

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 3558

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 SENATE OF THE UNITED STATES

JUNE 22, 2006

Mr. SANTORUM (for himself and Mrs. FEINSTEIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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 Congress makes the following findings:

6 (1) Approximately 1,400,000 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 1,400,000  
9 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 \$2,500,000,000 (\$2000 per in-  
14 fected person). The lifetime cost of the hepatitis B  
15 virus in 2000—before the availability of most of the  
16 current therapies—was approximately \$80,000 per  
17 person chronically infected, or more than  
18 \$100,000,000,000.

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

22 Title III of the Public Health Service Act (42 U.S.C.  
23 241 et seq.) is amended by adding at the end of the fol-  
24 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 biennial 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) expanding the availability of vac-  
14                  cines for all susceptible adults to protect  
15                  them from becoming acutely or chronically  
16                  infected, including ethnic populations with  
17                  high prevalence rates of chronic hepatitis  
18                  B infection; and

19                  “(iv) expanding the availability of vac-  
20                  cines for all susceptible adults, particularly  
21                  those in their reproductive age (women and  
22                  men less than 45 years of age), from the  
23                  risk of hepatitis B infection.

1           “(D) MEDICAL REFERRAL.—The Secretary  
2           shall support State, local, and tribal programs  
3           that support—

4                   “(i) referral of persons chronically in-  
5                   fected with hepatitis B—

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

11                           “(II) for regular monitoring of  
12                           liver function and screening for liver  
13                           cancer; and

14                          “(ii) referral of persons infected with  
15                          acute or chronic hepatitis B for drug and  
16                          alcohol abuse treatment where appropriate.

17           “(3) INCREASED SUPPORT FOR HEPATITIS B  
18           COORDINATORS.—The Secretary, acting through the  
19           Director of the Centers for Disease Control and Pre-  
20           vention, shall provide hepatitis B coordinators to  
21           State, local, and tribal health departments in order  
22           to enhance the additional management, networking,  
23           and technical expertise needed to ensure successful  
24           integration of hepatitis B prevention and control ac-  
25           tivities into existing public health programs.

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

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

20           “(2) the promotion of immunization programs  
21 that increase awareness and access to hepatitis B  
22 vaccines for susceptible adults and children;

23           “(3) the training of health care professionals  
24 and health educators to make them aware of the  
25 high rates of chronic hepatitis B in certain adult

1 ethnic populations, and the importance of preven-  
2 tion, detection, and medical management of hepatitis  
3 B and of liver cancer screening;

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

11 “(5) support for the implementation curricula  
12 described in paragraph (4) by State and local public  
13 health agencies; and

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

18 “(c) EPIDEMIOLOGICAL SURVEILLANCE.—

19 “(1) IN GENERAL.—The Secretary, acting  
20 through the Director of the Centers for Disease  
21 Control and Prevention, shall support the establish-  
22 ment and maintenance of a national chronic and  
23 acute hepatitis B surveillance program, in order to  
24 identify—

1           “(A) trends in the incidence of acute and  
2 chronic hepatitis B;

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

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

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

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

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

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

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

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

22          “(e) EXPANDED SUPPORT FOR UNDERSERVED AND  
23          DISPROPORTIONATELY AFFECTED POPULATIONS CHRON-  
24          ICALLY INFECTED WITH HBV.—In carrying out this sec-  
25          tion, the Secretary shall give priority to individuals with

1 limited access to health education, testing, and health care  
2 services and groups that may be disproportionately af-  
3 fected by hepatitis B, including populations such as Asian  
4 Americans with a high incidence of chronic hepatitis B  
5 and liver cancer.”.

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