

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6163

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IN THE SENATE OF THE UNITED STATES

SEPTEMBER 20, 2012

Received; read twice and referred to the Committee on Health, Education,  
Labor, and Pensions

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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 2012”.

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 and contracts, to public or private non-  
2 profit 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.

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; and

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

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

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

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

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

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

11          “(e) RESEARCH ON PEDIATRIC RARE DISEASES OR  
12          CONDITIONS.—

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

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

24                          “(B) conduct or coordinate one or more  
25                          multisite clinical trials of therapies for, or ap-

1 proaches to, the prevention, diagnosis, or treat-  
2 ment of one or more pediatric rare diseases or  
3 conditions; and

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

6 “(2) DATA COORDINATING CENTER.—

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

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

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

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

21 “(iv) To provide assistance to the  
22 Centers for Disease Control and Preven-  
23 tion in the establishment or expansion of  
24 patient registries and other surveillance  
25 systems.

1                   “(B) REPORTING.—The Director of NIH  
2                   shall—

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

12                  “(ii) as appropriate, incorporate infor-  
13                  mation reported under clause (i) into the  
14                  Director’s biennial reports under section  
15                  403.”.

                  Passed the House of Representatives September 19,  
2012.

Attest:

KAREN L. HAAS,

*Clerk.*