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110TH CONGRESS
1ST SESSION

H. R. 3944

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

OCTOBER 23, 2007

Mr. HONDA (for himself, Mr. DENT, Mr. SCHIFF, Mr. MCNULTY, Mr. TOWNS, and Mr. GERLACH) 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''National Hepatitis B Act''.

SEC. 2. FINDINGS.

The Congress makes the following findings:

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

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

(3) Chronic hepatitis B usually does not cause any symptoms early in the course of the disease, but after many years of a clinically ''silent'' phase, as many as 25 percent of infected individuals may develop end-stage liver disease or liver cancer.

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

to premature death. About 5,000 deaths per year in the United States can be attributed to chronic hepatitis B infection.

(5) Chronic hepatitis B infection disproportionately affects certain occupations and populations in the United States. Although representing only four percent of the population, Asian Americans and Pacific Islanders account for over half of the 1.4 million chronic hepatitis B cases in the United States.

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

(7) The diagnosis of chronic hepatitis B infection can be made with a simple blood test that is inexpensive and widely available. The early diagnosis of chronic hepatitis B can reduce the risk of further transmission of the virus through harm reduction education and the vaccination of household members and other susceptible persons at risk.

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

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

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

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

SEC. 3. COMPREHENSIVE HEPATITIS B PREVENTION, EDUCATION, RESEARCH, AND MEDICAL MANAGEMENT PROGRAM.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end of the following:

"PART S—COMPREHENSIVE HEPATITIS B PREVENTION, EDUCATION, RESEARCH, AND MEDICAL MANAGEMENT PROGRAM

"SEC. 399FF. PROGRAM DEVELOPMENT.

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

''(b) INPUT IN DEVELOPMENT OF PLAN.—In developing the plan under subsection (a), the Secretary shall—

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

''(2) consult with—

''(A) the Director of the Centers for Disease Control and Prevention;

''(B) the Director of the National Institutes of Health;

''(C) the Director of the National Cancer Institute;

''(D) the Administrator of the Health Resources and Services Administration;

''(E) the Administrator of the Substance Abuse and Mental Health Services Administration;

''(F) the heads of other Federal agencies or offices providing education services to individuals with viral hepatitis;

''(G) medical advisory bodies, such as the National Task Force on Hepatitis B: Focus on Asian and Pacific Islander Americans, the National Viral Hepatitis Roundtable, the Asian Liver Center at Stanford University, the Hepatitis B Foundation, the American Liver Foundation, Hepatitis Foundation International, and the Center for the Study of Asian American Health; and

''(H) the public, including—

''(i) individuals infected with hepatitis B; and

''(ii) advocates concerned with issues related to hepatitis B.

''(c) BIENNIAL UPDATE OF THE PLAN.—

''(1) IN GENERAL.—The Secretary shall conduct a biennial assessment of the plan developed under subsection (a) for the purposes of—

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

"(B) addressing gaps in the coverage or effectiveness of the plan.

"(2) PUBLICATION OF NOTICE OF ASSESSMENTS.—Not later than October 1 of the first even numbered year beginning after the date of enactment of this part, and October 1 of each even numbered year thereafter, the Secretary shall publish in the Federal Register a notice of the results of the assessments conducted under paragraph (1). Such notice shall include—

"(A) a description of any revisions to the plan developed under subsection (a) as a result of the assessment;

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

''(C) in the case of a determination by the Secretary that the plan does not need revision, an explanation of the basis for such determination.

''SEC. 399GG. ELEMENTS OF PROGRAM.

''(a) IMMUNIZATION, PREVENTION, AND CONTROL PROGRAMS.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall support the integration of activities described in paragraph (2) into existing clinical and public health programs at State, local, and tribal levels (including Asian and non-Asian community health clinics, programs for the prevention and treatment of HIV/AIDS, sexually transmitted diseases, and substance abuse, and programs for individuals in correctional settings).

''(2) ACTIVITIES.—

''(A) VOLUNTARY TESTING PROGRAMS.—

''(i) IN GENERAL.—The Secretary shall establish a mechanism by which to support and promote the development of State, local, and tribal voluntary hepatitis B testing programs to screen the high 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

client-centered education and counseling which concentrates on—

"(I) promoting testing of family members and their sexual partners; and

"(II) changing behaviors that place individuals at risk for infection;

"(ii) provide individuals chronically infected with hepatitis B with education, health information, and counseling to reduce their risk of—

"(I) dying from end stage liver disease and liver cancer; and

"(II) transmitting viral hepatitis to others; and

"(iii) provide women chronically infected with hepatitis B who are pregnant or in their childbearing age with culturally appropriate health information to alleviate fears associated with pregnancy or raising a family.

"(C) IMMUNIZATION.—The Secretary shall support State, local, and tribal efforts to expand the current vaccination programs to protect every child in the country and all suscep-

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

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

"(ii) ensuring that the recommendations of the Advisory Committee on Immunization Practices are followed regarding hepatitis B vaccinations for newborns;

"(iii) requiring proof of hepatitis B vaccination for entry into public or private day care, preschool, elementary school, secondary school, and institutions of higher education;

"(iv) expanding the availability of vaccines for all susceptible adults to protect them from becoming acutely or chronically infected, including ethnic populations with high prevalence rates of chronic hepatitis B infection; and

"(v) expanding the availability of vaccines for all susceptible adults, particularly

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

''(D) MEDICAL REFERRAL.—The Secretary shall support State, local, and tribal programs that support—

''(i) referral of persons chronically infected with hepatitis B—

''(I) for medical evaluation to determine the appropriateness for antiviral treatment to reduce the risk of progression to cirrhosis and liver cancer; and

''(II) for regular monitoring of liver function and screening for liver cancer; and

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

''(3) INCREASED SUPPORT FOR HEPATITIS B COORDINATORS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide hepatitis B coordinators to State, local, and tribal health departments in order to enhance the additional management, networking,

and technical expertise needed to ensure successful integration of hepatitis B prevention and control activities into existing public health programs.

''(b) EDUCATION AND AWARENESS PROGRAMS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources and Services Administration, and the Administrator of the Substance Abuse and Mental Health Services Administration, and in accordance with the plan developed under section 399FF, shall implement programs to increase awareness and enhance knowledge and understanding of hepatitis B. Such programs shall include—

''(1) the conduct of culturally and language appropriate health education, public awareness campaigns, and community outreach activities (especially to the ethnic communities with high rates of chronic hepatitis B and other high-risk groups) to promote public awareness and knowledge about the value of hepatitis B immunization, risk factors, the transmission and prevention of hepatitis B, and the value of screening for the early detection of hepatitis B infection;

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

''(3) the training of health care professionals and health educators to make them aware of the high rates of chronic hepatitis B in certain adult ethnic populations, and the importance of prevention, detection, and medical management of hepatitis B and of liver cancer screening;

''(4) the development and distribution of health education curricula (including information relating to the special needs of individuals infected with hepatitis B, such as the importance of prevention and early intervention, regular monitoring, and appropriate treatment and liver cancer screening) for individuals providing hepatitis B counseling;

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

''(6) the provision of grants for the inclusion of viral hepatitis and liver wellness education curricula in elementary and secondary school health education programs.

''(c) EPIDEMIOLOGICAL SURVEILLANCE.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall support the establishment and maintenance of a national chronic and

acute hepatitis B surveillance program, in order to identify—

"(A) trends in the incidence of acute and chronic hepatitis B;

"(B) trends in the prevalence of acute and chronic hepatitis B infection among groups that may be disproportionately affected by hepatitis B; and

"(C) liver cancer and end stage liver disease incidence and deaths, caused by chronic hepatitis B in the various ethnic populations.

"(2) SEROPREVALENCE AND LIVER CANCER STUDIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall prepare a report outlining the population-based seroprevalence studies currently underway, future planned studies, the criteria involved in determining which seroprevalence studies to conduct, defer, or suspend, and the scope of those studies, the economic and clinical impact of hepatitis B, and the impact of hepatitis B on quality of life. Not later than one year after the date of enactment of this part, the Secretary shall submit the report to the Committee on Energy and Commerce of the House

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

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

''(d) RESEARCH.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, the Director of the National Cancer Institute, and the Director of the National Institutes of Health, shall—

''(1) conduct community-based research to develop, implement, and evaluate best practices for hepatitis B prevention especially in the ethnic populations with high rates of chronic hepatitis B and other high-risk groups;

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

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

''(e) EXPANDED SUPPORT FOR UNDERSERVED AND DISPROPORTIONATELY AFFECTED POPULATIONS CHRON-

ICALLY INFECTED WITH HBV.—In carrying out this section, the Secretary shall give priority to individuals with limited access to health education, testing, and health care services and groups that may be disproportionately affected by hepatitis B, including populations such as Asian Americans with a high incidence of chronic hepatitis B and liver cancer.''.

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