

A REPORT FROM WASHINGTON:

HEPATITIS B FOUNDATION ACHIEVES SUCCESS IN HOUSE APPROPRIATIONS BILL

This report highlights the Foundation's recent successes in Washington to have the House Appropriations Committee include language, at our request, to support policy and funding priorities at NIH, CDC and HHS and to fund a Community Project to create a Center of Public Health Excellence all targeted on finding better treatments and ultimately the elimination of hepatitis B.

On July 15, 2021, the House Appropriations Committee approved the fiscal year (FY) 2022 Labor, Health and Human Services, and Education Appropriations (Labor-HHS) bill that funds the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). The bill's accompanying report includes language, made at our request, that urges HHS, NIH and CDC to adopt funding and policy priorities to advance the mission of finding a cure and better treatments for hepatitis B. On July 28, 2021, the full House passed a 7-bill minibus that included the Labor-HHS bill completing one more step in the FY 2022 appropriations process.

More detail about these successes follow:

With regard to NIH, the Labor-HHS report included policy guidance at the request of the Hepatitis B Foundation. For example, the House Labor-HHS Committee urges NIH to implement the 2019 Strategic Plan for Trans NIH Research to Cure Hepatitis B by issuing new targeted calls for research. The Committee further requested an update of the Plan, as well as a specific plan to pursue a cure for hepatitis B in coordination with the Trans-NIH Hepatitis B Working Group. The Committee further included language, at the request of HBF, for the National Cancer Institute to support the research needed to develop a liver cancer screening test using the blood and saliva samples from widespread national COVID testing. Finally, language was included at the request of HBF and the Pennsylvania Biotech Center urging the National Center for Advancing Translational Science (NCATS) to explore ways to increase the success in meeting its mission by exploring funding opportunities or potential collaborations with business incubators that host small to midsize science, research, and pharmaceutical companies that use services-based approaches to nurture and guide the member companies to success.

With regard to CDC, the Committee included a \$5 million increase for the Division of Viral Hepatitis at the CDC, along with language urging the CDC to continue investing in hepatitis B grants to support community-based organizations and to expand the viral hepatitis disease tracking and surveillance capabilities of the States in order to permit an effective targeting of resources and evaluation of program effectiveness. There was also language urging the CDC to develop a plan to increase the rate of adult hepatitis B vaccination.

With regard to the HHS Office of the Secretary, two pieces of language were included. First, there is language that addresses the discriminatory policies of the U.S. Public Health Service and urges the Department to ensure that the Commissioned Corps' policies on the inclusion of employees with chronic hepatitis B are consistent with up-to-date medical knowledge and consistent with CDC recommendations for current and incoming personnel. Secondly, the Committee urged the Department



to implement the strategies laid out in the Viral Hepatitis National Strategic Plan to reverse the rates of viral hepatitis, prevent new infections, improve care and treatment, and ultimately eliminate viral hepatitis as a public health threat.

With regard to the Community Project Funding at our request, \$475,000 was added for HBF to create a Center of Public Health Excellence. The Center will centralize hepatitis B-elimination efforts and provide expert resources, advice, training, capacity building and technical assistance for state and local health departments, social service organizations, and community health providers on how to best prevent, treat and control hepatitis B and to increase the rate of adult vaccination for hepatitis B.

The Senate is expected to approve their version of the FY 2022 spending bills later this summer or in early fall. The bills will not be finalized and enacted until agreement is reached by both bodies and the President signs it into law. Nevertheless, the policy priorities reflected in the House Labor-HHS report which includes language requested by HBF can be considered final. While we are optimistic about the outcome of the Community Project Funding it can only be considered final after conference with the Senate.

Below is the complete HBF requested language that was included in the House Labor-HHS Report.

FY 2022 House Labor-HHS Report

Adopted by the full committee on July 15, 2021

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

Liver Cancer. —The Committee notes that liver cancer is the second deadliest cancer, with a five-year survival rate of only 20 percent. The number of liver cancer cases in the U.S. has increased by over 250 percent since 2000 and continues to increase. Since early detection of cancer in general and liver cancer in particular is the most effective way to reduce cancer mortality, the Committee urges NCI to support the research needed to develop a liver cancer screening test using the blood and saliva samples from widespread national COVID testing. This extensive and growing inventory of saliva and blood samples offers a unique opportunity to develop a liver cancer screening test that can soon reach over 100 million citizens, a number that will grow as COVID testing is expanded.

NCATS

Collaboration with Business Incubators. —The Committee urges NCATS to explore ways to increase the success in meeting its mission by exploring funding opportunities or potential collaborations with business incubators that host small to midsize science, research, and pharmaceutical companies that use services-based approaches to nurture and guide the member companies to success. Collaborations with such business incubators may offer the most effective way to advance translational science. Priority consideration should be given to nonprofit life science incubators that seek to advance biotechnology, maximize synergies between nonprofit scientists and their commercial colleagues, and launch new ideas



and discoveries that will make a difference including drug discovery, biomarker discovery and translational biotechnology around common research themes in an environment conducive to interaction, collaboration, and focus.

Office of the Director

Hepatitis B.—The Committee recognizes the estimated \$4 billion of annual medical costs associated with the care and treatment of those infected with the hepatitis B virus and urges NIH to redouble its efforts to identify more effective treatments for the disease. While there are treatments available to control HBV, they must be taken for years if not for life. Without treatment, one in four of those infected will die prematurely from cirrhosis, liver failure, and/or liver cancer. This serious public health threat results in over 800,000 worldwide deaths each year, making it the tenth leading cause of death in the world. The Committee commends NIH for it support in the development of the 2019 Strategic Plan for Trans NIH Research to Cure Hepatitis B and urges NIH to help implement the plan by issuing new targeted calls for research. The Committee requests that NIH support an update of the Strategic Plan for Trans-NIH Research to Cure Hepatitis B and that it submit it to the Committee, within 180 days of enactment of this Act, a specific plan to pursue a cure for hepatitis B in coordination with the Trans-NIH Hepatitis B Working Group.

Office of the Secretary:

Viral Hepatitis National Strategic Plan.—The Committee applauds the Department's update of the Viral Hepatitis National Strategic Plan, which was released in January 2021. The Viral Hepatitis Plan sets clear goals on how the United States can prevent, diagnose, treat, and manage viral hepatitis. The Committee urges the Department to implement the strategies laid out in this plan to reverse the rates of viral hepatitis, prevent new infections, improve care and treatment, and ultimately eliminate viral hepatitis as a public health threat.

Office of the Assistant Secretary for Health Commissioned Corps of the U.S. Public Health Service (USPHS).—The Committee urges the Department to ensure that the Commissioned Corps' policies on the inclusion of employees with chronic hepatitis B are consistent with up-to-date medical knowledge and that the USPHS adopt comprehensive, evidence based HBV policies consistent with CDC recommendations for current and incoming personnel.