

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1051

To amend the Public Health Service Act to reauthorize and extend certain programs to provide coordinated services and research with respect to children and families with HIV/AIDS.

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## IN THE SENATE OF THE UNITED STATES

MAY 17, 2005

Mr. DODD (for himself and Mr. BOND) 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 reauthorize and extend certain programs to provide coordinated services and research with respect to children and families with HIV/AIDS.

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 “Children and Family  
5       HIV/AIDS Research and Care Act of 2005”.

6       **SEC. 2. FINDINGS.**

7       Congress makes the following findings:

1           (1) More than 2,000 children worldwide are in-  
2           fected with HIV each day, the vast majority through  
3           mother to child transmission.

4           (2) More than 3,700 children and youth in the  
5           United States under the age of 13 are living with  
6           HIV and AIDS.

7           (3) Young people ages 15 through 24 represent  
8           50 percent of all new HIV infections worldwide.

9           (4) Each day more than 6,000 youth become  
10          infected with HIV.

11          (5) Of the more than 40,000 Americans newly  
12          infected with HIV every year, half are among people  
13          under 25 years old.

14          (6) Women account for more than a quarter of  
15          all new HIV infections in the United States and  
16          young women represent 58 percent of new HIV  
17          cases among people ages 13 to 19.

18          (7) Title IV of the Ryan White Comprehensive  
19          AIDS Resources Emergency Act of 1990 (Public  
20          Law 101–381) is a successful model of family-cen-  
21          tered, coordinated health care and supportive serv-  
22          ices for women, children, youth and families.

23          (8) Most programs under title IV of the Ryan  
24          White Comprehensive AIDS Resources Emergency  
25          Act of 1990 are the principal source of medical care

1 for HIV-positive children, youth, and pregnant  
2 women in their geographic area.

3 (9) Children and youth living with HIV and  
4 AIDS have unique needs for specialized services in  
5 medical care and psychosocial support.

6 (10) Title IV of the Ryan White Comprehensive  
7 AIDS Resources Emergency Act of 1990, including  
8 its Adolescent Initiative, is the leading national ef-  
9 fort to link HIV-positive youth to comprehensive  
10 medical care and support services.

11 (11) Each year more than 53,000 women, chil-  
12 dren, and youth receive services funded under title  
13 IV of the Ryan White Comprehensive AIDS Re-  
14 sources Emergency Act of 1990.

15 (12) With no preventive intervention, an HIV-  
16 positive pregnant woman has a 25 percent chance of  
17 passing on the virus to her baby. With optimal care,  
18 including preventive drug interventions, the rate of  
19 mother-to-child transmission of HIV drops to 1 to 2  
20 percent.

21 (13) Services provided by programs funded  
22 under title IV of the Ryan White Comprehensive  
23 AIDS Resources Emergency Act of 1990 have been  
24 essential in reducing the number of mother-to-child

1 HIV infections in the United States from approxi-  
2 mately 2,000 to fewer than 200 per year.

3 (14) The Institute of Medicine recommends  
4 routine, voluntary HIV testing of pregnant women  
5 as a means to increasing the proportion of women  
6 tested and, ultimately, reducing mother-to-child  
7 transmission of HIV.

8 (15) The Centers for Disease Control and Pre-  
9 vention also recommends a routine, voluntary ap-  
10 proach to HIV testing of pregnant women as an ef-  
11 fective means to reduce mother-to-child transmission  
12 of HIV.

13 (16) Experts believe that vaccines to prevent  
14 HIV infection offer the best hope of controlling the  
15 global pandemic. However, some of the populations  
16 hardest hit by the disease (infants, preadolescents,  
17 and adolescents) are at risk of being left behind in  
18 the search for an effective vaccine against the virus.

19 (17) To date, the vast majority of HIV vaccine  
20 trials have not included pediatric populations. Of the  
21 110 trials that have been completed, only two of  
22 them included these populations. Of the 40 trials  
23 that are currently being conducted, only one involves  
24 pediatric populations.

1           (18) Because we cannot assume that a vaccine  
2 tested in adults will also be safe and effective when  
3 used in pediatric populations, it will be important to  
4 ensure that promising vaccines are tested in all rel-  
5 evant pediatric populations as early as is medically  
6 and ethically appropriate.

7 **SEC. 3. ENSURING FAMILY-CENTERED, COORDINATED**  
8                   **CARE FOR CHILDREN AND FAMILIES OF HIV/**  
9                   **AIDS.**

10       Section 2671 of the Public Health Service Act (42  
11 U.S.C. 300ff–71) is amended—

12           (1) in subsection (d)(1), by striking “for” and  
13 inserting “coordinated, family-centered care, includ-  
14 ing”; and

15           (2) in subsection (k), by striking “1996 through  
16 2000” and inserting “2006 through 2011”.

17 **SEC. 4. EXPANDING CARE FOR YOUTH.**

18       Section 2671(a) of the Public Health Service Act (42  
19 U.S.C. 300ff–71(a)) is amended by adding at the end  
20 thereof the following:

21           “(3) In the case of youth with HIV, providing  
22 health care and other supportive services designed to  
23 recruit and retain youth in care. For purposes of  
24 this paragraph, the term ‘youth with HIV’ means in-

1       dividuals ages 13 through 24 infected through all  
2       modes of transmission including mother-to-child.”.

3       **SEC. 5. ENSURING ADEQUATE RESOURCES FOR CHILDREN**  
4                                   **AND FAMILIES.**

5       (a) WOMEN, INFANTS, CHILDREN, AND YOUTH PRO-  
6       VISIONS.—

7               (1)           EMERGENCY           RELIEF.—Section  
8       2603(a)(3)(C)(i) of the Public Health Service Act  
9       (42 U.S.C. 300ff–13(a)(3)(C)(i)) is amended by in-  
10      serting “, or for purposes of granting priority under  
11      section 2604(b)(4),” after “pursuant to this para-  
12      graph”.

13              (2)           GENERAL           GRANTS.—Section  
14      2618(a)(2)(D)(i) of the Public Health Service Act  
15      (42 U.S.C. 300ff–28(a)(2)(D)(i)) is amended by in-  
16      serting “, or for purposes of granting priority under  
17      section 2611,” after “section 2620”.

18              (3) REPORT.—Not later than October 1, 2007,  
19      the Secretary of Health and Human Services shall  
20      submit to the appropriate committees of Congress a  
21      report on—

22                           (A) the status of HIV case data implemen-  
23                           tation in relation to the allocation of funds  
24                           under sections 2603 and 2618 of the Public

1 Health Service Act (as amended by this sub-  
2 section); and

3 (B) if such data is being used for allo-  
4 cating resources under this title XXVI of the  
5 Public Health Service Act (42 U.S.C. 300ff–11  
6 et seq.), the impact of the transition from  
7 AIDS case data to HIV case data on the re-  
8 sources directed to women, infants, children  
9 and youth under section 2603 and section  
10 2618.”.

11 (b) CDC GUIDELINES FOR PREGNANT WOMEN.—  
12 Section 2671 of the Public Health Service Act (42 U.S.C.  
13 300ff–71) is amended—

14 (1) by redesignating subsection (k) as sub-  
15 section (l); and

16 (2) by inserting after subsection (j) the fol-  
17 lowing:

18 “(k) DEMONSTRATION GRANTS.—

19 “(1) IN GENERAL.—The Secretary shall award  
20 demonstration grants to public and nonprofit private  
21 entities to enable such entities to conduct assess-  
22 ments of the effectiveness of each of the following  
23 strategies in reducing the mother-to-child trans-  
24 mission of HIV:

1           “(A) Increasing the routine, voluntary HIV  
2           testing of pregnant women, including rapid  
3           testing at the time of labor for women whose  
4           HIV status is unknown.

5           “(B) Increasing access to prenatal care for  
6           HIV-positive pregnant women and providing in-  
7           tensive case management and support services  
8           for HIV-positive pregnant women.

9           “(2) PRIORITY.—In awarding grants under this  
10          subsection, the Secretary shall give priority to enti-  
11          ties that serve pregnant women in areas where  
12          mother-to-child HIV transmission persists.

13          “(3) AUTHORIZATION OF APPROPRIATIONS.—  
14          There is authorized to be appropriated to carry out  
15          this subsection, \$10,000,000 for fiscal year 2006,  
16          and such sums as may be necessary for each of fis-  
17          cal years 2007 through 2011.”.

18 **SEC. 6. ENSURING ACCESS TO RESEARCH FOR INFANTS,**  
19 **CHILDREN, AND YOUTH.**

20          (a) IN GENERAL.—Part D of title XXVI of the Pub-  
21          lic Health Service Act is amended by inserting after sec-  
22          tion 2673 (42 U.S.C. 300ff-73) the following:

23 **“SEC. 2673A. PEDIATRIC HIV VACCINE TESTING.**

24          “(a) IN GENERAL.—Not later than 120 days after  
25          the date of enactment of the Children and Family HIV/

1 AIDS Research and Care Act of 2005, the Director of the  
2 National Institutes of Health, acting through the Director  
3 of the Office of AIDS Research and in collaboration with  
4 the Secretary of Defense, relevant institutes and centers  
5 of the National Institutes of Health, and other federally  
6 funded HIV vaccine research programs, shall submit to  
7 the Committee on Health, Education, Labor, and Pen-  
8 sions of the Senate and the Committee on Energy and  
9 Commerce of the House of Representatives, a report on  
10 the status of activities under the most recent plan of the  
11 National Institutes of Health for HIV-related research re-  
12 lated to the testing of potential HIV vaccine candidates  
13 in relevant pediatric populations.

14       “(b) REQUIREMENTS.—The report submitted under  
15 subsection (a) shall include—

16               “(1) plans for expanding existing capacity for  
17 HIV vaccine candidate testing in relevant pediatric  
18 populations across all institutes, centers, and clinical  
19 trials networks of the National Institutes of Health,  
20 and other federally funded HIV vaccine research  
21 programs;

22               “(2) plans for increasing coordination across  
23 relevant institutes and centers of the National Insti-  
24 tutes of Health, other federally funded HIV vaccine  
25 research programs, the Food and Drug Administra-

1       tion, the Centers for Disease Control and Preven-  
2       tion, and the Partnership for AIDS Vaccine Evalua-  
3       tion, in advancing pediatric HIV vaccine testing and  
4       for identifying opportunities for collaboration with  
5       activities under the authority of the Office of the  
6       Global HIV/AIDS Coordinator;

7               “(3) appropriate principles for initiating HIV  
8       vaccine testing in relevant pediatric populations, in-  
9       cluding recommendations for sequencing the enroll-  
10      ment of adults and relevant pediatric populations  
11      and for addressing issues related to human subjects  
12      protections for children involved in clinical research;  
13      and

14              “(4) proposed community education efforts in  
15      support of the inclusion of relevant pediatric popu-  
16      lations in HIV vaccine clinical trials.

17      “(c) GUIDANCE.—Not later than 120 days after the  
18      date of enactment of the Children and Family HIV/AIDS  
19      Research and Care Act of 2005, the Commissioner of  
20      Food and Drugs, in consultation with appropriate public  
21      and private entities, shall issue guidance on—

22              “(1) the minimum requirements for obtaining  
23      approval of the Food and Drug Administration to  
24      test an HIV vaccine in pediatric populations; and

1           “(2) the minimum requirements for obtaining  
2       Food and Drug Administration approval of a pedi-  
3       atric indication of an HIV vaccine.

4       “(d) COMMITMENT TO ADDITIONAL RESEARCH.—  
5       The Director of the National Institutes of Health shall  
6       invest in domestic and international research on the fol-  
7       lowing:

8           “(1) The long-term health effects of preventive  
9       drug regimens on HIV-exposed pediatric popu-  
10      lations.

11          “(2) The long-term health, psycho-social, and  
12      prevention needs for pediatric populations  
13      perinatally HIV-infected.

14          “(3) The transition to adulthood for HIV-in-  
15      fected pediatric populations.

16          “(4) Safer and more effective treatment options  
17      for pediatric populations with HIV disease.

18      “(e) PEDIATRIC POPULATIONS.—In this section, the  
19      term ‘pediatric populations’ includes neonate, infants, chil-  
20      dren, and adolescents, and the term ‘relevant pediatric  
21      populations’ means pediatric populations at risk of HIV  
22      infection, including infants, preadolescents, and adoles-  
23      cents.”.

24      (b)           COORDINATED           SERVICES.—Section  
25      2671(b)(1)(C) of the Public Health Service Act (42 U.S.C.

- 1 300ff-71(b)(1)(C) is amended by inserting “including
- 2 HIV vaccine research” after “linkages to research”.

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