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Global Liver Institute 4323 Westover Place, NW Washington, DC 20016

Email: Info@GlobalLiver.org Website: www.GlobalLiver.org Twitter: @GlobalLiver February 2, 2021

President Joseph Biden 1401 Constitution Ave., NW Washington, DC 20230

Dear President Biden,

Global Liver Institute (GLI) is a nonpartisan nonprofit patient advocacy organization committed to improving the lives of individuals and families impacted by liver disease by promoting innovation, encouraging collaboration, and scaling optimal approaches to help eradicate liver diseases. As the only global liver patient advocacy organization, we applaud the steps you have already taken to seek and then follow recommendations from the scientific community during the deadly COVID-19 pandemic.

With this in mind, over the last year we have seen a continued rise of liver disease prevalence and mortality both directly and indirectly connected to the impact of COVID-19 on our healthcare system. Research shows, and the Centers for Disease Control and Prevention (CDC) has highlighted that COVID-19 has been found to cause increased levels of liver enzymes and liver damage leading to increased mortality rates among people with chronic liver disease and cirrhosis. Coupled with this startling finding is the harsh reality that liver disease and COVID-19 are more prevalent in communities of color adding to long-standing racial and ethnic health disparities that we have sought to eliminate for years. In response, we regard the severity with which this Administration prioritizes ending the pandemic and helping those that have been disproportionately impacted.

We applaud your diverse Cabinet and administration selections. Key nominations such as Xavier Becerra as the lead for the Department of Health and Human Services (HHS), and Dr. Rochelle Wilensky, MD, MPH as Director of the Centers for Disease Control and Prevention (CDC). Additionally, we appreciate your nomination of Dr. Vivek Murthy to return as Surgeon General, Rachel Levine for assistant secretary of health at HHS, Andrea Palm as deputy secretary of HHS, and Regina LaBelle as the acting head of the White House Office of National Drug Control Policy. Each of your early choices and actions recognize the value of collaboration, and

willingness to listen to evidence-based science and medical professionals. Most importantly it underlines the point that you understand that investments in public health along with scientific discovery are crucial to improving the nation's health and economy in both the near- and long-term.

As representatives of the liver health advocacy community, we want to also acknowledge one recent choice in particular, Dr. Janet Woodcock as Interim Commissioner of the U.S. Food and Drug Association (FDA). The current public health crisis requires a Commissioner with specialized knowledge and extensive experience who will continue to lead the Agency in the right direction during these unprecedented times. Dr. Woodcock is especially qualified for this role as she joined the FDA in 1986 and has continued to dedicate her service in varying roles, most recently as Director of the Center for Drug Evaluation and Research (CDER).

As Director of CDER, Dr. Woodcock managed a complete restructuring of the center, ultimately improving the specialization of the drug review divisions. In following through on this action, Dr. Woodcock demonstrated immense leadership, and a willingness to take on the monumental challenge of structural sustainable change. As we continue to grapple with an ongoing global COVID-19 crisis, similar structural change is critical to consider so that we are better prepared to prevent, document, and respond to the public health emergencies of the future. This need is no more apparent than when we look at the continued rise of liver disease prevalence and mortality over the last year both directly and indirectly connected to the impact of COVID-19, and continued health inequities within our healthcare system.

Dr. Woodcock also understands the crucial role of including patient communities and clinical experts as key stakeholders in all aspects of health. Dr. Woodcock has followed through on critical provisions within FDASIA and the 21st Century Cures Act (Cures Act) to form meaningful partnerships with patient communities, and innovate to accelerate medical product development. Going forward the FDA must continue to expand upon patient representation in evidence collection, product development, and regulatory review. Thankfully, Dr. Woodcock understands the value of ensuring an evidence-based focus that concentrates on unfulfilled patient needs. Under her leadership, patients that require lifesaving treatments and cures will be centered in the FDA agenda. In her endeavors, Dr. Woodcock leads with precision and vigor holding diversity of stakeholders and patient input in high regard.

In conclusion, we commend your nominations and selections to lead vital federal health agencies thus far. You have selected true experts that demonstrate your commitment to the support and treatment of all Americans especially during a global crisis. This foundation of leaders that follow evidence based science is even more critical as we begin to move past the COVID-19 pandemic. We look forward to working with each of them to address the next national health crisis of chronic diseases like chronic liver disease. We are also excited to see who your final choices will be to fill the final valuable open leadership positions. If you have any questions please don't hesitate to reach out to our Policy Director, Andrew Scott, at ascott@globabliver.org or 831-246-1586.

Sincerely.

Donna R. Cryer, JD President & CEO

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