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Entitled
"Present Challenges and Progress on COVID-19 in Africa"

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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.[1] 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.[2] 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,[3] thus providing a fertile environment for COVID-19 mutations. In fact, it is believed that

[1] 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.

[2] 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]

[3] https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview

the Omicron variant emerged from an HIV patient.[4] 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.[5] There have been five variants designated by the WHO as variants of concern to date.[6] 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

[4] https://www.latimes.com/science/story/2021-12-02/did-omicron-coronavirus-variant-arise-in-patient-with-uncontrolled-hiv
[5] https://www.who.int/news/item/22-02-2022-statement-on-omicron-sublineage-ba.2
[6] https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/

Moderna similarly dropped from 89.2 percent to 58 percent.[7] 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.[8]

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 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).[9] 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.[10] And more recently, Moderna has made the same request.[11] 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

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[7] 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.

[8] "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.

[9] 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

[10] "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.

[11] 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.[12] This heterologous vaccination regimen allows the recipient to benefit from the features of each vaccine [13] 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,[14] 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,[15]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.[16] 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.[17] 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.

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[12] 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

[13] Heterologous ChAdOx1-nCoV19–BNT162b2 vaccination provides superior immunogenicity against COVID-19 - The Lancet Respiratory Medicine

[14] https://www.biorxiv.org/content/10.1101/2021.11.29.470440v2

[15] https://www.nature.com/articles/s41586-021-03594-0

[16] https://youtu.be/YA4Qme4C5CM

[17] 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 BiolgicE 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.