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(Original Signature of Member)

109TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, education, research, and medical management program that will lead to a marked reduction in liver cirrhosis and a reduction in the cases of, and improved survival of, liver cancer caused by chronic hepatitis B infection.

IN THE HOUSE OF REPRESENTATIVES

Mr. DENT (for himself and Mr. HONDA) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, education, research, and medical management program that will lead to a marked reduction in liver cirrhosis and a reduction in the cases of, and improved survival of, liver cancer caused by chronic hepatitis B infection.

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



1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “National Hepatitis B
3 Act”.

4 **SEC. 2. FINDINGS.**

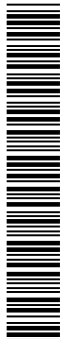
5 The Congress makes the following findings:

6 (1) Approximately 1.4 million Americans are
7 chronically infected with hepatitis B. The number of
8 chronically infected persons in the United States is
9 believed to be increasing each year with the influx of
10 new immigrants from areas where it is endemic.

11 (2) Hepatitis B is extremely infectious. In fact,
12 the disease is 100 times more infectious than HIV.
13 The hepatitis B virus (HBV) is transmitted the
14 same way as HIV: from mother to newborn at birth,
15 from infected blood or injections contaminated by in-
16 fected blood, and from unprotected sex.

17 (3) Chronic hepatitis B usually does not cause
18 any symptoms early in the course of the disease, but
19 after many years of a clinically “silent” phase, as
20 many as 25 percent of infected individuals may de-
21 velop end-stage liver disease or liver cancer.

22 (4) The major burden of hepatitis B infection
23 in the United States is from chronic hepatitis B in-
24 fection. Persons chronically infected with hepatitis B
25 are at higher risk of developing cirrhosis (scarring)
26 of the liver and liver cancer, both of which can lead



1 to premature death. About 5,000 deaths per year in
2 the United States can be attributed to chronic hepa-
3 titis B infection.

4 (5) Chronic hepatitis B infection disproportion-
5 ately affects certain occupations and populations in
6 the United States. Although representing only four
7 percent of the population, Asian Americans and Pa-
8 cific Islanders account for over half of the 1.4 mil-
9 lion chronic hepatitis B cases in the United States.

10 (6) Hepatitis B infection is preventable through
11 currently available vaccinations and by reducing
12 high-risk behavior. The hepatitis B vaccine is safe
13 and effective and has the designation of being the
14 “first anti-cancer vaccine”.

15 (7) The diagnosis of chronic hepatitis B infec-
16 tion can be made with a simple blood test that is in-
17 expensive and widely available. The early diagnosis
18 of chronic hepatitis B can reduce the risk of further
19 transmission of the virus through harm reduction
20 education and the vaccination of household members
21 and other susceptible persons at risk.

22 (8) If the diagnosis of hepatitis B infection is
23 made at an early stage of the infection, treatment of
24 chronic hepatitis B infection with antiviral therapy
25 similar to that employed in HIV, when appropriate,



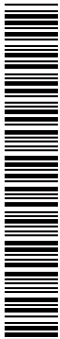
1 can reduce the risk of progression to liver cancer
2 and cirrhosis.

3 (9) For those who are chronically infected, reg-
4 ular monitoring can lead to the early detection of
5 liver cancer at a stage where cure is still possible.
6 Liver cancer is one of the deadliest types of cancer
7 and one that has received little funding for research
8 and prevention.

9 (10) Although the costs of education, research,
10 and treatment are not trivial, they are substantially
11 less than the annual health care cost attributable to
12 hepatitis B in the Unites States, which is estimated
13 to be approximately \$2.5 billion (\$2000 per infected
14 person). The lifetime cost of the hepatitis B virus in
15 2000—before the availability of most of the current
16 therapies—was approximately \$80,000 per person
17 chronically infected, or more than \$100 billion.

18 **SEC. 3. COMPREHENSIVE HEPATITIS B PREVENTION, EDU-**
19 **CATION, RESEARCH, AND MEDICAL MANAGE-**
20 **MENT PROGRAM.**

21 Title III of the Public Health Service Act (42 U.S.C.
22 241 et seq.) is amended by adding at the end of the fol-
23 lowing:



1 **“PART R—COMPREHENSIVE HEPATITIS B PRE-**
2 **VENTION, EDUCATION, RESEARCH, AND**
3 **MEDICAL MANAGEMENT PROGRAM**

4 **“SEC. 399AA. PROGRAM DEVELOPMENT.**

5 “(a) IN GENERAL.—The Secretary shall develop and
6 implement a plan for the prevention, control, and medical
7 management of hepatitis B, which includes strategies for
8 expanded vaccination programs, primary and secondary
9 preventive education and training, surveillance and early
10 detection, and research.

11 “(b) INPUT IN DEVELOPMENT OF PLAN.—In devel-
12 oping the plan under subsection (a), the Secretary shall—

13 “(1) be guided by existing recommendations of
14 the Department of Health and Human Services, the
15 Centers for Disease Control and Prevention, and the
16 National Institutes of Health; and

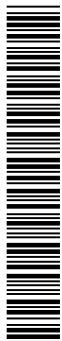
17 “(2) consult with—

18 “(A) the Director of the Centers for Dis-
19 ease Control and Prevention;

20 “(B) the Director of the National Insti-
21 tutes of Health;

22 “(C) the Director of the National Cancer
23 Institute;

24 “(D) the Administrator of the Health Re-
25 sources and Services Administration;



1 “(E) the Administrator of the Substance
2 Abuse and Mental Health Services Administra-
3 tion;

4 “(F) the heads of other Federal agencies
5 or offices providing education services to indi-
6 viduals with viral hepatitis;

7 “(G) medical advisory bodies, such as the
8 National Task Force on Hepatitis B: Focus on
9 Asian and Pacific Islander Americans, the Na-
10 tional Viral Hepatitis Roundtable, the Asian
11 Liver Center at Stanford University, the Hepa-
12 titis B Foundation, the American Liver Foun-
13 dation, Hepatitis Foundation International, and
14 the Center for the Study of Asian American
15 Health; and

16 “(H) the public, including—

17 “(i) individuals infected with hepatitis
18 B; and

19 “(ii) advocates concerned with issues
20 related to hepatitis B.

21 “(c) BIENNIAL UPDATE OF THE PLAN.—

22 “(1) IN GENERAL.—The Secretary shall con-
23 duct a biannual assessment of the plan developed
24 under subsection (a) for the purposes of—



1 “(A) incorporating into such plan new
2 knowledge or observations relating to hepatitis
3 B (such as knowledge and observations that
4 may be derived from clinical, laboratory, and
5 epidemiological research and disease detection,
6 prevention, and surveillance outcomes); and

7 “(B) addressing gaps in the coverage or ef-
8 fectiveness of the plan.

9 “(2) PUBLICATION OF NOTICE OF ASSESS-
10 MENTS.—Not later than October 1 of the first even
11 numbered year beginning after the date of enact-
12 ment of this part, and October 1 of each even num-
13 bered year thereafter, the Secretary shall publish in
14 the Federal Register a notice of the results of the
15 assessments conducted under paragraph (1). Such
16 notice shall include—

17 “(A) a description of any revisions to the
18 plan developed under subsection (a) as a result
19 of the assessment;

20 “(B) an explanation of the basis for any
21 such revisions, including the ways in which such
22 revisions can reasonably be expected to further
23 promote the original goals and objectives of the
24 plan; and



1 “(C) in the case of a determination by the
2 Secretary that the plan does not need revision,
3 an explanation of the basis for such determina-
4 tion.

5 **“SEC. 399BB. ELEMENTS OF PROGRAM.**

6 “(a) IMMUNIZATION, PREVENTION, AND CONTROL
7 PROGRAMS.—

8 “(1) IN GENERAL.—The Secretary, acting
9 through the Director of the Centers for Disease
10 Control and Prevention, shall support the integra-
11 tion of activities described in paragraph (2) into ex-
12 isting clinical and public health programs at State,
13 local, and tribal levels (including Asian and non-
14 Asian community health clinics, programs for the
15 prevention and treatment of HIV/AIDS, sexually
16 transmitted diseases, and substance abuse, and pro-
17 grams for individuals in correctional settings).

18 “(2) ACTIVITIES.—

19 “(A) VOLUNTARY TESTING PROGRAMS.—

20 “(i) IN GENERAL.—The Secretary
21 shall establish a mechanism by which to
22 support and promote the development of
23 State, local, and tribal voluntary hepatitis
24 B testing programs to screen the high
25 chronic hepatitis B prevalence populations



1 (such as Asian Americans, new immigrants
2 or foreign-born United States residents,
3 and persons with one or both foreign-born
4 parents) to aid in the early identification
5 of chronically infected individuals.

6 “(ii) CONFIDENTIALITY OF THE TEST
7 RESULTS.—The Secretary shall prohibit
8 the use of the results of a hepatitis B test
9 conducted by a testing program developed
10 or supported under this subparagraph for
11 any of the following:

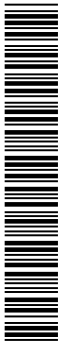
12 “(I) Issues relating to health in-
13 surance.

14 “(II) To screen or determine
15 suitability for employment.

16 “(III) To discharge a person
17 from employment.

18 “(B) COUNSELING.—The Secretary shall
19 support State, local, and tribal programs in a
20 wide variety of settings, including those pro-
21 viding primary and specialty health care serv-
22 ices in the private and public sectors, to—

23 “(i) provide individuals with ongoing
24 risk factors for hepatitis B infection with



1 client-centered education and counseling
2 which concentrates on—

3 “(I) promoting testing of family
4 members and their sexual partners;
5 and

6 “(II) changing behaviors that
7 place individuals at risk for infection;

8 “(ii) provide individuals chronically in-
9 fected with hepatitis B with education,
10 health information, and counseling to re-
11 duce their risk of—

12 “(I) dying from end stage liver
13 disease and liver cancer; and

14 “(II) transmitting viral hepatitis
15 to others; and

16 “(iii) provide women chronically in-
17 fected with hepatitis B who are pregnant
18 or in their child bearing age with culturally
19 appropriate health information to alleviate
20 their fears of becoming pregnant or raising
21 a family.

22 “(C) IMMUNIZATION.—The Secretary shall
23 support State, local, and tribal efforts to ex-
24 pand the current vaccination programs to pro-
25 tect every child in the country and all suscep-



1 tible adults, particularly those from the high-
2 prevalence ethnic populations and other high
3 risk groups, from the risks of acute and chronic
4 hepatitis B infection by—

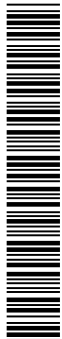
5 “(i) ensuring continued funding for
6 hepatitis B vaccination for all children 19
7 years of age or under through the Vaccines
8 for Children Program;

9 “(ii) ensuring that the recommenda-
10 tions of the Advisory Committee on Immuni-
11 zation Practices are followed regarding
12 hepatitis B vaccinations for newborns;

13 “(iii) requiring proof of hepatitis B
14 vaccination for entry into public or private
15 day care, preschool, elementary school, sec-
16 ondary school, and institutions of higher
17 education;

18 “(iv) expanding the availability of vac-
19 cines for all susceptible adults to protect
20 them from becoming acutely or chronically
21 infected, including ethnic populations with
22 high prevalence rates of chronic hepatitis
23 B infection; and

24 “(v) expanding the availability of vac-
25 cines for all susceptible adults, particularly



1 those in their reproductive age (women and
2 men less than 45 years of age), from the
3 risk of hepatitis B infection.

4 “(D) MEDICAL REFERRAL.—The Secretary
5 shall support State, local, and tribal programs
6 that support—

7 “(i) referral of persons chronically in-
8 fected with hepatitis B—

9 “(I) for medical evaluation to de-
10 termine the appropriateness for
11 antiviral treatment to reduce the risk
12 of progression to cirrhosis and liver
13 cancer; and

14 “(II) for regular monitoring of
15 liver function and screening for liver
16 cancer; and

17 “(ii) referral of persons infected with
18 acute or chronic hepatitis B for drug and
19 alcohol abuse treatment where appropriate.

20 “(3) INCREASED SUPPORT FOR HEPATITIS B
21 COORDINATORS.—The Secretary, acting through the
22 Director of the Centers for Disease Control and Pre-
23 vention, shall provide hepatitis B coordinators to
24 State, local, and tribal health departments in order
25 to enhance the additional management, networking,

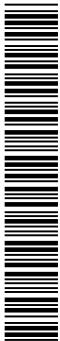


1 and technical expertise needed to ensure successful
2 integration of hepatitis B prevention and control ac-
3 tivities into existing public health programs.

4 “(b) EDUCATION AND AWARENESS PROGRAMS.—The
5 Secretary, acting through the Director of the Centers for
6 Disease Control and Prevention, the Administrator of the
7 Health Resources and Services Administration, and the
8 Administrator of the Substance Abuse and Mental Health
9 Services Administration, and in accordance with the plan
10 developed under section 399AA, shall implement programs
11 to increase awareness and enhance knowledge and under-
12 standing of hepatitis B. Such programs shall include—

13 “(1) the conduct of culturally and language ap-
14 propriate health education, public awareness cam-
15 paigns, and community outreach activities (especially
16 to the ethnic communities with high rates of chronic
17 hepatitis B and other high-risk groups) to promote
18 public awareness and knowledge about the value of
19 hepatitis B immunization, risk factors, the trans-
20 mission and prevention of hepatitis B, and the value
21 of screening for the early detection of hepatitis B in-
22 fection;

23 “(2) the promotion of immunization programs
24 that increase awareness and access to hepatitis B
25 vaccines for susceptible adults and children;



1 “(3) the training of health care professionals
2 and health educators to make them aware of the
3 high rates of chronic hepatitis B in certain adult
4 ethnic populations, and the importance of preven-
5 tion, detection, and medical management of hepatitis
6 B and of liver cancer screening;

7 “(4) the development and distribution of health
8 education curricula (including information relating
9 to the special needs of individuals infected with hep-
10 atitis B, such as the importance of prevention and
11 early intervention, regular monitoring, and appro-
12 priate treatment and liver cancer screening) for indi-
13 viduals providing hepatitis B counseling;

14 “(5) support for the implementation curricula
15 described in paragraph (4) by State and local public
16 health agencies; and

17 “(6) the provision of grants for the inclusion of
18 viral hepatitis and liver wellness education curricula
19 in elementary and secondary school health education
20 programs.

21 “(c) EPIDEMIOLOGICAL SURVEILLANCE.—

22 “(1) IN GENERAL.—The Secretary, acting
23 through the Director of the Centers for Disease
24 Control and Prevention, shall support the establish-
25 ment and maintenance of a national chronic and



1 acute hepatitis B surveillance program, in order to
2 identify—

3 “(A) trends in the incidence of acute and
4 chronic hepatitis B;

5 “(B) trends in the prevalence of acute and
6 chronic hepatitis B infection among groups that
7 may be disproportionately affected by hepatitis
8 B; and

9 “(C) liver cancer and end stage liver dis-
10 ease incidence and deaths, caused by chronic
11 hepatitis B in the various ethnic populations.

12 “(2) SEROPREVALENCE AND LIVER CANCER
13 STUDIES.—The Secretary, acting through the Direc-
14 tor of the Centers for Disease Control and Preven-
15 tion, shall prepare a report outlining the population-
16 based seroprevalence studies currently under way,
17 future planned studies, the criteria involved in deter-
18 mining which seroprevalence studies to conduct,
19 defer, or suspend, and the scope of those studies, the
20 economic and clinical impact of hepatitis B, and the
21 impact of hepatitis B on quality of life. Not later
22 than one year after the date of enactment of this
23 part, the Secretary shall submit the report to the
24 Committee on Energy and Commerce of the House



1 of Representatives and the Committee on Health,
2 Education, Labor, and Pensions of the Senate.

3 “(3) CONFIDENTIALITY.—The Secretary shall
4 not disclose any individually identifiable information
5 identified under paragraph (1) or derived through
6 studies under paragraph (2).

7 “(d) RESEARCH.—The Secretary, acting through the
8 Director of the Centers for Disease Control and Preven-
9 tion, the Director of the National Cancer Institute, and
10 the Director of the National Institutes of Health, shall—

11 “(1) conduct community-based research to de-
12 velop, implement, and evaluate best practices for
13 hepatitis B prevention especially in the ethnic popu-
14 lations with high rates of chronic hepatitis B and
15 other high-risk groups;

16 “(2) conduct research on hepatitis B natural
17 history, pathophysiology, improved treatments, and
18 non-invasive tests that helps to predict the risk of
19 progression to liver cirrhosis and liver cancer; and

20 “(3) conduct research that will lead to better
21 non-invasive or blood tests to screen for liver cancer,
22 and more effective treatments of liver cancer caused
23 by chronic hepatitis.

24 “(e) EXPANDED SUPPORT FOR UNDERSERVED AND
25 DISPROPORTIONATELY AFFECTED POPULATIONS CHRON-



1 ICALLY INFECTED WITH HBV.—In carrying out this sec-
2 tion, the Secretary shall give priority to individuals with
3 limited access to health education, testing, and health care
4 services and groups that may be disproportionately af-
5 fected by hepatitis B, including populations such as Asian
6 Americans with a high incidence of chronic hepatitis B
7 and liver cancer.”.

