For Immediate Release

ATS Statement on Latest COVID-19 Policy Actions: Convalescent Plasma and Testing of Asymptomatic Patients

Aug. 28, 2020 -- The American Thoracic Society is alarmed by two federal agency policy actions that may significantly impact our nation's COVID-19 response. This week, the FDA issued an emergency use authorization (EUA) for the use of convalescent plasma to treat COVID-19 disease. This action was taken despite a lack of adequate evidence demonstrating a clear benefit for most patients. As pulmonary and critical care clinicians and researchers who treat individuals with COVID-19, we are concerned that an EUA for convalescent plasma has the potential to put patients at risk.

While convalescent plasma currently indicates promise as a treatment for some patients with COVID-19, more study is needed to determine who might benefit from treatment, when treatment is most effective and what risks might accrue to patients treated with it. Answers to these important questions will only be gained through rigorous clinical trials, ideally randomized controlled trials. However, this EUA may discourage enrollment in clinical trials, may lead to use in low-volume settings where outcomes are generally worse, and may limit monitoring of adverse treatment outcomes.

We are also deeply concerned that the lack of transparency surrounding the EUA announcement has undermined the scientific credibility of the FDA. The ATS urges the FDA to publicly disclose the evidence base for issuing the EUA in the context of concerns raised by the scientific community, including the NIH leadership, to reassure the community and ensure public confidence in the FDA decision making process.

Secondly, the ATS is gravely concerned by the CDC's revised guidance on COVID-19 testing. Public health evidence clearly indicates that asymptomatic individuals are important source vectors of SARS-CoV2 community transmission. Testing asymptomatic individuals who are close contacts of those known to have COVID-19 infection is an evidence-based public health intervention that slows infectious disease transmission, along with other critical interventions including contact tracing and isolation. It is unclear what the scientific rationale is for changes that will lead to reduced testing of asymptomatic close contacts of COVID-19 positive individuals.

In addition, the revised CDC guidance was communicated to the public with insufficient clarification and little supporting evidence, leaving important interpretation to the lay press and general public, resulting in confusion for health professionals and the public. Changes in guidance without a clear scientific basis undermine trust in the CDC, our nation's frontline public health agency, and has the potential to further hinder our COVID-19 response.

The ATS recommends that the CDC restore the previous guidance on COVID testing and further, articulate a comprehensive plan for testing, contact tracing and isolation that minimizes

community spread of SARS-CoV2. Finally, the ATS urges the Administration to adopt a comprehensive communication strategy that reinforces public confidence that decision-making on our pandemic response is driven by science and evidence-based public health practice, not politics.