



Legal Intervention in Clinical Practice Exposes Patients to Serious Harm

More than a year into the COVID-19 pandemic, clinicians, scientists and public health leaders on the front lines of our response remain eager for new safe and effective therapies to treat COVID-19. The suffering and loss of life due to COVID-19 are tragic. We empathize with patients and their loved ones and are working to ensure the best care and outcomes for all.

It is for this reason that we insist upon rigorous scientific review processes and standards to ensure the safety and efficacy of COVID-19 therapies and that we entrust medical decision-making to experts. To provide optimal outcomes for infected patients, treatment decisions should be made using evidence-based data and not anecdotal opinions. Efforts to influence clinical practice through lawsuits, including recent cases ordering hospitals to treat COVID-19 patients with ivermectin, could expose patients to serious harm and undermine the evaluation of COVID-19 treatments.

Regulatory Drug Review

It is critical to our nation's public health that COVID-19 therapies be adequately studied and that data supporting their use be evaluated by the Food and Drug Administration in a transparent manner. FDA is considered the global gold standard for safety and effectiveness review of medical products, and we rely upon FDA expertise now more than ever. Established FDA processes help to ensure that treatments are safe and effective, inform clinicians on optimal use and build public confidence.

To make therapies available as rapidly as possible during the pandemic, FDA has reviewed data quickly and utilized the [Emergency Use Authorization](#) mechanism repeatedly, including to authorize nine therapeutics for COVID-19 (as of May 9, 2021). To date, ivermectin has not been authorized as a COVID-19 treatment by FDA.

COVID-19 Clinical Guidelines

The National Institutes of Health and professional societies have rapidly developed and updated clinical guidelines to keep pace with evolving science and therapeutic options. In March 2020, IDSA formed a multidisciplinary panel of experts composed of infectious diseases clinicians, pharmacists and guideline specialists to develop rapid, [evidence-based guidelines on COVID-19 treatment and management](#). These guidelines have been continuously updated since that time to reflect new research findings. In assessing the literature regarding the use of ivermectin in patients with COVID-19, the guideline panel has determined the certainty of evidence is very low for both hospitalized patients and outpatients. For this reason, the panel has made a conditional recommendation against the use of ivermectin in these populations outside the context of a clinical trial. The panel has also stated that well-designed, adequately

powered and well-executed clinical trials are needed to inform decisions on treating COVID-19 with ivermectin.¹

Clinicians treating patients with COVID-19 are relying upon their extensive training, evidence-based guidelines and peer reviewed literature to evaluate individual patients and make the recommendations and treatment decisions most likely to result in positive outcomes. To ensure patients receive evidence-based care and achieve optimal outcomes, it is critical to avoid inappropriate interference in the practice of medicine.

¹ Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19. Infectious Diseases Society of America **2021**; Version 4.2.0. Available at <https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>. Accessed 7 May, 2021.