

109TH CONGRESS  
1ST SESSION

# H. R. 4550

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.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 15, 2005

Mr. DENT (for himself and Mr. HONDA) 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 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 United 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



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

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

“(I) Issues relating to health insurance.

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

“(III) To discharge a person from employment.

“(B) COUNSELING.—The Secretary shall support State, local, and tribal programs in a wide variety of settings, including those providing primary and specialty health care services in the private and public sectors, to—

“(i) provide individuals with ongoing 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 Immu-  
11                  nization 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.”.

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