

## **Liver Disease Highlights from the Senate Appropriations Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, FY 2020**

### **Nonalcoholic Steatohepatitis [NASH]**

The Committee recognizes that incidences of NASH and non-alcoholic fatty liver disease are growing. The Committee encourages CDC to support prevention, education, diagnosis, and treatment efforts in both pediatric and adult populations to combat existing incidence and support prevention activities.

### **Liver Cancer**

The Committee commends NCI for increasing resources focused on liver cancer and its inter-Institute work to encourage more research focused on liver cancer, but urges greater prioritization on addressing the threat of liver cancer, the second deadliest cancer with a 5 year survival rate of 20 percent. The Committee also notes that the link between hepatitis B infection and primary liver cancer is well established with up to 60 percent of global liver cancer cases caused by the hepatitis B virus and, therefore, encourages continued close collaboration with NIAID and NIDDK and active participation in the Director's newly established Trans-NIH Hepatitis B working group. The Committee requests an update on NCI's activities in these areas in the fiscal year 2021 CJ.

### **Deadliest Cancers**

The Committee remains concerned that while more effective screening methods and treatments have lowered overall cancer incidence and death rates, several cancer types with particularly low survival rates have limited screening methods, and effective treatments for these cancers are also limited. The Recalcitrant Cancers Research Act of 2012 defined "recalcitrant cancers" as those with a 5 year survival rate below 50 percent. These cancers account for nearly half of all cancer deaths in the United States and include cancers of the brain, esophagus, liver, lung, ovary, pancreas, and stomach. The Committee notes that in 2020 NCI will report on the effectiveness of the scientific frameworks process NCI undertook for pancreatic adenocarcinoma and small cell lung cancer to improve prevention, detection, diagnosis and treatment. NCI developed these frameworks at Congress' direction for cancers with a 5 year survival rate of less than 20 percent and expected toll of at least 30,000 deaths per year in the United States. The Committee appreciates that NCI has led scientific planning efforts in recent years to explore research opportunities related to pancreatic cancer, small cell lung cancer, liver cancer, and glioblastoma. Given the high cost recalcitrant cancers exact on society and the lack of diagnostic and treatment resources currently available to help patients, the Committee directs NCI develop a scientific framework using the process outlined in the Recalcitrant Cancer Research Act of 2012 for stomach and esophageal cancers. These cancers have 5 year

survival rates below 50 percent and are collectively expected to kill approximately 27,000 Americans in 2020. The Committee also urges NIH and NCI to continue to support research with an emphasis on developing screening and early detection tools and more effective treatments for all recalcitrant cancers. The Committee expects to receive an update on NCI-supported research to advance these goals in the fiscal year 2021 CJ. Also, the Committee directs NIH to add esophageal and stomach cancers to future Research, Condition, and Disease Categorization reports. Finally, the Committee recognizes that while overall cancer death rates continue to decline, successful treatment for some cancers, including many forms of childhood cancer, remains elusive. The Committee encourages NCI to place a high priority on researching these cancers, which include anaplastic astrocytoma, diffuse intrinsic pontine glioma, glioblastoma, Juvenile myelomonocytic leukemia, high-risk neuroblastoma, recurrent osteosarcoma, rhabdomyosarcoma, and diffuse anaplastic Wilms tumors. The Committee requests an update on the progress being made for childhood cancer research in the fiscal year 2021 CJ.

### **Liver Diseases**

The Committee notes the emphasis that NIDDK has placed on liver disease research, including transplantation issues, through the annual Recent Advancements and Emerging Opportunities report and related research plans. NIDDK is encouraged to continue to feature liver diseases research considering recent progress and improvements for liver disease patients.

### **Fibrotic Diseases**

The Committee remains concerned about the human and economic toll of fibrotic diseases, such as pulmonary fibrosis, and encourages NIH to vigorously support dedicated funding and research into fibrotic diseases affecting different organs, including the lungs, liver, kidneys, heart, skin, and bones. NIH should ensure enhanced coordination among its Institutes as they conduct necessary, expanded single organ or cross-organ fibrotic disease research to save lives and reduce healthcare expenses in future years. The Committee also encourages NIH to explore naturally occurring fibrotic disease in domestic animals to investigate opportunities to improve human and animal lives. Since many fibrotic diseases are individually rare diseases, a strategy that provides collaboration across disease and organ areas is recommended. The Committee requests a report on the current NIH Fibrosis Interest Group and its progress no later than 90 days after the passage of this act. The Committee encourages the Interest Group to continue its efforts to bring together key stakeholders, at the NIH and elsewhere, to develop strategic paths forward to maximize efforts in fibrotic disease research. The Committee also encourages NIH to enhance its patient-centered clinical research into pulmonary fibrosis to include traditional observational and interventional studies looking at reducing healthcare utilization such as hospitalizations, improving symptoms such as cough, and prolonging life, and directs NIH to include an update in its fiscal year 2021 CJ on its work relating to idiopathic pulmonary fibrosis following the November 2012 NHLBI workshop: “Strategic Planning for Idiopathic Pulmonary Fibrosis.” The Committee also commends CDC on its recent work

identifying and studying clusters of pulmonary fibrosis in workers, including dentists and miners, and encourages NIH and CDC to collaborate on such findings to include further research efforts and data sharing that could lead to better understanding of this disease and life-saving treatments. The Committee also encourages NIH to create a funding mechanism to fund fibrosis research across all organs, building on the progress and leveraging data that has and may result from NHLBI funded projects.

### **Organ Donation and Transplantation**

The Committee provides \$27,549,000 for organ donation and transplantation activities, an increase of \$2,000,000, to expand financial support for living donors and increase public education and awareness about organ donation. Funds support a scientific registry of organ transplant recipients and the National Organ Procurement and Transplantation Network [OPTN] to match donors and potential recipients of organs. A portion of the appropriated funds may be used to educate the public and health professionals about organ donations and transplants and to support clearinghouse and technical assistance functions. The Committee is disappointed that OPTN continues to try to move forward with a model for the allocation of donated livers that is mired in controversy, and that HHS and HRSA urged the OPTN to move forward with the new allocation policies for other donated organs. HRSA is directed to submit a report to the Committees on Appropriations of the House of Representatives and the Senate no later than 90 days after enactment on the following related to the Acuity Circles model for the allocation of donated livers: (1) costs to transplant programs; (2) costs to liver recipients; (3) impact on transportation of livers, including costs related to transport, which should take into account multiple models that encompass several data sets and specifically outline the amount of livers lost due to increased flying and transportation of donated organs across greater distances than before; and (4) health disparities, with a particular focus on the effects among vulnerable populations, including whether effects vary due to socioeconomic status or rural location. Further, the Committee directs HRSA to provide a report to the Committees on Appropriations of the House of Representatives and the Senate within 180 days of enactment on changes that can be made to ensure the OPTN contract is viable for other contractors to compete.

### **Inflammatory Bowel Diseases [IBD]**

The Committee continues to encourage NIDDK to incorporate patient centrality in IBD research, including support for a translational “bedside-to-bench” systematic research initiative that leverages patient priorities and perspectives with respect to biomedical research, such as personalized medicine approaches, to address a patient-identified clinical need. Specifically, the Committee recognizes interactions among food, the gut, and the brain/nervous system as an area of high interest to patients and relevant to multiple chronic gastrointestinal diseases that is supported by a growing body of evidence, and identifies it as a potential topic for further research.

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### **Immunization Program**

The Committee notes that in 2019 there has been a concerning increase in reports of vaccine preventable diseases, including the highest number of measles cases in decades. There is also more to be done to combat outbreaks of diseases like pertussis and mumps, address hepatitis A and B, and better protect communities against influenza. The Committee expects CDC to use the resources provided to continue increasing awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, with the goal of increasing rates of vaccination across all ages, as applicable, particularly in communities with low rates of vaccination, to reduce and eliminate vaccine-preventable diseases. The Committee further urges CDC to continue identifying communities at high risk of outbreaks related to vaccine-preventable diseases and improve vaccination rates in such communities, including through improved surveillance, culturally and linguistically appropriate interventions, and research initiatives.

### **Hepatitis B**

The Committee is concerned that as a result of the opioid epidemic, infections of hepatitis B have spiked in many parts of the nation with acute infections increasing over 100 percent in some States. The Committee notes that a 2017 report by the National Academies of Sciences, Engineering, and Medicine 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. The Committee encourages CDC, in consultation with State, local, and tribal health departments, criminal justice programs, and relevant patient and community stakeholder organizations to develop a plan that takes into account best practices and model strategies to increase immunization coverage among adults and reduce the number of hepatitis B cases. The Committee requests an update on these efforts in the fiscal year 2021 CJ.

### **Hepatitis B Virus [HBV]**

The Committee notes that infection with HBV is a serious public health threat and 1 in 20 Americans has been infected and more than 2,000,000 are chronically infected, increasing by 70,000 a year. Based on findings from the National Academies of Sciences, Engineering, and Medicine 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 \$48,000,000 in fiscal year 2014 to an estimated \$42,000,000 in fiscal year 2019, despite

declarations from the National Academies of Sciences, Engineering, and Medicine in 2017 that the elimination of HBV 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 HBV. The Committee urges NIDDK to pursue the many critical research opportunities identified by the scientific community and to work in coordination with other NIH Institutes on HBV research planning.

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### **Hepatitis B**

The Committee commends the Director’s office for establishing a trans-NIH Hepatitis B Working Group to include representation from NCI, NIAID, NIDDK, and NIMHD to coordinate 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-NIH 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-NIH Hepatitis B Working Group and requests a status report be sent to the Committee within 90 days of enactment.

### **Hepatitis C**

The elimination of the deadly hepatitis C virus, which affects more than 2,400,000 Americans, is a top public health priority for both the Federal and State governments. The Committee is supportive of States' efforts to implement innovative payment models and public health elimination initiatives that dramatically increase access to the medications that cure hepatitis C. The Committee urges NIH to prioritize research aimed at supporting hepatitis C elimination.

### **Public Health in Indian Country**

The Committee recommends that the Secretary examine current public health initiatives within the Department that address public health crises such as viral hepatitis, HIV/AIDS, and opioids that impact Indian Country. The Committee requests that HHS provide an update on these efforts in the fiscal year 2021 CJ.