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Open Letter to the Biden Administration and US Congress Calling for Urgent High-Level US Leadership to Address Escalating Global COVID-19 Vaccine Crisis

The unprecedented wave of COVID-19 now engulfing India, Brazil, and other nations—and the extreme and widening global inequities in access to vaccines—test our collective conscience and threaten our national security. Worsening mass illness and deaths, a preventable humanitarian catastrophe, are destabilizing, and projected to increase. Urgent action is required to stem global circulation of the virus and the consequent inevitable emergence of new variants, which threaten to undermine Americans' hard-fought but fragile vaccine immunity, putting lives and economic recovery at risk.

President Biden has promised to restore American leadership abroad. The world is now in great need of high-level engagement that up to now has been conspicuously absent—to mitigate death and suffering in the short term, chart a sustained exit from the COVID-19 pandemic in the medium term, and insure against another global pandemic in the long term.

As a global community, we are extremely fortunate that our collective partnerships across the public sector, philanthropy, industry, and academia have yielded multiple safe and highly effective vaccines that are protecting Americans against COVID-19. These vaccines offer an exit route out of the pandemic—but only if they reach a critical mass of people in need across continents, socioeconomic strata, and marginalized populations.

Today, the vaccines are predominantly available in only a few select high-income countries, leaving much of the world unvaccinated and vulnerable. Forty-six percent of Americans and over a quarter of Europeans have received at least one dose of a COVID-19 vaccine, but only 14% of those in South America, 4.8% in Asia, and 1.2% in Africa. Addressing this inequity requires an urgent mobilization that adapts the successes achieved in the US to bring the same benefits to all those in dire need as quickly as possible.

American leadership is required to ensure universal global access to high-quality and safe vaccines, support rapid vaccine distribution and administration, and build a sustainable global network of vaccine manufacturing capacity. The Biden administration has already taken several steps in this direction, including providing funding through Gavi, the Vaccine Alliance, for the lower and lower-middle income countries eligible for support under the COVAX Advance Market Commitment (AMC); supporting a temporary waiver of some intellectual property protections for vaccines; and brokering voluntary licensing deals for vaccine manufacturing. The administration and Congress must build on these steps to address critical needs within the next 6-9 months and provide a foundation for broad and sustainable access to vaccines for the long term.

We propose five specific areas for urgent action.

1. Designate a clear leader to coordinate the US global response, leading to a robust and sustainable global strategy

Appointment of a White House Coronavirus Response Coordinator has been critical to assure that coordinated actions have led to tremendous progress in vaccine production and distribution domestically. To extend that success globally, a White House Global Coronavirus Response Coordinator should be appointed to manage and coordinate strategy, resources, and activities for global response across agencies and departments. The Global Coordinator would work closely with the White House Coronavirus Response Coordinator.

This appointment should be coupled to the establishment of a clear and coherent strategy with input and participation from diverse government entities, including the National Security Council, Departments of State, Health and Human Services, Defense, Commerce, and Treasury, USAID and the Office of the United States Trade Representative.

US leadership should advance the implementation of an effective and sustainable strategy to optimize short-term supply, allocation, and distribution, and long-term development of a robust, globally distributed system of production of, and access to, safe and highly-effective, reliably manufactured vaccines. Actions 2 and 3 below should be initiated immediately, in parallel with leadership and strategy development.

2. Share vaccine doses now at the maximum amount feasible, while preparing for future needs

The US should commit to sharing COVID-19 vaccine doses immediately and continue sharing based on ongoing analysis of projected national needs. Given current purchase agreements and anticipated emergency use authorization of the Novavax vaccine, and accounting for vaccination of adolescents and the potential need for a booster in the fall, we project that the US will have several hundred million excess doses in the next 3-6 months. As the US continues to make advance purchases to prepare for unexpected domestic events or the need for boosters, it should simultaneously share all excess doses.

The US should allocate doses through COVAX (the global collaboration to accelerate equitable access to COVID-19 vaccines), regional bodies, and bilateral mechanisms, prioritizing countries that are most vulnerable and/or those that have later delivery dates for their own vaccine orders. One priority should be immediate donation of all available doses of AstraZeneca vaccine, following urgent FDA review for product quality but without waiting for US authorization. Allocation through bilateral and multilateral

channels, including COVAX, should consider how best limited supply could most effectively reduce disease impact, transmission, and risk of variants of concern in countries that have authorized the AstraZeneca vaccine.

Liability protection can be addressed through extension of indemnification and no-fault compensation models through the CARES Act (domestically) and COVAX (globally).

US commitments should spur other nations with substantial access to high-quality vaccines to donate these as well. The US could significantly boost global efforts by collaborating with other G7 nations to pledge at the June G7 Leaders' Summit to collectively share at least 1 billion doses by the end of 2021.

3. Strengthen and expand the manufacturing capacity for US-authorized and supported vaccines

The US government should substantially enhance production of high-quality vaccines within the next 6-9 months.

The US should finance the accelerated buildout of additional short-term manufacturing capacity for US-authorized vaccines, including ingredient processing, bulk drug production, and fill-finish, with the explicit commitment by partners that the vast majority of short-term supply will support global access at non-profit pricing. This investment will also help assure long-term reliable manufacturing capacity for future preparedness.

The US should also provide seed financing for high-quality regional manufacturing, led by the US International Development Finance Corporation (DFC), to expedite expanded capacity in existing plants in regional hubs in low- and middle-income countries, such as with the Quad Vaccine Partnership investment in Biological E in India. The US FDA could provide regulatory assistance in assuring vaccine quality and safety, and the US could also contribute to purchases of doses either directly or through COVAX. Priority should be given to investments that could credibly lead to new vaccine manufacturing within 6 months. The US should work actively with partners to ensure that there is future demand for vaccines and capacity to finance their purchase.

Increased high-quality manufacturing requires building on US steps to strengthen supply chains, including capacity of input materials such as manufacturing equipment, bioreactor bags and filters. The US already obtains data from authorized and potential high-quality US manufacturers to anticipate bottlenecks across supply chains for each vaccine. This US effort must include investment of financial and technical resources in supply chain enhancement to avoid these bottlenecks, commensurate with bold action necessary to accelerate short-term vaccine manufacturing. Expanding these efforts in collaboration with other interested nations would lead to more robust and diverse supply chains. In addition, coordination with the COVAX Manufacturing Task Force could amplify impact and would provide a path toward lifting export restrictions on both supplies and high-quality vaccines globally.

4. Support distribution and delivery infrastructure, especially for low-income countries

There is an immediate need to strengthen vaccine distribution and delivery capabilities to translate vaccines into vaccinations. The US has bilateral and multilateral mechanisms to support delivery needs, including through USAID. Multilateral development banks (MDBs) have disbursed over \$40 billion to support health systems and vaccination needs. The US can take immediate steps to strengthen national and sub-national delivery infrastructure using these resources and learnings, including from PEPFAR and The Global Fund. Coordination and collaboration with Gavi and its partners will help ramp up national vaccination campaigns quickly. The US should also work with these and other organizations to reinforce global efforts to boost demand for and confidence in vaccines and address misinformation.

In countries with health systems that have collapsed under the burden of COVID-19, USAID and CDC deployment could help provide a humanitarian response in collaboration with the UN and non-UN humanitarian actors.

5. Commit to leading development and implementation of a comprehensive, sustainable, 5-year plan for long-term scale-up of global vaccine manufacturing capacity

Developing globally distributed high-quality manufacturing capacity is a top priority for many leaders, especially in low- and middle-income countries. Investments are necessary in human capital development and knowledge transfer, to build up sustainable capacity in Africa, Latin America, and Asia beyond India. US-facilitated voluntary licensing agreements will enable knowledge transfer to bring high-quality American vaccines to the world.

Bringing brand new manufacturing capacity online will likely take one to two years. But starting now with clear commitment, funding, and technical assistance would drive this process forward, providing greater global health benefits—as well as diplomatic benefits for the US.

In conjunction with US efforts to increase short- and longer-term supply chain and manufacturing capacity, the US should work with other contributing nations and global partners to develop and refine clear goals by quarter for vaccine supply, distribution, and administration by region and country, aligned with dynamic needs and grounded in equitable access.

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The US government, with a clear strategy and strong leadership, will be positioned to push for similar strategies and commitments from other global leaders, especially at the upcoming G20 Global Health Summit hosted by Italy May 21, World Health Assembly in Switzerland May 24 – June 1, and G7 Leaders’ Summit hosted by the UK June 11-13. Looking ahead to these events, the US government should pledge to create partnership mechanisms for cost-sharing, co-investment, and dose-sharing.

What we are proposing is ambitious, and clearly not without risk of challenges and setbacks in what is likely to be an extended fight. However, the history of global health crises tells us that bold American leadership, amid considerable uncertainty, is essential for success. When engaged by the President and Congress on what is at stake, Americans will stand behind timely and meaningful U.S. vaccination leadership that will protect against further COVID-19 threats, promote economic growth, and establish reliable world-leading manufacturing capabilities against future infectious diseases. By saving lives abroad, we will save lives at home. For the pandemic will not end here until it ends everywhere.

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