

117TH CONGRESS
1ST SESSION

S. 3041

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

OCTOBER 21, 2021

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 2021”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

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

1 (2) The Division of Cancer Control and Popu-
2 lation Sciences of the National Cancer Institute esti-
3 mated that there will be 42,230 new liver cancer di-
4 agnoses in the year 2021, and approximately 30,200
5 individuals will die from the disease.

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

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

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

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

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

24 (8) Hepatitis B is a primary risk factor for de-
25 veloping liver cancer, and approximately 15 to 25

1 percent of those chronically infected with hepatitis B
 2 develop cirrhosis, liver failure, or liver cancer.

3 (9) More than half of all individuals with hepa-
 4 titis B in the United States are Asian American or
 5 Pacific Islander, though this group accounts for only
 6 6 percent 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 12, and African immigrants make
 10 up 12 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 70 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 pro-
 5 vide for an expansion and intensification of the conduct
 6 and support of—

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

9 “(2) clinical research and related activities con-
 10 cerning the causes, prevention, detection, and treat-
 11 ment of liver cancer;

12 “(3) control programs with respect to liver can-
 13 cer, in accordance with section 412, including com-
 14 munity-based programs designed to assist members
 15 of medically underserved populations (including
 16 women), low-income populations, or minority groups;
 17 and

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

21 “(c) INTER-INSTITUTE WORKING GROUP.—The Di-
 22 rector of the Institute shall establish an inter-institute
 23 working group to coordinate research agendas focused on
 24 finding treatments and cures for liver cancer and other

1 liver diseases, including hepatitis B and nonalcoholic
2 steatohepatitis.

3 “(d) GRANTS AND COOPERATIVE AGREEMENTS.—

4 “(1) IN GENERAL.—The Secretary may award
5 grants and enter into cooperative agreements with
6 entities for the purpose of expanding, conducting,
7 and supporting research on—

8 “(A) conditions known to increase an indi-
9 vidual’s risk of developing a major liver disease,
10 such as liver cancer, hepatitis B, hepatitis C,
11 nonalcoholic fatty liver disease, nonalcoholic
12 steatohepatitis, and cirrhosis of the liver; and

13 “(B) early detection and diagnostic meas-
14 ures for such a disease, including the study of
15 molecular pathology and biomarkers for early
16 detection.

17 “(2) EXPERIMENTAL TREATMENT AND PRE-
18 VENTION.—In the case of an entity that is a hospital
19 or a health care facility, the Secretary may award a
20 grant or enter into a cooperative agreement with
21 such an entity for the purpose of supporting an ex-
22 perimental treatment or prevention program for liver
23 cancer carried out by such entity.

24 “(3) AUTHORIZATION OF APPROPRIATIONS.—

25 For purposes of carrying out this subsection, there

1 is authorized to be appropriated \$45,000,000 for
 2 each of fiscal years 2023 through 2027.”.

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

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

8 **“SEC. 3300. LIVER CANCER AND DISEASE PREVENTION,**
 9 **AWARENESS, AND PATIENT TRACKING**
 10 **GRANTS.**

11 **“(a) PREVENTION 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 and
 15 enter into cooperative agreements with entities for
 16 the purpose of expanding and supporting—

17 **“(A)** prevention activities (including pro-
 18 viding screenings, vaccinations, or other pre-
 19 ventative interventions) for conditions known to
 20 increase an individual’s risk of developing a
 21 major liver disease, such as liver cancer, hepa-
 22 titis B, hepatitis C, nonalcoholic fatty liver dis-
 23 ease, nonalcoholic steatohepatitis, and cirrhosis
 24 of the liver;

1 “(B) activities relating to detection and
2 provision of guidance for individuals at high
3 risk for contracting liver cancer and other liver
4 diseases; and

5 “(C) viral hepatitis surveillance to provide
6 for timely and accurate information regarding
7 progress to eliminate viral hepatitis.

8 “(2) REPORT.—An entity that receives a grant
9 or cooperative agreement under paragraph (1) shall
10 submit to the Secretary, at a time specified by the
11 Secretary, a report describing each activity carried
12 out pursuant to such paragraph and evaluating the
13 effectiveness of such activity in promoting prevention
14 and treatment of liver cancer and other liver dis-
15 eases.

16 “(3) AUTHORIZATION OF APPROPRIATIONS.—
17 For purposes of carrying out this subsection, there
18 is authorized to be appropriated \$90,000,000 for
19 each of fiscal years 2023 through 2027.

20 “(b) AWARENESS INITIATIVE GRANT PROGRAM.—

21 “(1) IN GENERAL.—The Secretary, acting
22 through the Director of the Centers for Disease
23 Control and Prevention, may award grants to eligi-
24 ble entities for the purpose of raising awareness for
25 liver cancer and other liver diseases, which may in-

1 include the production, dissemination, and distribution
2 of informational materials targeted towards commu-
3 nities and populations with a higher risk for devel-
4 oping liver cancer and other liver diseases.

5 “(2) ELIGIBLE ENTITIES.—To be eligible to re-
6 ceive a grant under paragraph (1), an entity shall
7 submit to the Secretary an application, at such time,
8 in such manner, and containing such information as
9 the Secretary may require, including a description of
10 how the entity, in disseminating information on liver
11 cancer and other liver diseases pursuant to para-
12 graph (1), will—

13 “(A) with respect to any community or
14 population, consult with members of such com-
15 munity or population and provide such informa-
16 tion in a manner that is culturally and linguis-
17 tically appropriate for such community or popu-
18 lation;

19 “(B) highlight the range of preventative
20 measures and treatments available for liver can-
21 cer and other liver diseases;

22 “(C) integrate information on available
23 hepatitis B and hepatitis C testing programs
24 into any liver cancer presentations carried out
25 by the entity; and

1 “(D) address communities and populations
2 with a higher risk for contracting liver cancer
3 and other liver diseases.

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

7 “(A) work with a federally-qualified health
8 center;

9 “(B) are community-based organizations;
10 or

11 “(C) serve communities and populations
12 with a higher risk for contracting liver cancer
13 and other liver diseases.

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

21 “(5) AUTHORIZATION OF APPROPRIATIONS.—
22 For purposes of carrying out this subsection, there
23 is authorized to be appropriated \$10,000,000 for
24 each of fiscal years 2022 through 2027.”.

1 **SEC. 5. HEPATITIS B RESEARCH.**

2 The Director of the National Institutes of Health
3 shall, in collaboration with the Director of the National
4 Institute of Allergy and Infectious Diseases, issue targeted
5 calls for hepatitis B research proposals focused on key re-
6 search questions identified by the research community and
7 discussed in peer-reviewed research journal articles.

8 **SEC. 6. CHANGES RELATING TO NATIONAL INSTITUTE OF**
9 **DIABETES AND DIGESTIVE AND KIDNEY DIS-**
10 **EASES.**

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

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

20 (2) TREATMENT OF DIRECTOR OF NATIONAL
21 INSTITUTE OF DIABETES AND DIGESTIVE AND KID-
22 NEY DISEASES.—The individual serving as the Di-
23 rector of the National Institute of Diabetes and Di-
24 gestive and Kidney Diseases as of the date of enact-
25 ment of this Act may continue to serve as the Direc-
26 tor of the National Institute of Diabetes and Diges-

1 tive, Kidney, and Liver Diseases commencing as of
2 that date.

3 (3) REFERENCES.—Any reference to the Na-
4 tional Institute of Diabetes and Digestive and Kid-
5 ney Diseases, or the Director of the National Insti-
6 tute of Diabetes and Digestive and Kidney Diseases,
7 in any law, regulation, document, record, or other
8 paper of the United States shall be deemed to be a
9 reference to the National Institute of Diabetes and
10 Digestive, Kidney, and Liver Diseases, or the Direc-
11 tor of the National Institute of Diabetes and Diges-
12 tive, Kidney, and Liver Diseases, respectively.

13 (4) CONFORMING AMENDMENTS.—

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

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

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

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

8 (2) by striking “and kidney, urologic, and hem-
9 atologic diseases” and inserting “kidney, urologic,
10 and hematologic diseases, and liver diseases”.

11 (c) DATA SYSTEMS AND INFORMATION CLEARING-
12 HOUSES.—Section 427 of the Public Health Service Act
13 (42 U.S.C. 285c–1) is amended by adding at the end the
14 following new subsection:

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

1 (d) REESTABLISHMENT OF LIVER DISEASE RE-
 2 SEARCH BRANCH WITHIN DIVISION OF DIGESTIVE DIS-
 3 EASES AND NUTRITION AS DIVISION OF LIVER DIS-
 4 EASES.—

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

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

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

**CRINOLOGY, 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

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

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

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

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

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

4 (1) in paragraph (1), by striking “and kidney,
5 urologic, and hematologic diseases” and inserting
6 “kidney, urologic, and hematologic diseases, and
7 liver diseases”; and

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

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

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

21 (2) in subsection (b)(2)(A)(i)—

22 (A) by striking “the Director of the Na-
23 tional Institute of Diabetes and Digestive and
24 Kidney Diseases” and inserting “the Director

1 of the National Institute of Diabetes and Diges-
 2 tive, Kidney, and Liver Diseases”; and

3 (B) by striking “and the Division Director
 4 of the National Institute of Diabetes and Diges-
 5 tive and Kidney Diseases” and inserting “and
 6 the Division Director of the National Institute
 7 of Diabetes and Digestive, Kidney, and Liver
 8 Diseases”.

9 (g) RESEARCH AND TRAINING CENTERS.—Section
 10 431 of the Public Health Service Act (42 U.S.C. 285c–
 11 5) is amended—

12 (1) by redesignating subsection (e) as sub-
 13 section (f); and

14 (2) by inserting after subsection (d) the fol-
 15 lowing new subsection:

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

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

24 “(2) shall develop and conduct basic and clin-
 25 ical research into the cause, diagnosis, early detec-

1 tion, prevention, control, and treatment of liver dis-
 2 eases and related functional, congenital, metabolic,
 3 or other complications resulting from such diseases;

4 “(3) shall encourage research into and pro-
 5 grams for—

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

11 “(B) model programs for cost effective and
 12 preventive patient care; and

13 “(C) training physicians and scientists in
 14 research on such diseases and complications;
 15 and

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

21 (h) ADVISORY COUNCIL SUBCOMMITTEES.—Section
 22 432 of the Public Health Service Act (42 U.S.C. 285c–
 23 6) is amended—

24 (1) by striking “and a subcommittee on kidney,
 25 urologic, and hematologic diseases” and inserting “a

1 subcommittee on kidney, urologic, and hematologic
2 diseases, and a subcommittee on liver diseases”; and
3 (2) by striking “and kidney, urologic, and hem-
4 atologic diseases” and inserting “kidney, urologic,
5 and hematologic diseases, and liver diseases”.

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