

May 3, 2021

The Honorable Joseph R. Biden
President
The White House
Washington, DC

Dear Mr. President,

The worsening COVID crises in India, Brazil and elsewhere has intensified the need for all interested global parties – governments, industry, multilateral organizations and non-profit organizations -- to urgently step-up efforts to get COVID vaccines and therapeutics to the patients who need them most, wherever in the world they may live.

In the past year, over 950 research and development projects to address COVID have been launched, 70% of them by small and medium sized companies. These efforts can only truly be successful if they result in patients around the world receiving safe, effective treatments and vaccines. Clearly further action is needed if we are to achieve true global social justice in addressing the COVID crisis. The United States is poised, with existing and soon-to-be-expanded capacity, to truly be the world's "arsenal of vaccines" as you called for last week.

With this goal in mind, we at BIO would like to suggest the establishment of a **COVID Global Strategy for Harnessing Access Reaching Everyone (SHARE) Program**, to be implemented immediately. The Global SHARE Program would consist of three parts: 1) Ensuring sufficient global *supply* of vaccines; 2) Ensuring safe and expeditious global *access* to vaccines and therapeutics; and, 3) Ongoing Efforts to strengthen and support healthcare systems in low-and middle-income countries in addressing COVID.

We propose the following policies and actions be taken:

1) Ensuring Sufficient Global Supply

- To facilitate optimal production of safe and effective vaccines globally, governments, with the support of the WTO, need to *adopt policies that facilitate and expedite the export of key raw materials* and manufacturing supplies needed for COVID-19 vaccine manufacturing. This will help speed the delivery of doses produced by ALL manufacturers worldwide.
- Governments, working with industry, *urgently need to identify key bottlenecks in the global supply chain* for vaccines, and determine how to most quickly but safely facilitate the development of new supply where necessary. A global mechanism for tracking the supply chain, managed by an independent third party, will soon be announced. This initiative should help ensure timely and accurate data on product shortages and supplies and should be strongly supported by the US government.
- *COVID vaccine manufacturers need to continue to make all practicable efforts to increase their output in a safe and effective manner*, by putting in new capacity and by engaging in voluntary licenses with partners who are capable of meeting regulatory GMP standards. BIO is pleased acknowledge for example the recent announcement of

Moderna to increase its production of vaccines to 3 billion doses next year. Current projections show that global manufacturing capacity continues to grow and should reach or exceed 10 billion doses before the end of 2021.

- The United States government should work with its allies to further *strengthen the global supply chain by encouraging and coordinating investments in global suppliers* of raw materials and consumables. Efforts can be undertaken to add suppliers of key materials in the short and long term to best support the increased level of vaccine manufacturing capacity around the world.

2) Ensuring Safe and Expeditious Global Access to Vaccines

- The United States government, and other governments with significant domestic vaccine supplies, should *pledge to donate a meaningful proportion of these supplies to low- and middle-income countries* through COVAX or other effective means.
- The United States should work with U.S.-based manufacturers *to allow export of COVID-19 vaccines from American facilities*. Many vaccine manufacturers have significantly increased their U.S. capacity and this could be used to urgently supply doses to both COVAX and countries with bi-lateral arrangements with companies. The United States is now poised to be, as President Biden declared “the arsenal of vaccines” for world.
- *COVID manufacturers* should likewise, through COVAX or other direct means, put in place and announce concrete plans to *commit and ship significant quantities of vaccines to low- and middle-income countries*. In some cases, this will require legal permissions by governments to allow for the export of finished vaccine doses.
- The United States should demonstrate global leadership with other high-income countries and multilateral organizations by *urgently donating resources to low-and middle-income healthcare systems to ensure that vaccines can be distributed and provided safely and effectively to needy populations*.
- *Low-and middle-income countries should adopt policies to accept and adopt regulatory approvals in countries of origin* with stringent regulatory agencies (e.g., FDA, EMA, MHRA), and forgo putting in place additional regulatory hurdles in place that would slow access to vaccines.
- The U.S. government should provide *aid to the COVAX countries seeking to implement the WHO’s No-Fault Compensation program* and continue to invest funds to strengthen national pharmaco-vigilance and surveillance programs. These continued investments will help protect patients and providers, provide essential information about SARS-Cov-2 variants and vaccine efficacy, and build vital infrastructure for future pandemics.
- Vaccines and other products procured by COVAX or by individual nations for donation to low-and middle-income countries should be delivered at no cost to the recipient countries.

3.) Establish ongoing efforts to help global healthcare systems address COVID

The United States government should examine opportunities to implement broader initiatives that leverage the learnings of the President’s Emergency Plan for AIDS Relief (PEPFAR). While the issues surrounding the COVID-19 pandemic are not exactly the same as the AIDS epidemic,

elements such as White House leadership, close coordination with global allies, strong metrics and reporting mechanisms and commitments to invest in both developing country health systems and strategic partnerships for product access helped make the program a global health success.

- The Administration's Global Coronavirus Coordinator could lead this initiative by working closely with stakeholders to determine a set of activities that will positively impact both access to vaccines and therapeutics worldwide but also strengthen overall global preparedness.
- BIO and its members welcome the opportunity to work with the Administration on a PEPFAR-like set of initiatives that can provide mid and long-term solutions.

We acknowledge of course that this may not be the full universe of possible and practical solutions. BIO stands ready to work with the United States government and all key global parties to build on this framework and find such solutions.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'MMH', with a long horizontal flourish extending to the right.

Michelle McMurry-Heath, MD, PhD
President and Chief Executive Officer