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HOUSE OF REPRESENTATIVES
REPORT
111–640

PEDIATRIC RESEARCH CONSORTIA ESTABLISHMENT ACT

SEPTEMBER 28, 2010.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 758]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 758) to amend title IV of the Public Health Service Act to provide for the establishment of pediatric research consortia, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pediatric Research Consortia Establishment Act".

SEC. 2. NATIONAL PEDIATRIC RESEARCH CONSORTIA.

Subpart 7 of part C of title IV of the Public Health Service Act (42 U.S.C. 285g et seq.) is amended by adding at the end the following:

"SEC. 452H. NATIONAL PEDIATRIC RESEARCH CONSORTIA.

"(a) IN GENERAL.—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 all other Institutes of the National Institutes of Health that support pediatric research, may, subject to the availability of funds, award grants, contracts, or cooperative agreements to public or nonprofit private entities to pay all or part of the cost of planning, establishing, and providing basic operating support for up to 20 national pediatric research consortia. The Director of NIH shall take unmet research needs into account when making awards under this section.

"(b) RESEARCH.—Research conducted under this section shall supplement, but not replace, research that is otherwise conducted or supported as part of the comprehensive pediatric research portfolio of entities receiving awards under subsection (a). Consortia established under subsection (a) shall, in the aggregate, conduct basic, clinical, behavioral, social, or translational research to meet unmet research needs, as well as training in and demonstration of advanced diagnostic and treatment methods relating to pediatrics, as appropriate.

"(c) COORDINATION OF CONSORTIA REPORTS.—The Director of NIH shall—

"(1) as appropriate, provide for the coordination of information among consortia established under subsection (a) and ensure regular communication between such consortia; and

"(2) require the periodic preparation of reports on the activities of the consortia and the submission of the reports to the Director.

"(d) ORGANIZATION OF CONSORTIUM.—Each consortium established under subsection (a) shall be formed from a collaboration of cooperating institutions with a lead institution, meeting such requirements as may be prescribed by the Director of NIH, including participation in a network of such consortia.

"(e) LIMITATION.—Payments under subsection (a) shall not exceed $2,500,000 per year for each consortium in the first 5-year cycle.

"(f) DURATION OF PAYMENTS.—Payments under subsection (a) for a consortium may be provided under this section for a period of 5 years and may be extended for additional periods of 5 years each, with enhanced funding opportunities based on a review of the operations by an appropriate scientific review.".

PURPOSE AND SUMMARY

H.R. 758, the "Pediatric Research Consortia Establishment Act", was introduced on January 28, 2009, by Rep. Diana DeGette (D–CO), and referred to the Committee on Energy and Commerce.

The goal of H.R. 758 is to authorize the creation of up to 20 pediatric research consortia focused on diseases that affect children. The bill allows the Director of the National Institutes of Health to establish pediatric research consortia across the country to help focus and coordinate research on pediatric diseases.

BACKGROUND AND NEED FOR LEGISLATION

There is growing evidence that the relationship between health and disease begins before birth and during the pediatric years. There are very few institutions dedicating resources specifically to pediatric research. A network of consortia is a proven mechanism that will promote efficiency and collaboration at all levels of pediatric research, and provide patients and institutions new access to relevant, disease-specific research.

COMMITTEE CONSIDERATION

H.R. 758, the "Pediatric Research Consortia Establishment Act", was introduced by Ms. DeGette of Colorado on January 28, 2009, and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on February 2, 2009. On September 15, 2010, the Subcommittee held a legislative hearing on the bill. The Subcommittee met in open markup session to consider H.R. 758 on September 16, 2010. An amendment in the nature of a substitute (manager's amendment) by Ms. DeGette was adopted by a voice vote. Subsequently, H.R. 758 was favorably forwarded to the full Committee, amended, by a voice vote.

On September 23, 2010, the Committee on Energy and Commerce met in open markup session and considered H.R. 758 as approved by the Subcommittee. There were no amendments offered in full Committee and subsequently the Committee ordered H.R. 758 favorably reported to the House, as amended by the Subcommittee on Health, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. A motion by Mr. Waxman ordering H.R. 758 reported to the House, as amended, was approved by a voice vote. There were no record votes taken during consideration of this bill.

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII and clause (2)(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portions of this report, including the finding that a network of consortia will help coordinate research on pediatric illnesses.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 758 would result in no new budget authority, entitlement authority, or tax expenditures or revenues.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report, including the goal to support pediatric research efforts.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional au-

thority for H.R. 758 is provided under article I, section 8, clauses 3 and 18 of the Constitution of the United States.

EARMARKS AND TAX AND TARIFF BENEFITS

H.R. 758 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI of the Rules of the House of Representatives.

FEDERAL ADVISORY COMMITTEE STATEMENT

The Committee finds that the legislation does not establish or authorize the establishment of an advisory committee within the definition of 5 U.S.C. App., section 5(b) of the Federal Advisory Committee Act.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1 requires a description of the application of this bill to the legislative branch where the bill relates to terms and conditions of employment or access to public services and accommodations. H.R. 758 contains no such provisions.

FEDERAL MANDATES STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act of 1974 (as amended by section 101(a)(2) of the Unfunded Mandates Reform Act, Public Law 104–4) requires a statement on whether the provisions of the report include unfunded mandates. In compliance with this requirement the Committee adopts as its own the analysis of federal mandates prepared by the Director of the Congressional Budget Office regarding H.R. 758.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the cost estimate of H.R. 758 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

With respect to the requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 758 from the Director of Congressional Budget Office:

SEPTEMBER 24, 2010.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 758, the Pediatric Research Consortia Establishment Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Jamease Kowalczyk.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 758—Pediatric Research Consortia Establishment Act

Summary: H.R. 758 would authorize the Director of the National Institutes of Health (NIH) to provide funding to plan, establish, and operate national consortia to conduct and coordinate research on pediatric health issues. CBO estimates that implementing H.R. 758 would cost $168 million over the 2011–2015 period, assuming appropriation of the necessary amounts. Enacting H.R. 758 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 758 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 758 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2011	2012	2013	2014	2015	2011–2015
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	5	25	50	50	50	180
Estimated Outlays	4	20	44	50	50	168

Basis of estimate: For this estimate, CBO assumes that H.R. 758 will be enacted near the beginning of fiscal year 2011 and that the necessary amounts will be appropriated each year. The bill would authorize the Director of NIH to make grants to, or enter into contracts or cooperative agreements with entities to plan, establish and operate up to 20 consortia to conduct and coordinate research on pediatric health issues. The bill would limit payments to each consortium to $2.5 million a year during the first five years of the program. Based on the experience of establishing consortia for the National Network for Transforming Clinical and Translational Research, the estimate assumes that about 10 consortia would receive funding in 2012 and 20 would receive funding in 2013 and subsequent years. Assuming the appropriation of the necessary amounts, CBO estimates that implementing H.R. 758 would cost $4 million in fiscal year 2011 and $168 million over the 2011–2015 period.

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 758 contains no intergovernmental or private-sector mandates as defined in UMRA. Activities authorized in the bill would benefit public entities that plan, establish, and operate consortia that conduct pediatric research.

Estimate prepared by: Federal costs: Jamease Kowalczyk; Impact on state, local, and tribal governments: Lisa Ramirez-Branum; Impact on the private sector: Sarah Axeen.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the Act may be cited as the "Pediatric Research and Consortia Act".

Section 2. National Pediatric Research Consortia

Section 2 amends the Public Health Service Act to authorize the Director of the National Institutes of Health (NIH), acting through the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and in collaboration with all other NIH institutes that support pediatric research, to award grants to, or enter into contracts or cooperative agreements with, public or nonprofit private entities to establish up to 20 national pediatric research consortia.

EXPLANATION OF AMENDMENTS

During the Subcommittee on Health markup of H.R. 758, Ms. DeGette of Colorado offered an amendment in the nature of a substitute (manager's amendment), which was adopted by a voice vote. The substance of the substitute amendment is reflected in the section-by-section analysis contained in this report.

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 (new matter is printed in italic and 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 C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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Subpart 7—Eunice Kennedy Shriver National Institute of Child Health and Human Development

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SEC. 452H. NATIONAL PEDIATRIC RESEARCH CONSORTIA.

(a) IN GENERAL.—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 all other Institutes of the National Institutes of Health that support pediatric research, may, subject to the availability of funds, award grants, contracts, or cooperative agreements to public or nonprofit private entities to pay all or part of the cost of planning, establishing, and providing basic operating support for up to 20 national pediatric re-

search consortia. The Director of NIH shall take unmet research needs into account when making awards under this section.

(b) RESEARCH.—Research conducted under this section shall supplement, but not replace, research that is otherwise conducted or supported as part of the comprehensive pediatric research portfolio of entities receiving awards under subsection (a). Consortia established under subsection (a) shall, in the aggregate, conduct basic, clinical, behavioral, social, or translational research to meet unmet research needs, as well as training in and demonstration of advanced diagnostic and treatment methods relating to pediatrics, as appropriate.

(c) COORDINATION OF CONSORTIA REPORTS.—The Director of NIH shall—

(1) as appropriate, provide for the coordination of information among consortia established under subsection (a) and ensure regular communication between such consortia; and

(2) require the periodic preparation of reports on the activities of the consortia and the submission of the reports to the Director.

(d) ORGANIZATION OF CONSORTIUM.—Each consortium established under subsection (a) shall be formed from a collaboration of cooperating institutions with a lead institution, meeting such requirements as may be prescribed by the Director of NIH, including participation in a network of such consortia.

(e) LIMITATION.—Payments under subsection (a) shall not exceed $2,500,000 per year for each consortium in the first 5-year cycle.

(f) DURATION OF PAYMENTS.—Payments under subsection (a) for a consortium may be provided under this section for a period of 5 years and may be extended for additional periods of 5 years each, with enhanced funding opportunities based on a review of the operations by an appropriate scientific review.

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