

113TH CONGRESS  
1ST SESSION

# H. R. 225

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.

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## 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

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## 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 (c) 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.”.

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