

112TH CONGRESS  
2D SESSION

# H. R. 6163

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

JULY 19, 2012

Mrs. MCMORRIS RODGERS (for herself, Mrs. CAPPES, Mr. HARPER, Ms. DEGETTE, 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 2012”.

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 cooperative agreements  
23 and grants to public or private nonprofit enti-  
24 ties—

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.

12 “(B) RESEARCH.—The Director of NIH  
13 shall ensure that—

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

20 “(ii) one or more such consortia pro-  
21 vides training described in subparagraph  
22 (A)(ii)(II).

23 “(C) NUMBER OF CONSORTIA.—The Direc-  
24 tor of NIH may make awards under this para-

1 graph for not more than 20 pediatric research  
2 consortia.

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

6 “(i) be formed from a collaboration of  
7 cooperating institutions;

8 “(ii) be coordinated by a lead institu-  
9 tion; and

10 “(iii) meet such requirements as may  
11 be prescribed by the Director of NIH.

12 “(E) SUPPLEMENT, NOT SUPPLANT.—Any  
13 support received by a consortium under sub-  
14 paragraph (A) shall be used to supplement, and  
15 not supplant, other public or private support for  
16 activities authorized to be supported under this  
17 paragraph.

18 “(F) DURATION OF SUPPORT.—Support of  
19 a consortium under subparagraph (A) may be  
20 for a period of not to exceed 5 years. Such pe-  
21 riod may be extended by the Director of NIH  
22 for additional periods of not more than 5 years.

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

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

6           “(B) require the periodic preparation and  
7           submission to the Director of reports on the ac-  
8           tivities of each such consortium.

9           “(e) RESEARCH ON PEDIATRIC RARE DISEASES OR  
10          CONDITIONS.—

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

16           “(A) focus primarily on pediatric rare dis-  
17           eases or conditions (including any such diseases  
18           or conditions that are genetic disorders (such as  
19           spinal muscular atrophy and Duchenne mus-  
20           cular dystrophy) or are related to birth defects  
21           (such as Down syndrome and fragile X));

22           “(B) conduct or coordinate one or more  
23           multisite clinical trials of therapies for, or ap-  
24           proaches to, the prevention, diagnosis, or treat-

1           ment of one or more pediatric rare diseases or  
2           conditions; and

3           “(C) rapidly and efficiently disseminate  
4           scientific findings resulting from such trials.

5           “(2) DATA COORDINATING CENTER.—

6           “(A) ESTABLISHMENT.—In connection  
7           with support of consortia described in para-  
8           graph (1), the Director of NIH shall establish  
9           a data coordinating center for the following  
10          purposes:

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

13                  “(ii) To provide assistance in the de-  
14                  sign and conduct of collaborative research  
15                  projects and the management, analysis,  
16                  and storage of data associated with such  
17                  projects.

18                  “(iii) To organize and conduct  
19                  multisite monitoring activities.

20                  “(iv) To provide assistance to the  
21                  Centers for Disease Control and Preven-  
22                  tion in the establishment of patient reg-  
23                  istries.

24           “(B) REPORTING.—The Director of NIH  
25           shall—

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

10           “(ii) as appropriate, incorporate infor-  
11           mation reported under clause (i) into the  
12           Director’s biennial reports under section  
13           403.

14           “(3) DEFINITION.—In this subsection, the term  
15           ‘pediatric rare disease or condition’ means a rare  
16           disease or condition (as defined in section 526(a)(2)  
17           of the Federal Food, Drug, and Cosmetic Act) that  
18           affects pediatric populations.”.

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