

111TH CONGRESS } HOUSE OF REPRESENTATIVES {
 2d Session REPORT
 111-631

SCLERODERMA RESEARCH AND AWARENESS ACT OF 2010

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. 2408]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2408) to expand the research and awareness activities of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the Centers for Disease Control and Prevention with respect to scleroderma, and for other purposes, 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 “Scleroderma Research and Awareness Act of 2010”.

SEC. 2. NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; SCLERODERMA RESEARCH EXPANSION.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

“SEC. 409K. SCLERODERMA RESEARCH.

“The Director of NIH may expand, intensify, and coordinate the activities of the National Institutes of Health with respect to scleroderma, with particular emphasis on the following:

“(1) Research focused on the etiology of scleroderma and the development of new treatment options.

“(2) Clinical research to evaluate new treatments options.

“(3) Basic research on the relationship between scleroderma and secondary conditions such as pulmonary hypertension, gastroparesis, Raynaud’s phenomenon, Sjögren’s Syndrome, and other diseases as determined by the Director.”.

SEC. 3. PROMOTING PUBLIC AWARENESS OF SCLERODERMA.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

“SEC. 399V-5. PROMOTING PUBLIC AWARENESS OF SCLERODERMA.

“The Secretary may carry out an educational campaign to increase public awareness of scleroderma. Print, video, and Web-based materials distributed through this campaign may include—

“(1) basic information on scleroderma and its symptoms; and

“(2) information on—

“(A) the incidence and prevalence of scleroderma;

“(B) diseases and conditions affiliated with scleroderma; or

“(C) the importance of early diagnosis and treatment of scleroderma.”.

PURPOSE AND SUMMARY

H.R. 2408, the “Scleroderma Research and Awareness Act of 2010”, was introduced by Rep. Lois Capps (D-CA) on May 14, 2010, and referred to the Committee on Energy and Commerce.

The goal of H.R. 2408 is to address the need for research on scleroderma, a chronic systemic autoimmune disease.

BACKGROUND AND NEED FOR LEGISLATION

Scleroderma is a chronic connective tissue disease that can involve changes in the skin, blood vessels, muscles, and internal organs. An estimated 300,000 people in the United States have scleroderma. The exact cause or causes of scleroderma are still unknown and there is no cure, necessitating more research into and awareness of this disease.

COMMITTEE CONSIDERATION

H.R. 2408, the “Scleroderma Research and Awareness Act of 2010”, was introduced by Mrs. Capps of California on May 14, 2010, and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on May 15, 2010. On September 15, 2010, the Subcommittee held a legislative hearing on the bill. The Subcommittee met in open markup session to consider H.R. 2408 on September 16, 2010. An

amendment in the nature of a substitute (manager's amendment) by Mrs. Capps of California was adopted by a voice vote. Subsequently, H.R. 2408 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. 2408 as approved by the Subcommittee on Health. There were no amendments offered in full Committee and subsequently the Committee ordered H.R. 2408 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. Pallone ordering H.R. 2408 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 there is a need for increased research on and awareness of scleroderma.

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. 2408 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 of increasing research on and awareness of scleroderma.

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 authority for H.R. 2408 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. 2408 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. 2408 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. 2408.

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. 2408 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. 2408 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. 2408, the Scleroderma Research and Awareness Act of 2010.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Jamease Kowalczyk and Stephanie Cameron.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 2408—Scleroderma Research and Awareness Act of 2010

Summary: H.R. 2408 would encourage the Director of the National Institutes of Health (NIH) to expand, intensify, and coordi-

nate scleroderma research activities. It also would authorize the Secretary of Health and Human Services (HHS) to conduct an educational campaign to increase public awareness of scleroderma. CBO estimates that implementing H.R. 2408 would cost \$12 million over the 2011–2015 period, assuming appropriation of the necessary amounts. Enacting H.R. 2408 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 2408 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. 2408 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	3	5	4	0	0	12
Estimated Outlays	1	3	4	3	1	12

Basis of estimate: For this estimate, CBO assumes that H.R. 2408 will be enacted near the beginning of fiscal year 2011 and that the necessary amounts will be appropriated each year. The bill would encourage the Director of NIH to expand, intensify, and coordinate scleroderma-related activities with a focus on the etiology and development of new treatments for scleroderma, clinical research for new treatment options, and basic research on the relationship between scleroderma and secondary conditions. Currently, those activities are underway at NIH, so implementing those provisions would have no budgetary effect.

H.R. 2408 also would authorize the Secretary of HHS to conduct an educational campaign through print, video, and Web-based materials to increase public awareness of scleroderma. Based on spending by the Centers for Disease Control and Prevention for similar activities, CBO estimates that implementing H.R. 2408 would cost \$1 million in 2011 and \$12 million over the 2011–2015 period.

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 2408 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Stephanie Cameron and Jamease Kowalczyk; **Impact on state, local, and tribal governments:** Lisa Ramirez-Branum; **Impact on the private sector:** Jimmy Jin.

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 “Scleroderma Research and Awareness Act of 2010”.

Section 2. National Institute of Arthritis and Musculoskeletal and Skin Diseases; Scleroderma research expansion

Section 2 amends the Public Health Services Act (PHSA) to authorize the Director of the National Institutes of Health (NIH) to expand, intensify, and coordinate the activities of NIH with respect to scleroderma.

Section 3. Promoting public awareness of scleroderma

Section 3 amends the PHSA to authorize the Secretary of Health and Human Services to carry out an educational campaign to increase public awareness of scleroderma.

EXPLANATION OF AMENDMENT

During the Subcommittee on Health markup of H.R. 2408, Mrs. Capps of California offered an amendment in the nature of a substitute (manager), 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 italics and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

**TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC
HEALTH SERVICE**

* * * * *

PART P—ADDITIONAL PROGRAMS

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SEC. 399V-5. PROMOTING PUBLIC AWARENESS OF SCLERODERMA.

The Secretary may carry out an educational campaign to increase public awareness of scleroderma. Print, video, and Web-based materials distributed through this campaign may include—

- (1) basic information on scleroderma and its symptoms; and
- (2) information on—
 - (A) the incidence and prevalence of scleroderma;
 - (B) diseases and conditions affiliated with scleroderma; or
 - (C) the importance of early diagnosis and treatment of scleroderma.

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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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SEC. 409K. SCLERODERMA RESEARCH.

The Director of NIH may expand, intensify, and coordinate the activities of the National Institutes of Health with respect to scleroderma, with particular emphasis on the following:

- (1) *Research focused on the etiology of scleroderma and the development of new treatment options.*
- (2) *Clinical research to evaluate new treatments options.*
- (3) *Basic research on the relationship between scleroderma and secondary conditions such as pulmonary hypertension, gastroparesis, Raynaud's phenomenon, Sjögren's Syndrome, and other diseases as determined by the Director.*

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