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(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R.

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

Mrs. CAPPS introduced the following bill; which was referred to the Committee
on _____

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”.

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

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

5 (1) by redesignating subsection (d) as sub-
6 section (f); and

7 (2) by inserting after subsection (e) the fol-
8 lowing:

9 “(d) NATIONAL PEDIATRIC RESEARCH NETWORK.—

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

20 “(2) PEDIATRIC RESEARCH CONSORTIA.—

21 “(A) IN GENERAL.—The Director of the
22 Institute may award funding, including through
23 grants, contracts, or other mechanisms, to pub-
24 lic or private nonprofit entities—

1 “(i) for planning, establishing, or
2 strengthening pediatric research consortia;
3 and

4 “(ii) for providing basic operating
5 support for such consortia, including with
6 respect to—

7 “(I) basic, clinical, behavioral, or
8 translational research to meet unmet
9 needs for pediatric research; and

10 “(II) training researchers in pe-
11 diatric research techniques in order to
12 address unmet pediatric research
13 needs.

14 “(B) RESEARCH.—The Director of NIH
15 shall ensure that—

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

22 “(ii) one or more such consortia pro-
23 vide training described in subparagraph
24 (A)(ii)(II).

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

5 “(D) ORGANIZATION OF CONSORTIUM.—
6 Each consortium receiving an award under sub-
7 paragraph (A) shall—

8 “(i) be formed from a collaboration of
9 cooperating institutions;

10 “(ii) be coordinated by a lead institu-
11 tion;

12 “(iii) agree to disseminate scientific
13 findings, including from clinical trials, rap-
14 idly and efficiently; and

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

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

23 “(F) DURATION OF SUPPORT.—Support of
24 a consortium under subparagraph (A) may be
25 for a period of not to exceed 5 years. Such pe-

1 riod may be extended at the discretion of the
2 Director of NIH.

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

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

10 “(B) require the periodic preparation and
11 submission to the Director of reports on the ac-
12 tivities of each such consortium.

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

20 “(e) RESEARCH ON PEDIATRIC RARE DISEASES OR
21 CONDITIONS.—

22 “(1) IN GENERAL.—In making awards under
23 subsection (d)(2) for pediatric research consortia,
24 the Director of NIH shall ensure that an appro-

1 appropriate number of such awards are awarded to such
2 consortia that agree to—

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

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

14 “(2) DATA COORDINATING CENTER.—

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

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

22 “(ii) To provide assistance in the de-
23 sign and conduct of collaborative research
24 projects and the management, analysis,

1 and storage of data associated with such
2 projects.

3 “(iii) To organize and conduct
4 multisite monitoring activities.

5 “(B) REPORTING.—The Director of NIH
6 shall—

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

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