## 111TH CONGRESS 1ST SESSION

## H. R. 1128

To establish the National Center on Liver Disease Research, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

February 23, 2009

Mr. Lynch (for himself and Mr. King of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce

## A BILL

To establish the National Center on Liver Disease 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 Research En-
- 5 hancement Act of 2009".
- 6 SEC. 2. FINDINGS.
- 7 The Congress finds as follows:
- 8 (1) An estimated 30,000,000 people in the
- 9 United States are affected by a liver or liver-related
- disease.

- 1 (2) In excess of \$15,000,000,000 is spent annually to provide medical care for people in the United States with hepatitis C. This cost is projected to grow substantially over the next decade without a vaccine, cure, or the discovery of better treatments.
  - (3) There are over 5,000,000 people in the United States who are or have been infected with hepatitis C, 3,200,000 of whom are chronically infected.
  - (4) Due to limited research, current treatments for hepatitis B and C are effective in approximately 50 percent of the cases.
  - (5) A vaccine has not been developed for hepatitis C.
    - (6) There are 10,000 to 12,000 deaths each year due to hepatitis C, and the annual death total is projected to triple absent increased public health and research interventions.
    - (7) Hepatitis C is the leading cause of death among people co-infected with HIV.
    - (8) Chronic hepatitis B and C affect over 6 million Americans with nearly half of those individuals unaware of their infection.
  - (9) Chronic infection with hepatitis B or C is associated with an increased incidence of primary

- liver cancer in the United States, the fastest growing cancer in incidence, despite a decline in most other types of cancers.
  - (10) There are 1,400,000 people in the United States who have been infected with hepatitis B, and 1 out of 4 individuals with chronic hepatitis B will die prematurely from end-stage liver disease or liver cancer.
    - (11) One out of 10 Asian and Pacific-Islander Americans are chronically infected with hepatitis B, and the Centers for Disease Control and Prevention has reported a reduction in long-term protection from the current hepatitis B vaccines.
    - (12) It is estimated that as many as 20 percent of Americans have fatty liver disease which can lead to cirrhosis and liver failure.
    - (13) There are 15,000 children hospitalized in the United States each year due to liver disease.
    - (14) The only option for many individuals with advanced or chronic liver disease is a liver transplant.
    - (15) Approximately 17,000 people in the United States are on the waiting list for a liver transplant, but because of the limited supply of livers available

- for transplantation, only approximately 6,000 liver
- 2 transplants are performed each year.
- 3 (16) There are 1,300 people in the United
- 4 States who die each year waiting for a liver trans-
- 5 plant.
- 6 (17) To address the public health threat posed
- 7 by liver disease, there is a need for the establishment
- 8 of a National Center on Liver Disease Research to
- 9 provide dedicated scientific leadership, to create a
- 10 research action plan, to ensure the funding of the
- scientific opportunities identified by the plan, and
- the coordination of efforts across the institutes and
- centers of the National Institutes of Health.
- 14 SEC. 3. NATIONAL CENTER ON LIVER DISEASE RESEARCH.
- Subpart 3 of part C of title IV of the Public Health
- 16 Service Act (42 U.S.C. 285c, et seq.) is amended by add-
- 17 ing at the end the following:
- 18 "NATIONAL CENTER ON LIVER DISEASE RESEARCH
- 19 "Sec. 434B. (a) Establishment.—There is estab-
- 20 lished the National Center on Liver Disease Research
- 21 (hereafter in this section referred to as the 'Center') in
- 22 the National Institute of Diabetes and Digestive and Kid-
- 23 ney Diseases.
- 24 "(b) DIRECTOR.—The Center shall be headed by a
- 25 Director, who shall be appointed by the Director of the
- 26 Institute, in consultation with the Director of NIH, from

- 1 among individuals with the highest scientific credentials.
- 2 The Director of the Center shall report directly to the Di-
- 3 rector of the Institute.
- 4 "(c) Duties.—To ensure the development of in-
- 5 creased understanding of and better treatments and cures
- 6 for liver disease through a dedicated scientific leadership
- 7 and an adequate allocation of resources, the Director
- 8 shall—
- 9 "(1) assist the Liver Disease Research Advisory
- 10 Board to develop the Liver Disease Research Action
- 11 Plan; and
- 12 "(2) encourage and coordinate the implementa-
- tion of the Plan by the national research institutes,
- including by issuing research solicitations and by
- using all other available mechanisms.
- 16 "(d) Liver Disease Research Advisory
- 17 Board.—
- 18 "(1) Establishment.—Not later than 90 days
- 19 after the date of the enactment of the Liver Re-
- search Enhancement Act of 2009, the Director of
- NIH shall establish a board to be known as the
- Liver Disease Research Advisory Board (hereafter in
- this section referred to as the 'Advisory Board').
- 24 "(2) Duties.—The Advisory Board shall advise
- and assist the Director of the Center concerning

- 1 matters relating to liver disease research, including 2 by developing and revising the Liver Disease Re-3 search Action Plan in accordance with subsection
- (e).

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- "(3) Voting members.—The Advisory Board 6 shall be composed of 18 voting members appointed 7 by the Director of NIH, in consultation with the Di-8 rector of the Institute, of whom 12 shall be eminent 9 scientists and 6 shall be lay persons. The Director 10 of NIH, in consultation with the Director of the Institute, shall select 1 of the members to serve as the 12 Chair of the Advisory Board.
  - "(4) Ex officio members.—The Director of NIH shall appoint each director of a national research institute that funds liver disease research to serve as a nonvoting, ex officio member of the Advisory Board. The Director of NIH shall invite 1 representative of the Food and Drug Administration, and 1 representative of the Department of Veterans Affairs, to serve as a nonvoting, ex officio member of the Advisory Board. Each ex officio member of the Advisory Board may appoint an individual to serve as that member's representative on the Advisory Board.
- "(e) LIVER DISEASE RESEARCH ACTION PLAN.— 25

- "(1) DEVELOPMENT.—Not later 1 than 15 2 months after the date of the enactment of the Liver Research Enhancement Act of 2009, the Advisory 3 4 Board shall develop (with appropriate support from 5 the Director and staff of the Center) a comprehen-6 sive plan for the conduct and support of liver disease 7 research to be known as the Liver Disease Research 8 Action Plan. The Advisory Board shall submit the 9 Plan to the Director of NIH and the head of each 10 institute or center within the National Institutes of 11 Health that funds liver disease research.
  - "(2) CONTENT.—The Liver Disease Research Action Plan shall identify scientific opportunities and priorities of liver disease research necessary to increase understanding of and to prevent, cure, and develop better treatment protocols for liver diseases.
  - "(3) REVISION.—The Advisory Board shall revise the Liver Disease Research Action Plan every 3 years, but shall meet annually to review progress and to amend the Plan as may be appropriate because of new scientific discoveries.
- "(f) Allocation of Funds.—Subject to the availability of appropriations, the Director of each institute or center within the National Institutes of Health shall allocate to liver disease research through peer-reviewed meth-

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- 1 ods, the amounts necessary to fund existing scientific re-
- 2 search opportunities and, subject to completion and subse-
- 3 quent updates of the Liver Disease Research Action Plan,
- 4 amounts adequate to carry out the recommendations of

5 the Plan.".

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