111TH CONGRESS
2D SESSION

S. 3711

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 referral program for viral hepatitis infection that will lead to a marked reduction in the disease burden associated with chronic viral hepatitis and liver cancer.

IN THE SENATE OF THE UNITED STATES

AUGUST 5, 2010

Mr. KERRY 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 referral program for viral hepatitis infection that will lead to a marked reduction in the disease burden associated with chronic viral hepatitis and liver cancer.

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 ''Viral Hepatitis and Liver Cancer Control and Prevention Act of 2010''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Approximately 5,300,000 Americans are chronically infected with the hepatitis B virus (referred to in this section as ''HBV''), the hepatitis C virus (referred to in this section as ''HCV''), or both.

(2) In the United States, chronic viral hepatitis is the most common cause of liver cancer, one of the most lethal and fastest growing cancers in this country. It is the most common cause of chronic liver disease, liver cirrhosis, and the most common indication for liver transplantation. It is also a leading cause of death in Americans living with HIV/AIDS, many of whom are coinfected with chronic hepatitis B, hepatitis C, or both. At least 15,000 deaths per year in the United States can be attributed to chronic viral hepatitis.

(3) According to the Centers for Disease Control and Prevention (referred to in this section as the ''CDC''), approximately 2 percent of the population of the United States is living with chronic hepatitis B, hepatitis C, or both. The CDC has rec-

ognized HCV as the Nation's most common chronic bloodborne virus infection.

(4) Hepatitis B is easily transmitted and is 100 times more infectious than HIV. According to the CDC, HBV is transmitted through percutaneous (i.e., puncture through the skin) or mucosal contact with infectious blood or body fluids. Hepatitis C is transmitted by percutaneous (i.e., passage through the skin) exposures to infectious blood.

(5) The CDC conservatively estimates that in 2007 approximately 17,000 Americans were newly infected with HCV and more than 40,000 Americans were newly infected with HBV. The number of people in the United States with chronic hepatitis B and chronic hepatitis C is believed to be increasing each year.

(6) Chronic hepatitis B and chronic hepatitis C usually do not cause 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 cirrhosis, end-stage liver disease, or liver cancer. Since most of those with chronic viral hepatitis are unaware of their infection, they do not know to take precautions to prevent the

spread of their infection and can unknowingly exacerbate their own disease progression.

(7) Hepatitis B and hepatitis C disproportionately affect certain populations in the United States. Although representing only 4 percent of the population, Asian and Pacific Islanders account for over half of the 1,400,000 domestic chronic hepatitis B cases. Baby boomers (those born between 1946 and 1964) account for more than half of domestic chronic hepatitis C cases. In addition, African-Americans, Latinos, and American Indian/Native Alaskans are among the groups which have disproportionately high rates of HBV and HCV infections in the United States.

(8) Hepatitis A (referred to in this section as ''HAV'') and HBV infection are preventable through currently available vaccinations. The hepatitis B vaccine is safe and effective and has the designation of being the ''first anti-cancer vaccine'' since prevention of HBV infection also prevents HBV-related liver cancer. There is currently no vaccine available to prevent HCV infection.

(9) For both chronic hepatitis B and chronic hepatitis C, behavioral changes can slow disease progression if diagnosis is made early. Early diagnosis,

which is available through simple tests, can reduce the risk of transmission and disease progression through education and vaccination of household members and other susceptible persons at risk.

(10) For those chronically infected with HBV or HCV, 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, prevention, and treatment.

(11) Treatment for chronic hepatitis C is curative and can eradicate the disease in approximately 50 percent of those who are treated. Treatment for chronic hepatitis B is not curative, but can reduce the level of virus in about 50 percent of those treated. Treatment for both chronic hepatitis B and chronic hepatitis C can reduce the risk of progression to cirrhosis and liver cancer.

(12) To combat the HCV epidemic in the United States, the CDC developed Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease in 1998 and the National Hepatitis C Prevention Strategy in 2001. To combat the HBV epidemic, the CDC developed Recommendations for Identification

and Public Health Management of Persons with Chronic Hepatitis B Virus Infection in 2008. The National Institutes of Health convened Consensus Development Conferences on the Management of Hepatitis C in 1997 and 2002 and the Management of Hepatitis B in 2008. These recommendations and guidelines provide a framework for HBV and HCV prevention, education, control, research, and medical management referral programs.

(13) Although the costs of education, research, and treatment are not trivial, they are substantially less than the annual health care cost attributable to viral hepatitis in the United States. For HBV, it is estimated to be approximately $2,500,000,000 ($2,000 per infected person). The lifetime cost of HBV in 2000—before the availability of most of the current therapies—was approximately $80,000 per person chronically infected, or more than $100,000,000,000. For HCV, medical costs alone for patients are expected to increase from $30,000,000,000 in 2009 to over $85,000,000,000 in 2024. Such costs will undoubtedly increase in the absence of expanded prevention and treatment efforts.

(14) Federal support is necessary to increase knowledge and awareness of HBV and HCV and to assist State and local prevention and control efforts in reducing the morbidity and mortality of these epidemics.

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

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended—

(1) by striking section 317N (42 U.S.C. 247b–15); and

(2) by adding at the end the following:

"PART S—COMPREHENSIVE HEPATITIS B AND HEPATITIS C PREVENTION, EDUCATION, RESEARCH, AND MEDICAL MANAGEMENT REFERRAL 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 and hepatitis C, which includes strategies for expanded vaccination programs for hepatitis B in adults, primary and secondary preventive

education and training, surveillance, screening, 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 Director of the Agency for Healthcare Research and Quality;

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

''(H) the director of the Department of Veterans Affairs;

''(I) medical advisory bodies that address issues related to viral hepatitis; and

''(J) the public, including—

''(i) individuals infected with hepatitis B, hepatitis C, or both; and

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

''(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 and hepatitis C (such as knowledge and observations that may be derived from clinical, laboratory, and epidemiological research and disease detection, prevention, and surveillance outcomes);

''(B) addressing gaps in the coverage or effectiveness of the plan; and

''(C) evaluating and, if appropriate, updating recommendations, guidelines, or educational

materials of the Centers for Disease Control and Prevention or the National Institutes of Health for health care providers or the public on viral hepatitis in order to be consistent with the plan.

''(2) PUBLICATION OF NOTICE OF ASSESSMENTS.—Not later than October 1 of the first even numbered year beginning after the date of the 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) 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 and hepatitis C. Such programs shall include—

''(1) the conduct of culturally and language appropriate health education in primary and secondary schools, college campuses, public awareness campaigns, and community outreach activities (especially to the ethnic communities with high rates of chronic hepatitis B and chronic hepatitis C and other high-risk groups) to promote public awareness and knowledge about the value of hepatitis A and hepatitis B immunization, risk factors, the transmission and prevention of hepatitis B and hepatitis C, the value of screening for the early detection of hepatitis B and hepatitis C, and options available for the treatment of chronic hepatitis B and chronic hepatitis C;

''(2) the promotion of immunization programs that increase awareness and access to hepatitis A

and hepatitis B vaccines for susceptible adults and children;

''(3) the training of health care professionals regarding the importance of vaccinating individuals infected with hepatitis C and individuals who are at risk for hepatitis C infection against hepatitis A and hepatitis B;

''(4) the training of health care professionals regarding the importance of vaccinating individuals chronically infected with hepatitis B and individuals who are at risk for chronic hepatitis B infection against the hepatitis A virus;

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

''(6) the development and distribution of health education curricula (including information relating to the special needs of individuals infected with hepatitis B and hepatitis C, such as the importance of prevention and early intervention, regular monitoring, the recognition of psychosocial needs, appro-

priate treatment, and liver cancer screening) for individuals providing hepatitis B and hepatitis C counseling; and

''(7) support for the implementation curricula described in paragraph (6) by State and local public health agencies.

''(b) 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, territorial, and tribal levels (including 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, territorial, and tribal voluntary hepatitis B and hepatitis C testing

programs to screen the high-prevalence populations 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 or hepatitis C 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 REGARDING VIRAL HEPATITIS.—The Secretary shall support State, local, territorial, and tribal programs in a wide variety of settings, including those providing primary and specialty health care services in nonprofit private and public sectors, to—

''(i) provide individuals with ongoing risk factors for hepatitis B and hepatitis C infection with client-centered education and counseling which concentrates on—

"(I) promoting testing of individuals that have been exposed to their blood, 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 or hepatitis C 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 or hepatitis C who are pregnant or of childbearing age with culturally and language appropriate health information, such as how to prevent hepatitis B perinatal infection, and to alleviate fears associated with pregnancy or raising a family.

"(C) IMMUNIZATION.—The Secretary shall support State, local, territorial, and tribal efforts to expand the current vaccination pro-

grams to protect every child in the country and all susceptible adults, particularly those infected with hepatitis C and 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 younger through the Vaccines for Children Program;

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

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

''(iv) expanding the availability of hepatitis B vaccination for all susceptible adults to protect them from becoming acutely or chronically infected, including ethnic and other populations with high

prevalence rates of chronic hepatitis B infection;

''(v) expanding the availability of hepatitis B vaccination for all susceptible adults, particularly those in their reproductive age (women and men less than 45 years of age), to protect them from the risk of hepatitis B infection;

''(vi) ensuring the vaccination of individuals infected, or at risk for infection, with hepatitis C against hepatitis A, hepatitis B, and other infectious diseases, as appropriate, for which such individuals may be at increased risk; and

''(vii) ensuring the vaccination of individuals infected, or at risk for infection, with hepatitis B against hepatitis A virus and other infectious diseases, as appropriate, for which such individuals may be at increased risk.

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

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

''(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 ongoing medical management including regular monitoring of liver function and screening for liver cancer; and

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

''(3) INCREASED SUPPORT FOR ADULT VIRAL HEPATITIS COORDINATORS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide increased support to Adult Viral Hepatitis Coordinators in State, local, territorial, and tribal health departments in order to enhance the additional management, networking, and technical expertise needed to ensure successful integration of hepatitis B and hepatitis C prevention and control activities into existing public health 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 and hepatitis C surveillance program, in order to identify—

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

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

''(C) trends in liver cancer and end-stage liver disease incidence and deaths, caused by chronic hepatitis B and chronic hepatitis C in the high-risk 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 hepatitis C, and the impact of chronic hepatitis B and chronic hepatitis C infections on the quality of life. Not later than one year after the date of the 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 epidemiologic and community-based research to develop, implement, and evaluate best practices for hepatitis B and hepatitis C prevention especially in the ethnic populations with high rates of chronic hepatitis B and chronic hepatitis C and other high-risk groups;

''(2) conduct research on hepatitis B and hepatitis C natural history, pathophysiology, improved treatments and prevention (such as the hepatitis C vaccine), and noninvasive tests that help to predict the risk of progression to liver cirrhosis and liver cancer;

''(3) conduct research that will lead to better noninvasive or blood tests to screen for liver cancer, and more effective treatments of liver cancer caused by chronic hepatitis B and chronic hepatitis C; and

''(4) conduct research comparing the effectiveness of screening, diagnostic, management, and treatment approaches for chronic hepatitis B, chronic hepatitis C, and liver cancer in the affected communities.

''(e) UNDERSERVED AND DISPROPORTIONATELY AFFECTED POPULATIONS.—In carrying out this section, the Secretary shall provide expanded support for individuals with limited access to health education, testing, and health care services and groups that may be disproportionately affected by hepatitis B and hepatitis C.

''(f) EVALUATION OF PROGRAM.—The Secretary shall develop benchmarks for evaluating the effectiveness of the programs and activities conducted under this sec-

tion and make determinations as to whether such benchmarks have been achieved.

"SEC. 399HH. GRANTS.

"(a) IN GENERAL.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, States, political subdivisions of States, territories, Indian tribes, or nonprofit entities that have special expertise relating to hepatitis B, hepatitis C, or both, to carry out activities under this part.

"(b) APPLICATION.—To be eligible for a grant, contract, or cooperative agreement under subsection (a), an entity shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"SEC. 399II. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to carry out this part $90,000,000 for fiscal year 2011, $90,000,000 for fiscal year 2012, $110,000,000 for fiscal year 2013, $130,000,000 for fiscal year 2014, and $150,000,000 for fiscal year 2015.".

SEC. 4. ENHANCING SAMHSA'S ROLE IN HEPATITIS ACTIVITIES.

Paragraph (6) of section 501(d) of the Public Health Service Act (42 U.S.C. 290aa(d)) is amended by striking

''HIV or tuberculosis'' and inserting ''HIV, tuberculosis, or hepatitis''.

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