### 117TH CONGRESS 1ST SESSION

# H. R. 5675

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

### IN THE HOUSE OF REPRESENTATIVES

OCTOBER 21, 2021

Ms. Velázquez (for herself, Mr. Fitzpatrick, Mr. Espaillat, and Ms. Norton) introduced the following bill; which was referred to the Committee on Energy and Commerce

# 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:

- 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.
  - (2) The Division of Cancer Control and Population Sciences of the National Cancer Institute estimated that there will be 42,230 new liver cancer diagnoses in the year 2021, 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.

- 1 (7) The most common causes of liver cancer in-2 clude hepatitis B virus and hepatitis C virus infec-3 tion.
  - (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.
- 20 (12) Hispanics/Latinos are 60 percent more likely to die from viral hepatitis than non-Hispanic 22 Whites.

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## 1 SEC. 3. LIVER CANCER AND DISEASE RESEARCH.

2	Subpart 1 of part C of title IV of the Public Health
3	Service Act (42 U.S.C. 285 et seq.) is amended by adding
4	at the end the following new section:
5	"SEC. 417H. LIVER CANCER AND DISEASE RESEARCH.
6	"(a) Expansion and Coordination of Activi-
7	TIES.—The Director of the Institute shall expand, inten-
8	sify, and coordinate the activities of the Institute with re-
9	spect to research on liver cancer and other liver diseases.
10	"(b) Programs for Liver Cancer.—In carrying
11	out subsection (a), the Director of the Institute shall—
12	"(1) provide for an expansion and intensifica-
13	tion of the conduct and support of—
14	"(A) basic research concerning the etiology
15	and causes of liver cancer;
16	"(B) clinical research and related activities
17	concerning the causes, prevention, detection,
18	and treatment of liver cancer;
19	"(C) control programs with respect to liver
20	cancer, in accordance with section 412, includ-
21	ing community-based programs designed to as-
22	sist members of medically underserved popu-
23	lations (including women), low-income popu-
24	lations, or minority groups; and

1	"(D) information and education programs
2	with respect to liver cancer, in accordance with
3	section 413;
4	"(2) issue targeted calls for proposals from re-
5	search scientists for purposes of funding priority
6	areas of liver cancer research;
7	"(3) establish a special emphasis panel (as de-
8	fined by the National Institutes of Health) to review
9	any proposal submitted pursuant to paragraph (2);
10	and
11	"(4) based on reviews by the special emphasis
12	panel under paragraph (3), select which proposals to
13	fund or support.
14	"(c) Inter-Institute Working Group.—The Di-
15	rector of the Institute shall establish an inter-institute
16	working group to coordinate research agendas focused on
17	finding better outcomes and cures for liver cancer and
18	other liver diseases, including hepatitis B and nonalcoholic
19	steatohepatitis.
20	"(d) Grants and Cooperative Agreements.—
21	"(1) In General.—The Secretary may award
22	grants and enter into cooperative agreements with
23	entities for the purpose of expanding and supporting
24	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 PRE-VENTION.—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 2022 through 2026. Any amounts appropriated under this paragraph shall remain available until expended.".

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1	SEC. 4. LIVER CANCER AND DISEASE PREVENTION, AWARE-
2	NESS, AND PATIENT TRACKING GRANTS.
3	Subpart I of part D of title III of the Public Health
4	Service Act (42 U.S.C. 254b et seq.) is amended by adding
5	at the end the following new section:
6	"SEC. 3300. LIVER CANCER AND DISEASE PREVENTION,
7	AWARENESS, AND PATIENT TRACKING
8	GRANTS.
9	"(a) Prevention Initiative Grant Program.—
10	"(1) In General.—The Secretary, acting
11	through the Director of the Centers for Disease
12	Control and Prevention, may award grants and
13	enter into cooperative agreements with entities for
14	the purpose of expanding and supporting—
15	"(A) prevention activities (including pro-
16	viding screenings, vaccinations, or other pre-
17	ventative treatment) for conditions known to in-
18	crease an individual's risk of developing a major
19	liver disease, such as liver cancer, hepatitis B,
20	hepatitis C, nonalcoholic fatty liver disease,
21	nonalcoholic steatohepatitis, and cirrhosis of the
22	liver;
23	"(B) activities relating to surveillance,
24	diagnostics, and provision of guidance for indi-
25	viduals at high risk for contracting liver cancer
26	and other liver diseases; and

1 "(C) a robust hepatitis surveillance infra-2 structure to provide for timely and accurate in-3 formation regarding progress to eliminate viral 4 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 2022 through 2026. 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

1	into any liver cancer presentations carried out
2	by the entity; and
3	"(D) target communities and populations
4	with a higher risk for contracting liver cancer
5	and other liver diseases.
6	"(3) Preference.—In awarding grants under
7	paragraph (1), the Secretary shall give preference to
8	entities that—
9	"(A) are, or work with, a Federally-quali-
10	fied health center; or
11	"(B) are community-based organizations.
12	"(4) Report.—An entity that receives a grant
13	under paragraph (1) shall submit to the Secretary,
14	at a time specified by the Secretary, a report de-
15	scribing each activity carried out pursuant to such
16	paragraph and evaluating the effectiveness of such
17	activity in raising awareness for liver cancer and
18	other liver diseases.
19	"(5) Authorization of appropriations.—
20	For purposes of carrying out this subsection, there
21	is authorized to be appropriated \$10,000,000 for
22	each of fiscal years 2022 through 2026. Any
23	amounts appropriated under this paragraph shall re-
24	main available until expended and shall be used to

1 supplement and not supplant other Federal funds 2 provided for activities under this subsection.". 3 SEC. 5. HEPATITIS B RESEARCH. 4 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: 6 7 "SEC. 434B. HEPATITIS B. "The Director of the Institute shall, in collaboration 8 with the Director of the National Institute of Allergy and 10 Infectious Diseases, issue targeted calls for hepatitis B research proposals focused on key research questions identi-11 12 fied by the research community and discussed in peer-reviewed research journal articles.". 14 SEC. 6. CHANGES RELATING TO NATIONAL INSTITUTE OF 15 DIABETES AND DIGESTIVE AND KIDNEY DIS-16 EASES. 17 (a) Change of Name of National Institute of DIABETES AND DIGESTIVE AND KIDNEY DISEASES.— 18 19 (1) IN GENERAL.—Subpart 3 of part C of title 20 IV of the Public Health Service Act (42 U.S.C. 285c 21 et seq.) is amended in the subpart heading by strik-22 ing "National Institute of Diabetes and Digestive and Kidney Diseases" and inserting 23 24 "National Institute of Diabetes and Digestive, Kidney, and Liver Diseases". 25

- 1 (2) Treatment of director of national 2 INSTITUTE OF DIABETES AND DIGESTIVE AND KID-3 NEY DISEASES.—The individual serving as the Director of the National Institute of Diabetes and Di-5 gestive and Kidney Diseases as of the date of enact-6 ment of this Act may continue to serve as the Direc-7 tor of the National Institute of Diabetes and Diges-8 tive, Kidney, and Liver Diseases commencing as of 9 that date.
  - (3) References.—Any reference to the National Institute of Diabetes and Digestive and Kidney 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 in-

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- serting "The National Institute of Diabetes and Digestive, Kidney, and Liver Diseases.".
- 3 (B) Section 409A(a) of the Public Health
  4 Service Act (42 U.S.C. 284e(a)) is amended by
  5 striking "the National Institute of Diabetes and
  6 Digestive and Kidney Diseases" and inserting
  7 "the National Institute of Diabetes and Diges-
- 9 (b) Purpose of the Institute.—Section 426 of 10 the Public Health Service Act (42 U.S.C. 285c) is amend-11 ed—

tive, Kidney, and Liver Diseases".

- 12 (1) by striking "National Institute of Diabetes 13 and Digestive and Kidney Diseases" and inserting 14 "National Institute of Diabetes and Digestive, Kid-15 ney, and Liver Diseases"; and
- 16 (2) by striking "and kidney, urologic, and hem-17 atologic diseases" and inserting "kidney, urologic, 18 and hematologic diseases, and liver diseases".
- 19 (c) Data Systems and Information Clearing-20 Houses.—Section 427 of the Public Health Service Act
- 21 (42 U.S.C. 285c-1) is amended by adding at the end the
- 22 following new subsection:

- 23 "(d) The Director of the Institute shall (1) establish
- 24 the National Liver Diseases Data System for the collec-
- 25 tion, storage, analysis, retrieval, and dissemination of data

- 1 derived from patient populations with liver diseases, in-
- 2 cluding, where possible, data involving general populations
- 3 for the purpose of detection of individuals with a risk of
- 4 developing liver diseases, and (2) establish the National
- 5 Liver Diseases Information Clearinghouse to facilitate and
- 6 enhance knowledge and understanding of liver diseases on
- 7 the part of health professionals, patients, and the public
- 8 through the effective dissemination of information.".
- 9 (d) Reestablishment of Liver Disease Re-
- 10 SEARCH BRANCH WITHIN DIVISION OF DIGESTIVE DIS-
- 11 EASES AND NUTRITION AS DIVISION OF LIVER DIS-
- 12 EASES.—
- 13 (1) IN GENERAL.—The Liver Disease Research
- 14 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
- 18 Branch") is hereby redesignated and promoted as
- the Division of Liver Diseases, which shall be within
- 20 the National Institute of Diabetes and Digestive,
- 21 Kidney, and Liver Diseases, as redesignated by sub-
- section (a), as a separate division from the other di-
- visions within such Institute.

1	(2) DIVISION DIRECTOR.—Section 428 of the
2	Public Health Service Act (42 U.S.C. 285c–2) is
3	amended—
4	(A) in the section heading, by striking
5	"DIVISION DIRECTORS FOR DIABETES, EN-
6	DOCRINOLOGY, AND METABOLIC DIS-
7	EASES, DIGESTIVE DISEASES AND NUTRI-
8	TION, AND KIDNEY, UROLOGIC, AND HEM-
9	ATOLOGIC DISEASES" and inserting "DIVI-
10	SION DIRECTORS FOR DIABETES, ENDO-
11	CRINOLOGY, AND METABOLIC DISEASES,
12	DIGESTIVE DISEASES AND NUTRITION,
13	KIDNEY, UROLOGIC, AND HEMATOLOGIC
14	DISEASES, AND LIVER DISEASES";
15	(B) in subsection (a)(1)—
16	(i) in the matter preceding subpara-
17	graph (A), by striking "and a Division Di-
18	rector for Kidney, Urologic, and Hemato-
19	logic Diseases" and inserting "a Division
20	Director for Kidney, Urologic, and Hem-
21	atologic Diseases, and a Division Director
22	for Liver Diseases"; and
23	(ii) in subparagraph (A), by striking
24	"and kidney, urologic, and hematologic dis-

1	hematologic diseases, and liver diseases";
2	and
3	(C) in subsection (b)—
4	(i) in the matter preceding paragraph
5	(1), by striking "and the Division Director
6	for Kidney, Urologic, and Hematologic
7	Diseases" and inserting "the Division Di-
8	rector for Kidney, Urologic, and Hemato-
9	logic Diseases, and the Division Director
10	for Liver Diseases"; and
11	(ii) in paragraph (1), by striking "and
12	kidney, urologic, and hematologic diseases"
13	and inserting "kidney, urologic, and hem-
14	atologic diseases, and liver diseases".
15	(3) Treatment of director of liver dis-
16	EASE RESEARCH BRANCH.—The individual serving
17	as the Director of the Liver Disease Research
18	Branch as of the date of enactment of this Act may
19	continue to serve as the Division Director for Liver
20	Diseases commencing as of that date.
21	(4) Transfer of Authorities.—The Sec-
22	retary of Health and Human Services shall delegate
23	to the Division Director for Liver Diseases all duties
24	and authorities that were vested in the Director of

- the Liver Disease Research Branch as of the day be-
- 2 fore the date of enactment of this Act.
- 3 (5) References.—Any reference to the Liver
- 4 Disease Research Branch, or the Director of the
- 5 Liver Disease Research Branch, in any law, regula-
- 6 tion, document, record, or other paper of the United
- 7 States shall be deemed to be a reference to the Divi-
- 8 sion of Liver Diseases, or the Division Director for
- 9 Liver Diseases, respectively.
- 10 (e) Interagency Coordinating Committees.—
- 11 Section 429(a) of the Public Health Service Act (42
- 12 U.S.C. 285c-3(a)) is amended—
- (1) in paragraph (1), by striking "and kidney,
- 14 urologic, and hematologic diseases" and inserting
- 15 "kidney, urologic, and hematologic diseases, and
- liver diseases"; and
- 17 (2) in the matter following paragraph (2), by
- striking "and a Kidney, Urologic, and Hematologic
- 19 Diseases Coordinating Committee" and inserting "a
- 20 Kidney, Urologic, and Hematologic Diseases Coordi-
- 21 nating Committee, and a Liver Diseases Coordi-
- 22 nating Committee".
- 23 (f) Advisory Boards.—Section 430 of the Public
- 24 Health Service Act (42 U.S.C. 285c-4) is amended—

1	(1) in subsection (a), by striking "and the Na-
2	tional Kidney and Urologic Diseases Advisory
3	Board" and inserting "the National Kidney and
4	Urologic Diseases Advisory Board, and the Liver
5	Diseases Advisory Board"; and
6	(2) in subsection (b)(2)(A)(i)—
7	(A) by striking "the Director of the Na-
8	tional Institute of Diabetes and Digestive and
9	Kidney Diseases" and inserting "the Director
10	of the National Institute of Diabetes and Diges-
11	tive, Kidney, and Liver Diseases"; and
12	(B) by striking "and the Division Director
13	of the National Institute of Diabetes and Diges-
14	tive and Kidney Diseases" and inserting "and
15	the Division Director of the National Institute
16	of Diabetes and Digestive, Kidney, and Liver
17	Diseases".
18	(g) Research and Training Centers.—Section
19	431 of the Public Health Service Act (42 U.S.C. 285c-
20	5) is amended—
21	(1) by redesignating subsection (e) as sub-
22	section (f); and
23	(2) by inserting after subsection (d) the fol-
24	lowing new subsection:

1	"(e) The Director of the Institute shall provide for
2	the development or substantial expansion of centers for
3	research in liver diseases. Each center developed or ex-
4	panded under this subsection—
5	"(1) shall utilize the facilities of a single insti-
6	tution, or be formed from a consortium of cooper-
7	ating institutions, meeting such research qualifica-
8	tions as may be prescribed by the Secretary;
9	"(2) shall develop and conduct basic and clin-
10	ical research into the cause, diagnosis, early detec-
11	tion, prevention, control, and treatment of liver dis-
12	eases and related functional, congenital, metabolic,
13	or other complications resulting from such diseases;
14	"(3) shall encourage research into and pro-
15	grams for—
16	"(A) providing information for patients
17	with such diseases and complications and the
18	families of such patients, physicians and others
19	who care for such patients, and the general
20	publie;
21	"(B) model programs for cost effective and
22	preventive patient care; and
23	"(C) training physicians and scientists in
24	research on such diseases and complications;
25	and

1	"(4) may perform research and participate in
2	epidemiological studies and data collection relevant
3	to liver diseases in order to disseminate such re-
4	search, studies, and data to the health care profes-
5	sion and to the public.".
6	(h) Advisory Council Subcommittees.—Section
7	432 of the Public Health Service Act (42 U.S.C. 285c-
8	6) is amended—
9	(1) by striking "and a subcommittee on kidney,
10	urologic, and hematologic diseases" and inserting "a
11	subcommittee on kidney, urologic, and hematologic
12	diseases, and a subcommittee on liver diseases"; and
13	(2) by striking "and kidney, urologic, and hem-
14	atologic diseases" and inserting "kidney, urologic,
15	and hematologic diseases, and liver diseases".

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