

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Liver Illness Visibility,
5 Education, and Research Act of 2019”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

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

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

5 (3) Liver cancer is a leading cause of cancer
6 death among the Asian American and Pacific Is-
7 lander community.

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

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

14 (6) Among the Asian and Pacific Islander pop-
15 ulation, the higher incidence rate of liver cancer is
16 partially explained by higher incidence rates of hepa-
17 titis B and diabetes, which are comorbidities shown
18 to increase an individual's risk of developing liver
19 cancer.

20 (7) The most common causes of liver cancer in-
21 clude hepatitis B virus and hepatitis C virus infec-
22 tion.

23 (8) Hepatitis B is a primary risk factor for de-
24 veloping liver cancer, and 1 in 4 of those chronically

1 infected with hepatitis B develop cirrhosis, liver fail-
 2 ure, or liver cancer.

3 (9) Half of all individuals with hepatitis B in
 4 the United States are Asian American or Pacific Is-
 5 lander, though this group accounts for only 5 per-
 6 cent of the population of the United States.

7 (10) Among African immigrants in the United
 8 States, the prevalence of hepatitis B infection is ap-
 9 proximately 1 in 10, and African immigrants make
 10 up 30 percent of those with chronic hepatitis B in-
 11 fection in the United States.

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

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

18 **SEC. 3. LIVER CANCER AND DISEASE RESEARCH.**

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

22 **“SEC. 417H. LIVER CANCER AND DISEASE RESEARCH.**

23 “(a) EXPANSION AND COORDINATION OF ACTIVI-
 24 TIES.—The Director of the Institute shall expand, inten-

1 sify, and coordinate the activities of the Institute with re-
 2 spect to research on liver cancer and other liver diseases.

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

5 “(1) provide for an expansion and intensifica-
 6 tion of the conduct and support of—

7 “(A) basic research concerning the etiology
 8 and causes of liver cancer;

9 “(B) clinical research and related activities
 10 concerning the causes, prevention, detection,
 11 and treatment of liver cancer;

12 “(C) control programs with respect to liver
 13 cancer, in accordance with section 412, includ-
 14 ing community-based programs designed to as-
 15 sist members of medically underserved popu-
 16 lations (including women), low-income popu-
 17 lations, or minority groups; and

18 “(D) information and education programs
 19 with respect to liver cancer, in accordance with
 20 section 413;

21 “(2) issue targeted calls for proposals from re-
 22 search scientists for purposes of funding priority
 23 areas of liver cancer research;

24 “(3) establish a special emphasis panel (as de-
 25 fined by the National Institutes of Health) to review

1 any proposal submitted pursuant to paragraph (2);
2 and

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

6 “(c) INTER-INSTITUTE WORKING GROUP.—The Di-
7 rector of the Institute shall establish an inter-institute
8 working group to coordinate research agendas focused on
9 finding better outcomes and cures for liver cancer and
10 other liver diseases, including hepatitis B and nonalcoholic
11 steatohepatitis.

12 “(d) GRANTS AND COOPERATIVE AGREEMENTS.—

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

17 “(A) conditions known to increase an indi-
18 vidual’s risk of developing a major liver disease,
19 such as liver cancer, hepatitis B, hepatitis C,
20 nonalcoholic fatty liver disease, nonalcoholic
21 steatohepatitis, and cirrhosis of the liver; and

22 “(B) opportunities for preventative and di-
23 agnostic measures for such a disease, including
24 the study of molecular pathology and biomark-
25 ers for early detection of such disease.

1 “(2) EXPERIMENTAL TREATMENT AND PRE-
 2 VENTION.—In the case of an entity that is a hospital
 3 or a health care facility, the Secretary may award a
 4 grant or enter into a cooperative agreement with
 5 such an entity for the purpose of supporting an ex-
 6 perimental treatment or prevention program for liver
 7 cancer carried out by such entity.

8 “(3) AUTHORIZATION OF APPROPRIATIONS.—
 9 For purposes of carrying out this subsection, there
 10 is authorized to be appropriated \$45,000,000 for
 11 each of fiscal years 2020 through 2024. Any
 12 amounts appropriated under this paragraph shall re-
 13 main available until expended.”.

14 **SEC. 4. LIVER CANCER AND DISEASE PREVENTION, AWARE-**
 15 **NESS, AND PATIENT TRACKING GRANTS.**

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

19 **“SEC. 330N. LIVER CANCER AND DISEASE PREVENTION,**
 20 **AWARENESS, AND PATIENT TRACKING**
 21 **GRANTS.**

22 “(a) PREVENTION INITIATIVE GRANT PROGRAM.—

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

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

3 “(A) prevention activities (including pro-
4 viding screenings, vaccinations, or other pre-
5 ventative treatment) for conditions known to in-
6 crease an individual’s risk of developing a major
7 liver disease, such as liver cancer, hepatitis B,
8 hepatitis C, nonalcoholic fatty liver disease,
9 nonalcoholic steatohepatitis, and cirrhosis of the
10 liver;

11 “(B) activities relating to surveillance,
12 diagnostics, and provision of guidance for indi-
13 viduals at high risk for contracting liver cancer
14 and other liver diseases; and

15 “(C) a robust hepatitis surveillance infra-
16 structure to provide for timely and accurate in-
17 formation regarding progress to eliminate viral
18 hepatitis.

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

1 and treatment of liver cancer and other liver dis-
2 eases.

3 “(3) AUTHORIZATION OF APPROPRIATIONS.—

4 For purposes of carrying out this subsection, there
5 is authorized to be appropriated \$90,000,000 for
6 each of fiscal years 2020 through 2024. Any
7 amounts appropriated under this paragraph shall re-
8 main available until expended and shall be used to
9 supplement and not supplant other Federal funds
10 provided for activities under this subsection.

11 “(b) AWARENESS INITIATIVE GRANT PROGRAM.—

12 “(1) IN GENERAL.—The Secretary, acting
13 through the Director of the Centers for Disease
14 Control and Prevention, may award grants to eligi-
15 ble entities for the purpose of raising awareness for
16 liver cancer and other liver diseases, which may in-
17 clude the production, dissemination, and distribution
18 of informational materials targeted towards commu-
19 nities and populations with a higher risk for devel-
20 oping liver cancer and other liver diseases.

21 “(2) ELIGIBLE ENTITIES.—To be eligible to re-
22 ceive a grant under paragraph (1), an entity shall
23 submit to the Secretary an application, at such time,
24 in such manner, and containing such information as
25 the Secretary may require, including a description of

1 how the entity, in disseminating information on liver
2 cancer and other liver diseases pursuant to para-
3 graph (1), will—

4 “(A) with respect to any community or
5 population, consult with members of such com-
6 munity or population and provide such informa-
7 tion in a manner that is culturally and linguis-
8 tically appropriate for such community or popu-
9 lation;

10 “(B) highlight the range of treatments
11 available for liver cancer and other liver dis-
12 eases;

13 “(C) integrate information on available
14 hepatitis B and hepatitis C testing programs
15 into any liver cancer presentations carried out
16 by the entity; and

17 “(D) target communities and populations
18 with a higher risk for contracting liver cancer
19 and other liver diseases.

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

23 “(A) are, or work with, a Federally-quali-
24 fied health center; or

25 “(B) are community-based organizations.

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

8 “(5) AUTHORIZATION OF APPROPRIATIONS.—
 9 For purposes of carrying out this subsection, there
 10 is authorized to be appropriated \$10,000,000 for
 11 each of fiscal years 2020 through 2024. Any
 12 amounts appropriated under this paragraph shall re-
 13 main available until expended and shall be used to
 14 supplement and not supplant other Federal funds
 15 provided for activities under this subsection.”.

16 **SEC. 5. HEPATITIS B RESEARCH.**

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

20 **“SEC. 434B. HEPATITIS B.**

21 “The Director of the Institute shall, in collaboration
 22 with the Director of the National Institute of Allergy and
 23 Infectious Diseases, issue targeted calls for hepatitis B re-
 24 search proposals focused on key research questions identi-

1 fied by the research community and discussed in peer-re-
 2 viewed research journal articles.”.

3 **SEC. 6. CHANGES RELATING TO NATIONAL INSTITUTE OF**
 4 **DIABETES AND DIGESTIVE AND KIDNEY DIS-**
 5 **EASES.**

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

8 (1) IN GENERAL.—Subpart 3 of part C of title
 9 IV of the Public Health Service Act (42 U.S.C. 285c
 10 et seq.) is amended in the subpart heading by strik-
 11 ing “**National Institute of Diabetes and Di-**
 12 **gestive and Kidney Diseases**” and inserting
 13 “**National Institute of Diabetes and Diges-**
 14 **tive, Kidney, and Liver Diseases**”.

15 (2) TREATMENT OF DIRECTOR OF NATIONAL
 16 INSTITUTE OF DIABETES AND DIGESTIVE AND KID-
 17 NEY DISEASES.—The individual serving as the Di-
 18 rector of the National Institute of Diabetes and Di-
 19 gestive and Kidney Diseases as of the date of enact-
 20 ment of this Act may continue to serve as the Direc-
 21 tor of the National Institute of Diabetes and Diges-
 22 tive, Kidney, and Liver Diseases commencing as of
 23 that date.

24 (3) REFERENCES.—Any reference to the Na-
 25 tional Institute of Diabetes and Digestive and Kid-

1 ney Diseases, or the Director of the National Insti-
 2 tute of Diabetes and Digestive and Kidney Diseases,
 3 in any law, regulation, document, record, or other
 4 paper of the United States shall be deemed to be a
 5 reference to the National Institute of Diabetes and
 6 Digestive, Kidney, and Liver Diseases, or the Direc-
 7 tor of the National Institute of Diabetes and Diges-
 8 tive, Kidney, and Liver Diseases, respectively.

9 (4) CONFORMING AMENDMENTS.—

10 (A) Section 401(b)(3) of the Public Health
 11 Service Act (42 U.S.C. 281(b)(3)) is amended
 12 by striking “The National Institute of Diabetes
 13 and Digestive and Kidney Diseases.” and in-
 14 serting “The National Institute of Diabetes and
 15 Digestive, Kidney, and Liver Diseases.”.

16 (B) Section 409A(a) of the Public Health
 17 Service Act (42 U.S.C. 284e(a)) is amended by
 18 striking “the National Institute of Diabetes and
 19 Digestive and Kidney Diseases” and inserting
 20 “the National Institute of Diabetes and Diges-
 21 tive, Kidney, and Liver Diseases”.

22 (b) PURPOSE OF THE INSTITUTE.—Section 426 of
 23 the Public Health Service Act (42 U.S.C. 285c) is amend-
 24 ed—

1 (1) by striking “National Institute of Diabetes
2 and Digestive and Kidney Diseases” and inserting
3 “National Institute of Diabetes and Digestive, Kid-
4 ney, and Liver Diseases”; and

5 (2) by striking “and kidney, urologic, and hem-
6 atologic diseases” and inserting “kidney, urologic,
7 and hematologic diseases, and liver diseases”.

8 (c) DATA SYSTEMS AND INFORMATION CLEARING-
9 HOUSES.—Section 427 of the Public Health Service Act
10 (42 U.S.C. 285c–1) is amended by adding at the end the
11 following new subsection:

12 “(d) The Director of the Institute shall (1) establish
13 the National Liver Diseases Data System for the collec-
14 tion, storage, analysis, retrieval, and dissemination of data
15 derived from patient populations with liver diseases, in-
16 cluding, where possible, data involving general populations
17 for the purpose of detection of individuals with a risk of
18 developing liver diseases, and (2) establish the National
19 Liver Diseases Information Clearinghouse to facilitate and
20 enhance knowledge and understanding of liver diseases on
21 the part of health professionals, patients, and the public
22 through the effective dissemination of information.”.

23 (d) REESTABLISHMENT OF LIVER DISEASE RE-
24 SEARCH BRANCH WITHIN DIVISION OF DIGESTIVE DIS-

1 EASES AND NUTRITION AS DIVISION OF LIVER DIS-
 2 EASES.—

3 (1) IN GENERAL.—The Liver Disease Research
 4 Branch within the Division of Digestive Diseases
 5 and Nutrition of the National Institute of Diabetes
 6 and Digestive and Kidney Diseases (referred to in
 7 this subsection as the “Liver Disease Research
 8 Branch”) is hereby redesignated and promoted as
 9 the Division of Liver Diseases, which shall be within
 10 the National Institute of Diabetes and Digestive,
 11 Kidney, and Liver Diseases, as redesignated by sub-
 12 section (a), as a separate division from the other di-
 13 visions within such Institute.

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

17 (A) in the section heading, by striking
 18 **“DIVISION DIRECTORS FOR DIABETES, EN-**
 19 **DOCRINOLOGY, AND METABOLIC DIS-**
 20 **EASES, DIGESTIVE DISEASES AND NUTRI-**
 21 **TION, AND KIDNEY, UROLOGIC, AND HEM-**
 22 **ATOLOGIC DISEASES”** and inserting **“DIVI-**
 23 **SION DIRECTORS FOR DIABETES, ENDO-**
 24 **CRINOLOGY, AND METABOLIC DISEASES,**
 25 **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”

1 and inserting “kidney, urologic, and hem-
2 atologic diseases, and liver diseases”.

3 (3) TREATMENT OF DIRECTOR OF LIVER DIS-
4 EASE RESEARCH BRANCH.—The individual serving
5 as the Director of the Liver Disease Research
6 Branch as of the date of enactment of this Act may
7 continue to serve as the Division Director for Liver
8 Diseases commencing as of that date.

9 (4) TRANSFER OF AUTHORITIES.—The Sec-
10 retary of Health and Human Services shall delegate
11 to the Division Director for Liver Diseases all duties
12 and authorities that were vested in the Director of
13 the Liver Disease Research Branch as of the day be-
14 fore the date of enactment of this Act.

15 (5) REFERENCES.—Any reference to the Liver
16 Disease Research Branch, or the Director of the
17 Liver Disease Research Branch, in any law, regula-
18 tion, document, record, or other paper of the United
19 States shall be deemed to be a reference to the Divi-
20 sion of Liver Diseases, or the Division Director for
21 Liver Diseases, respectively.

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

1 (1) in paragraph (1), by striking “and kidney,
2 urologic, and hematologic diseases” and inserting
3 “kidney, urologic, and hematologic diseases, and
4 liver diseases”; and

5 (2) in the matter following paragraph (2), by
6 striking “and a Kidney, Urologic, and Hematologic
7 Diseases Coordinating Committee” and inserting “a
8 Kidney, Urologic, and Hematologic Diseases Coordi-
9 nating Committee, and a Liver Diseases Coordi-
10 nating Committee”.

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

13 (1) in subsection (a), by striking “and the Na-
14 tional Kidney and Urologic Diseases Advisory
15 Board” and inserting “the National Kidney and
16 Urologic Diseases Advisory Board, and the Liver
17 Diseases Advisory Board”; and

18 (2) in subsection (b)(2)(A)(i)—

19 (A) by striking “the Director of the Na-
20 tional Institute of Diabetes and Digestive and
21 Kidney Diseases” and inserting “the Director
22 of the National Institute of Diabetes and Diges-
23 tive, Kidney, and Liver Diseases”; and

24 (B) by striking “and the Division Director
25 of the National Institute of Diabetes and Diges-

1 tive and Kidney Diseases” and inserting “and
 2 the Division Director of the National Institute
 3 of Diabetes and Digestive, Kidney, and Liver
 4 Diseases”.

5 (g) RESEARCH AND TRAINING CENTERS.—Section
 6 431 of the Public Health Service Act (42 U.S.C. 285c–
 7 5) is amended—

8 (1) by redesignating subsection (e) as sub-
 9 section (f); and

10 (2) by inserting after subsection (d) the fol-
 11 lowing new subsection:

12 “(e) The Director of the Institute shall provide for
 13 the development or substantial expansion of centers for
 14 research in liver diseases. Each center developed or ex-
 15 panded under this subsection—

16 “(1) shall utilize the facilities of a single insti-
 17 tution, or be formed from a consortium of cooper-
 18 ating institutions, meeting such research qualifica-
 19 tions as may be prescribed by the Secretary;

20 “(2) shall develop and conduct basic and clin-
 21 ical research into the cause, diagnosis, early detec-
 22 tion, prevention, control, and treatment of liver dis-
 23 eases and related functional, congenital, metabolic,
 24 or other complications resulting from such diseases;

1 “(3) shall encourage research into and pro-
2 grams for—

3 “(A) providing information for patients
4 with such diseases and complications and the
5 families of such patients, physicians and others
6 who care for such patients, and the general
7 public;

8 “(B) model programs for cost effective and
9 preventive patient care; and

10 “(C) training physicians and scientists in
11 research on such diseases and complications;
12 and

13 “(4) may perform research and participate in
14 epidemiological studies and data collection relevant
15 to liver diseases in order to disseminate such re-
16 search, studies, and data to the health care profes-
17 sion and to the public.”.

18 (h) ADVISORY COUNCIL SUBCOMMITTEES.—Section
19 432 of the Public Health Service Act (42 U.S.C. 285c-
20 6) is amended—

21 (1) by striking “and a subcommittee on kidney,
22 urologic, and hematologic diseases” and inserting “a
23 subcommittee on kidney, urologic, and hematologic
24 diseases, and a subcommittee on liver diseases”; and

- 1 (2) by striking “and kidney, urologic, and hem-
- 2 atologic diseases” and inserting “kidney, urologic,
- 3 and hematologic diseases, and liver diseases”.

○