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# NATIONAL PEDIATRIC RESEARCH NETWORK ACT OF 2013

FEBRUARY 4, 2013.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

# R E P O R T

[To accompany H.R. 225]

The Committee on Energy and Commerce, to whom was referred the bill (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, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

CONTENTS

| | Page |
|---|---|
| Purpose and Summary | 1 |
| Background and Need for Legislation | 2 |
| Hearings | 2 |
| Committee Consideration | 2 |
| Committee Votes | 3 |
| Committee Oversight Findings | 3 |
| Statement of General Performance Goals and Objectives | 3 |
| New Budget Authority, Entitlement Authority, and Tax Expenditures | 3 |
| Earmark, Limited Tax Benefits, and Limited Tariff Benefits | 3 |
| Committee Cost Estimate | 3 |
| Congressional Budget Office Estimate | 3 |
| Federal Mandates Statement | 4 |
| Duplication of Federal Programs | 4 |
| Disclosure of Directed Rule Makings | 4 |
| Advisory Committee Statement | 4 |
| Applicability to Legislative Branch | 4 |
| Section-by-Section Analysis of the Legislation | 4 |
| Changes in Existing Law Made by the Bill, as Reported | 5 |

## PURPOSE AND SUMMARY

H.R. 225, the "National Pediatric Research Network Act of 2013," was introduced on January 14, 2013, by Rep. Lois Capps (D-CA) and referred to the Committee on Energy and Commerce.

The legislation would amend the Public Health Service Act (PHSA) to allow the Director of the National Institutes of Health (NIH), as part of the NIH Pediatric Research Initiative, to provide for the establishment of a National Pediatric Research Network comprised of pediatric research consortia. The purpose of such consortia is to promote coordinated, multi-centered research activities that focus on translating research to practice in order to improve care for children.

## BACKGROUND AND NEED FOR LEGISLATION

According to NIH, some 6,000 to 7,000 human diseases are considered "rare," affecting 25 to 30 million people.[1] Most of these are pediatric diseases. Unfortunately, doctors do not have sufficient therapies to treat them. The use of pediatric research consortia is a proven way to support pediatric applied research and promote coordinated research activities that focus on translating research to practice. Such efforts, in turn, can improve the health and well-being of those children afflicted with rare pediatric diseases and conditions.

H.R. 225, the "National Pediatric Research Network Act of 2013," would amend the PHSA to allow the Director of the NIH, (acting through the Director of the National Institute of Child Health and Human Development) to provide for the establishment of a national pediatric research network. Such network would be comprised of up to 20 pediatric research consortia. Each consortium would include groups of collaborating institutions coordinated by a lead institution. Among these consortia, an appropriate number must be focused primarily on addressing pediatric rare diseases and conditions.

The Director could provide funding to plan, establish, or strengthen pediatric research consortia and to provide for basic operating support for such consortia, including training for researchers specializing in pediatrics. Funding support would be available through grants, contracts or other appropriate funding mechanisms.

H.R. 225 would also require the NIH Director to establish a data coordinating center related to the work of the consortia. The purpose of the center is threefold: to distribute scientific findings of the consortia; to provide assistance in the design and conduct of collaborative research; and to organize and conduct multistate monitoring activities. No funds are specifically allocated under the legislation. It is the Committee's expectation that the NIH Director will choose to create the network with existing funds and build upon the current portfolio of pediatric research at NIH.

## HEARINGS

No hearings were held on this legislation.

## COMMITTEE CONSIDERATION

On January 22, 2012, the Energy and Commerce Committee met in open markup session and approved H.R. 225, the "National Pediatric Research Network Act of 2013," by unanimous consent.

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[1] http://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=126

## COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 225 reported. A motion by Mr. Upton to order H.R. 225 reported to the House, without amendment, was agreed to by unanimous consent.

## COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight hearings on this legislation.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of the legislation is the establishment of a National Pediatric Research Network comprised of pediatric research consortia to advance treatment for pediatric diseases.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 225, the "National Pediatric Research Network Act of 2013," would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 225, "National Pediatric Research Network Act of 2013", contains no earmarks, limited tax benefits, or limited tariff benefits.

## COMMITTEE COST ESTIMATE

The Committee traditionally adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office (CBO) pursuant to section 402 of the Congressional Budget Act of 1974. Because this cost estimate was not timely submitted to the Committee before the filing of this report, the Committee adopts the informal cost estimate provided to the Committee by CBO. Based on verbal conversations with CBO, H.R. 225 will have no effect on direct spending. CBO also estimates the bill will cost $1 million for FY 2013–2018 for agency workload costs.

The Committee notes that CBO also provided an informal cost estimate to the Committee during the 112th Congress for H.R. 6163, the "National Pediatric Research Network Act of 2012." According to that informal cost estimate, H.R. 6163 had no cost.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

The cost estimate required pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, which is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974, was not timely

submitted to the Committee before the filing of this report, and therefore, not included in this report.

## FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

## DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 225 establishes or reauthorizes a program of the Federal government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

## DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that H.R. 225 specifically directs to be completed no specific rule makings within the meaning of 5 U.S.C. 551.

## ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

## APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

*Section 1. Short title*

Section 1 states the legislation may be cited as the "National Pediatric Research Network Act of 2013."

*Section 2. National Pediatric Research Network*

Section 2 would amend section 409D of the PHSA to allow the Director of NIH, acting through the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, to provide for the establishment of a National Pediatric Research Network comprised of pediatric research consortia. The number of pediatric research consortia could not exceed twenty. Among these, an appropriate number of consortia must have a primary focus on pediatric rare diseases or conditions.

Section 2 would also require the NIH Director to establish a data coordinating center related to the consortia to distribute scientific findings from the consortia, to provide assistance in the design and conduct of collaborative research, and to organize and conduct multistate monitoring activities. The center also would provide regular reports to the Director of NIH and the Commissioner of the Food and Drugs Administration on the work of the consortia.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

## PUBLIC HEALTH SERVICE ACT

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## TITLE IV—NATIONAL RESEARCH INSTITUTES

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### PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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PEDIATRIC RESEARCH INITIATIVE

SEC. 409D. (a) * * *

* * * * * * *

*(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 period 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 appropriate 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.*

**[**(d)**]** *(f)* TRANSFER OF FUNDS.—The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

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