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1st Session
HOUSE OF REPRESENTATIVES
REPORT
110–379

ALS REGISTRY ACT

OCTOBER 15, 2007.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

REPORT

[To accompany H.R. 2295]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2295) to amend the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis Registry, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

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 "ALS Registry Act".

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Amyotrophic lateral sclerosis (referred to in this section as "ALS") is a fatal, progressive neurodegenerative disease that affects motor nerve cells in the brain and the spinal cord.

(2) The average life expectancy for a person with ALS is 2 to 5 years from the time of diagnosis.

(3) The cause of ALS is not well understood.

(4) There is only one drug currently approved by the Food and Drug Administration for the treatment of ALS, which has thus far shown only modest effects, prolonging life by just a few months.

(5) There is no known cure for ALS.

(6) More than 5,000 individuals in the United States are diagnosed with ALS annually and as many as 30,000 individuals may be living with ALS in the United States today.

(7) Studies have found relationships between ALS and environmental and genetic factors, but those relationships are not well understood.

(8) Scientists believe that there are significant ties between ALS and other motor neuron diseases.

(9) Several ALS disease registries and databases exist in the United States and throughout the world, including the SOD1 database, the National Institute of Neurological Disorders and Stroke repository, and the Department of Veterans Affairs ALS Registry.

(10) A single national system to collect and store information on the prevalence and incidence of ALS in the United States does not exist.

(11) In each of fiscal years 2006 and 2007, Congress directed $887,000 to the Centers for Disease Control and Prevention to begin a nationwide ALS registry.

(12) The Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry have established three pilot projects, beginning in fiscal year 2006, to evaluate the science to guide the creation of a national ALS registry.

(13) The establishment of a national registry will help—

(A) to identify the incidence and prevalence of ALS in the United States;

(B) to collect data important to the study of ALS;

(C) to promote a better understanding of ALS;

(D) to collect information that is important for research into the genetic and environmental factors that cause ALS;

(E) to strengthen the ability of a clearinghouse—

(i) to collect and disseminate research findings on environmental, genetic, and other causes of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS;

(ii) to make available information to patients about research studies for which they may be eligible; and

(iii) to maintain information about clinical specialists and clinical trials on therapies; and

(F) to enhance efforts to find treatments and a cure for ALS.

SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

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. 399R. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY.

"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—Not later than 1 year after the receipt of the report described in subsection (b)(3), the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with a national voluntary health organization with experience serving the population of individuals with amyotrophic lateral sclerosis (referred to in this section as 'ALS'), shall—

"(A) develop a system to collect data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

“(B) establish a national registry for the collection and storage of such data to include a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

“(2) PURPOSE.—It is the purpose of the registry established under paragraph (1)(B) to gather available data concerning—

“(A) ALS, including the incidence and prevalence of ALS in the United States;

“(B) the environmental and occupational factors that may be associated with the disease;

“(C) the age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease;

“(D) other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

“(E) other matters as recommended by the Advisory Committee established under subsection (b).

“(b) ADVISORY COMMITTEE.—

“(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the ‘Advisory Committee’). The Advisory Committee shall be composed of at least one member, to be appointed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention, representing each of the following:

“(A) National voluntary health associations that focus solely on ALS and have demonstrated experience in ALS research, care, and patient services, as well as other voluntary associations focusing on neurodegenerative diseases that represent and advocate on behalf of patients with ALS and patients with other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

“(B) The National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences.

“(C) The Department of Veterans Affairs.

“(D) The Agency for Toxic Substances and Disease Registry.

“(E) The Centers for Disease Control and Prevention.

“(F) Patients with ALS or their family members.

“(G) Clinicians with expertise on ALS and related diseases.

“(H) Epidemiologists with experience in data registries.

“(I) Geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases.

“(J) Statisticians.

“(K) Ethicists.

“(L) Attorneys.

“(M) Other individuals with an interest in developing and maintaining the National ALS Registry.

“(2) DUTIES.—The Advisory Committee shall review information and make recommendations to the Secretary concerning—

“(A) the development and maintenance of the National ALS Registry;

“(B) the type of information to be collected and stored in the Registry;

“(C) the manner in which such data is to be collected;

“(D) the use and availability of such data including guidelines for such use; and

“(E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

“(3) REPORT.—Not later than 1 year after the date on which the Advisory Committee is established, the Advisory Committee shall submit a report concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

“(c) GRANTS.—Notwithstanding the recommendations of the Advisory Committee under subsection (b), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

"(d) COORDINATION WITH STATE, LOCAL, AND FEDERAL REGISTRIES.—

"(1) IN GENERAL.—In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

"(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, including—

"(i) the 3 ALS registry pilot projects initiated in fiscal year 2006 by the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry at the South Carolina Office of Research & Statistics; the Mayo Clinic in Rochester, Minnesota; and Emory University in Atlanta, Georgia;

"(ii) the Department of Veterans Affairs ALS Registry;

"(iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center;

"(iv) the Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

"(v) State-based ALS registries, including the Massachusetts ALS Registry;

"(vi) the National Vital Statistics System; and

"(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

"(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

"(2) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Notwithstanding the recommendations of the Advisory Committee established in subsection (b), and consistent with applicable privacy statutes and regulations, the Secretary shall ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

"(e) DEFINITION.—For the purposes of this section, the term 'national voluntary health association' means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $25,000,000 for fiscal year 2008, and $16,000,000 for each of the fiscal years 2009 through 2012.".

PURPOSE AND SUMMARY

The purpose of H.R. 2295, the ALS Registry Act, is to provide for the creation and maintenance of a single nationwide Amyotrophic Lateral Sclerosis (ALS) Registry at the Centers for Disease Control and Prevention (CDC). The registry would collect key data and information as determined by a newly created Federal Advisory Committee on the National ALS Registry.

BACKGROUND AND NEED FOR LEGISLATION

Amyotrophic Lateral Sclerosis, also known as Lou Gehrig's disease, is a fatal, progressive neurodegenerative disease that affects motor nerve cells in the brain and spinal cord. Approximately 5,600 people in the U.S. are diagnosed with ALS each year, and it is estimated that as many as 30,000 Americans have the disease at any given time. The average life expectancy for a person with ALS is two to five years from the time of diagnosis. The causes of ALS are not well understood, and there is no known cure.

In fiscal year 2006, Congress directed nearly $1 million to CDC to begin a National ALS Registry. This funding has enabled the Centers for Disease Control and Prevention's Agency for Toxic Substances and Disease Registry to launch three registry pilot projects, which are evaluating the science to guide the creation of a National ALS Registry.

A single national patient registry that collects and stores information on the prevalence and incidence of ALS does not exist in the United States today. The establishment of a national registry will help identify the incidence and prevalence of ALS and other related motor neuron disorders in the United States as well as the etiology of the diseases. The patient registry would collect data that is urgently needed for ALS research, disease management, and the development of standards of care in order to significantly enhance the Nation's efforts to find a treatment and cure for ALS and other related motor neuron disorders.

HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On Thursday, July 19, 2007, the Subcommittee on Health met in open markup session and ordered H.R. 2295 favorably forwarded to the full Committee, amended, by a voice vote. On Thursday, September 27, 2007, the full Committee met in open markup session and ordered H.R. 2295 favorably reported to the House, as amended by the Subcommittee, by a voice vote. No amendments were offered during full Committee consideration.

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 recorded votes taken during consideration or in ordering reported H.R. 2295 to the House. A motion by Mr. Dingell to order H.R. 2295 favorably reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the oversight findings of the Committee are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

H.R. 2295 would require the Secretary of Health and Human Services, acting through the Director of CDC, (1) to develop a system to collect data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, or progress to ALS; and (2) to establish a national registry for the collection and storage of such data.

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. 2295 would result in no new or increased budget authority, entitlement authority, or tax expenditures.

EARMARKS AND TAX AND TARIFF BENEFITS

In compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 2295 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

OCTOBER 4, 2007.

Hon. JOHN D. DINGELL,
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. 2295, the ALS Registry Act.

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

Sincerely,

PETER R. ORSZAG.

Enclosure.

H.R. 2295—ALS Registry Act

H.R. 2295 would modify the Public Health Service Act to authorize funding for the establishment of a national registry for the collection and storage of data on amyotrophic lateral sclerosis (ALS). It would authorize the appropriation of $25 million for 2008 and $16 million a year over the 2009–2012 period for the Centers for Disease Control and Prevention for those activities. Based on historical patterns of spending for similar activities, CBO estimates that implementing H.R. 2295 would cost $10 million in 2008 and $75 million over the 2008–2012 period, assuming appropriation of the authorized amounts. Enacting the bill would not affect direct spending or revenues.

H.R. 2295 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act. Grants and other activities authorized in the bill to collect, analyze, and report data on ALS would benefit state and local governments.

The estimated budgetary impact of H.R. 2295 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars				
	2008	2009	2010	2011	2012
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Authorization Level	25	16	16	16	16
Estimated Outlays	10	17	16	16	16

The CBO staff contact for this estimate is Tim Gronniger. This estimate was approved by Keith J. Fontenot, Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.

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.

ADVISORY COMMITTEE STATEMENT

Regarding section 5(b) of the Federal Advisory Committee Act, H.R. 2295 requires the Secretary of Health and Human Services, acting through CDC, to establish an advisory committee regarding the national ALS registry that would be established pursuant to the bill. The Committee finds that establishing the advisory committee is the most efficient way of carrying out the policies involved.

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 this legislation is provided in the provisions of Article I, section 8, clause 1, that relate to expending funds to provide for the general welfare of the United States.

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 establishes the short title of the Act as the “ALS Registry Act”.

Section 2. Findings

Section 2 sets out the findings of the Act.

Section 3. Amendment to the Public Health Service Act

Section 3 amends the Public Health Service Act by adding a new Section to require the Secretary of Health and Human Services, acting through the Director of CDC, to: (1) develop a system to collect data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, or progress to ALS; and (2) establish a national registry for the collection and storage of such data.

It requires the Secretary, acting through the Director of CDC, to establish the Advisory Committee on the National ALS Registry to review information and make recommendations to the Secretary concerning: (1) the development and maintenance of the registry; (2) the type of information to be included; (3) the manner in which data is to be collected; (4) the use and availability of such data; and (5) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

Allows the Secretary, acting through the Director of CDC, to award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders.

Requires the Secretary, acting through the Director of CDC, to: (1) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible; and (2) provide for research access to ALS data as recommended by the Advisory Committee in a manner that protects personal privacy.

The term "national voluntary health association" is defined.

Authorizes to be appropriated to carry out this section $25,000,000 for fiscal year 2008, and $16,000,000 for each of the fiscal years 2009 through 2012.

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 III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART P—ADDITIONAL PROGRAMS

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SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 1 year after the receipt of the report described in subsection (b)(3), the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with a national voluntary health organization with experience serving the population of individ-

uals with amyotrophic lateral sclerosis (referred to in this section as "ALS"), shall—

(A) develop a system to collect data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

(B) establish a national registry for the collection and storage of such data to include a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(2) PURPOSE.—It is the purpose of the registry established under paragraph (1)(B) to gather available data concerning—

(A) ALS, including the incidence and prevalence of ALS in the United States;

(B) the environmental and occupational factors that may be associated with the disease;

(C) the age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease;

(D) other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

(E) other matters as recommended by the Advisory Committee established under subsection (b).

(b) ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the "Advisory Committee"). The Advisory Committee shall be composed of at least one member, to be appointed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention, representing each of the following:

(A) National voluntary health associations that focus solely on ALS and have demonstrated experience in ALS research, care, and patient services, as well as other voluntary associations focusing on neurodegenerative diseases that represent and advocate on behalf of patients with ALS and patients with other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(B) The National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences.

(C) The Department of Veterans Affairs.

(D) The Agency for Toxic Substances and Disease Registry.

(E) The Centers for Disease Control and Prevention.

(F) Patients with ALS or their family members.

(G) Clinicians with expertise on ALS and related diseases.

(H) Epidemiologists with experience in data registries.

(I) Geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases.

(J) Statisticians.

(K) Ethicists.

(L) Attorneys.

(M) Other individuals with an interest in developing and maintaining the National ALS Registry.

(2) DUTIES.—The Advisory Committee shall review information and make recommendations to the Secretary concerning—

(A) the development and maintenance of the National ALS Registry;

(B) the type of information to be collected and stored in the Registry;

(C) the manner in which such data is to be collected;

(D) the use and availability of such data including guidelines for such use; and

(E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

(3) REPORT.—Not later than 1 year after the date on which the Advisory Committee is established, the Advisory Committee shall submit a report concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

(c) GRANTS.—Notwithstanding the recommendations of the Advisory Committee under subsection (b), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(d) COORDINATION WITH STATE, LOCAL, AND FEDERAL REGISTRIES.—

(1) IN GENERAL.—In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, including—

(i) the 3 ALS registry pilot projects initiated in fiscal year 2006 by the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry at the South Carolina Office of Research & Statistics; the Mayo Clinic in Rochester, Minnesota; and Emory University in Atlanta, Georgia;

(ii) the Department of Veterans Affairs ALS Registry;

(iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center;

(iv) the Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illi-

nois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

(v) State-based ALS registries, including the Massachusetts ALS Registry;

(vi) the National Vital Statistics System; and

(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

(2) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Notwithstanding the recommendations of the Advisory Committee established in subsection (b), and consistent with applicable privacy statutes and regulations, the Secretary shall ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

(e) DEFINITION.—For the purposes of this section, the term "national voluntary health association" means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $25,000,000 for fiscal year 2008, and $16,000,000 for each of the fiscal years 2009 through 2012.

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