

106TH CONGRESS  
1ST SESSION

# S. 1131

To promote research into, and the development of an ultimate cure for,  
the disease known as Fragile X.

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## IN THE SENATE OF THE UNITED STATES

MAY 26, 1999

Mr. EDWARDS (for himself and Mr. HAGEL) introduced the following bill;  
which was read twice and referred to the Committee on Health, Edu-  
cation, Labor, and Pensions

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## A BILL

To promote research into, and the development of an  
ultimate cure for, the disease known as Fragile X.

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 “Fragile X Research  
5       Breakthrough Act of 1999”.

6       **SEC. 2. FINDINGS.**

7       Congress makes the following findings:

8               (1) Fragile X is the most common inherited  
9       cause of mental retardation. It affects 1 in every

1       2,000 boys and 1 in every 4,000 girls. One in 260  
2       women is a carrier.

3           (2) Most children with Fragile X require a life-  
4       time of special care at a cost of over \$2,000,000 per  
5       child.

6           (3) Relatively newly-discovered and relatively  
7       unknown, even in the medical profession, Fragile X  
8       is caused by the absence of a single protein that can  
9       be produced synthetically but that cannot yet be ef-  
10      fectively assimilated.

11          (4) Fragile X research, both basic and applied,  
12      is vastly underfunded in view of its prevalence, the  
13      potential for the development of a cure, the estab-  
14      lished benefits of currently available interventions,  
15      and the significance that Fragile X research has for  
16      related disorders.

17          (5) Fragile X is a powerful research model for  
18      other forms of X-linked mental retardation, as well  
19      as neuropsychiatric disorders, including autism,  
20      schizophrenia, mood disorders, and pervasive devel-  
21      opmental disorder. Individuals with Fragile X are a  
22      homogeneous study population for advancing under-  
23      standing of these disorders.

1 **SEC. 3. NATIONAL INSTITUTE OF CHILD HEALTH AND**  
 2 **HUMAN DEVELOPMENT; RESEARCH ON FRAG-**  
 3 **ILE X.**

4 Subpart 7 of part C of title IV of the Public Health  
 5 Service Act (42 U.S.C. 285g et seq.) is amended by adding  
 6 at the end the following:

7 **“SEC. 452E. FRAGILE X.**

8 “(a) EXPANSION AND COORDINATION OF RESEARCH  
 9 ACTIVITIES.—The Director of the Institute, after con-  
 10 sultation with the advisory council for the Institute, shall  
 11 expand, intensify, and coordinate the activities of the In-  
 12 stitute with respect to research on the disease known as  
 13 Fragile X.

14 “(b) RESEARCH CENTERS.—

15 “(1) IN GENERAL.—The Director of the Insti-  
 16 tute, after consultation with the advisory council for  
 17 the Institute, shall make grants to, or enter into  
 18 contracts with, public or nonprofit private entities  
 19 for the development and operation of centers to con-  
 20 duct research for the purposes of improving the di-  
 21 agnosis and treatment of, and finding the cure for,  
 22 Fragile X.

23 “(2) NUMBER OF CENTERS.—In carrying out  
 24 paragraph (1), the Director of the Institute shall, to  
 25 the extent that amounts are appropriated, provide

1 for the establishment of at least 3 Fragile X re-  
2 search centers.

3 “(3) ACTIVITIES.—

4 “(A) IN GENERAL.—Each center assisted  
5 under paragraph (1) shall, with respect to  
6 Fragile X—

7 “(i) conduct basic and clinical re-  
8 search, which may include clinical trials  
9 of—

10 “(I) new or improved diagnostic  
11 methods; and

12 “(II) drugs or other treatment  
13 approaches; and

14 “(ii) conduct research to find a cure.

15 “(B) FEES.—A center may use funds pro-  
16 vided under paragraph (1) to provide fees to in-  
17 dividuals serving as subjects in clinical trials  
18 conducted under subparagraph (A).

19 “(4) COORDINATION AMONG CENTERS.—The  
20 Director of the Institute shall, as appropriate, pro-  
21 vide for the coordination of the activities of the cen-  
22 ters assisted under this section, including providing  
23 for the exchange of information among the centers.

24 “(5) CERTAIN ADMINISTRATIVE REQUIRE-  
25 MENTS.—Each center assisted under paragraph (1)

1 shall use the facilities of a single institution, or be  
 2 formed from a consortium of cooperating institu-  
 3 tions, meeting such requirements as may be pre-  
 4 scribed by the Director of the Institute.

5 “(6) DURATION OF SUPPORT.—Support may be  
 6 provided to a center under paragraph (1) for a pe-  
 7 riod of not to exceed 5 years. Such period may be  
 8 extended for 1 or more additional periods, each of  
 9 which may not exceed 5 years, if the operations of  
 10 such center have been reviewed by an appropriate  
 11 technical and scientific peer review group established  
 12 by the Director and if such group has recommended  
 13 to the Director that such period be extended.

14 “(7) AUTHORIZATION OF APPROPRIATIONS.—  
 15 For the purpose of carrying out this subsection,  
 16 there are authorized to be appropriated \$10,000,000  
 17 for fiscal year 2000, and such sums as may be nec-  
 18 essary for each subsequent fiscal year.”.

19 **SEC. 4. NATIONAL INSTITUTE OF CHILD HEALTH AND**  
 20 **HUMAN DEVELOPMENT; LOAN REPAYMENT**  
 21 **PROGRAM REGARDING RESEARCH ON FRAG-**  
 22 **ILE X.**

23 Part G of title IV of the Public Health Service Act  
 24 (42 U.S.C. 288 et seq.) is amended by inserting after sec-  
 25 tion 487E the following:

1   **“SEC. 487F. LOAN REPAYMENT PROGRAM REGARDING RE-**  
2                           **SEARCH ON FRAGILE X.**

3           “(a) IN GENERAL.—The Secretary, in consultation  
4 with the Director of the National Institute of Child Health  
5 and Human Development, shall establish a program under  
6 which the Federal Government enters into contracts with  
7 qualified health professionals (including graduate stu-  
8 dents) who agree to conduct research regarding Fragile  
9 X in consideration of the Federal Government’s agreement  
10 to repay, for each year of such service, not more than  
11 \$35,000 of the principal and interest of the educational  
12 loans owed by such health professionals.

13          “(b) APPLICABILITY OF CERTAIN PROVISIONS.—  
14 With respect to the National Health Service Corps Loan  
15 Repayment Program established in subpart III of part D  
16 of title III, the provisions of such subpart (including sec-  
17 tion 338B(g)(3)) shall, except as inconsistent with sub-  
18 section (a) of this section, apply to the program estab-  
19 lished in such subsection in the same manner and to the  
20 same extent as such provisions apply to the National  
21 Health Service Corps Loan Repayment Program estab-  
22 lished in such subpart.

23          “(c) AUTHORIZATION OF APPROPRIATIONS.—For the  
24 purpose of carrying out this section, there are authorized  
25 to be appropriated \$2,000,000 for fiscal year 2000, and  
26 such sums as may be necessary for each subsequent fiscal

1 year. Amounts appropriated for a fiscal year under the  
2 preceding sentence shall remain available until the expira-  
3 tion of the second fiscal year beginning after the fiscal  
4 year for which the amounts were appropriated.”.

