

S 1445 IS

110th CONGRESS

1st Session

**S. 1445**

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, research, and medical management referral program for hepatitis C virus infection.

**IN THE SENATE OF THE UNITED STATES**

**May 22, 2007**

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

**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, research, and medical management referral program for hepatitis C virus 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 `Hepatitis C Epidemic Control and Prevention Act'.

**SEC. 2. FINDINGS.**

Congress makes the following findings:

(1) Approximately 5,000,000 Americans are infected with the hepatitis C virus (referred to in this section as `HCV'), and more than 3,000,000 Americans are chronically infected, leading the Centers for Disease Control and Prevention (referred to in this section as the `CDC') to recognize HCV as the Nation's most common chronic blood-borne virus

infection.

(2) According to the CDC, nearly 2 percent of the population of the United States have been infected with HCV.

(3) The CDC conservatively estimates that approximately 30,000 Americans are newly infected with HCV each year, and that number has been growing since 2001.

(4) HCV infection, in the United States, is the most common cause of chronic liver disease, liver cirrhosis, and liver cancer, the most common indication for liver transplant, and the leading cause of death in people with HIV/AIDS. In addition, there may be links between HCV and certain other diseases, given that a high number of people infected with HCV also suffer from type 2 diabetes, lymphoma, thyroid and certain blood disorders, and autoimmune disease. Moreover, methamphetamine abuse--which is a matter of increasing concern to Congress and public health officials across the country--is recognized by the National Institute on Drug Abuse to be inextricably linked to HCV.

(5) The majority of individuals infected with HCV are unaware of their infection. Individuals infected with HCV serve as a source of transmission to others and, since few individuals are aware they are infected, they are unlikely to take precautions to prevent the spread or exacerbation of their infection.

(6) There is no vaccine available to prevent HCV infection.

(7) Treatments are available that can eradicate the disease in approximately 50 percent of those who are treated, and behavioral changes can slow the progression of the disease.

(8) Conservative estimates place the costs of direct medical expenses for HCV at more than \$1,000,000,000 in the United States annually, and such costs will undoubtedly increase in the absence of expanded prevention and treatment efforts.

(9) 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, and the National Institutes of Health convened Consensus Development Conferences on the Management of Hepatitis C in 1997 and 2002. These recommendations and guidelines provide a framework for HCV prevention, control, research, and medical management referral programs.

(10) The Department of Veterans Affairs (referred to in this paragraph as the `VA'), which cares for more people infected with HCV than any other health care system, is the Nation's leader in HCV screening, testing, and treatment. Since 1998, it has been the VA's policy to screen for HCV risk factors all veterans receiving VA health care, and the VA currently recommends testing for all those who are found to be `at risk' for the virus and for all others who wish to be tested. In fiscal year 2004, over 98 percent of VA patients had been screened for HCV risk factors, and over 90 percent of those `at risk' were tested. For all veterans who test positive for HCV and enroll in VA medical care, the VA offers medications that can help HCV or its complications. The VA also has programs for HCV patient and provider education, clinical care, data-based quality improvement, and research, and it has 4 Hepatitis C Resource Centers to develop and disseminate innovative practices and tools to improve patient care. This comprehensive program should be commended and could potentially serve as a model for future HCV programs.

(11) Federal support is necessary to increase knowledge and awareness of HCV and to assist State and local prevention and control efforts.

### **SEC. 3. PREVENTION, CONTROL, AND MEDICAL MANAGEMENT OF HEPATITIS C.**

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

#### ***`PART S--PREVENTION, CONTROL, AND MEDICAL MANAGEMENT OF HEPATITIS C***

##### ***`SEC. 399II. FEDERAL PLAN FOR THE PREVENTION, CONTROL, AND MEDICAL MANAGEMENT OF HEPATITIS C.***

`(a) In General- The Secretary shall develop and implement a plan for the prevention, control, and medical management of the hepatitis C virus (referred to in this part as `HCV') that includes strategies for 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 Centers for Disease Control and Prevention (referred to in this part as the `CDC') and the National Institutes of Health, and the comprehensive HCV programs that have been implemented by the Department of Veterans Affairs, including

the Hepatitis C Resource Center program; and

ˆ (2) consult with--

ˆ (A) the Director of the CDC;

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

ˆ (C) the Administrator of the Health Resources and Services Administration;

ˆ (D) the heads of other Federal agencies or offices providing services to individuals with HCV infections or the functions of which otherwise involve HCV;

ˆ (E) medical advisory bodies that address issues related to HCV; and

ˆ (F) the public, including--

ˆ (i) individuals infected with the HCV; and

ˆ (ii) advocates concerned with issues related to HCV.

ˆ (c) Biennial Assessment of Plan-

ˆ (1) IN GENERAL- The Secretary shall conduct a biennial assessment of the plan developed under subsection (a) for the purpose of incorporating into such plan new knowledge or observations relating to HCV and chronic HCV (such as knowledge and observations that may be derived from clinical, laboratory, and epidemiological research and disease detection, prevention, and surveillance outcomes) and addressing gaps in the coverage or effectiveness of the plan.

ˆ (2) PUBLICATION OF NOTICE OF ASSESSMENTS- Not later than October 1 of the first even numbered year beginning after the date of enactment of the Hepatitis C Epidemic Control and Prevention Act, 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--

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

ˆ (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. 399JJ. ELEMENTS OF THE FEDERAL PLAN FOR THE PREVENTION, CONTROL, AND MEDICAL MANAGEMENT OF HEPATITIS C.**

^ (a) Education and Training- The Secretary, acting through the Director of the CDC, shall implement programs to increase awareness and enhance knowledge and understanding of HCV. Such programs shall include--

^ (1) the conduct of health education, public awareness campaigns, and community outreach activities to promote public awareness and knowledge about risk factors, the transmission and prevention of infection with HCV, the value of screening for the early detection of HCV infection, and options available for the treatment of chronic HCV;

^ (2) the training of healthcare professionals regarding the prevention, detection, and medical management of the hepatitis B virus (referred to in this part as 'HBV') and HCV, and the importance of vaccinating HCV-infected individuals and those at risk for HCV infection against the hepatitis A virus and HBV; and

^ (3) the development and distribution of curricula (including information relating to the special needs of individuals infected with HBV or HCV, such as the importance of early intervention and treatment and the recognition of psychosocial needs) for individuals providing hepatitis counseling, as well as support for the implementation of such curricula by State and local public health agencies.

^ (b) Early Detection and Surveillance-

^ (1) IN GENERAL- The Secretary, acting through the Director of the CDC, shall support activities described in paragraph (2) to promote the early detection of HCV infection, identify risk factors for infection, and conduct surveillance of HCV infection trends.

^ (2) ACTIVITIES-

^ (A) VOLUNTARY TESTING PROGRAMS-

^ (i) IN GENERAL- The Secretary shall support and promote the development of State, local, and tribal voluntary HCV testing programs to aid in the early identification of infected individuals.

^ (ii) CONFIDENTIALITY OF TEST RESULTS- The results of a HCV test conducted by a testing program developed or supported under this subparagraph shall be considered protected health information (in a manner consistent with regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 and may not be used 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, and tribal programs in a wide variety of settings, including those providing primary and specialty healthcare services in nonprofit private and public sectors, to--

^ (i) provide individuals with information about ongoing risk factors for HCV infection with client-centered education and counseling that concentrates on changing behaviors that place them at risk for infection; and

^ (ii) provide individuals infected with HCV with education and counseling to reduce the risk of harm to themselves and transmission of the virus to others.

^ (C) VACCINATION AGAINST VIRAL HEPATITIS- With respect to individuals infected, or at risk for infection, with HCV, the Secretary shall provide for--

^ (i) the vaccination of such individuals against hepatitis A virus, HBV, and other infectious diseases, as appropriate, for which such individuals may be at increased risk; and

^ (ii) the counseling of such individuals regarding hepatitis A, HBV, and other viral hepatitis.

^ (D) MEDICAL REFERRAL- The Secretary shall support--

^ (i) referral of persons infected with or at risk for HCV, for drug or alcohol abuse treatment where appropriate; and

^ (ii) referral of persons infected with HCV--

^ (I) for medical evaluation to determine their stage of

chronic HCV and suitability for antiviral treatment; and

^ (II) for ongoing medical management of HCV.

^ (3) HEPATITIS C COORDINATORS- The Secretary, acting through the Director of the CDC, shall, upon request, provide a Hepatitis C Coordinator to a State health department in order to enhance the management, networking, and technical expertise needed to ensure successful integration of HCV prevention and control activities into existing public health programs.

^ (c) Surveillance and Epidemiology-

^ (1) IN GENERAL- The Secretary shall promote and support the establishment and maintenance of State HCV surveillance databases, in order to--

^ (A) identify risk factors for HCV infection;

^ (B) identify trends in the incidence of acute and chronic HCV;

^ (C) identify trends in the prevalence of HCV infection among groups that may be disproportionately affected by HCV, including individuals living with HIV, military veterans, emergency first responders, racial or ethnic minorities, and individuals who engage in high risk behaviors, such as intravenous drug use; and

^ (D) assess and improve HCV infection prevention programs.

^ (2) CONFIDENTIALITY- Information contained in the databases under paragraph (1) shall be de-identified in a manner consistent with regulations under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

^ (d) Research Network- The Secretary, acting through the Director of the CDC and the Director of the National Institutes of Health, shall--

^ (1) conduct epidemiologic research to identify best practices for HCV prevention;

^ (2) establish and support a Hepatitis C Clinical Research Network for the purpose of conducting research related to the treatment and medical management of HCV; and

^ (3) conduct basic research to identify new approaches to prevention (such as vaccines) and treatment for HCV.

^ (e) Referral for Medical Management of Chronic HCV- The Secretary shall support and promote State, local, and tribal programs to provide HCV-positive individuals with referral for medical evaluation and management, including currently recommended antiviral therapy when appropriate.

^ (f) 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 healthcare services and groups that may be disproportionately affected by HCV.

^ (g) Evaluation of Program- The Secretary shall develop benchmarks for evaluating the effectiveness of the programs and activities conducted under this section and make determinations as to whether such benchmarks have been achieved.

### ^ **SEC. 399KK. GRANTS.**

^ (a) In General- The Secretary may award grants to, or enter into contracts or cooperative agreements with, States, political subdivisions of States, Indian tribes, or nonprofit entities that have special expertise relating to HCV, 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. 399LL. AUTHORIZATION OF APPROPRIATIONS.**

^ There are authorized to be appropriated to carry out this part \$90,000,000 for fiscal year 2008, and \$72,000,000 for each of fiscal years 2009 through 2012.'

*END*