

113TH CONGRESS  
1ST SESSION

# H. R. 225

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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “National Pediatric Re-  
3 search Network Act of 2013”.

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

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

8 (1) by redesignating subsection (d) as sub-  
9 section (f); and

10 (2) by inserting after subsection (c) the fol-  
11 lowing:

12 “(d) NATIONAL PEDIATRIC RESEARCH NETWORK.—

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

23 “(2) PEDIATRIC RESEARCH CONSORTIA.—

24 “(A) IN GENERAL.—The Director of the  
25 Institute may award funding, including through

1 grants, contracts, or other mechanisms, to pub-  
2 lic or private nonprofit entities—

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

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

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

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

16 “(B) RESEARCH.—The Director of NIH  
17 shall ensure that—

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

1 Director's biennial reports under section  
2 403.".

Passed the House of Representatives February 4,  
2013.

Attest:

*Clerk.*





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