



December 7, 2020

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Vivek Murthy, MD, MBA  
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Marcella Nunez-Smith, MD, MBS  
Co-Chair  
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Dear Drs. Kessler, Murthy, and Nunez-Smith:

Since the beginning of the COVID-19 pandemic, AABB, America's Blood Centers, and the American Red Cross – which collectively represent the nation's blood collection establishments, transfusion services and transfusion medicine professionals – have come together to collect, manufacture, distribute, and provide COVID-19 patients with access to COVID-19 convalescent plasma (CCP). We have worked in collaboration with Operation Warp Speed, the Food and Drug Administration (FDA), which establishes the regulatory framework, and the Biomedical Advanced Research and Development Authority (BARDA), which provides cost recovery for CCP doses under contracts with America's Blood Centers and the American Red Cross. This time of transition for the administration is also a critical time for CCP.

Throughout the pandemic, blood collectors in the U.S. have been the exclusive providers of CCP for transfusion, an invaluable "bridge" therapy for treating patients with COVID-19 while the nation awaits the development of vaccines and other therapies. To date, blood collectors have collected and distributed more than 400,000 doses of this potentially life-saving product to patients hospitalized with COVID-19. The supply of this product is continuously tenuous as it relies on donations from volunteers who have recovered from COVID-19. The current surge in COVID-19 cases has placed significant pressure on the supply of this therapy and demand is outpacing collections. At the same time, the existing contracts with BARDA will need to be revisited given current collection and demand forecasts for CCP utilization. For these reasons, we urge the Biden-Harris transition team to begin to work with our organizations as quickly as possible in order to ensure an adequate supply of CCP for this winter's pandemic demands.

We encourage the Biden-Harris Administration to:

- **Raise awareness of the need for CCP donation:** Unlike other COVID-19 therapeutics, the availability of CCP is limited by the willingness of Americans who have recovered from COVID-19 to give of themselves. The blood community appreciates that government and private-sector partners have been actively engaged in raising CCP donor awareness and supporting recruitment efforts. Messaging from public health officials is an important component of assuring Americans of the safety of donation, the need for CCP to help in the fight against COVID-19, and the essential need for donations. We request that the Biden administration continue amplifying messages that support the need for CCP donation and utilize trusted public health officials in encouraging donation.
- **Maintain BARDA payments directly to blood collectors for CCP:** BARDA's current contracts for CCP encourage collections and remove potential barriers to access to this therapy. Hospitals and patients do not

pay for the CCP units that BARDA purchases. However, BARDA's current contractual commitments will be exhausted long before hospital demand will abate. Since CCP is intended to be a bridge therapy in place until other therapeutics for COVID-19 become available, we urge the Biden administration to continue this payment model and make sure BARDA extends the CCP contracts as dictated by demand.

- **Prioritize Blood Center Workforces:** Blood center staff are not immune from the personal impact of COVID-19. Currently, approximately 10 percent of blood center staff are out of work at any given time due to either being personally sick or in quarantine for possible exposure. Some geographies have experienced even greater reductions in their workforce due to outbreaks leading to limits on collections. We urge the administration to prioritize blood center staff in the distribution of vaccines in the Phase 1-A group and for testing to ensure individuals negative for the virus can return to work in a timely manner.
- **Support research and physician education related to CCP:** We encourage the Biden administration to continue supporting clinical trials evaluating CCP so that we better understand its efficacy and optimal treatment regimens. Additionally, since our knowledge of CCP is continuously evolving, we encourage the Biden administration to support physician education related to this novel therapy. Proper physician education on the best clinical indications of use for this limited therapy will ensure its availability for those patients in need.

Our organizations look forward to working with the Biden-Harris Administration in continued efforts to battle the COVID-19 pandemic by providing CCP to patients in need and completing the bridge to vaccines and other therapies. As we navigate the upcoming months there may be situations where the blood industry needs support prioritizing our supply chains with our manufacturing partners for such items as blood bags, laboratory supplies (including pipette tips), and PPE equipment to keep our staff safe. As these situations arise, we will communicate those needs and are grateful for your consideration and support.

Our organizations are available as resources and look forward to working with the President-elect and the Vice President-elect transition team, the Transition COVID-19 Advisory Board, and the Biden-Harris Administration. If you have any questions, please contact Leah Stone (301-215-6554, [lmstone@aabb.org](mailto:lmstone@aabb.org)), Diane Calmus (202-654-2988, [dcalmus@americasblood.org](mailto:dcalmus@americasblood.org)) or Julie Manes (202-417-5147, [julie.manes@redcross.org](mailto:julie.manes@redcross.org)).

Sincerely,

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