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S. 1143

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 23, 2003

Mrs. HUTCHISON (for herself, Mr. KENNEDY, Mr. CAMPBELL, Mr. BIDEN, Mr. SMITH, Mr. DODD, Mr. CORNYN, Mr. BINGAMAN, Mr. DASCHLE, Mr. BREAUX, Mr. JOHNSON, Mr. SCHUMER, Mrs. CLINTON, and Mr. JEFFORDS) 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”.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Over 3,000,000 individuals in the United
4 States are chronically infected with the hepatitis C
5 virus (referred to in this section as “HCV”), making
6 it the Nation’s most common blood borne virus in-
7 fection.

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

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

13 (4) HCV infection can cause life-threatening
14 liver disease.

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

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

22 (7) Treatments are available to slow the pro-
23 gression of chronic hepatitis C.

24 (8) An estimated 2,400,000 to 2,700,000 peo-
25 ple who are chronically infected with hepatitis C are
26 receiving no treatment.

1 (9) Conservative estimates place the costs of
2 lost productivity and medical care arising from
3 chronic hepatitis C in the United States at more
4 than \$600,000,000 annually and such costs will un-
5 doubtedly increase in the absence of expanded pre-
6 vention 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 hepatitis C prevention, control, re-
18 search, and medical management referral programs.

19 (11) Federal support is necessary to increase
20 knowledge and awareness of hepatitis C and to as-
21 sist 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 which includes strategies for
 14 education and training, surveillance and early detection,
 15 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 hepatitis C virus (referred to in this part as
6 ‘HCV’) infections or the functions of which oth-
7 erwise involve hepatitis C;

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

10 “(F) the public, including—

11 “(i) individuals infected with the
12 HCV; and

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

15 “(c) BIENNIAL UPDATE OF PLAN.—

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

11 “(2) the training of health care professionals
12 regarding the prevention, detection, and medical
13 management of hepatitis B and hepatitis C, and the
14 importance of vaccinating HCV-infected individuals
15 and those at risk for HCV infection against the hep-
16 atitis A virus and hepatitis B virus (referred to in
17 this part as ‘HBV’); 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 hepa-
14 titis C testing programs to aid in the early
15 identification of infected individuals.

16 “(ii) CONFIDENTIALITY OF TEST RE-
17 SULTS.—The results of a hepatitis C test
18 conducted by a testing program developed
19 or 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 (42 U.S.C. 1320d-2

1 note)) and may not be used for any of the
2 following:

3 “(I) Issues relating to health in-
4 surance.

5 “(II) To screen or determine
6 suitability for employment.

7 “(III) To discharge a person
8 from employment.

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

15 “(i) provide individuals with informa-
16 tion about ongoing risk factors for hepa-
17 titis C virus infection with client-centered
18 education and counseling which con-
19 centrates on changing behaviors that place
20 them at risk for infection; and

21 “(ii) provide individuals infected with
22 hepatitis C virus with education and coun-
23 seling to reduce the risk of harm to them-
24 selves and transmission of the virus to oth-
25 ers.

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

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

9 “(ii) the counseling of such individuals regarding hepatitis A, hepatitis B, and
10 other viral hepatides.
11

12 “(D) MEDICAL REFERRAL.—The Secretary
13 shall support—
14

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

18 “(ii) referral of persons infected with
19 HCV—

20 “(I) for medical evaluation to determine their stage of chronic hepatitis C and suitability for antiviral
21 treatment; and
22

23 “(II) for ongoing medical management of hepatitis C.
24
25

1 “(3) HEPATITIS C COORDINATORS.—The Sec-
2 retary, acting through the Director of the Centers
3 for Disease Control and Prevention, shall, upon re-
4 quest, provide a Hepatitis C Coordinator to a State
5 health department in order to enhance the additional
6 management, networking, and technical expertise
7 needed to ensure successful integration of hepatitis
8 C prevention and control activities into existing pub-
9 lic health programs.

10 “(c) SURVEILLANCE AND EPIDEMIOLOGY.—

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

15 “(A) identify risk factors for HCV infec-
16 tion;

17 “(B) identify trends in the incidence of
18 acute and chronic HCV;

19 “(C) identify trends in the prevalence of
20 HCV infection among groups that may be dis-
21 proportionately affected by hepatitis C, includ-
22 ing individuals living with HIV, military vet-
23 erans, emergency first responders, racial or eth-
24 nic minorities, and individuals who engage in

1 high risk behaviors, such as intravenous drug
2 use; and

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

5 “(2) SEROPREVALENCE STUDIES.—The Sec-
6 retary shall conduct a population-based
7 seroprevalence study to estimate the current and fu-
8 ture impact of hepatitis C. Such studies shall con-
9 sider the economic and clinical impacts of hepatitis
10 C, as well as the impact of hepatitis C on quality of
11 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 hepatitis C; 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 HEPATITIS C.—The Secretary shall support and
8 promote 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 health
16 care services and groups that may be disproportionately
17 affected by hepatitis C.

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

23 **“SEC. 399CC. GRANTS.**

24 “(a) IN GENERAL.—The Secretary may award grants
25 to, or enter into contracts or cooperative agreements with,

1 States, political subdivisions of States, Indian tribes, or
2 non-profit entities that have special expertise relating to
3 HCV, to carry out activities under this part.

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

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

10 “There are authorized to be appropriated to carry out
11 this part \$90,000,000 for fiscal year 2004, and such sums
12 as may be necessary for each of fiscal years 2005 through
13 2008.”.

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

15 Part A of title IV of the Public Health Service Act
16 (42 U.S.C. 281 et seq.) is amended by adding at the end
17 the following:

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

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

24 “(b) DUTIES.—The Advisory Board shall advise and
25 assist the Director of the Centers for Disease Control and

1 Prevention concerning matters relating to liver disease re-
2 search, including by developing and revising the Liver Dis-
3 ease Research Action Plan.

4 “(c) VOTING MEMBERS.—The Advisory Board shall
5 be composed of 18 voting members to be appointed by the
6 Director of the National Institutes of Health, in consulta-
7 tion with the Director of the Institute of Allergy and Infec-
8 tious Diseases, of whom 12 such individuals shall be emi-
9 nent scientists and 6 such individuals shall be lay persons.
10 The Director of the National Institutes of Health, in con-
11 sultation with the Director of the Institute, shall select
12 1 of the members to serve as the Chair of the Advisory
13 Board.

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

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

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

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

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

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