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US Emergency Plan for Global COVID-19 Relief: Urgent Action to End the Pandemic Globally and Accelerate US Recovery and Security

BACKGROUND

We are at an exceedingly perilous and urgent moment in the COVID-19 pandemic. The Delta variant, vastly more dangerous and pernicious than the original SARS-CoV-2 virus, has rapidly spread worldwide. It has been driving a deadly summer surge in the US; ripping through Latin America; causing Indonesia to become the next Asian hotspot; and fueling a third wave of the pandemic in Africa, where less than two percent of the population has been <u>fully vaccinated</u>.

The US has suffered due to the COVID-19 pandemic, including over 600,000 lives lost and massive economic impacts. There have been major achievements in the nation's response, including Operation Warp Speed for vaccine development and the Biden Administration's "all of government" plan to accelerate large-scale production and delivery of the most effective vaccines. With the emergence and domination of the Delta variant, the US is again experiencing rising infections and hospitalizations, requiring more aggressive public health measures and adding urgency to increase domestic vaccination rates. To respond, the US must build on the rapid development and availability of its highly effective vaccines — ensuring easy access for any American who wants to be vaccinated, and readiness to rapidly deploy boosters and vaccines for children. But as Delta has shown, an effective domestic response is not enough.

We are in a global war against a virus that doesn't respect borders and rapidly advances across continents. If the virus continues to circulate largely unchecked in many parts of the world, there is a very real prospect of new variants emerging that could totally pierce vaccine immunity, returning America and the rest of the world to square one.

The only way to prevent such a catastrophe is to dramatically decrease cases and slow transmission of the virus through widespread global vaccination, combined with other public health measures including improved surveillance to help inform vaccination strategies. Inequitable access to high-quality vaccines threatens to prolong the pandemic and destabilize economies and societies around the world.

To <u>date</u>, 82 percent of all COVID-19 vaccine doses that have gone into arms worldwide have been administered in high- and upper middle-income countries. By contrast, less than one percent have been administered in low-income countries. Meanwhile, COVAX, the multinational vaccine facility, is struggling to meet this challenge, having <u>distributed</u> only 153 million doses out of 4.1 billion administered <u>worldwide</u>.

We are facing the very real possibility that low- and lower-middle income countries will be stuck at low vaccine coverage levels through 2022 and beyond, an outcome that will be deadly. The deep divide between vaccine haves and have-nots is a challenge to our conscience and a major threat to our economic recovery and national security.

These COVID-19 threats highlight the urgent need for a comprehensive US plan with clear and achievable goals to systematically augment and complement the currently insufficient global response. The US COVID-19 Global Response and Recovery <u>Framework</u> released by the White House on July 1, 2021, is helpful but insufficient in scope, magnitude, urgency, and execution. The US must provide more substantive leadership for the global COVID-19 response to meet its moral, humanitarian, health, and economic responsibilities at home and around the world.

Billions more vaccine doses are needed. While supply will remain constrained over the next few months, there is reason for optimism that vaccine supply will pick up considerably in the next 3-6 months. Efforts such as US White House COVID-19 Task Force planning with vaccine manufacturers, the Joint US-EU COVID Manufacturing and Supply Chain <u>Taskforce</u> established in June, and the COVAX Supply Chain and Manufacturing <u>Taskforce</u>, are addressing short-term needs and helping significantly ramp up vaccine manufacturing. The US and G7 allies have committed to share roughly 900 million doses over the next year (including 580 million from the US). But these actions fall far short of the true scale and urgency required.

As vaccine supply and dose sharing ramps up, the lack of adequate distribution and delivery capacity is quickly becoming the key constraint in the race between vaccines and variants. Indeed, there are substantial excess doses *available now* due to increasingly clear gaps in the ability of countries to vaccinate their adult populations. The US has had difficulty in distributing its initial allocation of 80 million donated doses announced in May, originally scheduled to be completed by June but still underway, because of barriers to uptake and use in potential recipient countries. In addition, Pfizer reportedly offered to provide at cost up to one billion doses for US purchase and donation to support global vaccination efforts, but the US agreed to purchase only 500 million doses due to concerns about ability for these doses to be used.

Unless vaccine delivery capabilities markedly improve, we are headed for a global supply glut, even as the vast majority of people in many countries remain unvaccinated. To prevent this, urgent action is needed to translate doses into vaccinations. This should be part of a substantial US-led effort tied to on-the-ground implementation support, with local ownership and shared accountability for results. Just as PEPFAR augmented and galvanized the global response to HIV-AIDS, a US-led initiative can augment the efforts of COVAX, UNICEF, Gavi, WHO and others by providing not only needed vaccines, but systematic technical and public health assistance to address capacity barriers. With an ample supply of the world's best vaccines and the knowhow to distribute them effectively, America is uniquely positioned to lead.

US Leadership for Coordinated Global Action

To galvanize global action and get doses into arms, **President Biden should host a presidential-level** *Global Vaccination Summit* in the lead-up to the United Nations General Assembly meeting in September. The Summit should bring together public and private sector leaders from around the world, especially from low- and lower-middle income countries, and secure commitments to take the needed actions to close vaccine supply gaps and address financing and capacity gaps in vaccine distribution, delivery, and demand generation.

President Biden should also rally global leaders to commit before or at the Summit to meeting the goal of vaccinating 70 percent of the world's population by mid-2022, a bold but necessary target that is achievable with strengthened resources and capabilities. Such bold commitments, backed up by realistic plans and high-quality implementation, offer the best exit ramp from the acute phase of the pandemic.

Before or at the Summit, the US should also launch a US Emergency Plan for Global COVID-19 Relief (USEPCR) to help achieve that goal and augment multilateral efforts, including the COVAX/WHO-coordinated global response. US-led efforts would significantly enhance and support existing multilateral efforts, including ACT-A and COVAX and regionally-led efforts such as the Africa Vaccine Acquisition Task Team (AVATT). The US should continue to support those efforts, including ensuring full funding for ACT-A and COVAX, regular assessments, and reforms over time to make global efforts most effective.

The US Emergency Plan for Global COVID-19 Relief should be White House-led, spearheaded by a Global COVID-19 Emergency Response Coordinator reporting to the President and supported by a special inter-agency task force. The Global COVID-19 Emergency Response Coordinator should release the USEPCR within 30 days, with specific targets for high-quality vaccine production for global use and dose sharing, and for increasing global vaccination capabilities, capacity, and resources as well as surveillance. The USEPCR would identify specific ways in which US resources and capabilities would complement the COVAX/WHO-coordinated multinational response, as well as regional initiatives across low- and middle-income countries. The plan would seek to mobilize private resources to support vaccination capacity as well.

The plan's focus should be on immediate emergency relief, but it should be developed and implemented in a manner that advances long-term health system capacity for providing routine immunizations for children and adults, as well as other essential health services. Indeed, accelerating the response to the current crisis would be one of the most effective health systems strengthening initiatives ever undertaken. The plan would also serve as a catalyst and a model for efforts by other high-income nations to use their excess vaccine supplies and technical capabilities to augment the global response more effectively.

Key Elements of a US Emergency Plan for COVID-19 Relief

The USEPCR would build on the recent strategies that have worked domestically to vaccinate almost 70% of American <u>adults</u> and contain the most severe effects of the pandemic. A comprehensive global response could total \$50 billion based on <u>IMF</u> estimates. Significant resources for the US global response have already been appropriated by Congress. In addition, American and multinational private sector are also contributing extensively to the global response with both financial and in-kind resources, but would also benefit from a clear US plan for how to respond.

While this emergency plan can and should be implemented now, it would benefit from additional Congressional support. The administration and Congress should urgently work to advance legislation to fund and sustain a comprehensive international COVID-19 response as well as health systems strengthening and pandemic preparedness efforts.

1. Supply High-Quality Vaccines

The USEPCR should build on current US and multilateral initiatives to increase vaccine production and make more doses available globally as quickly as possible. As has been <u>described</u> <u>previously</u>, several urgent steps are necessary to move this effort forward.

Strengthen global coordination of vaccine supply chain and manufacturing.

Greater transparency and accountability in the vaccine marketplace are essential. The US should press for the development of comprehensive monthly estimates of global vaccine input availability (e.g., bioreactors, lipids, filters) and vaccine supply for the coming 12-18 months, so that the US and other countries will have assurances of sufficient doses for future domestic needs, while also maximizing the amount of high-quality vaccines available for global use. The US should also actively provide supply chain facilitation, identify and address critical bottlenecks across supply chains, ensure the free flow of vaccines and vaccine inputs across borders, and provide technical and financial assistance as needed to maximize short-term vaccine production globally.

Share more doses more quickly. The Biden administration has made world-leading commitments to share doses, at least 580 million doses over the coming year. Total global commitments toward dose-sharing stand at almost 900 million doses. These figures are still far short of what is needed and what is possible.

Fortunately, the supply of high-quality vaccines produced by US and allied manufacturers is projected to exceed 7 billion doses in 2021 and 14 billion doses in 2022 – more than enough to vaccinate the world. But doing so will require coordinated action by the US, other nations, and manufacturers to finance, allocate, and deliver doses where they are most acutely needed. The G7/EU have confirmed purchases of over 5.5 billion doses, enough to fully vaccinate ~3 billion people, three times the population of the G7/EU nations. Based on current purchase agreements, the US alone will likely have over 1 billion excess doses beyond domestic needs, even assuming full vaccination and boosters for the entire population.

Given current manufacturing capacity and purchases to date, the US should further increase its own commitment to at least 1 billion doses by mid-2022, bring forward the timing of donations to provide at least 500 million doses in 2021, and push other high-income countries, especially the G7/EU, to substantially increase donations. The US, along with G7/EU allies, should plan to donate a minimum of 1 billion doses by the end of 2021, and explore further steps to aim to increase donations to 2 billion doses by the end of the year. With allies, the US should further commit to ensuring enough supply to provide vaccines for 70% coverage for all countries by mid-2022.

Accelerate globally distributed manufacturing capacity for vaccines and vaccine

inputs. The US should provide financial and technical assistance and facilitation of private sector licensing and knowledge transfer to ramp up vaccine manufacturing capabilities and capacity in low- and middle-income countries, especially in Africa, Latin America, and Asia. The US International Development Finance Corporation (DFC), along with other bilateral and multilateral organizations including the IFC, has recently made three investments to support such manufacturing and supply chain capacity in India, South Africa, and Senegal. This successful model should be further expanded and accelerated. The US should also seek a global agreement on reducing the use of export restrictions for COVID-19 vaccines, therapeutics, diagnostics, and related inputs.

2. Support Country-Level Assessment, Capacity Development, and Vaccination Campaigns

The USEPCR would bring together the considerable US biomedical, distribution, and public health resources to augment global efforts to enhance vaccination capacity and implementation. It would include the following elements:

Distribution planning to maximize impact of available vaccines. The plan would identify priority countries for enhanced vaccination support, based on assessment of the capacity of each country to get shots in arms of those at highest risk for complications equitably. This assessment, in coordination with complementary efforts by COVAX partners and the multilateral development banks to assess absorptive capacity, would be based on the following criteria to support the goal of achieving effective and equitable vaccination in the partner country:

- History of bilateral collaboration and effective institutions, which would enable working through the US mission and with local representatives of the COVAX lead institutions and other multinational groups, to support national efforts to identify and address any critical gaps in vaccination and health system capacity
- Vaccination capacity assessments
- Ability of US resources to help countries address critical gaps identified in capacity to vaccinate, as described below
- Current and projected COVID-19 burden, as reflected in case rates and the resulting stress on the nation's health system
- US strategic interests

For countries with strong existing capabilities, support might simply include distribution of donated vaccines through COVAX. However, recent capacity assessments suggest that most countries have significant gaps in one or more of the critical areas described below, so that additional US assistance is critical for enabling vaccination efforts to succeed. The USEPCR might start with an initial target group of countries, then ramp up as quickly as possible as vaccine supply increases and as gaps in vaccination capacity are identified and addressed.

Country-level resource coordination through US mission: Using the principles, framework, and resources of the USEPCR, and in collaboration with local public health authorities, the US mission would co-develop and help implement a country-specific operating plan to coordinate all US vaccination support resources. This includes US government resources: FDA technical assistance to local and regional regulatory authorities for vaccine and manufacturing site authorization; USAID and other State Department assistance; CDC and US Public Health Service Corps deployments for technical assistance; PEPFAR and other US-supported infrastructure that could be augmented to support vaccination while still performing their other public health functions; and others including local or regional Department of Defense capabilities. The US mission would also help coordinate private-sector support from US and multinational corporations, e.g., in providing assistance with distribution, cold storage and personnel. The plan would be implemented in a manner that strengthens health system and pandemic response capacity for the long term, reflecting the growing US engagement in forward-looking pandemic preparedness.

Timely high-quality vaccine and manufacturer authorization: WHO has authorized use of the high-quality US and European vaccines, and COVAX has developed an indemnification framework for these vaccines. While these steps are critical for vaccine availability, in practice additional steps may be needed for timely use of available supplies. For example, local regulatory authorities need assurances that particular vaccine batches meet reliable manufacturing standards, and vaccines produced under US contracts and donated by the US do not automatically qualify for COVAX indemnity protection. Based on its close familiarity and extensive experience with the relevant vaccines, the US will provide regulatory expertise and technical assistance to assure that these issues are addressed for all supplied vaccines.

Storage and distribution capacity: Successful vaccination requires sufficient local storage and distribution capacity to get the high-quality vaccines to sites where they can be administered, while maintaining secure chain of custody and storage conditions that meet the labeled requirements for the vaccines. Updated requirements are available through US CDC and WHO documents. The highly effective mRNA vaccines require storage conditions that may be challenging in some settings, and all the vaccines require highly reliable adherence to these conditions to assure vaccine efficacy. Large-scale vaccine distribution in compliance with these storage conditions can present a major logistical challenge. Mission-led, country operating plans would provide technical and material assistance with these efforts.

Local distribution planning: For maximum impact, the US-supported vaccine supply should be targeted equitably to reach the highest-risk populations (older individuals and those with chronic diseases or other risk factors) in local communities and neighborhoods. The local US initiative would help countries address any significant gaps in planning for and reaching high-risk individuals.

Vaccinator capacity and data systems: Most countries do not have sufficient capacity to deliver shots in arms with suitable monitoring and management of any serious short-term reactions. In addition, tracking systems are needed to reliably identify individuals who have been vaccinated, and to assure follow-up for the second dose of the two-dose vaccines. As part of the USEPCR, US vaccination and treatment supports in many countries can be mobilized to help address any critical gaps in these areas, and the mission can help coordinate the use of additional US private and non-government resources to augment vaccinator capacity.

Safety monitoring and response: The rare serious side effects that have been detected with the US- and EU-authorized vaccines occur within days to several weeks after vaccination. Countries need a capacity to detect and manage rare but potentially significant vaccine side effects. Countries also need the ability to inform health care providers and the public about any safety updates related to the vaccines. Finally, countries need to know if serious breakthrough infections are occurring after vaccination. US public health experts at CDC and elsewhere have

extensive experience with all of these issues, as well as on-the-ground support in many countries for similar public health activities. The country operating plan would include technical assistance and support in assuring appropriate monitoring of vaccine safety and effectiveness.

Public education, engagement, and management of misinformation: With the rapid development of vaccines and substantial misinformation about vaccines in social media, a high prevalence of questions, uncertainty, and hesitancy about vaccination is a widespread global reality. The USEPCR will include public and private technical assistance and resources to help address important questions about the vaccines and other sources of vaccine hesitancy, in close collaboration with local providers and other trusted community leaders.

Summary

By hosting a Global Vaccination Summit, aligning global leaders to commit to vaccinate 70% of every country's population by mid-2022, and launching the US Emergency Plan for Global COVID-19 Relief to complement multilateral efforts, US action can serve as a catalyst and model for efforts by other high-income nations to use their excess vaccine supplies and technical capabilities to augment the global response.

By strengthening health systems to accelerate the response to the current pandemic, the US Emergency Plan for Global COVID-19 Relief would also support preparedness for the next pandemic. This effort would be aligned with, and complementary to, the Independent Panel for Pandemic Preparedness and Response (IPPPR) proposed International Pandemic Financing Facility, the G20-proposed Global Health Threats Fund, and the thrust of the proposed bipartisan International Pandemic Preparedness and COVID-19 Response Act. This plan should evolve to become part of a permanent initiative to increase preparedness for future pandemics.

This US Emergency Plan for Global COVID-19 Relief reflects both our ideals as a people and our interests as a nation. By galvanizing global efforts to vaccinate the population of the world's poorest, most afflicted countries, it will accelerate the end of the pandemic – here and everywhere.







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