

Union Calendar No. 2

113TH CONGRESS
1ST SESSION

H. R. 225

[Report No. 113-4]

To amend title IV of the Public Health Service Act to provide for a National Pediatric Research Network, including with respect to pediatric rare diseases or conditions.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 14, 2013

Mrs. CAPPS (for herself, Mrs. McMORRIS RODGERS, Ms. DEGETTE, Mr. HARPER, Ms. MATSUI, and Mr. KING of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce

FEBRUARY 4, 2013

Additional sponsors: Mrs. CHRISTENSEN, Ms. SCHAKOWSKY, Mr. WAXMAN, Mr. PALLONE, and Ms. CASTOR of Florida

FEBRUARY 4, 2013

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

A BILL

To amend title IV of the Public Health Service Act to provide for a National Pediatric Research Network, including with respect to pediatric rare diseases or conditions.

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 “National Pediatric Re-
5 search Network Act of 2013”.

6 **SEC. 2. NATIONAL PEDIATRIC RESEARCH NETWORK.**

7 Section 409D of the Public Health Service Act (42
8 U.S.C. 284h; relating to the Pediatric Research Initiative)
9 is amended—

10 (1) by redesignating subsection (d) as sub-
11 section (f); and

12 (2) by inserting after subsection (c) the fol-
13 lowing:

14 “(d) NATIONAL PEDIATRIC RESEARCH NETWORK.—

15 “(1) NETWORK.—In carrying out the Initiative,
16 the Director of NIH, acting through the Director of
17 the Eunice Kennedy Shriver National Institute of
18 Child Health and Human Development and in col-
19 laboration with other appropriate national research
20 institutes and national centers that carry out activi-
21 ties involving pediatric research, may provide for the
22 establishment of a National Pediatric Research Net-
23 work consisting of the pediatric research consortia
24 receiving awards under paragraph (2).

25 “(2) PEDIATRIC RESEARCH CONSORTIA.—

1 “(A) IN GENERAL.—The Director of the
2 Institute may award funding, including through
3 grants, contracts, or other mechanisms, to pub-
4 lic or private nonprofit entities—

5 “(i) for planning, establishing, or
6 strengthening pediatric research consortia;
7 and

8 “(ii) for providing basic operating
9 support for such consortia, including with
10 respect to—

11 “(I) basic, clinical, behavioral, or
12 translational research to meet unmet
13 needs for pediatric research; and

14 “(II) training researchers in pe-
15 diatric research techniques in order to
16 address unmet pediatric research
17 needs.

18 “(B) RESEARCH.—The Director of NIH
19 shall ensure that—

20 “(i) each consortium receiving an
21 award under subparagraph (A) conducts or
22 supports at least one category of research
23 described in subparagraph (A)(ii)(I) and
24 collectively such consortia conduct or sup-
25 port all such categories of research; and

1 “(ii) one or more such consortia pro-
2 vide training described in subparagraph
3 (A)(ii)(II).

4 “(C) NUMBER OF CONSORTIA.—The Direc-
5 tor of NIH may make awards under this para-
6 graph for not more than 20 pediatric research
7 consortia.

8 “(D) ORGANIZATION OF CONSORTIUM.—
9 Each consortium receiving an award under sub-
10 paragraph (A) shall—

11 “(i) be formed from a collaboration of
12 cooperating institutions;

13 “(ii) be coordinated by a lead institu-
14 tion;

15 “(iii) agree to disseminate scientific
16 findings, including from clinical trials, rap-
17 idly and efficiently; and

18 “(iv) meet such requirements as may
19 be prescribed by the Director of NIH.

20 “(E) SUPPLEMENT, NOT SUPPLANT.—Any
21 support received by a consortium under sub-
22 paragraph (A) shall be used to supplement, and
23 not supplant, other public or private support for
24 activities authorized to be supported under this
25 paragraph.

1 “(F) DURATION OF SUPPORT.—Support of
2 a consortium under subparagraph (A) may be
3 for a period of not to exceed 5 years. Such pe-
4 riod may be extended at the discretion of the
5 Director of NIH.

6 “(3) COORDINATION OF CONSORTIA ACTIVI-
7 TIES.—The Director of NIH shall—

8 “(A) as appropriate, provide for the coordi-
9 nation of activities (including the exchange of
10 information and regular communication) among
11 the consortia established pursuant to paragraph
12 (2); and

13 “(B) require the periodic preparation and
14 submission to the Director of reports on the ac-
15 tivities of each such consortium.

16 “(4) ASSISTANCE WITH REGISTRIES.—Each
17 consortium receiving an award under paragraph
18 (2)(A) shall provide assistance to the Centers for
19 Disease Control and Prevention in the establishment
20 or expansion of patient registries and other surveil-
21 lance systems as appropriate and upon request by
22 the Director of the Centers.

23 “(e) RESEARCH ON PEDIATRIC RARE DISEASES OR
24 CONDITIONS.—

1 “(1) IN GENERAL.—In making awards under
2 subsection (d)(2) for pediatric research consortia,
3 the Director of NIH shall ensure that an appro-
4 priate number of such awards are awarded to such
5 consortia that agree to—

6 “(A) focus primarily on pediatric rare dis-
7 eases or conditions (including any such diseases
8 or conditions that are genetic disorders (such as
9 spinal muscular atrophy and Duchenne mus-
10 cular dystrophy) or are related to birth defects
11 (such as Down syndrome and fragile X)); and

12 “(B) conduct or coordinate one or more
13 multisite clinical trials of therapies for, or ap-
14 proaches to, the prevention, diagnosis, or treat-
15 ment of one or more pediatric rare diseases or
16 conditions.

17 “(2) DATA COORDINATING CENTER.—

18 “(A) ESTABLISHMENT.—In connection
19 with support of consortia described in para-
20 graph (1), the Director of NIH shall establish
21 a data coordinating center for the following
22 purposes:

23 “(i) To distribute the scientific find-
24 ings referred to in paragraph (1)(C).

1 “(ii) To provide assistance in the de-
2 sign and conduct of collaborative research
3 projects and the management, analysis,
4 and storage of data associated with such
5 projects.

6 “(iii) To organize and conduct
7 multisite monitoring activities.

8 “(B) REPORTING.—The Director of NIH
9 shall—

10 “(i) require the data coordinating cen-
11 ter established under subparagraph (A) to
12 provide regular reports to the Director of
13 NIH and the Commissioner of Food and
14 Drugs on research conducted by consortia
15 described in paragraph (1), including infor-
16 mation on enrollment in clinical trials and
17 the allocation of resources with respect to
18 such research; and

19 “(ii) as appropriate, incorporate infor-
20 mation reported under clause (i) into the
21 Director’s biennial reports under section
22 403.”.

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