

106TH CONGRESS
2D SESSION

S. 2809

To protect the health and welfare of children involved in research.

IN THE SENATE OF THE UNITED STATES

JUNE 28, 2000

Mr. DODD (for himself and Mr. DEWINE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To protect the health and welfare of children involved in research.

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’s Research
5 Protection Act”.

6 **SEC. 2. FINDINGS, PURPOSES, AND DEFINITION.**

7 (a) FINDINGS.—Congress makes the following find-
8 ings:

1 (1) Children are the future of the Nation and
2 the preservation and improvement of child health is
3 in the national interest.

4 (2) The preservation and improvement of child
5 health may require the use of pharmaceutical prod-
6 ucts.

7 (3) Currently only 1 out of 5 drugs on the mar-
8 ket in the United States have been approved for use
9 by children. The enactment of the provisions of the
10 Food and Drug Administration Modernization Act
11 (Public Law 105–115) relating to pediatric studies
12 of drugs, however, is expected to increase the pedi-
13 atric testing of pharmaceuticals and thus to increase
14 the numbers of children involved in research.

15 (4) Children are a vulnerable population and
16 thus need additional protections for their involve-
17 ment in research relative to adults. Yet, current
18 Federal guidelines for the protection of children in-
19 volved in research have not been updated since
20 1981, do not currently apply to Food and Drug Ad-
21 ministration-regulated research that is not Federally
22 funded, and have not been adopted by all Federal
23 agencies that conduct research involving children.

24 (5) Currently, in the United States, there is a
25 shortage of pharmacologists trained to address the

1 unique aspects of developing therapies for children.
2 There are fewer than 200 academic-based clinical
3 pharmacologists in the United States, of which 20
4 percent or fewer are pediatricians. Currently, only
5 20 physicians complete clinical pharmacology spe-
6 cialty training programs each year, and of these,
7 only 2 or fewer specialize in pediatric pharmacology.

8 (b) PURPOSES.—It is the purpose of this Act to—

9 (1) ensure the adequate and appropriate protec-
10 tion of children involved in research by—

11 (A) reviewing and updating as needed the
12 Federal regulations that provide additional pro-
13 tections for children participating in research as
14 contained in subpart D of part 45 of title 46,
15 Code of Federal Regulations;

16 (B) extending such subpart D to all re-
17 search regulated by the Secretary of Health and
18 Human Services; and

19 (C) requiring that all Federal agencies
20 adopt regulations for additional protections for
21 children involved in research that is conducted,
22 supported, or regulated by the Federal Govern-
23 ment; and

24 (2) ensure that an adequate number of pedi-
25 atric clinical pharmacologists are trained and re-

1 tained, in order to meet the increased demand for
2 expertise in this area created by the pediatric studies
3 provisions of the Food and Drug Administration
4 Modernization Act (Public Law 105–115), so that
5 all children have access to medications that have
6 been adequately and properly tested on children.

7 (c) DEFINITION.—In this Act, the term “pediatric
8 clinical pharmacologist” means an individual—

9 (1) who is board certified in pediatrics; and

10 (2) who has additional formal training and ex-
11 pertise in human pharmacology.

12 **SEC. 3. REVIEW OF REGULATIONS.**

13 (a) REVIEW.—By not later than 6 months after the
14 date of enactment of this Act, the Secretary of Health and
15 Human Services shall have conducted a review of the regu-
16 lations under subpart D of part 45 of title 46, Code of
17 Federal Regulations, considered any modifications nec-
18 essary to ensure the adequate and appropriate protection
19 of children participating in research, and report the find-
20 ings of the Secretary back to Congress.

21 (b) AREAS OF REVIEW.—In conducting the review
22 under subsection (a), the Secretary of Health and Human
23 Services shall consider—

1 (1) the appropriateness of the regulations for
2 children of differing ages and maturity levels, includ-
3 ing legal status;

4 (2) the definition of “minimal risk” and the
5 manner in which such definition varies for a healthy
6 child as compared to a child with an illness;

7 (3) the definitions of “assent” and “permis-
8 sion” for child clinical research participants and
9 their parents or guardians and of “adequate provi-
10 sions” for soliciting assent or permission in research
11 as such definitions relate to the process of obtaining
12 the informed consent of children participating in re-
13 search and the parents or guardians of such chil-
14 dren;

15 (4) the definitions of “direct benefit to the indi-
16 vidual subjects” and “generalizable knowledge about
17 the subject’s disorder or condition”;

18 (5) whether or not payment (financial or other-
19 wise) may be provided to a child or his or her parent
20 or guardian for the participation of the child in re-
21 search, and if so, the amount and type given;

22 (6) the expectations of child research partici-
23 pants and their parent or guardian for the direct
24 benefits of the child’s research involvement;

1 (7) safeguards for research involving children
2 conducted in emergency situations with a waiver of
3 informed assent;

4 (8) parent and child notification in instances in
5 which the regulations have not been complied with;

6 (9) compliance with the regulations in effect on
7 the date of enactment of this Act, the monitoring of
8 such compliance, and enforcement actions for viola-
9 tions of such regulations; and

10 (10) the appropriateness of current practices
11 for recruiting children for participation in research.

12 (c) CONSULTATION.—In conducting the review under
13 subsection (a), the Secretary of Health and Human Serv-
14 ices shall consult broadly with experts in the field, includ-
15 ing pediatric pharmacologists, pediatricians, bioethics ex-
16 perts, clinical investigators, institutional review boards, in-
17 dustry experts, and children who have participated in re-
18 search studies and the parents or guardians of such chil-
19 dren.

20 (d) CONSIDERATION OF ADDITIONAL PROVISIONS.—
21 In conducting the review under subsection (a), the Sec-
22 retary of Health and Human Services shall consider and,
23 not later than 6 months after the date of enactment of
24 this Act, report back to Congress concerning—

1 appropriate expertise to provide training in pediatric clinical
2 pharmacology, such as the Pediatric Pharmacology Re-
3 search Units of the National Institute of Child Health and
4 Human Development, and the Research Units of the Na-
5 tional Institute of Mental Health, to enable such entities
6 to provide fellowship training to individuals who hold an
7 M.D. in order to ensure the specialized training of pedi-
8 atric clinical pharmacologists.

9 (b) AMOUNT OF GRANT.—In awarding grants under
10 subsection (a), the Secretary of Health and Human Serv-
11 ices shall ensure that each grantee receive adequate
12 amounts under the grant to enable the grantee to fund
13 at least 1 fellow each year for a 3-year period, at a total
14 of \$100,000 per fellowship per year.

15 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
16 purpose of carrying out this section, there are authorized
17 to be appropriated such sums as may be necessary for
18 each fiscal year.

19 **SEC. 6. LOAN REPAYMENT PROGRAM REGARDING CLIN-**
20 **ICAL RESEARCHERS.**

21 Part G of title IV of the Public Health Service Act
22 is amended by inserting after section 487E (42 U.S.C.
23 288–5) the following:

1 **“SEC. 487F. LOAN REPAYMENT PROGRAM REGARDING PE-**
2 **DIATRIC PHARMACOLOGY.**

3 “(a) IN GENERAL.—The Secretary, acting through
4 the Director of the National Institutes of Health, shall es-
5 tablish a program to enter into contracts with qualified
6 individuals who hold an M.D. under which such individ-
7 uals agree to undergo training in, and practice, pediatric
8 pharmacology, in consideration of the Federal Government
9 agreeing to repay, for each year of service as a pediatric
10 pharmacologist, not more than \$35,000 of the principal
11 and interest of the educational loans of such individuals.

12 “(b) APPLICATION OF PROVISIONS.—The provisions
13 of sections 338B, 338C, and 338E shall, except as incon-
14 sistent with subsection (a) of this section, apply to the pro-
15 gram established under subsection (a) to the same extent
16 and in the same manner as such provisions apply to the
17 National Health Service Corps Loan Repayment Program
18 established in subpart III of part D of title III.

19 “(c) FUNDING.—

20 “(1) AUTHORIZATION OF APPROPRIATIONS.—
21 For the purpose of carrying out this section, there
22 are authorized to be appropriated such sums as may
23 be necessary for each fiscal year.

24 “(2) AVAILABILITY.—Amounts appropriated for
25 carrying out this section shall remain available until
26 the expiration of the second fiscal year beginning

1 after the fiscal year for which the amounts were
2 made available.”.

3 **SEC. 7. EFFECTIVE DATE.**

4 The provisions of sections 5 and 6 shall take effect
5 on the date that is 6 months after the date of enactment
6 of this Act.

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