The original documents are located in Box 52, folder "8/13/76 HR12944 Six Month Extension of the Federal Insecticide Fungicide and Rodenticide Act (vetoed)" of the White House Records Office: Legislation Case Files at the Gerald R. Ford Presidential Library

Vetoed 8/13/76 Delivered to Clerk of the House of Reps 4:35 pm 8/13/76

8/13/76

THE WHITE HOUSE

WASHINGTON

ACTION

Last Day: August 21

August 12, 1976

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: H.R. 12944 - Six Month Extension of the Federal Insecticide, Fungicide and Rodenticide Act

Attached for your consideration is H.R. 12944, sponsored by Representatives Foley and Wampler.

The enrolled bill extends the appropriation authorization for the Environmental Protection Agency to carry out the provisions of the Federal Insecticide, Fungicide and Rodenticide Act for six months from April 1, 1977 until September 30, 1977 at a level of $19,735,100. The appropriation authorization for these activities does not terminate until March 31, 1977.

The bill would also subject rules and regulations issued under authority of the Act to a 60-day review period during which either House of Congress may disapprove the rule or regulation.

A detailed discussion of the provisions of the enrolled bill is provided in OMB's enrolled bill report at Tab A.

Because of the one-house veto provision, Justice, EPA, OMB, Max Friedersdorf, Counsel's Office (Lazarus) and I recommend disapproval of the enrolled bill.

DECISION

Sign H.R. 12944 at Tab B.

Approve _____ Disapprove _____

Disapprove H.R. 12944 and sign veto message at Tab C.
(The text of the message has been approved by Doug Smith)

Approve MF Disapprove _____

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

AUG 11 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill H.R. 12944 - Six month extension of the Federal Insecticide, Fungicide, and Rodenticide Act
Sponsors - Rep. Foley (D) Washington and Rep. Wampler (R) Virginia

Last Day for Action

August 21, 1976 - Saturday

Purpose

Extends the appropriation authorization for the Environmental Protection Agency (EPA) to carry out the provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for six months from April 1, 1977, until September 30, 1977, at a level of $19,735,100, and provides for a one-house veto of FIFRA regulations promulgated by EPA.

Agency Recommendations

Office of Management and Budget	Disapproval (Veto Message attached)
Department of Justice	Disapproval (Veto Message attached)
Environmental Protection Agency	Disapproval (Veto Message attached)
Department of Agriculture	Supports FIFRA extension; no position on one-house veto provision

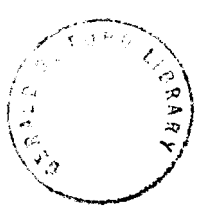
Discussion

The Federal Insecticide, Fungicide and Rodenticide Act is the basic authority under which the manufacture and sale of insecticides and pesticides are controlled. Under FIFRA, the use of hazardous chemicals is controlled by EPA through the registration of pesticides, the certification and training of pesticide users and residue monitoring, and through a research program which evaluates the behavior of pesticides and their impact on ecosystems. The appropriation authorization for these activities does not terminate until March 31, 1977.

H.R. 12944 extends the FIFRA appropriation authorization for the six months from April 1, 1977 to September 30, 1977, at a level of $19,735,100. This authorization conforms to the level which EPA had sought in a draft bill transmitted to Congress earlier this year.

H.R. 12944 would also require that any rule or regulation issued under FIFRA be transmitted to Congress immediately upon its final adoption. If either House of Congress disapproved by resolution such rule or regulation within 60 calendar days of its submission, the rule or regulation would cease to be in effect.

The Administration has consistently objected to provisions similar to this for two major reasons. First, such provisions are inconsistent with the principle of the separation of powers. Once Congress has entrusted a responsibility to the Executive Branch, that responsibility cannot be subjected to further congressional control except through the plenary legislative processes of repeal or amendment. Second, a disapproval of executive action by concurrent or one-house resolution violates Article 1, section 7, clauses 2 and 3 of the Constitution, which require that every bill and every resolution, the legal effect of which is not limited to internal congressional affairs, must be concurred in by both Houses and be presented to the President.



The House Agriculture Committee considered this one-house veto provision and rejected it by a vote of 18 to 16. However, its sponsor, Rep. Mathis (D-Georgia) was successful in adding the measure to H.R. 12944 on the House floor by a vote of 36 to 7. In floor debate, Rep. Mathis cited the growing trend for use of congressional veto provisions, especially with respect to Federal regulatory programs, and he argued that greater congressional oversight was needed for such programs. Subsequently, the House passed the bill by 347 to 33 and the Senate by a voice vote.

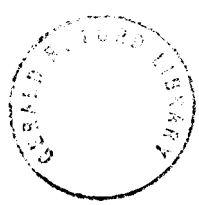
It should also be noted that in House floor debate, Rep. Levitas (D-Georgia), a strong proponent of congressional veto provisions, cited in support of the FIFRA amendment an analogous provision in the Federal Election Campaign Act which allows either House to veto regulations issued by the Federal Elections Commission. The constitutionality of this Federal Election Campaign Act provision is being challenged in U.S. District Court in a suit filed by former Attorney General Ramsey Clark. On May 11, 1976, in approving the Federal Election Campaign Act Amendments of 1976, you expressed your "fundamental concern" for this one-house veto provision and your signing statement noted that:

> "I have therefore directed the Attorney General to challenge the constitutionality of this provision at the earliest possible opportunity."

In this regard, on August 6, 1976, the Department of Justice announced that it was seeking permission to intervene in the Clark suit on behalf of the United States.

In their attached letters on the enrolled bill, both EPA and Justice strongly recommend disapproval, and Justice appropriately summarizes both agencies' primary objection to H.R. 12944 in noting that:

> "As we have often stated, the Justice Department considers provisions for review of executive action by resolution of one House unconstitutional.



> They violate the general principle of separation of power whereby Congress enacts but the President executes the laws. Furthermore, they violate Article I, section 7, which requires that resolutions having the force of law be sent to the President for his signature or veto."

In its enrolled bill letter, Agriculture favors extension of the FIFRA appropriation authorization and takes no position on the one-house veto provision. However, the Department notes that, as a general rule, it:

> "...is opposed to legislation that authorizes Congress to review and invalidate specific agency regulations because it would be extremely difficult for Congress to obtain the expertise necessary to evaluate adequately particular agency rules, and plenary Congressional oversight of individual agency regulations would be unduly burdensome to the regulatory responsibilities assigned to various Government agencies."

We concur in the EPA and Justice recommendations that you veto H.R. 12944. Specifically, a veto would:

- further demonstrate your continued strong opposition to the congressional trend in enacting bills with constitutionally objectionable encroachment provisions;

- be consistent with your recent disapproval of a bill authorizing appropriations for the Federal Fire Prevention and Control Act of 1974, which contained a related congressional veto provision; and,

- be in accord with the Attorney General's decision last week to join in the citizen's suit which challenges the constitutionality of a near identical encroachment provision in the Federal Election Campaign Act.

Moreover, as EPA notes in its enrolled bill letter, a veto would have minimal effect upon the FIFRA program because the current Act authorizes appropriations through March 31, 1977, leaving Congress with adequate time to reconsider the legislation.

We have prepared, for your consideration, a veto message that is nearly identical to the one submitted by Justice. Our modification of the Justice veto message simply clarifies that you would have no reservations about H.R. 12944, if the one-house veto provision is removed from it.

James M. Frey
Assistant Director for
Legislative Reference

Enclosures

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

August 10, 1976

Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D.C.

Dear Mr. Lynn:

In response to your request of August 8, 1976, for our views and recommendations on H.R. 12944, a bill "to extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for six months", this Department favors such an extension and takes no position on the other provisions of the bill.

The principal effect of the bill is to provide funding to effectuate the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act during the period from April 1, 1977, through September 30, 1977. The Department supports this aspect of the legislation. The bill also contains an amendment that would authorize either House of Congress to disapprove, by resolution, any rule or regulation promulgated under the Act if a resolution of disapproval is adopted by either House within a specified period of time. The Department takes no position on the amendment that would authorize Congress to review and disapprove regulations issued under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act. However, as a general rule, the Department is opposed to legislation that authorizes Congress to review and invalidate specific agency regulations because it would be extremely difficult for Congress to obtain the expertise necessary to evaluate adequately particular agency rules, and plenary Congressional oversight of individual agency regulations would be unduly burdensome to the regulatory responsibilities assigned to various Government agencies.

Sincerely,

Earl L. Butz

Earl L. Butz
Secretary

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 10 1976

OFFICE OF THE
ADMINISTRATOR

Dear Mr. Lynn:

This is in response to your August 6, 1976, request for a report on H.R. 12944, an enrolled bill "To extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for six months."

The bill would authorize the appropriation of $19,735,100 for carrying out the provisions of the Act from April 1, 1977 to September 30, 1977. In addition, the bill would amend section 25(a) of the Act by adding a provision granting either House of Congress authority to disapprove, by a resolution, any final regulation promulgated by any agency pursuant to FIFRA authority within 60 days of its adoption.

The Environmental Protection Agency strongly recommends that the bill be vetoed.

As we have expressed in testimony and reports to several Committees of the Congress and in correspondence to you, empowering the Congress to approve or disapprove regulations promulgated by an Executive Branch agency presents serious constitutional, legal, and practical problems.

Congressional veto of Executive Branch agency regulations disrupts the doctrine of separation of powers on which our government is based under the Constitution. The amendment would have a House of the Congress review a regulation before any judicial examination, thereby establishing the Congress as the initial interpreter of compliance with the statute, a role within the province of the judiciary. Further, by setting aside a regulation based on its own concept of desirable regulatory or enforcement policy, a House of the Congress intrudes on the province of the Executive.

A possible legal problem presented by the amendment is that it could force the effective date of regulations promulgated by the Agency past Congressional- or court-imposed deadlines, placing us in violation of the deadline.

A serious practical problem is that the amendment contains no procedure for providing EPA with specific guidance regarding the reasons for congressional disapproval, nor the steps to be taken by the Agency to bring the regulations into compliance.

The effect of veto of the bill on the Agency's pesticide program would at this time be minimal. The FIFRA at present authorizes appropriations through March 31, 1977, leaving sufficient time for the Congress to reconsider the legislation, should it be disapproved by the President. In addition, the Agency's appropriations as set out in H.R. 14233, including those for the pesticide program, have been enacted by the Congress through September 30, 1977, and the enrolled bill has been submitted to the President for signature.

Sincerely yours,

Russell E. Train
Administrator

Honorable James T. Lynn
Director
Office of Management and Budget
Washington, D.C. 20503

PESTICIDE EXTENSION VETO MESSAGE

I have vetoed H.R. 12944, the bill which extends the authorization of appropriations for the Environmental Protection Agency's pesticide regulatory program from April 1, 1977 through September 30, 1977. Unfortunately the bill includes a provision giving either House of the Congress the power to disapprove a final EPA regulation under the Federal Insecticide, Fungicide, and Rodenticide Act, the Federal pesticide regulatory authority, within 60 days of its promulgation.

During this Congress there have been several similar proposals relating to EPA authorities but this is the first one actually enacted requiring EPA to submit regulations to the Congress for review. This provision is an intrusion by the Congress on the functions of the Executive Branch and to a certain degree those of the Judiciary, clearly a disruption of the Constitution's doctrine of separation of powers.

First, by putting itself in the position of determining regulatory and enforcement measures to be taken by the Executive Branch, the Congress has in fact taken over the Executive function of carrying out laws enacted by the legislature.

Second, by positioning itself as first to review and determine an agency's compliance with a law it has enacted, the Congress has preempted a function given the Judiciary under the Constitution.

Beyond these fundamental problems, which preclude the possibility of approving the provision were it to be improved as follows, the Congressional approval scheme has basic practical problems. For example, it does not follow through on what the agency should do if its regulations are disapproved by a House of Congress. No guidance is provided in the bill as to what steps should be taken to improve the rejected regulations.

Further, the Congress has added another 60 day delay to a process it has often criticized as too slow, that of promulgating regulations, and by doing so may well be the cause of failure to meet deadlines it has imposed.

We also question whether the Congress has the means to adequately review regulations which have been developed by the comprehensive, exhaustive agency process, which includes hearings, receiving testimony and comments, review by non-government experts, an administrative due process procedure, and the work of agency professional and technical employees who actually carry out and are accountable for the regulations.

The Congressional review amendment would be bad law; I cannot approve it.

ASSISTANT ATTORNEY GENERAL
LEGISLATIVE AFFAIRS

Department of Justice
Washington, D.C. 20530

August 11, 1976

James T. Lynn
Director, Office of Management and Budget
Washington, D.C. 20503

Dear Mr. Lynn:

This is in response to your request for the views of the Department of Justice on H.R. 12944, an enrolled bill. The bill would extend the Federal Insecticide, Fungicide, and Rodenticide Act for six months. It would also subject rules and regulations issued under authority of the Act to a 60 day review period during which either House of Congress may disapprove the rule or regulation by simple resolution.

As we have often stated, the Justice Department considers provisions for review of executive action by resolution of one House unconstitutional. They violate the general principle of separation of power whereby Congress enacts but the President executes the laws. Furthermore, they violate Article I, section 7, which requires that resolutions having the force of law be sent to the President for his signature or veto. See, e.g., Statement of Assistant Attorney General Scalia in Congressional Review of Administrative Rulemaking, Hearings before the Subcommittee on Administrative Law and Governmental Relations, House Judiciary Committee, 94th Cong. 1st Sess. 373 (1975).

Since the bill includes no other provision except for a six month extension of authority, we believe that the President should veto this bill.

Sincerely,

Michael M. Uhlmann

Michael M. Uhlmann
Assistant Attorney General
Office of Legislative Affairs

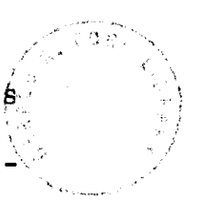
VETO MESSAGE

H.R. 12944

I am returning, without my approval, H.R. 12944, a bill "To extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for six months." If the only purpose of the bill were that set forth in its caption I would not have serious reservations about it.

The bill would, however, also make a serious substantive change in the law. It would subject rules and regulations issued under authority of the Act to a 60 day review period during which either House of Congress may disapprove the rule or regulation by simple resolution.

As I have indicated on previous occasions, I believe that provisions for review of regulations and other action by resolutions of one-House or concurrent resolution are unconstitutional. They are contrary to the general principle of separation of power whereby Congress enacts laws but the President and the agencies of government execute them. Furthermore, they violate Article I, section 7 which requires that resolutions having the force of law be sent to the President for his signature or veto. There is no provision in the Constitution for the procedure contemplated by this bill.



Congress has been considering bills of this kind in increasing number. At my direction, the Attorney General moved recently to intervene in a lawsuit challenging

the constitutionality of a comparable section of the Federal election law. I hope that Congress will reconsider H.R. 12944 and pass a bill which omits this provision.

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: August 11 Time: 615pm

FOR ACTION: George Humphreys - veto-
Dick Parsons
Max Friedersdorf veto
Ken Lazarus - veto
Bob Hartmann

cc (for information): Jack Marsh
Jim Cavanaugh
Ed Schmults

FROM THE STAFF SECRETARY

DUE: Date: August 12 Time: 300pm

SUBJECT:

H.R. 12944-Six mohhh extension of the Federal Insecticide Fungicide and Rodenticide Act

ACTION REQUESTED:

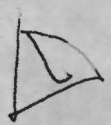
____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

please return to judy johnston, ground floor west wing



PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

K. R. COLE, JR.
For the President

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: AUgust 11 Time: 615pm

FOR ACTION: George Humphreys
Dick Parsons
Max Friedersdorf
Ken Lazarus

cc (for information): Jack Marsh
Jim Cavanaugh
Ed Schmults

FROM THE STAFF SECRETARY

DUE: Date: August 12 Time: 300pm

SUBJECT:

H.R. 12944-Six month extension of the Federal Insecticide Fungicide and Rodenticide Act

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

please return to judy johnston, ground floor west wing

I told Judy that I recommend veto

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: AUgust 11 Time: 615pm

FOR ACTION: George Humphreys
Dick Parsons
Max Friedersdorf
Ken Lazarus

cc (for information): Jack Marsh
Jim Cavanaugh
Ed Schmults

FROM THE STAFF SECRETARY

DUE: Date: August 12 Time: 300pm

SUBJECT:

H.R. 12944-Six month extension of the Federal Insecticide Fungicide and Rodenticide Act

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

please return to judy johnston, ground floor west wing

Recommend veto and have no objection to the substance of the draft veto message.

Ken Lazarus 8/12/76

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: August 11 Time: 615pm

FOR ACTION: George Humphreys
Dick Parsons
Max Friedersdorf
Ken Lazarus

cc (for information): Jack Marsh
Jim Cavanaugh
Ed Schmults

M.G.

FROM THE STAFF SECRETARY

DUE: Date: August 12 Time: 300pm

SUBJECT:

H.R. 12944-Six month extension of the Federal Insecticide Fungicide and Rodenticide Act

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

please return to judy johnston, ground floor west wing

Recommend Disapproval - MSF

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: AUgust 11 Time: 615pm

FOR ACTION: George Humphreys
Dick Parsons
Max Friedersdorf
Ken Lazarus

cc (for information): Jack Marsh
Jim Cavanaugh
Ed Schmults

FROM THE STAFF SECRETARY

DUE: Date: August 12 Time: 300pm

SUBJECT:

H.R. 12944-Six month extension of the Federal Insecticide Fungicide and Rodenticide Act

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS: I concur in the recommendation of disapproval.

please return to judy johnston, ground floor west wing

RR

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

THE WHITE HOUSE

Rec. 8/12/76 - 4:50 pm

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: AUgust 11 Time: 615pm

FOR ACTION: George Humphreys
Dick Parsons
Max Friedersdorf
Ken Lazarus
Robert Hartmann (veto message attached)

cc (for information): Jack Marsh
Jim Cavanaugh
Ed Schmults

FROM THE STAFF SECRETARY

DUE: Date: August 12 Time: 300pm

SUBJECT:

H.R. 12944-Six month extension of the Federal Insecticide Fungicide and Rodenticide Act

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

please return to judy johnston, ground floor west wing

8/12 - Copy sent for researching. nm

8/12 - Requested copy returned. nm

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

THE WHITE HOUSE Rec. 8/12/76 -4:50 pm

ACTION MEMORANDUM WASHINGTON LOG NO.:

To Res. 8/12/76 5:34pm
To OJS 8/12 6:05pm

Date: AUgust 11 Time: 615pm

FOR ACTION: George Humphreys
Dick Parsons
Max Friedersdorf
Ken Lazarus
Robert Hartmann (veto message attached)

cc (for information): Jack Marsh
Jim Cavanaugh
Ed Schmults

RETURN TO ROOM 128 RESEARCH

FROM THE STAFF SECRETARY

DUE: Date: August 12 Time: 300pm

SUBJECT:

H.R. 12944-Six month extension of the Federal Insecticide Fungicide and Rodenticide Act

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

please return to judy johnston, ground floor west wing

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

ok/jc

TO THE HOUSE OF REPRESENTATIVES

ok

I am returning, without my approval, H.R. 12944, a bill "To extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for ok months." If the only purpose of the bill were that set forth in its caption I would have no reservations about it.

The bill would, however, also make a serious substantive change in the law. It would subject rules and regulations issued under authority of the Act to a 60-day review period during which either House of Congress may disapprove the rule or regulation by simple resolution.

attached back-up

As I have indicated on previous occasions, I believe that provisions for review of regulations and other action by resolutions of one-house or concurrent resolution are unconstitutional. They are contrary to the general principle of separation of power whereby Congress enacts laws but the President and the agencies of government execute them. Furthermore, they violate Article I, section 7 which requires that resolutions having the force of law be sent to the President for his signature or veto. There is no provision in the Constitution for the procedure contemplated by this bill.

attached back-up

Congress has been considering bills of this kind in increasing number. At my direction, the Attorney General moved recently to intervene in a lawsuit challenging

the constitutionality of a comparable section of the Federal election law. I hope that Congress will reconsider H.R. 12944 and pass a bill which omits this provision.

THE WHITE HOUSE

August , 1976

TO THE HOUSE OF REPRESENTATIVES

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THE WHITE HOUSE

August , 1976

To- J. Cavanaugh 8-11-76 6:00 p.m.

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

AUG 11 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill H.R. 12944 - Six month extension of the Federal Insecticide, Fungicide, and Rodenticide Act
Sponsors - Rep. Foley (D) Washington and Rep. Wampler (R) Virginia

Last Day for Action

August 21, 1976 - Saturday

Purpose

Extends the appropriation authorization for the Environmental Protection Agency (EPA) to carry out the provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for six months from April 1, 1977, until September 30, 1977, at a level of $19,735,100, and provides for a one-house veto of FIFRA regulations promulgated by EPA.

Agency Recommendations

Office of Management and Budget	Disapproval (Veto Message attached)
Department of Justice	Disapproval (Veto Message attached)
Environmental Protection Agency	Disapproval (Veto Message attached)
Department of Agriculture	Supports FIFRA extension; no position on one-house veto provision

August 13, 1976

Received from the White House a sealed envelope said to contain H.R. 12944, "An Act to extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for six months," and a veto message thereon.

Edmund L. Henshaw Jr.
Clerk of the House of Representatives
by Dickett
4:35 pm.
Time received

TO THE HOUSE OF REPRESENTATIVES:

I am returning, without my approval, H.R. 12944, a bill "To extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for six months." If the only purpose of the bill were that set forth in its caption I would have no reservations about it.

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Gerald R. Ford

THE WHITE HOUSE,

August 13, 1976.

Delivered to Clerk of House: 8/13/76 (4:35 p)

(Stenciled)

94TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 94-1105

SIX-MONTH EXTENSION OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

MAY 6, 1976.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. FOLEY, from the Committee on Agriculture, submitted the following

REPORT

together with

DISSENTING VIEWS

[To accompany H.R. 12944]

The Committee on Agriculture, to whom was referred the bill (H.R. 12944), to extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for six months, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PURPOSE AND NEED FOR THE LEGISLATION

H.R. 12944 extends the authorization for appropriations for FIFRA for a six-month period until September 3, 1977, at a level of $19,735,100. The funding authorization currently in the Act terminates March 31, 1977, and without further action by the Congress, EPA would have no authorization to continue its activities under FIFRA beyond that date.

There would be a total authorization of appropriations under the Act for the fiscal year ending September 30, 1977, in the amount of $43,335,100 when account is taken of the authorization for the first six months of the fiscal year of $23,600,000 provided by Public Law 94-140 and the supplemental amount authorized by H.R. 12944 for the balance of the year. The authorization provided by H.R. 12944 covers all activities under FIFRA. A portion of the authorization would be available for research programs carried out under section 20 of the Act. There would be available for this purpose the amount authorized by the House in H.R. 12704.

Action is being taken at this time to extend the authorization through the balance of fiscal year 1977 because of the provisions of the

Congressional Budget Act of 1974. H.R. 12944 provides new budget authority for the fiscal year ending September 30, 1977, and under section 402(a) of that Act it would not be in order to consider the bill in the House, with an emergency waiver, if the bill were reported after May 15, 1976.

In the course of its hearings, the Committee heard testimony concerning problems arising from delays in registration and their effect on the ability of small formulators to remain in business. Following the hearings, additional statements were received by the Committee indicating that the delays in obtaining registration were also adversely affecting the basic producers and were the result of a number of complex factors. Issues were also raised relating to administration of section 3(c)(1)(D) and section 10(b) of the Act as well as the competitive implications of the Act.

The Committee believes that the problems appear to be largely problems of administration and not of legislation as the Administrator begins to implement the requirements of Section 3. The Committee expects the Administrator to make every effort to resolve these issues and to work closely with all parties involved. The Committee understands that EPA has several studies underway to that end. The Committee requests that prior to the convening of the 95th Congress, the EPA furnish the Committee with a detailed report regarding these matters, its decisions regarding resolution of the issues and any recommendations it might have for changes in legislation.

The Committee will examine these issues in detail during the oversight hearings early in 1977 at the time it will have before it for consideration legislation for a further extension of the Act. For the foregoing reasons, the Committee is of the view that oversight hearings at this time would be premature.

Committee Consideration

The Committee held hearings on April 6, 1976, at which time it heard testimony from John Quarles, Deputy Administrator for the Environmental Protection Agency in support of the bill. It also received testimony from a representative of the Pesticide Formulators Association regarding problems arising to small formulators as a result of delays in registrations by EPA. After the hearing, statements in support of the bill were received from the National Association of State Departments of Agriculture, American Farm Bureau Federation, National Agricultural Chemicals Association and National Council of Agricultural Employers. A supplemental statement was also received from the Pesticide Formulators Association addressing the Committee's attention again to problems the small formulators had encountered regarding registration delays and data compensation. It stated, however, that it did not request oversight hearings on these issues prior to enactment of H.R. 12944.

At the hearings a number of issues were discussed by Members of the Committee with Mr. Quarles, including the need for the immediate availability of pesticides to be used in a control or eradication program on fire ants which have continued to spread over increasingly large areas in the Southern part of the country.

The Committee held a markup session on April 29, 1976. At that

time Mr. Mathis proposed an amendment to provide that no regulation under the Federal Insecticide, Fungicide and Rodenticide Act shall become effective if within 30 days after receiving it in final form either Committee, following a public hearing, approves a resolution rejecting the regulation. It was amended to require action either by the House of Representatives or the Senate instead of by either Committee. A substitute proposal to increase the time for action to 30 legislative days was defeated. The Mathis amendment, as amended, was defeated by a rollcall vote of 16 yeas to 18 nays.

Members opposed to the Mathis amendment pointed out that failure of the Committee to report a resolution of disapproval within the prescribed time limit would, in effect, give the regulations the stamp of Congressional approval, even though they may at a later date prove troublesome and, in fact, unworkable. Chairman Foley indicated that problems with the regulations frequently do not surface until they have been implemented some time after expiration of the 30-day period for action under the amendment.

Secondly, a number of Members expressed grave concern over the effect of the Mathis amendment on overall Committee operation since the Committee presently faced a very crowded schedule made even more complex by provisions of the Congressional Budget and Impoundment Control Act. Strong sentiment was expressed that because of the crowded schedule as well as the highly technical nature of pesticide regulations issued by the Environmental Protection Agency running occasionally in excess of a hundred pages and the time constraints of the Mathis amendment itself, the Committee would be unable to give proper attention to the regulations and to their possible consequences prior to the end of the 30-day period.

Finally, Members opposed to the amendment argued that its adoption was unnecessary since the Congress already has authority to reverse any administrative regulation or action through enactment of legislation addressing the specific issue. Provisions of Public Law 94–140 now require the Administrator to provide the appropriate Committees with copies of all proposed and final regulations affecting pesticide matters in advance of their taking effect. Under existing law, if there were any apparent problems which may be evident to the Committee, it could exercise oversight by holding hearings and discussing the issues with EPA without concern of the time limitation in the amendment.

After the vote on the Mathis amendment, H.R. 12944 was ordered reported by a voice vote in the presence of a quorum with a recommendation that it do pass.

Administration Position

At the hearing, the following statement was received from Mr. John R. Quarles, Jr., Deputy Administrator, Environmental Protection Agency in support of H.R. 12944:

Statement of Hon. John R. Quarles, Jr., Deputy Administrator, Environmental Protection Agency

Good morning, Mr. Chairman, and members of the Committee. I am pleased to appear before you today in support of

H.R. 12944 and to review the Environmental Protection Agency's administration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As you know, this statute, amended by the 1972 Federal Environmental Pesticide Control Act (FEPCA), and further refined within recent months principally through the efforts of this Committee, provides the legal framwork to assure that pesticides registered by the Government are effective for their claimed purposes and will not pose an unreasonable risk to man or the environment.

The statute, and our Agency, recognize that there is a degree of risk which must be accepted in order to derive the substantial benefits afforded to society by pesticides. A no-risk concept for pesticide regulation is neither reasonable nor legally tenable. Most pesticides are intended to inflict harm on some form of life, or in some way to modify its structure or development. We thus expect pesticides to impose some degree of hazard; indeed, they would be no good to us if they did not.

But we also expect that more often than not the inherent ability of pesticides to modify or destroy is not limited solely to "pests". Certainly, we have been sadly reminded in recent months of the potential of pesticides to do non-target damage. The tragic incident in Hopewell, Virginia, and the episodes in Texas and Oklahoma in which children were killed by rodent poisons, testify to the damages of pesticide misuse, or simply failing to appreciate the risks they pose.

The 1972 law provides a number of new complementary tools which taken together, can substantially reduce unnecessary risk to Americans from accidental and incidental pesticide exposure or deliberate misuse. Substantial progress has been made in fulfilling the requirements of the FEPCA and in adjusting the program to the changes, including extended implementation periods, mandated by the 1975 amendments.

As you know, these latter amendments established a formal procedure for EPA to elicit the views of the Department of Agriculture in connection with the issuance of regulations or when cancelling or reclassifying a pesticide, and to advise this Committee of these proposed actions. A similar and concurrent review is accorded to a Scientific Advisory Panel. The creation of this body (which must conform to provisions of the Federal Advisory Committee Act) has, of course, been a necessary prerequisite to employing the consultation provisions in the Act. The Panel is not yet officially formed, but it has been chartered, nominees have been solicited from the National Institutes of Health and the National Science Foundation, and we expect it to be operating in the next several weeks. In the meantime, none of the actions requiring review by the panel has been initiated.

But even as these new formal procedures are being put into pracitce, we have undertaken to consult more regularly with USDA, the staff of this Committee and your Senate

colleagues, our state counterparts, and the pesticide user community. Only last week, the Association of American Pesticide Control Officials met in Washington with a heavy agenda of detailed items of mutual concern which they discussed with Administrator Train and numerous appropriate EPA staff. As you are aware, too, some months ago the Administrator established a Pesticide Policy Advisory Committee to enable him to obtain the advice and viewpoints of a wide spectrum of interests. The full Committee has met twice to date, and is scheduled to meet again this month. It has created three subcommittees which are already active, to focus on program strategies, benefit/risk assessment, and pesticide use and exposure. I understand the Committee may hold a series of public information hearings around the country this summer to solicit additional "grass roots" thoughts on pesticide use and policies.

I believe that the USDA witnesses will confirm my view that there has been substantial improvement in the substance and frequency of the dialogue between our staffs. In fact, today there is an EPA/USDA working group meeting to identify improved methods for putting better economic data into regulatory reviews of pesticides. Despite some recent criticism of these and other efforts to open up our decision making to broader participation and scrutiny, I maintain that these and related actions have strengthened our ability to reach decisions in applying the law that more fully and fairly reflect all of the pertinent information, knowledge, and evidence available from genuinely concerned parties throughout the country.

The massive job of evaluating all previously registered pesticides for reregistration is underway. The Office of Pesticide Programs has established a schedule for "calling in" chemicals by "batches," consisting of products grouped on the basis of similarity of formulation and broad use pattern. Reregistration guidance packages, explaining data needed to support the safety of the product, labeling instructions, submittal deadlines, and a proposed classification (i.e., general or restricted) are being sent to registrants at this time. We have every reason to be optimistic that we will be able to meet our assurances to this Committee that the likely restricted category pesticides—which we will review as our first priority—will be called in for reregistration by September, thus providing additional certainty for states which are tailoring applicator training programs to the range of chemicals which will be available for use only by applicators certified competent as of October 1977.

In addition, we published in the Federal Register on February 17 an explanation of reregistration procedures, and placed all pesticides into five categories: (1) those for which sufficient data are available for reregistration, (2) those for which long-term testing requirements must be met, (3) those for which short-term testing requirements must be met, (4)

those which trigger the rebuttable presumption against registration, and (5) those which have not yet been adequately reviewed for placement in one of the four primary categories. Since we are still in the process of validating information which may lead to rebuttable presumption notices, we have not yet determined which pesticides will fall into Category IV aside from kepone and chloroform.

This brings me to a topic of special interest to this Committee—the potential for the rebuttable presumption process to remove current products from the market. Although we held a briefing for you on this subject last June, I think it might be beneficial to discuss for a few moments what rebuttable presumption is, and is not.

Let me first re-emphasize that the entire process is predicated on open decision making. A notice of presumption against registration is not tantamount to cancellation; rather, such notice simply means that we have data indicating that one or more of the criteria for determining a potential "unreasonable adverse effect" has been met or exceeded. It is a notice which says formally to the manufacturer, "we have evidence that your product may pose unreasonable adverse effects to the environment and we therefore presume against registration . . . it is now your prerogative to overcome this presumption to achieve reregistration." In such cases, the registrant can show that we erred in issuing the notice—that the evidence upon which the notice is based is invalid. Or he may rebut the presumption by showing that the risk, while apparent, is not real due to absence of exposure in the specific use pattern. Two aspects of hazard or risk must be considered: inherent toxicity, measured by the registration regulations, and exposure, which is not measured in the regulations. Or he may present evidence that the benefits exceed the risks. Not only the registrant is notified of a rebuttable presumption, of course; a notice will appear in the Federal Register immediately after the registrant is contacted.

Then, as soon as our review schedules are set, USDA as well as other concerned user, industry, and environmental groups will be informed of our activities as early as possible. Thus, we can start receiving benefits data right away; we can start receiving minor use data right away. In short, the notice of presumption sets into motion an information gathering process in which all interested parties may participate, and upon which EPA can base a decision as to whether or not cancellation procedures or nonadjudicatory hearings should be commenced or registration granted. Of course, should EPA determine that cancellation is in order, the proposed action will be submitted to the Secretary of Agriculture and the Scientific Advisory Panel 60 days prior to public notice, with concurrent notification of this Committee and the Senate Committee on Agriculture and Forestry. Data and scientific views will also be solicited as appropriate from groups such as the National Cancer Institute, the National

Institue for Environmental Health Sciences, and the National Institute of Occupational Safety and Health. We will also be looking to EPA's Science Advisory Board and Cancer Assessment Group for guidance as appropriate.

In sum, the mechanism is designed to assure an open process where users, manufacturers, and public interest groups are not surprised by our actions; to provide for public input to the decision process as early in that process as possible to maximize the amount of relevant information available at the decision point; and to provide for a specific Agency risk/benefit position on each use, major or minor, at the time of decision, whether that decision be to cancel, register, or hold an information gathering hearing.

As we implement reregistration, we are becoming aware of the need for fine tuning our regulations when it becomes necessary for us to do so. We are reviewing current procedures to assure that, as applied especially to formulators of "me too" products, their effect is to avoid environmental harm and not to simply disrupt entry into the competitive market.

The knowledge that particularly toxic chemicals will not be available to persons unskilled in their use or unaware of their hazardous nature can be an important factor in decisions by the Administrator on whether a pesticide poses an "unreasonable adverse risk". Last year's amendments confirmed that a determination of competence need not be based on an examination, although the states have the discretion to require that option. With Congressional resolution of the uncertainty over the private applicator certification provisions of FIFRA, states are completing certification plans at an accelerating pace. The Governors of more than half of the states have submitted final plans, most of which have been approved or will soon be approved.

State operated training efforts are well underway with one-time seed money grants awarded and transfer funds to the USDA Extension Service defraying initial program development and training materials costs. State officials are carefully monitoring the number of applicators already involved in training programs against the anticipated number requiring eventual certification to guard against a last minute crunch. You may be interested to know that EPA has, or will have through fiscal year 1977, provided over $15 million to the training and certification effort, with additional Federal assistance from reprogramed USDA resources for training.

The Administration transmitted proposed legislation to the Congress which would have provided continued funding authorization for the balance of fiscal year 1977, and an additional full year, i.e., through fiscal year 1978, which is consistent in the funding levels authorized with H.R. 12944.

In closing, Mr. Chairman, I would like to observe that my appearance this morning marks the seventh occasion on which I have testified before the Committee in less than a

year. Since May 12 last year, when I testified on behalf of a 2-year extension of FIFRA authority, and was personally acquainted with only a very few members, we have acquired a great body of common experiences, agreed on the solutions to some problems, disagreed about the solutions to others, and found that not all of us agree that some matters are problems.

In remarks supporting adoption of the conference report on H.R. 8841, the Ranking Minority Member, Mr. Wampler, observed that, ". . . this bill reflects what I perceive to be a reasonable compromise between agricultural, environmental, congressional and executive branch points of view, . . . thus providing again that when Congress and the Administration really work at working together we can all do so." We fully support that proposition.

We are here at a time when the pesticide program badly needs certainty as to provisions previously adopted but only partially implemented. I urge that this brief but essential continuation of authorization be favorably reported so as to continue the momentum toward achievement of the important goals of the amended FIFRA.

That concludes my prepared statement, Mr. Chairman. I would be pleased to answer the Committee's questions.

The United States Department of Agriculture submitted the following report on H.R. 12944:

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, D.C., April 30, 1976.

Hon. THOMAS S. FOLEY,
Chairman, House Committee on Agriculture,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in reply to your request received April 6, 1976, for a report on H.R. 12944, a bill "To Extend the Federal Insecticide, Fungicide and Rodenticide Act, as amended, for six months."

The Department recommends that the bill be enacted.

We support the bill with the expectation that oversight hearings originally planned for March of 1977 will occur as anticipated. The Department clearly recognizes the monumental problem facing the U.S. Environmental Protection Agency (EPA). We believe that the basic Act passed in 1972 and recently amended in the fall of 1975, is a well-conceived statute. There are areas of activity within EPA that are of major interest to the Department. In the toxic substances and water toxic pollutants areas, we are working with EPA to increase our involvement.

We agree that the reregistration process now being initiated is a step forward in expediting the review of pesticides. The Department has been kept apprised of activities concerned with active ingredient reviews in the Office of Special Pesticide Review in EPA. Of course, the implications of the rebuttable presumption process are of continuing concern to the Department. However, EPA is committed to working closely with USDA to resolve these concerns.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

JOHN A. KNEBEL,
Acting Secretary.

CURRENT AND FIVE SUBSEQUENT FISCAL YEARS COST ESTIMATE

Pursuant to clause 7 of Rule XIII of the Rules of the House of Representatives, the Committee estimates that the authority provided for in this bill should result in a cost of $19,735,100 for the six-month period, April 1, 1977, through September 30, 1977. Costs incurred thereafter will depend upon future authorization from the Congress.

The cost estimate of the Congressional Budget Office is contained in the Congressional Budget Office section of this report.

The same cost estimate was submitted to the Committee by the Environmental Protection Agency.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4), Rule XI of the Rules of the House of Representatives, the Committee estimates that enactment of H.R. 12944 will have no inflationary impact on the national economy.

BUDGET ACT COMPLIANCE (SECTION 308 AND SECTION 403)

The provisions of clause 2(l)(3)(B) of Rule XI of the Rules of the House of Representatives and section 308(a) of the Congressional Budget Act of 1974 (relating to estimates of new budget authority or new or increased tax expenditures) are not considered applicable. The estimate and comparison prepared by the Director of the Congressional Budget Office under clause 2(l)(3)(C) of Rule XI of the Rules of the House of Representatives and section 403 of the Congressional Budget Act of 1974 submitted to the Committee prior to the filing of this report are as follows:

CONGRESS OF THE UNITED STATES,
CONGRESSIONAL BUDGET OFFICE,
Washington, D.C., April 28, 1976.

Hon. THOMAS S. FOLEY,
Chairman, Committee on Agriculture, U.S. House of Representatives,
Longworth House Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has prepared the attached cost estimate for H.R. 12944, Extension of the Federal Insecticide, Fungicide, and Rodenticide Act.

Should the Committee so desire, we would be pleased to provide further details on the attached cost estimate.

Sincerely,

ALICE M. RIVLIN, *Director.*

Congressional Budget Office Cost Estimate

April 27, 1976.

1. Bill Number: H.R. 12944.
2. Bill Title: Extension of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
3. Purpose of Bill:

The Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 136(y)), provides the authorization for the various pesticide control programs administered by the Environmental Protection Agency. Under the provisions of the Act, the EPA controls the use of hazardous chemicals through the registration of pesticides, the certification and training of pesticide users, residue monitoring and through a research program which evaluates the behavior of pesticides and their impact on ecosystems.

The last extension of FIFRA (Public Law 94–140) authorized funds for these programs through March 31, 1977. H.R. 12944 would authorize $19,735,100 for the six month period between April 1, 1977 and September 30, 1977, i.e., the second half of fiscal year 1977. This is an authorization bill and therefore requires subsequent appropriation action.

4. Cost Estimate: The budget impact of this proposed legislation is presented below.

BUDGET IMPACT

[In thousands of dollars]

	Fiscal year—				
	1977	1978	1979	1980	1981
Authorization level	19,735				
Costs	11,850	5,150	2,735		

5. Basis of Estimate: The estimate for the costs associated with the authorization total of $19,735,000 is based on an outlay distribution assumption of 60, 26, 14 percent for fiscal years 1977–1979, respectively.[1]
6. Estimate Comparison: None.
7. Previous CBO Estimate: None.
8. Estimate Prepared By: Robert M. Gordon (225–5275).
9. Estimate Approved by:

C. G. Nuckols,
(For James L. Blum,
Assistant Director for Budget Analysis.)

Oversight Statement

No summary of oversight findings and recommendations made by the Committee on Government Operations under clause 2(b)(2) of

[1] This distribution was provided by the Office of Program Management of the Environmental Protection Agency and reflects historical experience with the program.

Rule X of the Rules of the House of Representatives was available to the Committee with reference to the subject matter specifically addressed by H.R. 12944.

Changes in Existing Law

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

The Federal Insecticide, Fungicide, and Rodenticide Act, as Amended

* * * * * * *

SEC. 27. AUTHORIZATION FOR APPROPRIATIONS.

There is authorized to be appropriated such sums as may be necessary to carry out the provisions of this Act for each of the fiscal years ending June 30, 1973, June 30, 1974, and June 30, 1975. The amounts authorized to be appropriated for any fiscal year ending after June 30, 1975, shall be the sums hereafter provided by law. There is hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning July 1, 1975, and ending September 30, 1975, the sum of $11,967,000. There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1975, and ending September 30, 1976, the sum of $47,868,000, and for the period beginning October 1, 1975, and ending March 31, 1977, the sum of $23,600,000, *and for the period beginning April 1, 1977, and ending September 30, 1977, the sum of $19,735,100.*

DISSENTING VIEWS OF HON. DAWSON MATHIS, HON. TOM HAGEDORN, HON. GLENN ENGLISH, HON. WALTER B. JONES, HON. JOHN W. JENRETTE, JR., HON. STEVEN D. SYMMS, HON FLOYD J. FITHIAN, AND HON. W. HENSON MOORE

There is a need for greater Congressional oversight over not only the Environmental Protection Agency but all Federal regulatory agencies. Presently, the only effective methods for insuring that EPA regulations are within the intent of Congress are through corrective legislation or legal proceedings initiated by aggrieved parties. To supplement these cumbersome processes the Mathis Amendment, which was narrowly defeated during the Committee's consideration of H.R. 12994, would have allowed either House of Congress to invalidate any EPA regulation within thirty legislative days after receiving the regulation in final form. The Committee on Agriculture of the House or the Committee on Agriculture and Forestry of the Senate would have to approve, following a public hearing, a resolution rejecting the regulation before either House could take a final vote. This would not be a summary process as some critics feared.

The feeling of the ten Democrats and six Republicans who voted for the Mathis Amendment was that closer Congressional review of EPA rulemaking pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act would greatly assist in keeping EPA actions within the intent of Congress in passing this legislation.

Some Members expressed concern that Congress lacked the expertise to carefully review the highly technical regulations imposed by EPA and that failure of Congress to timely invalidate a regulation would put the Committee's stamp of approval on a regulation whose objectionable features might not become obvious until much later. Such an argument presumes that Congress, by failing to exercise oversight, can escape ultimate responsibility for the actions of an agency it created.

The concept of Congressional review of administrative rulemaking is not new. The authority of either House to overturn executive reorganization plans (5 U.S.C.A. 906) and regulations of the Federal Election Commission (2 U.S.C.A. 438(c)) are but two examples of the successful application of this procedure.

The Library of Congress has identified about one hundred similar provisions in existing law allowing either House or a single Committee to veto administrative regulations, and their Constitutionality has been well established.

If Congress is ever to reclaim or even share in the legislative powers delegated to the Executive Branch, then passage of the Mathis Amendment, or a similar provision, is an essential step. Contrary to the views of some of its critics the Amendment will not impede the orderly and

legitimate functioning of the EPA but rather will strengthen this functioning by keeping it within the legislative intent of Congress. The Mathis Amendment is expected to again be offered when the House begins consideration of H.R. 12994.

GLENN ENGLISH.
WALTER B. JONES.
JOHN W. JENRETTE, Jr.
W. HENSON MOORE.
DAWSON MATHIS.
STEVE SYMMS.
FLOYD FITHIAN.
TOM HAGEDORN.

H. R. 12944

Ninety-fourth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday, the nineteenth day of January, one thousand nine hundred and seventy-six

An Act

To extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for six months.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 27 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136(y)), is amended by inserting immediately before the period at the end of the section ", and for the period beginning April 1, 1977, and ending September 30, 1977, the sum of $19,735,100".

SEC. 2. Section 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is amended by adding the following new paragraph at the end thereof:

"(4) RULE AND REGULATION REVIEW.—

"(A) Any rule or regulation issued under authority of this Act after the date of enactment of this provision may by resolution of either House of Congress be disapproved, in whole or in part, if such resolution of disapproval is adopted not later than the end of the first period of 60 calendar days when Congress is in session (whether or not continuous) which period begins on the date such rule or regulation is finally adopted by the department or agency adopting same. The department or agency adopting any such rule or regulation shall transmit such rule or regulation to each House of Congress immediately upon its final adoption. Upon adoption of such a resolution of disapproval by either House of Congress, such rule or regulation, or part thereof, as the case may be, shall cease to be in effect.

"(B) Congressional inaction on or rejection of a resolution of disapproval shall not be deemed an expression of approval of such rule.".

Speaker of the House of Representatives.

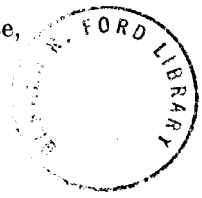
Vice President of the United States and
President of the Senate.

94TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 94-1005

HEALTH RESEARCH AND HEALTH SERVICES AMENDMENTS OF 1976

APRIL 2, 1976.—Ordered to be printed

Mr. STAGGERS, from the committee of conference, submitted the following



CONFERENCE REPORT

[To accompany H.R. 7988]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 7988) to amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment insert the following:

SECTION 1. (a) This Act may be cited as the "Health Research and Health Services Amendments of 1976".

(b) Whenever in this Act (other than in titles III, V, VI, VII, and XI) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

SEC. 101. (a) Congress finds and declares that—

(1) diseases of the heart, blood, and blood vessels collectively cause more than half of all the deaths each year in the United States and the combined effect of the disabilities and deaths from such diseases is having a major social and economic impact on the Nation;

57-006 O—76——1

(2) elimination of heart and blood vessel diseases as significant causes of disability and death could increase the average American's life expectancy by about eleven years and could provide for annual savings to the economy in lost wages, productivity, and cost of medical care of more than $40,000,000,000 per year;

(3) chronic lung diseases have been gaining steadily in recent years as important causes of disability and death, with emphysema being among the fastest rising causes of death in the United States;

(4) chronic respiratory diseases affect an estimated ten million Americans, emphysema an estimated one million, chronic bronchitis an estimated four million, and asthma an estimated five million;

(5) thrombosis (the formation of blood clots in the vessels) may cause, directly or in combination with other problems, many deaths and disabilities from heart disease and stroke which can now be prevented;

(6) blood and blood products are essential human resources whose value in saving life and promoting health cannot be assessed in terms of dollars;

(7) the provision of prompt and effective emergency medical services utilizing to the fullest extent possible advances in transportation and communications and other electronic systems and specially trained professional and paraprofessional health care personnel can reduce substantially the number of fatalities and severe disabilities due to critical illnesses in connection with heart, blood vessel, lung, and blood diseases;

(8) blood diseases, including nutritional anemia, anemia due to inherited abnormalities (such as sickle cell anemia and Cooley's anemia (thalassemia), anemias resulting from failure of the bone marrow, hemorrhagic defects (a common cause of death in patients with leukemia and other malignancies, and of disability from inherited diseases such as hemophilia)), and malignancies of the lymph nodes and bone marrow, such as leukemia, have a devastating impact in spite of recent advances, and constitute an important category of illness that requires major attention; and

(9) the greatest potential for advancement against heart, blood vessel, lung, and blood diseases lies in the National Heart, Lung, and Blood Institute, but advancement against such diseases depends not only on the research programs of that Institute but also on the research programs of other research institutes of the National Institutes of Health.

(b) It is the purpose of this title to enlarge the authority of the National Heart, Lung, and Blood Institute in order to advance the national attack upon heart, blood vessel, lung, and blood diseases and to enlarge its authority with respect to blood resources.

SEC. 102. Sections 411, 418(a)(6), and 419A(c) are each amended by striking out "National Heart and Lung Institute" and inserting in lieu thereof "National Heart, Lung, and Blood Institute".

SEC. 103. (a) Section 412 is amended—

(1) by inserting "and with respect to the use of blood and blood products and the management of blood resources" after "diseases" in the matter preceding paragraph (1);

(2) by inserting "and to the use of blood and blood products and the management of blood resources" before the semicolon at the end of paragraph (1);

(3) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (4);

(4) by inserting "and on the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (5);

(5) by striking out "heart diseases" in paragraph (6) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and the management of blood resources";

(6) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (7); and

(7) by inserting at the end of the section heading "AND IN THE MANAGEMENT OF BLOOD RESOURCES".

(b) Section 412 is amended by striking out "National Heart and Lung Advisory Council" and inserting in lieu thereof "National Heart, Lung, amd Blood Advisory Council".

SEC. 104. (a) Section 413(a) is amended—

(1) by striking out "Disease" in the first sentence and inserting in lieu thereof "Diseases and Blood Resources"; and

(2) by inserting "and blood resources" after "diseases" in such sentence and in paragraph (7).

(b) Section 413(b) is amended—

(1) by striking out "calendar" each place it occurs in paragraph (2) and inserting in lieu thereof "fiscal"; and

(2) by adding at the end of such paragraph the following: "Each such plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations to carry out the program during such five years".

(c) Section 413(c)(1) is amended by striking out "fifty" and inserting in lieu thereof "one hundred".

(d) Section 413(c)(2) is amended—

(1) by striking out "operate" and inserting in lieu thereof "operate, alter, renovate"; and

(2) by inserting "and blood resource" after "disease".

(e) Section 413(d) is amended—

(1) by striking out "Assistant Director for Health Information Programs" each place it occurs and inserting in lieu thereof "Assistant Director for Prevention Education, and Control";

(2) by striking out "and pulmonary" in the second sentence and inserting in lieu thereof ", blood, and pulmonary" and by inserting "and blood" after "pulmonary" in the third sentence; and

(3) by inserting "and blood resources" after "diseases" in the second sentence.

(f) The section heading of section 413 is amended by striking out "DISEASE" and inserting in lieu thereof "DISEASES AND BLOOD RESOURCES".

SEC. 105. Section 414(b) is amended (1) by striking out "and" after "1974,", and (2) by inserting before the period a comma and the following: "$10,000,000 for fiscal year 1976, and $30,000,000 for fiscal year 1977".

SEC. 106. (a)(1) Subsection (a)(1)(A) of section 415 is amended by—

(A) striking out "fifteen" and inserting in lieu thereof "ten", and

(B) striking out ", blood vessel, and blood diseases" and inserting in lieu thereof "diseases".

(2) Subsection (a)(1)(B) of such section is amended by striking out "fifteen" and inserting in lieu thereof "ten".

(3) Subsection (a)(1) of such section is amended—

(A) by striking out "and" at the end of subparagraph (A),

(B) by striking out the period at the end of subparagraph (B) and inserting in lieu thereof "; and", and

(C) by inserting after subparagraph (B) the following new subparagraph:

"(C) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources.".

(b) Section 415(a) is further amended—

(1) by inserting "and for research in the use of blood and blood products and in the management of blood resources" after "diseases" in paragraph (1) (A);

(2) by striking out "chronic" in paragraph (1)(B);

(3) by striking out "paragraph (1)(A)" in paragraph (2) and inserting in lieu thereof "paragraph (1)";

(4) by inserting ", pulmonary, and blood" before "diseases" in paragraph (2);

(5) by striking out "cardiovascular disease" in paragraph (2)(A) and inserting in lieu thereof "cardiovascular, pulmonary, and blood diseases"; and

(6) by striking out "such disease" in subparagraphs (B), (C), and (D) of paragraph (2) and inserting in lieu thereof "such diseases".

(c) Section 415(b) is amended—

(1) by inserting "the management of blood resources and" before "advanced"; and

(2) by amending the first sentence after paragraph (4) to read as follows: "The aggregate of payments (other than payments for construction) made to any center under such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed $5,000,000 in any year, except that the aggregate of such payments in any year may exceed such amount to the extent that the excess amount is attributable to increases in such year in appropriate costs as reflected in the Consumer Price Index published by the Bureau of Labor Statistics.".

(d) The section heading of section 415 is amended by inserting "AND BLOOD RESOURCES" after "DISEASES".

SEC. 107. (a) Section 417(a)(1) is amended by striking out "Director of the Office of Science and Technology" and inserting in lieu thereof "Director of the National Science Foundation".

(b) Section 417 is amended by striking out "National Heart and Lung Advisory Council" in subsection (a) and in subsection (b)(3) and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

(c) The section heading of section 417 is amended by striking out "AND LUNG" and inserting in lieu thereof ", LUNG, AND BLOOD".

SEC. 108. Section 418 is amended—

(1) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraphs (1), (2), (3), and (4) of subsection (a);

(2) by redesignating paragraphs (4), (5), and (6) of subsection (a) as paragraphs (5), (6), and (7), respectively, and by adding after paragraph (3) the following new paragraph:

"(4) recommend to the Secretary (A) areas of research in heart, blood vessels, lung, and blood diseases and in the use of blood and blood products and the management of blood resources which it determines should be supported by the awarding of contracts in order to best carry out the purposes of this part, and (B) the percentage of the budget of the Institute which should be expended for such contracts;"; and

(3)(A) by amending paragraph (2) of subsection (b) to read as follows:

"(2) The Council shall submit a report to the Secretary for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress on the progress of the Program toward the accomplishment of its objectives during the preceding fiscal year.".

(B) For purposes of section 418(b)(2) of the Public Health Service Act (as amended by subparagraph (A)), the period beginning July 1, 1975, and ending September 30, 1976, shall be considered a fiscal year.

(C) The amendment made by subparagraph (A) shall take effect as of January 1, 1976.

SEC. 109. Section 419A is amended—

(1) by inserting "and projects with respect to the use of blood and blood products and the management of blood resources" after "training projects" in subsection (a);

(2) by inserting "and into the use of blood and blood products and the management of blood resources" after "diseases" in subsection (b);

(3) by inserting "and for research and training in the use of blood and blood products and the management of blood resources" after "diseases" in subsection (c);

(4) by striking out "in amounts not to exceed $35,000" in paragraph (1) of subsection (c) and inserting in lieu thereof "if the direct costs of such research and training do not exceed $35,000, but only"; and

(5) by striking out "in amounts exceeding $35,000" in paragraph (2) of subsection (c) and inserting in lieu thereof "if the direct costs of such research and training exceed $35,000, but only".

SEC. 110. Section 419B is amended—

(1) by striking out "and" after "1974," and by inserting before the period at the end of the first sentence a comma and the following: "$339,000,000 for fiscal year 1976, and $373,000,000 for fiscal year 1977"; and

(2) by striking out "diseases of the blood" and inserting in lieu thereof "blood diseases and blood resources".

SEC. 111. (a) Section 301 is amended by striking out "heart diseases" in paragraphs (c) and (h) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and blood resources".

(b) Section 301 is amended by striking out "National Heart and Lung Advisory Council" in paragraphs (c) and (h) and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

SEC. 112. The title of Part B of title IV is amended to read as follows:

"PART B—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE".

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

SEC. 201. (a)(1) Subsection (a)(1)(A)(i) of section 472 is amended (A) by striking out "in matters" and inserting in lieu thereof "or under programs administered by the Division of Nursing of the Health Resources Administration, in matters", and (ii) by inserting before "are directed" the following: "or Division of Nursing".

(2) Subsections (a)(1)(A)(iii) and (a)(1)(B) of such section are each amended by striking out "non-Federal".

(b) Subsection (c)(1)(A)(i) of such section is amended by striking out "health research or teaching" and inserting in lieu thereof "health research or teaching or any combination thereof which is in accordance with usual patterns of academic employment".

(c) Subsection (c)(2)(A) of such section is amended by striking out "health research or teaching" and inserting in lieu thereof "health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment".

(d) The first sentence of subsection (d) of such section is amended by inserting a comma before the period and the following: "$165,000,000 for fiscal year 1976, and $185,000,000 for fiscal year 1977".

SEC. 202. (a) Subsection (a)(1)(A)(i) of section 472 is amended by striking out "the disease or (diseases) or other health problems to which the activities of the Institutes and Administration are directed" and inserting in lieu thereof "diseases or other health problems".

(b) Subsection (b)(2) of section 472 is amended by striking out "to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration" and inserting in lieu thereof "within the Department of Health, Education, and Welfare".

SEC. 203. (a)(1) Subparagraph (A) of the first paragraph (4) of subsection (c) of section 472 is amended by striking out "and the interest on such amount" down through and including "was made".

(2) The last sentence of subparagraph (B) of such paragraph is amended by striking out "at the same rate as that fixed by the Secretary of the Treasury under subparagraph (A) to determine the amount due the United States" and inserting in lieu thereof "at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount".

(b) The amendments made by subsection (a) shall apply with respect to National Research Awards under section 472 which are made from appropriations for fiscal years ending on or after June 30, 1975.

SEC. 204. Section 473(b) is amended by adding after paragraph (2) the following new paragraph:

"(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of the National Institutes of Health.".

SEC. 205. Subsection (c) of section 473 is amended by striking out "March 31" and inserting in lieu thereof "September 30".

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

SEC. 301. (a)(1) The President's Biomedical Research Panel (established by section 201(a) of the National Cancer Act Amendments of 1974 (Public Law 93-352)) and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by section 201 of the National Research Act (Public Law 93-348)) shall each conduct an investigation and study of the implication of the disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education, and Welfare (hereinafter in the subsection referred to as the "Secretary") in connection with an application or proposal submitted, during the period beginning January 1, 1975, and ending December 31, 1975, to the Secretary for a grant, fellowship, or contract under the Public Health Service Act. In making such investigation and study the Panel and the Commission shall each determine the following:

(A) The number of requests made to the Secretary for the disclosure of information contained in such research protocols, hypotheses, and designs and the interests represented by the persons for whom such requests were made.

(B) The purposes for which information disclosed by the Secretary pursuant to such requests was used.

(C) The effect of the disclosure of such information on—

(i) proprietary interests in the research protocol, hypothesis, or design from which such information was disclosed and on patent rights;

(ii) the ability of peer review systems to insure high quality federally funded research; and

(iii) the (I) protection of the public against research which presents an unreasonable risk to human subjects of such research and (II) the adequacy of informed consent procedures.

(2)(A) Not later than May 31, 1976, the Panel shall complete the investigation and study required to be made by the Panel by paragraph (1), and, not later than June 30, 1976, the Panel shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Panel deems appropriate.

(B) Not later than November 30, 1976, the Commission shall complete the investigation and study required to be made by the Commission by paragraph (1), and, not later than December 31, 1976, the Commission shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Commission deems appropriate.

(b) Section 211(b) of the National Research Act (Public Law 93-348) is amended by striking out "July 1, 1976" and inserting in lieu thereof "January 1, 1977".

TITLE IV—GENETIC DISEASES

SEC. 401. This title may be cited as the "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act".

SEC. 402. In order to preserve and protect the health and welfare of all citizens, it is the purpose of this title to establish a national program to provide for basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic diseases, including sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

SEC. 403. (a) Title XI is amended by striking out parts A and B and inserting in lieu thereof the following:

"PART A—GENETIC DISEASES

"TESTING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

"SEC. 1101. (a)(1) The Secretary, through an identifiable administrative unit within the Department of Health, Education, and Welfare, may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities, for projects to establish and operate voluntary genetic testing and counseling programs primarily in conjunction with other existing health programs, including programs assisted under title V of the Social Security Act.

"(2) The Secretary shall carry out, through an identifiable administrative unit within the Department of Health, Education, and Welfare, a program to develop information and educational materials relating to genetic diseases and to disseminate such information and materials to persons providing health care, to teachers and students, and to the public generally in order to most rapidly make available the latest advances in the testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. The Secretary may, under such program, make grants to public and nonprofit private entities and enter into contracts with public and private entities and individuals for the development and dissemination of such materials.

"(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $30,000,000 for fiscal year 1976, $30,000,000 for fiscal year 1977, and $30,000,000 for fiscal year 1978.

"RESEARCH PROJECT GRANTS AND CONTRACTS

"SEC. 1102. In carrying out section 301, the Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals, and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases,

and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

"VOLUNTARY PARTICIPATION

"SEC. 1103. The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

"APPLICATIONS; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS

"SEC. 1104. (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require. Each applicant shall—

"(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

"(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

"(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part;

"(4) in the case of an applicant for a grant or contract under section 1101(a)(1) for the delivery of services, provide assurances satisfactory to the Secretary that (A) the services for community-wide testing and counseling to be provided under the program for which the application is made (i) will take into consideration widely prevalent diseases with a genetic component and high-risk population groups in which certain genetic diseases occur, and (ii) where appropriate will be directed especially but not exclusively to persons who are entering their child-producing years, and (B) appropriate arrangements will be made to provide counseling to persons found to have a genetic disease and to persons found to carry a gene or chromosome which may cause a deleterious effect in their offspring; and

"(5) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

"(b) In making any grant or entering into any contract for testing and counseling programs under section 1101, the Secretary shall (1) take into account the number of persons to be served by the program supported by such grant or contract and the extent to which rapid and effective use will be made of funds under the grant or contract; and (2) give priority to programs operating in areas which the Secretary determines have the

greatest number of persons who will benefit from and are in need of the services provided under such programs.

"(c) In making grants and entering into contracts for any fiscal year under section 301 for projects described in section 1102 or under section 1101 the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics.

"PUBLIC HEALTH SERVICE FACILITIES

"SEC. 1105. The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

"REPORTS

"SEC. 1106. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part.

"(b) The report required by this section shall contain such recommendations for additional legislation as the Secretary deems necessary.".

(b)(1) Section 1121(b)(5) is amended by striking out "ending June 30," each place it occurs.

(2) Parts C and D are redesignated as parts B and C, respectively.

(3) The heading of such title is amended to read as follows:

"TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME."

(c) The amendments made by subsections (a) and (b) shall take effect July 1, 1976.

TITLE V—FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

SEC. 501 (a) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 410 (21 U.S.C. 349) the following new section:

"VITAMINS AND MINERALS

"SEC. 411. (a)(1) Except as provided in paragraph (2)—

"(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

"(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

"(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of any synthetic or natural—

"(i) vitamin,

"(ii) mineral, or

"(iii) other ingredient of food,

within a food to which this section applies.

"(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term 'children' means individuals who are under the age of twelve years.

"(b)(1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403(i)(2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

"(2)(A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 403. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

"(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

"(i) vitamins,

"(ii) minerals, or

"(iii) represented as a source of vitamins or minerals.

"(c)(1) For purposes of this section, the term 'food to which this section applies' means a food for humans which is a food for special dietary use—

"(A) which is or contains any natural or synthetic vitamin or mineral, and

"(B) which—

"(i) is intended for ingestion in tablet, capsule, or liquid form, or

"(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

"(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

"(3) For purposes of paragraph (1) and of section 403 (j) insofar as that section is applicable to food to which this section applies, the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

"(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

"(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

"(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.".

(b) The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 411 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.

SEC. 502. (a)(1) Section 403(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(a)) is amended (A) by inserting "(1)" after "If", and (B) by inserting before the period at the end a comma and the following: "or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2)".

(2)(A) Section 201(n) of such Act is amended by inserting "or advertising" after "labeling" each time it occurs.

(B) Section 303 of such Act is amended by adding at the end the following new subsection:

"(d) No person shall be subject to the penalties of subsection (a) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising, and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead.".

(C) Section 304(a) of such Act (21 U.S.C. 334(a)) is amended by adding after paragraph (2) the following new paragraph:

"(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

"(i) is misbranded under section 403(a)(2) because of its advertising, and

"(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

"(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

"(i)(I) the food's advertising which resulted in the food being misbranded under section 403(a)(2) was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

"(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

"(III) all or part of the cost of such advertising was paid by such owner or operator; and

"(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.".

(b) Chapter VII of such Act is amended by adding after section 706 (21 U.S.C. 376) the following new section:

"ADVERTISING OF CERTAIN FOODS

"SEC. 707. (a)(1) Except as provided in subsection (c), before the Secretary may initiate any action under chapter III—

"(A) with respect to any food which the Secretary determines is misbranded under section 403(a)(2) because of its advertising, or

"(B) with respect to a food's advertising which the Secretary determines causes the food to be so misbranded,

the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

"(2) The notice required by paragraph (1) shall—

"(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary's determination that such advertising has caused such food to be misbranded, and

"(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

"(b)(1) If the Secretary notifies the Federal Trade Commission under subsection (a) of action proposed to be taken under chapter III with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

"(A) it has initiated under the Federal Trade Commission Act an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

"(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 with respect to such advertising,

"(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act respecting such advertising, or

"(D) pursuant to section 16(b) of such Act it has made a certification to the Attorney General respecting such advertising,

the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice to the Federal Trade Commission.

"(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a)—

"(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary's notice,

"(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

"(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a). The Commission shall promptly notify the Secretary of the commencement by

the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

"(c) The requirements of subsections (a) and (b) do not apply with respect to action under chapter III with respect to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health.

"(d) For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under chapter III because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act with respect to such advertising."

(c) The amendments made by subsection (a) shall take effect 180 days after the date of the enactment of this Act.

TITLE VI—ARTHRITIS ACT AMENDMENTS

SEC. 601. This title may be cited as the "National Arthritis Act Technical Amendments of 1976".

SEC. 602. (a) Section 2 of the National Arthritis Act of 1974 (Public Law 93-640) (hereinafter in this section referred to as the "Act") is amended by—

(1) inserting "(a)" after "SEC. 2.";

(2) inserting a comma and "including $2,500,000,000 in medical expenses," after "$9,200,000,000" in paragraph (3); and

(3) inserting a new subsection (b) at the end thereof as follows:

"(b) It is therefore the purpose of this Act to provide for—

"(1) the formulation of a long-range plan—

"(A) to expand and coordinate the national research, treatment, and control effort against arthritis;

"(B) to advance educational activities for patients, professional and allied health personnel, and the public which will alert the citizens of the United States to the early indications of arthritis; and

"(C) to emphasize the significance of early detection and proper control of these diseases and of the complications which may evolve from them;

"(2) the establishment and support of programs to develop new and improved methods of arthritis screening, detection, prevention, and referral;

"(3) the establishment of a central arthritis screening and detection data bank; and

"(4) the development, modernization, and operation of centers for arthritis screening, detection, diagnosis, prevention, control, treatment, education, rehabilitation, and research and training programs.".

(b) Section 3 of the Act is amended by striking out "chief medical officer" and inserting in lieu thereof "Chief Medical Director" in subsection (b)(4).

(c) The section heading for section 4 of the Act is amended by striking out "DEMONSTRATION" after "COMMITTEE,".

SEC. 603. (a)(1) Section 431(c) of the Public Health Service Act is amended by inserting "(hereinafter in this part collectively referred to as 'arthritis')" after "musculoskeletal diseases".

(2) The fourth sentence of section 434(b) of such Act is amended by striking out "and related musculoskeletal diseases".

(3) Section 434(e) of such Act is amended by striking out "and related musculoskeletal diseases (hereinafter in this part collectively referred to as 'arthritis')".

(b) Section 438 of such Act is amended by—

(1) inserting "the" before "health" the first time it appears in the first sentence of subsection (a); and

(2) inserting "established" after "bank" in the second sentence of subsection (a).

(c) Section 439 of such Act is amended by—

(1) inserting "new and existing" before "centers" in the first sentence of subsection (a);

(2) striking out "$13,000,000" and inserting in lieu thereof "$8,000,000", and striking out "$15,000,000" and inserting in lieu thereof "$20,000,000" in subsection (h); and

(3) redesignating subsections (e), (f), (g), and (h) as subsections (d), (e), (f), and (g), respectively.

TITLE VII—DIABETES PLAN

SEC. 701. Section 3(i)(2) of the National Diabetes Mellitus Research and Education Act (42 U.S.C. 289c-2) is amended to read as follows:

"(2) The Commission shall cease to exist after September 30, 1976.".

TITLE VIII—HEALTH SERVICES

AMBULATORY SURGICAL SERVICES

SEC. 801. (a) Section 319(a)(7) is amended by—

(1) inserting after subparagraph (K) the following new subparagraph:

"(L) ambulatory surgical services;" and

(2) redesignating subparagraphs (L) and (M) as subparagraph (M) and (N), respectively.

(b) Section 330(b)(2) is amended by—

(1) inserting after subparagraph (K) the following new subparagraph:

"(L) ambulatory surgical services;" and

(2) redesignating subparagraphs (L) and (M) as subparagraphs (M) and (N), respectively.

TITLE IX—INDIAN HEALTH SERVICE

SEC. 901. Section 225 is amended by adding at the end thereof the following new subsection—

"(j) Notwithstanding any other provision of law, the Secretary may, where he deems advisable, allow the Indian Health Service to utilize nonprofit recruitment agencies to assist in obtaining personnel for the Public Health Service.".

TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

SEC. 1001. All appointments to advisory committees established to assist in implementing the Public Health Service Act, the Mental Retardation

Facilities and Community Mental Health Centers Construction Act of 1963, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, shall be made without regard to political affiliation.

TITLE XI—MISCELLANEOUS PROVISIONS

SEC. 1101. Section 212 of the Public Health Service Act is amended by adding after subsection (d) the following new subsection:

"(e) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Soldiers' and Sailors' Civil Relief Act of 1940 (50 App. U.S.C. 501 et seq.).".

SEC. 1102. (a) The second paragraph (4) of subsection (c) of section 472 of the Public Health Service Act is redesignated as paragraph (5).

(b) Section 507 of the Public Health Service Act is amended by striking out "hospitals of the Service, of the Veterans' Administration, or of the Bureau of Prisons of the Department of Justice, and to Saint Elizabeths Hospital, except that grants to such" and insert in lieu thereof "Federal institutions, except that grants to".

SEC. 1103. Title IV of the Public Health Service Act is amended by adding after section 475 the following new section:

"VISITING SCIENTIST AWARDS

"SEC. 476. (a) The Secretary may make awards (referred to as 'Visiting Scientist Awards') to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

"(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe."

SEC. 1104. Section 786 of the Public Health Service Act is amended by inserting before the period at the end of the first sentence "and $3,500,000 for the fiscal year ending June 30, 1975 and $2,000,000 for the fiscal year ending June 30, 1976".

SEC. 1105. (a) Section 742(a) of the Public Health Service Act is amended by striking out "and" after "1974," and by inserting after "1975" the following: ", and $60,000,000 for the fiscal year ending June 30, 1976".

(b) Section 740(b)(4) of such Act is amended by striking out "1975" and inserting in lieu thereof "1976".

SEC. 1106. Section 1511(b)(5) of the Public Health Service Act is amended by striking out "1535" and inserting in lieu thereof "1536".

(b) Section 1613 of such Act is amended by striking out "1510" and inserting in lieu thereof "1610".

(c) The last sentence of section 1631 of such Act is repealed.

SEC. 1107. (a) Section 132(a)(1)(A) of the Developmental Disabilities Services and Facilities Construction Act (42 U.S.C. 6062) (hereinafter in this section referred to as the "Act") is amended by striking out "134" and inserting in lieu thereof "133".

(b) Section 134(b)(1) of the Act is amended by striking out "134" and inserting in lieu thereof "133".

(c) Section 134(b)(1) of the Act is amended by striking out "136" and inserting in lieu thereof "135".

(d) Section 301(a) of the Developmentally Disabled Assistance and Bill of Rights Act is amended by striking out "101(7)" and inserting in lieu thereof "102(7)".

And the Senate agree to the same.

HARLEY O. STAGGERS,
PAUL G. ROGERS,
DAVID E. SATTERFIELD,
JAMES W. SYMINGTON,
JAMES H. SCHEUER,
TIM LEE CARTER,
JAMES T. BROYHILL,
Managers on the Part of the House.

HARRISON A. WILLIAMS, JR.,
CLAIBORNE PELL,
EDWARD M. KENNEDY,
WALTER F. MONDALE,
ALAN CRANSTON,
WILLIAM D. HATHAWAY,
JOHN A. DURKIN,
THOMAS F. EAGLETON,
GAYLORD NELSON,
JACOB K. JAVITS,
RICHARD S. SCHWEIKER,
ROBERT TAFT,
J. GLENN BEALL, JR.,
ROBERT T. STAFFORD,
PAUL LAXALT,
Managers on the Part of the Senate.

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 7988) to amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study on the release of research information, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The Senate amendment struck out all of the House bill after the enacting clause and inserted a substitute text.

The House recedes from its disagreement to the amendment of the Senate with an amendment which is a substitute for the House bill and the Senate amendment. The differences between the House bill, the Senate amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

Findings

The Senate amendment, in a provision not in the House bill, specified Congressional findings, with respect to the impact of diseases of the heart, lung and blood vessels and blood disease and the need for the proposed legislation.

The conference substitute conforms to the Senate amendment, with technical changes.

Advisory Council

The House bill changed the name of the National Heart Lung Advisory Council to the National Heart, Lung and Blood Advisory Council.

The Senate amendment contained no comparable provision.

The conference substitute conforms to the House bill.

Experts and Consultants

Existing law authorizes the Director of the National Heart and Lung Institute to obtain the services of not more than 50 experts and consultants.

The House amendment increased this number to 100.
The Senate amendment contained no comparable provision.
The conference substitute conforms to the House bill.

Assistant Director

Existing law establishes within the National Heart and Lung Institute (redesignated as the National Heart, Lung and Blood Institute under provisions of both the House bill and the Senate amendment) an Assistant Director for Health Information Programs.
The House bill changed the name to Assistant Director for Prevention, Education, and Control.
The Senate amendment changed the name to Assistant Director for Prevention and Information.
The conference substitute conforms to the House bill.

Authorization for Prevention and Control Programs

The House bill authorized appropriations of $20 million for fiscal year 1976 and $30 million for fiscal year 1977 for heart, blood vessel, lung, and blood disease control programs.
The Senate amendment authorized appropriations of $10 million for fiscal year 1976 and $25 million for fiscal year 1977 for such programs.
The conference substitute authorizes $10 million for fiscal year 1976 and $30 million for fiscal year 1977 for such programs.

Centers

Existing law authorizes the development of fifteen centers for research, training, and demonstrations respecting heart, blood vessel, and blood diseases, and fifteen such centers for chronic lung diseases.
The House bill increased the responsibilities of the heart, blood vessel, and blood disease centers to include research in the use of blood and blood products and in the management of blood resources. Further, the House bill expanded the responsibilities of the lung disease centers by deleting the word "chronic."
The Senate amendment authorized the development of ten centers for research, training, and demonstrations respecting heart diseases; ten such centers for chronic lung diseases; and ten such centers for blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources.
The conference substitute conforms to the Senate amendment, except that it authorizes the development of ten centers for lung diseases, as opposed to chronic lung diseases.

Functions of the Advisory Council

The House bill added to the existing authority of the National Heart, Lung, and Blood Advisory Council the prerogative to recommend to the Secretary of Health, Education, and Welfare areas of research conducted or supported by the newly designated National Heart, Lung, and Blood Institute which the Council determines should be supported by the awarding of contracts and the percentage of the budget of the Institute which should be expended for such contracts.
The Senate amendment contained no comparable provision.
The conference substitute conforms to the House bill.

Report of the Advisory Council

Both the House bill and the Senate amendment required that the Advisory Council submit by November 30 of each year a report to the Secretary for simultaneous transmittal to the President and to the Congress on the progress of the National Heart, Blood Vessel, Lung, and Blood Disease Program during the preceding fiscal year. However, the Senate amendment stipulates that for purposes of this requirement, the period beginning July 1, 1975 and ending September 30, 1976 shall be considered a fiscal year and the House amendment contains no comparable provision.
The conference substitute conforms to the Senate amendment.

Authorizations for Research

The House bill authorized appropriations of $340 million for fiscal year 1976 and $375 million for fiscal year 1977 for carrying out the programs of the redesignated National Heart, Lung, and Blood Institute (except prevention and control programs).
The Senate amendment authorized $338 million for fiscal year 1976 and $372 million for fiscal year 1977 for such purposes.
The conference substitute authorized $339 million for fiscal year 1976 and $373 million for fiscal year 1977 for such purposes.

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

Authorizations

The House bill authorized appropriations of $175 million for fiscal year 1976 and $200 million for fiscal year 1977 for payments for National Research Services Awards.
The Senate amendment authorized $160 million for fiscal year 1976 and $176 million for fiscal year 1977 for such purposes.
The conference substitute authorizes $165 million for fiscal year 1976 and $185 million for fiscal year 1977 for such purposes.

Accrual of Interest

Under existing law, interest accrues on National Research Service Awards from the time the award is made in instances in which recipients fail to fulfill applicable service requirements.
The House bill changed existing law to make interest on the award computed from the time the United States becomes entitled to recover all or part of the award.
The Senate bill contained no comparable provision.
The conference substitute conforms to the House bill.

Study Respecting Biomedical and Behavioral Research Personnel

Under existing law, the Secretary is to annually submit a study respecting biomedical and behavioral research personnel.
The Senate amendment changed the date for submission of the report to September 30, and the House bill contained no comparable

provision. The House bill required that the entity conducting the study conduct such study in consultation with the Director of the National Institutes of Health.

The conference substitute conforms to the changes made in existing law by both the House bill and the Senate amendment.

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

The House bill contained a provision which required the President's Biomedical Research Panel to conduct an investigation and study of the implication of disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary in conjunction with an application or proposal for a grant, fellowship, or contract under the Public Health Service Act and to submit a report on the investigation and study to the House Committee on Interstate and Foreign Commerce and the Senate Committee on Labor and Public Welfare. The House bill also included a provision which deferred, from July 1, 1976 to January 1, 1977, the establishment of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research.

The Senate amendment contained no comparable provisions.

The conference substitute conforms to the House bill, except that the National Commission for the Protection of Human Subjects is also required to conduct the investigation and study, and technical changes are made with respect to the dates on which the Panel is to complete its investigation and submit its report.

The Conferees express their concern that inadequate attention is being paid to the problems of transfer of research progress, technology, and information from the "bench to the bed", an area frequently referred to as the interface between research and the health care delivery system. This includes such areas as extensive clinical trials, demonstration projects, specific disease control programs, the assessment of new health technologies, health education, and the fields of preventive medicine and public health. The Conferees have received assurance that the report of the President's Biomedical Research Panel will address these important issues.

TITLE IV—GENETIC DISEASES

Short Title and Statement of Purpose

The House bill provided for the following short title: "National Genetic Diseases Act." Under the Senate amendment the short title was "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs and Genetic Diseases Act."

The House bill stated a purpose of establishing a national program for genetic diseases, including sickle cell anemia, Cooley's anemia and Tay-Sachs disease. The Senate amendment, in its statement of purpose, stipulated that genetic diseases are to include but not be limited to sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

The conference substitute conforms to the Senate amendment.

Testing and Counseling Programs and Information and Education Programs

The house bill required that testing and counseling programs be established and operated primarily in conjunction with other existing health programs, including programs established under title X of the Public Health Service Act (family planning programs) and under title V of the Social Security Act (maternal and child health programs). The Senate amendment contained comparable requirements, except that it did not specify programs under title X of the Public Health Service Act or under title V of the Social Security Act.

The conference substitute conforms to the House bill, except that only programs assisted under title V of the Social Security Act are specified.

The Senate amendment further provided that a priority in the awarding of grants and contracts for genetic disease counseling and testing programs was to be given to projects which are recipients of awards for sickle cell anemia testing and counseling programs on the date of enactment. There was no similar provision in the House bill.

The conference substitute conforms to the Senate amendment with technical amendments.

The House bill authorized $20 million for each of fiscal years 1976 and 1977 to support genetic disease testing and counseling programs and information and education programs. The Senate amendment authorized $20 million for fiscal year 1976, $25 million for fiscal year 1977, and $30 million for fiscal year 1978 for such programs; and an additional $15 million for each of fiscal years 1976, 1977, and 1978 to support sickle cell anemia testing and counseling programs.

The conference substitute authorizes $30 million for each of fiscal years 1976, 1977, and 1978 to support genetic diseases testing and counseling programs and information and education programs, and provides that the Secretary shall give special consideration in the awarding of grants and contracts to sickle cell anemia testing and counseling project applications.

Research Project Grants and Contracts

Both the House bill and the Senate amendment authorized the Secretary to award grants and contracts for research projects with respect to genetic diseases.

Both the House bill and the Senate amendment set forth four purposes for which the Secretary could award research grants and contracts. They are identical except that as the first purpose the House bill provided that projects for basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases would be eligible for funding. The Senate amendment included projects for basic research, including lower organisms, applied research, and research training.

The conference substitute conforms to the House bill.

The House bill instructed the Secretary to undertake genetic disease research under the general authority of section 301 of the Public Health Service Act. The Senate amendment provided for a specific authority and authorized $80 million for fiscal year 1976, $100 million for fiscal year 1977, and $120 million for fiscal year 1978; and ear-

marked 10 percent of the sums appropriated each year under the authority for research projects with respect to Cooley's anemia. The Senate amendment further provided for a separate authorization for sickle cell anemia research of $15 million for each of fiscal years 1976, 1977, and 1978.

The conference substitute conforms to the House bill, except that the Secretary is directed, in making grants and entering into contracts for research projects, to give priority to applications which are submitted for research on sickle cell anemia or for research on Cooley's anemia.

Title V.—Vitamins and Minerals

The Senate amendment contained provisions not included in the House bill relating to regulation of vitamin and mineral products under the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as "the Act").

Under the Senate amendment, the Secretary of Health, Education and Welfare would generally have been prohibited from establishing maximum limits on the potency of vitamins or minerals in dietary supplements or classifying vitamins or minerals as drugs solely because they exceeded the level of potency determined by him to be nutritionally rational or useful. In addition, the Secretary would have been prohibited from limiting the combination of vitamins, minerals or other ingredients in dietary supplements. However, under the Senate amendment, the Secretary would have retained full authority to limit the potencies and combinations of vitamins, minerals and other ingredients in foods in the exercise of his authority under chapter V of the Act (relating to drugs) and under provisions of the Act respecting unsafe foods which are not generally recognized as safe. In addition, the Senate amendment contained provisions rendering the amendment's limitations on the authority of the Secretary inapplicable to vitamin and mineral products for use by children or by pregnant or lactating women.

The Senate amendment also contained provisions with respect to the labeling and advertising of vitamin and mineral products. It prohibited a product containing vitamins or minerals from being deemed misbranded solely because its label lists all ingredients of such a product. However, the amendment required that the labeling of such products could not list ingredients which are not vitamins or minerals except as a part of a list of all ingredients of the product and unless such ingredients are listed in accordance with applicable regulations. Moreover, the Senate amendment prohibited the labeling of or advertising for any such product to give prominence to or emphasize ingredients which are not vitamins or minerals or are not represented as a source of vitamins or minerals.

In addition, the Senate amendment afforded the Secretary significant new authority with respect to the advertising of certain products containing vitamins or minerals. (Under existing law, the Federal Trade Commission has exclusive authority with respect to the advertising of such products.) Under the Senate amendment, such products would be deemed misbranded if their advertising were false or misleading in a material respect. However, criminal penalties could not be imposed against persons who were in violation of the prohibitions against false or misleading advertising unless such a violation

was committed with the intent to defraud or mislead. Further, such products which are misbranded because their advertising is false or misleading in a material respect and are held for sale to the ultimate consumer in an establishment not owned by a manufacturer, packer or distributor, could not be seized unless (1) the advertising was disseminated in the establishment in which the product was held for sale to the ultimate consumer, the advertising was disseminated by or under the direction of the owner or operator of such establishment, or all or part of the cost of such advertising was paid for by the owner or operator, and (2) the owner or operator used the advertising to promote the sale of the product. Finally, the Senate amendment required the Secretary to consult with the Federal Trade Commission prior to initiating action with respect to such products deemed misbranded because of their advertising.

The Conference substitute conforms to the Senate amendment except that:

(1) It adds two technical amendments (clarifying the intention of the Senate amendment) to provide specifically that foods represented for use by individuals in the treatment or management of specific diseases or disorders and foods represented for use as the sole item of a meal or of the diet are excluded from the limitations on the Secretary's authority.

(2) Except in instances in which immediate action is necessary to eliminate an imminent hazard to health, it requires the Secretary to provide notification to the Federal Trade Commission of his intention to initiate an action with respect to false or misleading advertising, and it affords the Federal Trade Commission the opportunity to take specific enforcement action against false or misleading advertising for a period of up to 90 days before the Secretary may take comparable action.

Since the House has taken no action during this Congress with respect to this matter, it is important to provide more legislative history concerning these complex new provisions. Thus, presented below is a detailed description of the new provisions, as well as statements of the intentions of the managers with respect to their implementation.

Products Subject to the Conference Substitute

Under the conference substitute, products subject to its provisions are defined as safe human foods for special dietary use which are or contain any natural or snythetic vitamin or mineral and which are intended for ingestion in tablet or capsule form or in small units of liquid measure. In addition, such foods not intended for ingestion in tablet, capsule, or liquid form are subject to the provisions of the substitute only if they do not simulate conventional foods, if they are not represented to be conventional foods, and if they are not represented for use as the sole item of a meal or of the diet.

The definition of "special dietary use" in the conference substitute applies only to the foods to which the substitute is applicable and not to other foods, such as foods represented for use by infants or foods represented for use as the sole item of a meal or of the diet, that may be subject to 403(j) of the Act.

Thus, vitamins and minerals in tablet, capsule, or liquid form as well as those products which are represented for special dietary use in humans and which do not simulate and are not represented as conventional foods or substitutes for conventional foods and which are not represented for use as the sole item of a meal or of the diet, are products subject to the provisions of the substitutes.

Except with respect to products defined above, the conference substitute does not alter existing provisions of the Federal Food, Drug, and Cosmetic Act with respect to foods and drugs.

The Secretary retains his current authority to regulate the nutritional formulation and composition of, and potency of vitamins, minerals and other ingredients in conventional foods such as milk, enriched bread and enriched rice, as well as in products which simulate conventional foods such as soybased protein substitutes for meats and poultry. The Secretary also retains his current authority to regulate the nutritional formulation and composition of, and potency of vitamins, minerals and other ingredients in foods represented by labeling, advertising, or other promotional materials for use as the sole item of a meal or of the diet. Because consumers purchase these foods as nutritional equivalents of a well-balanced meal or diet, the conferees believe it is essential that the consumer of such products can be confident that a meal or diet based upon such products is nutritionally adequate and balanced and provides for the proper maintenance of the user's health for the duration of his use of these products.

Limitations on the Secretary's Authority

Under the conference report, three significant restrictions would be imposed on the Secretary with regard to the regulation of products subject to the conference substitute. First, new section 411(a)(1)(A) of the Act prohibits the Secretary from using his existing authority under sections 201(n) or 403 of the Act (relating to misbranding) or under section 401 of the Act (relating to standards of identity) to impose maximum limits on the potency of safe vitamins and minerals contained in products subject to the conference substitute. This provision would not restrict the Secretary from prescribing minimum potency levels for vitamins or minerals in such products in order to prevent the addition of insignificant or useless amounts.

Second, new section 411(a)(1)(B) of the Act prohibits the Secretary from classifying as a drug a natural or synthetic vitamin or mineral, offered by itself or in combination, solely because it exceeds the level of potency that the Secretary determines is nutritionally rational or useful.

Third, new section 411(a)(1)(C) of the Act prohibits the Secretary from using his authority with respect to misbranding or establishment of standards of identity to limit the combination or number of any safe vitamin, mineral or other ingredient of food in products subject to the conference substitute.

Exceptions to Limitations on the Secretary

Under the conference substitute (proposed new section 411(a)(2) of the Act), the limitations on the Secretary, described above, do not apply with respect to a product otherwise subject to the provisions

of the conference substitute where such product is represented for use by (1) individuals in the treatment or management of specific diseases or disorders, (2) children, or (3) pregnant or lactating women.

The provision with respect to foods intended for use in the treatment or management of specific diseases or disorders was adopted in conference in order to make clear that the proposed new section 411(a) of the Act does not override the Secretary's authority under sections 401, 403, or 201(n) of the Act to limit the potency and combination of vitamins, minerals, other ingredients in foods, or foods, represented for use in the dietary treatment or management of individuals with specific diseases or disorders, or of post-operative or convalescing medical patients. Since each of these foods must be precisely formulated to meet the needs of individuals with specific diseases and disorders, the conferees believe it to be important that the language in the conference substitute clearly preserve the authority of the Secretary to regulate as foods the nutritional formulation, composition, and potency of each product represented for such uses. Inclusion of this language is not, however, intended to permit the Secretary to limit (under sections 401, 403, or 201(n) of the Act) the potency or combination of a safe vitamin, mineral, food ingredient, or food represented in its labeling and advertising to be solely for use by adults, other than pregnant or lactating women, as a nutritional supplement to general human dietary intake.

Dietary management with these products is not only of major clinical value to the individual, but can be lifesaving in many instances. In the case of a number of inborn abnormalities of metabolism, such as phenylketonuria and maple syrup urine disease, these foods provide the only means for prevention of mental retardation, particularly in infants and young children, or for the partial restoration of mental capacity in older children. Special formula feedings are essential to long-term maintenance of severely debilitated individuals. Low sodium foods are useful in dietary management of individuals with severe forms of hypertension, acute heart failure, acute nephritis, toxemias of pregnancy and similar disorders when the degree of sodium restriction must be greater than that achievable with conventional foods. Chemically defined formula diets are extremely useful for nutritional management of patients prior to and subsequent to gastrointestinal surgery.

The Senate amendment included, in proposed new section 411(a)(2) of the Act, a specific reference to the Secretary's authority to act by regulation. This reference was deleted by the conferees as unnecessary. It is not intended that the omission of this reference should be understood as in any way restricting the Food and Drug Administration's present authority to adopt regulations defining and enforcing the provisions of the Act. The Secretary in recent years has relied increasingly on administrative rulemaking to enforce the requirements of the law. Rulemaking affords opportunity for broader participation in the formulation of agency policy, promotes clarity of legal requirements, and assures equitable application of the law, while at the same time it reduces the cost to the taxpayer of case-by-case enforcement. The Secretary's legal authority, under section 701(a) of the Act, to adopt binding regulations has been recognized by the Supreme Court. *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973); *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967). This

authority has recently been upheld by the United States Court of Appeals for the Second Circuit. *National Nutritional Foods Assn.* v. *Weinberger*, 512 F. 2d 688 (C.A. 2, 1975).

For the purposes of the conference substitute, the term "children" is defined to mean individuals under the age of 12 years. The conferees are also concerned that attention should be given to those vitamin and mineral preparations that are not intended for use by infants, children or pregnant or lactating women, but may be taken by or administered to them inadvertently. Just as the fetus may be affected by excessive doses of some food supplements, excessive doses of vitamins and minerals taken by children during the period of rapid growth and maturation can interfere with their normal development. Because of such possibilities of unrecognized or unanticipated harm, it is intended that the Secretary retain full authority to promulgate regulations designed to assure that unsuitable or inappropriate vitamin and mineral preparations are not inadvertently administered to individuals in these vulnerable groups.

Except as specifically provided, the conference substitute does not alter the drug or food provisions of the Federal Food, Drug, and Cosmetic Act. If a product containing vitamins, minerals or other ingredients is a drug within the meaning of section 201 (g) of the Act, the Secretary may, with respect to such product, exercise his authority under Chapter V of the Act. For example, the Secretary may bring an action for misbranding of a product which purports to be or is represented as a drug (within the meaning of section 201 (g) of the Act) if its labeling fails to bear adequate directions for its purported use or for the use for which it is represented (within the meaning of section 502 (f)(1) of the Act). See *V. E. Irons, Inc. v. United States*, 244 F. 2d 34 (C.A. 1, 1957); *Alberty Food Products v. United States*, 194 F. 2d 463 (C.A. 9, 1952); *United States v. Vitasafe Co.*, 345 F. 2d 864 (C.A. 3, 1965); *United States v. Article of Drug . . . B-Complex Cholinos Capsules*, 362 F. 2d 923 (C.A. 3, 1966).

The Secretary also has the authority to regulate the composition and potency of a product subject to the provisions of the conference substitute on the basis of safety. If a high potency preparation of a vitamin or mineral is a drug as defined by section 201 (g) of the Act and the Secretary determines that within the meaning of section 503 (b) of the Act, it is not safe for use except under the supervision of a physician, such a high potency preparation is subject to regulation as a prescription drug under the Act.

Similarly, if any vitamin, mineral or other food ingredient is not generally recognized as safe by qualified experts and meets the other criteria of the definition of a "food additive" under section 201 (s) of the Act, it would be subject to regulation under section 409 of the Act. If such a vitamin, mineral or other ingredient is intentionally added to a food, such food is adulterated (within the meaning of section 402 (a)(2)(C) of the Act) unless its use is in conformity with a regulation issued by the Secretary which prescribes the conditions under which it may be safely used or exempts it for investigational use by qualified experts. It is on precisely this basis that the Secretary has, by regulation, restricted the potency of the vitamin folic acid that may be added to a food.

Provisions with Respect to Labeling and Advertising

Under the conference substitute, the Secretary retains the authority to initiate enforcement actions against a product to which the conference substitute is applicable if its labeling is false or misleading in any particular. In addition, the conference substitute contains special provisions respecting the labeling and advertising of these products.

The conference substitute provides that a food to which the conference substitute is applicable shall not be deemed misbranded under section 403 of the Act solely because its label bears a listing of all of the ingredients in the food, or solely because its advertising contains references to ingredients in the food that are not vitamins or minerals. Thus, for example, if a tablet or capsule of vitamin C contains rutin, a substance that the Secretary has concluded has no dietary usefulness, the list of ingredients as well as the advertising for the product may refer to rutin without causing the food to be deemed misbranded. However, because of the conferees' concern that consumers not be misled into a belief that such substances have nutritional value, the conference substitute provides that the labeling so such a product may not list ingredients that are not vitamins or minerals except as a part of a list of all the ingredients of the food, in accordance with applicable regulations promulgated by the Secretary pursuant to section 403 of the Act. The Secretary is directed that in circumstances where compliance with this provision is impracticable or results in deception or unfair competition, exceptions shall be established by regulation. Further, the conference substitute provides that the labeling or advertising of a food to which the conference substitute is applicable may not give prominence to or emphasize ingredients which are not vitamins or minerals or are not represented as a source of vitamins or minerals.

The conference substitute also provides the Secretary new authority over the advertising of foods subject to the conference substitute. Seizure and injunction actions are authorized in instances in which the advertising of a food to which the conference substitute is applicable is false or misleading in a material respect. However, in order to protect an innocent retailer from seizures based upon deceptive advertising claims made by a manufacturer, the conference substitute provides that libel for condemnation may not be instituted against such products which are misbranded because of their advertising unless (1) the advertising was disseminated in the establishment in which the product was held for sale to the ultimate consumer, the advertising was disseminated by or under the direction of the owner or operator of such establishment, or all or part of the cost of such advertising was paid for by the owner or operator, and (2) the owner or operator used the advertising in the establishment to promote the sale of the food.

The conference substitute would also add a new section 707 to the Federal Food, Drug, and Cosmetic Act which would require that the Federal Trade Commission be afforded the opportunity to take certain specific enforcement actions under the Federal Trade Commission Act for a period of up to 90 days before the Secretary could initiate an enforcement action under Chapter III of the Act with respect to the advertising of a product subject to the provisions of the conference substitute. It would prohibit the Secretary, except under limited

circumstances, from initiating such an enforcement action before, during, or after the expiration of the 90 day period, if the Federal Trade Commission takes action in accordance with the conference substitute.

These provisions are intended to provide the Secretary with authority to protect the public from consumer fraud perpetrated by the false advertising of these products. They are intended to serve as a partial substitute for the authority denied to the Secretary under other provisions of the conference substitute.

Proposed new section 707 of the Act would require the Secretary to notify the Federal Trade Commission before he initiates any action, under Chapter III of the Federal Food, Drug, and Cosmetic Act, with respect to any food which the Secretary determines is misbranded under proposed new section 403(a)(2) of the Act because of its advertising or a food's advertising which the Secretary determines causes the food to be so misbranded. The notice by the Secretary must contain (1) a description of the Secretary's proposed action, (2) a description of the advertising which the Secretary has determined causes the food to be misbranded under section 403(a)(2) of the Act, and (3) a statement of the reasons for the Secretary's determination that the advertising has caused the food to be so misbranded. In addition, the notice from the Secretary must be accompanied by records, documents, and other written materials which the Secretary determines support his determination that the food is so misbranded because of its advertising.

If, within a 30 day period beginning on the date of receipt of the notice and accompanying written materials from the Secretary, the Federal Trade Commission notifies the Secretary in writing that—

(1) it has initiated an investigation of the advertising (referred to in the Secretary's notice) to determine if it is prohibited by the Federal Trade Commission Act or a rule or order promulgated thereunder;

(2) it has commenced or intends to commence a civil action in the courts under section 5, 13, or 19 of such Act with respect to such advertising or the Attorney General has commenced or intends to commence a civil action under section 5 of such Act with respect to such advertising;

(3) it has issued and served or intends to issue and serve a complaint under section 5(b) of such Act with respect to such advertising; or

(4) it had made certification to the Attorney General under section 16(b) of such Act with respect to such advertising,

the Secretary is prohibited from initiating his proposed action for an additional period of time, which is not to exceed 60 days. If the Commission notifies the Secretary that neither the Attorney General nor the Commission intends to take any of these actions or fails to respond to the Secretary in writing within the 30 day period, the Secretary may initiate his proposed action.

If, before the expiration of the 60 day period beginning on the date the Secretary receives the notice from the Commission that the Attorney General or the Commission intends to take one of the actions described above, the Commission or the Attorney General has not commenced a civil action, the Commission has not issued and served a complaint or made certification to the Attorney General

which has caused appropriate criminal proceedings to be brought against the advertising, the Secretary may act under Chapter III of the Federal Food, Drug, and Cosmetic Act.

The Commission is required to notify the Secretary promptly of the commencement of a civil action, the issuance and service of a complaint, or the causing by the Attorney General of criminal proceedings to be brought against the advertising described in the Secretary's notice.

The conferees intend that the Commission or the Attorney General, where practical, take appropriate regulatory action under the Federal Trade Commission Act pursuant to a notice from the Secretary. The conferees believe that the period of 90 days provided in the converence substitute is sufficient time within which to take such action. However, in instances in which the Secretary determines that, although action has not been taken by the Commission or the Attorney General within the 90 day period, such action is imminent, he may defer taking his proposed action to permit the Commission or the Attorney General to take action.

Under the conference substitute the notification and other procedural requirements in subsections (a) and (b) of proposed new section 707 of the Act do not apply with respect to any action under Chapter III of the Act with respect to any food or food advertising to which the conference substitute is otherwise applicable, if the Secretary determines that such action is required to eliminate an imminent hazard to health. Under these circumstances the Secretary would neither be required to provide formal notification to the Commission nor delay his proposed enforcement action. However, under the conference substitute, if the Secretary takes any action under Chapter III of the Act with respect to a food because of its advertising or with respect to a food's advertising under proposed section 403(a)(2) of the Act, proposed section 707(d) of the Act requires the Secretary to coordinate the action with any action of the Federal Trade Commission with respect to the advertising of such food.

The conferees recognize that for many years the Food and Drug Administration and the Federal Trade Commission have operated in overlapping areas of jurisdiction in the regulation of false claims and that both agencies have been functioning under written memoranda of understanding concerning jurisdiction and liaison since 1954. The conferees expect both agencies to continue to coordinate their regulatory actions in a manner to avoid unnecessary duplication and waste. The conferees also emphasize that the conference substitute is not intended to modify the primary role of the Federal Trade Commission in exercising its regulatory authority over the false or misleading advertising of food products.

Although the substitute gives the Secretary substantial new authority with respect to the advertising of vitamin and mineral products, the conferees intend that the Secretary use his authority under existing section 306 of the Federal Food, Drug, and Cosmetic Act which provides for written notice or warning in lieu of judicial action where the Secretary believes that such notification or warning adequately protects the public interest.

TITLE VI—ARTHRITIS ACT AMENDMENT

The Senate amendment contained a title, not included in the House bill, which amended the National Arthritis Act (Public Law 93-640) The Senate amendment (1) made it clear that arthritis and related musculoskeletal diseases are to be collectively referred to as arthritis for the purposes of the Act; (2) added a statement of purposes of the Act; (3) corrected the reference to the Chief Medical Director of the Veterans Administration as an ex-officio member of the National Commission on Arthritis; (4) lowered the authorization of appropriations under that Act for the Arthritis Commission from $2 million to $1.5 million; (5) revised the authorizations of appropriations under the Public Health Service Act for arthritis screening, detection, prevention, and referral demonstration projects and the Arthritis Screening and Detection Data Bank from $2 million for fiscal year 1975, $3 million for fiscal year 1976 and $4 million for fiscal year 1977 to $1.5 million for fiscal year 1975, $4 million for fiscal year 1976, and $4 million for fiscal year 1977; and (6) amended section 439 of the Public Health Service Act to provide that the Secretary may assist in the development, modernization, and operation of *new and existing* comprehensive arthritis centers and to revise the authorizations from $11 million for fiscal year 1975, $13 million for fiscal year 1976, and $15 million for fiscal year 1977 to $5 million for fiscal year 1975, $13 million for fiscal year 1976, and $21 million for fiscal year 1977.

The conference substitute conforms to the Senate amendment, except that it would authorize under the Public Health Service Act $11 million for fiscal year 1975, $8 million for fiscal year 1976 and $20 million for fiscal year 1977 for the development, modernization and operation of new and existing comprehensive arthritis centers, and would not change existing law with respect to authorizations for demonstration projects and the Arthritis Screening and Detection Data Bank.

TITLE VII—DIABETES PLAN

The Senate amendment contained a title, not included in the House bill, which extended the expiration date of the National Diabetes Commission (established under Public Law 93-354) to September 30, 1976.

The conference substitute conforms to the Senate amdnement.

TITLE VIII—HEALTH SERVICES

The Senate amendment contained a title, not included in the House bill, which amended sections 319 (migrant health centers) and 330 (community health centers) of the Public Health Service Act to add ambulatory surgical services as a supplemental health service which could be offered by such centers.

The conference substitute conforms to the Senate amendment.

TITLE IX—INDIAN HEALTH SERVICE

The Senate amendment contained a title, not included in the House bill, which amended section 225 of the Public Health Service Act to permit the Indian Health Service to utilize non-profit recruitment agencies to assist in obtaining personnel for the Public Health Service.

The conference substitute conforms to the Senate amendment.

TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

The Senate amendment contained a title, not included in the House bill, which prohibited consideration of political affiliation in making appointments to advisory committees established to assist the Secretary in implementing the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, and the Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970.

The conference substitute conforms to the Senate amendment.

TITLE XI—MISCELLANEOUS PROVISIONS SOLDIERS' AND SAILORS' CIVIL RELIEF ACT

The Senate amendment contained a provision, not included in the House bill, which equated active service of commissioned officers of the Public Health Service with active military service in the Armed Forces for the purposes of all rights, privileges, immunities, and benefits provided under the Soldiers' and Sailors' Civil Relief Act of 1940.

The conference substitute conforms to the Senate amendment.

VISITING SCIENTIST AWARDS

The Senate amendment contained provisions, not included in the House bill, which (1) authorized the Secretary to grant stipends, in amounts not to exceed $25,000 per annum, to visiting scientists who enter into agreements with the Secretary to assist minority schools in developing programs in biomedical sciences, and (2) authorized the Secretary to make grants to minority schools to initiate the development of undergraduate programs relating to biomedical sciences.

The conference substitute authorizes the Secretary to make awards (referred to as "Visiting Scientist Awards") to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. The amount of each such award shall include such sum as is commensurate with the salary or remuneration which the individual had received from the institution with which he has, or had, a permanent or immediately prior affiliation.

HEALTH PROFESSIONS STUDENT ASSISTANCE

The Senate amendment contained provisions, not included in the House bill, which extended the authorizations of appropriations for physician shortage area scholarships at $3.5 million for fiscal year 1975 and $2 million for fiscal year 1976, and for health professions student loans at $60 million for fiscal year 1976.

The conference substitute conforms to the Senate amendment.

HARLEY O. STAGGERS,
PAUL G. ROGERS,
DAVID E. SATTERFIELD,
JAMES W. SYMINGTON,
JAMES H. SCHEUER,
TIM LEE CARTER,
JAMES T. BROYHILL,
Managers on the Part of the House.
HARRISON A. WILLIAMS, JR.,
CLAIBORNE PELL,
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WALTER F. MONDALE,
ALAN CRANSTON,
WILLIAM D. HATHAWAY,
JOHN A. DURKIN,
THOMAS F. EAGLETON,
GAYLORD NELSON,
JACOB K. JAVITS,
RICHARD S. SCHWEIKER,
ROBERT TAFT,
J. GLENN BEALL, JR.,
ROBERT T. STAFFORD,
PAUL LAXALT,
Managers on the Part of the Senate.

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FOR IMMEDIATE RELEASE August 14, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

TO THE HOUSE OF REPRESENTATIVES:

I am returning, without my approval, H.R. 12944, a bill "To extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended for six months." If the only purpose of the bill were that set forth in its caption I would have no reservations about it.

The bill would, however, also make a serious substantive change in the law. It would subject rules and regulations issued under authority of the Act to a 60-day review period during which either House of Congress may disapprove the rule or regulation by simple resolution.

As I have indicated on previous occasions, I believe that provisions for review of regulations and other action by resolutions of one house or concurrent resolution are unconstitutional. They are contrary to the general principle of separation of power whereby Congress enacts laws but the President and the agencies of government execute them. Furthermore, they violate Article I, section 7 which requires that resolutions having the force of law be sent to the President for his signature or veto. There is no provision in the Constitution for the procedure contemplated by this bill.

Congress has been considering bills of this kind in increasing number. At my direction, the Attorney General moved recently to intervene in a lawsuit challenging the constitutionality of a comparable section of the Federal election law. I hope that Congress will reconsider H.R. 12944 and pass a bill which omits this provision.

THE WHITE HOUSE,
August 13, 1976

GERALD R. FORD

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