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

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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.[1] 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,[2] 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.

[1] Hepatitis B vaccines: WHO position paper - July 2017. https://www.cabdirect.org/globalhealth/abstract/20173352346
[2] Botswana Approves Corbevax Covid Vaccine, Plans Local Output: Bloomberg News - March 2022. https://www.bnnbloomberg.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.