June 9, 2020

The Honorable Mitch McConnell  The Honorable Nancy Pelosi
Majority Leader  Speaker of the House
United State Senate  United States House of Representatives
317 Russell Senate Office Building  1236 Longworth House Office Building
Washington, DC 20510  Washington, DC 20515

The Honorable Chuck Schumer  The Honorable Kevin McCarthy
Minority Leader  Minority Leader
United States Senate  United States House of Representatives
322 Hart Senate Office Building  2468 Rayburn House Office Building
Washington, D.C. 20510  Washington, DC 20515

Dear Leader McConnell, Leader Schumer, Speaker Pelosi, and Leader McCarthy:

As Congress develops its next legislative response to the COVID-19 public health emergency, the American Association for the Study of Liver Diseases (AASLD) would like to express our support for your efforts to provide funding and relief to protect patient access to safe and effective health care services. AASLD is the leading organization of scientists and healthcare professionals committed to the prevention of liver disease, early diagnosis and care of liver disease, and advancing research for treatments and cures for liver disease. Our members continue to provide care to vulnerable and disadvantaged patients with complex, chronic conditions, like cirrhosis, hepatitis, and fatty liver disease, as well as patients under immunosuppression due to liver transplant, and disproportionately higher rates of Black and minority patients, who are at much higher risk during this public health emergency. Today, we urge you to take additional steps to protect the health of our patients and to support providers as Congress develops the contents of the fourth COVID-19 stimulus package.

We implore you to include the following provisions to protect vulnerable patients with liver disease:

- **Provide research funding to study how COVID-19 impacts patients with liver disease.** We appreciate that the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136) provided funding for the National Institutes of Health (NIH), including specific institutions like the National Institute of Allergy and Infectious Diseases and the National Heart, Lung, and Blood Institute. However, this law did not include funding for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which supports significant amounts of research on liver disease, obesity-associated fatty liver disease, diabetes, transplantation, and other chronic diseases. As we have come to learn more about the signs, symptoms and complications of COVID-19 patients, it is very clear that comorbid, chronic conditions significantly increase the risk of death when COVID-19 infections occur. There is a significant gap in knowledge and research on how COVID-19 impacts patients with comorbidities, including chronic liver diseases. The Centers for Disease Control and
Prevention (CDC) even underlines this point in their recently released resource, “What to Know About Liver Disease and COVID-19.” CDC acknowledges that some research has found that COVID-19 can cause increased levels of liver enzymes and that liver damage is more common in patients with COVID-19, but more research is needed. Without additional funding, NIDDK will not have the capacity to continue existing research projects and undertake new research on COVID-related comorbidities that will be critical both for disease mitigation and the development of effective treatments and vaccines.

- **Appropriate funds to restart NIH-funded research.** As a result of the COVID-19 public health emergency, NIH-funded research laboratories have either shut down or scaled back significantly. Many have donated or repurposed personal protective equipment (PPE) from their laboratories to hospitals and front-line providers facing shortages, have lost or needed to destroy cell samples, and may need to replace animal colonies. Without Congressional action, replacing these resources will come at a significant cost that will have to be paid with existing grant funding or other sources. Preliminary estimates show that this shortfall will be in the range of $10 billion or more to support both extramural and intramural research reopening and to restart research and clinical training programs safely. Given the limited funding that currently supports research in liver disease, it is critically important for Congress to provide additional funds to NIH to support grantees as they cover the costs to re-start the research enterprise and not impede critical research progress.

- **Suspend prior authorization (PA) and step therapy requirements during the public health emergency.** PA and step therapy requirements imposed in many Medicare Advantage (MA), Medicaid, VA drug benefit, and commercial plans create significant barriers and delay access to life-saving therapies under normal circumstances (e.g., curative treatment for Hepatitis C). During the public health emergency, these barriers are creating unnecessary risks to patients with liver disease who are already at higher risk should they contract COVID-19. Doctors and their office staff who have been working remotely are not receiving PA requests in a timely fashion and have limited ability to approve them at this time. In many cases, patients’ inability to access their medications can lead to hospitalization, adding additional burden to hospitals focused on treating COVID-19 patients. The solution is to suspend any PA and step therapy requirements in MA, Medicaid, VA drug benefit, and commercial plans until the pandemic is over and physicians and staff are back in their offices.

- **Provide additional direct relief for providers.** Like other physicians, hepatologists have been affected profoundly by COVID-19. They have substantially decreased their practice due to see only patients with urgent needs. To reduce the risk of COVID-19 transmission, they have converted significant portions of their practice to telehealth visits which reimburse less than in-person office visits. At the same time, decisions are being made at their institutions and in their private practices to reduce salaries, furlough key practice management staff, or potentially to close the practice. Despite the financial relief provided by Congress to date, there remains a need for additional action.
Congress should provide additional direct relief to hepatologists and other providers, including grants, interest-free loans, and other mechanisms. This will ensure patients can continue to receive necessary care both related to COVID-19 and their ongoing chronic conditions for the duration of this pandemic and beyond, when a strong public health infrastructure must be in place to meet the health care needs of Americans and to be better prepared for the next wave of COVID-19 infections or pandemic. Congress should direct the Secretary of the Department of Health and Human Services to disburse any remaining or new Public Health and Social Services Emergency Fund dollars to providers and their practices which have both lost revenue and incurred increased operating costs since the start of the COVID-19 outbreak, particularly those that may have large Medicaid patient populations.

- **Support public health programs serving those with underlying liver disease.** Given the additional risk of complications and death posed by COVID-19 to those with underlying liver disease, it is imperative that public health programs serving this patient population are supported during the pandemic. AASLD recommends the following:
  - Providing increased funding for viral hepatitis and population health programs that address liver disease;
  - Improving the capacity of public health laboratories and public health departments to address the current and any future public health emergencies;
  - Addressing disparities in viral hepatitis screening and testing; and
  - Supporting vaccination programs to protect against other vaccine-preventable diseases, like hepatitis A and hepatitis B, to prevent other disease outbreaks during the public health emergency.

Thank you again for all that you are doing to support patients and providers during this difficult time and for considering these additional policy recommendations. Please contact Greg Bologna at gbologna@aasld.org if you have any questions.

Sincerely,

Jorge A. Bezerra, MD, FAASLD
President, AASLD

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