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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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''National Pediatric Research Network Act of 2013''.

SEC. 2. NATIONAL PEDIATRIC RESEARCH NETWORK.

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

(1) by redesignating subsection (d) as subsection (f); and

(2) by inserting after subsection (c) the following:

''(d) NATIONAL PEDIATRIC RESEARCH NETWORK.—

''(1) NETWORK.—In carrying out the Initiative, the Director of NIH, acting through the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research, may provide for the establishment of a National Pediatric Research Network consisting of the pediatric research consortia receiving awards under paragraph (2).

''(2) PEDIATRIC RESEARCH CONSORTIA.—

''(A) IN GENERAL.—The Director of the Institute may award funding, including through grants, contracts, or other mechanisms, to public or private nonprofit entities—

"(i) for planning, establishing, or strengthening pediatric research consortia; and

"(ii) for providing basic operating support for such consortia, including with respect to—

"(I) basic, clinical, behavioral, or translational research to meet unmet needs for pediatric research; and

"(II) training researchers in pediatric research techniques in order to address unmet pediatric research needs.

"(B) RESEARCH.—The Director of NIH shall ensure that—

"(i) each consortium receiving an award under subparagraph (A) conducts or supports at least one category of research described in subparagraph (A)(ii)(I) and collectively such consortia conduct or support all such categories of research; and

"(ii) one or more such consortia provide training described in subparagraph (A)(ii)(II).

''(C) NUMBER OF CONSORTIA.—The Director of NIH may make awards under this paragraph for not more than 20 pediatric research consortia.

''(D) ORGANIZATION OF CONSORTIUM.—Each consortium receiving an award under subparagraph (A) shall—

''(i) be formed from a collaboration of cooperating institutions;

''(ii) be coordinated by a lead institution;

''(iii) agree to disseminate scientific findings, including from clinical trials, rapidly and efficiently; and

''(iv) meet such requirements as may be prescribed by the Director of NIH.

''(E) SUPPLEMENT, NOT SUPPLANT.—Any support received by a consortium under subparagraph (A) shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported under this paragraph.

''(F) DURATION OF SUPPORT.—Support of a consortium under subparagraph (A) may be for a period of not to exceed 5 years. Such pe-

riod may be extended at the discretion of the Director of NIH.

''(3) COORDINATION OF CONSORTIA ACTIVITIES.—The Director of NIH shall—

''(A) as appropriate, provide for the coordination of activities (including the exchange of information and regular communication) among the consortia established pursuant to paragraph (2); and

''(B) require the periodic preparation and submission to the Director of reports on the activities of each such consortium.

''(4) ASSISTANCE WITH REGISTRIES.—Each consortium receiving an award under paragraph (2)(A) shall provide assistance to the Centers for Disease Control and Prevention in the establishment or expansion of patient registries and other surveillance systems as appropriate and upon request by the Director of the Centers.

''(e) RESEARCH ON PEDIATRIC RARE DISEASES OR CONDITIONS.—

''(1) IN GENERAL.—In making awards under subsection (d)(2) for pediatric research consortia, the Director of NIH shall ensure that an appro-

priate number of such awards are awarded to such consortia that agree to—

"(A) focus primarily on pediatric rare diseases or conditions (including any such diseases or conditions that are genetic disorders (such as spinal muscular atrophy and Duchenne muscular dystrophy) or are related to birth defects (such as Down syndrome and fragile X)); and

"(B) conduct or coordinate one or more multisite clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of one or more pediatric rare diseases or conditions.

"(2) DATA COORDINATING CENTER.—

"(A) ESTABLISHMENT.—In connection with support of consortia described in paragraph (1), the Director of NIH shall establish a data coordinating center for the following purposes:

"(i) To distribute the scientific findings referred to in paragraph (1)(C).

"(ii) To provide assistance in the design and conduct of collaborative research projects and the management, analysis,

and storage of data associated with such projects.

"(iii) To organize and conduct multisite monitoring activities.

"(B) REPORTING.—The Director of NIH shall—

"(i) require the data coordinating center established under subparagraph (A) to provide regular reports to the Director of NIH and the Commissioner of Food and Drugs on research conducted by consortia described in paragraph (1), including information on enrollment in clinical trials and the allocation of resources with respect to such research; and

"(ii) as appropriate, incorporate information reported under clause (i) into the Director's biennial reports under section 403.".

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