

108TH CONGRESS  
1ST SESSION

# H. R. 3539

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 HOUSE OF REPRESENTATIVES

NOVEMBER 19, 2003

Mrs. WILSON of New Mexico (for herself and Mr. TOWNS) 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, 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) Over 3,000,000 individuals in the United  
2 States are chronically infected with the hepatitis C  
3 virus (referred to in this section as “HCV”), making  
4 it the Nation’s most common blood-borne viral infec-  
5 tion.

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

8           (3) Conservative estimates indicate that ap-  
9 proximately 35,000 Americans are newly infected  
10 with HCV each year.

11          (4) HCV infection can cause life-threatening  
12 liver disease.

13          (5) Individuals infected with HCV serve as a  
14 source of transmission to others and, since few indi-  
15 viduals are aware they are infected, are unlikely to  
16 take precautions to prevent the spread or exacer-  
17 bation of their infection.

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

20          (7) Treatments are available to slow the pro-  
21 gression of chronic HCV.

22          (8) An estimated 2,400,000 to 2,700,000 peo-  
23 ple who are chronically infected with HCV are re-  
24 ceiving no treatment.

1           (9) Conservative estimates place the costs of  
2 lost productivity and medical care arising from  
3 chronic HCV in the United States at more than  
4 \$600,000,000 annually, and such costs will undoubt-  
5 edly increase in the absence of expanded prevention  
6 and treatment efforts.

7           (10) To combat the HCV epidemic in the  
8 United States, the Centers for Disease Control and  
9 Prevention developed Recommendations for Preven-  
10 tion and Control of Hepatitis C Virus (HCV) Infec-  
11 tion and HCV-Related Chronic Disease in 1998 and  
12 the National Hepatitis C Prevention Strategy in  
13 2001, and the National Institutes of Health con-  
14 vened Consensus Development Conferences on the  
15 Management of Hepatitis C in 1997 and 2002.  
16 These recommendations and guidelines provide a  
17 framework for HCV prevention, control, research,  
18 and medical management referral programs.

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

1 **SEC. 3. PREVENTION, CONTROL, AND MEDICAL MANAGE-**  
2 **MENT OF HEPATITIS C.**

3 Title III of the Public Health Service Act (42 U.S.C.  
4 241 et seq.) is amended by adding at the end the fol-  
5 lowing:

6 **“PART R—PREVENTION, CONTROL, AND MEDICAL**  
7 **MANAGEMENT OF HEPATITIS C**

8 **“SEC. 399AA. FEDERAL PLAN FOR THE PREVENTION, CON-**  
9 **TROL, AND MEDICAL MANAGEMENT OF HEPA-**  
10 **TITIS C.**

11 “(a) IN GENERAL.—The Secretary shall develop and  
12 implement a plan for the prevention, control, and medical  
13 management of hepatitis C (referred to in this part as  
14 ‘HCV’) which includes strategies for education and train-  
15 ing, surveillance and early detection, and research.

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

18 “(1) be guided by existing recommendations of  
19 the Centers for Disease Control and Prevention and  
20 the National Institutes of Health; and

21 “(2) consult with—

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

24 “(B) the Director of the National Insti-  
25 tutes of Health;

1           “(C) the Director of the Health Resources  
2           and Services Administration;

3           “(D) the heads of other Federal agencies  
4           or offices providing services to individuals with  
5           HCV infections or the functions of which other-  
6           wise involve HCV;

7           “(E) medical advisory bodies that address  
8           issues related to HCV; and

9           “(F) the public, including—

10                  “(i) individuals infected with HCV;

11                  and

12                  “(ii) advocates concerned with issues  
13                  related to HCV.

14           “(c) BIENNIAL UPDATE OF PLAN.—

15                  “(1) IN GENERAL.—The Secretary shall con-  
16                  duct a biennial assessment of the plan developed  
17                  under subsection (a) for the purpose of incor-  
18                  porating into such plan new knowledge or observa-  
19                  tions relating to HCV and chronic HCV (such as  
20                  knowledge and observations that may be derived  
21                  from clinical, laboratory, and epidemiological re-  
22                  search and disease detection, prevention, and surveil-  
23                  lance outcomes) and addressing gaps in the coverage  
24                  or effectiveness of the plan.

1           “(2) PUBLICATION OF NOTICE OF ASSESS-  
2           MENTS.—Not later than October 1 of the first even-  
3           numbered year beginning after the date of enact-  
4           ment of this part, and October 1 of each even-num-  
5           bered year thereafter, the Secretary shall publish in  
6           the Federal Register a notice of the results of the  
7           assessments conducted under paragraph (1). Such  
8           notice shall include—

9                   “(A) a description of any revisions to the  
10                  plan developed under subsection (a) as a result  
11                  of the assessment;

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

17                   “(C) in the case of a determination by the  
18                  Secretary that the plan does not need revision,  
19                  an explanation of the basis for such determina-  
20                  tion.

21   **“SEC. 399BB. ELEMENTS OF THE FEDERAL PLAN FOR THE**  
22                   **PREVENTION, CONTROL, AND MEDICAL MAN-**  
23                   **AGEMENT OF HEPATITIS C.**

24           “(a) EDUCATION AND TRAINING.—The Secretary,  
25   acting through the Director of the Centers for Disease

1 Control and Prevention, shall implement programs to in-  
2 crease awareness and enhance knowledge and under-  
3 standing of HCV. Such programs shall include—

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

11           “(2) the training of health care professionals  
12 regarding the prevention, detection, and medical  
13 management of hepatitis B (referred to in this part  
14 as ‘HBV’) and HCV, and the importance of vacci-  
15 nating HCV-infected individuals and those at risk  
16 for HCV infection against the hepatitis A virus and  
17 hepatitis B virus; and

18           “(3) the development and distribution of cur-  
19 ricula (including information relating to the special  
20 needs of individuals infected with HBV or HCV,  
21 such as the importance of early intervention and  
22 treatment and the recognition of psychosocial needs)  
23 for individuals providing hepatitis counseling, as well  
24 as support for the implementation of such curricula  
25 by State and local public health agencies.

1 “(b) EARLY DETECTION AND SURVEILLANCE.—

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

9 “(2) ACTIVITIES.—

10 “(A) VOLUNTARY TESTING PROGRAMS.—

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

16 “(ii) CONFIDENTIALITY OF TEST RE-  
17 SULTS.—The results of an HCV test con-  
18 ducted by a testing program developed or  
19 supported under this subparagraph shall  
20 be considered protected health information  
21 (in a manner consistent with regulations  
22 promulgated under section 264(c) of the  
23 Health Insurance Portability and Account-  
24 ability Act of 1996) and may not be used  
25 for any of the following:

1                   “(I) Issues relating to health in-  
2                   surance.

3                   “(II) To screen or determine  
4                   suitability for employment.

5                   “(III) To discharge a person  
6                   from employment.

7                   “(B) COUNSELING REGARDING VIRAL HEP-  
8                   ATITIS.—The Secretary shall support State,  
9                   local, and tribal programs in a wide variety of  
10                  settings, including those providing primary and  
11                  specialty health care services in the private and  
12                  the public sectors, to—

13                  “(i) provide individuals with informa-  
14                  tion about ongoing risk factors for HCV  
15                  infection with client-centered education  
16                  and counseling which concentrates on  
17                  changing behaviors that place them at risk  
18                  for infection; and

19                  “(ii) provide individuals infected with  
20                  HCV with education and counseling to re-  
21                  duce the risk of harm to themselves and  
22                  transmission of the virus to others.

23                  “(C) VACCINATION AGAINST VIRAL HEP-  
24                  TITIS.—With respect to individuals infected, or

1 at risk for infection, with HCV, the Secretary  
2 shall provide for—

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

8 “(ii) the counseling of such individuals  
9 regarding hepatitis A, hepatitis B, and  
10 other viral hepatides.

11 “(D) MEDICAL REFERRAL.—The Secretary  
12 shall support—

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

16 “(ii) referral of persons infected with  
17 HCV—

18 “(I) for medical evaluation to de-  
19 termine their stage of chronic HCV  
20 and suitability for antiviral treatment;  
21 and

22 “(II) for ongoing medical man-  
23 agement of HCV.

24 “(3) HEPATITIS C COORDINATORS.—The Sec-  
25 retary, acting through the Director of the Centers

1 for Disease Control and Prevention, shall, upon re-  
2 quest, provide a Hepatitis C Coordinator to a State  
3 health department in order to enhance the additional  
4 management, networking, and technical expertise  
5 needed to ensure successful integration of HCV pre-  
6 vention and control activities into existing public  
7 health programs.

8 “(c) SURVEILLANCE AND EPIDEMIOLOGY.—

9 “(1) IN GENERAL.—The Secretary shall pro-  
10 mote and support the establishment and mainte-  
11 nance of State HCV surveillance databases, in order  
12 to—

13 “(A) identify risk factors for HCV infec-  
14 tion;

15 “(B) identify trends in the incidence of  
16 acute and chronic HCV;

17 “(C) identify trends in the prevalence of  
18 HCV infection among groups that may be dis-  
19 proportionately affected by HCV, including in-  
20 dividuals living with HIV, military veterans,  
21 emergency first responders, racial or ethnic mi-  
22 norities, and individuals who engage in high  
23 risk behaviors, such as intravenous drug use;  
24 and

1           “(D) assess and improve HCV infection  
2           prevention programs.

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

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

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

19                 “(1) conduct epidemiologic research to identify  
20                 best practices for HCV prevention;

21                 “(2) establish and support a Hepatitis C Clin-  
22                 ical Research Network for the purpose of conducting  
23                 research related to the treatment and medical man-  
24                 agement of HCV; and

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

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

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

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

21 **“SEC. 399CC. GRANTS.**

22          “(a) IN GENERAL.—The Secretary may award grants  
23 to, or enter into contracts or cooperative agreements with,  
24 States, political subdivisions of States, Indian tribes, or

1 nonprofit entities that have special expertise relating to  
2 HCV, to carry out activities under this part.

3 “(b) APPLICATION.—To be eligible for a grant, con-  
4 tract, or cooperative agreement under subsection (a), an  
5 entity shall prepare and submit to the Secretary an appli-  
6 cation at such time, in such manner, and containing such  
7 information as the Secretary may require.

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

9 “There are authorized to be appropriated to carry out  
10 this part \$90,000,000 for fiscal year 2004, and such sums  
11 as may be necessary for each of fiscal years 2005 through  
12 2008.”.

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

14 Part B of title IV of the Public Health Service Act  
15 (42 U.S.C. 284 et seq.) is amended by adding at the end  
16 the following:

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

18 “(a) ESTABLISHMENT.—Not later than 90 days after  
19 the date of enactment of this section, the Director of the  
20 National Institutes of Health shall establish a board to  
21 be known as the Liver Disease Research Advisory Board  
22 (referred to in this section as the ‘Advisory Board’).

23 “(b) DUTIES.—The Advisory Board shall advise and  
24 assist the Director of the National Institutes of Health  
25 concerning matters relating to liver disease research, in-

1 cluding by developing and revising the Liver Disease Re-  
2 search Action Plan.

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

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

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

1           “(1) DEVELOPMENT.—Not later than 15  
2 months after the date of the enactment of this sec-  
3 tion, the Advisory Board shall develop (with appro-  
4 priate support from the Director) a comprehensive  
5 plan for the conduct and support of liver disease re-  
6 search to be known as the Liver Disease Research  
7 Action Plan. The Advisory Board shall submit the  
8 Plan to the Director of NIH and the head of each  
9 institute or center within the National Institutes of  
10 Health that funds liver disease research.

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

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

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