

109TH CONGRESS  
1ST SESSION

# H. R. 1353

To amend the Public Health Service Act to increase the provision of scientifically sound information and support services to patients receiving a positive test diagnosis for Down syndrome or other prenatally diagnosed conditions.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 16, 2005

Mr. SENSENBRENNER (for himself, Mr. SESSIONS, and Mr. HOSTETTLER) 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 increase the provision of scientifically sound information and support services to patients receiving a positive test diagnosis for Down syndrome or other prenatally diagnosed conditions.

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 “Prenatally Diagnosed  
5       Condition Awareness Act”.

1 **SEC. 2. FINDINGS AND PURPOSES.**2 (a) FINDINGS.—Congress makes the following find-  
3 ings:4 (1) Pregnant women who choose to undergo  
5 prenatal genetic testing should have access to timely,  
6 scientific, and nondirective counseling about the con-  
7 ditions being tested for and the accuracy of such  
8 tests, from health care professionals qualified to pro-  
9 vide and interpret these tests. Informed consent is a  
10 critical component of all genetic testing.11 (2) A recent, peer-reviewed study and two re-  
12 ports from the Centers for Disease Control and Pre-  
13 vention on prenatal testing found a deficiency in the  
14 data needed to understand the epidemiology of pre-  
15 nately diagnosed conditions, to monitor trends accu-  
16 rately, and to increase the effectiveness of health  
17 intervention.18 (b) PURPOSES.—It is the purpose of this Act, after  
19 the diagnosis of a fetus with Down syndrome or other pre-  
20 nately diagnosed conditions, to—21 (1) increase patient referrals to providers of key  
22 support services for women who have received a  
23 positive test diagnosis for Down syndrome, or other  
24 prenatally diagnosed conditions, as well as to provide  
25 up-to-date, science-based information about life-ex-  
26 pectancy, development potential, and quality of life

1 for a child born with Down syndrome or other pre-  
2 nately diagnosed condition;

3 (2) provide networks of support through a Cen-  
4 ters for Disease Control and Prevention patient and  
5 provider outreach program;

6 (3) improve available data by incorporating in-  
7 formation directly revealed by prenatal testing into  
8 existing State-based surveillance programs for birth  
9 defects and prenatally diagnosed conditions; and

10 (4) ensure that patients receive up-to-date, sci-  
11 entific information about the accuracy of the test.

12 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**

13 **ACT.**

14 Part P of title III of the Public Health Service Act  
15 (42 U.S.C. 280g et seq.) is amended by adding at the end  
16 the following:

17 **“SEC. 399O. SUPPORT FOR PATIENTS RECEIVING A POSI-**  
18 **TIVE TEST DIAGNOSIS OF DOWN SYNDROME**  
19 **OR OTHER PRENATALLY DIAGNOSED CONDI-**  
20 **TIONS.**

21 “(a) DEFINITIONS.—In this section:

22 “(1) DOWN SYNDROME.—The term ‘Down syn-  
23 drome’ refers to a chromosomal disorder caused by  
24 an error in cell division that results in the presence  
25 of an extra whole or partial copy of chromosome 21.

1           “(2) HEALTH CARE PROVIDER.—The term  
2       ‘health care provider’ means any person or entity re-  
3       quired by State or Federal law or regulation to be  
4       licensed, registered, or certified to provide health  
5       care services, and who is so licensed, registered, or  
6       certified.

7           “(3) PRENATALLY DIAGNOSED CONDITION.—  
8       The term ‘prenatally diagnosed condition’ means any  
9       fetal health condition identified by prenatal genetic  
10      testing or prenatal screening procedures.

11          “(4) PRENATAL TEST.—The term ‘prenatal  
12       test’ means diagnostic or screening tests offered to  
13       pregnant women seeking routine prenatal care that  
14       are administered on a required or recommended  
15       basis by a health care provider based on medical his-  
16       tory, family background, ethnic background, pre-  
17       vious test results, or other risk factors.

18          “(b) INFORMATION AND SUPPORT SERVICES.—The  
19       Secretary, acting through the Director of the National In-  
20       stitutes of Health, the Director of the Centers for Disease  
21       Control and Prevention, or the Administrator of the  
22       Health Resources and Services Administration, may au-  
23       thorize and oversee certain activities, including the award-  
24       ing of grants, contracts or cooperative agreements, to—

1           “(1) collect, synthesize, and disseminate current  
2           scientific information relating to Down syndrome or  
3           other prenatally diagnosed conditions; and

4           “(2) coordinate the provision of, and access to,  
5           new or existing supportive services for patients re-  
6           ceiving a positive test diagnosis for Down syndrome  
7           or other prenatally diagnosed conditions, including—

8               “(A) the establishment of a resource tele-  
9               phone hotline and Internet website accessible to  
10              patients receiving a positive test result;

11              “(B) the establishment of a clearinghouse  
12              of scientific information, clinical course, life ex-  
13              pectancy, development potential, and quality of  
14              life relating to Down syndrome or other pre-  
15              nationally diagnosed conditions;

16              “(C) the establishment of national and  
17              local peer-support programs;

18              “(D) the establishment of a national reg-  
19              istry, or network of local registries, of families  
20              willing to adopt newborns with Down syndrome  
21              or other prenatally diagnosed conditions, and  
22              links to adoption agencies willing to place ba-  
23              bies with Down syndrome or other prenatally  
24              diagnosed conditions, with families willing to  
25              adopt; and

1                         “(E) the establishment of awareness and  
2                         education programs for health care providers  
3                         who provide the results of prenatal tests for  
4                         Down syndrome or other prenatally diagnosed  
5                         conditions, to patients, consistent with the pur-  
6                         pose described in section 2(b)(1) of the Pre-  
7                         natal Diagnosis Support Act.

8                         “(c) DATA COLLECTION.—

9                         “(1) PROVISION OF ASSISTANCE.—The Sec-  
10                         retary, acting through the Director of Centers for  
11                         Disease Control and Prevention, shall provide assist-  
12                         ance to State and local health departments to inte-  
13                         grate the results of prenatal testing into State-based  
14                         vital statistics and birth defects surveillance pro-  
15                         grams.

16                         “(2) ACTIVITIES.—The Secretary shall ensure  
17                         that activities carried out under paragraph (1) are  
18                         sufficient to extract population-level data relating to  
19                         national rates and results of prenatal testing.

20                         “(d) PROVISION OF INFORMATION BY PROVIDERS.—

21                         Upon receipt of a positive test result from a prenatal test  
22                         for Down syndrome or other prenatally diagnosed condi-  
23                         tions performed on a patient, the health care provider in-  
24                         volved (or his or her designee) shall provide the patient  
25                         with the following:

1           “(1) Up-to-date, scientific, written information  
2 concerning the life expectancy, clinical course, and  
3 intellectual and functional development and treat-  
4 ment options for a fetus diagnosed with or child  
5 born with Down syndrome or other prenatally diag-  
6 nosed conditions.

7           “(2) Referral to supportive services providers,  
8 including information hotlines specific to Down syn-  
9 drome or other prenatally diagnosed conditions, re-  
10 source centers or clearinghouses, and other edu-  
11 cation and support programs as described in sub-  
12 section (b)(2).

13           “(e) PRIVACY.—

14           “(1) IN GENERAL.—Notwithstanding sub-  
15 sections (c) and (d), nothing in this section shall be  
16 construed to permit or require the collection, mainte-  
17 nance, or transmission, without the health care pro-  
18 vider obtaining the prior, written consent of the pa-  
19 tient, of—

20           “(A) health information or data that iden-  
21 tify a patient, or with respect to which there is  
22 a reasonable basis to believe the information  
23 could be used to identify the patient (including  
24 a patient’s name, address, healthcare provider,  
25 or hospital); and

1                   “(B) data that are not related to the epi-  
2                   demiology of the condition being tested for.

3                   “(2) GUIDANCE.—Not later than 180 days  
4                   after the date of enactment of this section, the Sec-  
5                   retary shall establish guidelines concerning the im-  
6                   plementation of paragraph (1) and subsection (d).

7                   “(f) REPORTS.—

8                   “(1) IMPLEMENTATION REPORT.—Not later  
9                   than 2 years after the date of enactment of this sec-  
10                   tion, and every 2 years thereafter, the Secretary  
11                   shall submit a report to Congress concerning the im-  
12                   plementation of the guidelines described in sub-  
13                   section (e)(2).

14                   “(2) GAO REPORT.—Not later than 1 year  
15                   after the date of enactment of this section, the Gov-  
16                   ernment Accountability Office shall submit a report  
17                   to Congress concerning the effectiveness of current  
18                   healthcare and family support programs serving as  
19                   resources for the families of children with disabil-  
20                   ties.

21                   “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
22                   is authorized to be appropriated to carry out this section,  
23                   \$5,000,000 for each of fiscal years 2006 through 2010.”.

