

# GLOBAL HUMAN RIGHTS, RE: PROGRESS AND PRESENT CHALLENGES ON COVID-19 IN AFRICA

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## HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH,  
AND GLOBAL HUMAN RIGHTS

OF THE

COMMITTEE ON FOREIGN AFFAIRS

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTEENTH CONGRESS

SECOND SESSION

—————  
MARCH 31, 2022  
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**Serial No. 117-112**

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Printed for the use of the Committee on Foreign Affairs



Available: <http://www.foreignaffairs.house.gov/>, <http://docs.house.gov/>,  
or <http://www.govinfo.gov>

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U.S. GOVERNMENT PUBLISHING OFFICE

47-168PDF

WASHINGTON : 2022

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**GLOBAL HUMAN RIGHTS, RE: PROGRESS AND  
PRESENT CHALLENGES ON COVID-19 IN  
AFRICA**

**Thursday, March 31, 2022**

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, AND  
GLOBAL HUMAN RIGHTS,  
COMMITTEE ON FOREIGN AFFAIRS,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 2:25 p.m., via Webex, Hon. Karen Bass [chairwoman of the subcommittee] presiding.

Ms. BASS. The Subcommittee on Africa, Global Health, and Global Human Rights will come to order.

Without objection, the chair is authorized to declare a recess of the subcommittee at any point. And all members will have 5 days to submit statements, extraneous material, and questions for the record, subject to the length limitation in the rules.

To insert something into the record, please have your staff email the previously mentioned address or contact full committee staff.

As a reminder to members, please keep your video function on at all times, even when you are not recognized by the chair. Members are responsible for muting and unmuting themselves. And please remember to mute yourself after you finish speaking.

Consistent with House Resolution 965 and the accompanying regulations, staff will only mute members and witnesses as appropriate, when they are not under recognition, to eliminate background noise.

I see that we have a quorum, and I will now recognize myself for opening statements.

Pursuant to notice, we are holding a hearing on the progress and present challenges to COVID-19 in Africa, to receive an update on the ongoing COVID pandemic in Africa, and to examine the continued challenges the continent is facing. It is my hope that with this discussion we can identify opportunities the United States and the greater international community can take to work with African leaders and the African Union in addressing these challenges.

To lead that conversation, I want to thank our witnesses for being here today: Dr. Ahmed Ogburn, deputy director of the Africa Centres for Disease Control; Dr. Patrick Soon-Shiong, founder and executive chairman of NantWorks; and Dr. Maria Elena Bottazzi, codirector of Texas Children's Hospital Center for Vaccine Development. I welcome your testimony and the discussion surrounding it.

I look forward to hearing our experts describe what has or has not changed in the past 13 months since the subcommittee's last

COVID-19 hearing. I also look forward to hearing the various ways in which the U.S. and the greater international community can work with African leaders to assist with treatments, vaccines, manufacturing on the continent, and how COVID-19 has impacted the economies of African nations and the livelihoods of their people.

I must also note today that the Russian war on Ukraine has exacerbated the already damaging effects that COVID-19 has had on the world, including on the Continent of Africa. Economies that have been suffering due to the pandemic have worsened, national security of all countries have been threatened, and the global food crisis has been dangerously exacerbated.

Several African countries rely heavily on Ukrainian imports to feed their populations, so an unnecessary and unjustifiable war, coupled with the ongoing pandemic, is a grave cause for concern. The witnesses might speak to that or might make reference to that if they have such information.

For the past 2 years, there have been nearly 8 million COVID cases on the continent, and the disease has taken the lives of over 160,000 Africans. With the most recent wave of the Omicron variant, new variants continuing to emerge, and without a clear end date to this pandemic in sight, it is a priority to get vaccines in the arms of as many Africans as possible.

Africa has notably lagged behind the rest of the world in terms of vaccination rates, with only about 11 percent of the total population being vaccinated. In recent efforts, the Biden Administration has surged \$250 million of its global vaccine access funding to 11 countries in Sub-Saharan Africa based on the burden of COVID-19 on their populations, the capacity of their health system, and their readiness to quickly administer vaccine doses.

The U.S. Agency for International Development has led this interagency initiative, with a focus on vaccine delivery, meaning not just providing vaccines, but also the requisite support to get them into people's arms as trends have shown throughout the pandemic that donations alone are not sufficient to sustain a continent. This is why I believe manufacturing on the continent is essential, not only for the current pandemic, but also for future health threats.

Currently, only five countries have capacity for vaccine production on the continent. One of our witnesses here today, Dr. Patrick Soon-Shiong, has opened a COVID-19 manufacturing plant in South Africa. The steps we are seeing in South Africa are also being taken in other countries on the continent such as Rwanda. I look forward to hearing about more of those manufacturing plans.

Unfortunately, the COVID-19 pandemic caused unemployment, income loss, and pushed tens of millions of Africans into extreme poverty. It was learned in February, during this subcommittee's hearing on education, that learning losses are likely to have consequences for future educational attainment and lead to challenges in finding employment. And COVID-19 disrupted the learning of 1.6 billion students.

That is why just this week, I, along with my colleague and Ranking Member Smith, introduced the READ Act Reauthorization of 2022 to expand access to basic education for children around the globe, particularly marginalized children, including women and

girls. This reauthorization will allow for a total of 10 years of access to quality basic education across the globe. With that in mind, my colleagues and I will be interested to hear from the witnesses how COVID-19 impacts on poverty, food insecurity, and implications on trade and investment.

As the continent continues to strive for self-sustainability, U.S. partnerships in trade and investment are essential to enhance the vitality of the economies on the continent and here in the U.S.

Finally, it is critical to learn today from our witnesses what other steps need to be taken to see progress. Though vaccine donations remain essential to safeguard health and save lives in the short-term, donations must be combined with strategies that include funding and investments and help infrastructure, technology, healthcare professionals to create a self-sustainable continent, capable of ending this pandemic in Africa, and prepare it against future epidemics and health threats.

I now recognize the ranking member for the purpose of making an opening statement.

Mr. SMITH.

Mr. SMITH. Thank you very much, Madam Chair. And I want to especially thank you for convening this important hearing on the challenges and the progress of COVID-19 in Africa in trying to mitigate its terrible consequences.

Our hearing and discourse need to recommit to assisting Africa not only in the fight against COVID-19, but also against other looming crises, in particular and you made mention of it as well, a food insecurity that will undoubtedly be exacerbated by the disruption of the supply chain in wheat shortages due to Vladimir Putin's ongoing barbaric invasion of Ukraine.

Obviously, we live in an interrelated and interdependent world. Mindful of that, I am especially happy and want to thank one of our witnesses, His Excellency President Masisi for Botswana, along with 27 other African nations voting in favor of U.N. General Assembly's resolution condemning Russia's war on Ukraine.

Thank you, Mr. President, for not only what you are doing on COVID-19, but also for peace in Ukraine and throughout the world.

As we are joined together in this fight against Vladimir Putin's brutality, we are also unified in building Africa's resilience against COVID-19 food insecurity, as well as Chinese Communist Party and the Russian influence in that region. To that end, I would also note that Botswana has demonstrated a commitment to democracy in elections, which is one of the best in Sub-Saharan Africa.

Again, thank you, Mr. President, for that leadership.

We all know that COVID-19 has hit Africa particularly hard and has pushed tens of millions into extreme poverty, meaning that ground once gained has now been lost in the battle against hunger and poverty, a ground that we must make up.

Although Africa witnessed fewer cumulative confirmed cases in deaths per capita than other parts of the world, notwithstanding low vaccination rates, we wonder how much of this is due to under-reporting, perhaps sometimes something our witnesses can address at this hearing today.

I would also like our witnesses, if they could, to give their frank opinions with regards to Russia and China's vaccine diplomacy and whether it comes with strings attached. Are there concerns as well about the efficacy of those vaccines?

I would also appreciate your frank appraisal of the role that the WHO and Dr. Tedros, someone with whom I have met with many times. I do believe that he has a lot to answer for, not only for what I believe was his covering up for the People's Republic of China with disinformation the WHO spread during the early days and weeks of COVID, but also his role as Ethiopian health minister, where I first met him, where he covered up a cholera outbreak in Ethiopia.

I would also like to hear your perspective on whether there is truly a shortage of vaccines or, rather, a distribution and supply chain issue. It has been reported that in Nigeria, one million expired doses had to be destroyed late last year. Other countries, including DR Congo, Liberia, South Sudan, earlier had reported destroying collectively nearly half a million expired vaccines. In Namibia, 268,000 doses it was reported were slated to be destroyed last November due to slow uptake and due to vaccine hesitancy.

Meanwhile, in Somalia, the government of Mogadishu has politicized the distribution of vaccines due to the ambiguous international status of the de facto independent nation of Somaliland. The government in Mogadishu was the recipient of doses to be given to Somaliland, which they allegedly dropped off at the border 2 days before expiration, leaving them sitting out in the sun and rendering them useless. Any comments on that by our distinguished witnesses' insights would be helpful.

To build Africa's long-term resilience in the face of COVID-19 and a future health crisis, we thus should work with governments in mitigating obstacles to vaccine distribution, including the approval process, scaling complex manufacturing and, most importantly, resolving transportation challenges, given the limited shelf life and ultra cold storage needed for at least some of the vaccines.

There is also an untapped potential for Africa, and this is really exciting, to produce and manufacture its own vaccines, which will help get doses to individual's arms quicker, while developing its biotechnology sector and encouraging cross-country collaboration by licensing agreements.

Why shouldn't Africa become a manufacturing center, a hub for pharmaceuticals instead of, for example, the People's Republic of China? To do so, however, we need to be cognizant to have protection of intellectual property rights, incentives, R&D, as well as it ensures the quality and, again, the efficacy of vaccines to ensure uninterrupted standard.

Yet Africa has fallen victim, like many countries, to criminal syndicates infiltrating the market with fake vaccines and medicines. With Africa producing just 1 percent of its vaccines, the need to immediately address the root problems, innovation and prosperity gaps caused by weak legal and political frameworks for property rights in Africa, as well as trade barriers that suppress innovation and partnerships.

While the issue of patents remains controversial, especially in the wake of the closed-door compromise 2 weeks ago on the Trade-



Related Aspects on Intellectual Property Rights, or TRIPS, waiver presented to the WTO led by India and South Africa, there are also many promising initiatives that side step some of the controversy.

The idea behind a patent-free option financed by private philanthropy such as Corbevax, a vaccine developed by Texas Children's Hospital—and I think it is a good one—we need to look toward to hearing our witnesses—I look forward, we all do—including Dr. Maria Bottazzi, to elaborate on that.

Again, I want to thank Chairwoman Bass for convening this hearing, and look forward to our witnesses' statements.

I yield back.

Ms. BASS. Thank you Representative Smith.

I would like to welcome Dr. Ami Bera to our committee, who is a global health expert. And then, without objection, we are glad to welcome our colleague, Representative Sheila Jackson Lee, to participate in today's subcommittee hearing after our subcommittee members have been recognized.

With that, I would like to introduce our witnesses for today's hearing. First, we have Dr. Ahmed Ogwell, who currently serves as the first deputy director at the Africa Centre for Diseases Control and Prevention. In his capacity, he works closely with governments and other partners to safeguard the health and well-being of African nations.

Dr. Ogwell is a well-respected expert in public health, with over 25 years of experience in different settings, ranging from the national government NGO's to the U.N. system and the AU. His area of expertise includes responses to health emergencies, prevention and control of noncommunicable diseases, influencing health policy, and health global diplomacy.

Our second witness, Dr. Patrick Soon-Shiong, is a surgeon, scientist, inventor, and philanthropist, with over 500 issued worldwide patents and 100 scientific publications. He serves as chairman and chief executive officer of NantWorks, an organization that addresses healthcare, clean energy, and communication. He also has an ecosystem of other companies with developments in a wide variety of complex industries, from medical science to biomaterials, from data transport to AI, and from communications to mobilities.

Final witness is Dr. Maria Elena Bottazzi. She is an internationally recognized tropical and emerging disease vaccinologist, global health advocate, and cocreator of patent-free open science COVID-19 vaccine technology that led to the development of Corbevax, a COVID-19 vaccine for the world. She pioneers and leads innovative partnerships for the advancement of a robust vaccine development portfolio, tackling diseases that affect disproportionately the world's poorest populations, making significant contributions to catalyze policies and disseminate science information to reach a diverse set of audiences.

In 2022, alongside vaccine researcher, Peter Hotez, she was nominated for the Nobel Peace Prize.

We appreciate all of you for being here today and look forward to your testimony. Your written statements will appear in the hearing record. And under committee rule 6, each witness should limit your oral presentation to a 5-minute summary of your written statement. And you can see the 5-minute clock that is there. After

each of you provide testimony, we will have a round of questions from committee members.

Thank you very much. And why do not we go to our first witness, Dr. Ogwell.

**STATEMENT OF DR. AHMED OGWELL, DEPUTY DIRECTOR,  
AFRICA CENTRES FOR DISEASE CONTROL**

Dr. OGWELL. Thank you very much Chairperson Bass, Ranking Member Smith, and all the distinguished members of this subcommittee.

I bring you greetings from the Africa CDC and the African Union. And we are pleased with the invitation to come and testify at this hearing today.

Africa has faced a lot of challenges in addressing the control of this COVID-19 pandemic on the continent. And when we look at it from different perspectives, including public health, social and economic factors, Africa has really been hit quite hard by the pandemic over the last 2 years.

African Union has, through the Africa CDC, been leading the work of coordinating the response to this pandemic on the continent. And then our experience has seen significant adjustments to the way that we handle health security on the continent. As you know, Africa CDC has the mandate of coordinating the health security agenda on the continent. And, in fact, we see this investment in the Africa CDC by the African Union heads of States as one very smart investment indeed.

You will recall that Africa CDC is really an institution that was borne out of the crisis in West Africa during the Ebola disease outbreak, and it has brought together many possibilities of Africa responding differently. And we have seen that happening during the COVID-19 pandemic.

Africa CDC is a very young organization, only 5 years old. And the mandate that we have been given by the heads of States of the African Government goes to show that Africa is changing and investing in areas that before were being handled by nonindigenous organizations.

When we look at the last 5 years of existence of Africa CDC, it has gone through many different phases. Most recently, in February, the African Union assembly has elevated the Africa CDC to be an autonomous health body of the union, and in this way giving it more possibilities of responding faster, engaging with more partners and, therefore, protecting and safeguarding the health of the continent in a more effective way.

Africa has gone through four waves. And right now, although we are at the bottom of the—just past the fourth wave, we still have challenges, particularly around vaccinations. The African Union established the Africa Vaccines Acquisition Task Team, and working together with COVAX, we have actually facilitated the delivery of over 750 million doses to the continent. The major challenge still remains how do we get those doses into people's arms.

We propose some very clear areas of how we can be able to address these challenges on the continent. And the three recommendations that we would like to give the committee today is, one, support for Africa CDC's vaccination rollout initiative across

the continent. We are working very closely with our partners and our member States to try and increase the rate of vaccination because we are only at 15 percent at the moment.

Second is we are recommending that support is given to the use of existing health assets to improve COVID-19 vaccination. This is particularly important when we look at infrastructure for HIV, for example, that PEPFAR has been

[inaudible] over a long period of time, if those are able to be deployed for use in vaccination rollout.

And finally is to support the strengthening of the—whole of the health system. Particularly, the cold chain capacity on the continent needs to be increased and improved so that we do not end up with any vaccines being lost.

With these three recommendations, I put it to ourselves that if we address these, we are going to be able to get much better vaccination rollout on the continent than we are currently facing.

I thank you for the opportunity.

[The prepared statement of Dr. Ogwell follows:]

**TESTIMONY**

**Ahmed E. Ogwell OUMA, MPH, MPhil**

Deputy Director,

Africa Centers for Disease Control and Prevention (Africa CDC)

African Union Commission

Hearing on “COVID19”

US House of Representatives

House Foreign Affairs Committee

Sub-Committee on Africa, Global Health, and Global Human Rights

March 31, 2022

**Introduction**

The Honorable Chairperson Bass, Ranking Member Smith, and all distinguished members of the sub-committee – I bring warm greetings from the Africa Centers for Disease Control and Prevention (Africa CDC) and indeed from the African Union. I thank you for inviting me to testify at this hearing on COVID19 and share our experiences with preparedness and response to the COVID19 pandemic.

Africa has been battling with the COVID19 pandemic from many different perspectives including public health, social and economic sectors. The African Union has led the African response working through the Africa CDC, by coordinating preparedness and response activities across the continent. In doing this, Africa CDC has cemented its mandate and role in the health security space in Africa and globally and emerged as the premier public health agency in Africa. It is noteworthy that Africa CDC is only five (5) years old but has been entrusted with coordinating Africa’s response to the pandemic. The success of

Africa CDC translates into the success of the African Union and therefore the success of Africa as a continent.

The Heads of State and Government of Africa have shown confidence in the Africa CDC and provided the agency with political capital and some resources to coordinate response to the pandemic. They have also repeatedly reaffirmed that Africa CDC should be strengthened to improve its ability to manage disease threats. This culminated in the AU Assembly decision in February 2022 to elevate Africa CDC to an autonomous health body of the African Union with expanded mandate to manage epidemics, pandemics, and disease threats on the continent.

#### **Current situation of COVID19 in Africa**

As of March 24, 2022, Africa has experienced four (4) waves of this pandemic with each wave recording higher numbers of positive cases than the previous ones. Over 11.3 million cases have been documented cumulatively with about 251,000 deaths. Africa has fared much better than other parts of the world in terms of the number of positive cases, morbidity and even mortality.

The response to the pandemic has now evolved and vaccination has become a key tool amongst other public health measures. While initially African countries struggled to secure enough doses of vaccines, the Africa Vaccines Acquisition Task Team (AVATT) working together with COVAX and bilateral donors, facilitated the delivery of about 750 million doses of COVID19 vaccines to Africa. These doses continue to help Africa to increase the proportion of the fully vaccinate population.

The major challenge in Africa now is efficient and fast vaccination rollout to get the COVID19 vaccines into people's arms. This entails ramping up the following:

- 1) Establishing an efficient mechanism to get vaccines from the port of entry into the vaccination centers across the country. This will require an **optimal cold chain system** for the type of vaccines acquired and a **secured transportation mechanism** that will keep the vaccines safe and viable.
- 2) **Vaccination centers** that are easy for the public to reach including mobile units and opportunistic approaches that take the vaccination centers to when the public are e.g., in markets, worship areas, into the community sporting events etc. The availability of vaccinations centers in terms of numbers and reach must be nimble and adaptive.
- 3) **Community engagement** must be sustained over the rollout period and use a language and imagery that is relevant to the target audience. Local trusted individuals trained and deployed as community health workers is valuable and has been shown to be cost effective.
- 4) Utilizing **existing health infrastructure** and other public health assets already within a country ensures synergy in health programs and reduces the stress of creating new systems. A good example is the use of HIV programme infrastructure for testing and vaccination rollout. This has seen some African countries like South Sudan, Uganda and Zambia rapidly scale up vaccination numbers; and
- 5) Capacity building for all cadres involved in vaccination rollout and monitoring of adverse effects whenever they occur. Apart from optimal training, the capability of health workers to perform their duties well also needs to be improved and sustained during the rollout phase. This means that they must be facilitated with the right tools and work environment.

### **Recommendations for United States Policy and Action**

#### *Recommendation 1: Support Africa CDC's vaccination rollout initiative*

As Africa CDC has demonstrated competence in coordinating vaccination rollout in Africa, support its strategic initiatives that are aimed at increasing vaccination rollout on the continent.

*Recommendation 2: Support the use of other health assets for COVID19 vaccination rollout*

Other health programs like HIV, TB and malaria have well established infrastructure that should be deployed to increase vaccination rollout.

*Recommendation 3: Support the strengthening of the health systems' cold chain capability*

This is a critical part of strengthening health systems to ensure that vaccines are safely transported from one point to the next, in a manner that provides speed and reliability in delivery of vaccine doses.

\*\*\*\*\*

Ms. BASS. Thank you very much.  
 Dr. Soon-Shiong?  
 I think you are—oh, there you go.

**STATEMENT OF DR. PATRICK SOON-SHIONG, FOUNDER AND  
 EXECUTIVE CHAIRMAN, NANTWORKS**

Dr. SOON-SHIONG. Sorry. So thank you for inviting me today.

I am a surgeon, scientist, and have devoted my career to cancer, infectious diseases. And I was born in South Africa, which gives me unique perspective of the unmet needs of Africa.

In 1997, I launched an injectable pharmaceutical company in the United States called American Pharmaceutical Partners. And by 2017, we were manufacturing a million vials a day of key injectable products. Our company was one of the only major remaining safe supplier of a blood thinner called heparin during the heparin crisis. And this highlighted for me the urgent need for our Nation to establish and manufacture in biological capacity for national global preparedness and readiness for pandemics such as COVID.

As has been said, we are not safe until we are all safe. The coronavirus we are facing today is not influenza, as some would like us to believe. Unlike flu, this virus enters into our body through a receptor in our blood vessels. Since it uses a receptor in blood vessels, it reaches any organ of the body, including the lungs, the heart, the brain, and even the pancreas. So my concern is the long-term consequences of a COVID infection, even asymptomatic. We may be facing the next generation of concerns we do now refer to a long COVID.

My fear is the complacency of stating that today's vaccines prevent death and, therefore, are OK and that we should learn to live with COVID is misguided. Already we are seeing young people with stroke, with cardiac disease, and even with a high chance of diabetes unless we kill this virus. Once it enters the cell and reduces its load and prevents transmission, we may be faced with large increases of heart disease, neurological disease, and diabetes, all devastating for the population to the healthcare systems.

So why does this pandemic rage on 2 years in? Largely because we have not heeded the warnings that it would be inevitable and expected that the virus would mutate and that merely short-lived antibody-based vaccines as has been developed to date would become ineffective against these mutations. Rapid mutational change in COVID has now been seen as we all predicted, especially in patients who are immunosuppressed with HIV and TB, where mutations will thrive.

In Africa, we have an estimated 25 million people living with HIV and 2.5 million with TB, providing a fertile environment for viral mutations.

With each new variant, we are faced with efficacy questions. Protection is declining rapidly over months, not years. The question that remains open, therefore, is it viable to subject the population to four shots of an antibody-based vaccine, especially in Africa where cold chain issues exist and logistics of even getting a single vaccine is a problem? Could multiple boosts of a vaccine with declining efficacy and questionable potential protect against variants against which a virus can easily mutate be the answer?



While this necessitates, then, the development of a durable, broad acting pan-vaccine that offers protection against all coronavirus of today and tomorrow—and it is even more vital with Africa—I cannot emphasize more strongly to the committee the need for us to generate a second-generation vaccine that drives T cells which will kill the virus so that it does not propagate in our body and spread, the need to develop a universal COVID vaccine predicting against infection regardless of variants generated against a spike protein.

So utilizing our own resources, and unfortunately without any Federal support, we have attempted since the COVID outbreak to develop this durable second-generation vaccine and bring self-reliance in Africa to reduce risk for all.

First, we have developed second-gen vaccines across multiple platforms, some now in phase 3 clinical trials, that has a potential to be delivered at room temperature and thus avoid the cold chain issues.

Second, we have built manufacturing plants in the United States, in South Africa, and in Botswana to enable self-reliance and build human capital in Africa. I think the opportunity for our country to export know-how and knowledge transfer as diplomatic foreign policy is critically important.

Third, we have initiated the process of enhancing the regulatory authorities capabilities in Sub-Saharan Africa and are collaborating with regulatory authorities to support education and improving the standards there.

And, finally, we have acquired a large manufacturing facility in the State of New York, bringing our vaccine capability to a billion doses a year, and thus helping to establish a national preparedness for the Nation for a universal COVID vaccine and to be ready with large-scale biological capacity for the inevitable next pandemic.

So, in closing, Madam Chair, I propose three solutions which sorely need support: One, the development of a second generation, universal, durable COVID-19 vaccine; two, establishment of State-of-the-art biomanufacturing capacity in Africa, but with quality standards matching the FDA; and three, the support for a national preparedness program that addresses a universal COVID vaccine that is durable, can be stored at room temperature, and can be rapidly deployed to face any viral challenge facing the Nation and the world.

I thank you for this opportunity to present today and would be happy to answer any questions.

[The prepared statement of Dr. Soon-Shiong follows:]

Testimony of Patrick Soon-Shiong, M.D.  
Chairman & CEO, NantWorks;  
Executive Chairman & Global Chief Medical Officer ImmunityBio

Before the  
Subcommittee on Africa, Global Health, and Global Human Rights  
of the House Committee on Foreign Affairs

Entitled  
“Present Challenges and Progress on COVID-19 in Africa”

March 31, 2022  
2:00 P.M.

#### Introduction

Chairwoman Bass, Ranking Member Smith, and Members of the Subcommittee, thank you for holding today’s hearing entitled, “Present Challenges and Progress on COVID-19 in Africa.”

My name is Patrick Soon-Shiong. I have devoted my life to medicine as a surgeon, scientist, professor, inventor and philanthropist with over 500 issued worldwide patents and 100 scientific publications. I began my efforts in medicine with pioneering work on novel treatments for both diabetes and cancer, including development of the nation’s first protein nanoparticle chemotherapy for breast, lung and pancreatic cancer called Abraxane. I currently serve as Chairman and Chief Executive Officer of NantWorks, an ecosystem of companies with interests in a variety of complex industries affecting global health stretching from life threatening diseases to existential concerns of climate change. As such, the ecosystem of Nantworks companies span 3 key pillars: health and life sciences addressing pandemics and endemics of cancer and infectious disease; energy and bioplastics affecting the environment and digital infrastructure enabling secure real time communication, supercomputing networks and augmented intelligence. Under this umbrella organization, I also serve as Executive Chairman of ImmunityBio, Inc., a publicly traded biotechnology company focused on vaccines and natural killer and T-cell therapy for cancer and infectious diseases. Additionally, as Chairman and CEO of NantHealth, a publicly traded healthcare company, we are endeavoring to converge biomolecular medicine and bioinformatics with deep learning AI to empower physicians, patients, payers, and pharmaceutical manufacturers to deliver the right care at the right time.

In 2021, I established NantAfrica, Nant South Africa (NantSA) and Nant Botswana (NantBW) to establish a coalition of organizations to accelerate the advancement of healthcare in Africa with the goal of manufacturing a billion doses of vaccines in South Africa by 2025. Earlier this year, I supported the launch of the non-profit organization, Access to Advanced Health Institute

(AAHI), to continue the groundbreaking research of the former Infectious Disease Research Institute (IDRI) headquartered in Seattle, Washington on a global scale. These projects across the African continent are of particular importance to me as I was born and raised in South Africa during Apartheid. I received my medical training as well as education in South Africa, and am now a citizen of the United States living in California since 1980. In my testimony, I will elaborate on how the global community's response to the COVID-19 pandemic has been executed primarily for the benefit of resource-rich countries, leaving Africa and other low-and-middle income countries (LMICs) across the globe unprotected. The challenges that Africa faces are not unique, but they are a stark contrast to what we consider currently to be the challenges here in the United States and other resource-rich countries. Today, I focus on a critical problem: the need to increase Africa's low COVID-19 vaccination rates. The two solutions I propose are: (1) the development of a second generation COVID-19 vaccine that can stop transmission and is more suitable for delivery to hard-to-reach areas than currently available vaccines; and (2) the establishment of a state-of-the-art medical sciences and biomanufacturing industry in Africa, including infrastructure and a trained workforce.

While much has been accomplished towards the prevention and treatment of COVID-19 in the past two years, we must invest in novel second-generation vaccines and manufacturing infrastructure to bring the current pandemic to a definitive end, or at least under reasonable control, and properly prepare for the next pandemic on a global scale.

#### Support the Research and Development of a Second-Generation Vaccine

Today, Americans across the country are seeing decreasing hospitalization rates, lifting of mask mandates, and a slow return to normal. This is in large part due to high vaccination rates. In the United States, 271 million individuals are fully vaccinated -- approximately 66 percent of the total population. In LMICs, only 14 percent of individuals are fully vaccinated and another five percent have received at least one dose of the initial two dose regimen required for the mRNA-based vaccines.<sup>1</sup> In my home country of South Africa, we have 17.55 million individuals fully vaccinated—approximately 30% of the population—but in smaller, rural areas of the continent such as Burundi, only 10,000 individuals have been fully vaccinated.<sup>2</sup> This presents a basic biological problem – viruses mutate, and they tend to do so in immunocompromised and unvaccinated populations. East and Southern Africa are home to the largest population of individuals with HIV (human immunodeficiency virus) in the world, an estimated 20.7 million in 2019,<sup>3</sup> thus providing a fertile environment for COVID-19 mutations. In fact, it is believed that

<sup>1</sup> According to Our World in Data, "fully vaccinated" is defined as an individual who has received two doses of the Pfizer-BioNTech or Moderna vaccines or one dose of the Johnson & Johnson Janssen vaccine.

<sup>2</sup> Hannah Ritchie, Edouard Mathieu, Lucas Rodés-Guirao, Cameron Appel, Charlie Giattino, Esteban Ortiz-Ospina, Joe Hasell, Bobbie Macdonald, Diana Beltekian and Max Roser (2020) - "Coronavirus Pandemic (COVID-19)". Published online at OurWorldInData.org. Retrieved from: 'https://ourworldindata.org/coronavirus' [Online Resource]

<sup>3</sup> <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview>

the Omicron variant emerged from an HIV patient.<sup>4</sup> Therefore, for the world to be safe from COVID-19, vaccination rates must increase in LMICs especially those in Africa which are lower compared to other LMICs across the globe.

Unfortunately, the vaccines currently being distributed to LMICs present critical suitability and thus accessibility problems for the majority of African countries and their populations, especially the Pfizer-BioNTech and Moderna mRNA vaccines. These vaccines cannot be stored at room temperature, require multiple doses, and are only offered by subcutaneous injection.

In Africa, crumbling or lack of infrastructure, such as roads and bridges, prevents the distribution of these first-generation vaccines from reaching certain communities. Moreover, this limited infrastructure prevents individuals from traveling to city centers to access modern health care facilities where vaccines and treatments may be available. In the event vaccines do reach rural villages, the cold-chain technology - that is freezers or refrigeration - required to keep vaccines viable is rarely available. This has led to vaccine wastage and is, in fact, a challenge also encountered in the United States when freezers shut down or electrical grids fail.

Furthermore, there are lingering suspicions concerning the use of modern medicine within some African populations, leading to the discouragement of vaccination. Therefore, attempting to administer one dose of a vaccine, much less four, is a serious challenge. Ultimately, this results in vulnerable populations failing to seek medical care in a timely manner resulting in worse health outcomes and even death. While these social conditions have proven surmountable in the United States and other resource-rich countries; it is much more challenging in Africa.

To effectively inoculate the continent, Africa needs a more durable and broad-acting vaccine that is shelf stable.

In two years, we've seen dozens of variants of SARS-COV-2, including subvariants such as Omicron BA.2, which is currently a variant of concern according to the World Health Organization.<sup>5</sup> There have been five variants designated by the WHO as variants of concern to date.<sup>6</sup> As each new variant emerged, we were faced with vaccine efficacy questions. In November 2021, as the Omicron variant overtook the United States, a study from the Public Health Institute (PHI), in coordination with the Veterans Health Administration and the University of Texas Health Science Center, found that protection against COVID-19 infection declined for all vaccine types, with overall vaccine protection declining from 87.9 percent in February 2021 to 48.1 percent in October 2021. The decline was greatest for Johnson & Johnson's vaccine, with protection declining from 86.4 percent in March 2021 to 13.1 percent in September 2021. Pfizer-BioNTech's vaccine declined from 86.9 percent to 43.3 percent and

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<sup>4</sup> <https://www.latimes.com/science/story/2021-12-02/did-omicron-coronavirus-variant-arise-in-patient-with-uncontrolled-hiv>

<sup>5</sup> <https://www.who.int/news/item/22-02-2022-statement-on-omicron-sublineage-ba.2>

<sup>6</sup> <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/>

Moderna similarly dropped from 89.2 percent to 58 percent.<sup>7</sup> Even more concerning is recent data published by the U.S. Centers for Disease Control and Prevention (CDC), which shows that protection against hospitalization for COVID-19 waned even after booster doses of both Pfizer-BioNTech or Moderna vaccines were administered.<sup>8</sup>

Uncertainties regarding these emerging variants--combined with the recent research strongly indicating waning immunity from approved vaccines--necessitates the development of a broad acting pan-vaccine that offers protection against all coronaviruses, including SARS-COV-2, to protect against the variants of today and those that may develop in the future.

Additionally, this vaccine should offer a more durable immune response, a critical feature of an efficacious vaccine. Unlike childhood vaccination for diseases such as measles, mumps, and rubella that comprises an initial dose and perhaps a boost years later, Pfizer-BioNTech, Moderna, and Johnson & Johnson have received clearance for at least one booster to be administered to patients two to five months after initial dose(s).<sup>9</sup> On March 15, Pfizer-BioNTech became the first manufacturer to request authorization from the Food and Drug Administration (FDA) for a fourth dose of their vaccine for individuals 65 and older.<sup>10</sup> And more recently, Moderna has made the same request.<sup>11</sup> This points to declining protection provided by these vaccines over months, not years, and suggests the need for a vaccine that provides more durable protection.

My company ImmunityBio in partnership with the Access to Advanced Health Institute is committed to producing second-generation vaccines that can effectively vaccinate the African continent and thus the world against COVID-19.

Specifically, ImmunityBio is developing two distinct second-generation vaccine regimens. The first is a heterologous regimen comprising a unique self-amplifying RNA vaccine that is highly potent, thermostable at room temperature, and can be administered intranasally; used with an adenovirus vaccine targeting both the SARS-CoV-2 spike and nucleocapsid (S+N) proteins. The adenovirus vaccine has already been shown to induce a 10-fold increase in T-cell response in

<sup>7</sup> Cohn, Barbara C, et al. "SARS-CoV-2 Vaccine Protection and Deaths among US Veterans during 2021." *Science*, vol. 375, no. 6578, 4 Nov. 2021, pp. 331–336, <https://doi.org/https://www.science.org/doi/10.1126/science.abm0620>.

<sup>8</sup> "Waning 2-Dose and 3-Dose Effectiveness of Mrna Vaccines against COVID-19--Associated Emergency Department and Urgent Care Encounters and Hospitalizations among Adults during Periods of Delta and Omicron Variant Predominance - Vision Network, 10 States, August 2021--January 2022." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 17 Feb. 2022, [https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.htm?s\\_cid=mm7107e2\\_w](https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.htm?s_cid=mm7107e2_w).

<sup>9</sup> [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html?s\\_cid=11706:covid%20vaccine%20booster;sem.ga:p:RG:GM:gen:PTN:FY22](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html?s_cid=11706:covid%20vaccine%20booster;sem.ga:p:RG:GM:gen:PTN:FY22)

<sup>10</sup> "Pfizer and BioNTech Submit for U.S. Emergency Use Authorization of an Additional Booster Dose of Their COVID-19 Vaccine for Older Adults." *Pfizer*, 15 Mar. 2022, <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-us-emergency-use-authorization>.

<sup>11</sup> <https://investors.modernatx.com/news/news-details/2022/Moderna-Submits-Amendment-to-the-Emergency-Use-Authorization-for-an-Additional-Booster-Dose-of-its-COVID-19-Vaccine-in-the-U.S/default.aspx>

clinical trial participants.<sup>12</sup> This heterologous vaccination regimen allows the recipient to benefit from the features of each vaccine<sup>13</sup> and together, the two have been shown in preclinical models to provide some of the broadest protection against SARS-CoV-2 including variants of concern,<sup>14</sup> and are predicted to provide durable and broad protection across SARS-CoV-2 variants. ImmunityBio and the Access to Advanced Health Institute stand ready to manufacture nearly half a billion doses of this vaccine in the next six months.

Our second vaccine candidate is a protein vaccine combined with a strong immune-stimulating molecule known as an adjuvant that has the potential to provide lasting protection against not just SARS-CoV-2 variants, but future coronaviruses. The significance of this pan-coronavirus vaccine, which was recently published in *Nature*,<sup>15</sup> has been cited by National Institutes of Health (NIH) officials as an extremely important proof of concept that should be aggressively pursued in human trials.<sup>16</sup> Similar to our first approach, this vaccine could be rapidly scaled for broad deployment across the United States and around the globe. Even more exciting is the possibility that an investment in this technology could make the need to completely re-engineer vaccines for the inevitable next coronavirus pandemic obsolete – a good type of obsolescence to plan for.

As we fight to get even a single dose of an effective vaccine against COVID-19 to every person on the planet, now is the time for the federal government to double down its investment on vaccination strategies that lead to years of strong protection across multiple strains of SARS-CoV-2, and we stand ready to assist in that effort.

#### Support the Development of Africa's Biomedical Industrial Base

Today and moving forward, we must ensure Africa is making vaccines for Africa. Currently, Africa imports 99 percent of the vaccines it administers across the health care spectrum, and COVID-19 vaccines are no different.<sup>17</sup> While the United States ultimately donated millions of vaccines to African countries, vaccine donations do not equate to a sustainable nor effective solution to COVID-19 in Africa and other LIMCs. While Africa has tremendous workforce capital, the country lacks health care manufacturing infrastructure, including specific workforce expertise, and the technical knowledge on how to produce modern COVID-19 therapies. Efforts to initiate manufacturing in Africa are also impeded by international patent laws. Without assistance and coordination from private industry, local government and the international community, Africa cannot become self-sufficient.

<sup>12</sup> <https://immunitybio.com/immunitybio-announces-single-prime-had5-covid-19-vaccination-induces-a-10-fold-increase-in-t-cell-response-equivalent-to-t-cell-responses-from-patients-previously-infected-with-sars-cov-2/>  
<https://www.medrxiv.org/content/10.1101/2021.04.05.21254940v2>

<sup>13</sup> Heterologous ChAdOx1-nCoV19–BNT162b2 vaccination provides superior immunogenicity against COVID-19 - *The Lancet Respiratory Medicine*

<sup>14</sup> <https://www.biorxiv.org/content/10.1101/2021.11.29.470440v2>

<sup>15</sup> <https://www.nature.com/articles/s41586-021-03594-0>

<sup>16</sup> <https://youtu.be/YA4Qme4C5CM>

<sup>17</sup> <https://www.nature.com/articles/d41586-021-01048-1>

Therefore, in 2022, in partnership with South African President Cyril Ramaphosa and President Massisi of Botswana, we launched an initiative to establish self-reliance in SubSaharan Africa. Starting with my home country together with Pres Ramaphosa, we launched NantSA and the Coalition to Accelerate Africa's Access to Advanced Healthcare (AAAH Coalition). The AAAH Coalition unites biotechnology and pharmaceutical companies, government agencies, non-profit organizations, and academia. It harnesses expertise from science, technical training, manufacturing infrastructure, and regulatory bodies. Together, it will enable the country to sustain domestic production of pharmaceuticals, biologics, and vaccines. As part of this initiative, on January 19, 2022, NantSA officially opened a new pharmaceutical manufacturing plant in Cape Town, South Africa to manufacture Africa's first locally produced COVID-19 vaccines. Once the plant is fully operational it will be capable of producing one billion vaccine doses per year. Full capabilities are expected by 2025.

The COVID pandemic has shown that while the typical nonprofit research model often excels at innovation, such organizations typically do not have the finances or ability to scale. Partnerships with large pharmaceutical companies can provide funding and scalability for commercial use, but often not for low-resource areas of the world, thus equity suffers. To address this issue, the Access to Advanced Health Institute will serve as the nucleus for the formation of the AAAH Coalition with the mission of providing Africa access to advanced healthcare. The AAAH coalition has prioritized collaboration with reliable, trustworthy partners who share our mission and values, leveraging our immunologic platforms to create products that improve patient's lives, including in historically underserved populations.

Our parallel initiative in Botswana, in collaboration with President Massisi, the Botswana Medicines Regulatory Authority (BoMRA) and NantBotswana, has culminated with the first imminent approval of a Botswana regulated vaccine developed by Baylor College of Medicine and manufactured by BioljicE in India. This vaccine known as Pula Corbevax marks a milestone in Africa and portends to the second-generation vaccines fully manufactured in Africa by next year.

These efforts are just the beginning of a budding biomedical sciences industry in Africa where the cost of research and development of pharmaceuticals and therapies is substantially lower than here in the United States. I know this will lead to Africans pioneering innovative approaches to prevention and treatment of the world's top diseases and diseases that plague their continent – diseases that resource-rich countries no longer contend with such as Malaria, Yellow Fever, Dengue, Ebola and HIV. Attached is a briefing book that provides an in-depth overview of this collaboration.

Furthermore, to have a successful manufacturing base, Africa needs trained human capital. Currently the number of individuals with advanced scientific degrees from African universities is limited because there are few job opportunities once they graduate. As we build out the manufacturing infrastructure in Cape Town, I have also pledged to provide scholarships for 100

South African students so that they can learn Good Manufacturing Practice (GMP) and be employed in local biomedical manufacturing facilities.

**Closing**

In closing, I would like to voice concern that the United States' federal response has shifted away from the research and development of effective countermeasures at a time when we may need them most.

We simply cannot continue to rely solely on vaccines that were developed in the early phase of the pandemic at a time when both the virus and our understanding of how to prevent infection and disease have matured. There is a path forward. We have embarked on that path to develop second-generation vaccines, despite the absence of U.S government funding. It is my contention that a better future exists if the federal government acts to financially and scientifically support a second-generation vaccine that provides broad, durable protection coupled with the ability to be quickly manufactured and distributed both domestically and globally.

I want to thank the members of this committee for holding this important hearing. To ensure an end to this pandemic, we must focus on vaccinating populations such as those across the African continent, while also ensuring these LMICs begin building infrastructure and technical expertise on pharmaceutical manufacturing to be fully prepared to help themselves when, not if, the next pandemic occurs.



Ms. BASS. Thank you very much.  
And our final witness is Dr. Maria Elena Bottazzi.

**STATEMENT OF DR. MARIA ELENA BOTTAZZI, CO-DIRECTOR,  
TEXAS CHILDRENS HOSPITAL CENTER FOR VACCINE DE-  
VELOPMENT**

Dr. BOTTAZZI. Chair Bass, Ranking Member Smith, and distinguished members of the subcommittee, thank you for the invitation to testify today. I am honored.

As you know from my testimony, I am codirector of Texas Children's Hospital Center for Vaccine Development, associate dean and professor of the National School of Tropical Medicine at Baylor College of Medicine.

Our academic and children's hospital-based center for vaccine development has a 20-year track record leading and advancing vaccines for poverty-related neglected tropical and emerging infectious diseases of pandemic importance. The scientists in our center create and make vaccines right in our laboratories in Houston, Texas. We transfer our knowledge in vaccines with a philosophy that ensures open science, the removal of barriers such as intellectual property protections, and with transparent communications, to help incentivize, build, and strengthen the capacity for vaccine development locally and with foreign nations. In doing so, we guide and influence policy and advocacy through vaccine diplomacy, bridging national and international cooperation and partnerships, achieving vaccine equity and access, leading to self-reliance, solidarity, prosperity and peace.

Our model vaccine development works. We are the first center to develop a safe, effective, and affordable COVID-19 vaccine technology suitable for global access. There are five principles we use: A technology that can be produced at large scales, easy to learn, and adaptable as the vaccine needs change; a known technology by many vaccine manufacturers, including those in middle-income countries, with an existing work force infrastructure and a supply chain ecosystem; a technology with long shelf life and easy cold chain requirements for storage and distribution, affordability due to the economies of scale, and prior track record of safety and efficacy, facilitating the regulatory review and approval and leading to increased consumer confidence.

The conventional recombinant protein technology using microbial fermentation and yeast checks all these five boxes. This approach has been used for decades, producing a highly effective, safe recombinant hepatitis B vaccine for adults and children. It was also shown to be highly successful against SARS in preclinical studies.

We were able to accelerate the development of our yeast protein vaccine technology by leveraging a decade of research developing SARS and MERS vaccines, relying on transparent and high-performing partnerships, and with nimble funding, almost exclusively from private philanthropists based in Texas, New York, and elsewhere.

Corbevax, developed in partnership with India-based Biological E, has now received emergency authorization in India and in Botswana. Its production capacity exceeds 140 million vaccine doses per month. And both governments combined committed to purchase

400 million doses to date. In less than 2 weeks after deployment, more than 16 million doses of Corbevax have reached the arms of kids 12 to 14 years of age. In parallel, our technology, which has no patents, is advancing as a halal vaccine in Indonesia and Bangladesh. Yeast technology is vegan and contains no animal-derived products or human cell lines.

Importantly, our partnership with ImmunityBio and Nant in Botswana is contributing to the establishment of vaccine production capacity in Africa, setting the precedent of a scalable blueprint for vaccine development and distribution in the continent.

Corbevax has the capacity to fill the access gaps created by the more expensive vaccine technologies, rapidly reach the countries in Africa with less than 20 percent of vaccinated populations. In clinical trials, it showed superior effectiveness greater than 90 percent, including variants of concerns, with responses that are persistent against B and T cells and, therefore, is ideal for a vaccination strategy to expand access in children as a booster or second generation, and sustain the need of surplus doses.

There are four overarching needs: ensure investments for multiple technologies, sustain vaccine research and development, support and strengthen the creation of the hubs for vaccine manufacturing, invest in training the next generation of vaccine scientists, and increase partnerships with research universities, supply chain actors, and strengthen national regulatory authorities.

Thanks for your attention. Happy to answer any questions.

[The prepared statement of Dr. Bottazzi follows:]



**House Foreign Affairs Africa, Global Health, and Global Human Rights Subcommittee  
"Present Challenges and Progress on COVID-19 in Africa"**

Dr. Maria Elena Bottazzi, Co-Director, Texas Children's Hospital Center for Vaccine Development  
March 31, 2022

**I. Introduction**

Chair Bass, Ranking Member Smith, and distinguished members of the subcommittee, thank you for the invitation to testify today. My name is Dr. Maria Elena Bottazzi. I am Co-Director of the Texas Children's Hospital Center for Vaccine Development and Associate Dean of the National School of Tropical Medicine at Baylor College of Medicine. I am also a Professor in Baylor College's Departments of Pediatrics and Molecular Virology and Microbiology, Division Chief of Pediatric Tropical Medicine, as well as an Adjunct Professor in Rice University's Department of Bioengineering, the Tulane School of Public Health and Tropical Medicine and the University of Texas School of Public Health's Division of Epidemiology, Human Genetics and Environmental Sciences. Additionally, I am a member of the American Society of Tropical Medicine and Hygiene, the American Society for Microbiology, the American Association for the Advancement of Science and an Emerging Leader in Health and Medicine Scholar of the National Academy of Medicine. I am honored to testify before you today.

The Texas Children's Hospital Center for Vaccine Development ("the Center") was established in 2011 when the Sabin Vaccine Institute Product Development Partnership ("PDP") moved from Washington, D.C. to Houston, Texas. With the support of Texas Children's Hospital, the Center has become one of the leading academic- and children's hospital-based vaccine development centers in the world. The Center has acquired a national and international reputation as a non-profit PDP, advancing vaccines for poverty-related neglected tropical diseases and emerging infectious diseases of pandemic importance. In addition, the Center is committed to building and strengthening capacity for vaccine development locally and with foreign nations, which it does in part by leading global efforts to guide and influence vaccine policy and advocacy through "vaccine diplomacy" as an international bridge for vaccine equity and access leading to self-reliance, prosperity and peace.

Among other accomplishments, the Center, in collaboration with Baylor College of Medicine, signed a non-exclusive license with Biological E Limited (BioE) to develop the first low-cost and affordable COVID-19 vaccine technology for global access. The resulting vaccine, called Corbevax, received emergency authorization in India in December of 2021 and in Botswana in March of 2022. In addition, the Center has also licensed the COVID-19 vaccine technology to BioFarma in Indonesia, which is advancing a Halal COVID-19 vaccine, to Incepta in Bangladesh and to ImmunityBio to establish additional vaccine production capacity and sites in the African nation.

Beyond COVID-19, the Center has developed innovative vaccines for other emerging coronavirus infections including SARS and MERS; developed the first vaccine for human hookworm, now entering phase 2 of clinical trials; developed the first vaccine for intestinal schistosomiasis, now entering phase 2 of clinical trials; developed the first vaccine for Chagas disease, soon to enter phase 1 of clinical trials; signed and implemented historic capacity building agreements with Brazil, Mexico, Malaysia, Philippines, Botswana and the Kingdom of Saudi Arabia; and led dialogue on the vaccine education movements nationally and globally.

The Center operates at the intersection of vaccine science and diplomacy. Core to our philosophy are removing barriers to access (IP/Patents) and ensuring open science—the sharing of knowledge, data and reagents. This not only allows for the free flow of goods and technical knowledge to increase production capacity and improve scientific data access, but it also enhances national and international cooperation, which will enable us to decolonize the vaccine sciences. We are committed to promoting transparency and solidarity, while also emphasizing equity. These practices have empowered the Center to develop an unprecedented number of vaccine partnerships, with developers across the globe joining the effort and allowing us to scale-up and scale-out in parallel to our own vaccine product development.

Looking beyond the immediate COVID-19 pandemic, we will continue to work towards the scaling of supply inputs and manufacturing capabilities worldwide. We aim to contribute towards the increase in efficiency of existing vaccine development capacity, repurpose existing or unused capacity, and add new capacity. Ultimately, vaccine diplomacy requires the balancing of emerging and traditional technologies to achieve our goals of increased access and affordability; safety and efficacy; global production and consistent, trusted quality; collaborative vaccine research; and combatting global anti-vaccine activity. We strive for an ecosystem in which portfolios are aligned, opportunity-costs are identified, and development risks are shared and/or reduced. The global COVID-19 vaccine needs are constantly changing with regard to variants of concern, length of immunity, access and availability to children, need for boosters or second generation vaccines, and the development and maintenance of surplus doses. I hope through this afternoon’s subcommittee hearing, we can begin to work towards these goals, appropriately convey to the decision makers here today the urgent needs of our global community and come together around actions that must be taken.

## II. General Vaccine & Development Information

### *CORBEVAX*

As the pandemic entered its third year in 2022, the Texas Children’s Hospital Center for Vaccine Development and the Baylor College of Medicine gifted the world the first COVID-19 vaccine designed specifically for global health. This patent-free vaccine technology, co-developed alongside Biological E Limited (BioE) and called Corbevax, is a milestone for global health equity. We developed this vaccine with no major federal or G7 support, instead relying almost exclusively on private philanthropy based in Texas, New York and elsewhere.

I am proud to be a part of the team and our institution that developed the vaccine technology, that licensed the vaccine prototype and that transferred its technology in 2020 to BioE, a company based in Hyderabad, India. On December 28, 2021, the Indian regulators authorized the vaccine for emergency use, and the Indian government advance purchased 300,000 million doses. On March 16, 2022, the Indian government initiated the delivery of Corbevax across its states. As of March 29, more than 13 million doses have reached the arms of adolescents between 12-14 years of age. BioE plans to produce and deliver more than one billion additional doses to other countries. This means that if it is widely authorized, Corbevax could soon vaccinate more people than have the vaccine doses that have been donated thus far by the U.S. government or any other G7 country.

Our decade-long studies advancing coronavirus vaccine prototypes have led to the creation of this vaccine, which will fill the access gaps created by the more expensive, newer vaccine technologies and that today are still not able to be quickly scaled for global production.

*Recombinant Protein Technology*

Based on an older, conventional and more widely used technology than the now well-known COVID-19 mRNA vaccines, Corbevax uses a recombinant protein that mimics the receptor binding domain of the coronavirus spike and that is produced through microbial fermentation in yeast. This recombinant protein-based technology will enable its production at large scales, making it widely accessible to inoculate the global population. This approach has been used for decades to produce a highly safe and effective recombinant Hepatitis B vaccine for adults and children.<sup>1</sup> It was also shown to be highly successful against SARS in preclinical studies.

We are working with low- and middle-income country (LMIC) vaccine manufacturers to technologically transfer our recombinant protein vaccine. Based on the use of the Hepatitis B vaccine, we anticipate people will more readily accept Corbevax and similar recombinant protein COVID-19 vaccines than other COVID-19 vaccine types. If there was ever a COVID-19 vaccine that might triumph over vaccine hesitancy and refusal in some parts of the world, this could be the one.

*A Scalable Blueprint for Vaccine Distribution in Africa*

Our success and approach serves as a blueprint for developing a potent vaccine for pandemic use in the absence of substantial public funding. The recombinant protein technology has been successfully transferred to India, Indonesia, Bangladesh and elsewhere including the African continent, where it is being produced at industrial scales and evaluated in the clinic. We have seen that the India model has snowballed to other countries (including Botswana) and this could be replicated in other African countries, which are in dire need of vaccine access.

The need for safe, streamlined, low-cost vaccines for middle- to low-income countries is central to the world's fight against the COVID-19 pandemic and to prevent the next pandemic. Without widespread vaccination of populations in the Global South, additional virus variants will arise, hindering the progress achieved by currently available vaccines in the United States and other Western countries.

**III. Global Vaccination Efforts**

Our success in India has led to agreements with other vaccine producers, such as BioFarma in Indonesia, Incepta in Bangladesh, and most recently, ImmunityBio, enabling the strengthening of vaccine production in Botswana. By licensing our vaccine with no patents and partnering with local vaccine producers, costs can be kept extremely low and doses can be provided to as many individuals as possible—the average cost of Corbevax in India is expected to be \$2 per dose.

Just this week, Pula Corbevax was approved for use in Botswana,<sup>2</sup> and the government announced it acquired 100 million doses of Corbevax in partnership with BioE and ImmunityBio. Doses of the vaccine currently in production have been reserved for Botswana and will ultimately be locally manufactured at a factory that is being built in the outskirts of the Kalahari desert, which is to be ready by 2026.

<sup>1</sup> Hepatitis B vaccines: WHO position paper - July 2017. <https://www.cabdirect.org/globalhealth/abstract/20173352346>

<sup>2</sup> Botswana Approves Corbevax Covid Vaccine, Plans Local Output: Bloomberg News - March 2022. <https://www.bnbloomberg.ca/botswana-approves-corbevax-covid-vaccine-plans-local-output-1.1743985>

This builds off the success in India, where Corbevax, has shown in clinical trials to have demonstrated superior immune response in comparison with the CoviShield vaccine when assessed for Neutralizing Antibody Titers indicative of vaccine effectiveness of >90% for prevention of symptomatic infections and with 50% fewer adverse events. In the continuous monitoring of study participants, Corbevax also showed high persistence of immune response.

According to the World Health Organization, African countries have fully vaccinated about 15% of their adult population, while fifteen countries have yet to reach 10% of their population fully vaccinated. Twenty-one African countries have fully vaccinated between 10% and 19% of their populations, and only five countries have fully vaccinated between 40% and 69% of their populations.

While it is important to make vaccines more widely available to increase rates of vaccination, increasing the supply is an incomplete solution. Of the 714 million doses received so far, only 435 million—or 61%—have been administered. One issue is the short shelf life of some vaccines, making it so supplies cannot be procured and doses cannot be administered before they expire. There is also a lack of public health infrastructure, personnel and funding to implement coordinated vaccination campaigns, as well as a level of vaccine hesitance in the region.

#### **IV. Recommendations**

##### *Invest in Multiple Vaccine Technologies*

It is essential that investment and support for vaccine research and development is sustained to ensure multiple vaccine technologies are assessed and made widely available. There is no obvious way to predict ahead of time the best vaccine technology for any specific pathogen. For example, VSV was effective for the Ebola virus but failed for SARS-CoV-2; similarly, the mRNA approach may or may not be widely successfully beyond SARS-CoV-2. The vaccine inequities seen in the COVID-19 pandemic reminds us that producing exciting new vaccine technologies is not sufficient. It is equally urgent to maintain traditional technologies, ones that can be easily transferred and scaled up by vaccine producers globally.

##### *Support Vaccine Manufacturers in Low- and Middle-Income Countries*

We must also consider how vaccines are produced and who leads their development. The current vaccine ecosystem still depends heavily on multinational companies to advance innovations and provide safe and effective vaccines. But the fact that much of the global South still remains essentially unvaccinated, now two years into the COVID-19 pandemic, emphasizes the deficiencies of this approach. We must find ways to better engage existing vaccine manufacturers in low- and middle-income countries and provide them with adequate support and supply chains so that they can expand their missions.

##### *Invest in Global Production Hubs for Major Vaccine Technologies*

We must also look towards creating and building additional global production or development hubs for all the major vaccine technologies. This is true for both COVID-19-specific candidates and new disease targets. Such hubs must embrace mRNA, VSV vector technology, adenovirus-vectored vaccines, and VLPs emerging technologies, while also preserving the traditional approaches, e.g., whole-inactivated viruses and recombinant protein vaccines. In addition to the pediatric recombinant protein vaccines for Hepatitis B and for COVID-19, we are also now evaluating this approach for a variety of parasitic infections and other neglected diseases of poverty.

*Public Private Partnerships in Multiple Regions*

Investing in new vaccine development and production hubs goes beyond building plants and factories—successful vaccine development and production requires maintaining cadres of well-trained scientists who are knowledgeable not only about production processes, but also about quality control and assurance practices, together with detailed knowledge of the regulatory science. This also means establishing public-private partnerships between these chemical, manufacturing, and control hubs, the ecosystem of supply-chain actors and national regulatory authorities. Such partnerships should be built and funded so they function in multiple regions and low- and middle-income countries across the global South, especially in Africa, where almost no vaccine development or manufacturing is currently underway. This is not to overlook other world regions, including Latin America and southeast Asia, which also lag in many of these areas.

An expansion of vaccine science is also required for research universities in the global South. There is urgency in establishing new doctoral and postdoctoral programs, together with training in vaccine quality practices and regulatory science so a new generation of scientists can staff future manufacturing hubs in the global South. This includes the sharing of vaccine technology and manufacturing processes, to encourage collaboration with the wider scientific community.

Ms. BASS. Thank you. Thank you so much.

Let me thank all of our witnesses. And now we will go into questions, and each member will have 5 minutes.

Dr. Soon-Shiong, I wanted to know, you mentioned the need for a second generation of vaccines. And I wanted to know, where are we in that development, from your own efforts and also from the efforts that you know in the U.S. and in the world?

Dr. SOON-SHIONG. Well, we are right now in phase 3 clinical trials in South Africa. We completed phase 1 in the United States. I think the idea of the second generation is to derive vaccines that actually drive T cells. It is now very clear that T cells can actually overcome all these mutations and, more importantly, drive memory. So we are now in clinical trials both in Africa, Botswana, and United States.

Ms. BASS. Could you briefly explain the difference between that, driving T cells and the current vaccines?

Dr. SOON-SHIONG. The current vaccines are derived so that we can actually block the entry of the virus into the cell using antibodies. That has been the traditional way of actually creating vaccines. That is what we do for flu. However, this virus, once it gets into the cell, has a way to mutate, not only mutate but proliferate and transmit. So unless you can kill the cell that is infected so you prevent propagation of this virus and prevent transmission, the only way to do that is with a T cell.

So our body has T cells, and when you had COVID equivalent to about 17 years ago, the memory T cells of this virus is present so that it can kill any mutation, any virus entering. So it is a very big difference when you derive a vaccine that can kill the factory versus just block the entry, and that is the big difference.

Ms. BASS. That is a very clear description. And so what contribution, if any, does the U.S. Government contribute to this research? Is the only place that this research is happening is South Africa?

Dr. SOON-SHIONG. Unfortunately, you know, we have not been recipient of any of the support. I have supported IDRI, which is now called AAHI. We were redeveloping one, the self-amplifying RNA, redeveloping an adeno, and redeveloping, as you heard, the subunit protein with Baylor. But, actually, taking these three platforms, and you can mix and match, you have a mitigation of supply chain, you can actually derive now durable responses, and you can actually have room temperature.

So we have taken the approach that this was necessary despite the absence of support. And we have gone where we think it is needed, which is in Africa. And we have built capacity and self-reliance in South Africa, as well as in Botswana.

But I have also built manufacturing capacity in the United States. We built in Los Angeles, Chicago, Colorado, and now in New York. We have taken over a 400,000 square feet manufacturing facility so we can have a million doses available. I think national preparedness for this virus, as well as the next pandemic, is so critical for the Nation.

Ms. BASS. Wonderful. Thank you.

I would like for you to, not at this time but maybe on a second round, if you could quantify what you—what support from the U.S. would look like.



And, Dr. Ogwell, I wanted to ask you that as well, because you gave—in your three recommendations, you talked about support for the CDC, the African CDC, support for access. And I wanted to know specifically what kind of support. What specifically? I mean, obviously dollars, but I am talking about in terms of where or what.

Dr. OGWELL. Right. And I thank you. Thank you for the question.

In as far as supporting the vaccination rollout is concerned, there are three big buckets of activities that right now we are focusing on which are open for partnership. One is ensuring that there is a system of getting the vaccines from the port of entry to the vaccination centers, wherever it is they are in whichever country.

Two is ensuring that the vaccination centers are not static. They need to have mobile capacity so that we are reaching the public where they actually are, because the economic situation is such that people have to go out to look for their daily bread. And then to exchange that and go and queue for vaccination at a static health center, that becomes no choice. So they will not go for vaccination. But if you take it to them where they are, whether it is a marketplace, you know, the religious institutions, wherever, then it becomes easy, and we have seen that change.

And the third bucket is actual engagement. Vaccine hesitancy is not very high on the continent, but we need to get members of the public to appreciate that there actually are vaccines that can be able to be brought close to them. So that public engagement is where we need to be.

And as far as where is concerned, across the continent, most of the countries have this challenge. And as the pandemic evolves, we can be able to provide a clearer list based on the timing of that support.

Thank you.

Ms. BASS. Thank you.

And let me move to our ranking member, Representative Smith.

Mr. SMITH. Thank you very much, Madam Chair.

If I could, Dr. Soon-Shiong, the issue of therapeutics, which we haven't touched on yet today, I know we are talking about vaccines, and I think you made a great point about the second generation producing T cells in the importance of killing the COVID. And I am wondering if you could, are we doing enough at our own NIH to focus on that kind of capability?

Second, on the whole idea of long-haul COVID, there are a number of long-haul COVID centers in my district that have reached out because, you know, there is a growing recognition that, you know, these people who even had mild symptoms can get very sick. Matter of fact, there was a study from the University of Washington that said that long-haul COVID afflicts almost one in three people who contract coronavirus and does not seem to discriminate based on a patient's age or prior health.

So this secondary effect that is somewhat underappreciated, if you could speak to that.

I mean, in my own State district, ContraState in Freehold, has a center for the treatment of long-haul COVID, as does at Robert Wood Johnson. So if you could speak to that as to how patients in

Africa are being addressed when it comes to this other shoe dropping.

And then if you could, finally, speak to, briefly, the efficacy of the Chinese and the Russian vaccines. Have they performed well?

And I do have other questions, but I would like to get to those first.

Dr. SOON-SHIONG. Thank you. I think the first question about long-haul COVID, it has been underappreciated. And I think we really should be concerned about that. And the whole idea, as I believe, this is because of the viral load, what is happening with this virus, that actually because it enters through the blood vessels, it causes inflammation of the blood vessels, so now you have myocarditis and heart attacks, young people. You now have strokes. I have young people—a colleague who is 44 years old had a stroke. You have people with high incidence of diabetes.

So this is unlike any other virus. It has the capacity almost to act like cancer, where when it gets into you, it actually has a way to immunosuppress your body. So it is critical that now we take a different strategy of not having just an antibody-based vaccine that covers the outer part of the virus called spike. There is an inner part of the virus called nucleocapsid, the inside of the virus that allows it to replicate. And for some reason, we are the only organization, one of maybe few, going after both the outer spike and the inner nucleocapsid.

So all of the vaccines, including in China, including in Russia, including United States, have gone after the spike vaccine to try and block it because that is the general regular dogmatic way of going after vaccines. But if you treat cancer and you treat this kind of virus, you need to generate a different kind of strategy, and that is what we have been doing.

With regard to support from the NIH and even broader, Chairman Bass asked us the real direct question. One of the tragedies is we went way into clinical trials prior to COVID for cancer without vaccine, as well as then when COVID hit, we reverted the DPAS letter, which apparently only went to people that received funds from BARDA. We were denied. So other supply chain dried up. We had no access to simple things like bags, media to this very day. So we had to ration between our cancer program and the COVID program, which drove us then to find ways to create mitigation or supply chain strategy, and that was the blessing where we had recombinant protein as—from Texas. And we developed the sRNA and as well as our adenoviruses.

The other question I think you asked—I am sorry, I forget the other question.

Mr. SMITH. Well, it really was whether or not about therapeutics, but above all whether that the CDC and especially NIH were cooperating with, you know, your vision, which seems to have been somewhat bypassed.

Dr. SOON-SHIONG. Yes. I think, with all due respect, we have tried. We have gone to BARDA, NIH and made multiple presentations. And I think, you know, the—even during the Warp Speed era our pleas were not answered.

Mr. SMITH. Missed opportunity. Thank you so much for that leadership. And I hope, you know, Chairwoman Bass and I can fur-

ther take that vision. Because, I mean, you make excellent points and now it is being borne out with this long-haul COVID that—I mean, I know many people who are suffering exactly what you just talked about, strokes that you would never expect it among young people. And they are in my district, and they have got to be in Africa as well, and we probably do not know enough about.

So thank you so much, Doctor. Really appreciate it.

Dr. SOON-SHIONG. Thank you.

Ms. BASS. Representative Bera.

Mr. BERA. Thank you, Chairwoman.

I have the privilege of being a doctor as well as someone who has spent a lot of time thinking about pandemics, and certainly was in Africa post-Ebola and Sierra Leone, and chaired the first hearing on COVID-19—or at that time we did not have the novel coronavirus back in February 2020. Now it seems we are losing track of time.

And, Dr. Bottazzi, also had the pleasure in March 2020 having your colleague, Peter Hotez, as one of our witnesses in the committee I chaired.

At that time when we were learning about this, many of us were very concerned that, you know, what we were seeing in New York, when the virus got to Africa, would be devastating. Yet given, I think as Dr. Soon-Shiong already pointed out, you know, the comorbidities of tuberculosis, HIV, et cetera. And we did not quite see it play out the way we thought it might.

And, you know, I guess I would ask the panelists—and I was reading a New York Times article last week, I think, that was looking at Sierra Leone. And I was in Sierra Leone in West Africa a month ago. And it is not that COVID wasn't there, because when you look at serologic studies and, you know, antibody studies of the population, a lot of the population is showing antibodies. But it does not seem as though the number of fatalities were what we would have expected epidemiologically.

And I would just be curious if any of the panelists have any thoughts on that. Is it just that people are dying but they are just not being taken to hospitals, given the healthcare system in Africa, or is it something else that we should be thinking about studying, if there is something unique?

Dr. Bottazzi, if you want to—

Dr. BOTTAZZI. Thank you very much, Congressman. I think you are right. I think it has been challenging overall, because we knew that we were seeing how COVID-19 and the access to all these possible solutions, right? Vaccines and, you know, therapeutics, and understanding the clinical management was not trickling down to the countries that we could have prepared better seeing the experience from countries that already were suffering, right? You know, certainly starting from not only Italy, where I was born, and you know, my family really suffered through. And, you know, then later, certainly United States and other high-income countries.

And I think it is because we did not recognize, as our representative here from Africa CDC, that, you know, we have to continually strengthen the health systems. And certainly enable that not only there is an access to when these solutions arrive to those countries can be deployed, but that we can empower them—because the ca-

pability is there, we can empower them to produce them in their own way.

Thank you.

Mr. BERA. Right. Yes. No. And obviously, again, from epidemiological perspective, lots of theories, younger population that still got infected but did not suffer the mortality that, you know, older populations as in Italy or in New York City and across the United States.

Dr.—yes, please.

Dr. SOON-SHIONG. Maybe I just sort of react to maybe the science behind some of the immunology of patients in Africa. It is interesting, what we have now discovered, there is a thing called cross-reactive T cells; meaning that if you had previous infections even of coronaviruses, you may have T cells that actually recognize this COVID and actually ablate them.

The other thing is that the patients in Africa have BCG vaccinations from TB. There is now evidence that BCG in its own right generates these cross-reactive protectivity. So it is still unproven science, but what is interesting as was being very clear is that there is a cross-reactivity of T cells that can protect, and maybe that can account for some of the difference in death rates in Africa.

Mr. BERA. Certainly that was something, you know, the BCG argument, I have talked to folks at UCF and others, because there was a case to be made, we did not see it early on in India and other—in countries where you have folks with high rates of BCG and then in places like Italy or the United States where we do not use BCG. But there is speculation there.

And on the cross-immunity piece, again, early on, we would have expected to see high rates in Japan where you have an older population, et cetera, which has never really panned out. So I do think that there is more research to understand this virus from the epidemiology perspective.

Dr. Soon-Shiong has laid out a novel approach that, you know, just from my medical background makes some sense. As a virologist and someone who is an expert in vaccine development, I would ask your thoughts on the approach.

Dr. SOON-SHIONG. Sorry, Congressman. Are you asking me that question?

Mr. BERA. I was going to ask your colleague from—Dr. Bottazzi, to give your opinion on the novel approach to go after the nucleotides as well as the spike proteins.

Dr. BOTTAZZI. So we also are firm believers, like Dr. Soon-Shiong mentioned, that you really have to tackle this immunologically from many aspects. In our case, which we focus, of course, on recombinant protein technologies, we address this through formulation science, right; through, what do you pair the vaccine protein antigen with? And we have seen now from work that we have done, not only with Dr. Soon-Shiong, but also with our partners from AAHI, or IDRI, that toll-like receptors from the class of agonists of TLR 4, TLR 7/8, TLR 9 really complement really well with very conventional adjuvants such as aluminum. And then by doing also the strategies of prime boosting and—primary immunization and then boosting, like, you know what we are doing, again, with Dr. Soon-Shiong, which is bringing RNA with protein, viral vectors

with protein. Those are the strategies that probably will really accelerate, as well as bring solutions.

And, again, we do not know what works in what situation based on what microbe we are dealing with. So we need to be able to be very flexible and really adapt and use the technologies in a way where rapidly you can collaborate and fold in different scientific tools to be able to address what works well and in what moment in time during a given emergency or pandemic.

Thank you.

Mr. BERA. I—

Ms. BASS. Thank you.

Representative ISSA.

Oh, I am sorry, Dr. Bera, but we will come back on another round.

Mr. BERA. No, I was just—I was yielding back. Thank you.

Ms. BASS. OK.

Representative ISSA.

You are muted.

Mr. ISSA. OK. Here we go.

Dr. Bottazzi, your organization, your boss actually, has commented that the CDC and Operation Warp Speed could care less about the work that you are doing and that is why you had to go and get all of your funding from philanthropy. Is that an accurate statement, from what I understand, or characterization?

Dr. BOTTAZZI. So we—thank you so much, Congressman Issa. We have engaged in conversations with multiple stakeholders in the U.S. Government: the White House COVID Task Force, the State Department, USAID, you know, even the Development Finance Corporation, certainly NIH, BARDA, you name it. Very generally supportive, always telling us how we are doing wonderful work. But the reality is that it really hasn't led to any substantial financial support for our center.

In parallel, we have seen that the Quad summit has been quite supportive of Biological E. So I think that it is really how—how we haven't been given the opportunity of raising the visibility that—you know, a lot of the work that enabled a vaccine such as Corbevax really started in Houston, and in Texas, and in the United States. And I think that it really should be, you know, an honor, of course, of highlighting that we are really contributing to also, you know, the work that, you know, can come and close the gap overseas and globally.

Mr. ISSA. And I appreciate that. One question I have: What was the total philanthropy dollars that it took to develop this vaccine? Do you have a number?

Dr. BOTTAZZI. Yes. Thank you for your question. And we were actually reviewing those numbers the other day. And for the COVID-19 program, we received approximately \$5 million in philanthropy, direct philanthropy. And then maybe a couple, \$2 or \$3 million more. So a total of \$8 million in grants, but that came from philanthropic foundation organizations. A small bridging fund we got from the National Institutes of Health, approximately \$500,000.

Mr. ISSA. I do not want to call this an indictment on NIH, but you developed a lot for very little money. And as other committees are reviewing those organizations, perhaps this is a good piece to

transfer from this committee to the committees that have to look at whether or not NIH stands for not invented here or whether CDC was really giving a fair allocation of massive resources that Congress gave them.

Do you have any intellectual property protection on this vaccine? Have you applied for patents?

Dr. BOTTAZZI. No, Congressman, we have not. It really came from a philosophy of the fact that we had been working on neglected diseases for, you know, 20 years, and we want to remove barriers. The fact that we use a technology that it is, to be quite honest, relatively generic, right? Even though we do create these seed banks and this genetic engineer that does have intellectual property because our scientists are the creators, we prefer to not patent it because our mission is to really then share our knowledge and enable others to be able to learn from it.

Mr. ISSA. Now, if we are going to see this vaccine used more broadly outside of India, it is going to require both the WHO and other organizations to test it. Who is funding the testing of that? And is there anything we should be doing to expedite that?

Dr. BOTTAZZI. Yes, very good question. And, in fact, when I was mentioning of how much we are—vaccine center was able to fundraise, we also agreed amongst our partners that we would delink the way that how the vaccine program would move forward. So, for example, BioE did not have to fund us, nor we had to, of course, fund them. But each of us had that ownership or accountability. And BioE, fortunately, for the Quad summit, they did receive some help from the U.S. Government, but they also had to tap into other global sources and their own country and their own internal moneys.

So I think that, you know, it is again that there are many ways that probably you can break this paradigm. But it is clear that the inequity also on who decides where the funding should go to diversify a portfolio of solutions is where we struggled a little bit.

Mr. ISSA. Well, I want to thank you for the work you have done, because most of Africa has had to put up with Sputnik and other untested comparatively and questionable vaccines. So the fact that there is one that has American confidence behind it is welcomed.

And, Madam Chair, I appreciate this hearing, and yield back.

Ms. BASS. Well, Mr. Issa, before I move on to Mr. Phillips, let me just suggest that since we are in appropriation season, maybe it would be an opportunity for us to do a bipartisan letter calling on you—know, calling out these issues.

Mr. ISSA. It would be most welcome. Consider me signed on. Let me know where.

Ms. BASS. OK. Wonderful, wonderful.

Mr. PHILLIPS.

Mr. PHILLIPS. Thank you, Madam Chairwoman. And greetings to our wonderful witnesses. So grateful to all of you. I was hoping to compliment President Masisi on Botswana's remarkable vaccination rate, which is unique amongst African countries, of course.

But I will direct my first question to you, Dr. Ogwel. How did Botswana become so successful vis—vis its neighbors in administering the vaccines? What tactics and techniques and strategies could we all learn from?

Dr. OGWELL. Thank you, Representative Phillips.

Botswana did three things, which may be not so unique, but they did them well.

One is they used very effectively their traditional systems. They have communities that have chiefs, and they live within relatively well-defined areas. So using those traditional mechanisms, they could reach out to literally every Botswana, wherever it is that they were. So they used this system very effectively.

Second is Botswana started the vaccination drive very early. They did not wait to have loads of vaccines to be able to go out and do very effective community engagement. So the public was sort of waiting for the vaccines to be able to come, and this made uptake much faster than if the public had not been engaged.

The third thing they did and they did very well is they constantly were seeking out vaccines. Even when vaccines were not very easy to come by, Botswana was out there engaging with the Africa CDC, the African Union to try and get as many doses as was possible. So they invested their own money in getting extra vaccines.

The final thing I must add is that they utilized public health systems that were already in play. As you know, Botswana has a very relatively high prevalence of HIV during the time that it was very divided to the continent, and they utilized those mechanisms and that infrastructure to be able to get the vaccines out to the public.

So this is some of the things that they did and they did very well, and I think it is a good example not just for Africa, but for elsewhere as well.

Mr. PHILLIPS. Absolutely. Thank you.

And which brings me to my next question, which is about youth. You did not mention the engagement of the young people to be Ambassadors in their own communities. Are there examples of youth being engaged to become Ambassadors and advocates for vaccinations, considering their influence in so many communities?

Dr. OGWELL. Absolutely. In fact, we have just launched what we call the Bingwa Initiative. Bingwa in Swahili means "champion," and this is purely for the youth. And we are rolling this out across the continent, getting the youth to speak to the youth, and getting champions within the youth to be able to drive that agenda.

One example that I would like to mention here is more local, where they used the youth and technology very effectively to get them out to get vaccinated, and they did this very early in the vaccination rollout, and the numbers that they are showing for vaccination are very good, and we are trying to adopt that onto the whole continent.

The youth are the least vaccinated on the continent, and they are the next target that we are aiming at in improving the vaccination rate on the continent here.

Mr. PHILLIPS. Wonderful, and I appreciate that.

Before my time expires, I would also like to question you about food insecurity. Of course, the war in Ukraine is affecting food supplies, surely will affect them around the world. How is it doing so right now in Africa? Anything you might share with us, either what is occurring now or what you might be concerned about because of the war?

Dr. OGWELL. We are already seeing the effects of interrupted supply, and across the continent, for example, the price of staple things like bread and wheat products are suddenly just going up. Oil, vegetable oils, those are just going up, and this is expected to become worse in the coming days, certainly very much and directly related to the conflict that is going on in Eastern Europe.

Mr. PHILLIPS. And is there anything that we, the United States, can do to ensure that our aid dollars are directed to the places that need it most and for the reasons most needed?

Dr. OGWELL. Yes. And I mean, my—being from Africa CDC, I will say that we need to bring the pandemic under quick control—

Mr. PHILLIPS. Yes.

Dr. OGWELL [continuing]. So that the health issues do not bog down economic recovery, and this will be a very good place to invest. As I was saying, the idea of the vaccination rollout and us strengthening infrastructure that is going to support not just this pandemic, but any other epidemic that may be able to come in the future, these are very good areas to invest and ensure that people are healthy enough to go out and do their economic activities devoid of any health challenges.

Mr. PHILLIPS. Thank you, sir.

And with that, Madam Chair, I yield back.

Ms. BASS. Thank you.

And I will call on Representative Omar in 1 second. But, Representative Phillips, maybe one thing that we could do would be to help more African countries grow wheat.

Mr. PHILLIPS. Yes, exactly.

Ms. BASS. So that African countries do not have to import.

Mr. PHILLIPS. And representing a State and district that does a lot of that, I am happy to make some connections.

Ms. BASS. All right. Thank you.

Representative OMAR.

Ms. OMAR. Thank you, Chairwoman.

And I cosign on helping Africa grow more wheat. Countries like Sudan import 50 percent of their wheat from Ukraine and Russia, and they are going to feel the impact of this war.

Again, I want to thank you so much, Chairwoman, for holding this important hearing and thank our witnesses for their incredible testimonies.

I would like to direct this question to Dr. Ogwell. I would like to ask you about how the pace and delivery of vaccine donations is impacting the public rollout. Last year the AU and the Africa CDC and COVAX criticized the pace and manner in which vaccine donations have been provided to Africa.

As I understand it, the unpredictability of shipment, coupled with extremely complicated but necessary storing and delivery processes, isn't allowing communities enough time to operate the needed outreach and public campaigns to reach those that need the vaccines. As a result, the supply chain can become extremely backlogged, the cold chain equipment strained to capacity, and worst-case scenarios, some of the vaccines could actually go unused because of expiration. In fact, the Africa CDC requested a month-long pass in February of this year.



Dr. Ogwell, could you speak to some of these challenges and to what extent they can be remedied?

And how do you think these issues have impacted vaccine hesitancy?

I am really interested in seeing how the U.S. Government and international partners can help with these issues.

Dr. OGWELL. Thank you, Representative Omar.

And let me start with the last question around hesitancy. We are not seeing high levels of hesitancy on the continent. It is not the problem. The problem is the vaccines need to get to the public, and the public are not coming to the static health facilities. So we need new strategies that get the vaccines to where members of the public are. And that is one very opportune area of investment of getting the vaccination rollout initiative that we are rolling out at the Africa CDC to reach the public where they are, whether that is in the marketplaces, in the schools, in the religious institutions, CDC. Wherever the public will be, that is where we go.

Now, when we look at acquisition of vaccines during this period when vaccines have been available, right from the beginning, sometime in the middle of last year when we were really urging availability of vaccines early on the continent, it was difficult to come across those. And, unfortunately, we saw a situation where, by the end of the year last year, we were still getting trickles of vaccines.

Now, the flood came early this year, where we were getting donations and where we were going to purchase the vaccines were becoming more available, and the system of absorbing those vaccines are not strong on the continent.

So you end up with a situation where you have donations coming in. The vaccines that African companies have purchased are coming in. And at the same time, the system is not absorbing enough, so you end up with a lot of idle capacity in as far as vaccines are concerned.

So what we need to do, and what we are working very hard at Africa CDC to do is, one, to encourage a pause in the donations, because we need the vaccines, but we do not need them now. We need them later on, probably in the second quarter of the year, because of fixing the vaccination rollout capacity. We are not saying do not donate; we are saying donate a bit later so that we fix what we have already.

And if we do that, then we can be able to ensure that we reach members of the public where they are, we get the information over to the members of the public that the vaccine is still safe and they are still useful, and also to get those who have been vaccinated to get boosted.

So we see the investment earlier is the one of vaccination rollout, and sent to the health systems so that any future vaccines that will come we will also be able to easily get to the public.

Thank you.

Ms. OMAR. Yes. I recently learned about the Kitengela, the national vaccine depot in Kenya which operates a very complex, cold storage facility and delivers vaccines to people across nine counties. Yet, during the rainy season, one road leading to the depot is often washed out, shutting down these critical and crucial efforts. And when I was just in Liberia, the CDC director there was talking

about some of these infrastructure challenges, and I know that we cannot have a comprehensive discussion about these issues without talking about some of the infrastructure challenges that exist.

What are some that you have noticed and ways that we can help some of these African countries address their infrastructure issues?

Dr. OGWELL. Two that are very much related to vaccination roll-out are, one, the cold chain system. We have very good cold chain facilities in the capitals when the vaccines arrive, but then getting the vaccines to a storage facility outside into the rural areas becomes a challenge.

So it means that small doses, small numbers of doses are being sent to the rural areas, and that leaves people out to queue to get the small doses, while the facility in the capital is having a lot of doses. So fixing that cold chain is extremely valuable and one area of investment.

Second is ensuring that we can be able to get the communities to understand the importance of vaccination within their own context. A lot of the messages that we are having now are very, very broad, and addressed relatively well-educated populations. But if you get the community health workers to be out in the communities, engaging with members of the public, then they would be able to translate that message in their own local context, using their own cultural idioms and imagery, and that would be able to encourage more people to get out and get vaccinated.

So these are two really big areas for partnership and investment that would really help vaccination rollout very rapidly.

Let me add one thing that—

Ms. BASS. Let me move on to one other person, but we will come back around, OK?

Dr. OGWELL. That's fine.

Ms. BASS. We are past time.

Ms. OMAR. Thank you, Chairwoman. I yield back.

Ms. BASS. Sure. Absolutely.

Representative JACOBS.

Ms. JACOBS. Well, thank you, Madam Chair.

So, Dr. Ogwell, I would actually like to followup on some of the questions from my colleague, Congresswoman Omar. I know that, you know, she talked about a lot of the challenges related to vaccine distribution and delivery, and one of the starkest issues being supplies and logistics. And you just spoke about the logistical and supply challenges different countries have faced, but I was wondering if you could talk about the flip side.

Can you speak to the infrastructure and cold chain systems some countries have built over the past 2 years? Representative Omar mentioned Kenya, who has made remarkable process in training its health workers in vaccination and cold chain systems. So which countries have been able to do this, and what do those countries need to make sure they can make the best use of the infrastructure they have spent 2 years building?

Dr. OGWELL. Thank you, Representative Jacobs.

And I will give three countries—many more have done a lot, but there is three standouts. One is Uganda, second is Zambia, and third is Rwanda. They have utilized the existing infrastructure for different public health and primary healthcare programs that they

have in the country, and upgraded them with a cold chain infrastructure that has enabled vaccines to be able to reach the rural areas. And the result has been a jump in the number—the percentage of vaccinations. Uganda, for example, was in the 6–7 percent, but right now it is above 25.

So the utilization of existing infrastructure and revamping it has resulted in the cold chain industry in these countries really going up in a very fast way.

So a very easy way of trying to get the cold chain system up and running would be to check what is already in existence, because you already have immunization programs in each and every country. It is just that now they are not being used. They are laying idle while we are trying to fix a new system for COVID-19. We need to use infrastructure that we already have, and that has been shown in those three countries that I have given an example of.

Ms. JACOBS. Well, thank you very much.

Dr. Soon-Shiong, I want to talk a little about the CorbeVax vaccine. Obviously, if this can be widely manufactured and distributed among low-income countries across the African continent, it would be transformational as I think we've heard you talk about today. But which countries do you expect would be prepared to take this new vaccine on and what would that timeline look like?

Dr. SOON-SHIONG. Well, first of all, thank you for the question.

The answer is every country could take this on, including our own country, and what has happened as you heard in terms of who was funding the trials, I think the question that Dr. Issa, Congressman Issa asked, we are funding the trials actually.

And so, not only the CorbeVax vaccine, which is the RBD plus an adjuvant, we are funding the next generation COVID vaccine where the adjuvant is actually from 3M, which is a better adjuvant even.

So not only are we funding those trials, we actually are funding—we actually have both GMP manufacturing in the United States and soon you will have full GMP manufacturing in Botswana, and also in South Africa, so the ability to actually create this is not only very real.

Let me just speak, however, to this whole conversation that has been happening in the last 30 minutes about the cold chain. I think that is actually the wrong root cause. The root cause is not the cold chain. I do not think fixing cold chain with the electricity issues and the power and the infrastructure is the answer actually. It is actually fixing the vaccine that does not require cold chain is the root cause, and that is the problem. And we need to solve that, not only with this current CorbeVax vaccine, but the vaccines coming along with the saRNA which is actually stable at room temperature. I think that is the root cause, and this idea of thinking that Africa with its power, electricity, coal-generating plant problem can actually have cold chain is actually the wrong way of actually putting resources together.

The second thing, with regard to the opportunity here is exactly as was spoken, we need to bring it to the community. And in South Africa, I am working with 67 mobile vans in the South African government bringing the vaccines to where the community is, and we are developing that.

The third thing, with regard to the food insecurity, is not just the food insecurity, but water. So I am already working with South Africa developing, actually, ways of extricating water from the atmosphere to actually generate the water.

So these are what I call root solutions to root causes, and I think what I am concerned about is we look in the wrong direction. The vaccines should be T cell-based vaccines, not antibody-based vaccines. The vaccines should be room temperature-based vaccines, not minus 80-degree vaccines. And then in regard to the food insecurity, we need water.

So these are the things that we are developing, and I am pleased to say the reason we brought Pula Corbevax to Botswana, President Masisi asked me to be his health advisor. And one of the things we brought to Botswana was not only the manufacturing, but working with Biological E and Texas Health and, you know,

[inaudible], we developed this program. And now the next generation of this RBD we will be using a 3M product, and, again, now manufactured fully in Botswana.

So all of these products are fully manufacturable in Africa for Africa by Africans, and then gives themselves self-reliance.

Ms. JACOBS. Thank you so much.

Madam Chair, I yield back.

Ms. BASS. Thank you, Representative Jacobs.

Now let me invite Representative Jackson Lee.

Ms. JACKSON LEE. Madam Chair, let me thank you so very much to you and the ranking member, Congressman Smith, for—with a little bit of humor, bringing me back.

Ms. BASS. You are always welcome here.

Ms. JACKSON LEE. I am warmed by the work of this committee, and have great respect for your work and you, and as you well know, we have done this over the years, and I am glad to now, after the pandemic, join you on a very, very important issue.

Let me acknowledge all of the witnesses that are here, and particularly welcome Dr. Bottazzi, who is the codirector of the Baylor Children's Hospital dealing with vaccine technology. And I would like to just put a little bit on the record that that facility is very, very unique because it has dealt with poverty-related neglected tropical diseases which find themselves both on the continent of Africa and other developing communities. The diseases are such as hookworm, and now this team has created a low-cost vegan vaccine, effective COVID-19 vaccine for low-income countries.

So Dr. Bottazzi's partner, as I understand it, is Dr. Hotez, who I have worked with for many, many years, and this has been something that he has spearheaded, joined by Dr. Bottazzi, and they are now in India, and it is produced by Biological E where it is known as CorbeVax, and CorbeVax now has been given to more than 15 million children and adolescents in India for its first 2 weeks of a rollout campaign. And now the leadership of Botswana plants are underway for 100 million doses, and the hope is more than 1 billion doses will be made to address global vaccine inequity.

I wanted the committee to know that, and I wanted to acknowledge Dr. Bottazzi for her presence here. She and Dr. Peter Hotez make a very powerful team.

I had the privilege of meeting the President of Botswana in Houston as he was being introduced to this unique vaccine which there is a commitment to produce it in Botswana, and I think it can be one of the first steps, among many, to deal with this issue.

So let me ask, Dr. Ahmed Ogwel, your view of vaccines being produced on the continent, and the importance of being able to have access in any number of countries to treat and to vaccinate Africans with the produced vaccine already there.

Dr. OGWELL. Thank you, Representative Jackson Lee.

Local production of vaccines, indeed any other health product that we need in an emergency response, is a very high priority for the African continent. And this is a lesson we have learned because of the disruption of supply chain when you have something as big as a pandemic happening across the globe.

Our local production is an ambition that we have made into action, and as you have heard, there are many countries that are now in the process of setting up facilities to produce vaccines on the continent because right now we only have 1 percent being produced. We import 99 percent. Our ambition is that by 2040, we will be manufacturing 60 percent on the continent and only importing a maximum of 40.

So the local production will ensure that we can be able to have the vaccines and other products more easily available because it is within the continent. If anything is happening elsewhere in the world, it does not disrupt that supply chain.

The only thing that we need to fix is how do we get the markets to actually purchase the vaccines here on the continent, because a lot of the vaccines are being purchased through facilities that—

Ms. JACKSON LEE. Thank you so very much.

Let me quickly ask Dr. Bottazzi and Dr. Soon-Shiong, if I pronounced the last name right, are your vaccines mutually exclusive, or do they find a way of complementing each other, one blocking, as I understand—attacking the T cell, if I understand, and the other one blocking?

Dr. Bottazzi?

Dr. BOTTAZZI. Sure. Thank you.

Ms. JACKSON LEE. And if I could get Dr. Soon-Shiong to answer as well.

Dr. BOTTAZZI.

Dr. BOTTAZZI. Thank you. And thanks, Representative Jackson Lee, for being here.

It is very complementary. I think Dr. Soon-Shiong already mentioned that we are even having to continue improving our vaccine technology, complementing it to look for, you know, temperature stability, including additional adjuvants, including additional strategies that could potentially even combine different technologies. So I think it is the way to go. It is the future of vaccine development.

Ms. JACKSON LEE. Dr. Soon-Shiong.

Dr. SOON-SHIONG. Well, we have actually published this, what we call mix and match, so the opportunity to take an antibody-based vaccine added to a T-cell vaccine as a prime and a boost has shown potent antibodies, potent T cells and, most importantly, memory T cells and memory B cells. So this has now been shown pre-clinically, and we are in trials.

What is exciting is if you combine that with room temperature and maybe even nasally administered, you now find the holy grail where you can have a durable vaccine, a mix-and-match vaccine, room temperature vaccine, and durable long-term protection as universal COVID.

We are there, I think, very much there from a science perspective. What we need now is to have the vision and leadership and funding and support to make this available to the world.

Ms. JACKSON LEE. Madam Chair, thank you so very much. I hope you will count me as trying to encourage our government to jump and leap into the funding partnership that can help both of these scientists to go even further to help our friends on the continent and elsewhere.

Just a personal note to congratulate Dr. Bottazzi and Dr. Hotez for being nominated for a Nobel Prize for their work, and I think that should be on the record. They are a team, Dr. Peter Hotez and Dr. Bottazzi, and I hope that we will be able to have him as a witness in the near future to complement his outstanding and excellent partner.

With that, Madam Chair, I will yield back with the many, many questions I still have, but thank you.

Ms. BASS. And you are welcome to stay because we are going to do another round. So with what you shared, I guess we will come back looking for you for your signature.

Ms. JACKSON LEE. Yes, you will.

Ms. BASS. Dr. Soon-Shiong, just a quick question, and then I am going to go to Mr. Smith.

If an individual has had four shots, which I guess we are on our fourth shot now, of Pfizer or Moderna—I understand that the vaccine that you are proposing acts differently on the body, so I am assuming that there would not be a problem to go from Pfizer to the vaccine that you are proposing—I guess that you are developing?

Dr. SOON-SHIONG. Thank you, Madam Chair.

On the contrary, frankly. We have actually looked at the blood of patients or subjects or healthy volunteers that receive just the current approved vaccines and look at the T cell—what you call T cells in the blood. There is a test called the ELISpot. We find very little T cells.

When we have looked then at subjects who have received both the Pfizer and our vaccine, we see not only the antibodies, but we see potent T cells and potent T cells to both the outside of the virus as well as inside of the virus called the nucleocapsid. What is exciting is that that portion of the virus on the image of the virus does not mutate because if it does mutate, it cannot replicate.

So by having T cells as well as antibodies, and what we call this mix-and-match opportunity of a prime and boost, we really can now answer basically long-term durable protection, rather than having four shots of an antibody vaccine that continues to wane, and really almost chasing your tail with the variant. So, yes, the answer is the combination of a boost is a reality.

Ms. BASS. Thank you.

Mr. SMITH.

Mr. SMITH. Thank you very much, Madam Chair.

You know, the idea of a monopoly of thought by, whether it be CDC or NIH, often precludes wonderful ideas like what you are talking about, Dr. Soon-Shiong, and I find that to be very disturbing.

You know, over the course of my career, I have been in Congress 42 years. The first amendment I offered in Congress with Tom Daschle was to make Agent Orange and its contaminants

[inaudible] Compensating service connection disabled so the people receive some compensation and some help. It failed because there was a consensus at DOD and IOM and elsewhere that it was not causing the deleterious effects in veterans that we said. Ten years later it was all accepted.

I offered the Persian Gulf Illness Bill, and we were being told it was just anxiety that was producing these symptoms, and so, my bill did become law, but you keep learning that we push aside something that does not fit a narrative and good ideas are lost.

So I want to thank you for what you are doing, Dr. Soon-Shiong. If you could provide all of us—I think it would be helpful for the record—how BARDA and others precluded your participation, and you said it went right back to warp speed, so it is right from the start, I think that is very important for us to know that and also to have a lessons learned. And I do appreciate the great work you are doing there.

Let me also say, even on Lyme disease, I chaired a Lyme disease caucus—in 1998, I had a bill that wanted to bring Lyme literate doctors into the equation because people were saying take 1 month of Doxycycline and you are cured, and that is not true. We finally got it a few years ago, and everyone said, Oops, we missed that. But there was a monopoly on the thought, and even Dr. Fauci was a part of that back then.

So I thank you if you could make that available to us.

Second, your views—and this would go to all three of our very distinguished witnesses and experts—on the Administration of vaccines to children, which seems to be somewhat open-ended as to how safe and efficacious it is, how young—I would and I think my colleagues would love to know what your expert opinions are. And, very briefly, Chinese and Russian vaccines, do they compare? Are they as good, equivalent to those like from Pfizer, Moderna, AstraZeneca? And I do have a letter—thank you.

Dr. SOON-SHIONG. Thank you, Congressman. I certainly will provide that information.

Mr. SMITH. Thank you.

Dr. SOON-SHIONG. With regard to children, I think it is very important—you know, we begin to see, unfortunately, even unvaccinated children and deaths in young children. So I think, like every other vaccine, it is really, really important that once demonstrated to be safe in children that children get vaccinated.

The good news, the CorbeVax vaccine at least I know now has been put into, as I said, 15 of 16 million children, but, more importantly, just been approved I think from 5 to 11 years.

With regard to the Chinese vaccines and the Russian vaccines, the Sputnik vaccine, unfortunately, there is very little publication to really—for me to as a scientist to give you a definitive idea. The hearsay is, unfortunately, it is less effective because, one, it is first

generation, what we would call adenovirus, which you and I have antibodies against first-generation adenovirus.

And then, second, it is, again, the spike vaccine against the antibodies that wane. So, unfortunately, the material that is being sent to Africa has been a lot of the Sputnik, as well as the Chinese vaccines, which has not been as effective.

Mr. SMITH. Would the other experts, witnesses, like to answer or weigh in on vaccines for children and the efficacy of the Russian and Chinese?

Dr. BOTTAZZI. If possible, Congressman, I can comment just to expand on what Dr. Soon-Shiong mentioned about CorbeVax that, indeed, we know Biological E, it is advancing with studies from 5 years of age and above. We, of course, behind the scenes, have seen the data. I think the regulators are doing their final review in India to extend then the authorization, which I think is wonderful news because it will, of course, you know, also benefit that age range of population. Indeed, they are going to be evaluating them below the 5-year of age. I think it is also important to recognize that we can look at below the 5-year age to evaluate their safety.

And I think I concur with Dr. Soon-Shiong that, you know, as scientists, we do not have a lot of data with regards to the other vaccines, but it is clear that we are seeing, based on how Omicron has taken over, how reinfections and infections are going on in areas where we know primarily were being vaccinated with these poorly activated vaccines that, clearly, vaccines such as CorbeVax and other strategies have to come in and rescue, and rescue them as certainly boosters, and ideally to also confer more durable and long-term protection, both as Dr. Soon-Shiong mentioned in the not only humoral antibody but also cellular responses.

Thank you.

Mr. SMITH. Thank you so much.

Dr. Ogwell?

Ms. BASS. How about I move on?

Mr. SMITH. OK.

Ms. BASS. Thank you, Ranking Member.

Dr. BERA.

Mr. BERA. Thank you, Madam Chairwoman.

Dr. Bottazzi, for the CorbeVax, what price point—what is the cost to produce?

Dr. BOTTAZZI. Thank you for that question.

So we, based on certainly ourselves' experience of seeing how much hepatitis B vaccines cost around the world, and because of the type of supply chain and components that recombinant protein vaccines have, they usually range below the \$2 per dose. Now we know that Biological E which, of course, you know, established those price points with their own governments and on the basis of their negotiations, have now also shown that CorbeVax in India is less than \$2 per dose.

So I think that it is something that is very aligned to the platform that it uses. We could possibly go even lower, but as you know, adjuvants, especially new proprietary adjuvants, may be the ones that are increasing the cost. But for the most part, all of the components are not only widely available, the cost of production uses reagents that are usually very affordable, and that is inherent



in the way that we designed the technology to ensure that we minimize by using very standard industry, you know, procedures that we know that they would have access. Therefore, we do see the cost of the goods.

Mr. BERA. In your clinical trial data, what was the efficacy—and, obviously, the safety profile was good, in terms of efficacy?

Dr. BOTTAZZI. Yes. So I can speak for what—now we know there is a couple of publications that Biological E has already uploaded in the med archives while they are being peer-reviewed, but the clinical strategy that they did ultimately ended up in a phase 3 trial as a superiority trial comparing CorbeVax with Covishield. Covishield is the AstraZeneca vaccine produced in India, and it showed superiority, so it met the superiority standards. And based on the correlates of protection that Moderna and Pfizer uses with regards to neutralizing antibodies, it showed greater than 90 percent efficacy against the original Wuhan virus, but more than 80 percent protections against Alpha, Beta, and Delta. And now we know also behind the scenes that it is still holding up pretty nicely against Omicron, and I think that Dr. Soon-Shiong can attest to that because he has seen some of this data.

The great news is that it also was superior in safety. It showed, again, as comparison that 50 percent less adverse reactions were observed when CorbeVax was used with regards to safety signals. So we are very confident that it is superior.

Mr. BERA. And for CorbeVax, for manufacturing capacity, it is older technology, so you can tap into global manufacturing fairly easy, as compared to mRNA vaccines?

Dr. BOTTAZZI. Absolutely. And, in fact, what we did, we evaluated the entire world ecosystem of who makes hepatitis B vaccines, and that is how, in addition, of course, of working with Biological E, we are working with Biofarma in Indonesia, who is, right now, finishing up their clinical development, and hopefully they will have their Halal approval this summer. We are working with groups like Incepta in Bangladesh. And as we mentioned, we are also now working with Botswana and the group from ImmunityBio and Nant to also then bring that capacity to the African continent. In addition, we are in conversations with Argentina, with Mexico, with Panama, with Colombia, with Vietnam.

So this is, you know, not only those who can make it, but those who want to learn how to make it. Protein-based vaccines can really serve as the base because if you learn how to make that conventional traditional platform, then they can bounce off and collaborate among vaccine manufacturers. You know, I think it is a good way to certainly start building the capacity.

Mr. BERA. So we in the United States have been using the COVAX facility as a mechanism to get vaccine distribution. Has COVAX taken a look at your vaccine?

Dr. BOTTAZZI. That is a very good question.

And so all of the manufacturers that we work with have an aspiration and certainly have prior track records of having their vaccines pre-qualified, which is one of the requirements, of course, to be able to be then received by COVAX and then COVAX distributed.

So all of these manufacturers are working with the World Health Organization through their systems of how to get them to the process. At the same time, they are working with stringent regulatory agencies. For example, Biological E is working with the Australian regulatory body, TGA, mostly also because it is part of the Quad Summit Agreement that Australia was going to support the regulatory framework to, you know, enable CorbeVax to also reach other countries, such as the small Asian countries supported by financiers like the Asian Development Bank, for example.

So there are parallel mechanisms that would also enable the quality stamp so that it can be much better received by not only the end consumer but certainly the countries that, you know, are aspiring to receive the vaccine.

Mr. BERA. Madam Chairwoman, thank you for indulging. If I could last one last question?

Ms. BASS. Go right ahead.

Mr. BERA. Given, let's say, at a \$2 price point—and I am guessing that Pfizer is at—the mRNA vaccines are at about the \$20 price point in purchasing?

Dr. BOTTAZZI. I believe that based on what I have seen in the UNICEF tracker, that is approximately—you are correct.

Mr. BERA. So we—and efficacy is very similar, and we as the stewards of the American taxpayer are to make a decision on how we can purchase and ramp up as much as possible. And it would be very difficult for other countries to quickly stand up and run production facilities that they will be starting from scratch. We, as the U.S. Government, ought to be looking at, you know, CorbeVax and others. Would that be an accurate statement?

Dr. BOTTAZZI. We would be honored to find a partner within the United States that could—similar to what we are working already with Nant and ImmunityBio, could enable possibly the access of producing more vaccines that could even be eventually then evaluated within the regulatory framework of the United States. I think it will come and certainly address the hesitancy gap that we are seeing in the U.S. It may increase the access, especially for pediatric vaccinations, and give an option also for booster strategies within not only the U.S., but maybe even other countries like Canada or even European countries that may find a value of bringing an alternative technology.

We just need to, of course, not only—our priority, Congressman, is low-, middle-income countries, right, that we need to bridge that gap. That is the ultimate, you know, essential because we want to really block this virus to continue mutating. But there is a huge value of also being able to do this with partners here in the United States and other countries.

Mr. BERA. Dr. Soon-Shiong, it looks like you had a question.

Dr. SOON-SHIONG. Yes, I just want to react to that. You now, quietly behind the scenes, we have actually built that GMP facility both now in Colorado, and now just acquired a massive facility in Dunkirk, Buffalo, New York, so that this CorbeVax-type recombinant protein, together with the next generation adjuvant can be made.

So that is a reality now. We are doing this, again, without any support, without any financial support, and the opportunity for us

to create this national preparedness and, as you heard, 100 million doses per month is a real easily scalable opportunity here.

I have then taken that same opportunity and gone into Capetown and gone into Gaborone, and the two plants are already there now in which we are doing the same thing.

So I think you are right. I think we are—the Congressman talked about, you know, the dogma of thought, and the absence of, you know, looking beyond the opportunity is really frustrating from our perspective. But the good news is we have taken action, and we have now both a large scale GMP facility in the West Coast as well as the East Coast of the United States.

Ms. BASS. I am going to go to Representative Jackson Lee, and then we will wrap up with the ranking member.

Ms. Jackson Lee.

Ms. JACKSON LEE. Thank you, Madam Chair.

And the previous discussion was insightful and inciting, almost got a medical school tutorial there. It was extremely informative.

But let me pose the questions to, again, our scientists, Dr. Soon-Shiong and Dr. Bottazzi. How important—I am reminded of the efforts that we made in Houston with Dr. Peter Hotez and your team, Dr. Bottazzi, to reach out to the

[inaudible] Construct in the past Administration, and it was extremely difficult and nonresponsive. Seemingly, over and over again, we attempted to get them to understand the importance of the work being done.

But let me say to both of you how important is it for there to be some governmental, Federal Governmental partnerships in the work that you are doing?

Dr. Bottazzi?

Dr. BOTTAZZI. Thank you, Representative Jackson Lee.

I think it is very important. It is very important because, ultimately, it really brings the sustainability, you know, and the shared responsibility and accountability of enabling that these types of solutions eventually reach the people that are in need. And we are very appreciative and very excited to be working with groups such as the group from Dr. Soon-Shiong. But, ultimately, you know, it is all leaving the responsibility to the private sector, and I think we need to break the paradigm where if we want to see progress, we need to not only bring the government, bring certainly the research academic institutions, bring all of the different stakeholders to diversify and balance the way that we do science, and really change this paradigm and look at it where not only the big multinationals have the capacity or the interest, but, clearly, even from the roots of, you know, a research center in a children's hospital in Texas is able to play in the big leagues, right? And then partnering, you know, doing very unique but, at the same time, very selective partnerships, transparent and certainly open that we are like-minded, we have been able to advance this work where, as you said, maybe we did not get the recognition nor the support as we should have.

Thank you.

Ms. JACKSON LEE. Thank you. Thank you so much.

Dr. Ogwell—and I do not know if Dr. Soon-Shiong is still there or had to depart. But we are expecting in the United States another Omicron surge about mid-April as my facts seem to indicate.

I would like you to comment on the impact of a surge or a spread in one continent that can ultimately impact Africa. And can you tell me, do you think the numbers of infection and mortality may not have been accounted for and that you may have had more deaths on the continent and more infection on the continent than have been accounted for just because of the largeness and other difficulties in getting reporting?

Dr. OGWELL.

Dr. OGWELL. Thanks. Thank you, Representative Jackson Lee.

The facts on the last question, if there is a surge anywhere in the world, due to the way in which goods and, particularly, human beings travel, it really easily will be able to cross borders, and even continents to another part of the world. So any site anywhere becomes a risk for anywhere else, including Africa.

You know, as far as the unaccounted for numbers are concerned, sero surveys are showing us that the testing, testing numbers are certainly not giving us the exact figure. We have seen testing numbers that are lower than the reality of the sero surveys.

As far as deaths are concerned, this is something that we are still looking at to see what the excess deaths actual rate is. We do not have those figures yet. But, clearly, looking at the testing figures being lower than the actual, we expect that the death rates also will be able to be different, but we do not think it will be by a huge amount. It will not necessarily change the fact that Africa has seen there to be lower deaths during this pandemic.

Thank you.

Ms. JACKSON LEE. Dr. Soon-Shiong, you are here, and so let me give to you the issue or the question of the importance of government collaboration on some of the work that you and Dr. Bottazzi are doing. But I also want you to comment on the reality of the fact of this new Omicron. This infectious disease, this COVID-19, is this here to stay with us? Is this going to be—even though your technology suggests that it can be obliterated, but in any event, it seems that it is a growing phenomenon that it goes from one continent to the next in terms of intensity.

Doctor?

Dr. SOON-SHIONG. Sorry. I think I lost connection for a second.

Ms. JACKSON LEE. Did you hear my question?

Dr. SOON-SHIONG. Sorry. Go ahead. Sorry. I just lost connection for a second. If you could repeat the question.

Ms. JACKSON LEE. No problem, with the chairwoman's indulgence.

I asked the question, the importance of governmental collaboration between your work and, of course, Dr. Bottazzi's work. I know the difficulty we had in the last Administration to get any intention on some of these research reproaches, but the importance of that.

And then, can you give us an assessment about Omicron's seemingly long-lasting ability to thrive and grow? You do have research that suggests that you have an approach to that, but it does seem to reinvent itself because we are expecting a surge of Omicron here

in the United States which, obviously, will impact the rest of the world.

Dr. SOON-SHIONG. Thank you, Congresswoman. It is a really important question with regard to the importance of the government participation.

We suffered from the absence of that because, frankly, it is a catch-22. Without any support, we were then denied access to the thing called the DPAS. Without the DPAS, we couldn't even get supplies, even if we paid for it ourselves. So, yes, it is really critical for both of us to have government support and participation.

With regard to the Omicron, it is really very real. The Omicron B2 now is—what is very scary is if the recombination of what we call the Delta together with the Omicron, on the one hand, you get an increase in effectivity (ph); on the other one, you get increased diving into the lungs and increased toxicity.

So very much like AIDS, I worry that this virus then will hide. And, again, very much like with AIDS, unless you have a T cell—again, I sound like a broken record. We, in our body, have two cells, one called a natural killer cell; the other one called a T cell—that we were born with, God-given protection against viruses and infection. If we can activate those, educate those, which is exactly the strategy we have taken for cancer, as well as for COVID and HIV, we have a way to actually rid ourselves, rid our bodies of this virus, rather than it hiding.

So, yes, both of those are important questions. And my level of frustration is I think there are scientific answers to this problem.

Ms. JACKSON LEE. Let's hope we have given you a glimmer of hope. Again, let me express my appreciation to all of the witnesses and the chair for—this is a vital hearing, and I think we cannot move soon enough on our letters, and maybe an approach to the Administration, that I know is very eager to do what is right with their COVID-19 task force, to see some of this brilliant work that is being done, that maybe we can move that aspect as well, Madam Chair, in terms of their interface with government collaboration and support as we face what it looks to be a long journey with COVID, with Omicron, with the Delta variant, and something that we need to get in front of.

Thank you so very much.

Ms. BASS. Absolutely.

And let me just mention that although President Masisi was not able to be with us, I would like to, without objection, include into the record his testimony and make sure that all of the witnesses have his testimony as well.

Mr. SMITH.

[The prepared statement of Mr. Masisi follows:]

**Testimony of His Excellency Dr. Mokgweetsi E.K. Masisi**

President

The Republic of Botswana

Hearing on “Progress and Present Challenges on COVID-19 in Africa”

U.S. House of Representatives

House Foreign Affairs Committee

Subcommittee on Africa, Global Health, and Global Human Rights

March 31, 2022

Thank you, Chairperson Bass and Ranking Member Smith, for the opportunity to testify at this hearing. I am happy to be here today to testify on behalf of my fellow citizens and also share experiences and the strides we are making in Botswana and the African continent as a whole in addressing the COVID-19 global health pandemic.

You would have been taken through a brief on Botswana’s transformation from one of the poorest countries at Independence in 1966 to an Upper Middle-Income status today. Botswana offers universal access to free public healthcare to her citizens, and subsidized healthcare to non-citizens. Through the support of development partners like the United States of America, we have been able to confront pressing health challenges like HIV/AIDS. Chairperson, following the outbreak of COVID-19 in December 2019, Botswana established the Presidential Task Force which I chaired to respond to all cases related to the Pandemic. The Task-Force drew membership from Cabinet, scientists, public health experts, local authorities, civil society, the private sector and the media.

Botswana detected her first COVID-19 case on the 30th of March 2020. The outbreak rapidly evolved from imported cases to local clusters of cases driven by cross border movements to community transmission. To date over 2,600 COVID-19 deaths in Botswana have been reported with a Case Fatality Rate of 0.8% and a death rate of 110 deaths per 100 000 population. These are staggering numbers for a country with a population of 2.35 million (July 2021, estimate). The reason for this high mortality is twofold: Poor timely detection of cases owing to Botswana’s vast land area and hard to reach areas made it difficult to detect, isolate, and treat; Secondly, Botswana relies on centralized high-end health institutions situated in the cities. In response to the growing global and regional threat caused by the COVID 19 pandemic, Botswana acted proactively by instituting measures such as movement restrictions,

mandatory PCR tests for inbound travelers as well as contact tracing accompanied by isolation and quarantine following detection of cases. Public health prevention measures which were adopted in the early stages of the onset of the pandemic included wearing masks, social distancing, and restricted gatherings. Given the robust nature of the measures of containment, this could only be achieved through the declaration of the State of Public Emergency which was endorsed by Parliament in line with our Constitution. The ramifications of the State of Emergency included disruptions to the essential services, supplies and markets, school closures, adoption of new working methods, closure of public gatherings including religious assemblies. This did not just affect access to health commodities but also the economic activity which suffered due to closures of businesses including the diamond sector and tourism sector which Botswana heavily relies upon for her export receipts.

Despite these numerous containment measures instituted by my Government, Botswana still registered a significantly high mortality rate. Mortality cases spiked during July and August 2021 driven by the Delta Variant. This happened at the time when we were waiting to receive the vaccines which we had ordered through COVAX- and other bilateral procurement mechanisms, sometimes at a very high cost. These delays continue even today with the slow delivery of doses for children aged 5-11 years. Through investments made by Government and assistance provided by cooperating partners, we have achieved a vaccination coverage of 59%, (1.4 million Botswana are fully vaccinated), and managed to surpass the targets set by WHO and CDC of 40% vaccine coverage by Dec 2021. Botswana is among the top 5 African countries on track to achieve the 70% vaccine coverage by Mid-2022 target set by WHO. While these numbers are promising, we equally recognize that no one is safe until we are all safe.

Now turning to the experiences of Africa, Public Health emergencies remain common on the continent. From the beginning of the pandemic, Africa Heads of State met regularly to inspire a continental response through the African Union. These efforts together with the rallying of the private sector on the African continent worked together with the Africa CDC to develop the African solution to the pandemic. The COVID-19 experience has further reinforced the fact that preparedness, and equitable access to life saving medical commodities are key in responding to any emergency. The effects of COVID-19 and its aftermath have reinforced the need for a coordinated country, regional and continental capacity to adequately respond to the multiplicity of the public health emergencies in a sustainable manner. In the midst of the challenges that we faced, we managed to dig deeper with our scientists making a discovery a newOMICRON variant. In keeping with our international obligations, we took a decision and valiantly warned the world which, of course came with its negative consequences. On the positive side this demonstrates that we have human capacity to undertake and resolve complex research questions.

In a deliberate effort to build local manufacturing productive capacities, Botswana and NantWorks have partnered to establish a vaccine manufacturing plant. Through our local health regulatory authority the approval of a Botswana regulated vaccine developed by Texas

Children's Hospital and Baylor College of Medicine which is currently manufactured by Biological E in India was announced on 28 March 2022. This would lead to local manufacturing of the second-generation vaccine now aptly named PULAVax in Botswana for distribution in Africa and other parts of the world.

In conclusion, the experience of COVID-19 continues to demonstrate that global collaboration, and support of national and regional national health responses are critical in order to successfully eradicate the pandemic and heighten our preparedness to respond and contain future pandemics. All of our countries have a stake to play. Botswana and Africa have been very constructive and committed to the WHO reform discussions. We therefore wish to implore the United States to play a leadership role in resourcing and agreeing to new financing mechanism that complement international efforts.



Ms. JACKSON LEE. May I just thank—may I just give a special appreciation to President Masisi, since he was in my community and has been a leader in these issues?

Ms. BASS. Sure.

Ms. JACKSON LEE. Thank you so much.

Ms. BASS. OK.

Mr. SMITH.

Mr. SMITH. Thank you so much, Madam Chair. Thank you for another great hearing. I think this was very insightful, gives us items to work on and to expand.

And, you know, I would just say to Dr. Bottazzi, thank you for your tremendous work. You know, I have had Dr. Hotez at two of my hearings previously on neglected tropical diseases. When I read his book—I actually read it twice—it just blew me away with his expertise, but also the incidents, the prevalence of worms and everything else here, all the neglected tropical diseases that are out there.

And Karen and I actually authored a law. We tried to get it passed through the normal route, couldn't do it, for whatever reason, the Senate, but we added it to a must-pass bill, and it is now law to further expand the efforts on neglected tropical diseases. But it was all inspired by Dr. Hotez, so I do thank him for that.

And, again, I would like unanimous consent—ask unanimous consent to a letter to President Biden signed by 14 members of the Texas delegation asking that the CorbeVax be looked at. You know, it points out 300 of that vaccine have been purchased by the Indian Government, pre-purchased, and I would ask that it be made part of the record.

But, again, thank you, Karen. Thank you, Madam Chair, for another great hearing.

I yield back.

[The information referred to follows:]



## MEMORANDUM

March 23, 2022

**To:** House Foreign Affairs Subcommittee on Africa, Global Health, and Global Human Rights  
Attention: Cierra Pettiford

**From:** Alexis Arieff, Coordinator, Specialist in African Affairs, [aarieff@crs.loc.gov](mailto:aarieff@crs.loc.gov), 7-2459  
Shayerah I. Akhtar, Specialist in International Trade and Finance, [siliasakhtar@crs.loc.gov](mailto:siliasakhtar@crs.loc.gov), 7-9253  
Nicolas Cook, Specialist in African Affairs, [ncook@crs.loc.gov](mailto:ncook@crs.loc.gov), 7-0429  
Tomás F. Husted, Analyst in African Affairs, [thusted@crs.loc.gov](mailto:thusted@crs.loc.gov), 7-7754  
Sara M. Tharakan, Analyst in Global Health and International Development, [stharakan@crs.loc.gov](mailto:stharakan@crs.loc.gov), 7-9040

**Subject:** **COVID-19 in Sub-Saharan Africa: Impact, Responses, and Possible Questions**

This memo on the Coronavirus Disease 2019 (COVID-19) pandemic in sub-Saharan Africa (“Africa,” herein) was prepared at your request in support of a hearing. Material may be used in other CRS products; the confidentiality of your request will be preserved. Please contact the authors for any further assistance.

#### COVID-19 in Africa: Snapshot of Current Trends

As of mid-March 2022, most African countries had emerged from a “fourth wave” of COVID-19 cases—attributed to the Omicron variant, first detected in Botswana in late 2021—and were seeing a “sustained decline” in cases.<sup>1</sup> The pace of COVID-19 vaccinations in Africa has increased in recent weeks, as supplies have grown and several large countries have launched mass inoculation campaigns.<sup>2</sup> Additionally, in early March, the Africa Centres for Disease Control and Prevention (Africa CDC) and Pfizer reached an agreement to supply African countries with the firm’s COVID-19 antiviral drug.<sup>3</sup> In February, citing case trends and increased treatment capacity in many countries, World Health Organization (WHO) officials expressed optimism that Africa “can control the pandemic in 2022.”<sup>4</sup>

WHO officials caution, however, that Africa “still lags behind on vaccination” and that the pandemic has pushed tens of millions more Africans into extreme poverty.<sup>5</sup> Public fatigue with infection control measures, the emergence of new variants, and low vaccination rates have driven successive waves of

<sup>1</sup> World Health Organization (WHO), “Africa’s COVID-19 vaccine uptake increases by 15%,” March 17, 2022. WHO regional definitions diverge from some others; e.g., the WHO Africa region includes Algeria but excludes Djibouti, Somalia, and Sudan.

<sup>2</sup> Ibid.

<sup>3</sup> Reuters, “Africa CDC has MOU with Pfizer for supplies of COVID-19 pill,” March 10, 2022.

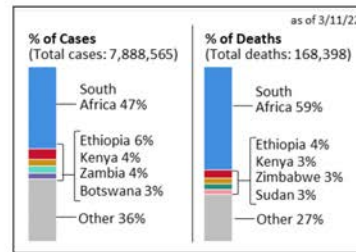
<sup>4</sup> WHO Regional Office for Africa, “Africa on track to control COVID-19 pandemic in 2022,” February 10, 2022.

<sup>5</sup> Ibid. Several African countries had among the world’s highest rates of extreme poverty prior to the pandemic.

cases.<sup>6</sup> In line with other regions, the Omicron wave in Africa appears to have subsided more quickly and caused fewer deaths (with a reported 0.8% regional case fatality rate, compared to 2.4-2.7% during prior waves).<sup>7</sup> Future COVID-19 trends in Africa (as elsewhere) nevertheless remain uncertain. Global and regional leaders have decried vaccine access inequality, particularly with respect to Africa, which WHO Director-General Tedros Ghebreyesus has termed “vaccine apartheid.”<sup>8</sup> Some analysts assert that low vaccination rates in the region could hasten the emergence of new variants and thus prolong the pandemic.<sup>9</sup>

Overall, Africa has seen fewer cumulative confirmed cases and deaths per capita than other regions. These have been concentrated in a few countries, led by South Africa (Figure 1). At the same time, caseloads and mortality may be significantly understated: a 2021 WHO assessment found that some six out of seven COVID-19 cases were going undetected in Africa and that two out of three deaths from COVID-19 were not being registered.<sup>10</sup> Demographic and other factors may have limited the pandemic’s toll in the region; experts stress that further research is needed to fully understand the interaction between COVID-19 and health conditions prevalent in parts of Africa, such as HIV/AIDS, tuberculosis (TB), and malaria.<sup>11</sup>

**Figure 1. Cumulative Confirmed COVID-19 Cases and Deaths in Africa**



Source: CRS graphic based on WHO COVID-19 Dashboard data, as of March 11, 2022.

### Vaccination and Other COVID-19 Response Efforts: Status and Key Challenges

Multiple initiatives support the development and production of, and equitable access to, COVID-19 vaccines, therapeutic drugs, and testing globally, including in Africa. The primary multilateral initiative is the Access to COVID-19 Tools (ACT) Accelerator, a WHO-led multi-stakeholder collaboration. The COVID-19 Global Access Initiative (COVAX), the vaccine arm of the ACT Accelerator, supports the development and distribution of COVID-19 vaccines.<sup>12</sup> In Africa, these efforts are complemented by a range of multilateral and public-private partnerships established by the African Union (AU) and its Africa CDC. These include the African Vaccine Acquisition Trust (AVAT), an effort to finance and bulk-procure vaccines for AU member states.<sup>13</sup> In addition to obtaining COVID-19 vaccines through COVAX and AVAT, many African governments have directly purchased supplies and/or received bilateral donations, including from the United States and other Western donors, China, and, to a lesser extent, Russia.

<sup>6</sup> WHO Africa, “Opening statement, COVID-19 Press Conference,” June, 24 2021.

<sup>7</sup> WHO Africa, “Africa on track to control COVID-19 pandemic in 2022,” February 10, 2022.

<sup>8</sup> Reuters, “World has entered stage of ‘vaccine apartheid’-WHO head,” May 17, 2021; see also *Business Day*, “Omicron Variant – Ramaphosa slams ‘selfish nations’ over bans and jabs,” December 7, 2021.

<sup>9</sup> Vanessa S. Lanzotti, et al., “Vaccine apartheid: This is not the way to end the pandemic,” *Journal of Paediatrics and Child Health*, October 21, 2021; and WHO, et al., “Vaccine inequity undermining global economic recovery,” July 22, 2021.

<sup>10</sup> Talha Khan Burki, “Undetected COVID-19 Cases in Africa,” *The Lancet*, 9(12): December 2021.

<sup>11</sup> Sofonias K. Tessema and John N. Nkengasong, “Understanding COVID-19 in Africa,” *Nature*, 21: August 2021.

<sup>12</sup> See CRS In Focus IF12013, *The U.S. Government’s Role in Domestic and Global COVID-19 Vaccine Supply and Distribution: Frequently Asked Questions*.

<sup>13</sup> The African Export-Import Bank and the World Bank finance AVAT COVID-19 vaccine purchases, while the U.N. Children’s Fund (UNICEF) procures and delivers them and supports related national logistics services in some African countries.

Despite such efforts, Africa continues to have the lowest vaccination rate of any world region (Figure 2). In 13 African countries, over 90% of the population had yet to receive a single dose as of mid-March 2022 (Figure A-1, Appendix). Until recently, a regional shortage of vaccine doses was a key hindrance. African countries, on average the poorest globally, were unable to compete with wealthy countries in the global COVID-19 vaccine procurement market. Other factors driving shortages included vaccine export bans in some countries (such as India, a major COVAX supplier, in 2021); inadequate global production; supply chain challenges; limited ultra-cold storage capacity; and a general dependence on external sourcing of vaccine supplies. Overall, about 1% of all vaccines used in Africa (of all types) are produced in the region.<sup>14</sup>

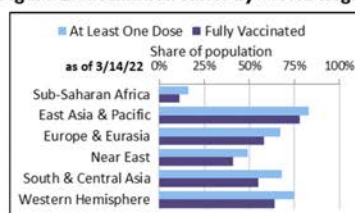
Donor-pledged vaccines were initially slow to arrive in Africa, and inadequate coordination complicated vaccine roll-out in many countries. In late 2021, the AU, Africa CDC, and COVAX asserted that most vaccine donations to Africa had “been ad hoc, provided with little notice and short shelf lives,” and did not cover freight costs. They called for a “predictable and reliable supply” of “large volumes” of vaccine donations and injection supplies (e.g., syringes and diluents) for Africa, along with related resources.<sup>15</sup> Vaccine hesitancy reportedly worsened due to the use of nearly expired or expired doses that medical experts contended were still usable. Officials in some countries destroyed such stocks.<sup>16</sup>

With vaccine supplies expanding in recent months, many countries face challenges related to their capacity to administer shots (e.g., with sufficient trained health workers) and the willingness of local populations to receive them. In February 2022, Africa CDC Director John Nkengasong requested a months-long pause in new vaccine shipments to the region, pending sufficient use of existing doses.<sup>17</sup> Skepticism about potential vaccine side effects, suspicions about the origin of the virus, past experience with unethical practices by pharmaceutical firms, and a wide range of misinformation and conspiracy theories (often shared by word of mouth or on social media) have reportedly fueled vaccine hesitancy.<sup>18</sup>

#### Building African Vaccine Manufacturing Capacity: Current Efforts

As many as 10 African countries, most in coordination with international partners, are pursuing efforts to manufacture COVID-19 vaccines and, in some cases, to develop shelf-stable vaccines that do not require ultra-cold storage, a key challenge in the region.<sup>19</sup> For example, two South African firms are pursuing separate “fill-and-finish” operations to produce COVID-19 vaccines, one of which is supported by the U.S. International Development Finance Corporation (DFC).<sup>20</sup>

**Figure 2. Vaccination Rates by World Region**



Source: CRS graphic based on WHO COVID-19 Dashboard data, as of March 14, 2022.

Note: Regional definitions follow U.S. State Department.

<sup>14</sup> U.S. International Development Finance Corporation (DFC), “DFC, IFC, Proparco, and DEG Support South African COVID-19 Vaccine Maker, Aspen,” June 30, 2021.

<sup>15</sup> COVAX, AU, and Africa CDC, “Joint Statement on Dose Donations of COVID-19 Vaccines to African Countries,” November 29, 2021.

<sup>16</sup> Devex, “African nations have destroyed 450,000 expired COVID-19 vaccine doses,” July 15, 2021.

<sup>17</sup> Daniel Payne, “Africa CDC to ask world to pause Covid-19 vaccine donations,” *PoliticoPro*, February 22, 2022.

<sup>18</sup> *New York Times*, “As Vaccines Trickle Into Africa, Zambia’s Challenges Highlight Other Obstacles,” December 11, 2021.

<sup>19</sup> Reuters, “Africa vaccine manufacturing drive is for long term, says CDC,” February 10, 2022.

<sup>20</sup> In fill-and-finish operations, vaccine components manufactured abroad are locally packaged and distributed. Under one project, part of a broader DFC and donor-backed effort, South Africa’s Aspen Pharmacare is finishing production of the Johnson &

Another South African firm, Afrigen Biologics, has used a publicly-available sequence of Moderna's mRNA COVID-19 vaccine to develop its own model of the vaccine, which may not require the same cold storage.<sup>21</sup> The South African Medical Research Council, the WHO, and other actors are aiding this effort, and local firm Biovac is expected to manufacture the vaccine.<sup>22</sup> Patrick Soon-Shiong, a South Africa-born U.S. doctor and entrepreneur, has opened a plant in South Africa to produce COVID-19 and other vaccines, using technology developed by his U.S. firm.<sup>23</sup>

In Senegal, the U.S. DFC and other donor agencies are investing in an effort to build the long-term capacity of the Fondation Institut Pasteur de Dakar to produce COVID-19 and other vaccines.<sup>24</sup> German firm BioNTech, in coordination with the AU, the WHO, and other actors, also is seeking to establish mRNA COVID-19 vaccine manufacturing facilities in Rwanda, Senegal, and potentially in South Africa, using shipping containers pre-equipped to produce 50 million or more vaccine doses per year. BioNTech staff are initially expected to carry out production—slated to start later in 2022 and to be offered to African buyers at a not-for-profit price—but the firm also reportedly plans to train local personnel to do this work. Output, which can be adjusted to support non-COVID-19 vaccine production, is to be shipped to Ghana for fill-and-finish processing.<sup>25</sup> Moderna also has signed an agreement with the Kenyan government to invest \$500 million to establish a manufacturing facility able to produce up to 500 million doses a year of varying types of mRNA vaccines, all slated for sale in Africa. The facility may also support fill-and-finish operations, which Moderna also plans to establish elsewhere in Africa.<sup>26</sup>

### COVID-19 and Health Systems in Africa

Most African countries faced stark public health challenges prior to the pandemic. According to the Joint U.N. Program on HIV/AIDS (UNAIDS), Africa has 16% of the global population, faces 26% of the world's overall disease burden, and on average allocates 7% of government budgets to health despite a regional commitment to allocate 15%.<sup>27</sup> The region imports 94% of its medical and pharmaceutical products, making it particularly vulnerable to global market fluxes and supply chain disruptions, which have increased during the pandemic.<sup>28</sup> According to the WHO, COVID-19 has negatively affected health systems in Africa, with periodic physical lockdown and quarantine measures disrupting access to health and social services in many countries (as discussed below). COVID-19 surges have strained health care providers' ability to respond both to the pandemic and other health issues, among other effects.<sup>29</sup>

Johnson vaccine, to be branded Aspenovax and sold in African markets. Under the other project, South African firm Biovac is to finalize production of and ship the Pfizer-BioNTech mRNA vaccine. DFC, "DFC, IFC," op cit.; Aspen Pharma, "Aspen Confirms Non-binding Term Sheet on Manufacture and Sale of an Aspen- Branded Covid-19 Vaccine Throughout Africa," November 30, 2021; and Pfizer, "Pfizer and BioNTech Announce Collaboration with Biovac to Manufacture and Distribute COVID-19 Vaccine Doses Within Africa," July 21, 2021.

<sup>21</sup> Reuters, "In World First, South Africa's Afrigen Makes mRNA COVID Vaccine Using Moderna Data," February 4, 2022; and WHO, "The mRNA Vaccine Technology Transfer Hub."

<sup>22</sup> This effort is supported by a WHO COVID-19 mRNA vaccine technology transfer program linked to broader U.N.-backed efforts to develop, produce, and scale-up access to drugs and vaccines in low- and middle-income countries. Under the same initiative, the WHO is to provide mRNA vaccine technology and training to Egypt, Kenya, Nigeria, Senegal, and Tunisia. WHO, "WHO supporting South African consortium to establish first COVID mRNA vaccine technology transfer hub," June 21, 2021.

<sup>23</sup> Reuters, "Billionaire Soon-Shiong opens new vaccine plant in South Africa," January 19, 2022.

<sup>24</sup> DFC, "DFC, IFC, EIB, and AFD Boosting COVID-19 Vaccine Production in Africa with Senegal-based Vaccine Manufacturer IPD," July 9, 2021.

<sup>25</sup> *GhanaToday*, "Ghana, Rwanda, Senegal Partner BioNTech to Produce Vaccines," February 17, 2022; AP, "BioNTech plans modular vaccine factories in Africa," February 16, 2022; and *New Times*, "Five things to know about Rwanda's vaccine manufacturing ambitions," February 16, 2022.

<sup>26</sup> APANEWS, "Kenya signs \$500m manufacturing deal with Moderna," March 8, 2022; and Moderna, "Moderna Announces Memorandum of Understanding with the Government of the Republic of Kenya to Establish Its First mRNA Manufacturing Facility in Africa," March 7, 2022.

<sup>27</sup> UNAIDS, *Investments in HIV, health and pandemics are vital for economic recovery in Africa*, February 15, 2022.

<sup>28</sup> Akalewold Gebremeskel, Akaninye Otu, and Seye Abimbola, et al., "Building Resilient Health Systems in Africa Beyond the COVID-19 Pandemic Response," *BMJ Global Health*, 6: June 2, 2021.

<sup>29</sup> WHO, *Second Round of the National Pulse Survey on Continuity of Essential Health Services During the COVID-19*

Health infrastructure constraints are likely to hamper efforts to launch and maintain mass COVID-19 vaccination campaigns without interrupting routine health services.<sup>30</sup> Public health experts have called for increased investment in community health workers and health infrastructure (e.g., disease surveillance and corresponding data on health outcomes, intensive care units, ventilators, and personal protective equipment), among other things, to mitigate the effects of the pandemic and secondary effects on other public health service delivery.<sup>31</sup> Some research shows that COVID-19 has led many African countries and donors to increase funding for health systems, focused especially on strengthening the health workforce and improving laboratory capacity.<sup>32</sup> The extent of the pandemic's long-term effects on health governance and financing remains to be seen.

**Secondary Public Health Effects of the COVID-19 Pandemic.** According to the WHO, many countries in Africa have experienced significant secondary public health effects due to COVID-19-related disruptions.<sup>33</sup> Reports indicate that treatment and diagnosis of chronic and infectious diseases, routine immunization services, and family planning and reproductive health services have suffered, among other issues. For example, in 2020, 8 million children in Africa reportedly missed their first doses of the Diphtheria-Tetanus-Pertussis, Measles, and Polio vaccines; in 2021, several countries reported measles outbreaks due to falling immunization coverage.<sup>34</sup> Some observers warn that health staff and resources in many African countries may be diverted from polio and malaria programs to implement mass COVID-19 vaccination campaigns, potentially compounding the effects of the pandemic on public health.<sup>35</sup> According to UNAIDS, COVID-19-related disruptions to healthcare, education, communications campaigns, and other services may cause an increase in HIV/AIDS infections in the next several years.<sup>36</sup>

The WHO has documented particularly negative effects on women's health, with 40% of African countries reporting disruptions to sexual, reproductive, maternal, newborn, child, and adolescent health services.<sup>37</sup> Services provided to women who experienced sexual or intimate partner violence had declined in 56% of surveyed African countries as of late 2021, compared to the same period pre-pandemic.<sup>38</sup> In Kenya, teenage pregnancies reportedly rose by up to 60% compared to pre-pandemic figures, reportedly fueled in part by pandemic-induced school closures.<sup>39</sup>

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*Pandemic: January-March 2021*, April 22, 2021.

<sup>30</sup> *The New York Times*, "In Africa, a Mix of Shots Drives an Uncertain Covid Vaccination Push," March 15, 2022.

<sup>31</sup> Bibi-Aisha Wadvala, "How Africa Has Tackled COVID-19," *BMJ*, July 16, 2020.

<sup>32</sup> Samuel Nkachukwu Uwaezuoke, "Strengthening Health Systems in Africa: The COVID-19 Pandemic Fallout," *Journal of the Pan African Thoracic Society*, 1(1): September 27, 2020.

<sup>33</sup> WHO, *Third Round of the National Pulse Survey on Continuity of Essential Health Services During the COVID-19 Pandemic: November-December 2021*, February 7, 2022. For example, in Uganda in early 2020, physical lockdown and quarantine measures reportedly contributed to limited access to treatment for chronic conditions like diabetes and hypertension, causing mortality to increase in one Kampala hospital from 1% to 10% (Apophia Agiresaasi, "Pandemic Response Forsakes Patients With Chronic Illnesses," *Global Press Journal*, February 2, 2022). In South Africa, roughly 25% of South Africans reportedly could not access condoms during the country's lockdown in 2020, while screening for cervical cancer declined by 66% during the same time period (Obasanjo Afolabi Bolarinwa, "Factors Associated with Access to Condoms and Sources of Condoms During the COVID-19 Pandemic in South Africa," *Archives of Public Health*, 79: October 27, 2021).

<sup>34</sup> WHO Regional Office for Africa, *COVID-19 Widens Routine Immunization Gaps in Africa*, July 29, 2021.

<sup>35</sup> *The New York Times*, "In Africa, a Mix of Shots Drives an Uncertain Covid Vaccination Push," March 15, 2022.

<sup>36</sup> UNAIDS, *Investments in HIV, Health and Pandemics Are Vital for Economic Recovery in Africa*, February 15, 2022.

<sup>37</sup> WHO, *COVID-19 Takes a Heavy Toll on Women's Health*, March 3, 2022.

<sup>38</sup> *Ibid.*

<sup>39</sup> Garazi Zulaika, Miriam Bulbarelli, and Elizabeth Nyothach, et al., "Impact of COVID-19 Lockdowns on Adolescent Pregnancy and School Dropout Among Secondary Schoolgirls in Kenya," *BMJ Global Health*, 7: January 13, 2022.

### Economic and Socioeconomic Impacts

COVID-19 has had severe economic impacts in Africa. The pandemic initially caused a drop in global demand and prices for African natural resource exports (especially oil and some minerals), disrupted trade and tourism, stemmed remittances from African workers abroad, and prompted local lockdown measures. According to International Monetary Fund (IMF) estimates, gross domestic product (GDP) contracted by 1.9% on average in Africa in 2020, the region's worst downturn on record.<sup>40</sup> As of late 2021, the IMF projected a regional rebound to 3.7% growth in 2021, the slowest projected recovery of any region.<sup>41</sup>

Economic impacts and recovery trajectories have varied across the region, reflecting differences in underlying economic conditions, policy responses, and fluctuations in global markets. Many oil- and mineral-rich countries (including Nigeria and South Africa, Africa's largest economies) experienced recessions in 2020, before rebounding in 2021 amid rising global commodity prices.<sup>42</sup> Countries less reliant on natural resource exports (e.g., Côte d'Ivoire, Ethiopia, Kenya, Senegal, and Tanzania) generally experienced less severe contractions in 2020, but these countries' prospects for growth in 2022 are mixed. Small tourism-dependent countries (e.g., Cabo Verde, Mauritius, and Seychelles) experienced some of the most dramatic downturns due to the pandemic. The outlook remains uncertain for many African countries as they struggle to expand COVID-19 vaccinations and as Russia's invasion of Ukraine roils global fuel and food markets, with evolving implications for African producers and consumers.

The pandemic has aggravated unemployment and underemployment, spurred income losses, and pushed tens of millions more Africans into extreme poverty.<sup>43</sup> Food insecurity has intensified across the region, particularly in countries affected by armed conflict or natural hazards.<sup>44</sup> COVID-19 prompted lengthy school closures in many countries, often without viable virtual options; U.N. agencies warn that learning losses are likely to have consequences for future educational attainment, and that many students may never return to class.<sup>45</sup> Socioeconomic challenges have been particularly acute among women and girls.<sup>46</sup>

### African Government Responses

Many African governments, drawing on lessons from managing other disease outbreaks, quickly ramped up COVID-19 surveillance and infection control measures in early 2020, imposing restrictions on travel, gatherings, and commerce. At the same time, some governments, most notably Tanzania under then-President John Magufuli and Burundi under then-President Pierre Nkurunziza, minimized or denied the risk of COVID-19. Many countries began to loosen restrictions in mid-2020, but some re-imposed them during case spikes, including during the Delta and Omicron waves. As of mid-March 2022, most African countries had lifted any stay-at-home requirements and reopened schools and workplaces.<sup>47</sup> Several have retained some mask requirements and restrictions on public events and large gatherings.

<sup>40</sup> IMF, *Regional Economic Outlook, Sub-Saharan Africa: Navigating a Long Pandemic*, April 2021. Regional growth rate does not account for Djibouti, Mauritania, Somalia, or Sudan, which the IMF includes in its Middle East and Central Asia grouping.

<sup>41</sup> IMF, *Regional Economic Outlook, Sub-Saharan Africa: One Planet, Two Worlds, Three Stories*, October 2021.

<sup>42</sup> Ibid; IMF, World Economic Outlook database, October 2021 update.

<sup>43</sup> See Mahler et al., "Updated estimates of the impact of COVID-19 on global poverty" World Bank Blogs, June 24, 2021.

<sup>44</sup> See Food and Agriculture Organization (FAO) and World Food Program (WFP), *Hunger Hotspots: FAO-WFP Early Warnings on Acute Food Insecurity*, February to May 2022 Outlook.

<sup>45</sup> U.N. Educational, Scientific, and Cultural Organization, (UNESCO), UNICEF, and World Bank, *The State of the Global Education Crisis: A Path to Recovery*, 2021.

<sup>46</sup> U.N. Women, *Measuring the Shadow Pandemic: Violence Against Women During COVID-19, 2021*; AU Commission (Women, Gender, and Development Directorate) et al., *Gender-Based Violence in Africa During the COVID-19 Pandemic*, 2020.

<sup>47</sup> See Our World in Data, "Policy Responses to the Coronavirus Pandemic," <https://ourworldindata.org/policy-responses-covid>.

Several countries have pursued innovative pandemic responses. Senegal's Institut Pasteur, for instance, is partnering with other institutions to produce an inexpensive rapid COVID-19 test.<sup>48</sup> Rwanda and Ghana have used drones to deliver medical supplies to rural areas, and Rwanda has used robots to take patient vital signs in clinics. South African cell phone firms supported the creation of a telemedicine system to reduce the pandemic's burden on the healthcare system. As noted above (see text-box), South African researchers are working to develop their own mRNA vaccine.

Limited fiscal resources have constrained many African countries' capacity to cushion the pandemic's economic shocks through stimulus measures and aid to vulnerable citizens. According to the World Bank, "budget support to people and firms" in Africa during the pandemic amounted to less than 3% of regional GDP as of late 2021, compared to an estimated 17% in advanced economies.<sup>49</sup> The IMF and G20, among others, have supported African governments' stimulus measures through concessional loans and debt service deferments; some countries have turned to commercial debt markets for financing. Sovereign debts have increased across the region, heightening existing debt sustainability concerns.<sup>50</sup> As of October 2021, 17 African countries had general government gross debt totaling more than 70% of their respective GDP—up from 12 in 2019, and five in 2011.<sup>51</sup> Zambia defaulted on its debt repayments in 2020.

**Governance Challenges.** COVID-19 has imposed new challenges on governments facing political tensions, insurgencies, and other instability. Economic hardships and anger at state-imposed restrictions have fueled unrest in some countries (e.g., Senegal in 2021), and the pandemic has provided a number of governments with a pretext to crack down on free speech and assembly.<sup>52</sup> Ethiopia postponed elections in 2020, while infection fears may have lowered turnout in others that proceeded as scheduled (e.g., Mali and Guinea). Officials in multiple countries (including Cameroon, the Democratic Republic of Congo, Kenya, Uganda, South Africa, and Zimbabwe) have been implicated in corruption or misuse of public health funds intended for COVID-19 response.<sup>53</sup> Top officials and opposition leaders in several countries have allegedly died of COVID-19, although the cause of death has not always been confirmed.<sup>54</sup>

### Selected Issues for Congress

**U.S. Support for COVID-19 Response in Africa.** As of late 2021, the State Department and the U.S. Agency for International Development (USAID) had provided \$1.95 billion in health, humanitarian, and economic assistance to 48 countries in Africa to counter COVID-19 and mitigate its social and economic impacts.<sup>55</sup> The United States also has donated vaccines from its domestic stocks and purchased additional doses to donate to African countries, in coordination with COVAX and the AU. As of March 18, the

<sup>48</sup> Mérieux Foundation, "Inauguration of the diaTROPIX production platform at the Institut Pasteur of Dakar," November 16, 2020; *TechCabal*, "Senegal to produce rapid Covid tests in tech deal with major biotech companies," July 19, 2021.

<sup>49</sup> World Bank, *Africa's Pulse: Climate Change Adaptation and Economic Transformation in Sub-Saharan Africa*, October 2021.

<sup>50</sup> Brookings, "Sub-Saharan Africa's debt problem: Mapping the pandemic's effect and the way forward," October 21, 2021.

<sup>51</sup> CRS assessment based on data from IMF, World Economic Outlook database, October 2021 update.

<sup>52</sup> See Human Rights Watch (HRW), "COVID-19 Triggers Wave of Free Speech Abuse," at <https://features.hrw.org/features/features/covid/index.html>.

<sup>53</sup> See, e.g., HRW, "IMF: Make Cameroon Loan Contingent on Anti-Corruption," June 18, 2021; Reuters, "Congo virus funds embezzled by 'mafia network,' says deputy minister," July 8, 2020; Devex, "Who received that money? Report probes Kenya's COVID-19 cash program," July 20, 2021; VOA, "Top Ugandan Officials Arrested in COVID-19 Purchasing Scandal," April 9, 2020; Reuters, "South African corruption probe flags COVID contracts worth \$137 million," January 25, 2022; BBC, "Coronavirus: Zimbabwe health minister in court on corruption charges," June 20, 2020.

<sup>54</sup> These include heads of state in Burundi and Tanzania (both unconfirmed), along with the top opposition leader in Mali. See also Jean-Benoît Falisse et al., "Why have so many African leaders died of COVID-19?" *BMJ Global Health*, 6: May 2021.

<sup>55</sup> State Department Office of Foreign Assistance, data provided to CRS on request, December 15, 2021. The top recipient was Ethiopia (\$397 million), followed by South Sudan (\$200 million), Somalia (\$159 million), and Nigeria (\$114 million).



United States had donated and delivered nearly 140 million COVID-19 vaccine doses to 43 African countries, making it the top country donor of vaccines to the region (and globally).<sup>56</sup> In late 2021, USAID launched Global VAX, which aims to accelerate vaccine access and delivery worldwide. The initiative reportedly will provide “intensive support” to at least 11 African countries.<sup>57</sup> Members of Congress may examine whether the United States can or should do more to support COVID-19 response and vaccination in Africa, and what the trade-offs might be for other U.S. budget, foreign assistance, and policy priorities.

**President’s Emergency Plan for AIDS Relief (PEPFAR) and COVID-19 Response.** The COVID-19 pandemic and its secondary effects continue to hinder HIV/AIDS diagnosis, treatment, and care delivery. Nevertheless, health systems strengthening under PEPFAR and other HIV-related investments has arguably played a role in mitigating the COVID-19 pandemic.<sup>58</sup> In early 2020, PEPFAR acted to minimize disruptions to HIV/AIDS treatment caused by the pandemic, with reportedly mixed results.<sup>59</sup> COVID-19 has reportedly disrupted service delivery, with data indicating that HIV testing fell by 41% between 2019 and 2020 in two dozen African countries. During the same period, referrals for HIV/AIDS care reportedly fell by 37%.<sup>60</sup> Growing evidence suggests that HIV/COVID-19 co-infection can increase the risk of developing severe or fatal cases of COVID-19 by as much as 30%.<sup>61</sup>

Congress provided \$3.75 billion under the American Rescue Plan Act of 2021 (P.L. 117-2) “to support programs for the prevention, treatment, and control of HIV/AIDS in order to prevent, prepare for, and respond to coronavirus, including to mitigate the impact on such programs from coronavirus and support recovery from the impacts of the coronavirus.” This included a \$3.5 billion one-time contribution to the Global Fund. Looking ahead, Congress may consider whether PEPFAR’s platforms will continue to be used to support COVID-19 control; the extent to which COVID-19 may continue to hamper HIV/AIDS control efforts; and given these issues, how (if at all) PEPFAR programs and budgets should shift.

**Global Health and Pandemic Response Aid.** Given the intersection of COVID-19 and other public health challenges, UNAIDS has called for increased international investment in pandemic preparedness, public health systems, and responses to specific infectious disease threats, such as HIV/AIDS and COVID-19.<sup>62</sup> Some other advocates have argued for PEPFAR and other preexisting U.S. global health programs in Africa to integrate COVID-19 responses, including by supporting COVID-19 vaccine rollouts.<sup>63</sup> As Congress considers proposals for pandemic-related funding and other global health priorities, PEPFAR’s possible reauthorization is also on the horizon in 2023.

<sup>56</sup> State Department, “COVID-19 Vaccine Donations,” Sub-Saharan Africa, at <https://www.state.gov/covid-19-recovery/vaccine-deliveries>; USAID, “Marking Delivery of Half a Billion U.S.-Donated COVID-19 Vaccines,” March 17, 2022.

<sup>57</sup> The 11 African priority countries for initial Global VAX support are reportedly: Angola, Côte d’Ivoire, Eswatini, Ghana, Lesotho, Nigeria, Senegal, South Africa, Tanzania, Uganda and Zambia (*Washington Post*, “U.S. Will ‘Surge’ Vaccine Support to 11 African Countries,” February 17, 2022). See also USAID, “Global VAX: A New Initiative for Global Vaccine Access” to Accelerate U.S. Vaccine Delivery Assistance Around the World,” Fact Sheet, December 6, 2021.

<sup>58</sup> State Department, *PEPFAR: 2021 Annual Report to Congress*, February 8, 2021; State Department, *PEPFAR Technical Guidance in Context of COVID-19 Pandemic*, May 6, 2021.

<sup>59</sup> Rachel Golin, Catherine Godfrey, and Jacqueline Firth, et al., “PEPFAR’s Response to the Convergence of the HIV and COVID-19 Pandemics in Sub-Saharan Africa,” *Journal of the International AIDS Society*, 8: August 23, 2020. Shirley Lee Lecher, Mary Naluguzi, and Christina Mwangi, et al., “Notes from the Field: Impact of the COVID-19 on HIV Viral Load Testing - PEPFAR Supported Countries January-June 2020,” *Morbidity and Mortality Weekly Report*, 70(21): May 28, 2021.

<sup>60</sup> The Global Fund, *The Impact of COVID-19 on HIV, TB and Malaria Services and Systems for Health: A Snapshot from 502 Health Facilities Across Africa and Asia*, 2021.

<sup>61</sup> WHO Global Clinical Platform for COVID-19, “Clinical features and prognostic factors of COVID-19 in people living with HIV hospitalized with suspected or confirmed SARS-CoV-2 infection,” July 15, 2021.

<sup>62</sup> UNAIDS, *Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030*, United Nations General Assembly High Level Meeting on HIV/AIDS, June 9, 2021.

<sup>63</sup> Tim Murphy, “John Nkengasong, Ph.D., Is Biden’s Pick to Fill the Long-Empty Role of U.S. Global AIDS Czar,” *The Body*:

Congress provided \$9.8 billion in USAID- and State-Department-administered Global Health Programs funds in the Consolidated Appropriations Act, 2022 (P.L. 117-103). Congress also provided roughly \$17 billion for international COVID-19 responses (including vaccine procurement and distribution, and the U.S. contribution to COVAX) through emergency supplemental appropriations in FY2020 and FY2022 (P.L. 116-36, P.L. 116-123, P.L. 116-260, and P.L. 117-2). Some advocates have questioned whether U.S. global health and pandemic response funds are sufficient given ongoing challenges presented by COVID-19.<sup>64</sup> Some Members of Congress agree that more funds are required, while others have expressed skepticism about the need for additional COVID-19 resources given the scale of appropriations to date.<sup>65</sup>

**Other Aid Objectives in Africa.** COVID-19 has complicated U.S. foreign assistance implementation and exacerbated many of the challenges that U.S. aid seeks to address (e.g., poverty, other health challenges, access to education, and food insecurity). Implementers have faced obstacles related to procurement, technology, and personnel movement.<sup>66</sup> Some U.S. aid programs have been extended in response to implementation delays.<sup>67</sup> The pandemic and related restrictions have also raised challenges for State Department and USAID oversight of program implementation.<sup>68</sup> More broadly, as discussed above, COVID-19 has diverted attention and resources from U.S.-backed efforts in other areas, including other public health needs, while fueling new governance and stability concerns. As Congress considers executive branch budget proposals and conducts oversight of foreign assistance, Members may consider whether and how to adjust U.S. programming in light of these developments.

**Potential Intellectual Property Rights (IPR) Waiver.**<sup>69</sup> The 1995 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contains protection and enforcement obligations for patents and other IPR. It also has exceptions and flexibilities, including transition periods for least-developed WTO members and scope for compulsory licenses of patents in certain conditions, such as in “public health crises.” WTO talks are ongoing on potential “TRIPS waivers” for COVID-19 vaccines, products, and technologies, which were first proposed by India and South Africa in October 2020 and are supported by many low- and middle-income countries (LMICs).<sup>70</sup> In May 2021, the Biden Administration voiced support for the idea of a limited IPR waiver for COVID-19 vaccines.<sup>71</sup> While waiver support has grown, some WTO members have been skeptical, including the European Union (EU). The WTO Director-General (DG) has urged members to reach a WTO pandemic response agreement quickly.<sup>72</sup> On March 15, 2022, the United States, the EU, India, and South Africa reportedly reached a compromise in high-level talks, facilitated by the DG, on a limited waiver of patent protections for COVID-19 vaccine production and supply by certain developing countries.<sup>73</sup> There is no

*the HIV/AIDS Resource*, October 12, 2021.

<sup>64</sup> See, e.g., Ashlee Thomas, *If Budgets Are Moral Documents, What Values Can We See in Biden's Foreign Aid Budget?* Oxfam America, May 28, 2021.

<sup>65</sup> *CQ*, “White House lowers expectations for COVID-19 supplemental, but GOP resistance remains,” March 3, 2022.

<sup>66</sup> Government Accountability Office (GAO), *Better USAID Documentation and More-Frequent Reporting Could Enhance Monitoring of Humanitarian Efforts*, GAO-22-104431, January 2022.

<sup>67</sup> The Millennium Challenge Corporation (MCC), for instance, has extended the length of several Compacts in Africa and provided additional funding in response to COVID-19-related delays.

<sup>68</sup> GAO, *Better USAID Documentation and More-Frequent Reporting Could Enhance Monitoring of Humanitarian Efforts*.

<sup>69</sup> See CRS In Focus IF11858, *Potential WTO TRIPS Waiver and COVID-19*.

<sup>70</sup> Other potential approaches include to make greater use of existing TRIPS flexibilities, facilitate more voluntary licensing agreements and technology transfer, ease export restrictions, and facilitate medical goods trade through other measures.

<sup>71</sup> Office of the U.S. Trade Representative (USTR), “Statement from Ambassador Katherine Tai on Covid-19 Trips Waiver,” May 5, 2021.

<sup>72</sup> WTO, “DG Calls on Members to Agree on Pandemic Response, Fisheries Subsidies by End-February,” December 2, 2021.

<sup>73</sup> As reported, under the proposed agreement, WTO members would have to decide, within six months of the decision date, whether to extend coverage to COVID-19 diagnostics and therapeutics. Ashleigh Furlong, “Compromise Reached on COVID-19

agreement on text to date.<sup>74</sup> Other WTO members generally support these efforts, but also have called for transparency. Discussion on the proposed agreement and compromise may broaden to include all 164 WTO members. WTO decisions generally are made by consensus.<sup>75</sup>

Members of Congress are divided on the need for potential new waivers to TRIPS obligations.<sup>76</sup> Supporters argue that current TRIPS flexibilities are too time-consuming and cumbersome to use, and that a new waiver would let innovators in LMICs make vaccines without fear of litigation and help LMICs respond to future COVID-19 variants.<sup>77</sup> Critics argue that current TRIPS flexibilities are sufficient, and that a waiver would stifle future innovation and not increase global vaccine production and access due to other constraints, e.g., related to supply chains and health infrastructure.<sup>78</sup> Recent developments have intensified the debate, including aforementioned WHO-backed efforts by a South African company to reverse-engineer the Moderna COVID-19 vaccine. Some stakeholders on both sides have raised concerns about the proposed new agreement.<sup>79</sup>

**Travel Restrictions.** African leaders and some public health experts decried the Biden Administration's decision in late 2021 to impose temporary travel restrictions on eight southern African countries in response to the spread of the Omicron variant.<sup>80</sup> Various other countries imposed similar or more expansive restrictions. Looking ahead at the possibility that additional variants may emerge in Africa, U.S. policymakers may examine the impact of travel restrictions on public health and diplomatic goals, including where these may conflict.

### Possible Questions

**U.S. Support for Pandemic Response in Africa.** What is your assessment of U.S. support for pandemic response efforts in Africa to date? Which U.S. efforts have been most successful, which have faced the greatest challenges, and where do you see the most urgent gaps? What might the United States learn from other donors' approaches? How have U.S. COVID-19 response efforts affected implementation of PEPFAR programs? How, if at all, can the U.S. government best leverage existing programs, such as those implemented through PEPFAR, to help counter secondary public health effects of the pandemic? In early March 2022, the Biden Administration signed a Memorandum of Cooperation with the Africa CDC. What is the anticipated effect of this agreement on ongoing COVID-19 control efforts in Africa?<sup>81</sup>

**Public Health Effects of the Pandemic.** Several studies by the WHO and others suggest that while reported COVID-19 cases and deaths in Africa have been relatively low, in reality transmission and probably mortality may have been much higher. Have Africa's youthful populations or other factors protected it somewhat from COVID-19? Has the impact of COVID-19 in Africa been underestimated? How can African countries safely implement existing public health programs while mitigating the threat

Vaccine Intellectual Property Rights Waiver," POLITICO; and WTO, "WTO DG Okonjo-Iweala Welcomes Breakthrough on COVID-19 Vaccine Waiver," press release, March 16, 2022.

<sup>74</sup> Ibid; USTR, "Statement from USTR Spokesperson Adam Hodge on the WTO TRIPS Waiver Discussions," March 15, 2022.

<sup>75</sup> CRS In Focus IF10002, *The World Trade Organization*, by Cathleen D. Cimino-Isaacs and Rachel F. Fefer.

<sup>76</sup> Various bills are pending to allow for more congressional input or approval before the Administration could agree to a waiver.

<sup>77</sup> See, e.g., February 26, 2021, letter from over 400 civil society organizations to President Biden, available at [https://www.citizen.org/wp-content/uploads/COVIDTRIPSWaiverSignOnLetter\\_022621.pdf](https://www.citizen.org/wp-content/uploads/COVIDTRIPSWaiverSignOnLetter_022621.pdf).

<sup>78</sup> See, e.g., March 5, 2021, letter from Pharmaceutical Manufacturers and Researchers of America (PhRMA) and Board members to President Biden.

<sup>79</sup> Saeed Shah, "Countries Try to Win Support for Deal to Waive Patent Protections on COVID-19 Vaccines," *The Wall Street Journal*, March 17, 2022; and Dever, "TRIPS Waiver Compromise Draws Mixed Response," March 17, 2022.

<sup>80</sup> See, e.g., BBC, "South Africa's president calls for lifting of Omicron travel bans," November 29, 2021; Cheikh Oumar Seydi, "Southern Africa: Last in line for vaccines, first in line for travel bans," Gates Foundation, December 9, 2021.

<sup>81</sup> State Department, "United States and the African Union Commission Sign Memorandum of Cooperation," March 11, 2022.

of COVID-19? What impact has COVID-19 had on routine vaccination programs? How has COVID-19 affected other public health efforts in Africa, such as countering HIV/AIDS and TB? To what extent, if at all, have social and economic pressures caused by the pandemic affected gender-based violence against women and girls in Africa? How has the health of other marginalized populations been affected by the pandemic? What noteworthy steps have African governments taken to address such challenges?

**Socioeconomic Impacts.** How has the COVID-19 pandemic affected food security in Africa? What are the possible long-term effects in Africa of the pandemic driving tens of millions more people into extreme poverty? Are we likely to see increased political unrest in African countries due to economic downturns attributable to the pandemic? Looking ahead, how might the pandemic's socioeconomic impacts in Africa, such as rising poverty, shape public health outcomes? How have the pandemic's socioeconomic and education-sector effects impacted women's and girls in Africa? Looking ahead, what consequences might tightening fiscal conditions in Africa have on regional efforts to address public health challenges?

**COVID-19 Vaccine Supply, Distribution, Uptake, and Related Issues.** What accounts for Africa's status as the world region with the lowest vaccination rates? Please discuss progress and challenges related to COVID-19 vaccine supply, administration, and uptake in Africa. How have such challenges affected Africans' access to COVID-19 therapeutics, diagnostics, and other medical countermeasures (such as medical oxygen)? How do you respond to charges that disparities in vaccine access amount to "vaccine apartheid," per the head of the WHO? What can be done to further vaccine campaigns in countries with low vaccination rates, including large populations in DRC and Nigeria? What countries in Africa have made the most progress in vaccinations, and how? To what extent have ultra-cold storage requirements affected access to mRNA vaccines in Africa, and particularly in areas lacking reliable electricity supply? Please describe the technical and commercial approaches pursued by doctor and entrepreneur Patrick Soon-Shiong as he seeks to develop vaccines in South Africa.

What are the pros, cons, and risks of the Africa CDC's recent request for a pause in new vaccine shipments pending use of existing stocks? In late 2021, AU, the Africa CDC and COVAX's criticized the pace and manner in which vaccines donations had been provided to Africa, stating that most such donations had "been ad hoc, provided with little notice and short shelf lives." To what extent have these challenges been remedied?

What are the main drivers of vaccine hesitancy in Africa? What approaches are African governments and partners, such as COVAX, taking to counter vaccine misinformation and hesitancy? How can the United States support efforts to provide reliable information on COVID-19 vaccines to African publics?

**Vaccine Production in Africa.** What are the prospects and timeline for Africa to become self-sufficient in the production of COVID-19 vaccines? What are the key obstacles? Please discuss progress and challenges in launching the WHO's mRNA vaccine technology transfer hub initiative, which to date has focused entirely on Africa. To what extent have firms such as Moderna and Pfizer-BioNTech supported this vaccine technology transfer initiative? How has Moderna responded to the South African Afrigen Biologics-led project to produce a COVID-19 mRNA vaccine based on a publicly-available sequence of Moderna's vaccine? Please discuss the support that BioNTech and Moderna are providing to enable the production of their respective vaccines in Africa, and the scale of production in question.

**Intellectual Property Rights (IPR) Issues.** How do patents and other IPR support or constrain access to COVID-19 vaccines in Africa? What are your views on the proposed agreement reached by the United States, the EU, India, and South Africa on an IPR waiver for COVID-19 vaccines, as opposed to a broader IPR waiver that would cover related medical countermeasures and technologies? What precedent might this set for U.S. trade policy? How has the current stage of the pandemic shaped the WTO talks?

**The AU, the ACT Accelerator, and COVAX.** Please describe the achievements and priorities in Africa of the multilateral COVAX initiative and the broader Access to COVID-19 Tools (ACT) Accelerator.

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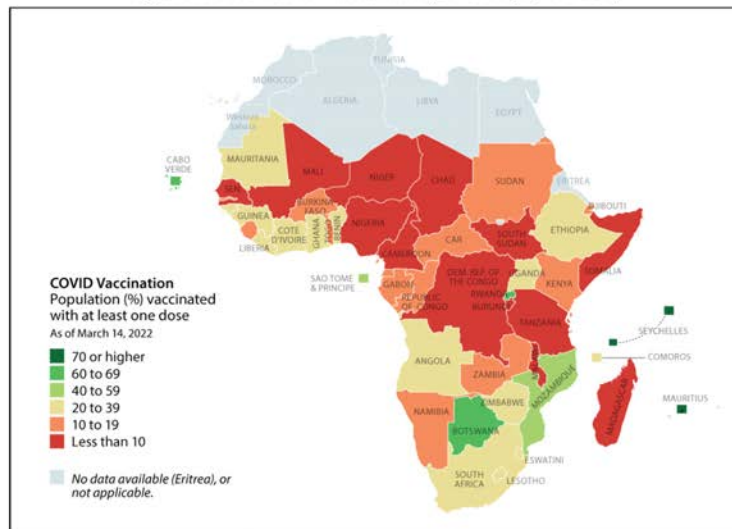
What are their current priorities and challenges? Please describe the approach and current focus of the Africa Medical Supplies Platform, a pooled procurement instrument. How are its activities financed?

**Booster Shots and COVID-19 Vaccine Donations.** The United States, along with several other high-income countries, is reportedly considering fourth booster shots for COVID-19, while 3 billion people worldwide remain unvaccinated, including many in Africa. What are your views on balancing domestic and global vaccine demands? How, if at all, are booster shot campaigns likely to affect the long-term supply of COVID-19 vaccines in low-income countries, including in Africa? How can COVAX and its partners ensure a continuous supply of vaccines to participating countries?

**Global Strategic Competition and COVID-19 Response.** To what extent, and how, have China and Russia leveraged the COVID-19 pandemic for strategic gain? How has the pandemic-related support that China and Russia have provided for Africa compare to U.S. support? What, if anything, might the United States do to increase recognition of U.S. health assistance at the local level in African countries?

#### Appendix. Map of Vaccination Rates in Africa

**Figure A-1. COVID-19 Vaccination ( $\geq 1$  Dose) by Country**



**Source:** CRS graphic based on WHO COVID-19 Dashboard data, as of March 14, 2022.

**Note:** Borders are not necessarily authoritative.

Ms. BASS. Absolutely.

Well, let me just thank our witnesses, one, for bearing with us. We went over time, but I think that this hearing was so rich that we needed to spend a little extra time and give members extra time to ask questions. But we will followup with you because you have raised several points and I think you have provided a little bit of a roadmap for us, and so, we will followup with each of you to get your specific recommendations quantified a bit more.

So with this, I would like to call the hearing adjourned.

[Whereupon, at 4:19 p.m., the subcommittee was adjourned.]

APPENDIX

**SUBCOMMITTEE HEARING NOTICE  
COMMITTEE ON FOREIGN AFFAIRS  
U.S. HOUSE OF REPRESENTATIVES  
WASHINGTON, DC 20515-6128**

**Subcommittee on Africa, Global Health, and Global Human Rights**

**Karen Bass (D-CA), Chair**

March 28, 2022

**\*REVISED\***

**TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS**

You are respectfully requested to attend an OPEN hearing of the Committee on Foreign Affairs, to be held virtually by the Subcommittee on Africa, Global Health, and Global Human Rights via Cisco WebEx (and available by live webcast on the Committee website at <https://foreignaffairs.house.gov/>):

**DATE:** Thursday, March 31, 2022

**TIME:** 2:00 p.m., EDT

**SUBJECT:** Progress and Present Challenges on COVID-19 in Africa

**WITNESSES:** His Excellency, President Mokgweetsi Masisi  
President of the Republic of Botswana  
Office of the President, Botswana

Dr. Ahmed Ogbwell  
Deputy Director  
Africa Centres for Disease Control

Dr. Patrick Soon-Shiong  
Founder and Executive Chairman  
NantWorks

\* **Dr. Maria Elena Bottazzi**  
Co-Director  
Texas Children's Hospital Center for Vaccine Development

**\*NOTE:** Witnesses have been added.

**\*\*NOTE:** Further witnesses may be added.

**By Direction of the Chair**

COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF SUBCOMMITTEE ON Africa, Global Health, & Global Human Rights HEARING

Day Thursday Date March 31, 2022 Room Virtual Web Ex

Starting Time 2:25 pm Ending Time 4:18 pm

Recesses ( ) ( to ) ( to ) ( to ) ( to ) ( to ) ( to )

Presiding Member(s)

Rep. Karen Bass

Check all of the following that apply:

Open Session [x]
Executive (closed) Session [ ]
Televised [ ]

Electronically Recorded (taped) [x]
Stenographic Record [x]

TITLE OF HEARING:

Progress and Present Challenges on COVID-19 in Africa

SUBCOMMITTEE MEMBERS PRESENT:

See attendance sheet

NON-SUBCOMMITTEE MEMBERS PRESENT: (Mark with an \* if they are not members of full committee.)

Rep. Sheila Jackson-Lee \*

HEARING WITNESSES: Same as meeting notice attached? Yes [x] No [ ]
(If "no", please list below and include title, agency, department, or organization.)

STATEMENTS FOR THE RECORD: (List any statements submitted for the record.)

TIME SCHEDULED TO RECONVENE
or
TIME ADJOURNED 4:18 pm

[Signature]
Subcommittee Staff Associate



**HOUSE COMMITTEE ON FOREIGN AFFAIRS**  
*SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, AND GLOBAL HUMAN RIGHTS*  
*COMMITTEE HEARING*  
MARCH 31, 2022

<i>PRESENT</i>	<i>MEMBER</i>
✓	Karen Bass, CA
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	Rony Jackson, TX

OPENING REMARKS FROM CHAIRMAN BASS

Rep. Bass Remarks

Virtual Hearing

“Progress and Present Challenges on COVID-19 in Africa”

Thursday, March 24, 2022 @ 2:00pm EST

**Chair (countdown):** Five, four, three, two, one.

*\*\*[Pause for three seconds, bang gavel]\*\**

**Chair:** The Subcommittee on Africa, Global Health, and Global Human Rights will come to order. Without objection, the Chair is authorized to declare a recess of the Subcommittee at any point, and all members will have five days to submit statements, extraneous material, and questions for the record, subject to the length limitation in the rules. To insert something into the record, please have your staff email the previously mentioned address or contact full committee staff.

As a reminder to Members, please keep your video function on at all times, even when you are not recognized by the Chair. Members are responsible for muting and unmuting themselves, and please remember to mute yourself after you finish speaking. Consistent with the H.Res. 965 and the accompanying regulations, staff will only mute members and witnesses as appropriate when they are not under recognition to eliminate background noise.

I see that we have a quorum and will now recognize myself for opening remarks.

Pursuant to notice, we are holding a hearing on *Progress and Present Challenges to COVID-19 in Africa* to receive an update on the ongoing COVID-19 pandemic in Africa and examine the continued challenges the continent is facing. It is my hope that with this discussion we can identify opportunities the United States and the greater international community can take to work with African leaders and the African Union in addressing these challenges.

To lead that conversation, I want to thank our witnesses for being here today - His Excellency, President Mokgweetsi Masisi of the Republic of Botswana; Dr. Ahmed Ogwell, Deputy Director of the Africa Centers for Disease Control; Dr. Patrick Soon-Shiong, Founder and Executive Chairman of NantWorks; and Dr. Maria Elena Bottazzi, Co-Director of Texas Children's Hospital Center for Vaccine Development. I welcome your testimony and the discussion surrounding it.

I look forward to hearing our experts describe what has or has not changed in the past thirteen months since this Subcommittee's last COVID-19 hearing. I also look

forward to hearing the various ways in which the U.S. and the greater international community can work with African leaders to assist with treatments, vaccines, manufacturing on the continent, and how COVID-19 has impacted the economies of African nations and the livelihoods of their people.

For the past two years, COVID-19 has taken the lives of over 168,000 Africans and has threatened the lives of nearly 8 million on the continent. With the most recent wave of the omicron variant, new variants continuing to emerge, and without a clear end date to the pandemic in sight, it is a priority to get vaccines in the arms of as many Africans as possible.

Africa has notably lagged behind the rest of the world in terms of vaccination rates, with only about 11 per cent of the total population being fully vaccinated. Though the continent has received tens of millions of donations from global initiatives, such as the World Health Organization led COVAX, to which the Biden Administration pledged 9 million vaccines to Africa, many of those donations have gone unused for various reasons, including reaching their expiration date before being administered.

However, in recent efforts, the Biden Administration has surged \$250 million of its Global Vaccine Access funding to 11 countries in sub-Saharan Africa based on the burden of COVID-19 on their populations, the capacity of their health systems, and their readiness to quickly administer vaccine doses. However, trends have shown throughout the pandemic that donations alone are not sufficient to sustain the continent.

This is why I believe manufacturing on the continent is essential, not only for the current pandemic, but also for future health threats. Currently, only five countries have capacity for vaccine production on the continent: Tunisia, Senegal, Egypt, Ethiopia, and South Africa. One of our witnesses here with us today, Dr. Patrick Soon-Shiong has opened a COVID-19 manufacturing plant in South Africa that will utilize technology from his U.S.-based firm to not only work on COVID-19 vaccines, but also vaccines targeting cancer, tuberculosis, and HIV. The steps we are seeing in South Africa are also being taken in other countries on the continent such as Rwanda. I look forward to hearing about more of those manufacturing plans.

Unfortunately, the COVID-19 pandemic caused unemployment, income loss, and pushed tens of millions of African into extreme poverty, as well as further intensified food insecurity. Further, the pandemic has caused lengthy school closures, contributing to learning losses.

It was learned in February, during this Subcommittee's hearing on education, that learning losses are likely to have consequences for future educational attainment, job training, and lead to challenges in finding employment; and COVID-19 disrupted the learning of 1.6 billion students globally. That is why just this week, I, along with my colleague Ranking Member Smith, introduced the READ Act Reauthorization Act of 2022, to expand access to basic education for children around the globe, particularly marginalized children, including women and girls. This reauthorization will allow for a total of 10 years of access to quality basic education across the globe.

With that in mind, my colleagues and I will be interested to hear from the witnesses how COVID-19 impacts on poverty, food insecurity, and implications on trade and investment. As the continent continues to strive for self-sustainability, U.S. partnerships in trade and investment are essential to enhance the availability

of jobs and strengthen the economies on the continent and here in the United States.

Finally, it is critical to learn today from our witnesses what other steps need to be taken to see progress. Though vaccine donations remain essential to safeguard health and save lives in the short term, donations must be combined with strategies that include funding and investments in health infrastructure, technology, and healthcare professionals to create a self-sustainable continent capable of ending this pandemic in Africa and prepared against future pandemics and health threats.

I now recognize the Ranking Member for the purpose of making his opening statement.

## RESPONSES TO QUESTIONS SUBMITTED FOR THE RECORD

**Questions for the Record Submitted to  
President Masisi and Dr. Maria Bottazzi  
Representative Ronny Jackson  
House Foreign Affairs Committee, AGH Subcommittee  
April 4, 2022**

**Questions:**

1. Dr. Bottazzi, what recommendations can you provide to increase partnerships between the US Government and private institutions like Texas Children's Hospital on global health initiatives?

*We have worked to raise the visibility of the success of our vaccine center so that others can replicate the model of how a U.S.-based children's hospital and academic institution can have a huge impact on addressing global problems. However, investments in vaccine research and development cannot just be made during times of crisis. Sustained support for vaccine research and development is critical.*

*An expansion of vaccine science is also required for research universities in the global South. There is urgency in establishing new doctoral and postdoctoral programs, together with training in vaccine quality practices and regulatory science so a new generation of scientists can staff future manufacturing hubs in the global South. This includes the sharing of vaccine technology and manufacturing processes, to encourage collaboration with the wider scientific community.*

2. For President Masisi – I believe the United States missed out on an opportunity in terms of COVID-19 vaccine diplomacy. We relied on COVAX and the UN to lead our vaccine distribution efforts, rather than taking control ourselves. Meanwhile, Russia and China gained concessions and deepened relationships by offering their lower-quality and untested vaccines. I am curious how COVAX versus Russian and Chinese vaccines are perceived, and how these conversations were handled. Were you offered vaccines from China and Russia, and did they include any strings attached? How is COVAX perceived by yourself and your counterparts across the continent?



**QUESTIONS FOR THE RECORD**  
**AGH Hearing**  
**“Progress and Present Challenges on COVID-19 in Africa”**  
Congresswoman Young Kim

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1. COVID-19 Vaccine Considerations

**Dr. Bottazzi:** This vaccine has been developed entirely from philanthropic contributions. What does this mean for vaccine accessibility and patent considerations? What sets apart the efforts of Texas Children’s Hospital from other initiatives? Could you also please provide a status update on your conversations with other countries on manufacturing agreements and COVID-19 vaccine procurement?

*Since we developed our vaccine entirely from philanthropic contributions without the backing of government funding, our vaccine development timeline was delayed. However, having solely philanthropic funding allowed us the flexibility to pivot our research as the pandemic evolved. We believe that this shows that there can be complementary models on how to engage in vaccine development. Because we do not have a patent, we are not restricted in our collaborations and are able to work with multiple groups and manufacturers. Our patent-free vaccine also enables others to learn how to develop the vaccine and ensures transparency in the vaccine development process.*

*We are unique in our efforts because we are a children’s hospital located in Texas, but also because we actually make vaccines. Most vaccine centers look at the immunology or basic scientific principles of vaccine development, but do not undertake the regulatory-enabling vaccine research or make vaccine prototypes to transfer to vaccine manufacturers. We uphold principles of open science and publish all our preclinical work. We also focus on traditional technologies during a time of emergency to enable rapid adoption and create a snowball effect of partnerships for production, testing and distribution. We delink the R&D process from costs to ensure that they do not burden the producers.*

*As for a status update, our COVID-19 technology is advancing as a Halal COVID-19 vaccine in Indonesia with Biofarma and in Bangladesh with Incepta. Our partnership with ImmunityBio and Botswana is contributing to the establishment of vaccine production capacity in Africa, setting the precedent for a scalable blueprint for vaccine development and distribution on the continent. We are also in discussions with countries, such as Vietnam, Argentina, Mexico, Panama and Colombia, to either transfer our technology or to educate them on the vaccine development process.*

2. Vaccination Rates in Developing Countries

**Dr. Bottazzi:** What do you assess to be the primary gaps in U.S. efforts to support expanded COVID-19 vaccination rates in developing countries? What needs to be done to address these shortcomings?

*According to the World Health Organization, African countries have fully vaccinated about 15% of their adult population, while fifteen countries have yet to reach 10% of their population fully vaccinated. Twenty-one African countries have fully vaccinated between 10% and 19% of their populations, and only five countries have fully vaccinated between 40% and 69% of their populations.*

*While it is important to make vaccines more widely available to increase rates of vaccination, increasing the supply is an incomplete solution. Of the 714 million doses received so far, only 435 million—or 61%—have been administered. One issue is the short shelf life of some vaccines, making it so supplies cannot be procured and doses cannot be administered before they expire. There is also a lack of public health infrastructure, personnel and funding to implement coordinated vaccination campaigns, as well as a level of vaccine hesitance in the region.*

*Our U.S.-made vaccine has helped to raise visibility of contributions from hospitals and academic institutions. We encourage investment in multiple vaccine technologies to best support vaccine research and development as well as in training for the next generation of vaccine scientists to excel in the chemistry, manufacturing, and regulatory sciences. It is critically important to increase partnerships with research universities and supply-chain actors and to strengthen national regulatory authorities.*

*The current vaccine ecosystem still depends heavily on multinational companies to advance innovations and provide safe and effective vaccines. But the fact that much of the global South still remains essentially unvaccinated, now two years into the COVID-19 pandemic, emphasizes the deficiencies of this approach. We must find ways to better engage existing vaccine manufacturers in low- and middle-income countries and provide them with adequate support and supply chains so that they can expand their missions.*

### 3. Partnership with U.S. Government

**Dr. Bottazzi:** What has been your experience working with the U.S. government in trying to partner on COVID-19 response efforts and contribute to U.S. vaccine diplomacy efforts? Further, what recommendations can you provide to support increased partnerships between the U.S. government and private institutions like Texas Children’s Hospital on global health initiatives?

*We have engaged in conversations with multiple stakeholders in the U.S. government, including the White House COVID-19 Task Force, the State Department, USAID, the Development Finance Corporation, as well as NIH, BARDA, HHS and other health agencies. All have been supportive of our efforts and have recognized the importance of our work, but this has not led to any substantial financial support for our center. In parallel, we have seen that the Quad summit has been quite supportive of BioE. We continue conversations with the State Department on how to partner in efforts to build vaccine infrastructure and*

*research and development in other areas of the world, especially Central America. Additionally, the diplomatic corps has also been very engaged in bridging the connections and conversations between countries.*

*We have worked to raise the visibility of the success of our vaccine center so that others can replicate the model of how a U.S.-based children's hospital and academic institution can have a huge impact on addressing global problems. However, investments in vaccine research and development cannot just be made during times of crisis. Sustained support for vaccine research and development is critical.*

*An expansion of vaccine science is also required for research universities in the global South. There is urgency in establishing new doctoral and postdoctoral programs, together with training in vaccine quality practices and regulatory science so a new generation of scientists can staff future manufacturing hubs in the global South. This includes the sharing of vaccine technology and manufacturing processes, to encourage collaboration with the wider scientific community.*