113TH CONGRESS 1ST SESSION

H.R. 225

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- | | | | | |
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| 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- |
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| 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- |
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| 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 |
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| 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 |
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| 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- |
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| 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 |

Director's biennial reports under section 403.".

Passed the House of Representatives February 4, 2013.

Attest:

Clerk.

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