The Time Is Now for U.S. Global Leadership on Covid-19 Vaccines

The CSIS Commission on Strengthening America’s Health Security

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Preface

It is in the United States’ strategic interests to ensure that the world mobilizes effectively to end the SARS-CoV-2 pandemic. A proactive U.S. role is essential to secure the gains underway in the United States and ensure Americans’ health, safety, and prosperity into the future. Helping to secure the future of lower- and middle-income countries is also simply the right thing to do, on humanitarian, economic, and security grounds.

Today, the United States is quickly approaching a moment of genuine promise, when exceptionally effective vaccines, accelerated distribution at home, and an enlarged American vaccine industrial base open the door for the Biden administration to bring American leadership to urgent global vaccine challenges. The United States’ health, economic, and national security interests argue for seizing this moment, beginning with presidential leadership to explain the stakes to Americans still legitimately worried about the epidemic at home. The United States ignores at its own peril the acute threat posed by viral variants, geopolitical rivals who take advantage of the moment, and deep vaccine inequity around the world. By sharing American vaccine resources starting at the soonest possible moment, the United States can claim ascendancy against these risks. That essential step should be part of a four-part U.S. diplomatic strategy that will:

1. Bring order to the Covid-19 vaccine marketplace;
2. Expand global Covid-19 vaccine supply, including by enhancing manufacturing capacity;
3. Build local Covid-19 vaccine distribution capacity; and
A Pivot Point of U.S. Confidence

The United States should launch a signature global initiative on Covid-19 vaccine supply, delivery, and demand, propelled by high-level U.S. diplomacy and combined with a robust strategy with concrete, quantifiable goals. The Biden administration is on track to reach a pivot point of confidence in managing the domestic epidemic over the course of the summer, and it should seize that opportunity to escalate its international engagement while attending to the ongoing domestic challenges and making the case for U.S. global engagement to the American people. The Biden administration has already taken important steps to support the global vaccination effort but should do more, quickly, to lay the diplomatic and operational groundwork, leveraging the global leadership role of the Office of the President and President Biden’s personal commitment. The administration should signal its intent to begin to scale up the sharing of vaccine doses with lower- and middle-income countries, beginning at the earliest possible moment and accelerating through the fall. It should work with international partners to develop an international coalitional effort to bring greater transparency and accountability to the global vaccine marketplace and to create voluntary incentives for technology transfer to increase regional manufacturing capacity. It should prioritize improving production, quality control, and pricing to ensure equitable access to vaccines. And it should spearhead innovations that will strengthen partner country readiness and increase public trust and confidence in vaccines and vaccine demand.

These are fundamentally ethical, economic, and national security matters. Concerted U.S. action internationally will strengthen the protection of Americans at home but also lift the threat posed by the pandemic to the world’s most vulnerable populations, expedite the reopening of the global economy, and enhance U.S. influence in shaping solutions that align with U.S. values and interests. These goals can be advanced while epidemic controls are consolidated at home. And even in the setting of a successful domestic vaccination campaign, failure to adequately address critical vaccine shortages abroad means extended time periods for Covid-19 transmission globally. This longer pandemic window will accentuate human suffering, hamper global economic development, continue to limit international travel for at least the next one to two years, and increase the risk of vaccine-escape variants that can undermine control in the United States and globally.

Why act now? The situation at home is changing fundamentally and rapidly. The United States possesses several exceptionally safe and effective vaccines, production is scaling up, and supply stockpiles will soon exceed domestic demand. The rapidly expanding domestic vaccine rollout is laying the groundwork for an exit out of the acute phase of the epidemic at home, at the same time that portions of the $1.9 trillion American Rescue Plan are consolidating the core components of the U.S. domestic response. Confidence is rising steadily that the United States will soon have the suite of tools needed to control the epidemic at home over the summer and stabilize and reopen the economy and society by fall.

These promising changes, arriving more quickly than originally anticipated, open the door for increased U.S. engagement globally. At home, leaders will still need to address the risk of a spring surge and the threat of vaccine-escape variants; plan to vaccinate older children by late summer and younger children by late 2021 and into 2022; address the possible manufacturing and distribution of booster shots and recurrent vaccines; continue to urge masking and social distancing measures and also find and stop clusters; and answer the questions of Americans who have concerns about vaccine safety or refuse to accept them. The race will continue to resolve scientific unknowns (e.g., how effectively vaccines stop infectious transmission by variants, including those that have not yet emerged; and how long immunity lasts). But with the rapid deepening of U.S. capacities and the expansion of vaccine coverage, the United States is in a much better position to manage these challenges—and engage more intensively outside its borders.
The Race against Health, Economic, and National Security Risks

Why the urgency? There are several unfolding threats the United States cannot ignore.

There is a widening, increasingly conspicuous gap between the world’s wealthiest and most powerful states and low- and middle-income countries in terms of timely and affordable vaccine access. High-income countries, while accounting for only one-fifth of the global population, have purchased over half of all vaccine doses. As of April 12, nearly 806 million vaccinations had been administered worldwide, but nearly 90 percent of those vaccines have gone to residents of high- and middle-income countries. A world divided into haves and have-nots will fail to bring the pandemic under control anytime soon, and global inequality will only increase in the absence of efforts to expand vaccine coverage in lower- and lower-middle-income countries.

The United States cannot ignore that there are not enough Covid-19 vaccine doses for people who need them around the world. Scarcity of vaccine supply and inadequate manufacturing capacity are increasingly a source of tension, leading to export bans, dubious political side deals, and calls for a temporary waiver of the Trade-Related Aspects of International Trade (TRIPS) Agreement to meet emergency needs. Vaccine manufacturers and suppliers who make the equipment, components, and materials for vaccine production are working to expand capacity at a moment when it remains difficult to predict global supply and demand dynamics or availability of essential inputs. As manufacturers and suppliers work to almost quadruple capacity to meet the world’s needs, governments and multilateral institutions have an essential role to play in setting norms and standards, investing to close gaps, and enabling the free flow of materials across global supply chains. At the same time, global agencies, including the World Health Organization (WHO), Gavi, the Vaccine Alliance, the World Bank Group, and UNICEF, can play a key role in advocating for the equitable distribution of Covid-19 vaccines among and within countries, providing necessary funding and supply chain access, and supporting national and local initiatives to strengthen vaccine confidence. Such initiatives should include enabling health workers and trusted community figures to help household decisionmakers, often women, make informed decisions about why and when to vaccinate their families.

The United States cannot ignore the perils of a global vaccine marketplace that invites price-gouging, fraud, and substandard products and that operates outside the norms and practices essential to guarantee safety, open sharing of information, accountability, and healthy outcomes. The scarcity of vaccine supply can create a black market for both illicit and unregistered or unlicensed vaccines. Such a marketplace openly benefits China and Russia, which have each not adhered to the standard rigors for testing and verifying the safety and efficacy of vaccines. When the United States deployed the Defense Production Act to stimulate domestic vaccine development and production, it inadvertently created shortages abroad. That experience and similar actions by other governments have brought home the lesson that in the future it will be critical to bring about heightened coordination with respect to global supply chains.

The United States cannot ignore the geopolitical dimensions of this emerging crisis. China and Russia are attempting to leverage vaccine donations for diplomatic and political gain, with limited transparency about the development, safety, effectiveness, and approval of vaccines and often pairing efforts with disinformation campaigns targeting U.S. and other Western vaccines.

The United States also cannot ignore the mounting threat posed by the emergence and spread of new SARS-CoV-2 variants worldwide. This profoundly increases the urgency of finding durable global solutions that can close the gaps in vaccine access, control spread, and put in place adequate diagnostic testing and genomic surveillance networks. Large populations with uncontrolled transmission anywhere will perpet-
uate widespread suffering, loss of life, and economic dislocations and increase the probability that even more dangerous variants will emerge and proliferate. Inequitable vaccine distribution will also jeopardize global economic recovery, including the resumption of international trade and travel.

A pressing companion concern is the lack of readiness in many countries to distribute and administer vaccines, track vaccinations, and monitor safety and disease spread. A recent World Bank report found that while 85 percent of 128 low- and middle-income countries have developed national vaccination plans, serious gaps remain, particularly in vaccinator capacity and community engagement and demand for Covid-19 vaccines.

These threats lead to a single powerful conclusion: the recent gains in controlling Covid-19 in America and elsewhere could easily be undermined if the United States does not take quick, effective action to accelerate global vaccination efforts. The United States simply cannot afford to act sequentially: if it turns to the global vaccination effort only after full domestic vaccination is complete, precious time and progress will be lost. Delay will not only cost lives and economic instability, but also increase the risk of even more dangerous variants emerging in populations that are not fully immunized and in which the spread of the virus is uncontrolled. It is in the health security and economic interests of the United States to expedite the delivery of vaccines to the entire U.S. population while simultaneously expanding equitable access to vaccines outside U.S. borders.

**America Approaches a Pivot Point—From Shortage to Plenty**

The Biden administration has understandably focused its initial efforts on addressing the profound crises Americans face at home: a spring surge; the difficult and decentralized early phase of the vaccine rollout; a fragile economy; and social instability, racial and ethnic violence, and highly polarized political divisions. Sharing vaccine doses internationally has been seen as an acutely sensitive issue which could invite backlash.

Yet the situation in America is changing.

In his March 11 **address** to the nation commemorating the anniversary of the Covid-19 shutdown, President Biden shortened the timeline for a national pivot. He directed all states to make all adults eligible for Covid-19 vaccines by May 1 and set forth a goal to “mark our independence from this virus” through small family celebrations on July 4. On April 6, he **accelerated** the timeline further, setting April 19 as the new deadline to make all adults eligible for Covid-19 vaccination. If vaccinations continue at the rate of about 3 million vaccinations per day, over **70 percent** of eligible Americans will be at least partially vaccinated by June 10.

Vaccine supply constraints are easing, moving from scarcity to abundance. **Operation Warp Speed**, a multi-agency public-private partnership created by the Trump administration, successfully expanded the U.S. industrial base for vaccine production. Accounting for all of its procurement deals (even for those vaccines that have not yet received emergency use authorizations [EUAs] from the U.S. Food and Drug Administration), the United States could generate 400 million or more excess doses in 2021, over and above what is required to vaccinate the **260 million** adults in the United States. Vaccinations of roughly 60 million children, a critical step in controlling the epidemic in the United States, could begin in the late summer and extend into 2022.

The actual surplus available will be subject to production, handling, and distribution factors. Ongoing investigations into a possible linkage between adenoviral vector vaccines (both AstraZeneca and Johnson & Johnson) and rare blood clots will shape outcomes. The timing of the EUAs for AstraZeneca, Novavax, and Sanofi vaccines will be another important factor.
A Diplomatic Leadership Moment Not to Be Missed

The progress in vaccine production and distribution that is steadily unfolding today in America is creating a much more favorable environment for purposeful U.S. diplomatic leadership globally. A clear strategy, long-term goals, and defined mechanisms for vaccine sharing still need to be developed.

The passage of the $1.9 trillion American Rescue Plan secured additional financing for the pandemic response, stabilization of the economy, and ambitious efforts to alleviate poverty. The bill also included $11 billion to support the global Covid-19 response, including $3.5 billion for the Global Fund, $3 billion for U.S. Agency for International Development (USAID), $650 million for the Centers for Disease Control and Prevention’s (CDC) global Covid-19 response, and $300 million for the Coalition for Epidemic Preparedness and Innovation (CEPI). These assets are now in position to undergird an expanded U.S. vaccine diplomacy.

On April 5, Secretary of State Antony Blinken announced the appointment of Gayle Smith, the administrator of USAID for President Obama and the president and CEO of the ONE Campaign, as the U.S. coordinator for global Covid response and health security. While acknowledging that the Biden-Harris administration’s first priority is stopping Covid-19 at home, Secretary Blinken articulated the need for U.S. leadership in the global response as well, noting, “this pandemic won’t end at home until it ends worldwide.” During an April 11 interview, Secretary Blinken reaffirmed this, noting, “… when all is said and done, you will see the United States as the leading country around the world in making sure that everyone has access to vaccines.”

President Biden has stated on several occasions that the United States is committed to sharing vaccines once U.S. needs have been met. There is $4 billion in the December 2020 FY 2021 appropriations bill, signed by President Trump, to support Gavi, the Vaccine Alliance, in the procurement and distribution of Covid-19 vaccines for the low- and lower-middle-income countries eligible for support under the Covid-19 Vaccines Global Access (COVAX) Advanced Market Commitment (AMC). That establishes the United States as the largest donor to COVAX, and by extension, the Access to Covid-19 Tools (ACT) Accelerator—the multilateral effort to equitably distribute Covid-19 diagnostics, therapies, and vaccines to low- and middle-income countries.

U.S. Covid-19 Vaccine Procurement Deals

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1.3 billion | 750 million

President Biden has consistently named global health security and international cooperation to stop Covid-19 as top foreign policy priorities, including in renewed U.S. membership in the WHO, remarks at the February 19 G-7 Summit and the Munich Security Conference, and in the Interim National Security Strategic Guidance issued by the White House and described by Secretary Blinken on March 3.

At the Quadrilateral Security Dialogue Summit on March 12, President Biden committed, in concert with Japan, India, and Australia, to expand India’s private sector vaccine production by 1 billion doses by the end of 2022, principally to benefit Association of Southeast Asian Nations (ASEAN) member states. Less than one week later, the administration announced that it would loan 4 million doses of the AstraZeneca vaccine it had procured to Mexico and Canada, where the vaccine has already been authorized.

A Four-Part U.S. Strategy

The United States will bring considerable leverage to any global strategy on vaccines. It is the biggest vaccine market and the biggest investor in vaccines, with the deepest impact on research and development of new products.

And the United States possesses unparalleled assets to shape the international Covid-19 vaccine distribution effort—in terms of political and diplomatic sway, financial resources, regulatory and research and development capacity, trade influence, intellectual property protection, and, soon, substantial vaccine surpluses. It has a record of highly successful partnerships with private sector innovators and, under the Biden administration, has openly recommitted to multilateralism. These assets provide the foundation of a coherent, strategic approach to renewing U.S. leadership, in partnership with others, to shape outcomes that align with U.S. values and national interests.

The Biden administration can build upon the legacy of the historic U.S. achievements in responding to the then-runaway global HIV/AIDS pandemic two decades ago. In launching the Global Fund to Fight AIDS, Tuberculosis and Malaria and the President’s Emergency Plan for AIDS Relief (PEPFAR), the George W. Bush administration acted strategically amid an urgent crisis. It struck long-term partnerships with industry, national governments, civil society, foundations, and others. It forged a multiyear approach that insisted upon accountability. It built these gains on durable bipartisan support in Congress and among the American people, who have committed billions of taxpayer dollars to innovative health programs. The lessons from HIV can inform actions today that aim for rapid and effective vaccine distribution and administration, matched by trust and confidence in their benefit. Over the longer term, these lessons can inform global efforts to better prepare for the next emerging infectious disease.

To carry forward this vision of U.S. global leadership, it will also be essential to move rapidly to fill or establish positions of senior leadership and accountability at the Departments of State and Health and Human Services, including the CDC, and at USAID.

The U.S. strategy can rest on four clear, concrete, quantifiable goals:

1. Bring Order to the Covid-19 Vaccine Marketplace

   - The United States should join with other partners in the establishment of a mechanism that will bring greater predictability, transparency, and investment partnerships to the vaccine marketplace, including creating incentives for technology transfer to increase regional vaccine manufacturing capacity. This effort should increase the visibility of manufacturing and supply chain needs and forecasts among manufacturers, suppliers, and purchasers; align regulations that improve the free
flow of materials and expertise across borders; and define concrete actions and norms to create a more transparent and accountable vaccine marketplace.

This could take the form of an ad hoc coalition of the willing, or an international task force under the auspices of the G-20. It would need to bring in major vaccine-producing countries as well as vaccine developers. To spearhead this effort, the appointment of a respected former statesperson—or multiple—would potentially add substantial credibility and gravitas. They would also need the support of a cadre of seasoned global health experts.

2. Expand Global Covid-19 Vaccine Supply

- The United States should ensure the success of COVAX in vaccinating 20 percent or more of the populations of its 92 AMC eligible lower- and lower-middle-income partner countries and can support efforts to increase that percentage as doses become available. Gavi, the Vaccine Alliance, will be launching an investment case for COVAX funding on April 15, co-hosted by Secretary Blinken, and the United States has further committed to supporting a June 2021 meeting intended to mobilize much-needed financing for COVAX.

  U.S. influence will be considerable in determining the allocation of its $4 billion contribution to Gavi (some of which will go toward non-vaccine purchases, as detailed below). The United States will potentially also have valuable contributions to make through the sharing of doses, provision of technical expertise, assistance in unwinding logistical and supply chain logjams, and participation in early planning for long-term financing.

- The United States should support efforts to expand Covid-19 vaccine manufacturing capacity in key countries with existing manufacturing and transport infrastructure, regional influence and reach, and demonstrated adherence to regulatory norms. This effort should build manufacturing for all safe and effective vaccine technologies, including mRNA, viral vector, and protein-based vaccines. The mRNA vaccine technology, including the Moderna and Pfizer-BioNTech vaccines, have substantial advantages, including faster production scale-up, greater ease and speed of adjustment to manage SARS-CoV-2 variants and future disease threats, and less vulnerability to production delay. The Johnson & Johnson vaccine, a single-dose adenovirus vaccine that can be stored in standard refrigerators, may be especially important in international settings where there is no ultra-cold chain.

  The United States should partner with industry to ensure the free flow of vaccine manufacturing components, facilitate voluntary licensing and technology transfers, and implement fair pricing models to ensure affordable access in low- and middle-income countries. This effort should be part of a longer-term strategy to build medical countermeasure capacity, vaccine manufacturing capabilities, and ownership outside of Europe and North America in an effort to strengthen global health security and combat inequity.

- The president should announce, as soon as possible, that the United States will be moving ahead with vaccine sharing and creating incentives for technology transfer to increase regional manufacturing capacity as central elements of its enlarged diplomatic engagement. The United States should begin to share doses soon thereafter, early in the summer, at an initial level of 10 percent of surplus stocks, growing incrementally to 50 percent of surplus stocks by the end of 2021. The effort can include substantial contributions from the AstraZeneca stockpile, building off of the recent precedent of the U.S. loan to Mexico and Canada. In the meantime, plans should be laid out in advance, now,
for production and sharing levels for 2022. The U.S. dose donation strategy should be reviewed and adjusted as more information about long-term immunity conferred by vaccines is made available.

The sharing of vaccine doses will likely be a mix of contributions to COVAX and U.S.-branded contributions to key regional bodies and partner countries with significant trade, transportation, and diaspora links to the United States. It will be important to refine the mix of criteria—disease burden, humanitarian stakes, geopolitical alliance, and economic stabilization—that will ultimately inform the distribution process.

There will have to be careful consideration of the national regulatory requirements and legal and indemnification issues that will complicate donating vaccines produced for the U.S. market. The United States can assist COVAX in the development of its shared-risk compensation fund that addresses liability issues.

The United States can also take a leadership position by supporting international organizations and nongovernmental organizations (NGOs) in efforts to establish and maintain no-fault systems to ensure that persons who suffer injuries associated with administration of Covid-19 vaccines receive prompt and fair compensation without the need for litigation. The WHO has recently established such a system for low- and middle-income countries that receive vaccines through the COVAX facility, but there is scope for the United States to offer its unique expertise with the design of vaccine injury compensation programs, as well as to assist with their funding.

The United States should extend further support for CEPI, which has taken a global leadership role in the development of variant vaccines, as well as sorting out raw material shortages in manufacturing. CEPI could also support technology transfer efforts. The American Rescue Plan set aside $300 million for CEPI. CEPI is further seeking a U.S. contribution of $200 million during its next five-year funding cycle.

3. Build Local Covid-19 Vaccine Distribution Capacity

- The United States should strengthen regional bodies—the Africa Centres for Disease Control and Prevention (ACDC), ASEAN, and the Pan American Health Organization (PAHO)—in their efforts to assist member states in achieving epidemic control. This can take several forms, such as sharing of doses, financing, and technical expertise, including secondment of U.S. personnel and strengthening and harmonizing regulatory processes.

- The United States should launch a concerted effort to strengthen key U.S. bilateral partner countries in achieving readiness in the equitable distribution, administration, and tracking of vaccines and in the establishment of integrated disease surveillance systems, including genomic sequencing systems. It will be critically important in this regard to leverage U.S. programmatic capacities, such as PEPFAR—especially their existing platforms and networks of health workers—to distribute vaccines and engage hard-to-reach populations.

- The United States should work with key multilateral partners, including COVAX, the UN High Commissioner for Refugees (UNHCR), UNICEF, and international NGOs, to ensure that vaccines reach the most vulnerable populations, including internally displaced populations, refugees, migrants, and detainees. COVAX has committed to reserving 5 percent of its stockpile to respond to acute outbreaks and support humanitarian organizations, but more concerted efforts will be needed to ensure that these groups are not left behind.
• The United States should work with multilateral efforts to create fiscal space in lower- and middle-income countries to invest in their health infrastructure, which will be essential for responding to the current crisis as well as making investments in future pandemic preparedness. The United States should also strengthen and bolster the World Bank’s technical assistance capacity for the dozens of countries that are leveraging World Bank loans and grants to bolster their frontline vaccine distribution capacities. At the same time, significant attention must be given to minimizing the unintended consequences of Covid-19 vaccine distribution on weakening essential health service delivery.

4. Strengthen Global Demand for Covid-19 Vaccines

• The United States, working with existing multilateral partners, including Gavi, the WHO, UNICEF, and bilateral partners, should reinforce global efforts to boost demand for and confidence in immunizations, including Covid-19 vaccines.

• The United States can press that there be a specific spending stream under its foreign assistance investments dedicated to increasing vaccine confidence. U.S. diplomats can emphasize the importance of equitable vaccine distribution in speeches and written communications and can support U.S. agency efforts at the country level to strengthen vaccine access and confidence in Covid-19 vaccines. The Vaccination Demand Hub is led by a coalition of partners, including the CDC, that gathers evidence and builds tools to promote demand for immunizations internationally. The United States can increase support for this coalition’s work that seeks to identify the best ways to improve communities’ confidence about vaccines.

• The United States, recognizing that Covid-19 vaccine misinformation and disinformation circulate internationally and undermine vaccine confidence, can work with social media companies and digital platforms to support domestic and international efforts to reduce the amplification of misinformation and better connect online users with compelling and accurate public health content.

The President Must Engage Americans to Seize This Moment

How can the United States move this vision forward?

The near future offers many choice international moments for advancing this vision, including the impending release of the Independent Panel for Pandemic Preparedness and Response (IPPPR) report, the EU/G-20 Global Health Summit on May 21, and the World Health Assembly (May 24–June 1).

As the window for greater U.S. global engagement opens, the Biden administration will need to build support for this signature foreign policy initiative through focused outreach to the American people. Selling heightened U.S. engagement to a divided and skeptical American population is not business as usual. It requires a strong rationale communicated in powerful, innovative ways.

A presidential speech in the spring of 2021 can make the case directly to the American people that U.S. efforts abroad will secure the gains at home; reduce the acute, growing global threat of virus variants; hasten the reopening of international travel and the global economy; push back on undue Chinese and Russian influence; and establish U.S. leadership that can shape outcomes that align with U.S. values and interests. All of that can be accomplished without compromising efforts at home to control the pandemic. Faith leaders, industry leaders, traditional and social media platforms, and state and local government officials should be enlisted to help communicate the message that building on current progress and ensuring a sustain-
able recovery from the epidemic in America will require global commitments and action. A U.S. national commission on the pandemic, modeled after the highly impactful 9/11 Commission, could also contribute significantly to building an informed consensus among Americans on what was experienced, at home and abroad, and the essential steps to better protect Americans and others into the future.

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For complete bios, please visit [https://healthsecurity.csis.org/members](https://healthsecurity.csis.org/members).

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This paper represents a majority consensus. No author is expected to endorse every single point contained in the document.

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