

108TH CONGRESS
2D SESSION

S. 2892

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.

IN THE SENATE OF THE UNITED STATES

OCTOBER 5, 2004

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

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 2004”.

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 300 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 “2005 through 2010”.

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 2604(b)(4)
 8 of the Public Health Service Act (42 U.S.C. 300ff–
 9 14(b)(4)) is amended by adding at the end the fol-
 10 lowing:

11 “(C) DATA.—In determining the amount
 12 of funds to use for services under subparagraph
 13 (A), the chief elected official of the eligible area
 14 involved shall use HIV case data (rather than
 15 AIDS case data) as soon as the use of such
 16 data is adopted for purposes of allocating any
 17 other funding authorized under this title.”.

18 (2) GENERAL GRANTS.—Section 2611(b) of the
 19 Public Health Service Act (42 U.S.C. 300ff–21(b))
 20 is amended by adding at the end the following:

21 “(3) DATA.—In determining the amount of
 22 funds to use for services under paragraph (1), the
 23 State involved shall use HIV case data (rather than
 24 AIDS case data) as soon as the use of such data is

1 adopted for purposes of allocating any other funding
2 authorized under this title.

3 “(4) REPORT.—Not later than October 1,
4 2007, the Secretary shall submit to the appropriate
5 committees of Congress a report on—

6 “(A) the status of HIV case data imple-
7 mentation in relation to the allocation of funds
8 under this subsection and under section
9 2604(b)(4); and

10 “(B) if such data is being used for allo-
11 cating resources under this title, the impact of
12 the transition from AIDS case data to HIV
13 case data on the resources directed to women,
14 infants, children and youth under this sub-
15 section and under section 2604(b)(4).”.

16 (b) CDC GUIDELINES FOR PREGNANT WOMEN.—
17 Section 2625 of the Public Health Service Act (42 U.S.C.
18 300ff–33) is amended by adding at the end the following:

19 “(d) DEMONSTRATION GRANTS.—

20 “(1) IN GENERAL.—The Secretary shall award
21 demonstration grants to public and nonprofit private
22 entities to enable such entities to conduct assess-
23 ments of the effectiveness of each of the following
24 strategies in reducing the mother-to-child trans-
25 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 2005,
 16 and such sums as may be necessary for each of fis-
 17 cal years 2006 through 2010.”.

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 2004, 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 2004, 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”.

