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Series: Saunders, G. Timothy (Tim) - Bill Files

Folder Title: 11/06/2002 [H.R. 4013] [771591]

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Collection Code: **SECLOG**

Staff Name:

Document Date:

Correspondent: **TIM SAUNDERS**

Subject/Description: **OVERSIZE ATTACHMENT # 9469 NARA # 9360 BOX 5
FOLDER 6E BILL FILE RECEIVED FROM THE OFFICE OF
THE EXECUTIVE CLERK - NOV 05 02 ENROLLED BILL H.R.
4013 - RARE DISEASES ACT OF 2002**



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D. C. 20503

October 30, 2002

THE DIRECTOR

THE PRESIDENT HAS SEEN

11-6-02

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 4013 - Rare Diseases Act of 2002
Sponsors - Rep. Shimkus (R) IL and 54 cosponsors

Last Day for Action

November 8, 2002 - Friday

Purpose

Establishes an Office of Rare Diseases within the National Institutes of Health (NIH) and authorizes appropriations for Rare Disease Regional Centers of Excellence.

Agency Recommendations

Office of Management and Budget

Approval

Department of Health and Human Services (HHS)

Approval

Discussion

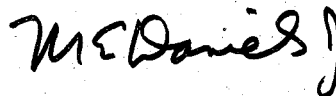
H.R. 4013 would establish in statute an Office of Rare Diseases within the Office of the Director of NIH. (The Office was established administratively in 1993.) A rare disease is defined as one that afflicts fewer than 200,000 individuals in the United States. According to the Food and Drug Administration, there are more than 6,000 rare diseases affecting 20 to 25 million people in the United States. The Office would be responsible for recommending an agenda for conducting and supporting research; promoting coordination and cooperation among NIH institutes and centers with regard to rare diseases; promoting the sufficient allocation of resources within NIH for conducting and supporting research on rare diseases; and encouraging the establishment of a centralized clearinghouse for rare and genetic disease information for use by the public, medical professionals, patients, and their families. H.R. 4013 would authorize appropriations of \$4 million for each of FYs 2003-2006 to carry out the responsibilities of the Office. The FY 2003 Budget requests \$11.3 million for the Office.

H.R. 4013 also would authorize appropriations of \$20 million for each of FYs 2003-2006 for Rare Disease Regional Centers of Excellence. The Office of Rare Diseases, in collaboration with other NIH institutes and centers, would enter into cooperative agreements with and make grants to public or private nonprofit entities for regional centers of excellence that would conduct research and training in the diagnosis, prevention, control, and treatment of rare diseases. Federal support of the centers of excellence would be limited to five years, but could, under certain conditions, be extended for up to an additional five years. The FY 2003 Budget does not include funding for rare disease regional centers of excellence.

Conclusion and Recommendations

HHS recommends approval of H.R. 4013. In its views letter on the enrolled bill, the Department states that the enrolled bill "is consistent with the Department's policies and objectives." For example, HHS notes that "NIH has been planning to establish Specialized Research and Diagnostic Centers of Excellence for Rare Diseases, which it considers crucial to coordinate research on rare diseases."

We join HHS in recommending approval of H.R. 4013, which passed the House by voice vote and the Senate by unanimous consent.



Mitchell E. Daniels, Jr.
Director

Enclosures

One Hundred Seventh Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Wednesday,
the twenty-third day of January, two thousand and two*

An Act

To amend the Public Health Service Act to establish an Office of Rare Diseases at the National Institutes of Health, and for other purposes.

*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 "Rare Diseases Act of 2002".

SEC. 2. FINDINGS AND PURPOSES.

(a) **FINDINGS.**—Congress makes the following findings:

(1) Rare diseases and disorders are those which affect small patient populations, typically populations smaller than 200,000 individuals in the United States. Such diseases and conditions include Huntington's disease, amyotrophic lateral sclerosis (Lou Gehrig's disease), Tourette syndrome, Crohn's disease, cystic fibrosis, cystinosis, and Duchenne muscular dystrophy.

(2) For many years, the 25,000,000 Americans suffering from the over 6,000 rare diseases and disorders were denied access to effective medicines because prescription drug manufacturers could rarely make a profit from marketing drugs for such small groups of patients. The prescription drug industry did not adequately fund research into such treatments. Despite the urgent health need for these medicines, they came to be known as "orphan drugs" because no companies would commercialize them.

(3) During the 1970s, an organization called the National Organization for Rare Disorders (NORD) was founded to provide services and to lobby on behalf of patients with rare diseases and disorders. NORD was instrumental in pressing Congress for legislation to encourage the development of orphan drugs.

(4) The Orphan Drug Act created financial incentives for the research and production of such orphan drugs. New Federal programs at the National Institutes of Health and the Food and Drug Administration encouraged clinical research and commercial product development for products that target rare diseases. An Orphan Products Board was established to promote the development of drugs and devices for rare diseases or disorders.

(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act, more than 220 new orphan drugs have been approved and marketed in the

THE WHITE HOUSE
OCT 28 2002

agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

"(c) USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

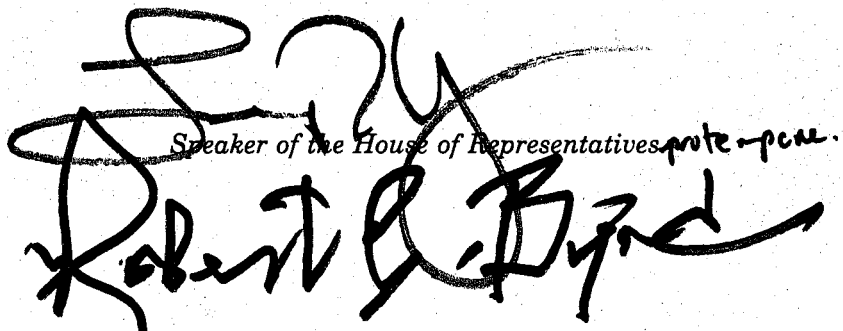
"(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

"(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

"(3) clinical research and demonstration programs.

"(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

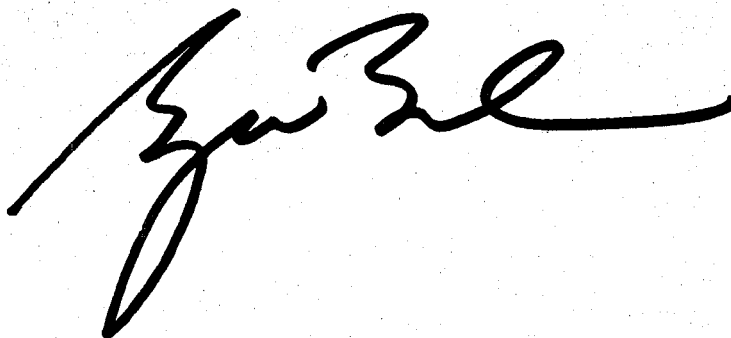
"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$20,000,000 for each of the fiscal years 2003 through 2006."


Speaker of the House of Representatives, pro tempore.

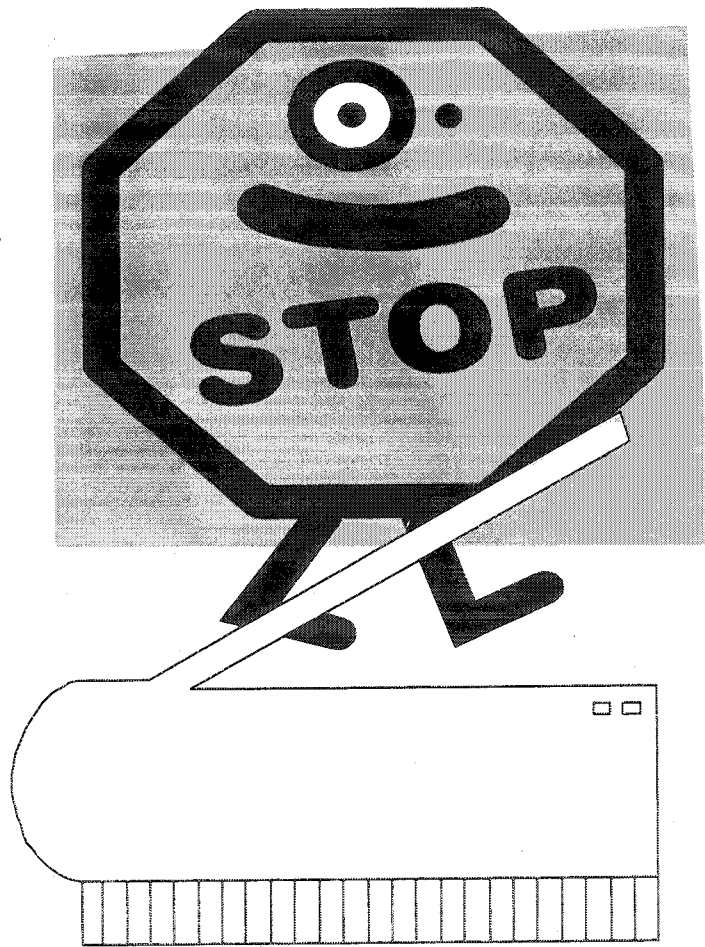
*Vice President of the United States and
President of the Senate, pro tempore.*

APPROVED

NOV - 6 2002



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Scanning insert sheet



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WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

Harriet E. Miers
 Assistant to the President
 and Staff Secretary
 Ext. 62702



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 30, 2002

THE DIRECTOR

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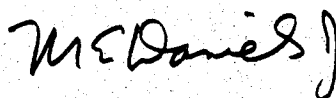
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Mitchell E. Daniels, Jr.
Director

Enclosures

Bills Received at the White House

Date received and
notification to OMB: 10/28/2002

Last day for action: 11/8/2002

H.R.4013

Official Title

An Act to amend the Public Health Service Act to establish
an Office of Rare Diseases at the National Institutes of
Health, and for other purposes.

518739

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT <i>no obj.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD <i>OK</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD <i>OK</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN <i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND <i>N/C</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO <i>OK</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON <i>N/C</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE <i>NC</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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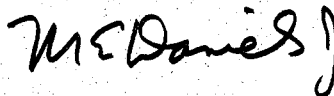
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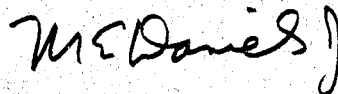
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Mitchell E. Daniels, Jr.
Director

Enclosures



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

October 25, 2002

The Honorable Mitchell E. Daniels, Jr.
Director, Office of Management
and Budget
Washington, D.C. 20503

Dear Mr. Daniels:

This responds to your request for the views of the Department of Health and Human Services (HHS) on H.R. 4013, an enrolled bill entitled the "Rare Diseases Act of 2002". We recommend that the President approve the bill.

H.R. 4013 adds section 404F to the Public Health Service Act (the "Act"), to establish in statute the NIH Office of Rare Diseases ("ORD"). Section 404F also makes the ORD director responsible for recommending a research agenda on "rare diseases" (defined as diseases affecting fewer than 200,000 persons in the United States); promoting coordination on rare diseases within NIH; promoting sufficient allocation of NIH resources related to rare diseases; promoting establishment of a centralized rare diseases information clearinghouse; preparing a biennial report on rare disease research activities and opportunities; preparing the NIH Director's annual report to Congress on rare disease research; and serving as the NIH Director's principal advisor on rare diseases. The section authorizes appropriations of such sums as may be necessary for FY 2002, and \$4 million for each of FY 2003 through 2006.

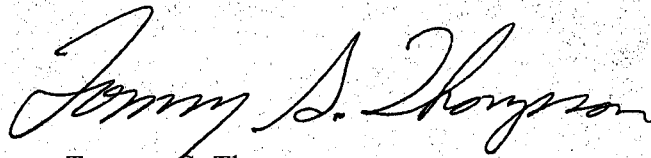
The bill also adds section 404G to the Act, authorizing NIH to fund, through grants and cooperative agreements, regional Centers of Excellence on rare diseases. The section authorizes appropriations of such sums as may be necessary for FY 2002, and \$20 million for each of FY 2003 through 2006.

The bill is consistent with the Department's policies and objectives. NIH established the Office of Rare Diseases by administrative action in 1993, and it is already carrying out many of the provisions in the bill. In particular, NIH has been planning to establish Specialized Research and Diagnostic Centers of Excellence for Rare Diseases, which it considers crucial to coordinate research on rare diseases.

Page 2 -- Honorable Mitchell E. Daniels, Jr.

For the foregoing reasons, we recommend that the President sign the bill.

Sincerely,

A handwritten signature in cursive script that reads "Tommy G. Thompson". The signature is written in dark ink and is positioned above the printed name.

Tommy G. Thompson

RARE DISEASES ACT OF 2002

JUNE 26, 2002.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 4013]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4013) to amend the Public Health Service Act to establish an Office of Rare Diseases at the National Institutes of Health, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

The purpose of H.R. 4013, the Rare Diseases Act of 2002, is to authorize in statute the Office of Rare Diseases at the National Institutes of Health ("NIH"). Rare diseases are diseases affecting fewer than 200,000 individuals in the United States. The Director of the Office of Rare Diseases will serve as the principal advisor to

the Director of the NIH with respect to rare diseases, and shall serve to promote sufficient allocation of NIH resources to rare disease research, and promote and encourage the establishment of a centralized clearinghouse for rare disease information for the benefit of the public, medical professionals, patients, and families.

BACKGROUND AND NEED FOR LEGISLATION

In 1993, the NIH created an Office of Rare Diseases within the Office of the Director of NIH, to respond to the reporting requirements of the Orphan Drug Act of 1983. The Office of Rare Diseases implements the recommendations of the National Commission on Orphan Diseases, and responds to requests for information on rare diseases.

Rare, or Orphan, Diseases affect fewer than 200,000 individuals in America. Presently, more than 6,000 rare diseases affecting more than 25 million Americans are known. Prior to the enactment of the Orphan Disease Act of 1983, there was not enough of an incentive for drug and biological manufacturers to invest in treatments for these diseases. The Orphan Drug Act created greater incentives through increased exclusivity (7 years) for drugs and biologicals which treat Orphan Diseases, among other things.

While the Orphan Drug Act has achieved dramatic increases in research into, and treatments for, rare diseases, more still needs to be done. One positive step includes authorizing in statute the Office of Rare Diseases. This action sends the strong signal of the Congress' commitment for both this Office as well as for rare disease research generally. Also, authorizing regional centers of excellence for rare disease research is a positive step, as it will enable the NIH to select sites to concentrate on finding cures and treatment methods for rare diseases. Both of these proposals are contained within H.R. 4013.

HEARINGS

The Subcommittee on Health held a hearing on "The National Institutes of Health: Investing in Research to Prevent and Cure Disease" on June 6, 2002. The Subcommittee received testimony from Claude Lenfant, M.D., Director, National Heart, Lung, and Blood Institute; Audrey S. Penn, M.D., Acting Director, National Institute of Neurological Disorders and Stroke; Robert O. Bonow, M.D., President-elect, American Heart Association; Eric Hargis, President and CEO, The Epilepsy Foundation; Edward Sanchez, M.D., M.P.H., Commissioner, Texas Department of Health; Daniel Jones, M.D., Vice Chancellor, University Medical Center, University of Mississippi.

COMMITTEE CONSIDERATION

On Wednesday, June 19, 2002, the Full Committee met in open markup session and favorably ordered reported H.R. 4013, the Rare Diseases Act of 2002, by voice vote, a quorum being present.

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. 4013 reported. A motion by Mr. Tauzin to order H.R. 4013 reported to the House, without amendment, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held an oversight hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of this legislation is to increase support for rare disease research within and without the National Institutes of Health through the statutory authorization of the Office of Rare Diseases and by allowing the Secretary to establish rare disease regional centers of excellence.

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. 4103, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

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, which is included in the report to accompany H.R. 4984.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 is included in the report to accompany H.R. 4984.

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. The estimate is included in the report to accompany H.R. 4984.

ADVISORY COMMITTEE STATEMENT

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

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 Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

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 that the short title for this legislation is the Rare Diseases Act of 2002.

Section 2. Findings and Purposes

Section 2 contains Congressional findings.

Section 3. NIH Office of Rare Diseases at National Institutes of Health

Section 3 establishes within the Office of the Director of the NIH an office to be known as the Office of Rare Diseases, and ensures that the Director of the Office of Rare Diseases will (1) recommend an agenda for conducting and supporting research on rare diseases; (2) promote, with respect to rare diseases, coordination and cooperation among NIH institutes and centers; and, (3) promote the sufficient allocation of the resources of the NIH for conducting and supporting research on rare diseases. The section also authorizes \$4 million in each of Fiscal Years 2003 through 2006 for these purposes.

Section 4. Rare Disease Regional Centers of Excellence

Section 4 empowers the Director of the Office of Rare Diseases, in collaboration with the directors of the other relevant institutes and centers of the NIH, to enter into cooperative agreements and make grants for the establishment of regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases. This section authorizes \$20 million in each of Fiscal Years 2003 through 2006 for these purposes.

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

* * * * *

TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

* * * * *

OFFICE OF RARE DISEASES

SEC. 404F. (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Rare Diseases (in this section referred to as the "Office"), which shall be headed by a Director (in this section referred to as the "Director"), appointed by the Director of NIH.

(b) DUTIES.—

(1) IN GENERAL.—The Director of the Office shall carry out the following:

(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 404G.

(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

(G) The Director shall prepare the NIH Director's annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.

(2) PRINCIPAL ADVISOR REGARDING ORPHAN DISEASES.—With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

(c) DEFINITION.—For purposes of this section, the term "rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

(d) *AUTHORIZATION OF APPROPRIATIONS.*—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$4,000,000 for each of the fiscal years 2003 through 2006.

RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

SEC. 404G. (a) COOPERATIVE AGREEMENTS AND GRANTS.—

(1) *IN GENERAL.*—The Director of the Office of Rare Diseases (in this section referred to as the "Director"), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

(2) *POLICIES.*—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

(b) *COORDINATION WITH OTHER INSTITUTES.*—The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

(c) *USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.*—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

(3) clinical research and demonstration programs.

(d) *PERIOD OF SUPPORT; ADDITIONAL PERIODS.*—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(e) *AUTHORIZATION OF APPROPRIATIONS.*—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$20,000,000 for each of the fiscal years 2003 through 2006.

* * * * *

One Hundred Seventh Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Wednesday,
the twenty-third day of January, two thousand and two*

An Act

To amend the Public Health Service Act to establish an Office of Rare Diseases at the National Institutes of Health, and for other purposes.

*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 "Rare Diseases Act of 2002".

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) Rare diseases and disorders are those which affect small patient populations, typically populations smaller than 200,000 individuals in the United States. Such diseases and conditions include Huntington's disease, amyotrophic lateral sclerosis (Lou Gehrig's disease), Tourette syndrome, Crohn's disease, cystic fibrosis, cystinosis, and Duchenne muscular dystrophy.

(2) For many years, the 25,000,000 Americans suffering from the over 6,000 rare diseases and disorders were denied access to effective medicines because prescription drug manufacturers could rarely make a profit from marketing drugs for such small groups of patients. The prescription drug industry did not adequately fund research into such treatments. Despite the urgent health need for these medicines, they came to be known as "orphan drugs" because no companies would commercialize them.

(3) During the 1970s, an organization called the National Organization for Rare Disorders (NORD) was founded to provide services and to lobby on behalf of patients with rare diseases and disorders. NORD was instrumental in pressing Congress for legislation to encourage the development of orphan drugs.

(4) The Orphan Drug Act created financial incentives for the research and production of such orphan drugs. New Federal programs at the National Institutes of Health and the Food and Drug Administration encouraged clinical research and commercial product development for products that target rare diseases. An Orphan Products Board was established to promote the development of drugs and devices for rare diseases or disorders.

(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act, more than 220 new orphan drugs have been approved and marketed in the

United States and more than 800 additional drugs are in the research pipeline.

(6) Despite the tremendous success of the Orphan Drug Act, rare diseases and disorders deserve greater emphasis in the national biomedical research enterprise. The Office of Rare Diseases at the National Institutes of Health was created in 1993, but lacks a statutory authorization.

(7) The National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research.

(8) Notwithstanding such increases, funding for rare diseases and disorders at the National Institutes of Health has not increased appreciably.

(9) To redress this oversight, the Department of Health and Human Services has proposed the establishment of a network of regional centers of excellence for research on rare diseases.

(b) PURPOSES.—The purposes of this Act are to—

(1) amend the Public Health Service Act to establish an Office of Rare Diseases at the National Institutes of Health; and

(2) increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders.

SEC. 3. NIH OFFICE OF RARE DISEASES AT NATIONAL INSTITUTES OF HEALTH.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by Public Law 107-84, is amended by inserting after section 404E the following:

“OFFICE OF RARE DISEASES

“SEC. 404F. (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Rare Diseases (in this section referred to as the ‘Office’), which shall be headed by a Director (in this section referred to as the ‘Director’), appointed by the Director of NIH.

“(b) DUTIES.—

“(1) IN GENERAL.—The Director of the Office shall carry out the following:

“(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

“(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

“(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 404G.

“(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

“(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

“(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

“(G) The Director shall prepare the NIH Director’s annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.

“(2) PRINCIPAL ADVISOR REGARDING ORPHAN DISEASES.—

With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

“(c) DEFINITION.—For purposes of this section, the term ‘rare disease’ means any disease or condition that affects less than 200,000 persons in the United States.

“(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$4,000,000 for each of the fiscal years 2003 through 2006.”

SEC. 4. RARE DISEASE REGIONAL CENTERS OF EXCELLENCE.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 3, is further amended by inserting after section 404F the following:

“RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

“SEC. 404G. (a) COOPERATIVE AGREEMENTS AND GRANTS.—

“(1) IN GENERAL.—The Director of the Office of Rare Diseases (in this section referred to as the ‘Director’), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

“(2) POLICIES.—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

“(b) COORDINATION WITH OTHER INSTITUTES.—The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and

agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

“(c) USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

“(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

“(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

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“(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

“(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$20,000,000 for each of the fiscal years 2003 through 2006.”.

Speaker of the House of Representatives.

*Vice President of the United States and
President of the Senate.*

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 30, 2002

THE DIRECTOR

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 4013 - Rare Diseases Act of 2002
Sponsors - Rep. Shimkus (R) IL and 54 cosponsors

Last Day for Action

November 8, 2002 - Friday

Purpose

Establishes an Office of Rare Diseases within the National Institutes of Health (NIH) and authorizes appropriations for Rare Disease Regional Centers of Excellence.

Agency Recommendations

Office of Management and Budget	Approval
Department of Health and Human Services (HHS)	Approval

Discussion

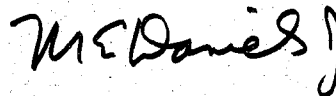
H.R. 4013 would establish in statute an Office of Rare Diseases within the Office of the Director of NIH. (The Office was established administratively in 1993.) A rare disease is defined as one that afflicts fewer than 200,000 individuals in the United States. According to the Food and Drug Administration, there are more than 6,000 rare diseases affecting 20 to 25 million people in the United States. The Office would be responsible for recommending an agenda for conducting and supporting research; promoting coordination and cooperation among NIH institutes and centers with regard to rare diseases; promoting the sufficient allocation of resources within NIH for conducting and supporting research on rare diseases; and encouraging the establishment of a centralized clearinghouse for rare and genetic disease information for use by the public, medical professionals, patients, and their families. H.R. 4013 would authorize appropriations of \$4 million for each of FYs 2003-2006 to carry out the responsibilities of the Office. The FY 2003 Budget requests \$11.3 million for the Office.

H.R. 4013 also would authorize appropriations of \$20 million for each of FYs 2003-2006 for Rare Disease Regional Centers of Excellence. The Office of Rare Diseases, in collaboration with other NIH institutes and centers, would enter into cooperative agreements with and make grants to public or private nonprofit entities for regional centers of excellence that would conduct research and training in the diagnosis, prevention, control, and treatment of rare diseases. Federal support of the centers of excellence would be limited to five years, but could, under certain conditions, be extended for up to an additional five years. The FY 2003 Budget does not include funding for rare disease regional centers of excellence.

Conclusion and Recommendations

HHS recommends approval of H.R. 4013. In its views letter on the enrolled bill, the Department states that the enrolled bill "is consistent with the Department's policies and objectives." For example, HHS notes that "NIH has been planning to establish Specialized Research and Diagnostic Centers of Excellence for Rare Diseases, which it considers crucial to coordinate research on rare diseases."

We join HHS in recommending approval of H.R. 4013, which passed the House by voice vote and the Senate by unanimous consent.



Mitchell E. Daniels, Jr.
Director

Enclosures

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 30, 2002

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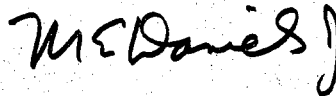
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Enclosures

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 30, 2002

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Last Day for Action

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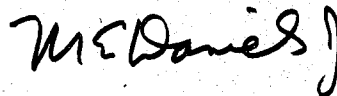
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Mitchell E. Daniels, Jr.
Director

Enclosures

 *** TX REPORT ***

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WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:
 PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
 BY 5:00 P.M.. THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY.

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
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CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

Harriet E. Miers
 Assistant to the President
 and Staff Secretary
 Ext. 62702

 *** TX REPORT ***

TRANSMISSION OK

TX/RX NO 1144
 CONNECTION TEL 69720
 CONNECTION ID
 ST. TIME 10/30 05:50
 USAGE T 01'13
 PGS. SENT 3
 RESULT OK

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
 BY 5:00 P.M.. THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY.

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
 BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY.
 THANK YOU.

RESPONSE:

Harriet E. Miers
 Assistant to the President
 and Staff Secretary
 Ext. 62702

 *** TX REPORT ***

TRANSMISSION OK

TX/RX NO 1162
 CONNECTION TEL 56958
 CONNECTION ID
 ST. TIME 10/30 06:19
 USAGE T 01'11
 PGS. SENT 3
 RESULT OK

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
 BY 5:00 P.M. THURSDAY OCTOBER 31 2002. WITH A COPY TO THE STAFF SECRETARY.

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

Harriet E. Miers
 Assistant to the President
 and Staff Secretary
 Ext. 62702

 *** TX REPORT ***

TRANSMISSION OK

TX/RX NO: 1151
 CONNECTION TEL: 67090
 CONNECTION ID: ADMIN
 ST. TIME: 10/30 06:02
 USAGE T: 01'23
 PGS. SENT: 3
 RESULT: OK

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:
 PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
 BY 5:00 P.M. THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY.

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

Harriet E. Miers
 Assistant to the President
 and Staff Secretary
 Ext. 62702

 *** TX REPORT ***

TRANSMISSION OK

TX/RX NO 1153
 CONNECTION TEL 62710
 CONNECTION ID CEQ
 ST. TIME 10/30 06:05
 USAGE T 01'12
 PGS. SENT 3
 RESULT OK

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:
 PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
 BY 5:00 P.M.. THURSDAY. OCTOBER 31. 2002, WITH A COPY TO THE STAFF SECRETARY.

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

Harriet E. Miers
 Assistant to the President
 and Staff Secretary
 Ext. 62702

 *** TX REPORT ***

TRANSMISSION OK

TX/RX NO 1156
 CONNECTION TEL 51005
 CONNECTION ID
 ST. TIME 10/30 06:10
 USAGE T 01'11
 PGS. SENT 3
 RESULT OK

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
 BY 5:00 P.M.. THURSDAY. OCTOBER 31. 2002. WITH A COPY TO THE STAFF SECRETARY.

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

Harriet E. Miers
 Assistant to the President
 and Staff Secretary
 Ext. 62702

 *** TX REPORT ***

TRANSMISSION OK

TX/RX NO 1167
 CONNECTION TEL 67090
 CONNECTION ID ADMIN
 ST. TIME 10/30 06:28
 USAGE T 01'14
 PGS. SENT 3
 RESULT OK

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
 BY 5:00 P.M. THURSDAY, OCTOBER 31, 2002 WITH A COPY TO THE STAFF SECRETARY

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM 5:30 PM '02

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

No comments

RESPONSE:

2002 OCT 30 PM 6:09

EXECUTIVE SECRETARY
THE WHITE HOUSE

Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702

WHITE HOUSE STAFFING MEMORANDUM

NOV 2 10 30 AM '02

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

(Handwritten mark)

Harriet E. Miers
 Assistant to the President
 and Staff Secretary
 Ext. 62702



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 30, 2002

THE DIRECTOR

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 4013 - Rare Diseases Act of 2002
Sponsors - Rep. Shimkus (R) IL and 54 cosponsors

Last Day for Action

November 8, 2002 - Friday

Purpose

Establishes an Office of Rare Diseases within the National Institutes of Health (NIH) and authorizes appropriations for Rare Disease Regional Centers of Excellence.

Agency Recommendations

Office of Management and Budget Approval

Department of Health and Human Services (HHS) Approval

Discussion

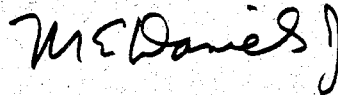
H.R. 4013 would establish in statute an Office of Rare Diseases within the Office of the Director of NIH. (The Office was established administratively in 1993.) A rare disease is defined as one that afflicts fewer than 200,000 individuals in the United States. According to the Food and Drug Administration, there are more than 6,000 rare diseases affecting 20 to 25 million people in the United States. The Office would be responsible for recommending an agenda for conducting and supporting research; promoting coordination and cooperation among NIH institutes and centers with regard to rare diseases; promoting the sufficient allocation of resources within NIH for conducting and supporting research on rare diseases; and encouraging the establishment of a centralized clearinghouse for rare and genetic disease information for use by the public, medical professionals, patients, and their families. H.R. 4013 would authorize appropriations of \$4 million for each of FYs 2003-2006 to carry out the responsibilities of the Office. The FY 2003 Budget requests \$11.3 million for the Office.

H.R. 4013 also would authorize appropriations of \$20 million for each of FYs 2003-2006 for Rare Disease Regional Centers of Excellence. The Office of Rare Diseases, in collaboration with other NIH institutes and centers, would enter into cooperative agreements with and make grants to public or private nonprofit entities for regional centers of excellence that would conduct research and training in the diagnosis, prevention, control, and treatment of rare diseases. Federal support of the centers of excellence would be limited to five years, but could, under certain conditions, be extended for up to an additional five years. The FY 2003 Budget does not include funding for rare disease regional centers of excellence.

Conclusion and Recommendations

HHS recommends approval of H.R. 4013. In its views letter on the enrolled bill, the Department states that the enrolled bill "is consistent with the Department's policies and objectives." For example, HHS notes that "NIH has been planning to establish Specialized Research and Diagnostic Centers of Excellence for Rare Diseases, which it considers crucial to coordinate research on rare diseases."

We join HHS in recommending approval of H.R. 4013, which passed the House by voice vote and the Senate by unanimous consent.



Mitchell E. Daniels, Jr.
Director

Enclosures

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

TOP SECRET

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

6:30
Be ANC 10/30

Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D. C. 20503

October 30, 2002

THE DIRECTOR

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 4013 - Rare Diseases Act of 2002
Sponsors - Rep. Shimkus (R) IL and 54 cosponsors

Last Day for Action

November 8, 2002 - Friday

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Agency Recommendations

Office of Management and Budget	Approval
Department of Health and Human Services (HHS)	Approval

Discussion

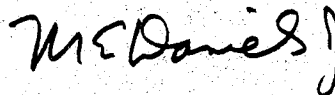
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Mitchell E. Daniels, Jr.
Director


Enclosures

SS/ RM NO. Ten

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES 	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

Cleared 10/30/02 JBN

RESPONSE:

Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:
PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148,
BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY.
THANK YOU.

RESPONSE:



Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

No Comment
PH Looney, CEO
10/30/02

Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

102 OCT 31 PM 5:48

	ACTION	FYI		ACTION	FYI
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BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

*cc Jay
Alan Philo
Tevi
no comments*

Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

02 OCT 31 PM 05

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO JIM JUKES, X53458, FAX X56148, BY 5:00 P.M., THURSDAY, OCTOBER 31, 2002, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

OK'D BY PHONE

10/31 4:13 PM

Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 30, 2002

THE DIRECTOR

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 4013 - Rare Diseases Act of 2002
Sponsors - Rep. Shimkus (R) IL and 54 cosponsors

Last Day for Action

November 8, 2002 - Friday

Purpose

Establishes an Office of Rare Diseases within the National Institutes of Health (NIH) and authorizes appropriations for Rare Disease Regional Centers of Excellence.

Agency Recommendations

Office of Management and Budget	Approval
Department of Health and Human Services (HHS)	Approval

Discussion

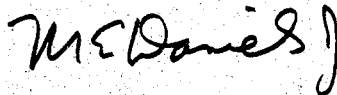
H.R. 4013 would establish in statute an Office of Rare Diseases within the Office of the Director of NIH. (The Office was established administratively in 1993.) A rare disease is defined as one that afflicts fewer than 200,000 individuals in the United States. According to the Food and Drug Administration, there are more than 6,000 rare diseases affecting 20 to 25 million people in the United States. The Office would be responsible for recommending an agenda for conducting and supporting research; promoting coordination and cooperation among NIH institutes and centers with regard to rare diseases; promoting the sufficient allocation of resources within NIH for conducting and supporting research on rare diseases; and encouraging the establishment of a centralized clearinghouse for rare and genetic disease information for use by the public, medical professionals, patients, and their families. H.R. 4013 would authorize appropriations of \$4 million for each of FYs 2003-2006 to carry out the responsibilities of the Office. The FY 2003 Budget requests \$11.3 million for the Office.

H.R. 4013 also would authorize appropriations of \$20 million for each of FYs 2003-2006 for Rare Disease Regional Centers of Excellence. The Office of Rare Diseases, in collaboration with other NIH institutes and centers, would enter into cooperative agreements with and make grants to public or private nonprofit entities for regional centers of excellence that would conduct research and training in the diagnosis, prevention, control, and treatment of rare diseases. Federal support of the centers of excellence would be limited to five years, but could, under certain conditions, be extended for up to an additional five years. The FY 2003 Budget does not include funding for rare disease regional centers of excellence.

Conclusion and Recommendations

HHS recommends approval of H.R. 4013. In its views letter on the enrolled bill, the Department states that the enrolled bill "is consistent with the Department's policies and objectives." For example, HHS notes that "NIH has been planning to establish Specialized Research and Diagnostic Centers of Excellence for Rare Diseases, which it considers crucial to coordinate research on rare diseases."

We join HHS in recommending approval of H.R. 4013, which passed the House by voice vote and the Senate by unanimous consent.



Mitchell E. Daniels, Jr.
Director

Enclosures

SS/ RM NO. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
CALIO	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HAWKINS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:
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THANK YOU.

Ok - Phillip Swager (EA)

RESPONSE:

Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702



OFFICE OF THE VICE PRESIDENT
WASHINGTON

02 OCT 31 PM 7:09

October 31, 2002

MEMORANDUM FOR JAMES JUKES
ASSISTANT DIRECTOR, OMB

FROM: JONATHAN BURKS
DEPUTY STAFF SECRETARY TO THE VICE PRESIDENT

SUBJECT: Enrolled Bill H.R. 4013 – Rare Diseases Act of 2002

The Office of the Vice President has reviewed the above-referenced draft and has no objection to the President signing the enrolled bill.

cc: Harriet Miers
Staff Secretary

WHITE HOUSE STAFFING MEMORANDUM

Date: 10-30-02 4:30 PM ACTION / CONCURRENCE / COMMENT DUE BY: 10-31-02 5:00 PM

Subject: ENROLLED BILL H.R. 4013 - RARE DISEASES ACT OF 2002

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	HUBBARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IRASTORZA	<input type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	JOHNSON	<input type="checkbox"/>	<input type="checkbox"/>
BLAKEMAN	<input type="checkbox"/>	<input type="checkbox"/>	LINDSEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input type="checkbox"/>	<input type="checkbox"/>
BRIDGELAND	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MIERS	<input type="checkbox"/>	<input type="checkbox"/>
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CONNAUGHTON	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RIDGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DANIELS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FLEISCHER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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RESPONSE:

*cc Jay
Alan/ Philo
Tevi*

OK

Harriet E. Miers
Assistant to the President
and Staff Secretary
Ext. 62702



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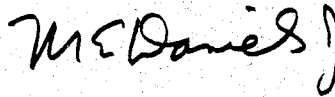
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Mitchell E. Daniels, Jr.
Director

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