



Dr Michelle McMurry-Heath
President & CEO

March 5, 2021

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

Dear Mr. President,

On behalf of the Biotechnology Innovation Organization (BIO) I would like to share our thoughts on how to best work together with global partners to ensure that patients around the world get access to COVID vaccines, therapeutics, and diagnostics. BIO is the world's largest biotechnology association, representing about 1,000 members in over 30 countries around the world who develop innovative products to improve the world's health, climate, and nutrition. We are committed to the principle that our world-leading scientific advances can only help humanity if people have access to them. Clearly, the global pandemic can only be ended with global efforts that reach everywhere this deadly virus is prevalent.

I am pleased to report that the global biotechnology community stepped in with truly unprecedented speed in 2020 to research and deploy COVID solutions. Our data shows that in the months following the outbreak of COVID, over 800 global development projects to create vaccines, treatments and diagnostics were launched.¹ About half of these projects have been generated from the United States and, significantly, about three-quarters are from small- and medium-sized enterprises.

BIO strongly supports strong, efficient, and effective efforts to see that successful COVID products get to patients everywhere in the world that need them. We are concerned about the unequal pace at which scarce vaccines and treatments are becoming available to different populations around the world. Given the scientific, regulatory, and logistical challenges, a solution will require cooperation among diverse parties on an unprecedented level. The COVAX initiative and "ACT-Accelerator" initiatives were organized to do just that, and we applaud the Biden Administration's decision for the United States to join these multilateral efforts, as well as its reengagement with the WHO. As the attached document demonstrates, moreover, there is a large and growing number of global collaborations inside and outside of these global initiatives, which have been developed in record time.

But, as much as has been achieved to date, clearly, there is much more work to be done to ensure the patients around the world get access to COVID vaccines and medicines. Regulatory harmonization of emergency use authorizations, suspension of tariffs, creative financing mechanisms, facilitating in-country vaccination campaigns, combating vaccine hesitancy and misinformation, and the use of restraint when considering export restrictions will be important in assembling a global strategy that meets the international need for vaccines and treatments.

¹ BIO COVID-19 Therapeutic Development Tracker, <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker>

BIO especially supports advancing the cooperative collaborations in ACT Accelerator and COVAX initiatives and would like to work with the Administration to make them more far-reaching and effective. Indeed, one of our immediate priorities is to ensure that the biotech community of small and medium sized companies get a seat at the table of ACT-A and COVAX, since they represent so much of the industry's work in this area, and because, as small companies, many lack the global connections necessary to ensure broad access to their products once developed. BIO has a long history of facilitating the partnering and collaborations that will be necessary to expand supply to meet the globe's need, and we stand ready to assist the Administration and its partners around the world in this critical endeavor.

In view of our commitment to finding effective means of ensuring broad global access to COVID solutions, we have strong concerns about some proposals being made that would set back and complicate such efforts. In particular, we consider the proposed WTO "TRIPS waiver" of all intellectual property rights is both a wrong-headed and ineffective means of spurring further efforts at access. First, the scientific and regulatory barriers required before one can safely and efficiently produce these advanced technologies are simply too high to be accomplished by anything other than cooperative, collaborative partnerships. The TRIPS waiver by contrast could spur a spate of confusing, mutually inconsistent and heavy-handed "compulsory" demands by governments all over the world for supply and technology transfer, which would distract from the need for coordinated international efforts and the cooperative work that currently is being advanced, and thus ultimately undermine the very goals of quick, safe access that it seeks to promote.

In short, we recognize that more must be done to address the world's need for COVID vaccines and treatments. America's and the world's biotech companies stand ready to continue and to expand the unprecedented efforts they have already made to bring COVID medicines to patients all over the world. We cannot do this alone, nor can any single party. But the world needs to be working together to advance the coordinated efforts that have been organized. The TRIPS waiver would be a divisive and ineffective detour from that critical work.

BIO looks forward to continuing its work with the Administration and other parties in developing policies that address global access considerations to COVID treatments and vaccines while also continuing to support innovative biotech research and development endeavors aimed at bringing this pandemic to an end as soon as possible.

Yours Sincerely,



Michelle McMurry-Heath, MD, PhD