

## A REPORT FROM WASHINGTON: Hepatitis B Foundation Requested Language Included in FY 2023 House and Senate Appropriation Reports

The Hepatitis B Foundation's (HBF) policy team spends considerable time and effort each year to increase federal prioritization and advocate for funding for hepatitis B and liver cancer research and public health programming. We conduct over 50 visits with legislators and leaders at the Department of Health and Human Services (HHS), including the National Institutes of Health (NIH). We also write and submit language to legislators, and advocate for them to support the inclusion of this language in the House and Senate Appropriation Reports. These efforts are necessary to ensure that hepatitis B, hepatitis D and liver cancer are prioritized, and are critical to ensuring progress towards viral hepatitis elimination efforts. We need a strong collective voice for these efforts - learn how you can join our policy efforts as <u>advocates</u> and <u>storytellers</u> – or <u>help support</u> the Foundation's policy and advocacy!

This report highlights the Foundation's recent successes in Washington to have the House and Senate Labor, Health and Human Services, and Education Appropriations (Labor-HHS) subcommittees include language that we requested, to increase support for the elimination of hepatitis B and liver cancer. Additionally, both the House and Senate Department of Defense (DOD) subcommittee reports included language, at our request, that is necessary to permit hepatitis B and liver cancer to continue to be eligible for funding by DOD's Biomedical and Cancer Research programs.

On June 30, 2022, the House Appropriations Committee approved the fiscal year (FY) 2023 Labor-HHS bill that funds the health programs of HHS including the NIH, the CDC and HRSA. The bill's accompanying report includes language, at our request, that urges HHS, NIH, CDC, and HRSA to adopt funding and policy priorities to advance the mission of expanding vaccination, as well as finding a cure and better treatments for hepatitis B and liver cancer.

On July 27, the Senate Appropriations Committee Majority released their FY 2023 bills and the accompanying reports. While these bills and reports did not go through the official markup process, they will nonetheless serve as the Senate marker for conference negotiations with the House.

More details about these HBF advocacy successes follow:

Both the House and Senate urged **NIH** to update and fund the *Strategic Plan for Trans NIH Research to Cure Hepatitis B* by issuing new targeted calls for research as identified by the Trans-NIH Hepatitis B Working Group in the updated strategic plan. The Committee further included language, at the request of HBF, urging the National Cancer Institute (NCI) to expand support for liver cancer research and noted that up to 60% of liver cancer cases are caused by hepatitis B. Finally, language was included urging the National Center for Advancing Translational Science (NCATS) to explore funding business incubators --such as the Pennsylvania Biotechnology Center --- that host small to midsize science, research, and pharmaceutical companies that use services-based approaches to nurture and guide the member companies to success as a way to leverage the NCATS mission.

Both the House and Senate included a \$13.5 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 viral hepatitis disease tracking and surveillance



capabilities of the states to permit an effective targeting of resources and evaluation of program effectiveness. Language was also included urging the CDC to help implement the new ACIP recommendations to vaccinate all adults aged 19 through 59 and to develop a plan to increase the rate of adult hepatitis B vaccination.

The House included language that encourages all **HRSA** funded community health centers to adopt the necessary practices and policies to comply with the new ACIP recommendation that all adults aged 19 through 59 be vaccinated for hepatitis B.

Language was included in both the House and Senate reports urging the **HHS** Office of the Assistant Secretary for Health (OASH) to support implementation of the new Advisory Committee on Immunization Practices (ACIP) adult hepatitis B recommendations including sponsoring an interagency summit to help ensure coordination and timely implementation of the recommendation that all adults aged 19 through 59 be vaccinated for hepatitis B.

Once again, the House included language in the FY 2023 **DOD** report that allows the Peer Reviewed Cancer Research Program to fund liver cancer related research. The Senate DOD report included language that allows for the same, as well as language allowing the Peer Reviewed Medical Research Program to fund Hepatitis B related research. It is typical for the House to only fund the Peer Reviewe Cancer Research program, but then to accept both programs in conference.

Below is the complete language as included in the House and Senate Labor-HHS and DOD reports.

# FY 2023 House Labor-HHS report language Adopted by the full committee on July 15, 2022

# Health Resources Services Administration

# Health Centers

*Vaccination and Screening for Hepatitis B* - The Committee encourages HRSA to urge health center grantees to adopt the necessary practices and policies to comply with the November 2021 Advisory Committee on Immunization Practices (ACIP) recommendation that all adults between 19 and 59 be vaccinated for hepatitis B. To implement this policy, the Committee further encourages HRSA to ensure that Health Centers screen all individuals for hepatitis B, offer to immunize all non-infected patients in the 19–59 age cohort, and navigate infected individuals into care. The Committee urges that this recommendation be implemented as early as possible in fiscal year 2023.

# Centers for Disease Control and Prevention

# HIV/AIDS, VIRAL HEPATITIS, SEXUALLY TRANSMITTED DISEASES, AND TUBERCULOSIS PREVENTION

*Viral Hepatitis* - The Committee includes an increase of \$13,500,000 to enhance efforts to eliminate the public health threat of viral hepatitis. The Committee is aware of the November 2021 ACIP recommendation that all adults between ages 19 and 59 be vaccinated for hepatitis B, and urges CDC to take any associated action as early as possible. In addition, the Committee urges CDC to expand the viral hepatitis disease tracking and surveillance capabilities of States to permit an effective targeting of resources and evaluation of program effectiveness. Furthermore, the Committee encourages CDC to expand outreach and communications efforts and related initiatives to promote hepatitis C screening



during pregnancy with the goal of ensuring that every pregnant individual gets tested for hepatitis C during each pregnancy.

### National Institutes of Health

#### **National Cancer Institute**

*Liver Cancer* - The Committee notes that liver cancer is the second most common cause of cancer worldwide, with cases in the U.S. increasing over 250 percent since 2000. The incidence of liver cancer is three times higher in men than women, and the burden is higher in African Americans, Hispanics, and Asians. The incidence of liver cancer geographically parallels the prevalence of viral hepatitis, with hepatis B estimated to cause up to 60 percent of the cases of liver cancer. For these reasons, the Committee applauds NCI for its collaboration in the effort to update the Strategic Plan for Trans-NIH Research to Cure Hepatitis B. The Committee also is supportive of the NCI intramural Liver Cancer Program, the Hepatobiliary and Hepatocellular Carcinoma (HCC) SPOREs, the new Diversity SPORE, the Translational Liver Cancer Network, the Hepatocellular Carcinoma Epidemiology Consortium, the large Genome-Wide Association Study (GWAS) of liver cancer and the need to expand the GWAS study to include a focus on Hispanic and African Descent populations. The Committee also urges NCI to continue its support of the Translational Liver Cancer Consortium, which supports research focused on early detection, and to support research to explore the usefulness of current and new interventions in reducing HBV associated HCC and whether early treatment with direct action antivirals or other strategies can reduce cancer risk.

#### NCATS

*Collaboration with Business Incubators* - The Committee urges NCATS to redouble its efforts to leverage its mission by exploring opportunities or potential collaborations with business incubators that host small to mid-size science, research, and pharmaceutical companies that use service-based approaches to nurture and guide their member companies to success.

#### **Office of the Director**

*Hepatitis B (HBV)* - The Committee applauds NIH for its work to update the Strategic Plan for Trans-NIH Research to Cure Hepatitis B and urges that the update identify what has been learned since the plan was first released and what additional research is needed to find a cure. The Committee is aware of strong interest in more research to understand and manage HBV reactivation and research to understand and develop biomarkers of disease and therefore recommends these research ideas be evaluated and supported. The Committee is also aware of the view within the scientific community that finding a cure for HBV is a winnable goal and is within reach in the near-term and therefore remains concerned that the slow growth in NIH-funded HBV research could compromise the goal of finding a cure. For these reasons, the Committee applauds efforts to create common resource services and materials for the research community and further urges that targeted calls for research, based on the needs as identified in the updated Plan, be issued and funded in fiscal year 2023 and beyond.

#### Office of the Secretary

# Office of the Assistant Secretary for Health

*Hepatitis B Adult Vaccination* - The Committee encourages the Office of the Assistant Secretary for Health (OASH) to host an interagency summit to discuss dissemination and implementation of the Advisory Committee Immunization Practices (ACIP) recommendation that all adults between 19 and 59 be vaccinated for hepatitis B. The Committee is also aware that CDC is actively considering a



complimentary universal hepatitis B vaccine screening policy and encourages OASH to support this process, as appropriate.

# <u>FY 2023 Senate Labor-HHS report language</u> <u>Reported by the Committee Majority on July 27, 2022</u>

# Centers for Disease Control and Prevention

#### **Immunization and Respiratory Diseases**

*Increasing Adult Hepatitis B Vaccination* - The Committee urges CDC to promote hepatitis B vaccination among all adults ages 19 through 59. Funding has been provided to ensure timely implementation of the ACIP recommendation in fiscal year 2023. The Committee urges CDC to provide leadership to ensure the new recommendation is implemented, and to coordinate implementation activities with the HHS Assistant Secretary for Health and HRSA and engage providers and community-based organizations as necessary. The Committee requests a report to Congress on what challenges and barriers currently exist to access that are limiting vaccination rates and preventing vaccine series completion required to achieve full immunity.

# National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases [STDs], and Tuberculosis Prevention [TB]

### **Division of Viral Hepatitis**

*Viral Hepatitis* - The Committee includes an increase of \$13,500,000 to enhance efforts to eliminate the public threat of viral hepatitis. The Committee encourages CDC to work to ensure that new ACIP recommendations for hepatitis B vaccination are implemented as early as possible in fiscal year 2023. Additionally, the Committee urges CDC to expand the viral hepatitis disease tracking and surveillance capabilities of the States to permit an effective targeting of resources and evaluation of program effectiveness.

# NATIONAL INSTITUTES OF HEALTH

#### **National Cancer Institute**

*Liver Cancer* - The Committee notes that liver cancer is the second most common cause of cancer worldwide with cases in the U.S. increasing over 250 percent since 2000. The incidence of liver cancer is three times higher in men than women and the burden is higher in African Americans, Hispanics, and Asians. The incidence of liver cancer geographically parallels the prevalence of viral hepatitis with hepatitis B [HBV] estimated to cause up to 60 percent of the cases of liver cancer. For these reasons, the Committee applauds NCI for its collaboration in the effort to update of the Strategic Plan for Trans-NIH Research to Cure Hepatitis B. The Committee also supports the NCI intramural Liver Cancer Program, the Hepatobiliary and Hepatocellular Carcinoma SPOREs, the new Diversity SPORE, the Translational Liver Cancer Network, the Hepatocellular Carcinoma Epidemiology Consortium, the large Genome Wide Association Study [GWAS] of liver cancer [HCC], and the need to expand the GWAS study to include a focus on Hispanic and African Descent populations. The Committee urges NCI to continue its support of the Translational Liver Cancer Consortium which supports research focused on early detection, and to support research to explore the usefulness of current and new interventions in reducing HBV-associated HCC and whether early treatment with direct action antivirals or other strategies can reduce cancer risk.



#### NIDDK

*Hepatitis B* - The Committee applauds the NIH for its work to update the Strategic Plan for Trans-NIH Research to Cure Hepatitis B and urges that the update identify what has been learned since the plan was first released and what additional research is needed to find a cure. The Committee is aware of strong interest in more research to understand and manage HBV reactivation and research to understand and develop biomarkers of disease and therefore recommends these research ideas be evaluated and funded. The Committee is also aware of the view within the scientific community that finding a cure for hepatitis B is a winnable goal and is within reach in the near-term and therefore remains concerned that the slow growth in NIH funded hepatitis B research could compromise the goal of finding a cure. For these reasons, the Committee applauds efforts to create common resource services and materials for the research community and further urges that targeted calls for research, based on the needs as identified in the updated Plan, be issued, and funded in fiscal year 2023 and beyond.

#### NCATS

*Collaboration with Business Incubators* - The Committee urges NCATS to redouble its efforts to leverage its mission by exploring opportunities or potential collaboration with business incubators that host small to midsize science, research and pharmaceutical companies that use service-based approaches to nurture and guide their member companies to success.

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#### **HHS Office of the Secretary:**

*Hepatitis B* - The Committee is aware of the November 2021 Advisory Committee Immunization Practices [ACIP] recommendation that all adults between 19 and 59 be vaccinated for hepatitis B and urges the Secretary to fully support the CDC to insure the ACIP recommendation is implemented as early as possible in fiscal year 2023. The Committee also urges the Secretary to host an interagency Summit to discuss dissemination and implementation of the new recommendation. The Committee is also aware that the CDC is actively considering a complimentary universal HBV screening policy and urges the OASH to support this process and be prepared to lead an implementation effort if it is adopted.



# FY 2023 House DOD report language Adopted by the full committee on June 22, 2022

**Peer Review Cancer Research Program** - The funds provided in the peer-reviewed cancer research program are directed to be used to conduct research in the following areas: bladder cancer; blood cancers; brain cancer; colorectal cancer; endometrial cancer; esophageal cancer; germ cell cancers; head and neck cancer; <u>liver cancer</u>; lymphoma; mesothelioma; metastatic cancers; myeloma; neuroblastoma; pediatric brain tumors; pediatric, adolescent, and young adult cancers; sarcoma; stomach cancer; thyroid cancer; and Von Hippel-Lindau syndrome malignancies (excluding cancers of the kidney and pancreas).

### FY 2023 Senate DOD report language Reported by the Committee Majority on July 27, 2022

**Peer Reviewed Cancer Research Program** - The funds provided in the peer-reviewed cancer research program are directed to be used to conduct research in the following areas: bladder cancer; blood cancers; brain cancer; endometrial cancer; esophageal cancer; colorectal cancer; kidney cancer; <u>liver</u> <u>cancer</u>; lung cancer; lymphoma; mesothelioma; metastatic cancer; myeloma; neuroblastoma; pancreatic cancer; pediatric brain tumors; pediatric, adolescent, and young adult cancers; stomach cancer; and Von Hippel-Lindau syndrome.

Peer-Reviewed Medical Research Program - The Committee recommends \$370,000,000 for the Peer-Reviewed Medical Research Program. The Committee directs the Secretary of Defense, in conjunction with the Service Surgeons General, to select medical research projects of clear scientific merit and direct relevance to military health. Research areas considered under this funding are restricted to: Alzheimer's; arthritis; autism; botulinum toxin type A; burn pit exposure; burn outcomes; celiac disease; Duchenne muscular dystrophy, dystonia; eating disorders; Ehlers-Danlos syndrome; eczema; neuroinflammatory responses to emerging viral diseases; endometriosis; epidermolysis bullosa; familial hypercholesterolemia; fibrous dysplasia/McCune-Albright syndrome; focal segmental glomerulosclerosis; food allergies; Fragile X; frontotemporal degeneration; Guillain-Barre syndrome; gulf war illness; hemorrhage control; hepatitis B; hereditary ataxia; hydrocephalus; hypercholesterolemia; inflammatory bowel diseases; interstitial cystitis; lupus; malaria; lymphatic disease; lymphedema; maternal mental health; mitochondrial disease; multiple sclerosis; musculoskeletal disorders related to acute and chronic bone conditions and injuries; myalgic encephalomyelitis/chronic fatigue syndrome; nephrotic syndrome; neuroactive steroids; neurofibromatosis; non-opioid therapy for pain management; orthopedics; pancreatitis; Parkinson's; peripheral neuropathy; polycystic kidney disease; pressure ulcers; proteomics; pulmonary fibrosis; reconstructive transplantation; respiratory health; rheumatoid arthritis; scleroderma; sickle-cell disease; sleep disorders and restriction; spinal cord; suicide prevention; tickborne diseases; trauma; tuberculosis; tuberous sclerosis complex; vision; and vascular malformations. The Committee emphasizes that the additional funding provided under the Peer-Reviewed Medical Research Program shall be devoted only to the purposes listed above.