

116TH CONGRESS  
1ST SESSION

# H. R. 3016

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

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## IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2019

Ms. VELÁZQUEZ (for herself, Mr. ESPAILLAT, Ms. LEE of California, Mr. FITZPATRICK, Ms. GABBARD, Mr. VELA, and Ms. NORTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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:

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

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

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

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

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

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

23          (7) The most common causes of liver cancer in-  
24          clude Hepatitis B virus and Hepatitis C virus infec-  
25          tion.

1           (8) Hepatitis B is a primary risk factor for de-  
2       veloping liver cancer, and 1 in 4 of those chronically  
3       infected with hepatitis B develop cirrhosis, liver fail-  
4       ure, or liver cancer.

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

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

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

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

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

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

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

2 “(a) EXPANSION AND COORDINATION OF ACTIVI-  
3 TIES.—The Director of the Institute shall expand, inten-  
4 sify, and coordinate the activities of the Institute with re-  
5 spect to research on liver cancer and other liver diseases.

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

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

10 “(A) basic research concerning the etiology  
11 and causes of liver cancer;

12 “(B) clinical research and related activities  
13 concerning the causes, prevention, detection,  
14 and treatment of liver cancer;

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

21 “(D) information and education programs  
22 with respect to liver cancer, in accordance with  
23 section 413;

24 “(2) issue targeted calls for proposals from re-  
25 search scientists for purposes of funding priority  
26 areas of liver cancer research;

1 “(3) establish a special emphasis panel (as de-  
2 fined by the National Institutes of Health) to review  
3 any proposal submitted pursuant to paragraph (2);  
4 and

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

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

13 “(d) GRANTS AND COOPERATIVE AGREEMENTS.—

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

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

23 “(B) opportunities for preventative and di-  
24 agnostic measures for such a disease, including

1 the study of molecular pathology and biomark-  
2 ers for early detection of such disease.

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

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

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

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

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

24 “(a) PREVENTION INITIATIVE GRANT PROGRAM.—

1           “(1) IN GENERAL.—The Secretary, through the  
2           Director of the Centers for Disease Control and Pre-  
3           vention, may award grants and enter into coopera-  
4           tive agreements with entities for the purpose of ex-  
5           panding and supporting—

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

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

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

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

1 effectiveness of such activity in promoting prevention  
2 and treatment of liver cancer and other liver dis-  
3 eases.

4 “(3) AUTHORIZATION OF APPROPRIATIONS.—

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

12 “(b) AWARENESS INITIATIVE GRANT PROGRAM.—

13 “(1) IN GENERAL.—The Secretary, through the  
14 Director of the Centers for Disease Control and Pre-  
15 vention, may award grants to eligible entities for the  
16 purpose of raising awareness for liver cancer and  
17 other liver diseases, which may include the produc-  
18 tion, dissemination, and distribution of informational  
19 materials targeted towards communities and popu-  
20 lations with a higher risk for developing liver cancer  
21 and other liver diseases.

22 “(2) ELIGIBLE ENTITIES.—To be eligible to re-

23 ceive a grant under paragraph (1), an entity shall  
24 submit to the Secretary an application, at such time,  
25 in such manner, and containing such information as



1 the Secretary may require, including a description of  
2 how the entity, in disseminating information on liver  
3 cancer and other liver diseases pursuant to para-  
4 graph (1), will—

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

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

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

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

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

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

1 “(B) are community-based organizations.

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

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

17 **SEC. 5. HEPATITIS B RESEARCH.**

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

21 **“SEC. 434B. HEPATITIS B.**

22 “The Director of the Institute shall, in collaboration  
23 with the Director of the National Institute of Allergy and  
24 Infectious Diseases, issue targeted calls for hepatitis B re-  
25 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”.

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