

105TH CONGRESS
1ST SESSION

H. R. 1451

To amend the Public Health Service Act with respect to research regarding the health of children.

IN THE HOUSE OF REPRESENTATIVES

APRIL 24, 1997

Mr. MORAN of Virginia (for himself, Mr. PAYNE, Mr. SERRANO, Mr. WOLF, Mrs. MORELLA, Mr. SCOTT, Mr. COYNE, Mr. UNDERWOOD, Mr. MILLER of California, Mr. DELLUMS, Mr. McDERMOTT, Mr. BENTSEN, Mr. FAZIO of California, Ms. JACKSON-LEE of Texas, Mr. HALL of Ohio, Ms. NORTON, Ms. MCKINNEY, Mr. BORSKI, Ms. RIVERS, Mr. THOMPSON, Ms. LOFGREN, Mr. STRICKLAND, Mr. ACKERMAN, Mr. BOUCHER, Mrs. MALONEY of New York, Mr. GREEN, and Mrs. THURMAN) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Public Health Service Act with respect to research regarding the health of children.

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 “Pediatric Research Ini-
5 tiative Act of 1997”.

6 SEC. 2. FINDINGS.

7 The Congress finds as follows:

1 (1) The savings from biomedical and behavioral
2 research is significant due to the potential years of
3 productive life saved, and to improvements in the
4 quality of life for children and their families.

5 (2) The opportunities for biomedical advance-
6 ments are greater than ever, given the enormous
7 growth in knowledge and developments in genetics,
8 immunology and related therapies.

14 (4) The average age of onset of cancer in chil-
15 dren is 6 years; for adults, it is 67 years. The poten-
16 tial to save a lifetime of productive years by invest-
17 ing in pediatric research is not adequately reflected
18 in the current allocation of Federal research dollars.

1 (6) Biomedical, behavioral and injury preven-
2 tion research which focuses on the unique needs of
3 children receive far less funding than similar re-
4 search for any other demographic group, including
5 for men, seniors, women and minorities.

6 (7) Research indicates that children face significant, long-term, and unique threats from environmental pollution.

14 **TITLE I—BIOMEDICAL AND**
15 **BEHAVIORAL RESEARCH**

16 SEC. 101. INTERAGENCY PLAN FOR PEDIATRIC RESEARCH.

17 Part B of title IV of the Public Health Service Act
18 (42 U.S.C. 284 et seq.) is amended by adding at the end
19 the following section:

20 “PEDIATRIC RESEARCH INITIATIVE

21 "SEC. 409B. (a) IN GENERAL.—

22 “(1) INTERAGENCY PLAN.—The Director of
23 NIH, after consultation with the Administrator of
24 the Environmental Protection Agency, shall establish
25 a comprehensive plan for the conduct and support
26 by the national research institutes of pediatric re-

1 search, and shall periodically review and as appropriate make revisions in the plan. The Director of NIH shall carry out this section in collaboration with the Director of the National Institute of Child Health and Human Development.

6 “(2) CONSULTATIONS WITH INSTITUTE DIRECTORS.—In carrying out this section, the Director of NIH shall consult with the directors of each of the national research institutes.

10 “(3) ADVISORY COUNCIL.—

11 “(A) The Secretary shall establish an advisory council to be known as the National Advisory Council on Pediatric Research (in this paragraph referred to as the ‘Advisory Council’).

16 “(B) The Advisory Council shall provide advice to the Secretary and the Director of NIH regarding the Plan. In carrying out the preceding sentence, the advisory council shall develop and submit to the Director proposals regarding the contents of the Plan.

22 “(C)(i) Subject to clause (ii), the Secretary shall appoint to the Advisory Council, as voting members, not more than 15 individuals. Such individuals shall be appointed from among indi-

14 “(D) The ex officio, nonvoting members of
15 the Advisory Council shall be the following:

1 “(E) The Secretary shall designate a mem-
2 ber of the Advisory Council to serve as the
3 chair of the Council.

4 “(b) GENERAL REQUIREMENTS FOR PLAN.—

5 “(1) IDENTIFICATION OF RELEVANT
6 PROJECTS.—In developing, reviewing, and revising
7 the Plan, the Director of NIH shall identify the
8 projects of pediatric research that are being con-
9 ducted or supported by the national research insti-
10 tute, and current proposals for such projects.

11 “(2) GENERAL REQUIREMENTS; CATEGORIES
12 OF RESEARCH.—The Director shall ensure that the
13 Plan specifies the following with respect to pediatric
14 research:

15 “(A) The categories of research that are to
16 be conducted and supported by the National In-
17 stitutes of Health.

18 “(B) Priorities among such categories.

19 “(C) The areas in which an insufficient
20 number or variety of projects have been con-
21 ducted or supported by such Institutes, and the
22 areas in which the activities of the national re-
23 search institutes are overlapping.

1 “(D) The process for coordinating research
2 activities among the national research insti-
3 tutes.

4 “(E) Promising areas in which the Na-
5 tional Institutes of Health will conduct or sup-
6 port research.

7 “(F) In the case of the research priorities
8 specified under subparagraph (B), mechanisms
9 to encourage public and private entities to initi-
10 ate research independently of solicitations by
11 the National Institutes of Health for proposals.

12 “(G) Objectives for the research conducted
13 or supported under the Plan, the means for
14 achieving the objectives, and the date by which
15 the objectives are expected to be achieved.

16 “(3) PARTICULAR PROJECTS.—In carrying out
17 paragraph (2) with respect to a category of research,
18 the Director of NIH may establish requirements re-
19 garding particular projects of research within a cat-
20 egory.

21 “(c) CERTAIN CONSIDERATIONS.—In developing, re-
22 viewing, and revising the Plan, the Director of NIH shall
23 consider the following with respect to children:

24 “(1) Epidemiological data, including the inci-
25 dence and prevalence of various causes of death or

1 disability, and including data on environmental fac-
2 tors.

3 “(2) The severity of various diseases and the
4 impact of the diseases on functional capacity.

5 “(3) The potential for significant progress in
6 the diagnosis, treatment, prevention, and control of
7 various diseases, disorders, and disabilities.

8 “(d) CERTAIN COMPONENTS OF PLAN.—The Direc-
9 tor of NIH shall ensure that the Plan provides for an ap-
10 propriate emphasis on the following:

11 “(1) Evaluations of the results of basic research
12 in order to develop and commence projects of clinical
13 research.

14 “(2) The support of proposals developed pursu-
15 ant to solicitations by the national research insti-
16 tutes, and the support of proposals developed inde-
17 pendently of such solicitations.

18 “(3) The support of proposals for projects
19 whose principal researchers will be individuals who
20 have not previously served as the principal research-
21 ers of projects supported by the national research in-
22 stitutes.

23 “(4) Both biomedical research and behavioral
24 research.

1 “(e) DATES CERTAIN REGARDING APPLICABILITY OF
2 PLAN; INITIAL REVIEW.—The initial Plan shall be devel-
3 oped and shall take effect not later than October 1, 1998.
4 The initial review of the Plan under subsection (a)(1) shall
5 be completed not later than October 1, 2000, and a review
6 shall be conducted not less than once during each subse-
7 quent two-year period.

8 “(f) BIENNIAL REPORT.—Each biennial report sub-
9 mitted by the Director of NIH under section 403 shall
10 include provisions describing the activities undertaken and
11 expenditures made under this section and section 409C.
12 The report may contain such comments of the Director
13 of NIH regarding this section and section 409C as the
14 Director determines to be appropriate.

15 “(g) DEFINITIONS.—For purposes of this section:

16 “(1) The term ‘pediatric research’ means bio-
17 medical and behavioral research regarding the health
18 of children.

19 “(2) The term ‘Plan’ means the plan estab-
20 lished, reviewed, and revised under subsection (a)(1).

21 “(h) AUTHORIZATION OF APPROPRIATIONS.—For the
22 purpose of carrying out this section, there are authorized
23 to be appropriated \$60,000,000 for fiscal year 1998,
24 \$75,000,000 for fiscal year 1999, \$100,000,000 for fiscal

1 year 2000, and such sums as may be necessary for fiscal
2 year 2001 and each subsequent fiscal year.”.

3 **SEC. 102. INCLUSION OF CHILDREN IN CLINICAL RE-**
4 **SEARCH.**

5 Part H of title IV of the Public Health Service (42
6 U.S.C. 289 et seq.) is amended by inserting after section
7 492B the following section:

8 “INCLUSION OF CHILDREN IN CLINICAL RESEARCH

9 “SEC. 492C. (a) IN GENERAL.—The Director of NIH
10 shall establish guidelines regarding the inclusion of chil-
11 dren as subjects in projects of clinical research conducted
12 or supported by the National Institutes of Health.

13 “(b) CERTAIN CONSIDERATIONS.—In establishing
14 guidelines under subsection (a), the Director of NIH shall
15 consider—

16 “(1) the principles applied under section 492B
17 by the Director in including women and members of
18 minority groups as subjects in projects of clinical re-
19 search; and

20 “(2) the factors underlying the plan developed
21 under section 409B (relating to the conduct and
22 support of pediatric research).

23 “(c) INCREASE REGARDING INCLUSION OF CHIL-
24 DREN.—

25 “(1) INCREASE REGARDING FISCAL YEAR
26 2000.—The Director of NIH shall ensure that, for

1 fiscal year 2000, the child-subject percentage is sig-
2 nificantly increased above such percentage for fiscal
3 year 1995.

4 “(2) CHILD-SUBJECT PERCENTAGE.—For pur-
5 poses of this section, the term ‘child-health percent-
6 age’, with respect to a fiscal year, means the per-
7 centage constituted by the ratio of—

8 “(A) the number of children who, during
9 the fiscal year, participated as subjects in
10 projects of clinical research conducted or sup-
11 ported by the National Institutes of Health; to

12 “(B) the number of individuals (adults and
13 children) who, during the fiscal year, partici-
14 pated as such subjects.”.

15 **TITLE II—PREVENTIVE HEALTH
16 RESEARCH**

17 **SEC. 201. INTERAGENCY PLAN FOR PEDIATRIC RESEARCH;
18 DISCRETIONARY FUND.**

19 Title III of the Public Health Service Act (42 U.S.C.
20 241 et seq.) is amended by adding at the end the following
21 part:

3 **“SEC. 399M. RESEARCH REGARDING CHILDREN AND PRE-**
4 **VENTABLE DISEASES, DISORDERS, AND INJU-**
5 **RIES.**

6 "(a) IN GENERAL.—The Secretary shall carry out a
7 program of research regarding preventable diseases, dis-
8 abilities, and injuries in children, including research on the
9 causes of death in children. The Secretary may conduct
10 the research directly or through making grants to public
11 and nonprofit private entities.

12 "(b) COLLABORATION WITH RELEVANT AGENCY
13 HEADS.—The Secretary shall carry out subsection (a) in
14 collaboration with the following:

15 “(1) The Director of the Centers for Disease
16 Control and Prevention

17 “(2) The Director of the National Institute of
18 Child Health and Human Development.

19 “(3) The Director of the National Center for
20 Injury Prevention and Control

21 “(4) The Director of the Maternal and Child
22 Health Bureau

23 “(5) The Administrator for Health Care Policy
24 and Research

1 “(6) Such other Federal officials as the Sec-
2 retary determines to be appropriate.

3 “(c) ADVISORY COMMITTEE.—

4 “(1) IN GENERAL.—The Secretary shall provide
5 for a committee to provide advice to the Secretary
6 regarding pediatric prevention research. The mem-
7 bers of the committee shall be appointed from indi-
8 viduals who have expertise in pediatric prevention
9 activities and who, subject to paragraph (2), are not
10 officers or employees of the Federal Government.

11 “(2) USE OF EXISTING COMMITTEES.—A Fed-
12 eral employee may serve as a member of the advi-
13 sory committee under paragraph (1) if the only Fed-
14 eral duty of the employee is to serve on one or more
15 Federal advisory committees, and if the individual,
16 when first appointed to such a committee, was not
17 a Federal officer or employee.

18 “(d) INTERAGENCY PLAN.—The Secretary—

19 “(1) shall establish a comprehensive plan for
20 carrying out subsection (a) through the Centers for
21 Disease Control and Prevention and such other
22 agencies of the Department as the Secretary deter-
23 mines to be appropriate; and

24 “(2) shall periodically review and as appropriate
25 make revisions in the plan.

1 “(e) GENERAL REQUIREMENTS FOR PLAN.—

2 “(1) PRELIMINARY EVALUATIONS.—

3 “(A) In developing, reviewing, and revising
4 the Plan, the Secretary shall—

5 “(i) identify and evaluate projects of
6 pediatric prevention research that are
7 being carried out through the agencies of
8 the Department, and proposals for such
9 projects; and

10 “(ii) to the extent practicable, identify
11 and evaluate the projects of pediatric pre-
12 vention research that are being carried out
13 through other public or private entities,
14 and proposals for such projects.

15 “(B) The projects identified and evaluated
16 by the Secretary under subparagraph (A) shall
17 include the following:

18 “(i) Demonstration projects that pro-
19 vide training in the prevention of injuries
20 in children.

21 “(ii) Demonstration projects that de-
22 velop curricula for such training for use in
23 the training of health professionals who
24 routinely provide care for children, includ-
25 ing such professionals in the fields of pub-

9 “(2) GENERAL REQUIREMENTS; CATEGORIES
10 OF RESEARCH.—The Secretary shall ensure that the
11 Plan specifies the following with respect to pediatric
12 prevention research:

13 “(A) The categories of research that are to
14 be conducted and supported by the Department.

15 “(B) The allocation among such agencies
16 of responsibilities for the categories designated
17 under subparagraph (A).

18 “(C) Priorities among such categories.

19 “(D) Objectives for the research conducted
20 or supported under the Plan, the means for
21 achieving the objectives, and the date by which
22 the objectives are expected to be achieved.

23 “(E) The process for coordinating and con-
24 solidating research activities among the agen-
25 cies of the Department.

1 “(3) PARTICULAR PROJECTS.—In carrying out
2 paragraph (2) with respect to a category of research,
3 the Secretary may establish requirements regarding
4 particular projects of research within a category.

5 “(f) CERTAIN CONSIDERATIONS.—In developing, re-
6 viewing, and revising the Plan, the Secretary shall con-
7 sider the following with respect to children.

8 “(1) Epidemiological data, including the inci-
9 dence and prevalence of various causes of death or
10 disability.

11 “(2) The severity of various diseases and inju-
12 ries and the impact of such diseases and injuries on
13 functional capacity.

14 “(3) The potential for significant progress in
15 the prevention of various diseases, disabilities, and
16 injuries.

17 “(g) MODEL PROGRAMS FOR SUPERVISORS OF CHIL-
18 DREN.—With respect to parents, teachers, and other indi-
19 viduals who routinely supervise children, the Secretary
20 shall ensure that the Plan provides for the development
21 of model programs for educating such individuals on pedi-
22 atric prevention activities.

23 “(h) DATES CERTAIN REGARDING APPLICABILITY OF
24 PLAN; INITIAL REVIEW.—The initial Plan shall be devel-
25 oped and shall take effect not later than October 1, 1998.

1 The initial review of the Plan under subsection (d)(2) shall
2 be completed not later than October 1, 2000, and a review
3 shall be conducted not less than once during each subse-
4 quent two-year period.

5 “(i) DISCRETIONARY FUND.—

6 “(1) IN GENERAL.—There is established a fund
7 to be known as the Pediatric Prevention Research
8 Initiative Fund, consisting of such amounts as may
9 be appropriated under subsection (l) for the Fund.

10 “(2) USE OF FUND.—Amounts in the Fund are
11 available to the Secretary for such activities regard-
12 ing pediatric prevention research as are authorized
13 under this Act, including activities under the Plan.

14 “(j) ANNUAL REPORT.—Not later than February 1
15 of each fiscal year, the Secretary shall submit to the Com-
16 mittee on Commerce and the Committee on Appropriations
17 (of the House of Representatives), and to the Com-
18 mittee on Labor and Human Resources and the Commit-
19 tee on Appropriations (of the Senate), a report describing
20 the activities undertaken and expenditures made under
21 this section during the preceding fiscal year, including
22 with respect to the Fund. The report may contain such
23 comments of the Secretary regarding this section as the
24 Secretary determines to be appropriate.

25 “(k) DEFINITIONS.—For purposes of this section:

1 “(1) The term ‘Department’ means the Depart-
2 ment of Health and Human Services, unless the con-
3 text of usage indicates otherwise.

4 “(2) The term ‘Fund’ means the fund estab-
5 lished in subsection (i)(1).

6 “(3) The term ‘pediatric prevention activities’
7 means activities for the prevention of diseases, dis-
8 abilities, and injuries in children.

9 “(4) The term ‘pediatric prevention research’
10 means research described in subsection (a).

11 “(5) The term ‘Plan’ means the plan estab-
12 lished, reviewed, and revised under subsection (d).

13 “(l) AUTHORIZATION OF APPROPRIATIONS.—For the
14 purpose of carrying out this section, there are authorized
15 to be appropriated \$30,000,000 for fiscal year 1998,
16 \$30,500,000 for fiscal year 1999, and \$50,000,000 for fis-
17 cal year 2000.”.

18 **TITLE III—DEVELOPMENT OF**
19 **IMPROVED PHARMA-**
20 **CEUTICALS AND OTHER**
21 **THERAPEUTIC AGENTS**

22 SEC. 301. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

23 Chapter V of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 501 et seq.) is amended by inserting after
25 section 505 the following section:

1 “PEDIATRIC STUDIES FOR NEW DRUG APPLICATIONS

2 “SEC. 505A. (a) If an application submitted under

3 section 505(b)(1) is approved on or after the date of en-

4 actment of this section, and such application includes re-

5 ports of pediatric studies described and requested in sub-

6 section (c), and such studies are completed and the reports

7 thereof submitted in accordance with subsection (c)(2) or

8 completed and the reports thereof accepted in accordance

9 with subsection (c)(3), the Secretary may not make the

10 approval of an application submitted under section

11 505(b)(2) or section 505(j) which refers to the drug for

12 which the section 505(b)(1) approval is granted effective

13 prior to the expiration of 6 months from the earliest date

14 on which the approval of such application for the drug

15 under section 505(b)(2) or section 505(j), respectively,

16 could otherwise be made effective under the applicable

17 provisions of this chapter.

18 “(b) If the Secretary makes a written request for pe-

19 diatric studies described in subsection (c) to the holder

20 of an approval under section 505(b)(1) for a drug, and

21 such studies are completed and the reports thereof submit-

22 ted in accordance with subsection (c)(2) or completed and

23 the reports thereof accepted in accordance with subsection

24 (c)(3), the Secretary may not make the approval of an

25 application submitted under section 505(b)(2) or section

1 505(j) which refers to the drug subject to the section
2 505(b)(1) approval effective prior to the expiration of 6
3 months from the earliest date on which an approval of
4 such application under section 505(b)(2) or section 505(j),
5 respectively, could otherwise be made effective under the
6 applicable provisions of this chapter. Nothing in this sub-
7 section shall affect the ability of the Secretary to make
8 effective a section 505(b)(2) or section 505(j) approval for
9 a subject drug if such approval is proper under such sub-
10 section and is made effective prior to the submission of
11 the reports of pediatric studies described in subsection (c).

12 “(c)(1) The Secretary may, pursuant to a written re-
13 quest for studies after consultation with the sponsor of
14 an application or holder of an approval for a drug under
15 section 505(b)(1), agree with the sponsor or holder for the
16 conduct of pediatric studies for such drug.

17 “(2) If the sponsor or holder and the Secretary agree
18 upon written protocols for such studies, the studies re-
19 quirement of subsection (a) or (b) is satisfied upon the
20 completion of the studies in accordance with the protocols
21 and the submission of the reports thereof to the Secretary.
22 Within 60 days after the submission of the report of the
23 studies, the Secretary shall determine if such studies were
24 or were not conducted in accordance with the written pro-

1 tocols and reported in accordance with the Secretary's re-
2 quirements for filing and so notify the sponsor or holder.

3 “(3) If the sponsor or holder and the Secretary have
4 not agreed in writing on the protocols for the studies, the
5 studies requirement of subsection (a) or (b) is satisfied
6 when such studies have been completed and the reports
7 accepted by the Secretary. Within 90 days after the sub-
8 mission of the reports of the studies, the Secretary shall
9 accept or reject such reports and so notify the sponsor
10 or holder. The Secretary's only responsibility in accepting
11 or rejecting the reports shall be to determine, within 90
12 days, that the studies fairly respond to the written re-
13 quest, that such studies have been conducted in accord-
14 ance with commonly accepted scientific principles and pro-
15 tocols, and that such studies have been reported in accord-
16 ance with the Secretary's requirements for filing.

17 “(4) As used in this section, ‘pediatric studies’ or
18 ‘studies’ means at least 1 human clinical investigation in
19 a population of adolescent age or younger. At the Sec-
20 retary's discretion, pharmacokinetic studies may be con-
21 sidered as clinical investigations.

22 “(d) If the Secretary determines that an approval of
23 an application under section 505(b)(2) or section 505(j)
24 for a drug may be made effective after submission of re-
25 ports of pediatric studies under this section but before the

1 Secretary has determined whether the requirements of
2 subsection (c) have been satisfied, the Secretary may delay
3 the effective date of any approval under section 505(b)(2)
4 or section 505(j), respectively, until the determination
5 under subsection (c) is made, but such delay shall not ex-
6 ceed 90 days. In the event that the requirements of this
7 section are satisfied, the 6-month period referred to in
8 subsection (a) or (b) shall be deemed to have begun on
9 the date an approval of an application under section
10 505(b)(2) or section 505(j), respectively, would have been
11 permitted absent action under this subsection.

12 “(e) The Secretary shall publish notice of any deter-
13 mination that the requirements of subsection (c)(2) or
14 (c)(3) have been met and that approvals for the drug will
15 be subject to deferred effective dates under this section.”.

16 **TITLE IV—RESEARCH ON**
17 **ENVIRONMENTAL RISKS**

18 **SEC. 401. ESTABLISHMENT OF INTERAGENCY PEDIATRIC**
19 **PROGRAM.**

20 Part B of title IV of the Public Health Service Act,
21 as amended by section 101 of this Act, is amended by add-
22 ing at the end the following section:

23 “INTERAGENCY PEDIATRIC RESEARCH REGARDING
24 ENVIRONMENTAL RISKS

25 “SEC. 409C. (a) IN GENERAL.—The Director of NIH
26 shall carry out a program for the conduct and support

1 of research with respect to factors in the environment that
2 affect the health of children differently than the factors
3 affect adults.

4 “(b) INTERAGENCY COOPERATION.—

5 “(1) AGENCIES OF NIH.—The program under
6 subsection (a) shall be carried out by the Director
7 of NIH in collaboration with the Director of the Na-
8 tional Institute of Child Health and Human Devel-
9 opment and the Director of the National Institute of
10 Environmental Health Sciences.

11 “(2) ENVIRONMENTAL PROTECTION AGENCY;
12 CENTERS FOR DISEASE CONTROL AND PREVEN-
13 TION.—In planning the program under subsection
14 (a), the Director of NIH shall consult with the Ad-
15 ministrator of the Environmental Protection Agency
16 and the Director of the Centers for Disease Control
17 and Prevention, including consultations regarding
18 priorities in research under the program. The Direc-
19 tor of NIH shall ensure that the results of projects
20 of research conducted or supported under the pro-
21 gram are reported to such agency heads.

22 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
23 purpose of carrying out this section, there are authorized

- 1 to be appropriated such sums as may be necessary for
- 2 each of the fiscal years 1998 through 2002.”.

○