January 3, 2021

The Honorable Patty Murray
Chair
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

Dear Senator Murray and Senator Burr,

On behalf of patients and families, and partnering patient advocacy organizations working together to improve the lives of all people impacted by liver disease, the undersigned organizations write to you today in support of the confirmation of Food and Drug Administration (FDA) commissioner nominee Dr. Robert Califf.

With rising rates of liver diseases, driven by factors as diverse as Covid-19, obesity, and substance use disorders, we need an FDA Commissioner who is able to lead from Day One. Dr. Califf is uniquely qualified by experience and expertise to do just that. His prolific academic research career at Duke University, his strength in building solution-based collaborations such as the Duke Clinical Research Institute, and his current leadership in real-world evidence generation and data as head of clinical policy and strategy for Verily and Google Health, where his Project Baseline partnership with the American Heart Association sets a new world standard for patient-partnered data-driven research distinguishes him as the best candidate to meet this needs of the FDA at this point in history.

We write to ensure that Dr. Califf is given sufficient credit for his commitment to patients and the patient advocacy community. Dr. Califf's support for the People-Centered Research Foundation strengthened the ability of patients and patient advocates to partner with researchers across the People-Centered Research Institute's PCORnet. Dr. Califf consistently approaches patient advocates with respect, thoughtfulness, and challenge to bring our substantive expertise to the table with other stakeholders.

For these reasons, Global Liver Institute (GLI) and GLI's Liver Action Network member organizations are confident that Dr. Califf is well equipped to take on the regulatory challenges of patients partnering to have drugs, devices, and other interventions to improve liver health.

Liver conditions continue to be misunderstood, mischaracterized, and stigmatized, resulting in under-diagnosis, under-treatment, and unnecessarily poor outcomes. Despite the development of vaccines and antiviral agents, the burden of liver disease is poised to grow further due to the confluence of several trends such as increasingly sedentary lifestyles and over-nutrition. This rise has only been amplified by the COVID-19 public health crisis and is in large part due to the harsh reality that the prevalence of metabolic liver diseases, including nonalcoholic fatty liver disease and alcohol-related liver disease, have increased, ultimately leading to more cases of end-stage liver diseases (liver failure, cirrhosis, and liver cancer).

In recent years thanks to FDASIA and the 21st Century Cures Act (Cures Act), the FDA has worked hard to form meaningful partnerships with patient communities, and innovate to accelerate medical product development. Dr. Califf has demonstrated throughout his career that he would ensure the FDA continues its expansion of these vital initiatives. His medical background and experience, with clinical policy and strategy will serve him well in the battle against the continued rise of liver conditions across the nation.

GLI and GLI's Liver Action Network look forward to being a resource, and assisting the FDA, and FDA Commissioner Nominee Dr. Robert Califf in his transition into the role. If you have any questions, please don't hesitate to reach out to Andrew Scott, the Policy Director at Global Liver Institute at ascott@globalliver.org or 831-246-1586.

Sincerely,

Global Liver Institute
Community Liver Alliance
Fatty Liver Alliance
Fatty Liver Foundation
HepCURE
Liver Coalition of San Diego
Liver Health Foundation
Midsouth Liver Alliance
NASH kNOWledge
Northeast Ohio Liver Alliance
Texas Liver Foundation