastructure for adult life-course vaccinations. Not just COVID; meningococcal, like, pneumococcus, influenza. And similarly, for treatments, I think that there needs to be a lot more thought about how we integrate, as the Global Recovery and Response Framework talks about, with health system strengthening.

And in fact, I think the ACT-A's update sort of focuses on that as well. How do you integrate COVID into this long-term management? How do you do it in a period of time when countries are battling with competing public health priorities, because of the impact of the last few years. I'm missing my last

point here, but I think that one of the things that we are sort of thinking about this is the moment of how you can take this as an opportunity to help build resilience against future pandemics as well. If you create ability to get testing and treatment, like we did with PEPFAR, right? The PEPFAR platform served this incredible both proof of concept as well as deliver mechanism through which even some of the COVID test or treat is now being delivered. And so if COVID treatments and access can increase diagnostics and treatments for other infectious diseases, that also is pandemic preparedness for the future as well.

Dr. Bliss: So we can really think about how our emergency programs have contributed assets to the current response, and think about how we can make those more sustainable in the longer term.

Well, Gary, you know, both Jenelle and Nahid have really laid out the importance of deliver as well. You know, it's great to have supply of therapies, and it's great to get them at least delivered to ports in different countries around the world. But if you don't get them to the clinics and to the people who need them, then you've kind of missed – you've got a big gap there that you have to cover.

So COVID Collaborative is working with a number of other organizations in the Quick Start Consortium. And so I wanted to ask you to talk about the rationale behind the formation of the consortium, in terms of delivering therapies, what the different partners bring to the effort, and what you all are doing as a partnership with priority countries to deliver therapies and really kind of collect lessons to share back with the global community.

Mr. Edson: I'm happy to do that. At the outset, let me say, picking up on what Nahid said, that the whole objective behind Quick Start is precisely to integrate test and treat into primary health care. Now, the Quick Start Consortium includes Duke University, the Clinton Health Access Initiative, COVID Collaborative, and Americares as implementing partners with support from the Open Society Foundations, the Hilton Foundation and Pfizer. And the consortium will be supporting ministries of health to implement test and treat in ten partner countries across sub-Saharan Africa and Southeast Asia. They include Ghana, Kenya, Laos, Malawi, Nigeria, Rwanda, South Africa, Uganda, Zambia, and Zimbabwe.

Now, it's going to be an 18-month project. It'll be kickstarted through a donation by Pfizer of 100,000 courses of Paxlovid, transitioning to low-cost, quality-assured, generics as they become available. We have three specific goals of Quick Start. First, to rapidly introduce and scale access to new COVID antivirals in high-risk populations with mild, moderate symptoms,

within five days of onset. Second, to establish a learning network open to all interested parties to share Quick Start learnings in real time and inform other efforts. And, third, to build sustainable COVID-19 outpatient test and treat programs with stable access to generics.

Now, true to the name Quick Start, the first shipment of Paxlovid will arrive in Zambia this month, with other countries following in short order. And the first session of our learning network is scheduled for December 7. And, as I said, that's open to all parties – implementers, multilaterals. We've been

coordinating and aligning efforts closely with the USAID effort. They will be participating as well.

I do, however, want to flag issue of concern. It's true that the ACT-A strategy going forward talks about the importance of test and treat and the therapies. But with ACT-A itself riding off into the sunset soon, no one is stepping up to own treatment, nor are donors prioritizing it. And I think that's one of the points in the report that is being issued. As a result, given the absence of any market signal from the U.S. or others to incentivize generic manufacturers to speed up commercialization, we believe that generic nirmatrelvir/ritonavir won't be available in LMICs until the third quarter of next year, at the earliest.

Now, we hope that by proving that oral antivirals can be introduced in LMICs and used effectively, Quick Start can help unlock the needed funding. We saw a similarly catalytic result from early demonstration projects with HIV antiretrovirals. We're hoping that Quick Start will have the same catalytic impact.

Dr. Bliss: So when you – the countries that – where you're working, you know, sound like they probably have rather different primary health-care programs. So part of – it sounds like part of what the consortium will be doing as well is really helping the different members and those who participate in the learning network to understand something about how to strengthen their health systems as well.

Mr. Edson: We're going to be sharing lessons learned. We're going to be looking at what works and what doesn't work. This is – this is not a clinical trial. It's operational research aimed at identifying the most efficient, effective, and sustainable pathways for new product introduction, implementation of test and treat, demand generation, and scaling up test and treat to a wider population. And, yes, there are going to be differences from country to country. And we're going to learn from country to country and share those learnings.

Dr. Bliss: So, Jenelle, can I turn to you for a second? I mean, Gary has mentioned, you know, this challenge where, you know, it looks like the generics may not even be available for, you know, a year or two. And, you know, I wanted to ask if you could shed light on just some of the challenges. I mean, there are all these licensing agreements that have been made. More than 100 countries, I think. But yet, not all of the manufacturers are – they're, I guess, not quite sensing market demand for the products, right? can you say a little bit about that?

Dr. Krishnamoorthy: I can. And I think this comes back to needing to continue a sustainable demand on some of these. And so, yes. We've had some of our licensees that

we have extended license that have given them back now because there isn't a demand in their country or in their continent for manufacturing the therapeutics. And so that is a real concern. And I think, you know, as we're looking at this long term, it's, one, with some of the manufacturing facilities, keeping them up and going too. As we have had, you know, experience with Ebola manufacturing in other places that, you know, you cannot be turning things on and off. And that – and be able to move things quickly.

And so I think it's the same thing as we're even talking about strengthening health-care systems. How can that be done sustainable to take care of the primary care and the prevention and the treatment? And so that when another infectious diseases occurs – one, our populations across the world are healthier, so that they are not coming into this infectious disease in a less healthy state. But two, that, again, goes end to end if they are getting the preventative care, and getting the medicines, and the vaccines throughout, that can have a sustainable generic industry to branded industry.

And I think that helps also with just the intellectual capacity as well of learning how to do the regulatory systems, and how to really be able to, when we have to ramp up for a pandemic, we're able to – because you have the foundation. And I think that's what was shocking across the world, was how vulnerable we were, even in developed countries, let alone looking on LMICs.

Dr. Bliss: So really keeping that capacity going at a – even if at a low level – for a period of time, so that when there's an emergency it can easily surge to meet that demand.

Dr. Krishnamoorthy: And being able to make that demand for noncommunicable disease now, so that then it can be turned on further and switch over. Which includes health-care workers and providers and all – you know, all of these things. How do we take the lessons learned now and look at our day-to-day functioning as health-care systems around the world?

Dr. Bliss: So, Nahid, I wanted to go back to a point that you made. You were talking about the role of ACT-A. And, you know, they have really been, I think, assessing country capacity to deliver therapies. Gary had expressed some skepticism –

Dr. Bhadelia: I was going to ask you if you were going to let me respond to Gary. (Laughter.)

Dr. Bliss: So, please.

Dr. Bhadelia: I will agree with Gary that with ACT-A going through evolution that we need a plan for the global response, not just for future pandemics but what

happens in a year from now, two years from now, if there's another COVID surge. And I will respond to Gary's part of the report from another part of your report, where you eloquently stated the multiple asks this administration has made to Congress for both global COVID, as well as domestic preparedness and response as well. I think that this is an important part – because what we're dealing now is a world that's not only dealing with pandemic as becoming potentially a long-term issue, but also recovery from longer issues.

And both here as well as abroad, the decision and the question that countries are making, and the governments, is all the way down ministries of health and all other sectors are making, is COVID versus all other public health priorities. And it's trying to make sure that we highlight this remains important, this remains a potential risk, a potential surge in the future. This is an unknown. And we're not just talking about future pandemics. We have to ensure that we keep in mind that COVID, and potentially a future more, you know, transmissible variant may pose an immediate threat. Maybe, hopefully not, as large as the first ones. But that exists.

And so I think that that's where U.S.'s current investments, U.S.'s ability to leverage convening and coordinating our partnerships with – you know, and work with multilateral organizations around imagining what the scale-up would look like, is important in this moment. And that's why public commitment, congressional support, is important to expand that.

Dr. Krishnamoorthy: Can I just – you know, I might take it just a step further. You know, in Europe, they're dealing with the energy crisis. So sometimes it's hard to even keep health on the agenda, I find. In Poland, Hungary, they're dealing with the surge from Russia and Ukraine. How do we, you know, absorb all these folks in our education, in our schools, and in other areas. And so I think, you know, it is something that for many countries it's hard to even keep health on the agenda as they're dealing with some of these other geopolitical crises that are front and center.

Dr. Bliss: So three years into a pandemic, you know, we're a moment where most of us want to just forget about it, and move on, and say, well, that was in the past. But here, you know, we are needing to continue thinking about COVID as a long-term prospect, but then maintain that as a priority against all of these other crises that are really captivating global attention.

I want to just ask you to kind of look ahead. COVID is still with us, but as we start thinking and planning and preparing for future pandemics, that we know will continue to – maybe they shouldn't surprise us, but we know that they'll continue to be part of our lives – what are kind of the top one or two lessons from this current experience that you hope we, as the United States, as a global community, will take forward?

Gary, let me – let me start with you. I think you – you might still be on mute.

Mr. Edson: I'm sorry. You missed the most brilliant think that I was thinking. (Laughter.)

I think there are three basic lessons. One, distribution, delivery, demand generation require much more upfront investment and work than have been applied, just as we saw with vaccines. That's one key lesson for the future. Second, health systems capabilities for test and treat generally should be key priorities, because they support primary health-care needs and they strengthen future pandemic preparedness. And the third thing, going back to this issue of financing, we need some sort of contingent financing availability for purchase of therapies in the future, and for future threats.

Whether it's some sort of advanced commitment facility or some other mechanism, we cannot be left the next time around going cap in hand. And, as we saw from this battle against COVID, the therapeutics pillar of ACT-A was grossly underfunded compared to the vaccine pillar. And in the future, we need to recognize that we need a full toolkit to respond to future threats. And I think the only way we're going to have financing available when we need it is if we have some sort of contingent financing facility.

Dr. Bliss: All right. So deliver, as well – delivery and demand. Health systems – a strong health system. And then surge financing, or really emergency financing, for a therapeutic process.

Jenelle, let me turn to you. Like, as you look ahead, what are two things about therapies, do you think, that we need to take from this experience to the next one?

Dr. Krishnamoorthy: I love this, because I can take his three and then add my two, right? (Laughter.)

Dr. Bhadelia: Think about me!

Dr. Krishnamoorthy: Yeah, yeah, this is great. I will add – so, strongly agree with what Gary said. I will add the other key component, especially now when everything across the world is very politicized, is having a good communication by trusted folks to the public, to health-care providers, to really explain what's the science, what's the evidence. So that individuals can make informed decisions during this time. And that is something – it was very difficult.

We were at a point in time where things were changing. We didn't know about this novel – this novel virus. But at the same time, the trust in government, the trust in science was all shaky. And so I think we – real

communication experts really have to understand this, because the likelihood of another pandemic occurring and us, as a globe, as a society, needing to do something – we need trusted people and a communications plan around that. So I think that's really important.

I think, two, what we found is regulatory harmonization. And I know from an industry perspective how frustrating it was at times when there was lots of delay trying to figure out how do we change labels and languages and ensuring different regulatory agencies are talking to each other. And there needs to be streamlining, especially during a pandemic, during these times. And I believe this is something many do understand. Again, that communication plan has to be involved, but not safety or efficacy as being at all reduced during this time. But once you find it safe and effective, you need to be able to distribute this across the globe and come up with streamlined ways that very efficacious, rigorous, regulatory systems can be talking to each other and communicating.

Dr. Bliss: So it sounds like communication on the one hand to address misinformation – that we've seen proliferate around so many unproven therapies during COVID – but also to help providers and patients understand and, as you said, make informed choices about what's best for them. But it sounds like also some communications among regulatory prospects as well, really enhancing that ability to communicate across.

Nahid, your top two lessons.

Dr. Bhadelia: Oh, so all of the above. And I would double down on part of what Gary said, which is that sustainable financing – not just for treatments, but actually all things in global health and pandemic preparedness are required, right? I feel like this is – we're starting as a globe potentially to move in this direction.

The Pandemic Fund was recently – as you know, as was renamed – over the – over the summer. A path potentially towards creating something that invests in sustainable health-care systems and potentially creates a place where there might be more accessible funding. But I think that remains an important element for national governments, for international community overall in terms of how you access flexible funds in the face of an emergency.

Two, I think I've said this in many different other places, which is that bricks generally break along fault lines, right? And, like, your weaknesses in your health-care systems, your weaknesses in your public health systems, what you didn't invest in in peacetime is generally what causes the most issues when you have an outbreak. And what you leave – the tangible resources you leave on the table for the intangible threats that might be coming down the road – and that is surge capacity in health-care systems, ensuring there's equity in access to primary care.

All those things may seem like very big problems, but when you talk about treatment those are the very things that are keeping us from getting access to – and we talk about demand generation. And very much needed. But part of demand generation is actually having people know they have access to this, and their willingness to be able to access that is associated with cost, trust in the system, all the other things that don't get created in the middle of a pandemic. They get created in the inter-peace system. And we have to keep investing in the R&D because the pathogens are growing smarter, right? We need to keep innovating to make sure that we have stuff in the arsenal in case there's something else coming down the pike.

Dr. Bliss: Thank you. So health systems, communications, trust and confidence in the system, and continued investments in R&D. It's not a – it's not a small order, but something that we need to think about for now and the future.

We got started a little bit late, so I do want to give some of the people here in the audience a chance to ask a question or two, if you would like. We do have a microphone over to the left, if anyone would like to. But we've covered a lot of ground as well, so. And please just say your name and your affiliation, and then your question for our group.

Q: Sure. Hi. Can you hear me? Great. Jamie Bay Nishi. I'm the executive director with the Global Health Technologies Coalition.

It's been a pleasure to be a part of the working group across the last year. And one topic that didn't come up quite today, haven't seen it in as much detail in the working group discussion, Nahid, you helped write also the AP3 report this year. Workforce. And we often talk about workforce in global

health as the frontline health workers, but what else is needed when we think about the regulatory bottlenecks? There just seemed to be when the pandemic hit drugs, vaccines, diagnostics, everything, a shortfall in technical experts on regulatory. How do we make sure that there's also strengthened workforce for the clinical research, for the R&D capacity not just here in the United States but around the world, as we think about the failures in equity in having a more regionally distributed plan to this type of work moving forward? Thanks.

Dr. Bliss: Thank you. And let's go ahead and take another question as well, please.

Q: Sure. I'm Jeff Sturchio. I'm a senior associate here at the Center for Strategic and International Studies.

You know, as we were talking today I was thinking of an old canard about how generals are always fighting the last war. And, you know, each of you

has had really sensible suggestions for how we can be prepared for the next pandemic. But what worries me, and I wonder if I could push you a little bit on this, is what's going to get politicians who make decisions about where to invest public funds, act any differently than they have in the past? You know, we do – you know, thanks to the support of the Biden administration, we now have a Pandemic Fund at the World Bank. But it has a pitifully small amount of money, when compared to the scope of the need. So that's, you know, one example of how governments have yet to actually step up to the plate, despite what we've learned in the past three years.

And, you know, the same thing could be said for all the other stakeholders in this. That, you know, companies like GSK and Merck do a great job of sort of planning for what they see just over the horizon in the next drugs and vaccines that they have to develop. But then those projects have to fight for all the other projects that are there, for diseases that aren't pandemics, that aren't infectious diseases. And it's sometimes hard to make sure that the right level of funding is put aside for these longer-term projects. And you could go down the list. But just, you know, is there anything we can do differently to ensure that all of the recommendations that the report and each of you has made lead to new action in a way that actually make us better prepared for future outbreaks?

Dr. Bliss: All right. So two not small questions here. (Laughs.) One really on the health workforce as an element of the health system. But not just the frontline health workers, but all the people who do data entry, and R&D, and manage the supply chain, and everything else. Really looking more comprehensively at that. What do we need to do in thinking about pandemic preparedness and therapies? And then the second question, you know, as

Nahid you mentioned, I mean, we have seen challenges in mobilizing funding recently for domestic and international COVID response here in the United States. So what can we do to get politicians – we have all these great ideas – but what can we do to get political commitment in really thinking ahead for future pandemics?

So, Gary, let me – let me start with you. And then we'll come back and wrap up here in the room.

Mr. Edson: I happen to be in violent agreement with Jeff. We are – we are tragically seeing a repeat of the old panic and neglect cycle. I think that the only way we're going to break through that is by making a stronger case, not only to leaders but to the public. I don't think – first of all, in my view, nothing of significance happens in global health – whether it's HIV, Ebola, COVID, or the next pandemic – without U.S. leadership. I think that that's critical and remains critical. And the administration has tried to exercise that

leadership. And, not to put too fine a point on it, does not have the resources to follow through at this point, from Congress.

I think in order to break that cycle we need to do a couple of things. We need to make a better economic case both to Congress and the American people, that investing in prevention is the best investment that we've got. As opposed to the cost of response. Secondly, we've got to make the national security case that this is an investment in our security to address pandemic threats globally. And that case needs to be made more powerfully, more frequently, in order – and I think that national security case can also help build the kind of bipartisan support that we saw for other prior initiatives for future pandemic response and preparedness.

So I think that those are the keys to doing it. It's not easy. I don't think there's a magic wand. But I think that the next crisis is a zoonotic leap or a new variant away. And we need to make the case powerfully now, so that we're not caught flat-footed the next time around.

Dr. Bliss: Thank you.

Jenelle, let me turn to you.

Dr. Krishnamoorthy: I think I'll go – you know, I'll leave off where Gary just said. I think many of the governments – the reason these individuals are serving in this public service way is to meet the demands of their constituencies. So as Gary was saying, we have to be able to explain why is this important so the constituencies – the American people, the French people, the German people – are all talking to their various governments and saying: We need you to do

something about this. My grandchild cannot be at home ever again in the future. Where are you going to put employees, and not just the health-care systems, the education system, all the systems in place there. The mental health systems, which we have not discussed. They all need to be discussed.

There has to be not just for medicines and vaccines a demand, a demand for, you know, the government officials that they must meet us as a people's needs. And we see that as work. You know, when Macron was talking to his people, he always said we need to make access very important. I mean, we watched – this is the magic sauce, right, and how we get the op-eds by different people in constituencies. So I think it also goes back to the communication. And I think it's very tricky, because it can't – I agree with Gary on the national security and being powerful. But we have to be careful that we're not scaring people. I mean, this is a – the communication part of this is extremely difficult, but we have to get it right.

And I also want to address that if we do not have professionals that see that they are valued doing clinical research, data, the regulatory – because many people don't. I'm a very geeky person, so I think this is very exciting. But a think it's, again, very important that our universities, our governments, industry across the globe, multilaterals, are really bolstering fellowships, internships, programs that can even start as early as middle school and high school to be getting young people really excited about these fields, and then helping them all the way through their journey. Because, you're right, we need the strong workforces in all of these areas.

Dr. Bliss: Well, and going back to what Gary said as well, I mean, there's an economic case to be made there too for, you know, people get the training and they themselves can do better for themselves and their communities.

Nahid, the last word.

Dr. Bhadelia: I will take Jamie's much – also hard question, but potentially easier than the first one – the second one that was posed. I think it requires a thinking – so I'm going to focus specifically on research-constrained areas that potentially don't have this workforce, right, already. And give the example of vaccine manufacturing. To get a viable vaccine manufacturing, you need a healthy bio economy. You need a demand for the vaccine. It needs to be linked to the needs that are endemic in that area. They need expertise in multiple levels. So you mentioned, of course, regulatory, but everything from, you know, the quality control, the building of the plans, to the safety – the health and safety oversight. The health-care workers who will give it. You know, the communicators who will talk about it.

A lot of that comes from the initial investment, and the maintenance, and the demand, right? And there's a lot of work. So what could we – what should be done? I think there's been one-off – you know, many, many wonderful investments in training, you know, regulatory pathways for manufacturers, for example. But to maintain that, to keep that as – now, I'm stepping out of my government role for a second and putting on my physician global health role for a second. You know, been part of so many training programs over my life about where you have skills that are important. But if there's no jobs and there's no continuing exercising of those skills, right, who's going to come to your training program and who's going to, you know, come to it not knowing that there's a job after it?

So I think it's both investment in the training, it's finding those people, training them, maintaining those trainings. But also sustaining that healthy bioeconomy, so there's something somewhere for those folks to be.

Dr. Bliss: Thank you.

Well, I want to thank each of you for joining the discussion today, and for really shedding light on the challenges associated with the development of therapies for COVID over the past three years in the current outbreak, but also the lessons and opportunities that we can apply to future pandemic preparedness activities.

This report that we've been talking about and the working group were part of the CSIS Commission on Strengthening America's Health Security, which has been in operation since about 2018, I think. I'm particularly grateful to Michaela Simoneau and Humzah Khan from the CSIS Global Health Policy Center, and the commission's secretariat for their efforts on behalf of the working group, the final report, and the video series. Many long edits and reviews and continued reviews. And really appreciate their effort and support.

The commission will be winding down its work – its current phase of work over the next few months. But we do anticipate launching a bipartisan alliance on global health security in the first part of 2023. And as that work on pandemic preparedness and response, along with HIV/AIDS and routine immunizations within global health security approaches takes shape, I hope you will continue to look for additional analysis and discussion about the place of therapies in the response to this pandemic, and future ones as well.

So thank you all for being here today. We are adjourned.

(END)