

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.

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## 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

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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, 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:

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.

## 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

1 treatment and the recognition of psychosocial needs)  
2 for individuals providing hepatitis counseling, as well  
3 as support for the implementation of such curricula  
4 by State and local public health agencies.

5 “(b) EARLY DETECTION AND SURVEILLANCE.—

6 “(1) IN GENERAL.—The Secretary, acting  
7 through the Director of the Centers for Disease  
8 Control and Prevention, shall support activities de-  
9 scribed in paragraph (2) to promote the early detec-  
10 tion of HCV infection, identify risk factors for infec-  
11 tion, and conduct surveillance of HCV infection  
12 trends.

13 “(2) ACTIVITIES.—

14 “(A) VOLUNTARY TESTING PROGRAMS.—

15 “(i) IN GENERAL.—The Secretary  
16 shall support and promote the development  
17 of State, local, and tribal voluntary HCV  
18 testing programs to aid in the early identi-  
19 fication of infected individuals.

20 “(ii) CONFIDENTIALITY OF TEST RE-  
21 SULTS.—The results of a HCV test con-  
22 ducted by a testing program developed or  
23 supported under this subparagraph shall  
24 be considered protected health information  
25 (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:

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—

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

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

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

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 de-  
23 termine their stage of chronic HCV  
24 and suitability for antiviral treatment;  
25 and

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-

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 disproportio-  
17 nately 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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