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IDSA
Infectious Diseases Society of America

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Peter W. Marks, MD, PhD
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave WO71-3128
Silver Spring, MD 20993-0002
ocod@fda.hhs.gov

Dear Dr. Marks:

The Infectious Diseases Society of America (IDSA) applauds the March 24 U.S. Food and Drug Administration (FDA) notice of emergency Investigational New Drug Applications (eINDs) for individual patients experiencing severe or life-threatening effects of COVID-19. Our society has closely followed FDA efforts to ensure safe and available testing and therapies to combat this pandemic, and we appreciate the agency's continued receptiveness to innovative and rapid solutions.

IDSA represents over 12,000 infectious diseases (ID) physicians and scientists devoted to patient care, prevention, public health, education, and research. Our members not only care for patients with serious infections such as HIV, tuberculosis, malaria, hepatitis viruses B & C and infections caused by antimicrobial resistant pathogens, but are often at the front lines of responses to public health emergencies such as Ebola virus, Zika virus, MERS-CoV, influenza, and most recently COVID-19. In light of the present situation, we believe that it is essential to explore a wide range of options for treating the increasing numbers of very ill patients with COVID-19 respiratory illness.

With the rapid advance of COVID-19 in the United States, emergency prevention and treatment options are required until effective vaccines and new antiviral treatments become available. IDSA thus supports the well-controlled utilization of passive immunization with convalescent plasma from recovered patients, which was used with success in the pre-vaccine era and further investigated following the 2009-10 H1N1 influenza pandemic and 2012 MERS-CoV epidemic.

IDSA recognizes that FDA is committed to protecting patients and we support your continued efforts to protect public health and facilitate access to treatment. Although many questions will have to be answered about dosage, indications for use, safety, and efficacy before this approach can be used in infection prevention, we encourage the collaboration and cooperation of academia, industry, and federal government to expedite scientific progress and regulatory approval of this promising approach. IDSA stands ready to assist in facilitating such collaboration.

Sincerely,

Thomas M. File, Jr., MD, MSc, FIDSA
President, IDSA