Biotechnology Innovation Organization

Dr Michelle McMurry-Heath
President & CEO

June 22, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Secretary Becerra,

The Biotechnology Innovation Organization ("BIO") is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. Our members are pioneering innovations in human health, food and agriculture, and industrial and environmental applications. Many of BIO's members have responded to the pandemic crisis to find fast solutions to prevent, treat, and diagnose COVID-19.

The partnership between the biopharmaceutical industry and the U.S. Government is largely responsible for where we are with the COVID-19 pandemic today. In just 16 months from the declaration of the pandemic, cases have dramatically dropped as more than 50% of U.S. adults have gotten vaccinated, and we now have proven treatments for cases of COVID-19. Despite this success, BIO and our members are concerned by the May 2021 change to the Biomedical Advanced Research and Development Agency (BARDA) Broad Agency Announcement (BAA) that suspends prioritization of Area of Interest (AOI) 9.2 -COVID-19 Therapeutics.

Over the past decade, industry has willingly partnered with BARDA on development of medical countermeasures (MCMs) for chemical, biological, radiological and nuclear (CBRN), pandemic influenza, and emerging infectious disease threats. The many successful public-private partnership efforts to develop vaccines and therapeutics for threats like pandemic influenza, smallpox, and anthrax provided the infrastructure for advanced research and development (ARD) and procurement of COVID-19 vaccines, therapeutics, and diagnostics.

While the pandemic has seemingly turned a corner in the U.S., cases are expected to rise again this winter and it is still premature to deprioritize advanced research and development (ARD) and procurement of therapeutics for COVID-19. Public health leaders anticipate that we will still see moderate and severe cases of COVID-19 infection that require treatment and possible hospitalization. Authorized COVID-19 monoclonal antibodies (mAbs) have been lifesaving. Therapeutics in the pipeline and optimized formulations of authorized mAbs feature different modalities, mechanisms of action and/or routes of administration and may offer broader protection against arising variants. These differences could offer important clinical and access benefits in terms of treating early-stage disease as well as severe disease. There is utility in having a broad array of products to treat COVID-19 cases as the pandemic continues, variants arise, and COVID-19 eventually becomes an endemic disease.

Additionally, due to the complexity of administration of current therapeutics and variability in access to healthcare, there have been disparities in access to these products. Continued investment in additional therapeutics is critical for ensuring equity across populations in terms of access to treatments. Continuous investment in a broader portfolio of COVID-19 therapeutics will facilitate access to new medical countermeasures through easier routes of

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administration, fewer potential doses, or more specific impact on clinical outcomes. This includes investment in products at all stages along the full development pipeline.

Finally, finishing the job with COVID-19 therapeutics will have applicability to our ability to rapidly respond to infectious disease threats in the future. While products may not necessarily be broad spectrum products that can be used to treat other viruses, there are products in development that treat the secondary effects of viral infections, such as acute respiratory distress syndrome (ARDS) and the debilitating impacts of 'long COVID'. Proven treatments will also provide established mechanisms, platforms, and approaches that can be leveraged for rapid response to a range of viral infections.

We applaud HHS for the recent announcement of the Antiviral Program for Pandemics. In addition we recommend that HHS more clearly articulate a strategy for continued development of other COVID-19 therapeutics. The American Rescue Plan (2021) provided $6.05B but it is unclear how much, if any, of these funds has been allocated to BARDA for the funding of ARD and procurement of improvements to existing COVID-19 therapeutics as well as support for next generation therapeutics. This strategy should include details on the necessary resource allocation for continuing BARDA's work in both ARD and procurement of COVID-19 therapeutics. Such a strategy is critical for industry partners in their research planning. This strategy is also an important part of the next stages of our response to this pandemic as we prepare for potential variants of concern or outbreaks in areas of the country. Industry responded to the call during the pandemic, and HHS should clearly communicate your ongoing strategy to partners.

We welcome the opportunity to discuss this issue in more detail with you and your staff. Please do not hesitate to reach out if BIO can serve as a resource on COVID-19 therapeutics or any issues related to MCM development.

Yours Sincerely,

Dr. Michelle McMurry-Heath
President & CEO
Biotechnology Innovation Organization (BIO)

Cc:
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