Advancing Transfusion and Cellular Therapies Worldwide

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American Red Cross

January 6, 2021

Peter Marks, M.D., Ph.D., Director
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Nicole Verdun, M.D., Director
Office of Blood Research and Review, CBER
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Drs. Marks and Verdun,

Since March of 2020, the U.S. blood community has been committed to the national effort to support the collection and distribution of COVID-19 convalescent plasma (CCP), in partnership with the Department of Health and Human Services, the U.S. Food and Drug Administration (FDA) and the Biomedical Advanced Research and Development Authority. CCP serves as a bridge therapy providing a potentially life-saving treatment for critically ill patients until additional treatment options become available. The purpose of this letter is to request FDA revise the guidance to clarify that it is not necessary to defer CCP donors following vaccination if the individual has recovered from infection with the SARS-CoV-2 virus and meets all criteria for CCP donation.

The implementation of the August 2020 Emergency Use Authorization (EUA) for CCP eased the administrative burden on hospitals and further expanded access to patients in need. In the CCP EUA Guidance, updated November 16th, the FDA retained the recommendation (first issued on September 2nd) that blood centers "should not collect COVID-19 convalescent plasma from individuals who have received an investigational COVID-19 vaccine because of the uncertainty regarding the quality of the immune response produced by such investigational vaccines." We understand FDA intended this recommendation to prevent CCP donation by vaccinated individuals who were never infected yet we are already seeing a growing number of vaccine deferrals for recovered COVID-19 patients who would otherwise be eligible to donate CCP. With the rapid rollout of vaccines across the population, we expect a large percentage of unnecessary vaccine deferrals of otherwise eligible CCP donors will negatively impact the national supply of CCP. These unnecessary deferrals currently include returning CCP donors who wish to continue donating CCP after vaccination and, perhaps more importantly, deferral following vaccination of recently recovered individuals who are more likely to have high titer CCP donations.

We are requesting that donors who were previously infected, subsequently recovered from COVID-19, and meet all criteria remain eligible to donate CCP following vaccination. We are requesting FDA revise the guidance to clarify that the agency recommends vaccinated individuals who have never been infected be deferred from CCP donation but does not recommend deferral of individuals who have recovered from infection, received the vaccination, and have been qualified, or will be qualified in the future, for CCP donation by virtue of antibody reactivity to both spike and nucleocapsid targets.

Thank you very much for your ongoing support and partnership in the effort to bring CCP to patients in need. Should you have questions, please contact Sharon Carayiannis (571-340-4565, SCarayiannis@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Scott Webber (404-427-1414, scott.webber@redcross.org).

Sincerely,



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Kate Fry
Chief Executive Officer
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J. Chris Hrouda
President, Biomedical Services
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