II

116TH CONGRESS
1ST SESSION

S. 3074

To amend the Public Health Service Act to provide for and support liver illness visibility, education, and research, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 17, 2019

Ms. DUCKWORTH introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to provide for and support liver illness visibility, education, and research, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Liver Illness Visibility, Education, and Research Act of 2019''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Liver cancer is the fastest-growing cause of cancer death in the United States and among the leading causes of cancer deaths globally.

(2) In 2018, approximately 42,220 people in the United States will be diagnosed with primary liver cancer, and approximately 30,200 will die from the disease.

(3) Liver cancer is a leading cause of cancer death among the Asian American and Pacific Islander community.

(4) The most vulnerable Asian Americans are those who are foreign-born, low-income, and living in ethnic enclaves.

(5) Asian and Pacific Islander men and women are more than twice as likely to develop liver cancer compared to the non-Hispanic White population.

(6) Among the Asian and Pacific Islander population, the higher incidence rate of liver cancer is partially explained by higher incidence rates of hepatitis B and diabetes, which are comorbidities shown to increase an individual's risk of developing liver cancer.

(7) The most common causes of liver cancer include hepatitis B virus and hepatitis C virus infection.

(8) Hepatitis B is a primary risk factor for developing liver cancer, and 1 in 4 of those chronically

infected with hepatitis B develop cirrhosis, liver failure, or liver cancer.

(9) Half of all individuals with hepatitis B in the United States are Asian American or Pacific Islander, though this group accounts for only 5 percent of the population of the United States.

(10) Among African immigrants in the United States, the prevalence of hepatitis B infection is approximately 1 in 10, and African immigrants make up 30 percent of those with chronic hepatitis B infection in the United States.

(11) Among Hispanic/Latino communities, liver cancer incidence and death rates are twice as high compared to the non-Hispanic White population.

(12) Hispanics/Latinos are 60 percent more likely to die from viral hepatitis than non-Hispanic Whites.

SEC. 3. LIVER CANCER AND DISEASE RESEARCH.

Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following new section:

"SEC. 417H. LIVER CANCER AND DISEASE RESEARCH.

''(a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute shall expand, inten-

sify, and coordinate the activities of the Institute with respect to research on liver cancer and other liver diseases.

''(b) PROGRAMS FOR LIVER CANCER.—In carrying out subsection (a), the Director of the Institute shall—

''(1) provide for an expansion and intensification of the conduct and support of—

''(A) basic research concerning the etiology and causes of liver cancer;

''(B) clinical research and related activities concerning the causes, prevention, detection, and treatment of liver cancer;

''(C) control programs with respect to liver cancer, in accordance with section 412, including community-based programs designed to assist members of medically underserved populations (including women), low-income populations, or minority groups; and

''(D) information and education programs with respect to liver cancer, in accordance with section 413;

''(2) issue targeted calls for proposals from research scientists for purposes of funding priority areas of liver cancer research;

''(3) establish a special emphasis panel (as defined by the National Institutes of Health) to review

any proposal submitted pursuant to paragraph (2); and

''(4) based on reviews by the special emphasis panel under paragraph (3), select which proposals to fund or support.

''(c) INTER-INSTITUTE WORKING GROUP.—The Director of the Institute shall establish an inter-institute working group to coordinate research agendas focused on finding better outcomes and cures for liver cancer and other liver diseases, including hepatitis B and nonalcoholic steatohepatitis.

''(d) GRANTS AND COOPERATIVE AGREEMENTS.—

''(1) IN GENERAL.—The Secretary may award grants and enter into cooperative agreements with entities for the purpose of expanding and supporting research on—

''(A) conditions known to increase an individual's risk of developing a major liver disease, such as liver cancer, hepatitis B, hepatitis C, nonalcoholic fatty liver disease, nonalcoholic steatohepatitis, and cirrhosis of the liver; and

''(B) opportunities for preventative and diagnostic measures for such a disease, including the study of molecular pathology and biomarkers for early detection of such disease.

''(2) EXPERIMENTAL TREATMENT AND PREVENTION.—In the case of an entity that is a hospital or a health care facility, the Secretary may award a grant or enter into a cooperative agreement with such an entity for the purpose of supporting an experimental treatment or prevention program for liver cancer carried out by such entity.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this subsection, there is authorized to be appropriated $45,000,000 for each of fiscal years 2020 through 2024. Any amounts appropriated under this paragraph shall remain available until expended.''.

SEC. 4. LIVER CANCER AND DISEASE PREVENTION, AWARENESS, AND PATIENT TRACKING GRANTS.

Subpart I of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following new section:

''SEC. 330N. LIVER CANCER AND DISEASE PREVENTION, AWARENESS, AND PATIENT TRACKING GRANTS.

''(a) PREVENTION INITIATIVE GRANT PROGRAM.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants and

enter into cooperative agreements with entities for the purpose of expanding and supporting—

''(A) prevention activities (including providing screenings, vaccinations, or other preventative treatment) for conditions known to increase an individual's risk of developing a major liver disease, such as liver cancer, hepatitis B, hepatitis C, nonalcoholic fatty liver disease, nonalcoholic steatohepatitis, and cirrhosis of the liver;

''(B) activities relating to surveillance, diagnostics, and provision of guidance for individuals at high risk for contracting liver cancer and other liver diseases; and

''(C) a robust hepatitis surveillance infrastructure to provide for timely and accurate information regarding progress to eliminate viral hepatitis.

''(2) REPORT.—An entity that receives a grant or cooperative agreement under paragraph (1) shall submit to the Secretary, at a time specified by the Secretary, a report describing each activity carried out pursuant to such paragraph and evaluating the effectiveness of such activity in promoting prevention

and treatment of liver cancer and other liver diseases.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this subsection, there is authorized to be appropriated $90,000,000 for each of fiscal years 2020 through 2024. Any amounts appropriated under this paragraph shall remain available until expended and shall be used to supplement and not supplant other Federal funds provided for activities under this subsection.

''(b) AWARENESS INITIATIVE GRANT PROGRAM.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to eligible entities for the purpose of raising awareness for liver cancer and other liver diseases, which may include the production, dissemination, and distribution of informational materials targeted towards communities and populations with a higher risk for developing liver cancer and other liver diseases.

''(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant under paragraph (1), an entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including a description of

how the entity, in disseminating information on liver cancer and other liver diseases pursuant to paragraph (1), will—

"(A) with respect to any community or population, consult with members of such community or population and provide such information in a manner that is culturally and linguistically appropriate for such community or population;

"(B) highlight the range of treatments available for liver cancer and other liver diseases;

"(C) integrate information on available hepatitis B and hepatitis C testing programs into any liver cancer presentations carried out by the entity; and

"(D) target communities and populations with a higher risk for contracting liver cancer and other liver diseases.

"(3) PREFERENCE.—In awarding grants under paragraph (1), the Secretary shall give preference to entities that—

"(A) are, or work with, a Federally-qualified health center; or

"(B) are community-based organizations.

''(4) REPORT.—An entity that receives a grant under paragraph (1) shall submit to the Secretary, at a time specified by the Secretary, a report describing each activity carried out pursuant to such paragraph and evaluating the effectiveness of such activity in raising awareness for liver cancer and other liver diseases.

''(5) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this subsection, there is authorized to be appropriated $10,000,000 for each of fiscal years 2020 through 2024. Any amounts appropriated under this paragraph shall remain available until expended and shall be used to supplement and not supplant other Federal funds provided for activities under this subsection.''.

SEC. 5. HEPATITIS B RESEARCH.

Subpart 3 of part C of title IV of the Public Health Service Act (42 U.S.C. 285c et seq.) is amended by adding at the end the following new section:

''SEC. 434B. HEPATITIS B.

''The Director of the Institute shall, in collaboration with the Director of the National Institute of Allergy and Infectious Diseases, issue targeted calls for hepatitis B research proposals focused on key research questions identi-

fied by the research community and discussed in peer-reviewed research journal articles.''.

SEC. 6. CHANGES RELATING TO NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES.

(a) CHANGE OF NAME OF NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES.—

(1) IN GENERAL.—Subpart 3 of part C of title IV of the Public Health Service Act (42 U.S.C. 285c et seq.) is amended in the subpart heading by striking ''**National Institute of Diabetes and Digestive and Kidney Diseases**'' and inserting ''**National Institute of Diabetes and Digestive, Kidney, and Liver Diseases**''.

(2) TREATMENT OF DIRECTOR OF NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES.—The individual serving as the Director of the National Institute of Diabetes and Digestive and Kidney Diseases as of the date of enactment of this Act may continue to serve as the Director of the National Institute of Diabetes and Digestive, Kidney, and Liver Diseases commencing as of that date.

(3) REFERENCES.—Any reference to the National Institute of Diabetes and Digestive and Kid-

ney Diseases, or the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, in any law, regulation, document, record, or other paper of the United States shall be deemed to be a reference to the National Institute of Diabetes and Digestive, Kidney, and Liver Diseases, or the Director of the National Institute of Diabetes and Digestive, Kidney, and Liver Diseases, respectively.

(4) CONFORMING AMENDMENTS.—

(A) Section 401(b)(3) of the Public Health Service Act (42 U.S.C. 281(b)(3)) is amended by striking ''The National Institute of Diabetes and Digestive and Kidney Diseases.'' and inserting ''The National Institute of Diabetes and Digestive, Kidney, and Liver Diseases.''.

(B) Section 409A(a) of the Public Health Service Act (42 U.S.C. 284e(a)) is amended by striking ''the National Institute of Diabetes and Digestive and Kidney Diseases'' and inserting ''the National Institute of Diabetes and Digestive, Kidney, and Liver Diseases''.

(b) PURPOSE OF THE INSTITUTE.—Section 426 of the Public Health Service Act (42 U.S.C. 285c) is amended—

(1) by striking ''National Institute of Diabetes and Digestive and Kidney Diseases'' and inserting ''National Institute of Diabetes and Digestive, Kidney, and Liver Diseases''; and

(2) by striking ''and kidney, urologic, and hematologic diseases'' and inserting ''kidney, urologic, and hematologic diseases, and liver diseases''.

(c) DATA SYSTEMS AND INFORMATION CLEARINGHOUSES.—Section 427 of the Public Health Service Act (42 U.S.C. 285c–1) is amended by adding at the end the following new subsection:

''(d) The Director of the Institute shall (1) establish the National Liver Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with liver diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing liver diseases, and (2) establish the National Liver Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of liver diseases on the part of health professionals, patients, and the public through the effective dissemination of information.''.

(d) REESTABLISHMENT OF LIVER DISEASE RESEARCH BRANCH WITHIN DIVISION OF DIGESTIVE DIS-

EASES AND NUTRITION AS DIVISION OF LIVER DISEASES.—

(1) IN GENERAL.—The Liver Disease Research Branch within the Division of Digestive Diseases and Nutrition of the National Institute of Diabetes and Digestive and Kidney Diseases (referred to in this subsection as the ''Liver Disease Research Branch'') is hereby redesignated and promoted as the Division of Liver Diseases, which shall be within the National Institute of Diabetes and Digestive, Kidney, and Liver Diseases, as redesignated by subsection (a), as a separate division from the other divisions within such Institute.

(2) DIVISION DIRECTOR.—Section 428 of the Public Health Service Act (42 U.S.C. 285c–2) is amended—

(A) in the section heading, by striking ''**DIVISION DIRECTORS FOR DIABETES, ENDOCRINOLOGY, AND METABOLIC DISEASES, DIGESTIVE DISEASES AND NUTRITION, AND KIDNEY, UROLOGIC, AND HEMATOLOGIC DISEASES**'' and inserting ''**DIVISION DIRECTORS FOR DIABETES, ENDOCRINOLOGY, AND METABOLIC DISEASES, DIGESTIVE DISEASES AND NUTRITION,**

KIDNEY, UROLOGIC, AND HEMATOLOGIC DISEASES, AND LIVER DISEASES'';

(B) in subsection (a)(1)—

(i) in the matter preceding subparagraph (A), by striking ''and a Division Director for Kidney, Urologic, and Hematologic Diseases'' and inserting ''a Division Director for Kidney, Urologic, and Hematologic Diseases, and a Division Director for Liver Diseases''; and

(ii) in subparagraph (A), by striking ''and kidney, urologic, and hematologic diseases'' and inserting ''kidney, urologic, and hematologic diseases, and liver diseases''; and

(C) in subsection (b)—

(i) in the matter preceding paragraph (1), by striking ''and the Division Director for Kidney, Urologic, and Hematologic Diseases'' and inserting ''the Division Director for Kidney, Urologic, and Hematologic Diseases, and the Division Director for Liver Diseases''; and

(ii) in paragraph (1), by striking ''and kidney, urologic, and hematologic diseases''

and inserting ''kidney, urologic, and hematologic diseases, and liver diseases''.

(3) TREATMENT OF DIRECTOR OF LIVER DISEASE RESEARCH BRANCH.—The individual serving as the Director of the Liver Disease Research Branch as of the date of enactment of this Act may continue to serve as the Division Director for Liver Diseases commencing as of that date.

(4) TRANSFER OF AUTHORITIES.—The Secretary of Health and Human Services shall delegate to the Division Director for Liver Diseases all duties and authorities that were vested in the Director of the Liver Disease Research Branch as of the day before the date of enactment of this Act.

(5) REFERENCES.—Any reference to the Liver Disease Research Branch, or the Director of the Liver Disease Research Branch, in any law, regulation, document, record, or other paper of the United States shall be deemed to be a reference to the Division of Liver Diseases, or the Division Director for Liver Diseases, respectively.

(e) INTERAGENCY COORDINATING COMMITTEES.—Section 429(a) of the Public Health Service Act (42 U.S.C. 285c–3(a)) is amended—

(1) in paragraph (1), by striking ''and kidney, urologic, and hematologic diseases'' and inserting ''kidney, urologic, and hematologic diseases, and liver diseases''; and

(2) in the matter following paragraph (2), by striking ''and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee'' and inserting ''a Kidney, Urologic, and Hematologic Diseases Coordinating Committee, and a Liver Diseases Coordinating Committee''.

(f) ADVISORY BOARDS.—Section 430 of the Public Health Service Act (42 U.S.C. 285c–4) is amended—

(1) in subsection (a), by striking ''and the National Kidney and Urologic Diseases Advisory Board'' and inserting ''the National Kidney and Urologic Diseases Advisory Board, and the Liver Diseases Advisory Board''; and

(2) in subsection (b)(2)(A)(i)—

(A) by striking ''the Director of the National Institute of Diabetes and Digestive and Kidney Diseases'' and inserting ''the Director of the National Institute of Diabetes and Digestive, Kidney, and Liver Diseases''; and

(B) by striking ''and the Division Director of the National Institute of Diabetes and Diges-

tive and Kidney Diseases'' and inserting ''and the Division Director of the National Institute of Diabetes and Digestive, Kidney, and Liver Diseases''.

(g) RESEARCH AND TRAINING CENTERS.—Section 431 of the Public Health Service Act (42 U.S.C. 285c–5) is amended—

(1) by redesignating subsection (e) as subsection (f); and

(2) by inserting after subsection (d) the following new subsection:

''(e) The Director of the Institute shall provide for the development or substantial expansion of centers for research in liver diseases. Each center developed or expanded under this subsection—

''(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

''(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of liver diseases and related functional, congenital, metabolic, or other complications resulting from such diseases;

''(3) shall encourage research into and programs for—

''(A) providing information for patients with such diseases and complications and the families of such patients, physicians and others who care for such patients, and the general public;

''(B) model programs for cost effective and preventive patient care; and

''(C) training physicians and scientists in research on such diseases and complications; and

''(4) may perform research and participate in epidemiological studies and data collection relevant to liver diseases in order to disseminate such research, studies, and data to the health care profession and to the public.''.

(h) ADVISORY COUNCIL SUBCOMMITTEES.—Section 432 of the Public Health Service Act (42 U.S.C. 285c–6) is amended—

(1) by striking ''and a subcommittee on kidney, urologic, and hematologic diseases'' and inserting ''a subcommittee on kidney, urologic, and hematologic diseases, and a subcommittee on liver diseases''; and

(2) by striking ''and kidney, urologic, and hematologic diseases'' and inserting ''kidney, urologic, and hematologic diseases, and liver diseases''.

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