

109TH CONGRESS
1ST SESSION

S. 521

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

MARCH 3, 2005

Mrs. HUTCHISON (for herself, Mr. KENNEDY, Mr. CORNYN, and Mr. SCHUMER) 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Hepatitis C Epidemic
5 Control and Prevention Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1 (1) Approximately 5,000,000 Americans are in-
2 fected with the hepatitis C virus (referred to in this
3 section as “HCV”), and more than 3,000,000 Amer-
4 icans are chronically infected, making HCV the Na-
5 tion’s most common chronic blood borne virus infec-
6 tion.

7 (2) Nearly 2 percent of the population of the
8 United States have been infected with HCV.

9 (3) Conservative estimates indicate that ap-
10 proximately 30,000 Americans are newly infected
11 with HCV each year, and that number has been
12 growing since 2001.

13 (4) HCV infection, in the United States, is the
14 most common cause of chronic liver disease, liver
15 cirrhosis, and liver cancer, the most common indica-
16 tion for liver transplant, and the leading cause of
17 death in people with HIV/AIDS. In addition, there
18 may be links between HCV and certain other dis-
19 eases, given that a high number of people infected
20 with HCV also suffer from type 2 diabetes,
21 lymphoma, thyroid and certain blood disorders, and
22 autoimmune disease.

23 (5) The majority of individuals infected with
24 HCV are unaware of their infection. Individuals in-
25 fected with HCV serve as a source of transmission

1 to others and, since few individuals are aware they
2 are infected, they are unlikely to take precautions to
3 prevent the spread or exacerbation of their infection.

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

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

10 (8) Conservative estimates place the costs of di-
11 rect medical expenses for HCV at more than
12 \$1,000,000,000 in the United States annually, and
13 such costs will undoubtedly increase in the absence
14 of expanded prevention and treatment efforts.

15 (9) To combat the HCV epidemic in the United
16 States, the Centers for Disease Control and Preven-
17 tion developed Recommendations for Prevention and
18 Control of Hepatitis C Virus (HCV) Infection and
19 HCV-Related Chronic Disease in 1998 and the Na-
20 tional Hepatitis C Prevention Strategy in 2001, and
21 the National Institutes of Health convened Con-
22 sensus Development Conferences on the Manage-
23 ment of Hepatitis C in 1997 and 2002. These rec-
24 ommendations and guidelines provide a framework

1 for HCV prevention, control, research, and medical
2 management referral programs.

3 (10) The Department of Veterans Affairs (re-
4 ferred to in this paragraph as the “VA”), which
5 cares for more people infected with HCV than any
6 other health care system, is the Nation’s leader in
7 HCV screening, testing, and treatment. Since 1998,
8 it has been the VA’s policy to screen for HCV risk
9 factors all veterans receiving VA health care, and
10 the VA currently recommends testing for all those
11 who are found to be “at risk” for the virus and for
12 all others who wish to be tested. In fiscal year 2004,
13 over 98 percent of VA patients had been screened
14 for HCV risk factors, and over 90 percent of those
15 “at risk” were tested. For all veterans who test posi-
16 tive for HCV and enroll in VA medical care, the VA
17 offers medications that can help HCV or its com-
18 plications. The VA also has programs for HCV pa-
19 tient and provider education, clinical care, data-
20 based quality improvement, and research, and it has
21 4 Hepatitis C Resource Centers to develop and dis-
22 seminate innovative practices and tools to improve
23 patient care. This comprehensive program should be
24 commended and could potentially serve as a model
25 for future HCV programs.

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

4 **SEC. 3. PREVENTION, CONTROL, AND MEDICAL MANAGE-**
 5 **MENT OF HEPATITIS C.**

6 Title III of the Public Health Service Act (42 U.S.C.
 7 241 et seq.) is amended by adding at the end the fol-
 8 lowing:

9 **“PART R—PREVENTION, CONTROL, AND MEDICAL**
 10 **MANAGEMENT OF HEPATITIS C**

11 **“SEC. 399AA. FEDERAL PLAN FOR THE PREVENTION, CON-**
 12 **TROL, AND MEDICAL MANAGEMENT OF HEPA-**
 13 **TITIS C.**

14 “(a) IN GENERAL.—The Secretary shall develop and
 15 implement a plan for the prevention, control, and medical
 16 management of the hepatitis C virus (referred to in this
 17 part as ‘HCV’) that includes strategies for education and
 18 training, surveillance and early detection, and research.

19 “(b) INPUT IN DEVELOPMENT OF PLAN.—In devel-
 20 oping the plan under subsection (a), the Secretary shall—

21 “(1) be guided by existing recommendations of
 22 the Centers for Disease Control and Prevention and
 23 the National Institutes of Health; and

24 “(2) consult with—

1 “(A) the Director of the Centers for Dis-
2 ease Control and Prevention;

3 “(B) the Director of the National Insti-
4 tutes of Health;

5 “(C) the Administrator of the Health Re-
6 sources and Services Administration;

7 “(D) the heads of other Federal agencies
8 or offices providing services to individuals with
9 HCV infections or the functions of which other-
10 wise involve HCV;

11 “(E) medical advisory bodies that address
12 issues related to HCV; and

13 “(F) the public, including—

14 “(i) individuals infected with the
15 HCV; and

16 “(ii) advocates concerned with issues
17 related to HCV.

18 “(c) BIENNIAL ASSESSMENT OF PLAN.—

19 “(1) IN GENERAL.—The Secretary shall con-
20 duct a biennial assessment of the plan developed
21 under subsection (a) for the purpose of incor-
22 porating into such plan new knowledge or observa-
23 tions relating to HCV and chronic HCV (such as
24 knowledge and observations that may be derived
25 from clinical, laboratory, and epidemiological re-

1 search and disease detection, prevention, and surveil-
2 lance outcomes) and addressing gaps in the coverage
3 or effectiveness of the plan.

4 “(2) PUBLICATION OF NOTICE OF ASSESS-
5 MENTS.—Not later than October 1 of the first even
6 numbered year beginning after the date of enact-
7 ment of the Hepatitis C Epidemic Control and Pre-
8 vention Act, and October 1 of each even numbered
9 year thereafter, the Secretary shall publish in the
10 Federal Register a notice of the results of the as-
11 sessments conducted under paragraph (1). Such no-
12 tice shall include—

13 “(A) a description of any revisions to the
14 plan developed under subsection (a) as a result
15 of the assessment;

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

21 “(C) in the case of a determination by the
22 Secretary that the plan does not need revision,
23 an explanation of the basis for such determina-
24 tion.

1 **“SEC. 399BB. ELEMENTS OF THE FEDERAL PLAN FOR THE**
 2 **PREVENTION, CONTROL, AND MEDICAL MAN-**
 3 **AGEMENT OF HEPATITIS C.**

4 “(a) EDUCATION AND TRAINING.—The Secretary,
 5 acting through the Director of the Centers for Disease
 6 Control and Prevention, shall implement programs to in-
 7 crease awareness and enhance knowledge and under-
 8 standing of HCV. Such programs shall include—

9 “(1) the conduct of health education, public
 10 awareness campaigns, and community outreach ac-
 11 tivities to promote public awareness and knowledge
 12 about risk factors, the transmission and prevention
 13 of infection with HCV, the value of screening for the
 14 early detection of HCV infection, and options avail-
 15 able for the treatment of chronic HCV;

16 “(2) the training of healthcare professionals re-
 17 garding the prevention, detection, and medical man-
 18 agement of the hepatitis B virus (referred to in this
 19 part as ‘HBV’) and HCV, and the importance of
 20 vaccinating HCV-infected individuals and those at
 21 risk for HCV infection against the hepatitis A virus
 22 and HBV; and

23 “(3) the development and distribution of cur-
 24 ricula (including information relating to the special
 25 needs of individuals infected with HBV or HCV,
 26 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 Centers for Disease
 Control and Prevention, shall support activities de-
 scribed in paragraph (2) to promote the early detec-
 tion of HCV infection, identify risk factors for infec-
 tion, 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 identi-
 fication of infected individuals.

“(ii) CONFIDENTIALITY OF TEST RE-
 SULTS.—The results of a HCV test con-
 ducted by a testing program developed or
 supported under this subparagraph shall
 be considered protected health information
 (in a manner consistent with regulations

1 promulgated under section 264(c) of the
 2 Health Insurance Portability and Account-
 3 ability Act of 1996 (42 U.S.C. 1320d-2
 4 note)) and may not be used for any of the
 5 following:

6 “(I) Issues relating to health in-
 7 surance.

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

10 “(III) To discharge a person
 11 from employment.

12 “(B) COUNSELING REGARDING VIRAL HEP-
 13 ATITIS.—The Secretary shall support State,
 14 local, and tribal programs in a wide variety of
 15 settings, including those providing primary and
 16 specialty healthcare services in nonprofit private
 17 and public sectors, to—

18 “(i) provide individuals with informa-
 19 tion about ongoing risk factors for HCV
 20 infection with client-centered education
 21 and counseling that concentrates on chang-
 22 ing behaviors that place them at risk for
 23 infection; and

24 “(ii) provide individuals infected with
 25 HCV with education and counseling to re-

1 duce the risk of harm to themselves and
2 transmission of the virus to others.

3 “(C) VACCINATION AGAINST VIRAL HEPATITIS.—With respect to individuals infected, or
4 at risk for infection, with HCV, the Secretary
5 shall provide for—
6

7 “(i) the vaccination of such individuals
8 against hepatitis A virus, HBV, and
9 other infectious diseases, as appropriate,
10 for which such individuals may be at increased risk; and
11

12 “(ii) the counseling of such individuals
13 regarding hepatitis A, HBV, and other
14 viral hepatides.

15 “(D) MEDICAL REFERRAL.—The Secretary
16 shall support—

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

20 “(ii) referral of persons infected with
21 HCV—

22 “(I) for medical evaluation to determine their stage of chronic HCV
23 and suitability for antiviral treatment;
24 and
25

1 “(II) for ongoing medical man-
2 agement of HCV.

3 “(3) HEPATITIS C COORDINATORS.—The Sec-
4 retary, acting through the Director of the Centers
5 for Disease Control and Prevention, shall, upon re-
6 quest, provide a Hepatitis C Coordinator to a State
7 health department in order to enhance the manage-
8 ment, networking, and technical expertise needed to
9 ensure successful integration of HCV prevention and
10 control activities into existing public health pro-
11 grams.

12 “(c) SURVEILLANCE AND EPIDEMIOLOGY.—

13 “(1) IN GENERAL.—The Secretary shall pro-
14 mote and support the establishment and mainte-
15 nance of State HCV surveillance databases, in order
16 to—

17 “(A) identify risk factors for HCV infec-
18 tion;

19 “(B) identify trends in the incidence of
20 acute and chronic HCV;

21 “(C) identify trends in the prevalence of
22 HCV infection among groups that may be dis-
23 proportionately affected by HCV, including in-
24 dividuals living with HIV, military veterans,
25 emergency first responders, racial or ethnic mi-

1 norities, and individuals who engage in high
 2 risk behaviors, such as intravenous drug use;
 3 and

4 “(D) assess and improve HCV infection
 5 prevention programs.

6 “(2) SEROPREVALENCE STUDIES.—The Sec-
 7 retary shall conduct a population-based
 8 seroprevalence study to estimate the current and fu-
 9 ture impact of HCV. Such studies shall consider the
 10 economic and clinical impacts of HCV, as well as the
 11 impact of HCV on quality of life.

12 “(3) CONFIDENTIALITY.—Information con-
 13 tained in the databases under paragraph (1) or de-
 14 rived through studies under paragraph (2) shall be
 15 de-identified in a manner consistent with regulations
 16 under section 264(c) of the Health Insurance Port-
 17 ability and Accountability Act of 1996.

18 “(d) RESEARCH NETWORK.—The Secretary, acting
 19 through the Director of the Centers for Disease Control
 20 and Prevention and the Director of the National Institutes
 21 of Health, shall—

22 “(1) conduct epidemiologic research to identify
 23 best practices for HCV prevention;

24 “(2) establish and support a Hepatitis C Clin-
 25 ical Research Network for the purpose of conducting

1 research related to the treatment and medical man-
2 agement of HCV; and

3 “(3) conduct basic research to identify new ap-
4 proaches to prevention (such as vaccines) and treat-
5 ment for HCV.

6 “(e) REFERRAL FOR MEDICAL MANAGEMENT OF
7 CHRONIC HCV.—The Secretary shall support and pro-
8 mote State, local, and tribal programs to provide HCV-
9 positive individuals with referral for medical evaluation
10 and management, including currently recommended
11 antiviral therapy when appropriate.

12 “(f) UNDERSERVED AND DISPROPORTIONATELY AF-
13 FECTED POPULATIONS.—In carrying out this section, the
14 Secretary shall provide expanded support for individuals
15 with limited access to health education, testing, and
16 healthcare services and groups that may be disproportion-
17 ately affected by HCV.

18 “(g) STUDY AND REPORT REGARDING VA PROGRAM
19 AND FEDERAL PLAN.—

20 “(1) STUDY.—The Secretary shall conduct a
21 study to examine the comprehensive HCV programs
22 that have been implemented by the Department of
23 Veterans Affairs (referred to in this subsection as
24 the ‘VA’), including the Hepatitis C Resource Center
25 program, to determine whether any of these pro-

1 grams, or components of these programs, should be
2 part of the Federal plan to combat HCV.

3 “(2) REPORT.—Not later than 12 months after
4 date of enactment of the Hepatitis C Epidemic Con-
5 trol and Prevention Act, the Secretary shall submit
6 to Congress a report that describes the results of the
7 study required under paragraph (1).

8 “(3) CONSIDERATION OF REPORT.—The Sec-
9 retary shall take into consideration the content of
10 the report required under paragraph (2) in con-
11 ducting the biennial assessment required under sec-
12 tion 399AA(c).

13 “(h) EVALUATION OF PROGRAM.—The Secretary
14 shall develop benchmarks for evaluating the effectiveness
15 of the programs and activities conducted under this sec-
16 tion and make determinations as to whether such bench-
17 marks have been achieved.

18 **“SEC. 399CC. GRANTS.**

19 “(a) IN GENERAL.—The Secretary may award grants
20 to, or enter into contracts or cooperative agreements with,
21 States, political subdivisions of States, Indian tribes, or
22 nonprofit entities that have special expertise relating to
23 HCV, to carry out activities under this part.

24 “(b) APPLICATION.—To be eligible for a grant, con-
25 tract, or cooperative agreement under subsection (a), an

1 entity shall prepare and submit to the Secretary an appli-
 2 cation at such time, in such manner, and containing such
 3 information as the Secretary may require.

4 **“SEC. 399DD. AUTHORIZATION OF APPROPRIATIONS.**

5 “There are authorized to be appropriated to carry out
 6 this part \$90,000,000 for fiscal year 2006, and such sums
 7 as may be necessary for each of fiscal years 2007 through
 8 2010.”.

9 **SEC. 4. LIVER DISEASE RESEARCH ADVISORY BOARD.**

10 Part B of title IV of the Public Health Service Act
 11 (42 U.S.C. 284 et seq.) is amended by adding at the end
 12 the following:

13 **“SEC. 409J. LIVER DISEASE RESEARCH ADVISORY BOARD.**

14 “(a) ESTABLISHMENT.—Not later than 90 days after
 15 the date of enactment of the Hepatitis C Epidemic Control
 16 and Prevention Act, the Director of the National Insti-
 17 tutes of Health shall establish a board to be known as
 18 the Liver Disease Research Advisory Board (referred to
 19 in this section as the ‘Advisory Board’).

20 “(b) DUTIES.—The Advisory Board shall advise and
 21 assist the Director of the National Institutes of Health
 22 concerning matters relating to liver disease research, in-
 23 cluding by developing and revising the Liver Disease Re-
 24 search Action Plan.

1 “(c) VOTING MEMBERS.—The Advisory Board shall
2 be composed of 18 voting members to be appointed by the
3 Director of the National Institutes of Health, in consulta-
4 tion with the Director of the National Institute of Diabe-
5 tes and Digestive and Kidney Diseases (referred to in this
6 subsection as the ‘NIDDK’), of whom 12 such individuals
7 shall be eminent scientists and 6 such individuals shall be
8 lay persons. The Director of the National Institutes of
9 Health, in consultation with the Director of the NIDDK,
10 shall select 1 of the members to serve as the Chair of the
11 Advisory Board.

12 “(d) EX OFFICIO MEMBERS.—The Director of the
13 National Institutes of Health shall appoint each director
14 of a national research institute that funds liver disease re-
15 search to serve as a nonvoting, ex officio member of the
16 Advisory Board. The Director of the National Institutes
17 of Health shall invite 1 representative of the Centers for
18 Disease Control and Prevention, 1 representative of the
19 Food and Drug Administration, and 1 representative of
20 the Department of Veterans Affairs to serve as such a
21 member. Each ex officio member of the Advisory Board
22 may appoint an individual to serve as that member’s rep-
23 resentative on the Advisory Board.

24 “(e) LIVER DISEASE RESEARCH ACTION PLAN.—

1 “(1) DEVELOPMENT.—Not later than 15
2 months after the date of enactment of the Hepatitis
3 C Epidemic Control and Prevention Act, the Advi-
4 sory Board shall develop (with appropriate support
5 from the Director) a comprehensive plan for the con-
6 duct and support of liver disease research to be
7 known as the Liver Disease Research Action Plan.
8 The Advisory Board shall submit the Plan to the Di-
9 rector of National Institutes of Health and the head
10 of each institute or center within the National Insti-
11 tutes of Health that funds liver disease research.

12 “(2) CONTENT.—The Liver Disease Research
13 Action Plan shall identify scientific opportunities
14 and priorities for liver disease research necessary to
15 increase understanding of and to prevent, cure, and
16 develop better treatment protocols for liver diseases.

17 “(3) REVISION.—The Advisory Board shall re-
18 vise every 2 years the Liver Disease Research Action
19 Plan, but shall meet annually to review progress and
20 to amend the Plan as may be appropriate because
21 of new scientific discoveries.”.

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