



Medical Societies Call for Treatment Approvals Based on Science

10/8/20

While the ongoing impacts of COVID-19 continue to highlight needs for new and proven tools to combat the spread and effects of this novel coronavirus, the development, evaluation and use of treatment strategies must be guided by science. Establishing the safety and efficacy of potential therapies is essential to ensuring their appropriate and effective use. The U.S. Food and Drug Administration must continue to base any approval, including Emergency Use Authorization of treatments and vaccines, on established scientific standards. Promising results among small numbers of patients to approaches that include antibody therapies are not a substitute for the rigorous scientific review that is essential to ensuring the safety and effectiveness of medicines. Relying on such limited data can put patients at risk of adverse events, and an EUA can reduce the ability to conduct the clinical trials that are needed to assess the safety and efficacy of antibody treatments. For this reason, we urge FDA to apply its highest standards and act with appropriate deliberation on the EUA application filed by Regeneron today, and on the planned application announced by Lilly this week.

As our fight against this pandemic continues, our understanding of the virus will continue to grow. **The practice of existing measures to prevent, contain and mitigate the spread of COVID-19 recommended by the U.S. Centers for Disease Control and Prevention, however, remains fundamental to protecting ourselves and each other.** The use of masks and maintaining physical distances, in any setting where transmission can occur, restricting the size of gatherings, as well as practicing strict hygiene, remain imperative. Testing for the virus and contact tracing of all people exposed to an infected, or potentially infected, person are crucial to identifying risks and targeting responses. People who are confirmed to be infected should remain isolated, whether receiving treatment or not, to avoid exposing additional people to the virus and its potentially deadly effects, and to avoid furthering its spread. For the same reason, people who have been exposed should be tested and quarantined.

The quest for vaccines and treatments continues. As we face the work ahead, the tragic toll of this pandemic demands a response guided by science and solidarity.

- **Thomas File, M.D., FIDSA – President, Infectious Diseases Society of America**
- **Jason M. Pogue, PharmD, BCPS, BCIDP -- President Society of Infectious Diseases Pharmacists**
- **Judith Feinberg, M.D. – Chair, HIV Medicine Association**
- **Mary Hayden, M.D., FIDSA, FSHEA – President-elect, Society for Healthcare Epidemiology of America**
- **Kristina A. Bryant, M.D., FPIDS — President, Pediatric Infectious Diseases Society**