

August 16, 2019

The Honorable Richard Shelby
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

The Honorable Patrick Leahy
Vice Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

The Honorable Roy Blunt
Chairman
Appropriations Subcommittee on Labor,
Health and Human Services, Education and
Related Agencies
United States Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Appropriations Subcommittee on Labor,
Health and Human Services, Education and
Related Agencies
United States Senate
Washington, DC 20510

Dear Chairman Shelby, Vice Chairman Leahy, Chairman Blunt, and Ranking Member Murray:

As you continue to work on the Fiscal Year (FY) 2020 Appropriations bill, we the undersigned organizations representing the hepatitis B advocacy community, respectfully request that you provide increased funding for hepatitis B surveillance and prevention at the Centers for Disease Control and Prevention (CDC), provide increased funding for hepatitis B and liver cancer research at the National Institutes of Health (NIH), and include appropriations report language that prioritizes hepatitis B in the Senate report. While we understand the challenge of appropriating additional resources in the current fiscal climate, there is an urgent need for prioritization and investment in resources to combat hepatitis B.

Up to 2.2 million people in the U.S. are infected with the hepatitis B virus (HBV), and an estimated 70% are unaware that they are living with the disease. There are 70,000 new HBV infections each year in the U.S., despite the availability of a safe and effective vaccine. Although the hepatitis B vaccine is more than 90% effective and provides lifelong protection, less than a quarter of adults in the U.S. are vaccinated, and the rate of acute HBV infection has recently spiked due to increased injection drug use within the opioid epidemic. Furthermore, little to no progress has been made in reducing rates of chronic HBV infection in the U.S. and, although hepatitis B is preventable and treatable, there is still no cure for the disease. Without early diagnosis and intervention, 1 in 4 of those chronically infected with hepatitis B will die prematurely from cirrhosis, liver failure, or liver cancer.

Additionally, tremendous HBV-related health disparities exist for people of Asian and Pacific Islander descent and recent African immigrants. These groups make up roughly 6% of the U.S. population yet represent more than 80% of those with chronic HBV infection in the U.S.

CDC Funding for Hepatitis B Surveillance and Prevention - We urge the Senate Appropriations Committee to support no less than \$50 million in funding for the CDC's Division of Viral Hepatitis in FY 2020, as provided by the House Appropriations Committee.

The CDC is the primary agency tasked with coordinating national efforts to prevent viral hepatitis, identify those living with viral hepatitis, and link those individuals to care and treatment. According to the 2016 CDC Professional Judgement Budget, a comprehensive, national viral hepatitis program would need at least \$3.9 billion over ten years to put the U.S. on the path to eliminating viral hepatitis, including hepatitis B. Currently the CDC's viral hepatitis programs are funded at \$39

million, less than 10 percent of the CDC's professional judgement per year. While increasing viral hepatitis programs to \$50 million would still be inadequate, it would provide much needed additional resources to increase surveillance, prevention, and treatment programs.

This increased funding is particularly urgent given increasing pressures of the opioid epidemic. New cases of acute HBV infection rose 20% nationally between 2010 and 2016, with significant regional increases in areas experiencing increased rates of injection drug use. This includes increases of 729% in Maine from 2015-2017; 114% in Kentucky, Tennessee, and West Virginia from 2009-2013; 78% in Southeastern Massachusetts in 2017; and 56% in North Carolina from 2014-2016.

Mother-to-child hepatitis B transmission also remains a challenge. Up to 90% of infants infected with the virus at birth develop chronic hepatitis B, putting them at a significantly higher risk of developing liver cancer in their lifetime. Although hepatitis B vaccination coverage among newborns has increased, there are still as many as 1,200 perinatal hepatitis B infections per year. These cases are preventable with early detection, treatment, and vaccination.

Increased funding for the CDC's viral hepatitis programs will allow the agency to build the infrastructure and programs necessary to prevent new viral hepatitis cases, including mother-to-child transmission; identify people living with viral hepatitis and link them to care and treatment; work with health care providers and insurers to improve access to screening, vaccination, and treatment; prioritize interventions among people who use drugs; improve surveillance and outbreak response; increase adult HBV vaccination rates and continue to improve infant HBV immunization rates; and conduct research and technical assistance. The ability to provide state and local health departments and other key stakeholders funding to build the necessary infrastructure to provide services combating viral hepatitis is integral to eliminating these diseases in the U.S.

NIH Funding for Hepatitis B and Liver Cancer Research - We urge the Senate Appropriations Committee to increase NIH funding for hepatitis B research by \$38.7 million per year for 6 years to develop a cure for hepatitis B. This amount would adequately fund key research initiatives identified by the Hepatitis B Foundation's *Roadmap for a Cure*. Further, we urge the Committee to request that NIH issue targeted calls for proposals for the research identified in the *Roadmap for a Cure*.

In FY 2018, NIH funding for hepatitis B was \$55 million, an amount not adequate to prioritize and fund research to develop a cure. While hepatitis B funding at NIH has increased since FY 2015, the lack of a cure for hepatitis B is costing the U.S. an estimated \$4 billion per year in medical costs and has a devastating effect on patients and their families. In the U.S., only seven medications are approved to manage chronic hepatitis B infection, none are curative, and most require lifelong use. These medications may only reduce the likelihood of death due to liver disease by 40-60%.

The link between hepatitis B infection and primary liver cancer is well established, with up to 60% of global liver cancer cases caused by the virus, making the need to find a hepatitis B cure even more urgent. In the U.S., liver cancer is the 2nd deadliest cancer with a 5-year survival rate of 20%. In 2016, the CDC reported that unlike other cancers, the rates of liver cancer incidence and death are rising. Primary liver cancer death rates have tripled since 1980, and death rates for liver cancer increased 43% from 2000-2016.

In recent years, a cure was discovered for hepatitis C. With increased prioritization and federal funding to support hepatitis B research, more effective medications to treat and cure hepatitis B can be developed as well. The World Health Organization and the U.S. National Academies of Science, Engineering, and Medicine have declared the elimination of hepatitis B is possible with adequate resources and support. Increasing NIH funding for hepatitis B research would significantly increase the likelihood of discovering a cure. If we are able to cure all individuals with chronic HBV infection,

in conjunction with utilizing the existing hepatitis B vaccine to prevent new infections, this would allow us to definitively eliminate hepatitis B in the U.S and around the world.

Hepatitis B Report Language - The recently passed House FY 2020 Appropriations bill included strong report language related to hepatitis B. We ask the Senate Appropriations Committee to support the same language in its final report for the purposes of clarification and ensuring appropriate resources are directed towards efforts to eliminate hepatitis B. Our requested report language is attached as an addendum to this letter.

We thank you for your continued work in combating the spread of hepatitis B. We welcome the opportunity to work with you and your staff on increasing federal investments to address hepatitis B in the United States and putting our nation on a path towards hepatitis B elimination. If you have any questions or need additional information, please have your staff contact Kate Moraras, Director of Hep B United, at Kate.Moraras@hepb.org. We thank you for your leadership and look forward to your support in the fight against hepatitis B.

Sincerely,

Hep B United
Hepatitis B Foundation (Co-Chair of Hep B United)
Association of Asian Pacific Community Health Organizations (Co-Chair of Hep B United)

Asian American Community Services
Asian Center - Southeast Michigan
Asian Health Coalition
Asian Pacific Health Foundation
Asian Pacific Liver Center
CPACS
Hawaii Health & Harm Reduction Center
Hep B Free Los Angeles
Hep B United Philadelphia
Hep Free Hawaii
Hepatitis Education Project
Immunization Action Coalition
Liver Health Connection
Mercy Housing and Human Development
National Task Force on Hepatitis B Focus on Asian and Pacific Islander Americans
National Viral Hepatitis Roundtable
NYU Center for the Study of Asian American Health

Addendum: FY 2020 Hepatitis B Report Language Requests

LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES

CENTERS FOR DISEASE PREVENTION AND CONTROL

CENTER FOR HIV, VIRAL HEPATITIS, SEXUALLY TRANSMITTED DISEASES, AND TUBERCULOSIS PREVENTION – Division of Viral Hepatitis

Hepatitis B- The Committee is concerned that as a result of the opioid epidemic, infections of HBV have spiked in many parts of the nation with, for example, acute HBV infections increasing over 100% in the states and areas with widespread opioid overuse. The Committee notes that in 2017 the National Academies of Sciences Engineering and Medicine (NASEM) report titled “A National Strategy for the Elimination of Hepatitis B and C” made a series of recommendations for vaccination, higher rates of diagnosis, care and treatment, which, if implemented, could eliminate Hepatitis B as a public health concern by 2030. While public health experts consider eliminating hepatitis B to be within reach, the Committee is concerned that the Division of Viral Hepatitis is decreasing hepatitis B resources. The Committee urges the Division of Viral Hepatitis to develop and implement a national chronic hepatitis B surveillance initiative so that a baseline is established to measure progress toward this important goal. The Committee also urges that the CDC continue and increase all current HBV specific programs and work with national hepatitis B organizations on a plan to implement the NASEM recommendations. The Committee requests that CDC submit this plan to the Committee within 180 days of enactment of this bill into law.

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASE – Immunization Services Division

Hepatitis B Vaccine- The Committee is concerned about the recent rise in acute hepatitis B (HBV) infection rates in many parts of the U.S. as a result of the ongoing opioid crisis, with rates increasing over 100% in some states and less than a quarter of adults age 19 and older are being immunized against hepatitis B. It is estimated that up to 2.2 million Americans are living with HBV. Chronic hepatitis B increases by up to 60% the chances of developing liver cancer. Despite the availability of HBV vaccines to protect against this devastating condition and prevent its spread, there are up to 70,000 new infections each year and up to 1,200 babies infected with hepatitis B at birth annually. The Committee encourages the Immunization Services Division to work to improve collaboration and coordination with HHS viral hepatitis and immunization programs by including guidance in upcoming funding opportunity announcements that encourage increased resources targeted on HBV prevention including immunizations among state immunization and infectious disease prevention programs. The Committee also urges the CDC to partner with state, local, and tribal health departments, criminal justice programs, along with relevant patient and community stakeholder organizations to develop a plan that takes into account best practices and model strategies to increase HBV immunization coverage among adults and reduce the number of HBV cases. The Committee requests a report within 90 days of enactment of this bill into law of CDC’s plan to increase the rate of HBV adult vaccination and to improve collaboration and coordination across the CDC.

NATIONAL INSTITUTES OF HEALTH

NATIONAL CANCER INSTITUTE

Liver Cancer –The Committee commends the NCI for increasing resources focused on liver cancer and its inter-institute work to encourage more research focused on liver cancer but urges greater priority to address the threat of liver cancer, the 2nd deadliest cancer with a 5-year survival rate of 20%. Unlike other cancers, the rates of liver cancer deaths and incidence are rising. In spite of growing mortality of liver cancer, research spending focused on liver cancer is still not among the 20 largest NCI cancers research programs, even though many new research questions have been identified in two peer-reviewed scientific journals, *Hepatology* and *Antiviral Research*, published in 2018. Therefore, to increase the 5-year survivability of liver cancer, the Committee urges that NCI issue targeted calls for proposals to fund the priority areas of research that have been identified and to further signal its interest in the field, NCI should create an ad hoc special emphasis panel to review liver cancer applications. The Committee also notes that the link between hepatitis B infection and primary liver cancer is well established with up to 60% of global liver cancer cases caused by the hepatitis B virus (HBV) and, therefore, urges close collaboration with NIAID and NIDDK and active participation in the Directors newly establish Trans-NIH Hepatitis B working group. The Committee requests that the NCI prepare a plan for the improved treatment and detection of liver cancer and submit it to the Committee within 180 days of enactment of this bill into law.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Hepatitis B – The Committee notes that infection with the hepatitis B virus (HBV) is a serious public health threat and 1 in 20 Americans have been infected and more than 2 million are chronically infected, increasing by 70,000 a year. Based on findings from National Academies of Sciences, Engineering and Medicine (NASEM) in 2017, 188,000 will die if left undiagnosed and untreated. In view of this public health threat, the Committee remains concerned that NIH research spending on HBV decreased from \$48 million in FY 2014 to an estimated \$42 million in FY 2019, despite the NASEM report that the elimination of hepatitis B is within reach. Additionally, the hepatitis B research community convened a virtual consensus conference to prepare a “Roadmap for a Cure” that resulted in articles published in 2018 in two peer reviewed scientific journals, *Hepatology* and *Antiviral Research*, identifying the most urgent research questions that must be answered to find a cure for hepatitis B. The Committee commends NIAID for plans to publish several requests for applications on HBV in FY 2019 and urges additional targeted calls for HBV research to fund the many critical research opportunities identified by the scientific community in the Roadmap for a Cure. The Committee urges active participation and leadership by NIAID in the Directors newly established Trans-NIH Hepatitis B working group and requests that NIAID submit within 180 days of enactment of this bill into law, a research plan to pursue a cure for hepatitis B in coordination with the other NIH institutes.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Hepatitis B - The Committee notes that infection with the hepatitis B virus (HBV) is a serious public health threat and 1 in 20 Americans has been infected and more than 2 million are chronically infected, increasing by 70,000 a year. Based on findings from the National Academies of Sciences, Engineering and Medicine (NASEM) in 2017, 188,000 will die if left undiagnosed and untreated. In view of this public health threat, the Committee remains concerned that NIH spending on HBV research has decreased from \$48 million in FY 2014 to an estimated \$42 million in FY 2019, despite

declarations from the National Academies of Sciences, Engineering and Medicine in 2017 that the elimination of hepatitis B is within reach. Additionally, the hepatitis B research community convened a virtual consensus conference to prepare a “Roadmap for a Cure” that resulted in articles published in 2018 in two peer reviewed scientific journals, *Hepatology* and *Antiviral Research*, identifying the most urgent research questions that must be answered to find a cure for hepatitis B. The Committee urges NIDDK to issue targeted calls for HBV research to pursue the many critical research opportunities identified by the scientific community and report to the Committee within 180 days of enactment of this bill into law the NIDDK research plan to pursue a cure for hepatitis B in coordination with other NIH institutes.

OFFICE OF THE DIRECTOR

Hepatitis B - The Committee commends the Director’s office for establishing an inter- Institute Hepatitis B Working group to include representation from NCI, NIAID, NIDDK and NIMHD to coordinate their research agendas to fund the research necessary to find a cure for hepatitis B and improve liver cancer outcomes. The Committee urges the Director to use the NIH Common Fund to support the integrated trans-Institute research needed to fully address these conditions. The Committee notes that both the World Health Organization and the National Academies of Sciences, Engineering and Medicine have declared that the elimination of hepatitis B is possible by 2030. Subsequent to that declaration, the hepatitis B research community convened a virtual consensus conference to prepare a “Roadmap for a Cure” that resulted in articles published in 2018 in two peer reviewed scientific journals, *Hepatology* and *Antiviral Research*, identifying the most urgent research questions that must be answered to find a cure for hepatitis B. Therefore, the Committee requests that the Office of the Director keep the Committee informed on progress of the Trans-Institute Hepatitis B Working Group and requests a status report be sent to the Committee within 90 days of enactment of this bill into law.